

DIVIDED WE FALL: THE SHORTCOMINGS OF THE EUROPEAN UNION'S PROPOSAL FOR INDEPENDENT MEMBER STATES TO REGULATE THE CULTIVATION OF GENETICALLY MODIFIED ORGANISMS

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1. INTRODUCTION

The European Union (EU) has the second largest amount of arable land in the world, but grows less than 1% of the world's genetically modified crops.¹ Believing this discrepancy in the ratio of arable land to genetically modified organisms (GMOs) violated a number of trade agreements, the United States, Argentina, and Canada requested that the World Trade Organization (WTO) review the EU's approval, application, and regulation of GMOs.² In 2006, the WTO found that the EU had essentially suspended the approval of GMOs, resulting in a *de facto* moratorium on biotech products with a significant impact on the world market.³ The WTO agreed with the United States and other parties that the *de facto* moratorium was an "across-the-board marketing ban" of GMOs and violated the Agreement on the Application of Sanitary

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¹ Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of Genetically Modified Foods*, 45 AM. BUS. L.J. 775, 778 (2008).

² See Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006) at 2–3 (describing the establishment a WTO panel to review the European Community's approval method for biotech products and certain prohibitions that member States impose on the marketing of biotech products).

³ See *id.* at 41 ("In terms of form, the *moratorium* consists of concerted acts and omissions of the European Communities and its member States to stall decision-making with respect to biotech product applications at key stages of the approval process.").

and Phytosanitary Measures (SPS Agreement).⁴ In a 2010 response to the WTO, the EU proposed to Member States that each nation may decide whether or not to cultivate GMOs within their borders.

While this proposal to decentralize GMO cultivation decision-making may better protect against risks associated with scientific uncertainty, decentralization is unsuitable for the EU's common marketplace due to the potential harm of GMO contamination and high transaction costs. Instead, the EU should form a Community-wide decision-making body to determine the effects of GMOs and approve appropriate biotechnologies through a precautionary principle lens.

This Comment will explore the issues surrounding the control of GMOs in the EU and why a centralized regulatory system is the best approach given the unique relationship between EU Member States. Section 2 will discuss the history of the WTO's 2006 decision and the EU's 2010 proposal. Section 3 will discuss the benefits of a centralized decision-making process regarding GMO cultivation. Section 4 will evaluate the EU's decentralized approach and describe the inefficiencies of the proposal given the distinctive nature of the EU's Common Market.

2. GMOs IN THE WORLD MARKET

On July 13, 2010, the EU proposed a regulation of the European Parliament and Council to allow Member States to decide whether to cultivate GMOs within their borders.⁵ Under the proposal, the

⁴ See *id.* at 41–44 (explaining how the moratorium violates the various provisions of the SPS Agreement).

⁵ See, e.g., *Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory*, at 2, COM (2010) 375 final (July 13, 2010) [hereinafter *EU 2010 Proposal*] (explaining that “[t]he European Union authorisation system is aimed at avoiding adverse effects of GMOs on human and animal health and the environment while establishing an internal market for those products”). By 2003, six member states had invoked “safeguard provisions” under EC Directive 90/220 (France, Germany, Austria, Italy, Luxembourg, and Greece), five member states banned the marketing of GMOs (Austria, France, Germany, Italy, and Luxembourg), and one member state banned the import of GMOs (Greece). Panel Report, *supra* note 2, at 31. Furthermore, Austria prohibited the marketing of three specific biotech maizes (Bt-176, MON810, and T25), France prohibited two rapeseed products (MS1/RF1 and Topas 19/2), Luxembourg and Germany prohibited one type of maize (Bt-176),

EU retains the right to decide what GMO seeds may be placed on the market, and Member States cannot interrupt the free circulation of products containing GMOs, GMO seeds, or related planting materials.⁶ Member States also may not affect the cultivation of plants that have an adventitious presence or “technically unavoidable traces” of any GMO approved by the EU.⁷ The European Parliament adopted the proposal at its first reading on July 5, 2011.⁸

2.1. *GMOs and the 2006 World Trade Organization Panel Report*

The EU’s proposal was in response to a 2006 panel report by the WTO that the EU’s approach to GMOs violated the SPS Agreement.⁹ Under the SPS Agreement, states cannot arbitrarily or unjustifiably discriminate against another member’s products when “identical or similar conditions prevail.”¹⁰ Nations are allowed to take appropriate, discriminatory actions against products “if there is a scientific justification.”¹¹ Scientific justification is established through a risk assessment on the impact to “human, animal, or plant life or health”¹² Nations must take into account risk assessment techniques such as processes and

Italy prohibited four types of maize (Bt-11, MON810, MON 809 and T25), and Greece prohibited the importation of Topas 19/2, an oilseed rape. *Id.*

⁶ See *EU 2010 Proposal*, *supra* note 5, at 12 (explaining that the relevant Directives pertain only to the cultivation of GMOs, but not to their free circulation).

⁷ *Id.*

⁸ Procedure File, *Genetically Modified Organisms GMOs: Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory (amend. Directive 2001/18/EC)* (July 5, 2011), available at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2011-0314>.

⁹ See Panel Report, *supra* note 2, at 681 (describing the Panel’s evidence for its conclusion that the Group of Five Countries and Commission had effected a moratorium without having adopted an EC rule or decision-making process).

