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POST-MORATORIUM EU REGULATION OF GENETICALLY MODIFIED PRODUCTS: TRADE CONCERNS

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Abstract

Trade in genetically modified (GM) products remains a major issue in agricultural trade policy. In particular, the European Union has sought to deny market access to GM-products. In the wake of a WTO case brought by Canada and the US, among others, against an import ban imposed on genetically modified agricultural products by the European Union (EU) – which the EU lost – the import ban was dropped and the EU put in place a new regulatory regime for GM-products. The EU suggests that the post-moratorium regulatory regime is compliant with its WTO obligations. As of June 2011, the operation of this new import regime has not been formally assessed. The first GM-crops are just now working their way through the post-moratorium regulatory system and an assessment of the operation of the regime is timely. The results of this assessment suggest that the EU's approval system is only partially based in science and thus is not in conformity with its SPS obligations under the WTO. Hence, the new EU regulatory regime could be challenged through a WTO Disputes panel

Keywords: EU regulatory regime, Genetically Modified (GM) products, Science, SPS

1.0 Introduction

The shaping of a revised regulatory regime for the assessment, authorization and importing of non-medical products produced using modern biotechnology – genetic modification (GM) – has been one of the most difficult, acrimonious and time consuming endeavours faced by policy makers in the European Union (EU). Arriving at a consensus upon which policy can be based has proved difficult because there are strongly held preferences against having GM products in the marketplace among some groups in European civil society; the prospect of large forgone potential benefits if the technology is not accommodated; and broad-based concern with ensuring that any approved products are safe both for human health and the environment. Add in the perception of trading partners that a failure of the EU to open its markets is simply another mechanism to provide economic protection to agricultural interests and one has a policy making dilemma with serious international ramifications.

The first time genetically modified crops were grown commercially anywhere in the world was in 1995. Prior to commercialization there was little controversy regarding biotechnology. Starting in 1990, the EU had a rigorous risk assessment system for GM products and a few crops developed using biotechnology were approved for production within the EU. The original EU assessment and approval regime, while rigorous, was still compatible with WTO commitments. With commercialization, however, opposition to products produced using biotechnology grew and became vocal. The GM-products issue became a major political issue in the EU and on the 25th of June, 1999 there was a vote in the EU's Council of Ministers where the majority of Member States voted to cease approvals of new GM products until a more stringent regulatory regime could be put in place. This *de facto* moratorium was applied to imports as well as approvals for domestic production. Devising a new regulatory regime that could accommodate the strong and polarised preferences of the various interests in the EU proved extremely difficult. The delays associated with the development of the new regulatory regime led trading partners faced with the moratorium to complain that it represented a barrier to trade motivated by economic protection and to eventually launch a formal dispute at the WTO. The dispute was initiated in 2003 by Canada and the United States.

Meanwhile, a new EU regime was finally agreed in 2003. The WTO dispute pertaining only to the moratorium continued with the Panel's decision coming down in September 2006. The WTO Panel supported the complainants. The EU said it would comply with the WTO Panel but requested extended time to do so. Extensions for the time required for compliance have been requested and discussions between the EU and the US continue. The new EU regulatory regime of 2003 is now in place and accepting applications for the approval of GM-products. The first product to successfully work its way through the revised EU-level approval process – BASF's Amylopectin ('Amflora') potato – received its approval on March 15, 2010 based on an application made in February 2005¹. Thus, it is only now that insights based on the actual workings of the new EU regime can be gleaned. Based on the procedures outlined in the Commission Directives there appear to be decision criteria that do not comply with the commitments embodied in the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) but any complaint by trading partners will have to await examination of the regulatory regime in operation. This paper examines the application of the new EU regulatory regime within the context of barriers to international trade.

¹ The Amflora potato is the first GM product to be assessed and approved by the post-moratorium regulatory regime. While Maize 810 is also approved for cultivation in the EU, it was approved in 1998, prior to the moratorium, under the previous regulatory system.

2.0 The SPS Agreement, the EU and GM Products

The Uruguay Round of multilateral trade negotiations was completed in 1994 prior to any commercialization of GM-crops. The EU was a signatory to the Uruguay Round agreements including a new General Agreement on Tariffs and Trade (GATT) sub-agreement – the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The motivation for the negotiation of the SPS arose because it was expected that disciplines on the use of border measures and subsidies for agricultural products would be agreed. The fear was that once constrained in their use of tariffs, import quotas and subsidies to support agricultural producers, governments faced with requests for protection from agricultural interests would resort to the use of SPS-based import measures justified on nefarious grounds to provide the requested protection (Smyth et al., 2009). There is a long history of accusations of economic protection being provided by SPS measures lacking a valid scientific justification (Kerr, 2004). The SPS was put in place to close off this avenue of protection.

Of course, countries have an inalienable right to protect human, animal and plant life or health (Isaac, 2007). Hence, if a legitimate justification exists WTO Member States may put in place trade barriers. The question that the SPS attempts to establish is what constitutes a *legitimate justification*. According to the SPS, unilateral (i.e. those not having been developed by an international scientific organization²) SPS measures must be ‘based on scientific principles’ and cannot be maintained ‘without sufficient scientific evidence’ unless it is a temporary measure put in place until sufficient evidence is acquired (SPS Agreement, Article 2.2). According to Isaac (2007, p. 385), “The science-based measures adopted must be proportional to the risk that is being targeted.” These were the commitments accepted by all Member States of the WTO, including the EU.

The EU, however, chafed under these commitments almost before the ink was dry on the SPS Agreement.³ These commitments were designed to limit the ability of governments to respond to agricultural producer interests’ requests for protection. With GM-products, however, requests for protection came not from traditional agricultural producer-based vested interests, but rather consumers and environmentalists. According to Kerr (2001) the anti-GM forces proved quite effective because this single issue garnered concern from four often disparate groups that tend to have strong preferences: (1) consumers worried about the safety and quality of their food; (2) environmentalists; (3) those with ethical concerns (e.g. that transgenic gene insertions were not achievable through natural selection and, hence, those using the technology are *playing God*) and; (4) those that are concerned about the influence multinational corporations might have over the food supply.

The WTO has no mechanism to allow governments to respond to groups other than producers seeking protection (Perdikis and Kerr, 1999; Kerr, 2010). Faced with determined opposition to the presence of GMs in the European market and environment from the anti-GM movement – including imports, EU policy makers began casting about for alternative ways to limit market access for GM-products. Given that some of the objections to having GM-products in the EU market arose from concerns related to human health and the environment, SPS measures were a natural avenue for limiting market access.

² There are three international organizations that establish international SPS standards that are recognized by the WTO; the Codex Alimentarius Commission for human health, the World Organization for Animal Health (OIE) for animal health and the International Plant Protection Convention (IPPC) for plants health (SPS Agreement, Article 5.1).

³ The first major SPS case dealing with an EU ban on imports of beef produced using growth hormones actually pre-dates the SPS agreement – see Kerr and Hobbs (2002) for a discussion of the beef hormone case.

To use SPS measures to limit market access for GM-products, the apparently strong commitments made in the SPS Agreement needed to be weakened. The EU's approach to weakening the commitments made in the SPS Agreement have had three major thrusts: (1) putting forth the proposition that science was only to inform the decision process used in establishing SPS measures rather than being the basis upon which decisions are made; (2) invoking a strong version of the precautionary principle whereby scientific information could always be considered insufficient to provide an acceptable degree of risk and; (3) arguing that trade in GM products was *special* and thus should be governed not by the WTO/SPS but rather by an alternative set of rules purposely designed for GM-products – specifically those set out in The Cartagena Protocol on Biosafety to the Convention on Biodiversity (hereafter the Biosafety Protocol - BSP). All three of these initiatives have been rejected by the US and other exporters of GM-products.

Isaac (2007) suggests that the differences in the approach to science in decision making between the US and Canada, among others, and the EU pertains to alternative approaches to the Risk Analysis Framework (RAF) which governments use to regulate new technologies and scientific processes. The objective of the RAF is to find the optimal balance between progress and precaution (Isaac et al., 2002). The RAF was developed by the US National Academy of Sciences in 1983 and widely adopted by other countries including the EU. Two approaches to the RAF have been identified by Isaac (2007); the *Scientific Rationality Approach* and the *Social Rationality Approach*. The EU uses the Social Rationality Approach in its domestic regulation of new technologies and would like to extend that approach to its SPS commitments. The SPS, as written, is firmly grounded in the Scientific Rationality Approach. According to Isaac (2007, p 386):

The difference between the two approaches begins with a fundamental difference in the belief about the appropriate role of science and technology in society. Scientific rationality holds that technology yields innovations and enhances efficiency; enhanced efficiency leads to economic development and growth, in turn, producing higher incomes. As incomes go up, demand increases for more stringent social regulations such as for food safety and environmental protection. The result is a regulatory race to the top made possible by scientific advancements. Therefore, this approach supports market access rules that are based upon scientific justifications.

In comparison:

The social rationality approach views science and technology not as 'drivers of economic development,' but as one facet of society, where society is a normative construct composed of the preferences and concerns of all constituents. As science and technology disrupts the prevailing normative construct, this approach supports regulatory policies that ensure socially responsive technological precaution. This focus on technological precaution essentially broadens the concept of legitimate justification beyond just scientific criteria (Isaac, 2007, pp. 387-388).

Finally:

Operationally, the social rationality approach ... permits greater scope for non-science information to be included in the determination of a legitimate justification. For example, risks are defined to include speculative risks which lack experience, data, a causal-consequence mechanism and an accepted analytical method for assessment; they are logical possibilities – irrefutable and untestable. Typically, such risks would have no standing within a science-based framework. Under the social rationality approach science only informs the decision and “other legitimate factors” are also weighed (Isaac, 2007, p. 388).

In particular, one of the other factors the EU wishes to include in its operationalization of the RAF is economic factors. Given that any new technology such as biotechnology will create losers as well as winners, negative economic consequences will exist. Allowing the erection of trade barriers on the basis of negative economic consequences is exactly the type of protection that the SPS was designed to prevent. Further, many of the risks that concern the opponents of biotechnology in the EU are speculative risks⁴. Thus, while the EU has enshrined the *Social Rationality Approach* in its domestic RAF processes, the approach has not been accepted by WTO disputes Panels which, thus far, appear firmly rooted in *Scientific Rationality* (Kerr and Hobbs, 2005; Isaac and Kerr, 2003). Hence, it is important to understand the post-2003 EU biotechnology regime to see if it is likely to be successfully challenged at the WTO.

The invoking of the *precautionary principle* has been the second mechanism the EU has used to justify SPS-based import barriers. The precautionary principle pertains to situations where scientific information is incomplete. Article 5:7 of the SPS states:

In cases where the relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable amount of time.

It is always possible to argue that insufficient scientific information exists for a decision to be made to approve a new product or technology. In the case of human health concerns one can always find new sub-populations upon which no tests have been conducted (e.g. pregnant women taking a specific combination of drugs at the same time as consuming a GM-food) or in the case of the environment a small area that is ecologically unique. Hence, it is not possible to ensure that a new technology is perfectly safe for all sub-populations or local ecosystems. It was probably hoped by the architects of the SPS that there would be a scientific consensus that would determine when enough science had been done (Smyth et al., 2010) – the deference to science-based organizations such as the Codex Alimentarius, the OIE and the IPPC is evidence of this. There were, however, two large assumptions built into this model: (1) that there would be a scientific consensus and; (2) that civil society would defer to the judgment of scientific experts. In the case of the first assumption, the nature of the scientific method is continual questioning of the conventional wisdom. Thus, it is always possible to find scientists that disagree with what a majority of scientist might have concluded. Hence, EU policy makers are often confronted with scientists that can be cited by the opponents of biotechnology. Second, groups in civil society in the EU may refuse to defer to scientific expertise. While the size of these groups is difficult to determine, they are of sufficient influence that policy makers in the EU feel that they cannot be ignored.

Hence, the EU has had great difficulty operationalizing decision-making under the *precautionary principle* (Kerr, 2001). Those that oppose biotechnology in the EU advocate for what Van den Belt (2003) calls the strong version of the precautionary principle. The strong version of the precautionary principle, however, is both logically inconsistent and likely to stifle any technological advance (Van den Belt, 2003). The advocates of the strong version of the precautionary principle have made it difficult for EU policy makers to devise an alternative for decision-making. The issue has been further confused by broadening decision making under the precautionary principle to include non-scientific factors such as socio-economic factors. This raises fears among trade policy critics that this opens decision making under

⁴ Isaac (2007) divides risks into three categories: (1) recognized risks (for which there are data for determining risks); (2) hypothetical risks (for which there are no data, but accepted analytical methods for determining risks) and (3) speculative risks which lack experience, data, a causal-consequence mechanism and an accepted analytical method for assessment; they are logical possibilities – irrefutable and untestable.

the precautionary principle to be captured by protectionist economic interests. The precautionary justification for SPS-based trade measures has not been fully tested at the WTO although the EU has been faulted for not actively seeking the required information and not doing a risk assessment as required by the SPS (Isaac and Kerr, 2003).

The third thrust of EU policy regarding their SPS commitments is to push for trade in GM-products to be governed by a Multilateral Environmental Agreement (MEA) rather than the WTO. There is a precedent for trade in some products to be governed by MEAs (Kerr and Hall, 2004; Belcher, 2007). Examples include the 1973 Convention on International Trade in Endangered Species (CITES) and the 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal. The EU has been a consistent advocate of the Biosafety Protocol being the appropriate governance instrument for trade in GM-products.

The BSP negotiations were initiated in 1995; it was signed in 2000, and entered into force in 2003 with ratification by the 50th country. It was negotiated under the umbrella of the 1992 Convention on Biological Diversity. The major exporters of GM-products have either not signed or not ratified the BSP. These include Canada, Argentina and China. The United States is not a party to the BSP because it has not ratified the Convention on Biodiversity and was, thus, not eligible to officially take part (Hobbs et al., 2005). Even if the US was allowed to be part of the BSP it is unlikely that it would participate. Thus, the BSP is largely in limbo without the membership of major exporters. Its rules do not apply to non-members of BSP. As both the EU and the major exporters are members of the WTO, it is the SPS commitments that apply. The EU can, however, use the BSP rules if its trading partner has ratified the BSP (Isaac et al., 2002).

The Protocol was initiated by developing countries (Falkner, 2002) in the wake of the Uruguay Round. The EU quickly seized on the BSP as a desirable alternative to its SPS commitments. According to Holtby et al. (2007, p. 19):

In order to satisfy its vocal anti-GM consumers and uphold its decision to ban imports, the EU had to gain credibility in trade disputes. Some of its decisions to ban imports were likely to be challenged by the United States under the WTO Dispute Settlement Mechanism. Therefore, through the BSP, the EU was looking to gain international credibility to support its decision to ban the importation of GM products.

An EU negotiator has openly admitted that one of their goals was to “bolster the EU defenses in the event of a WTO challenge” (Bail et al., 2002, p. 168). A number of other countries noted that this was part of the EU strategy at the BSP negotiations (Enright, 2002; Salamat, 2002; Nechay, 2002). Even if governance of trade in GM-products could not be formally moved to the BSP, the BSP might be able to influence WTO disputes Panels. According to Belcher’s (2007, p. 435) discussion of WTO Article XX – where, for example, exceptions pertaining to the management of renewable resources are found:

Given that international law governs the WTO agreements and their interaction with MEAs, and that MEAs are recognized as international treaties and therefore form part of international law, there appears to be considerable scope for an Appellate Body to consider MEAs in its interpretation of WTO agreements, including Article XX. It is worthwhile to note that in 1998 the Appellate Body decided that the interpretation of Article XX is to be read in light of the ‘contemporary concerns of the community of nations about the protection and conservation of the environment’. This decision appears to make Article XX particularly relevant to prevent disputes involving MEAs.

Thus, it seems clear that the EU saw the BSP as a potential means to lighten its SPS commitments, either directly or indirectly.

The BSP has a number of aspects that are antipathetic to SPS commitments including unfettered and unchallengeable use of the precautionary principle by importers and the officially recognized right for importers to consider potential economic effects in their decisions to limit imports (Hobbs et al., 2005). The major protectionist aspect of the BSP, however, is that an exporter must petition an importing country if it wants market access for its GM-product. The importing country alone makes the decision to allow imports. According to Holtby et al. (2007, p. 51):

Exporters have no means to overturn a decision, no matter what reasoning the importer uses to justify its trade embargo. Importers have complete authority over the review of decisions. They can change their own decision, at any time, based on new information or new circumstances However, exporters must appeal to the importer, the initial decision-maker, if they wish to challenge a decision.... The exporter can not, however, appeal based on a disagreement with the importer's reasoning. They can only appeal if they have new information or a new situation The lack of a third party in reviewing decisions makes it highly unlikely an exporter will successfully change an importer's decision. Therefore, an importer can block imports for any reason, and the exporter is powerless, in the context of the BSP, to do anything about it.

Given that the BSP gives a *de facto carte blanche* to importers to deny imports of GM-products, it is not surprising that major exporters of GM-products have not ratified it. As of June 2011, however, it is not clear how much influence the BSP might have over the decision of the WTO disputes Panel.

In summary, the EU's strategy of weakening its SPS commitments has not yet born concrete results but this groundwork may influence decisions if there is a dispute brought to the WTO on SPS grounds. Thus, it is important to understand the new EU regulatory mechanisms to deal with the approval of new GM-products for import. Does the new regulatory regime in the EU likely satisfy its SPS commitments or is it likely to be challenged by exporters at the WTO?

3.0 The EU Regulatory Environment for GMOs

The EU has several pieces of legislation governing genetically modified organisms (GMOs) – the official term in the EU – including their use in food and feed, their release into the environment and pertaining to traceability and labelling; these are summarised in Table 1. Individual member states also have legislation controlling the cultivation of GMO's within their jurisdiction. The legal acts institutionalize an evaluation process that determines whether 'the deliberate release into the environment or placing into the market and/or the use of GMOs for food or feed use will not have adverse effects on the environment, human or animal health' (Backus et al, 2008, p.64).