¹⁰ See Agreement on the Application of Sanitary and Phytosanitary Measures, art. 2(3), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 494 [hereinafter *SPS Agreement*] (providing that members are to “ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Member[] [States] where identical or similar conditions prevail”).

¹¹ *Id.* art. 3(3).

¹² See *id.* art. 5(1) (describing what assessments sanitary or phytosanitary measures should be based upon).

production methods, sampling and testing, and the prevalence of disease.¹³

In May 2003, the United States, Argentina, and Canada requested consultation with the EU regarding its policies on biotechnology, claiming that the EU had placed a moratorium on approving GMOs since October 1998 in violation of their trade treaties.¹⁴ After failing to come to an agreement, the United States requested that the WTO establish a panel to review the dispute.¹⁵ The WTO found that the EU directives on GMOs fell clearly within the authority of the SPS Agreement and that the EU had effectively enacted a moratorium on GMOs between June 1999 and August 2003,¹⁶ in violation of the first clause of Annex C(1)(b) and Article 8 of the SPS Agreement.¹⁷ The Panel found that five countries—

¹³ *Id.* art. 5(2).

¹⁴ *See* Panel Report, *supra* note 2, at 1 (introducing the procedural history of the three states' complaints). Before 1998, the EC had approved over ten biotech products, after which the EU suspended their approval process and no new biotech products had been approved since October 1998. *Id.* at 27–28. Although the EU never formally adopted a ban on GMOs, EU officials have acknowledged the moratorium. *Id.* at 19–20. The EU went on to note in its First Written Submission that it wished to:

underline from the very beginning that it has not adopted any general position either in favour or against any of the products subject to these proceedings. In accordance with its regulatory framework, the European Communities assesses each individual GMO on its own merits, in order to evaluate the potential benefits and risks of these novel products.

Id. at 64.

¹⁵ *See id.* at 3 (noting further that the dispute was over “(1) the operation and application by the European Communities of its regime for approval of biotech products; and (2) certain measures adopted and maintained by EC members States prohibiting or restricting the marketing of biotech products”).

¹⁶ *See id.* at 612–13 (discussing a panel finding that a moratorium on GMO approvals was established within the relevant time frame).

¹⁷ *See id.* at 682 (stating further that it was not necessary to determine whether or not the EU violated Article XI:1 of the GATT). Article C(1)(a) reads: “Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products.” *See SPS Agreement, supra* note 10, Annex C(1)(a). Article 8 of the SPS Agreement notes:

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or

Denmark, Italy, France, Greece, and Luxembourg—declared in 1999 that they would “do what was within their power” to ensure that no GMOs were approved until the European Commission had established guidelines on the labeling and traceability of biotechnology.¹⁸ The WTO accepted the EU’s argument that the Commission believed that it could not approve GMOs without the support of these five countries,¹⁹ and noted that no GMOs were approved on the Member State level between 1999 and 2003.²⁰ Regardless of the Five Countries’ actions, however, the WTO noted that the European Commission was not bound by the Member States’ position on GMOs and did not “make full use of the relevant procedures to complete the approval process.”²¹

The EU’s approval process is outlined in a 2001 Directive on the deliberate release into the environment of genetically modified organisms. Under the Directive, the decision whether to place a GMO on the market begins with a Member State receiving notification from an applicant.²² If the GMO is to be placed on the market for the first time, a “competent authority” of the Member State receiving the application must prepare a report.²³ After forwarding the notification to other Member States, the lead Member State reviews the notification, which includes

feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

Id. art. 8.

¹⁸ See Panel Report, *supra* note 2, at 612 (explaining a panel finding that showed a deliberate intent on the part of the Group of Five countries to prevent approval of GMO applications).

¹⁹ See *id.* (noting that because of a declaration by the Group of Five countries, the Commission did not think it could approve applications without the support of member states).

²⁰ See *id.* at 613 (noting that often one of the five member states cited the 1999 Declaration as a reason for disapproving GMO applications).

²¹ See *id.* at 613–14 (delineating reasons for the Panel’s inference of the Commission’s conduct).

²² See Directive 2001/18, of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, art. 13(1), 2001 O.J. (L 106) (stating that “a notification shall be submitted to the competent authority of the Member State where such a GMO is to be placed on the market for the first time”).

²³ See *id.* art. 15 (explaining that the competent authority “shall give consent in writing for placing on the market”).

environmental risk assessments, conditions for placing the bioproduct on the market, a plan for monitoring, and a plan for labeling and packaging the product.²⁴ The Member State then prepares an assessment report within ninety days of receiving the notification, indicating whether the GMO should be placed on the market.²⁵

No GMOs, furthermore, could be placed on the market unless it was authorized under Regulation 1829/2003.²⁶ In accordance with this regulation, Member States send GMO applications to the European Food Safety Authority (EFSA) for scientific assessments of the potential health and environmental risks.²⁷ The Member State also performs an environmental risk assessment if the application includes a request to cultivate the GMO. After all of the information and opinions are published on the EFSA website and circulated among Member States, the European Commission solicits public opinion and decides whether to approve the application.²⁸ Despite these clear regulations and approval procedures, however, the WTO found that the EU had not actually approved any GMO products between 1999 and 2003, and had only conducted risk assessments on fourteen of the twenty-seven pending applications for biotech products.²⁹

During the WTO's review, the United States maintained that, according to the scientific committees, there was no "rational

²⁴ *Id.* art. 13.

²⁵ *Id.* art. 14.