Table 1. EU Legislation and Regulations Governing the Authorization Process for GMOs	
Directive 2001/18/EC	Regulates the deliberate release of GMOs into the environment, including through cultivation, and requires a thorough environmental and health risk assessment
Directive 2008/27/EC	Amends Directive 2001/18/EC on the deliberate release into the environment of GMOs by introducing references to the new regulatory procedure with scrutiny. Adopted by the Council and Parliament, March 2008
Directive 2009/41	Recast Directive 90/219 concerning the common measures for the contained use of genetically modified micro-organisms for the purposes of protecting human health and the environment
Regulation 2004/65	Established a system for the development and assignment of unique identifiers for genetically modified organisms
Regulation 178/2002	Resulted in the creation of EFSA and the system of traceability with the concept of at least one step forwards and one step backwards in the food chain
Regulation 1829/2003	Establishes procedures for the authorization, supervision and labeling of genetically modified food and feed and aims to guarantee a high level of protection for human life and health, animal health, the environment and consumers' interests while ensuring that the internal market functions properly.
Regulation 1830/2003	Broadens the concepts contained in 1829/2003 and includes all types of foodstuffs containing or produced from GMOs (e.g. proteins), additives and flavorings for human consumption, and GMO animal feed.
Regulation 1946/2003	Concerns the transboundary movement and accompanying documentation for living modified organisms destined for deliberate release, or for food and feed or for immediate processing, under the terms of the Cartagena Protocol on Biosafety.
Regulation 1981/2006	Amends 1829/2003 to accommodate Community Reference Laboratory for GMOs
Regulation 2008/298	Amends 1829/2003 to confer power to the EC to determine whether a GMO product would be assessed according regulatory procedure with scrutiny in the areas of lowering thresholds for the labeling of adventitious GMO presence and measures regarding certain labeling and information requirements
Regulation 2004/641	Provides the detailed rules regarding an application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favorable risk evaluation
Regulation 298/2008	Amends regulation (EC) No 1829/2003 on genetically modified food and feed, as regards the implementing power conferred on the Commission. March 2008
Recommendation 2003/556/EC	Sets guidelines for the development of national strategies and best practices to ensure the coexistence of GMOs with conventional and organic farming, in order to help Member States develop national (legislative) strategies for coexistence. In March 2006, the Commission adopted a report on the implementation of such national measures (COM (2006)104).
Recommendation 2010/C200/01 Proposed July 2010	The Commission proposed to confer to Member States the freedom to allow, restrict or ban the cultivation of Genetically Modified Organisms (GMOs) on part or all of their territory. While keeping unchanged the EU's science-based GM authorization system, the adopted package consists of a Communication, a new Recommendation on co-existence of GM crops with conventional and/or organic crops and a draft Regulation proposing a change to the GMO legislation. The new Recommendation on co-existence allows more flexibility to Member States taking into account their local, regional and national conditions when adopting co-existence measures. The proposed regulation amends Directive 2001/18/EC to allow Member States to restrict or prohibit the cultivation of GMOs in their territory.

Source: adapted from Vicario, 2010, Davison and Bertheau, 2007 and Europa, 2008b.

As of January 18, 2011, the EU Register of GM Food and Feed lists 38 GM authorized products for food and/or feed use: 6 cotton varieties, 22 maize, 1 bacterial biomass, 1 yeast biomass, 3 varieties of rapeseed, 1 potato, 3 soybean types and 1 sugar beet (EC, n.d.b). The “Amflora” starch potato, with an altered starch composition, was approved for food and feed use, as well as cultivation, in the EU on March 13, 2010 after the initial application was filed in February 2005. This authorization is the first new GM organism approved for food/feed use as well as cultivation in the EU since the embargo on new GM organisms that began in 1998⁵ (McLeod, 2010). All other authorizations approved since 2003 (the end of the embargo) have been renewals of existing genetically modified organisms (GMOs) already present in the EU market.

Obtaining an authorization is imperative for a GM product’s legitimate sale and use in the EU market, therefore any firm wishing to export a GM product to the EU must undergo the application process. Given the EU’s favouring of a relatively strict *social rationality* approach over the science driven approach preferred by the US and Canada, the EU’s regulatory regime, and subsequently its mechanisms, can reasonably be expected to reflect political *precaution*⁶ in decision making (Isaac et al, 2002). In fact, the EU has codified the ‘use of criteria other than science to justify SPS measures’ (Freeman, 2003) in its regulatory regime for food and GMOs. The Preamble of the EU’s main legislation concerning food safety, Regulation (EC) No 178/2002, Point (19) states:

It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls (EC, 2002).

Greater *political precaution* in decision-making increases the risk for firms wanting to invest in international commercial activities such as bringing GMOs to the EU market (Kerr, 2002); therefore firms seeking to engage in the approval procedure for an authorization to market GM products in the EU market can reasonably expect a rigorous process that can be affected by political factors beyond their control, despite scientific evidence to the contrary.

The EU’s procedure for GMO’s is known as obtaining regulatory approval whereby the GMO in question is ‘authorized’ to be in the EU market (EC, 2003). An authorization is obtained via a two step risk assessment process which involves a scientific risk assessment, followed by a legislative approval procedure.

3.1 The Principles Guiding the Scientific Risk Assessment

A firm wishing to obtain an authorization to market a GM product in the EU will undergo a process that uses comparative analysis to assess food/feed safety, as well as traceability and labelling requirements. If the proposed GMO is to be released into the environment, an environmental risk assessment followed by monitoring is also required.

The EU GMO authorization process is guided by an overall risk assessment strategy that provides the criteria by which the application is judged and is a major component in determining whether the authorization is granted. The risks of a new GMO are assessed according to three factors:

⁵ While maize MON 810 is also approved for cultivation in the EU, it was approved in 1998, prior to the embargo on GMOs that began in 1999.

⁶ See Kerr (2002) for a discussion of political precaution.

- 1) *Risk assessment* where the identification of hazards and their potential adverse effects occur;
- 2) *Hazard characterization* where an assessment of the consequences of exposure, as well as the probability and possible levels of exposure are made, and;
- 3) *Risk characterization* where qualitative or if possible, quantitative estimates of probability and severity of effects in a given population are provided (EFSA, 2006a; EFSA, 2006b).

GMOs are classified according to complexity into single compounds, complex compounds not containing viable GMOs or products with viable GMO's/intact cloned DNA. The level of scrutiny and focus of the risk assessment differs for food and feed compounds based upon their complexity and derivative processes, history of use, familiarity and intended application with the most intense scrutiny directed at products containing viable GMOs (EFSA, 2006a; EFSA, 2006b).

In using a comparative approach, the concepts of 'body of knowledge' (or 'familiarity') and 'substantial equivalence' serve as a means to structure the assessment. Familiarity or body of knowledge allows the risk assessor to draw upon previous knowledge and experience gained via the introduction of similar organisms into food, feed and/or the environment. Substantial equivalence is a rationale that an existing microorganism with history of safe use as food or feed can serve as a comparator when assessing the safety of a GMO (EFSA, 2006a; EFSA, 2006b).

The assessment is guided by both concepts as it employs the record of safe use of a conventional counterpart(s) as a baseline against which the intended and potentially unintended outcomes of a GMO are compared. Intended effects fulfill the objectives of the GMO, with its effects compared to the conventional counterpart, while unintended effects are consistent differences between the GMO and its appropriate control lines. The comparative approach then identifies new or altered hazards of the GMO relative to the conventional counterpart in terms of potential environmental hazards, food or feed safety, and/or nutritional impact of the identified differences, intended or not (EFSA, 2006a; EFSA, 2006b).

The comparative approach is also used when conducting the assessment of environmental risk and monitoring. This process determines whether the GMO has access to and can survive in the natural environment, whether it can persist in the environment and assesses the receiving environment with the GMO's conventional counterpart(s) (EFSA, 2006a; EFSA, 2006b). The risk assessment and comparative approach mechanisms vary slightly between types and end applications of GMOs whether food, feed, microorganisms or plants but conceptually the same strategy is utilized in the authorization process.

The European Food Safety Authority (EFSA) has jurisdiction over the scientific assessment of GMO authorization applications. Its GMO Panel⁷ reviews each GMO authorization application on a case by case basis as no GMO is presumed to be safe. As part of its risk assessment, EFSA considers the following for every GMO authorization application received:

⁷ The GMO Panel consists of 21 independent experts supported by a number of specialized Working Groups drawing on a pool of more than 40 external experts in fields such as allergenicity, ecology, microbiology, toxicology, plant physiology and molecular genetics. All Scientific Panel and Working Group members are required to comply with EFSA's policy on Declaration of Interests including declaring any potential conflicting interests in advance of each meeting. Their Declarations are thoroughly screened by EFSA following strict internal procedures (EFSA, 2009).

- the molecular characterization 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 and taking into account its intended uses either for import, processing or cultivation (EFSA, n.d.b).

The EFSA, after consultation with stakeholders, published several guidance documents for applicants indicating the type of data required, the manner of data preparation and means of data presentation. The guidance documents are not one hundred percent prescriptive to specific study protocols and do not stipulate a mandatory list of tests to be performed under precise parameters. The EFSA does request fixed test protocols particularly for scientific issues where harmonization in tests is possible and valid test methods are agreed upon by international risk assessment bodies (EFSA, n.d.b.).