²⁶ See Commission Regulation 1829/2003, of the European Parliament and of the Council of 22 Sept. 2003 on Genetically Modified Food and Feed, 2003 O.J. (L 268) 1, 2 (stating that genetically modified food and feed should only be placed in the market after scientific evaluation by the European Food Safety Authority).

²⁷ See European Food Safety Authority, EFSA's Role in the GMO Regulatory Framework, available at <http://www.efsa.europa.eu/en/gmotopics/docs/gmoauthorisation.pdf> (outlining the procedure under which GMO applications are assessed).

²⁸ See *id.* (detailing the process for GMO application approval).

²⁹ Panel Report, *supra* note 2, at 37. The risk assessments examined "(1) the likelihood of the establishment or spread of a pest, and (2) the potential for adverse effects on human or animal health arising from the presence of toxins or disease-causing organisms in food or feedstuffs." See also *id.* at 39 ("As the nature of the risks associated with biotech products varies considerably from plant variety to variety, general assertions about the risks of biotech products, as a class, cannot be made. Each biotech product needs to be evaluated on a case-by-base basis, taking into consideration the factors outlined above.").

relationship” between the EU’s moratorium and the risk assessments for the unapproved biotech products.³⁰ In response, the EU contended that the “complaining parties seek to evade or ignore the whole socio-political, legal, factual, and scientific complexity of the case” and that the GMOs in question had characteristics that may pose potential threat to human and environmental health.³¹ GMOs, the EU insisted, are not the equivalent to their non-biotech counterparts.³² Nevertheless, the WTO decided that the EU “acted inconsistently with its obligations under” the SPS Agreement.³³

Two years after the WTO’s decision, the Council of the European Union issued a series of guidelines on GMOs.³⁴ Noting the necessity to improve the implementation of a GMO framework and “the necessity of continuing processing applications without undue delays,”³⁵ the Council called for EFSA and Member States to develop a framework for the authorization of GMOs that took into consideration environmental assessment and monitoring arrangements, socio-economic benefits and risks, the expertise of the scientific community, a labeling system for GMO seeds, and the possibility for protected areas.³⁶ Specifically, the Council noted that EFSA should develop and update transparent guidelines to

³⁰ See *id.* at 37 (arguing that product-specific moratoria are inconsistent with the SPS agreement because they are not based on the European Communities’ risk assessments).

³¹ *Id.* at 64–65 (detailing the European Communities’ responses to complaints filed against them).

³² See *id.* at 65–66 (arguing, overall, that the EU did not delay in reviewing applications and was not in violation of the SPS Agreement).

³³ See *id.* at 682; see also SPS Agreement, *supra* note 10, at annex C(1)(a) (providing the requirements of Annex C(1)(b) of the SPS Agreement, which are to check and ensure sanitary and phytosanitary measures).

³⁴ Council of the European Union, Council Conclusions on Genetically Modified Organisms 2 (Dec. 5, 2008), available at <http://register.consilium.europa.eu/pdf/en/08/st16/st16882.en08.pdf> (“It is therefore necessary to look for improvement of the implementation of this legal framework [for the authorization of GMOs] in order to better meet the objectives of the EC legislation, taking into consideration the necessity of continuing processing applications without undue delays and respecting the relevant EC international obligations.”).

³⁵ *Id.*

³⁶ See *id.* at 2–8 (explaining in greater detail the way countries can better use expertise, create labeling systems, and monitor arrangements).

assess the environmental risks of GMOs.³⁷ Additionally, while the Council did not mandate that Member States independently regulate the cultivation of GMOs within their borders, they did suggest the possibility.³⁸

2.2. The EU's Response

On July 5, 2011, the European Parliament adopted at its first reading the proposal amending the 2001 Directive.³⁹ In the amended Directive, "in accordance with Article 2(2)" [of the Treaty on the Functioning of the European Union] Member States should "be entitled to have a possibility to adopt binding legislative provisions concerning the cultivation of GMOs in their territory after the GMO has been legally authorised to be placed on the EU market."⁴⁰ Member States are authorized to adopt case-by-case restrictions or prohibitions regarding the cultivation of particular GMOs or groups of GMOs.⁴¹ While restrictions or prohibitions

³⁷ See *id.* at 3 (noting the Commission's mandate "to the EFSA to further develop and update its guidelines as regards the environmental risk assessments of GMOs").

³⁸ See *id.* (inviting member states to regulate the cultivation of GMOs).

³⁹ See *Report on the Proposal for a Regulation of the European Parliament and of the Council Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory*, Comm. on the Env't, Pub. Health & Food Safety, at 5-6 (April 20, 2011), available at http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2011-0170&language=EN&mode=XML#_part1_def2 [hereinafter *2011 Amended Proposal*] (describing Directive 2001/18/EC as only allowing GMOs to be placed on the market after specific environmental risk assessment is carried out).

⁴⁰ *Id.* amend. 5. Article 2(2) of the Treaty of the Functioning of the European Union provides:

When the Treaties confer on the Union a competence shared with the Member States in a specific area, the Union and the Member States may legislate and adopt legally binding acts in that area. The Member States shall exercise their competence to the extent that the Union has not exercised its competence. The Member States shall again exercise their competence to the extent that the Union has decided to cease exercising its competence.

Consolidated Version of the Treaty on the Functioning of the European Union art. 2(2), March 30, 2010, 2010 O.J. (C 83) 47 [hereinafter TFEU].

⁴¹ See *2011 Amended Proposal*, *supra* note 39, amend. 15 (proposing Amendment 16 to Directive 18/EC/2001 for measures to be based on grounds other than those related to the assessment of the adverse effect on health and the environment).

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may be based on “scientifically justified grounds relating to environmental impacts which might arise from the deliberate release or the placing on the market of GMOs,”⁴² the amended text enumerates a variety of reasons to exclude GMOs:

[T]he prevention of the development of pesticide resistance amongst weeds and pests; the invasiveness or persistence of a GM variety, or the possibility of interbreeding with domestic cultivated or wild plants; the prevention of negative impacts on the local environment caused by changes in agricultural practices linked to the cultivation of GMOs; the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability; the maintenance of local biodiversity, including certain habitats and ecosystems, or certain types of natural and landscape features; *the absence of adequate data* or the existence of contradictory data or *persisting scientific uncertainty* concerning the potential negative impacts of the release of GMOs on the environment of a Member State or region, including on biodiversity. . . . [T]he impracticability or the high costs of coexistence measures or the impossibility of implementing coexistence measures due to specific geographical conditions such as small islands or mountain zones; the need to protect the diversity of agricultural production; the need to ensure seed purity; *other grounds that may include land use, town and country planning, or other legitimate factors.*⁴³

All Member States’ measures, however, are limited to only the cultivation of GMOs, not to “the free circulation and import of genetically modified seeds and plant propagating material, as or in products, and of the products of their harvest.”⁴⁴ No Member State may prevent or restrict the cultivation of authorized GMOs in other Member States as long as those Member States take “effective measures” to prevent cross-border contamination.⁴⁵

⁴² *Id.* amend. 16.

⁴³ *Id.* (emphasis added).

⁴⁴ *Id.* amend. 7.

⁴⁵ *Id.* amend. 9.

Notably, the amended 2011 Directive cites authority under Article 192(1) of the Treaty on the Functioning of the European Union, instead of Article 114 as cited by the 2001 Directive.⁴⁶ Article 114 allows the European Parliament and the Council to enact legislation regarding the establishment and function of the Common Market,⁴⁷ while Article 192 allows the European Parliament and Council to take action to preserve, protect, and improve the environment and protect human health.⁴⁸ Reframing the Parliament's authority to regulate GMOs under an environmental lens and away from the economics of a Common Market allows Member States to potentially restrict or prohibit GMOs on ethical, social, and cultural grounds.⁴⁹

3. THE CASE FOR CENTRALIZED DECISION-MAKING REGARDING GMO CULTIVATION

The importance of food safety and the high spillover effects of GMO contamination limit the effectiveness of prohibitions promulgated by Member States. Centralized GMO regulation, on the other hand, could deal with spillover effects while still addressing location-specific concerns. Unlike environmental regulation in the United States, centralized environmental regulation in the EU considers both environmental concerns and incentivizing the free movement of goods in the Common Market.⁵⁰ As a result, centralized environmental policies better

⁴⁶ *Id.* amend. 1.

⁴⁷ See TFEU, *supra* note 40, art. 114 (stating that the European Parliament and Council shall "adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market").

⁴⁸ See *id.* art. 191, 192(1) (explaining that the policy of the European Parliament should have several human health and environmental protection objectives).

⁴⁹ See *EU Member States to be Allowed to Ban GM Crops*, GMO SAFETY (July 6, 2011), <http://www.gmo-safety.eu/news/1333.genetic-engineering-eu-parliament-national-cultivation-ban.html> (highlighting that "'scientific uncertainty' and socio-economic grounds" may serve as legitimate reasons for a national ban under the amended proposal).

⁵⁰ See Roger Van Den Bergh, *Economic Criteria for Applying the Subsidiarity Principle in European Environmental Law*, in ENVIRONMENTAL LAW, THE ECONOMY AND SUSTAINABLE DEVELOPMENT 80, 83 (Richard L. Revesz et al. eds., 2000) (arguing that centralized environmental regulation in the United States arose well after states were economically and politically integrated).

account for efficiency in the marketplace while still taking into account the specific circumstances of Member States.⁵¹

Under the Treaty of the European Economic Community, furthermore:

In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, *only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.*⁵²

In compliance with this principle of subsidiarity, environmental directives have used four reasons for justifying Communitywide actions: the demands of “transboundary environmental pollution,” the “need to create equal conditions” in the common market, the regulation of the “free movement of goods,” and the “protection of ‘European environmental and cultural heritage’ and human health.”⁵³ When addressing GMOs, centralization is appropriate because individual Member States cannot sufficiently address neither GMO transboundary pollution,⁵⁴ the need to create equal conditions for GMO and non-GMO goods,⁵⁵ the demands of regulating the free movement of GMO crops,⁵⁶ nor the effective protection of health and the environment.⁵⁷

3.1. Spillover Effects

Economist Wallace Oates’s 1972 Decentralization Theorem states that without spillovers, a decentralized system of

⁵¹ See *id.* (noting the importance of considering “location-specific circumstances and regionally diversity” when establishing policies).

⁵² Consolidated Version of the Treaty Establishing the European Community art. 5, Dec. 24, 2002, 2002 O.J. (C 325) 42 (emphasis added).

⁵³ Van Den Bergh, *supra* note 50, at 82 (citing EU Directives that exemplify each reason for centralization).