Any study carried out on the GMO and submitted to EFSA in the risk assessment application must comply with the Organization for Economic Cooperation and Development's (OECD) principles of Good Laboratory Practice (GLP), where applicable, and be accompanied by a formal statement of Quality Assurance. Should the data supplied be prepared by independent private (contracted) laboratories on behalf of the applicant, the laboratories must operate according to international laboratory standards, such as GLP, Good Manufacturing Practice (GMP) and those of the International Organization for Standardization (ISO). When the data received from the applicant is insufficient for EFSA's GMO Panel to make a full risk assessment, the applicant is required to provide the missing data before the GMO Panel proceeds with its evaluation. As of January 2011⁸, this has occurred in 95% of cases (EFSA, n.d.b.).

The EU's policy is that firms wishing to export to the European market carry the burden of proof in ensuring that the product(s) are safe (Freeman, 2003) and its legislation reflects this approach. Subsequently, the GMO authorization application must demonstrate the safety of the GM product in question and is obliged to present all of the necessary human/animal safety and environmental impact studies, according to the rules set by European legislation, to allow the European authorities to carry out a risk assessment. The applicant must also bear the costs associated with these studies proving the safety of the GMO in question. Additionally, should EFSA require further data, the applicant must also provide such information at its own expense prior to EFSA delivering its final risk assessment (EFSA, n.d.b.).

3.2 Applying for a GMO Authorization

There are two main types of GMO Authorizations; one for the placing of GM food and/or feed on the market, the other for the deliberate release of GMO's into the environment. Regulation EC 1829/2003 is the main legislation governing the former, while Regulation EC 2001/18 oversees the latter. Applications for cultivation of GMOs can be submitted under Regulation EC 1829/2003 for GM food and feed if those GMOs are to be used as source material in food and feed production. GMOs can also be authorized for the deliberate release of GMOs into the environment (Directive 2001/18/EC) for uses other than food/feed. The majority of GMO applications are for the import and processing of GMOs and/or their derivative products. Applications for the cultivation of GMOs cover approximately 15 percent of the applications under the EC Regulation 1829/2003 (EFSA, n.d.b.). For either type of authorization, the application process is a lengthy one, with procedures ranging from 1.5 to 8 years depending on the type of application (Backus et al, 2008).

⁸ As stated on the EFSA website in January 2011.

Firms seeking EU authorization for their GMO products must apply through a Member State (MS). An examination of the EFSA Register of Question⁹ indicates that most GMO applications are submitted through the Netherlands, Belgium, the United Kingdom (UK), Denmark, and a lesser number through the Czech Republic. A firm's choice of MS through which to submit their GMO authorization application is a strategic marketing decision. Factors contributing to this decision could potentially include but are not limited to:

- receptiveness of the MS government to GMOs in general, as well as to the particular GMO in question;
- the MS government's vested or strategic interests in supporting the GMO, for example:
 - the company in question is a significant component of a strategic sector emphasized by the MS,
 - there is particular demand for the GMO in question within that MS for example:
 - as a feed component in an MS that specializes in a particular livestock sector or
 - as food ingredient in a major manufacturing industry in the MS;
- political and/or economic influence of the firm in the MS;
- intended use or application of the GMO – i.e. food or feed use or cultivation;
- the MS's history of submitting applications for authorization and its lobbying ability at the Community level
- the firm's prior experiences working with the MS in GMO authorizations
- the relationship between the firm and the MS
- location of test plots or field trials

For example, BASF's recent GMO Authorization for its Amflora potato was submitted through the UK, but currently, BASF is undergoing the authorization process for a variant of the same potato¹⁰ with the application being submitted by Sweden. Dow AgroScience in partnership with Monsanto currently have GMO maize applications for food or feed use¹¹ submitted through the Netherlands as well as the Czech Republic. Syngenta currently has GMO maize applications for food or feed use submitted through Denmark, while authorizations for maize cultivation have been submitted through the UK. Recent applications for cultivation of GMOs have been submitted via Belgium, Netherlands, the UK, Denmark, the Czech Republic, and Sweden.¹²

A firm's choice of MS through which to submit their GMO application does not necessarily align with that particular MS's philosophical stance towards GMOs. The Netherlands, Belgium, Luxembourg, Denmark, Finland, Slovenia, Sweden and the UK are described as being 'pragmatic in their view towards GMOs but do not permit cultivation' (McLeod, 2010, p.16) yet current GMO applications for cultivation have been submitted via Belgium, the Netherlands, UK, Denmark and Sweden (EFSA, n.d.a). Nations that permit cultivation (Poland, Romania, Czech Republic, Portugal, Slovakia and Spain) (McLeod, 2010) are not necessarily those through which authorizations for cultivation are submitted. Of these, the Czech Republic is the only one through which current applications have been filed (EFSA, n.d.a.).

⁹ Lists all current and recent GMO applications for which EFSA is or has undertaken risk assessments. Available at: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO&questiontype=2>,

¹⁰ The existing authorization submitted via the UK is for derived food or feed use. The current application filed through Sweden is for food and feed use, import, processing and cultivation.

¹¹ In the Netherlands, the application is for MON8903 x 1507 x NK607 for food/feed, import and processing purposes. In Czech Republic, MON 89034 x 1507 x MON88017x 59122 for food/feed, import and processing purposes.

¹² As listed on EFSA's Register of Question, as of February 9, 2011, available at: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO&questiontype=2>

a. Authorization for placing a GMO for food or feed use on the market

Regulation EC 1829/2003 governs the authorization of GMOs for food or feed use. The cultivation of GM plants for food and/or feed use may also be authorized under EC 1829/2003. A companion piece of legislation, Regulation EC 1830/2003 expands coverage to include all types of foodstuffs containing or produced from GMOs (e.g. proteins, additives and flavourings) for human consumption, and GMO animal feed. GMOs for food use include GM plants for food use, food containing or consisting of GM plants or food produced from GM plants or containing ingredients produced from GM plants. GMOs for feed include GM plants for feed use, feed containing or consisting of GM plants and feed produced from GM plants (EFSA, n.d.b.).

A firm applying for an EU GMO food or feed authorization must first present its application to an EU member government's designated authority. The national authority acknowledges receipt of the application within 14 days (Plan and Van den Eede, 2010), and submits the application to the EFSA. The application must be accompanied by supporting documentation including, but not limited to, the designation of the food and its specification, including the transformation event used, research illustrating the safety of the product in terms of human health, animal health and environmental dangers, analysis showing substantial equivalence of the product, suggestions for product labelling, detection, sampling and identification methods, samples of the product, and if appropriate suggestions for post market monitoring (McLeod, 2010; GMO Compass, 2006). Articles 5 and 17 of the legislation provide the particulars required (Plan and Van den Eede, 2010) as do EFSA guidance documents.

The EFSA begins the process by preparing a summary of the application that is published on their website, which is then submitted to the European Commission (EC) and member governments for review and a three month consultation period. EFSA then undertakes the scientific assessment of the application that will be published as an *Opinion* and submitted to the Commission. While conducting its assessment, EFSA may ask the appropriate body of a MS to carry out a safety assessment of the food/feed and/or to carry out an environmental risk assessment (EFSA 2006a; EFSA 2006b). The verification of the detection method for GM food or feed is also part of the process and is conducted by the EC Joint Research Centre in its role as the Community Reference Laboratory for GM Food and Feed (Plan and Van den Eede, 2010). This validation will also be included in EFSA's opinion.

The EFSA *endeavours to respect* (Barkus et al, 2008) a six month deadline for the provision of its Opinion after receiving the application unless further data is required, for which each incident will extend the time limit as determined by circumstances. Within the six month time frame, EFSA will provide the Commission with its *Opinion* which will include the scientific safety assessment as well as suggestions for product labelling, any applicable restrictions or conditions, detection methods, and if applicable, an environmental monitoring plan ((EFSA 2006a; EFSA 2006b)). Note, the use of the term *Opinion* reinforces the *Social Rationality Approach* of the EU whereby science only informs the decision making process. The *Opinion* is also published on the Commission's website where public comment is accepted for 30 days from the date of publication. The EC analyses all comments and consults with EFSA to determine their merit and impact on the *Opinion*. The EC has three months after receiving EFSA's *Opinion* to produce a draft Decision, based on the *Opinion* but may differ from EFSA's conclusions (though this is rare) if written justification is provided. Whether the Commission agrees with EFSA's Opinion in its draft Decision or differs from it (and written justification is provided), the Commission must then submit its draft Decision to the EU's legislative procedures for approval as a legal measure. The first step of the legislative procedure is for the Commission to submit the draft Decision to the Committee process.

b. Authorization for the deliberate release of a GMO into the environment

This authorization is required for the experimental releases of GMOs into the environment such as for the purposes of research and development or for the distribution of a GMO on the market, whether for a fee or without charge, for the purposes of cultivation, importation or transformation into other products. Examples of products for deliberate release into the environment include the import and processing of GM plants, GM seeds and plant propagating material for cultivation, GM flowers with modified colour traits, seed mixture containing a GMO or a corn variety with resistance to a particular fungus. This particular authorization is governed by Regulation 2001/18/EC and its subsequent amendments.

An Authorization for the deliberate release of a GMO into the environment must first receive authorization from the MS within whose territory the release is to occur. The applicant must submit a *notification* to the designated national authority within the MS to complete a scientific assessment report on the notification within 30 days. Should the assessment be unfavourable, the firm may submit a new notification for the same GMO to a different MS's national authority that may issue a different report.

Should the assessment report provide a favourable opinion for the placing of the GMO concerned on the market, the MS will forward this assessment report to the Commission, which will within 30 days, forward the opinion to the other MS which may within 30 days, make comments on the opinion either via the Commission or directly to the national authority.

If neither the Commission nor other MS make any objections to the assessment report, the national authority that carried out the original assessment authorizes the placing of the product on the market. The authorized product may then be placed on the market throughout the EU so long as it meets with any conditions contained in the authorization. The authorization has a maximum duration of ten years and may be renewed provided certain conditions are met (for example on the basis of the results of the post-market monitoring program). If objections are raised, the procedure provides for a conciliation phase among the MS, the Commission and the applicant in order to resolve the outstanding questions. If, at the end of the conciliation phase the objections are maintained, a decision must be taken at the European level (EC, n.d.a.).

At this point, the procedure for both types of Authorizations converges as the Commission will seek the scientific opinion of the European Food Safety Authority (EFSA) and the process is the same, as detailed above, whether for GMOs intended for food/feed purposes or for release into the environment. The end result at this stage of the application process for either type of GMO authorization is EFSA provides its *Opinion* from which the Commission prepares a draft Decision which must be submitted for the same legislative procedure.

Effective March 1, 2011, the authorization procedures for GMO products will be governed by the Implementing Acts of the Treaty of Lisbon (Article 291). The Implementing Acts changes the EU's decision making procedures, thereby affecting the GMO authorization process *ex post* to the EC's completion of the draft Decision. Up to this point, the process remains unchanged.

c. The Legislative Approval Process Pre-Treaty of Lisbon up to March 1, 2011

Prior to March 1, 2011 the legislative procedure¹³ governing a GMO application for authorization

¹³ Since December 1, 2009, Article 289 of the Treaty on the Functioning of the EU (TFEU), Lisbon Treaty, and Council Decision 2006/512/EC amending the 1999 Decision on Comitology (1999/468/EC). More specifically

as considered *individual in scope* (as compared to a general scope issue¹⁴) and was therefore subject to Regulatory Procedure (Article 5 of Decisions 2006/512 and 1999/468) (Eurlex, 1999; Hardacre, 2011). Regulatory procedures required that the Commission's draft Decision on an individual GMO authorization be submitted to a regulatory committee of technical advisors as well as representatives of MS (usually SCoFCAH, the Standing Committee of Food Chain and Animal Health) for approval or rejection by a qualified majority vote (QMV)¹⁵. Should SCoFCAH not be able to reach a QMV, resulting in its giving *no opinion*, the Commission must submit the draft to the EU Council of Ministers (ECM) which must achieve a QMV to adopt or oppose the draft within three months from the date of submission. Should the ECM not be able to come to a QMV decision by the deadline, the draft reverts back to the Commission, which is then legislatively obligated to adopt the original draft and the GMO authorization is granted.

The SCoFCAH and ECM are usually evenly divided among the constituent MS on the issue of GMO authorizations and neither have ever reached a QMV within their allocated deadlines on GMO authorizations, thereby they commonly submit a decision of *no opinion* (Hardacre, 2011; EurLex.a, 2006a¹⁶ – 2010k). As a result, all GM authorizations in the EU have been adopted by the Commission because it is procedurally obligated to, often with 50 percent of the MS in opposition (Brans, 2010; EurLex.a, 2006a-2010k).

In the unlikely case that the SCoFCAH gives approval of the draft by QMV, the Commission submits the draft for scrutiny to the ECM which then votes by QMV to approve or oppose it. Approval by QMV enables the Commission to adopt the draft while opposition requires the Commission to either amend the existing draft or submit a new proposal for approval. Should the ECM also give **no opinion** the Commission is again obligated legislatively to adopt the draft and the GMO authorization is granted.

d. The Legislative Approval Process under Treaty of Lisbon (post March 1, 2011)

The Treaty of Lisbon Implementing Acts Regulation came into effect March 1, 2011 and governs market authorizations of all types, including for GMOs (EurActiv, 2011). Committees remain in place under Implementing Acts¹⁷ but now operate solely under either Advisory¹⁸ or Examination Procedures. Examination Procedures were created by the merging of the old Management and Regulatory Acts and apply, in particular, for the adoption of common agricultural policies, environment, security and safety or

pertaining to GMO's, Decision 2008/27 amends 2001/18 addressing the power of the Commission regarding the deliberate release of GMOs into the environment.

¹⁴ General Scope Issues are subject to a different legislative process known as Regulated Procedure with Scrutiny (RPS) which provides the European Parliament (EP) the power to veto legislation that they lack in Regular Procedure (Eurlex, 2006a). RPS was only put into legislation between 2006 and 2009 (when the Treaty of Lisbon came into force). The EP has the legislative power to co-decide the legislative acts on which the individual GMO authorizations are based, not the authorizations themselves. For example, RPS is only foreseen in Article 21 on labelling (threshold levels), Article 26 (labelling), Article 27 (annex changes), and Article 16 (criteria and information) of Regulation 2001/18/EC governing the release of GMO's into the environment. These are general scope tasks that will impact the legislation governing the processing of an individual GMO authorization (Hardacre, 2011).

¹⁵ A qualified majority is when 255 out of 345 votes is reached, representing a majority of the Member States and must also represent at least 62% of the EU population (Europa, n.d.). Qualified majority is defined by the Treaty of Nice where each Member State is allotted a specific number of votes according to its population (GMO Compass, 2006). Under the Lisbon Treaty, the existing QMV system will change in 2014.

¹⁶ GMO authorizations since 2006 were analyzed as these were governed by EC Decision 2006/512 which amended the original committee system established in EC Decision 1999/468.

¹⁷ The Treaty stipulates two kinds of Acts – Delegated and Implementing Acts. Delegated Acts are not relevant to this particular discussion on GMOs. Article 291 TFEU governs Implementing Acts.

¹⁸ Advisory Procedures are not relevant to a GMO application

protection of the health and safety of humans, animals or plants (EP, 2010). In other words, effective March 1, 2011, once the Commission has completed its draft Decision of a GMO authorization, the Decision will be submitted to Examination Procedures¹⁹ for discussion and QMV voting.

The Examination Procedure begins with the Commission's draft decision being submitted to an Examination Committee (SCoFCAH's role in the previous regime which will likely remain under the new system) to discuss and vote on its position by QMV. If the Committee delivers a positive opinion, the Commission shall adopt the draft measure. The European Parliament²⁰ and ECM have been given the right of scrutiny by Article 11, providing either body with the ability to assess whether the scope of the draft measure exceeds the Commission's legislative powers as afforded by the Lisbon Treaty and Comitology Acts (EC 1999/468, EC 2006/512) and can pass a non-binding resolution if they believe this has happened. This situation has rarely occurred in the past (Hardacre and Kaeding, 2010).

If the Examination Committee gives *no opinion* on the Commission's draft Decision because it cannot achieve a QMV, the Commission *may* adopt the draft measure (Brans, 2010; Hardacre and Kaeding, 2010). With the new regulations, when faced with a *no opinion* from the Examination Committee, the Commission has gained greater flexibility to either resubmit the draft Decision to the Examination Committee or it can adopt the measure, with specific exemptions. The Commission cannot adopt the measure should the implementing act be firstly, related to taxation, financial services, health and safety²¹, or to safeguard measures or secondly, if a simple majority opposes the adoption of the measure (Hardacre and Kaeding, 2010). However, should the Commission believe the measure is necessary and timeliness is an issue, it can submit the measure to a newly created Appeals Committee (AC) within one month of the Examination Committee's decision (Hardacre, 2011). Previously, under the Regulatory Procedure, if the Regulatory Committee gave *no opinion*, the Commission was obligated by legislation to forward the measure to the ECM and eventually adopt the measure, which was the case with GMO authorizations, thereby forcing the Commission into the controversial position of adopting a measure that 50 percent of the MS opposed (Hardacre and Kaeding, 2010).

If the Examination Committee delivers a negative opinion by QMV, the Commission *cannot* adopt the draft measure. The Commission can then either amend and resubmit the draft to the Examination Committee or forward the draft Decision to the AC which can change the text, adopt the text or reject it, again by QMV; the AC decision is binding upon the Commission. Should the AC vote against the measure, the Commission *cannot* adopt it and must amend the existing proposal or submit a new one. Should the AC vote for the measure, the Commission *shall* adopt it. However, as the AC is representative of the MS and MS positions will not change, agreement by QMV remains unlikely and the AC could conceivably offer *no opinion*. Again, it is here that the procedural change becomes apparent as the Commission is no longer obligated to adopt the legislation as it was previously; now in the case of *no opinion* the EC *may* adopt the draft but it can also refer it back to the Examination Committee (Hardacre and Kaeding, 2010; Hardacre, 2011).