⁵⁴ See *infra* Section 3.1 (discussing spillover costs of GMO cultivation).

⁵⁵ See *infra* Section 4.2 (noting the impact of GMO cultivation on the EU Common Market).

⁵⁶ See *infra* Section 3.3 (evaluating the ideological objections to and transaction costs associated with GMOs).

⁵⁷ See *infra* Section 4.1 (considering whether the EU proposal will prevent states from cultivating GMOs).

government should be preferred to a centralized one.⁵⁸ Oates writes:

It is generally desirable, as suggested by the condition of the perfect correspondence in the ideal model, to internalize, where possible, all the benefits and costs associated with the provision of a particular good. In this way decisions concerning levels of consumption will be more likely to take into account the interests of all those whose welfare they influence.⁵⁹

GMOs, however, have a high spillover cost in transboundary contamination, making spillover costs one of the greatest issues surrounding GMO cultivation. Unlike other WTO decisions regarding EU foodstuffs,⁶⁰ GMOs have a unique impact on the environment in that they can spread their altered genetic material without human intervention through cross-pollination and contaminate non-GMO crops and products. For example, although only two GMOs are grown in the EU,⁶¹ Greenpeace International's and GeneWatch UK's "GM Contamination Register" noted 141 instances of contamination by genetically modified organisms in Europe between 1997 and 2010.⁶² Such incidents include six

⁵⁸ See WALLACE E. OATES, *FISCAL FEDERALISM* 35 (1972) (summarizing the "Decentralization Theorem").

⁵⁹ *Id.* at 46.

⁶⁰ See, e.g., Howard F. Chang, *Risk Regulation, Endogenous Public Concerns, and the Hormones Dispute: Nothing to Fear but Fear Itself?*, 77 S. CAL. L. REV. 743, 745 (2004) (noting the WTO's decision in favor of the United States regarding its disagreement with the EU over banning meat containing hormones). The debate over animal hormones, however, is dissimilar to GMOs since livestock often provide high control over breeding, and hormones are not passed from generation to generation as altered genetic material.

⁶¹ Press Release, Europa, Questions and Answers on the EU's New Approach to the Cultivation of GMOs (July 13, 2010), <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/325&format=HTML&aged=0&language=EN&guiLanguage=en> (observing that only one GM maize, MON 810, and one GM potato, the Amflora potato, are "commercially cultivated in the EU," while other GMO products, including "one sugar beet, three soybean, three oilseed-rape, six cotton and seventeen maize products," are authorized to be on the EU market to be used as animal feed and for other uses).

⁶² *GM Contamination Register*, GENEWATCH UK & GREENPEACE INTERNATIONAL, <http://www.gmcontaminationregister.org> (last visited Feb. 14, 2012) (providing search results for incidents of contamination in Europe). The author's text accompanying notes 62-67 are based on 2010 data.

reports of unauthorized GM flax FP967 in Finland, traceable to shipments of seeds and products from other countries,⁶³ and numerous reports of contaminated maize seeds in Austria,⁶⁴ France,⁶⁵ Italy,⁶⁶ and other European nations.⁶⁷

Once contaminated seeds are introduced into an area, either through mislabeled seeds or importing illegal GMOs, a GMO can spread through cross-pollination, seed saving and planting, planting equipment, and harvesting and storage practices.⁶⁸ Although the pollen of a single crop may not bound across nations in a single season, the impact of GMO crops on national borders and the dispersal of pollen over several generations cannot be disregarded.⁶⁹

⁶³ See *Finland – Continues to Find Unauthorised Linseed FP967 from Canada*, GENEWATCH UK & GREENPEACE INTERNATIONAL, http://www.gmcontaminationregister.org/index.php?content=re_detail&gw_id=301®=0&inc=0&con=0&cof=0&year=2010&handle2_page= (last visited Feb. 14, 2012) (reporting that Finland informed the EU's Rapid Alert System for Food and Feed (RASFF) of the incidents).

⁶⁴ See *Austria – Greenpeace Reveal Contamination of Maize Seed*, GENEWATCH UK & GREENPEACE INTERNATIONAL, http://www.gmcontaminationregister.org/index.php?content=re_detail&gw_id=46®=reg.1&inc=1&con=3&cof=0&year=0&handle2_page=0 (last visited Feb. 14, 2012) (reporting that laboratory tests of Austrian maize revealed Monsanto and Novartis strains, both of which are genetically modified).

⁶⁵ See *France – GM Contamination of Maize Seed Reported*, GENEWATCH UK & GREENPEACE INTERNATIONAL, http://www.gmcontaminationregister.org/index.php?content=re_detail&gw_id=26®=reg.1&inc=1&con=3&cof=0&year=0&handle2_page=0 (last visited Feb. 14, 2012) (reporting on findings of the French Government's Food Inspection Agency).

⁶⁶ See *Italy – Over One-Hundred Farmers Discovered that the Seeds they had Bought and Planted were Contaminated by GM Maize*, GENEWATCH UK & GREENPEACE INTERNATIONAL, http://www.gmcontaminationregister.org/index.php?content=re_detail&gw_id=36®=reg.1&inc=1&con=3&cof=0&year=0&handle2_page=1 (last visited Feb. 14, 2011) (reporting that farmers in Northern Italy "unknowingly planted 400 hectares with GM contaminated maize").

⁶⁷ See generally *GM Contamination Register*, *supra* note 62 (highlighting incidents of contamination of seeds in Europe).

⁶⁸ See Alison Peck, *The New Imperialism: Toward an Advocacy Strategy for GMO Accountability*, 21 GEO. INT'L ENVTL. L. REV. 37, 43 (2008) (discussing sources of GM contamination).

⁶⁹ See, e.g., FRIENDS OF THE EARTH, *Farmers Briefing: Genetically Modified Crops and Animal Feed*, http://www.foe.co.uk/resource/briefings/gm_crops_animal_feed.html (last visited Feb. 11, 2012) (noting predictions that maize cross-pollination can occur over 500 meters, as well as cases of oilseed rape traveling 4 kilometers despite barriers erected to contain the pollen).

Moreover, the threat of cross-pollination is not limited to seed mingling and contamination in cultivation. In September 2011, the Court of Justice of the European Union held that honey produced from the pollen of genetically modified corn constituted “food . . . containing ingredients produced from [genetically modified organisms] within the meaning of Article 3(1)(c) of Regulation No. 1829/2003,” regardless of whether the genetically modified pollen was present intentionally or adventitiously.⁷⁰ In the case, Monsanto’s 810 maize was prohibited in Germany in 2009 by the German Federal Office for Consumer Protection and Food Safety.⁷¹ The Free State of Bavaria, however, owned land cultivated for research purposes and grew Monsanto’s 810 maize.⁷² In 2005, a neighboring beekeeper found trace amounts of MON 810 DNA in a number of honey samples and claimed that his product was no longer marketable or fit for consumption and was subjected to a “material interference” under German law.⁷³ Monsanto argued that Regulation No. 1829/2003 was not applicable to GMOs found in honey and, furthermore, honey could no longer contain a “GMO” because the pollen in the honey no longer possessed any capacity to reproduce.⁷⁴ The European Court of Justice agreed that the pollen was no longer a “genetically modified food” because it had lost its ability to transfer genetic material, but disagreed that Regulation 1829/2003 did not apply.⁷⁵ Because the honey was “food produced from or containing ingredients produced from GMOs,” it was subject to the EU’s labeling laws.⁷⁶ Finding

⁷⁰ Case C-442/09, *Bablok v. Freistaat Bayern*, 2011 EUR-Lex CELEX LEXIS 62009CJ0442, ¶ 109 (Sept. 6, 2011), available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=celex:62009CJ0442:en.html> (ruling that genetically modified food and feed must be interpreted as a substance which has lost its ability to reproduce) (internal quotation marks omitted); Commission Regulation 1829/2003, *supra* note 26, art. 3(1)(c).

⁷¹ Case C-442/09 ¶29 (2011) (discussing the cultivation of MON 810 maize prohibited in Germany).

⁷² *Id.* ¶¶ 30, 32.

⁷³ *See id.* ¶¶ 37, 39 (referring to MON 810 maize pollen as being no longer marketable or fit for consumption).

⁷⁴ *See id.* ¶¶ 43, 44 (arguing that Regulation No. 1829/2003 is not applicable to MON 810 maize pollen found in honey because it does not have the capability to reproduce).

⁷⁵ *Id.* ¶¶ 108, 109.

⁷⁶ *Id.* ¶ 109. The Court noted that the GMO pollen was an “ingredient” of the contaminated honey. *Id.* ¶ 79.

otherwise would allow “a foodstuff such as honey [to] . . . escape any safety checks, even though it might contain significant quantities of genetically modified material.”⁷⁷

Contamination costs have a tangible, important impact on EU farmers and producers in both the creation and marketing of goods. *Bablok v. Bayern* indicates that the European Courts will literally interpret GMO restrictions and strictly apply labeling laws such as Regulation No. 1829/2003, in which any foodstuffs containing more than 0.9% of GMO products must be labeled as containing GMOs.⁷⁸ While the 0.9% level allows a low threshold for adventitious presence and other unintended contamination of traditionally grown crops, it in effect requires the segregation of GMOs in all stages of production, handling, storage, shipment, processing, and marketing.⁷⁹ If GMOs contaminate crops that are marketed as organic or traditionally grown, those farmers will have to label their products as containing GMOs. Although those farmers may have invested heavily in keeping their crops organic or traditional, they will lose any economic benefit of being able to advertise as “GMO-free.”

3.2. Centralization Can Reduce Spillover Effects

The EU’s decentralized proposal places a significant burden on farmers in countries that prohibit the cultivation of GMOs. Presumably, nations that decide to ban GMOs put a high preference on traditionally grown crops; consumers in these countries, in turn, would most likely not purchase or would undervalue any crops contaminated by GMOs from a neighboring nation. The contaminated goods can no longer freely move in the market, and are no longer considered equal to their non-contaminated counterparts.

Under a centralized system, the EU could limit or internalize the costs of spillover by uniformly prohibiting or allowing the

⁷⁷ See *id.* ¶ 82 (discussing how the proposed interpretation would not be successful because foods such as honey escape safety checks for significant amounts of genetically modified material).

⁷⁸ Council Regulation 1829/2003, *supra* note 26, at 11 (regulating the labeling of GMO food and feed).