In the previous regime, the role of the Examination Committee was fulfilled by SCoFCAH, which is comprised of technical experts as well as representatives of MS. Under the new regime, the Examination Committee will likely remain SCoFCAH, with decision making being based upon a combination of scientific and socio-economic factors. The Appeals Committee will be comprised solely of one representative from each Member State (at the appropriate level), with no technical experts and

¹⁹ Under Article 5 of the Implementing Act

²⁰ This is the only role for the European Parliament in the approval of a GMO authorization.

²¹ Given that GMO's are often considered as part of consumer health and safety, the Commission could conceivably be barred from ever adopting a GMO draft decision should the Examination Committee be unable to achieve QMV, and the Commission will need to submit to the AC.

will be chaired by the Commission. It is a purely political body whose decision making is guided by the socio-economic and political factors of the individual MS and provides the ECM with an additional opportunity to review controversial measures (Hardacre, 2011).

These procedural changes were made partly to address an issue of legislative responsibility and the EU's principle of QMV. In the past, the Commission adopted the measures giving individual GMO authorizations because it was legislatively obligated to, due to the inability to achieve QMV, despite the opposition of many MS. These changes under Implementing Acts now give the Commission the opportunity to work towards a decision where it is not the final decision maker in the face of such opposition. Conceivably, for a highly contentious GMO authorization, the possibility exists for a continuous cycle of *no opinion* should the Examination Committee and the Appeals Committee consistently return *no opinion* results and the Commission does not wish to undertake the role of final arbiter (Hardacre, 2011).

Once the Commission adopts the draft Decision, that particular GMO is authorized. Individual GMO authorizations are valid throughout the EU for 10 years and are renewable (Plan and Van den Eede, 2010). The renewal process is similar to that of the original authorization and will include any new information pertaining to the GMO in question.

e. Other Requirements - Labelling and Traceability

All GMO authorized products, whether approved as food/feed or for environmental release must meet traceability and labelling requirements stipulated in Regulation EC1830/2003. All products consisting of or containing GMOs must be labelled as *containing GMOs* or *genetically modified [name or organism]* and must be labelled as such regardless of whether the DNA or protein resulting in the genetic modification is detectable. The same labelling requirement is applicable to GM animal feed thus any compound feed containing or produced from GMOs must be labelled as GM.²²

Mandatory traceability facilitates the control and verification of labelling claims, specialized monitoring of environmental and health effects where necessary and enables the withdrawal of products containing or consisting of GMOs if required (Plan and Van den Eede, 2010). If a product is produced from GMOs, labelling must indicate each of the food ingredients or feed components produced from GMOs. If a product contains or consists of GMOs, labelling must indicate that the product contains or consists of GMOs and provide the unique identifier(s) assigned to those GMOs. Traceability is required along the entire supply chain of a GM product.

4.0 Beyond the EU GMO Authorization - Individual Member States Policies

Once a GMO has received authorization from the Commission to be placed on the European market, whether as food, feed or to be released into the environment, barriers to market entry remain on an individual MS level, particularly for the cultivation of GM products. There has been dissatisfaction at the MS level pertaining to their lack of power to decide whether or not to cultivate GM crops within their territory, despite those crops having received EU authorization. The issue is highly contentious and the MS's dissatisfaction with the authorization process for cultivation is demonstrated by their use of safeguard measures as well as total bans against some authorized GM crops (McLeod, 2010).

²² Prior to 2003, highly refined food products such as oil obtained from GM soy or corn did not have to be labelled as GM. The same was true for feed containing GM soy or corn; prior to 2003, GM labelling was not required for feed produced from GMOs (Plan and Van den Eede, 2010).

4.1 *Safeguard Measures*

A Member State can impose safeguard bans (provisional restriction or prohibit the use and/or sale) of a GM product in their territory if new²³ evidence provides sufficient grounds to believe that the approved GM product poses threat to human or animal health or the environment. Emergency measures can be applied in the event of a severe risk and include the suspension or termination of the placing on the market of the GMO. A number of Member States have invoked the so-called *safeguard clause* of 2001/18/EC (Article 23) on nine separate occasions²⁴. There have been safeguard measures invoked by Greece²⁵ and Poland²⁶ against varieties of GM maize seeds while Austria, France, Greece, Hungary, Germany and Luxembourg currently maintain safeguard measures against the cultivation of GMOs in their territory (EC, n.d.a).

In the majority of these cases, the scientific evidence provided by the invoking MS as justification for their measures, was found by EFSA to be insufficient for repealing the original GMO authorization. The Commission was then forced through its legislative processes of comitology²⁷ to ask the MS to lift their safeguard measures; the Regulatory committee has consistently been unable to achieve QMV and recourse to the ECM has consistently resulted in rejection of the Commission's proposals for the MS to lift the bans²⁸ resulting in an extremely lengthy process. Bans are left in place until the final decision has been made by the ECM.

Currently, Austria, Hungary, France, Greece, Germany and Luxembourg have adopted safeguard measures prohibiting the cultivation of the GM maize MON810 on their territories. Austria, Luxembourg

²³ New evidence as found by their relevant national authorities, whether citing an independent study or one conducted on the behalf of or by the national authorities.

²⁴ Safeguards were invoked 3 times by Austria, twice by France, and once each by Germany, Luxembourg, Greece and the United Kingdom through the late 1990s and in 2000. The UK eventually withdrew its ban (EC, n.d.a).

²⁵ On 29 March 2006 Greece notified the EC of its prohibition for 18 months of the marketing of seeds of 31 maize MON 810 varieties, based on the safeguard clause of Directive 2001/18/EC. On 7 November 2006 EFSA adopted an opinion stating that the cultivation of MON810 in Greece is unlikely to have adverse effects on human health or on the environment. SCoFCAH offered no opinion in February 2009 (EC, 2009) and the matter is still in process.

²⁶ The EC examined a request from Poland to invoke the safeguard clause for the use of 16 varieties of MON810 on its territory (under Article 16(2) b) of Directive 2002/53/EC). On 1 March 2006 the EC authorized Poland to prohibit the use of these varieties of MON810 because they are not suitable to be cultivated in Poland due to their too high maturity class (EC, n.d.a)

²⁷ Comitology is the EU's system of committees that assist the EC in the management of the Union where decision making is achieved through QMV. The process is similar to that discussed for the legislative approval process for GMO authorizations.

²⁸ For example, the EC submitted draft decisions twice to the ECM requesting Austria to repeal its ban on the use and sale of maize MON810. The ECM Environment Council opposed the decision, forcing the EC to revert to EFSA for an assessment of MON 810's safety for the third time. EFSA returned the same favourable result on MON810's safety thereby the EC did not amend its draft proposal for Austria to lift its safeguard measures on MON 810 and resubmitted it to the ECM which then adopted the proposal on October 9, 2006. Austria was ordered by the ECM to comply within 20 days of the ECM's decision (EurLex, 2006b). Austria notified the EC of its ban on MON810 in June 1999; the entire process required nearly 7 years to complete. The EC has submitted various unsuccessful proposals to the ECM to force Austria to repeal its ban.

In January 2005, Hungary invoked the safeguard clause in order to prohibit the cultivation of MON 810 maize on its territory; the EC's proposal to lift the ban was referred to EFSA three times, the regulatory committee once, and the ECM three times. The ECM ultimately ordered Hungary to repeal its ban Jan 1, 2009, 4 years after Hungary's initial notification (EurLex, 2009).

The EC has made several attempts to force Austria and Hungary to comply with the decisions but these proposals have been rejected by the EU Environment Ministers by QMV (Euractiv, 2009), thereby eventually allowing Austria, Hungary, Greece, Luxembourg, Germany and France to maintain their bans on MON810. Greece banned it in 2001, France in 2008, followed by Germany and Luxembourg in 2009 (McLeod, 2010).

and Hungary have prohibited the cultivation of the “Amflora” potato. Poland has legislation in place forbidding the marketing of all GM seeds (EC, 2010c).

Essentially, despite having received official authorization at the EU level, GM products are still subject to bans at the national level based upon safeguard measures should the MS find any scientific information indicating a risk to human, animal health or the environment that was not included in EFSA’s scientific assessment during the approval process. Bans are implemented until the new information can be evaluated and can remain in place despite having been determined by the EFSA to be scientifically unfounded.

4.2 Adventitious Presence and Low Level Presence

The unintentional and seemingly unavoidable co-mingling of trace amounts of one type of seed, grain or food product with another during growing, harvesting, transport or processing is a common occurrence. When applied to the situation where GMOs are co-mingled with conventional products, two scenarios can occur. The first is when *authorized* GMOs are found in non-GM products and is commonly referred to as low level presence (LLP). The second is when *unauthorized* GMOs are found in non-GM products and is usually referred to as adventitious presence (AP).²⁹

The EU has a 0.9 percent threshold of tolerance for authorized GMO LLP in non-GM food and feed products. Should authorized GMO amounts greater than 0.9 percent be detected in non-GM products, the product must be labelled as GM. For seed products, the EU maintains a maximum threshold limit of 0.5 percent of GMO content for a specified list of seed products as per regulation EC 641/2004 (EurLex, 2004).

The EU maintains a zero tolerance policy for the AP of unauthorized GMOs; as every unauthorized GMO is presumed to be unsafe by the EU, even minute AP of an unauthorized GMO in a product can trigger a significant reaction from EU officials including emergency measures. Should unauthorized GMOs be discovered via the established detection and traceability system, the EC food safety regulation (Regulation (EC) 178/2002) allows the adoption of appropriate emergency measures for imported food and feed from a third country where the risk cannot be contained satisfactorily by the affected Member State(s) (EC, n.d.a).

The EU has enacted emergency measures three times since implementing Regulation EC 1829/2003; for Liberty Link (LL Rice 601) rice³⁰, Bt10 corn gluten³¹, both of US origin and Bt63 rice³² from China, all of which were unapproved in the source country as well as the EU. The 2009 detection of Triffid flax (FP967) – a GM flax – in Canadian exports to the EU has not resulted in the official implementation of emergency measures due to the development of a rigorous sampling and testing protocol by Canadian officials and stakeholders (CGC, 2010) that the Commission deemed acceptable. The situation with Triffid will be discussed in this paper’s companion paper ‘*Post-Moratorium European Union Regulation of Genetically Modified Products: The Case of Triffid Flax*’.

²⁹ While there are no universally agreed definitions, current industry and government parlance uses adventitious presence (AP) to describe co-mingling of GM material that is not approved in any jurisdiction while low level presence (LLP) is used to describe instances of where GM material is found that is not approved in the country of import but approved in another jurisdiction.

³⁰ Emergency measures enacted in 2006 (EC2006/601) and were repealed June 8, 2010 (EC, 2010a)

³¹ Emergency measures enacted in 2005 (EC 2005/317) and were repealed March 7, 2007 (EC 2007/157)(EC, 2007)

³² Emergency measures were enacted April 15, 2008 requiring certification for Chinese rice products (EC, 2008).

Beyond the EU's process for the authorization of GMOs for release into the European environment, whether as approved food, food ingredients or feed products, the EU also maintains a series of regulations for the release into the environment of *unauthorized* GMOs. There is zero tolerance for release of *unauthorized* GMOs into the environment in the EU.

Debate surrounding AP and LLP remains heatedly contentious within the EU as MS have strongly entrenched positions. The EU maintains zero tolerance for the AP of unauthorized GMOs in feed. The Commission proposed a "technical solution" for AP of unauthorized (but one for which an EFSA assessment is pending) in animal feed at 0.1 percent plus a level of uncertainty (SaskFlax, 2011), which is the lowest level that GMOs can reliably be detected after allowing for technically unavoidable uncertainties. Analytical results below the 0.1 percent would be considered equivalent to zero and that consignment of feed would be permitted (FSA, 2010). The technical solution is meant to reduce the risk of feed supply shortages and subsequent negative impacts on the EU livestock sector (EC, 2010d) which imports nearly 77 percent of its protein requirements from nations that are major GM producers. The proposal is only applicable to animal feed and not to food for human consumption. Member States disagree over the coverage of the proposal; some want the threshold to be applied only to GMOs that have already been approved by EFSA (Inside US Trade, 2011). The conditions under which unapproved GM crops would qualify for the threshold have been strengthened such that the crops in question must have been approved in one or more non-EU producing countries and an EU authorization application must have been filed with EFSA for at least three months (EurActiv, 2011b; SaskFlax, 2011). The regulation for this technical solution was endorsed by SCoFCAH on Feb 22, 2011 and it is now subject to scrutiny by the European Parliament and Council; if these bodies do not oppose the draft, the measure will be adopted by the Commission (EC, 2011)³³.

4.3 Coexistence

The cultivation of GMOs in the EU has implications for the manner in which agricultural production is organized. Co-existence is the means by which GM and traditional non-GM crops are kept segregated, maintaining the choice for producers between cultivating conventional, organic and GM crops in compliance with the legal obligations for labelling and purity standards. Co-existence measures therefore prevent the co-mingling of GMOs in non-GM crops in areas where GMOs are cultivated, and are an attempt to limit the potential economic loss and the impact such presence would have on conventional or organic crops (EC, 2010c). In July 2003, the EC adopted recommended guidelines (EC 2003/556) for individual member states' national strategies and best practices to ensure the co-existence of GM crops with conventional and organic farming. Many MS have implemented national approaches to co-existence and subsequently, there is no EU legislation on co-existence (Plan and Van den Eede, 2010).

Belgium, the Czech Republic, Germany, Hungary, Portugal, Romania and Slovakia have established national coexistence frameworks for organic, GM and conventional crops (McLeod, 2010). Austria, Denmark³⁴, Italy and Germany have drafted coexistence laws that are extremely restrictive of the activities of producers of GM crops (FAS, 2010). In implementing and managing coexistence, several MS demanded greater flexibility to accommodate local, regional and national particularities. Austria, Denmark and Italy were the most persistent in lobbying the Commission to adopt EU-wide regulation for coexistence (McLeod, 2010).

³³ The status of the technical solution in feed will likely be discussed at the next upcoming meetings of the GM Food and Feed Section of SCoFCAH, provisionally scheduled for July 20, 2011 and Sept 22-23, 2011.

³⁴ Ironically, as discussed previously, Denmark is one MS through which many firms submit their GMO authorization applications.

Any GM to be cultivated that receives authorization in the EU must follow each MS's regulations on coexistence. GM seeds and plants are most affected by coexistence requirements. Coexistence is also vulnerable to the impact that contamination can have. Producers must meet the threshold requirements of less than 0.9 percent for food and feed and 0.5 percent for seeds in order to label their products as non-GMO or organic, and must demonstrate that the co-mingling was technically unavoidable to authorities (Europa, 2008a).

5.0 The 2010 EU Regulation on Cultivation in Member States

In July 2010, the initial recommendation (EC 2003/556) on coexistence was replaced by Recommendation 2010/C200/01. Within it, the Commission has proposed an article (26b), applicable to all GMOs that will be authorized for cultivation in the EU, either under Directive 2001/18/EC or 1829/2003/EC, allowing MS to restrict or prohibit GMO cultivation in part or all of their territory without recourse to the safeguard clause (EC, 2010b). In other words, MS will be free to restrict or prohibit the cultivation of specific GM strains or GM crops as a whole, in parts of or in their entire territory, on socio-economic grounds (MEEP, 2010). The MS can only adopt such measures against the cultivation of GMOs; they cannot adopt measures prohibiting the import and/or the marketing in the EU of authorized GM seeds (EC, 2010c). This amendment will also be applicable to all GMOs that have already been authorized for cultivation in the EU, either under Directive 2001/18/EC or Regulation (EC) No 1829/2003 (EC, 2010c).

At the announcement of the 2010 Recommendation, Health and Consumer Policy Commissioner, John Dalli stated:

Experience with GMOs so far shows that Member States need more flexibility to organize the co-existence of GM and other types of crops such as conventional and organic crops. Granting genuine freedom on grounds other than those based on a scientific assessment of health and environmental risks also necessitates a change to the current legislation. I stress that, the EU-wide authorization system, based on solid science, remains fully in place (EC, 2010b).

The recommendation also allows MS to adopt LLP and AP thresholds below the existing labelling threshold of 0.9 percent for authorized GMOs. MS can also establish large *GMO-free* areas when co-existence measures are not sufficient to prevent the unintended presence of GMOs in conventional or organic crops within their territories (EC, 2010b). MS may use any grounds to do so, other than those covered by the health and environmental risk assessment of the EU authorization process (EC, 2010c).

The proposal for revising Directive 2001/18/EC aims to secure legal certainty for Member States when they decide on GMO cultivation policy based upon socio-economic grounds and not those based on a scientific assessment of health and environmental risks. Their decisions will not need to be authorized by the Commission, but MS must inform other MS and the Commission one month before the adoption of their measures. The proposal states that the MS will also have to respect the general principles of the Treaties and the Single Market, and be consistent with the international obligations of the EU (EC, 2010b) despite the fact that the proposal inherently contravenes the SPS Agreement. At the same time, the EU authorization system, based on scientific assessment of health and environmental risks will be maintained as will the functioning of the internal market for GM and non-GM seeds, food and feed. The legislative proposal for national level approval of GM cultivation within their territories will be adopted through co-decision with the European Parliament and the Council (EC, 2010b).

The amendment gives MS full freedom regarding the cultivation of GMOs in their territory; it also means that MS with existing bans on GMO cultivation now have legal justification to continue them. The amendment allows individual MS to conduct their own non-scientific impact assessment pertaining to the cultivation of the GMO and justify their actions according to their own national legislation. MS can now legally restrict or prohibit GMO cultivation, on socio-economic grounds, when no new scientific risk is identified and are now relieved of having to resort to the safeguard clause.

For a GMO product destined for cultivation, the 2010 Recommendation means that despite having received EU level authorization, it is still subject to arbitrary bans at the MS level. The Recommendation removes certainty for the GM product; even should it be permitted in a particular MS, the MS can subsequently decide to ban it arbitrarily. The Recommendation also has implications for GM products already being cultivated in the EU as the MS within whose territory the cultivation is currently taking place may now arbitrarily restrict or ban the cultivar. The introduction of such regulatory unpredictability greatly increases the market risk for a firm with a GM cultivar, be it established or one seeking EU authorization. The Commission is currently undertaking an evaluation of the EU regulatory framework governing the cultivation of GMOs and the results of the evaluation are expected in the first quarter of 2011 (EC, n.d.c).