⁷⁹ See Strauss, *supra* note 1, at 813 (noting further that many American manufacturers have not marketed their products in the EU because this process is not mandated in the United States).

cultivation of a GMO. The EU as a central body can better take into account the trans-boundary nature of GMO regulation. If *Bablok v. Bayern* occurred in a centralized system, for example, Bablok would not be unfairly burdened by his proximity to a research field. While a centralized system could not stop the contamination of his honey, all honey producers in Europe would theoretically be exposed to the same risk (or not exposed, depending on whether the MON 810 would be uniformly banned). The benefits and costs of GMOs would not be limited to borders of "GMO" and "non-GMO" countries, but would either be reduced by a ban or spread out by an approval.

3.3. Centralization and Lower Transaction Costs

In addition to the physical concern of contamination, the EU must also address ideological objections. A recent poll conducted on behalf of the European Commission indicates seventy percent of Europeans agree that GM foods are "fundamentally unnatural," while only twenty-three percent believe that the development of GMOs should be encouraged.⁸⁰ Before the decentralization proposal, six nations—Austria, Hungary, France, Greece, Germany, and Luxembourg—had already banned the cultivation of Monsanto's GM maize, while Austria, Luxembourg, and Hungary objected to the cultivation of the Amflora potato.⁸¹

The ideological impact of GMOs is clearly illustrated in Hungary, for example. In July 2011, the Ministry of Rural Development outlawed the cultivation and sale of GMO contaminated seeds.⁸² Contaminated crops and crops in a buffer

⁸⁰ European Commission, *Special Eurobarometer 341: Biotechnology*, at 18 (Oct. 2010), available at http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf (presenting survey data on European attitudes towards genetically modified foods).

⁸¹ See Robert Wielaard, *EU: Leave GMO Food Decisions for Governments*, BLOOMBERG BUSINESSWEEK (July 13, 2010, 11:38 AM), available at <http://www.businessweek.com/ap/financialnews/D9GU8H0G1.htm> (noting sentiments among anti-GMO advocacy groups that the EU decision to allow states to determine whether to permit GM crops exposes EU nationals to food and feed contamination risks).

⁸² See *The Ministry of Rural Development's New GMO Statute in Effect*, WEBSITE OF THE HUNGARIAN GOVERNMENT (July 15, 2011, 5:51 PM), <http://www.kormany.hu/en/ministry-of-rural-development/news/the-ministry-of-rural-development-s-new-gmo-statute-in-effect> ("In the case of seeds

area surrounding the vicinity must be quarantined and destroyed either by the crop producer or the Hungarian Central Agricultural Office.⁸³ On July 15, 2011, the day the law was put into effect, 940 hectares of GMO contaminated crops were destroyed and 2,500 hectares were slated to be deep ploughed.⁸⁴ According to the State Secretary, “keeping the country free of GMOs is an issue of national strategy and security. Pure, GMO-free seed cultivation and agriculture is a significant market advantage for Hungary.”⁸⁵

Importers and cultivators must balance anti-GMO legislation, such as that in Hungary, against pro-GMO legislation in other European nations, such as Romania.⁸⁶ Romania shares an extensive border with Hungary but has a very different approach to biotechnology. Before joining the EU in 2007, Romania was a significant producer of GMOs.⁸⁷ Although Romania has since banned the cultivation of all GMOs except for MON 810 maize, Romania’s Agriculture Minister Valeriu Tabara is adamant about cultivating more GMOs in the future.⁸⁸ Minister Tabara has requested the European Commission to reauthorize the cultivation of GMOs in Romania, noting “the agricultural potential of Romania in assuring vegetable protein, food and feed fell dramatically in 2007, once adhering to the EU, by banning GM soy.”⁸⁹ “Romania is losing around 1 billion euro per year,”

produced in Hungary the producer is responsible for keeping seeds GMO free, while in other cases the primary importer may be held accountable.”).

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *We Don’t Need Genetically Manipulated Organisms*, WEBSITE OF THE HUNGARIAN GOVERNMENT (Sept. 30, 2011, 7:16 PM), <http://www.kormany.hu/en/ministry-of-rural-development/news/we-don-t-need-genetically-manipulated-organisms>.

⁸⁶ Spain is also a fervent supporter of GMOs. As of 2009 it cultivated nearly seventy-five percent of all GMOs in the EU. *See*, Andrew Willis, *Spain a Key Ally of Pro-GMO America, Cables Reveal*, EUOBSERVER.COM (Dec. 20, 2010, 9:51 AM), <http://euobserver.com/9/31544>.

⁸⁷ *See* Marian Chiriac, *Romania to Push for Approval of GMO Soybeans*, BALKANINSIGHT (Apr. 12, 2011, 8:53 AM), <http://www.balkaninsight.com/en/article/romania-plans-to-grow-gm-soybeans>.

⁸⁸ *See id.* (statement of Valeriu Tabara) (“[W]e have to make every effort this year in order to reach agreement within the European Union for cultivating and exporting genetically modified soybeans.”).

⁸⁹ *Romanian Agriculture Minister Puts His Money Where His Mouth Is*, INFOMG (Feb. 05, 2011), <http://www.infomg.ro/web/en/Home/News/3/1287>.