5.1 *Implications*

Ultimately, the diverging approaches of the Commission and the various MS regarding GMO cultivation, and GMOs in general, has the potential to fracture the EU's cohesive policymaking and enforcement abilities. GMOs have been a contentious issue in the EU as the analysis of the approval process demonstrates. The cultivation of GMOs is proving to be even more controversial as issues of national sovereignty and the freedom of producers and consumers to choose are involved.

Given that some MS will support and permit GMO cultivation while others will restrict or ban it, and the EU's open internal borders will not impede the continued movement of authorized GM seeds or plants, complicated issues arise for all the MS, regardless of their treatment of GMOs.

MS that permit cultivation of GMOs will incur high monitoring, testing and transactions costs to ensure segregation of GM and non-GM products which is necessary for traceability, labelling and the provision of consumer information. In MS that permit cultivation, producers' productivity and efficiency gains due to GMO adoption will be offset by increased monitoring, labelling and traceability requirements for their product on-farm and in transit. They will benefit from access to markets that utilize GM products, such as high protein feed or specialized food ingredients but they will also face potentially reduced prices or loss of markets for their GM product in the general EU market due to the stigma associated with GM in some MS. Industries that rely on GM products as an input (i.e. as animal feed or as a food ingredient) could potentially source the input from a MS rather than a non-EU supplier, but will still need to incur traceability, labelling and transport costs.

Member States that restrict or ban the cultivation of GMOs will also incur high monitoring and testing costs, as well as significant enforcement costs to ensure that GMOs do not enter their territory. The practical aspect of enforcement in a customs union without borders is also questionable. Producers in those MS that restrict or ban the cultivation of GMOs will not achieve the associated productivity or efficiency gains. They may also lose access to markets that utilize GM products (i.e. high protein animal feed, food ingredients).

Firms, either domestic or international, with GM products wanting access to the EU market will face high transactions and fulfillment costs. It is entirely possible that should the EU follow a trajectory of devolving greater power to the Member States regarding GMOs, firms may actually be confronted with

the task of familiarizing themselves with the requirements of 28 different regulatory regimes for GM products (27 sets of individual MS regulations and the EU-level authorization process³⁵). Under the 2010 Recommendations, firms must still undergo the EU authorization process, and then will need to navigate individual MS regulatory regimes. As a result, information asymmetry and transactions costs will increase for firms. Even if firms are highly efficient and effective at meeting regulatory requirements, they will still be subject to greater risk due to the unpredictability and uncertainty in each MS market given the MS's proposed ability to restrict or ban GM cultivation. Firms will require rigorous supply chain monitoring, traceability and labelling systems that can accommodate the coexistence requirements of each MS. Firms will incur greater monitoring, marketing and legal costs as they adapt to each MS market and monitor their respective legal and regulatory regimes. There is also greater potential for disputes due to confusion that may arise from the varying regulations and policies between MS.

This discussion has provided a step by step analysis of the EU's regulatory environment for GMOs and the authorization process for GMOs. It is clear that the regulatory environment is complicated, involving a rigorously thorough scientific safety and risk assessment that has less standing than the political stance of individual Member States. The GMO authorization process reflects this given the two steps of scientific assessment and committee based legislative approval. The process is lengthy and complex and is subject more to the diverging political agendas of the MS rather than the science accepting the safety of the product. As the USDA FAS summarizes:

The EU's complex and administratively burdensome biotechnology approval process... relies heavily on the individual, sometimes, non-science based stances of its 27 Member States, which ironically, often come after the EFSA has issued its scientific opinions stating that the products are safe (McLeod, 2010, p.14).

As a result, the USDA's Mission to the EU states:

Biotechnology continues to be more of a political than scientific issue in Europe and the prospects for improvement remain dim. Many food processors and exporters have either reformulated or sought non-biotech sources in response to the mandatory traceability and labelling requirements implemented since 2004 (FAS, 2010).

6.0 A Final Caveat - Devolution

Clearly, the European Commission is attempting to balance the legal and administrative demands of the unified Community with the diverging interests of individual MS. The contentiousness of GMOs and intractable positions of several MS towards GMOs have illustrated a weakness in the EU's governing infrastructure. Should MS interests be as diametrically opposed to the EU's or other MS's as they have proven to be pertaining to GMOs, the Commission cannot force consensus, nor compel the divergent MS to tow the line. This threatens the founding principles of the common market and customs union upon which the EU is based.

GMOs have become a highly divisive wedge in the EU's legislative procedures, forcing inertia as QMV became less likely in the EU's committee system. The Commission had been forced into the position of final arbiter, often against the wishes of 50 percent of its members. The amendments made by

³⁵ For example, in June 2011, the level of AP threshold of GM at which shipment lots are rejected or must be labelled as GM is not consistent among MS; while most MS have zero tolerance or 0.1 percent, others have tolerance levels of 0.5 percent, 0.7 percent or 0.9 percent. MS are also able to adjust the control program in terms of sampling, number of samples taken, detection limits and decisions taken regarding labelling and enforcement (CSL, 2007). Firms must expend resources to remain current on each MS's individual policies.

the TFEU Implementing Acts of the Lisbon Treaty were the Commission's attempt to disperse responsibility for controversial decision making amongst the EU's other decision making bodies, and to provide itself with greater flexibility in controversial decision making.

With several MS maintaining bans on cultivation despite not having the legal grounds to do so, the Commission, by presenting its 2010 Recommendation, has attempted to defuse the issue by devolving the decision making power regarding cultivation to the MS level. There are consequences to devolution that defeat the economic arguments for promoting a single market in the first place. The economies of scale gained by a unified set of regulatory instruments are lost as the potential for 28 different sets of regulatory policies now exists, as compared to single mechanism had consensus been possible.

As a result, the Commission has recently put forth a legislative proposal that would devolve the authorization process for certain GMO related products back to the national level. The potential impact of this current debate is that there will no longer be GMO authorizations at the EU level (Hardacre, 2011). This proposal to modify the legislative framework would require the approval of both the ECM and EP under co-decision.³⁶

Should this proposal be accepted, the entire landscape for GMOs in Europe will change; the authorization processes detailed in this paper could potentially become obsolete as individual MS could pursue their own procedures. The status of authorized GMOs in individual member states will also be uncertain. Stakeholders in the GMO sector are advised to closely and carefully monitor the situation.

7.0 Conclusions

In 2006, a WTO Panel found that the EU's moratorium on the import of products derived from the use of modern biotechnology contravened the EU's obligations. The EU said it would comply with the Panel's ruling, but that it would take time. Although the EU had established the new regime to govern domestic management and imports of GM-products by 2003, an assessment of its full implications had to wait until the system could be seen in operation. Further, the EU regulatory regime for GM-products is very much a work in progress. In particular, as the Member States of the EU learn how the system operates, some Members have taken actions to prevent outcomes they don't like. The European Commission has had to acquiesce to considerable autonomy in Member State's regulatory regimes for GM-products. This latter phase of devolution of GM-policy to Member States is new and untested, meaning that the EU regulatory regime for GM-products is not transparent. There are two major areas of the EU regulatory regime for GM-products where there is a need for clarification. The first is the approval process for new GM-products in the EU. This is important for those considering investment in and licensing of new GM-products. The second is how imports contaminated with GM-products are dealt with in the regulatory regime. The case of Canadian flax exports contaminated by GM-flax has recently arisen and a new import regime put in place and is discussed in the companion discussion paper, '*Post-Moratorium Regulation of GMOs in the EU: The Case of Triffid Flax*'. A new GM-product has finally worked its way through the new EU approval process meaning that the regulatory regime for new products can be evaluated.

Does the new EU regulatory regime conform to its WTO obligations? Under the WTO, the process used to put trade barriers in place justified on sanitary and phytosanitary grounds are supposed to be science-based. In the EU, the regulatory regime for approval of new products is not fully science-based. In the case of new GM-products, science only informs the decision. There are a number of purely political institutions that can make decisions on approvals of new GM-products without referral to

³⁶ See footnote 14

scientific judgements. This is consistent with the EU's *social rationality* approach to new technologies whereby science only informs decision makers. Thus, the new EU regime for approvals would seem to contravene the EU's WTO obligations, and the EU regulatory regime for GM-products would seem open to a new challenge at the WTO. Of course, the political consequences of such a challenge would have to be carefully weighed.

The bottom line is that the EU approval process is, in effect, asymmetric in terms of the role of science. Science alone can deny approval. Science alone cannot secure approval. Once the scientific hurdle is passed, there are a number of decision steps where non-scientific criteria can factor into a decision to deny approval. Thus, it would seem that the post-moratorium EU regime to deal with trade in GMOs contravenes the EU's existing SPS obligations. The devolution of the power to approve the cultivation of GMOs to individual MS calls into question having the EU act as the single entity for the purposes of external trade.

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