Minister Tabara argued, "because it does not cultivate genetically modified soybeans."⁹⁰

The imbalance between Hungary's and Romania's positions on GMOs, in turn, significantly affects potential transaction costs.⁹¹ In addition to spillover effects from cross-border contamination,⁹² importers and enforcement agencies will incur costs to ensure GMO-goods coming from and going to pro-GMO Romania do not contaminate anti-GMO Hungarian cultivation. If the Member States' only concern was between GMOs and uncontaminated, traditionally grown products, each Member State could negotiate their rights between neighbors and obtain a system that preserves what they value most.⁹³ When dealing with a good as prolific and fundamental as foodstuff, however, decentralization presents exceedingly high costs in trading, inspecting, regulating, and informing for producers, consumers, corporations, and governments. As demonstrated in Eastern Europe (with the exception of Romania where laws may be less severe),⁹⁴ where producers and importers are held strictly responsible for keeping GMOs out of Hungarian fields, neighboring Member States and international importers alike may accrue high costs in keeping Hungary's soil GMO-free. Additionally, importers must consider costs of importing GMO seeds and planting instruments to countries where, in effect, it is illegal to use them. While the 2011 Amended Proposal only regards the cultivation of GMOs and not the sale of GMOs, the actual effect on companies producing a good that would be unusable in certain Member States cannot be overlooked.

⁹⁰ Chiriac, *supra* note 87.

⁹¹ See Louis Antoine, *Ciolo's Voices Misgivings About GMOs*, EUROPOLITICS (May 9, 2011), <http://www.europolitics.info/ciolo-voices-misgivings-about-gmos-art303301.html>.

⁹² See *supra* Section 3.1 (noting that GMOs can spread their altered genetic material through cross-pollination and contaminate non-GMO crops and products).

⁹³ See Ronald H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1, 15 (1960) (arguing that in a world without transaction costs, parties could rearrange rights to achieve the optimum value of production).

⁹⁴ See *The Ministry of Rural Development's New GMO Statute in Effect*, *supra* note 82 ("The Government decided . . . to act as forcefully as possible against companies selling seeds contaminated with genetically modified organisms (GMOs), and therefore requested the amendment of the Penal Code and the relevant legislation in order to ensure severe punishment and a strong deterrent.").

As a comparison, a decentralized GMO regime between Member States would be much like the emission standards of California and the United States. Except for a few exemptions, California laws forbid the use, sale, purchase, lease, rental, and distribution of any new motor vehicle that has not been certified by the state.⁹⁵ By allowing two different emission standards,⁹⁶ manufacturers either have to build “California standard cars” and “federal standard cars,” or simply build cars for the more stringent California standards (thus making separate federal standards moot). Consumers, similarly, have to conduct more research to ensure that they do not purchase a car that cannot be driven in their home state, or, alternatively, do not spend additional funds on a car that was built for standards that do not apply to them.⁹⁷ Motor vehicle importers and exporters need to monitor what products may be sold in each state, while inspectors need to have more control over imports and exports to ensure that they comply with state standards.

Although stricter emission standards provided an overall benefit for public health and the environment, the transaction costs of the fragmented system raised a real concern.⁹⁸ After the federal government enacted a law that will again centralize emission standards under a federal rule, automakers “welcomed a national plan that does not require them to build different vehicles for

⁹⁵ CAL. HEALTH & SAFETY CODE §§ 43150–43156 (West 2012).

⁹⁶ See *Vehicle Greenhouse Gas Emissions Standards*, CTR. FOR CLIMATE & ENERGY SOLUTIONS, http://www.c2es.org/what_s_being_done/in_the_states/vehicle_ghg_standard.cfm (last updated Oct. 31, 2011) (noting the difference between California and federal emissions standards and how the EPA and California have cooperated to enforce their respective standards).

⁹⁷ See, e.g., CAL. DEPT OF MOTOR VEHICLES, FAST FACT BROCHURE FFVR 29, BEFORE BUYING A VEHICLE FROM OUT OF STATE—BE SURE YOU CAN REGISTER IT IN CALIFORNIA (2010), available at http://dmv.ca.gov/pubs/brochures/fast_facts/ffvr29.htm (advising California residents to ensure any new vehicle purchase is certified to meet California’s smog law requirements).

⁹⁸ See Ken Bensinger, *California Emission Waiver Looms for Carmakers*, L.A. TIMES, Jan. 19, 2009, <http://articles.latimes.com/2009/jan/19/business/finance/2009-01-19> (stating that California’s emission standards pose “a nightmare scenario for automakers, which argue that complying with the California guidelines would create regulatory headaches and a technology burden that could add at least \$1,000 and as much as \$5,000 to the cost of each vehicle”).

different markets to comply with varying state laws.”⁹⁹ The Vice President of the Alliance of Automobile Manufacturers, Gloria Bergquist, praised the centralization of emission standards, noting “[a] year ago, we were facing piecemeal policies set out by EPA, DOT, and groups of different states. Our auto engineers cannot design vehicles to different standards.”¹⁰⁰

Likewise, under a centralized GMO cultivation standard, producers, manufacturers, and corporations will only have to comply with one unified standard.¹⁰¹ Importers and exporters will not have to limit their resources, reroute supply lines, or change the flow of commerce to comply with potentially conflicting standards in each Member State. Finally, while individual consumers may still have high costs of consumption based on their personal preferences, a centralized GMO cultivation policy may better standardize information and make the variety of food choices easier to understand.

In sum, centralized decision-making over the cultivation of GMOs is important because of the physical realities of the European Union. While Member States have a key responsibility to their citizens as sovereigns, Member States also have a responsibility to each other. Unlike the United States, Member States must balance between regulation as distinct sovereigns and regulation to “ensure the economic and social progress of [the] States by common action to eliminate the barriers which divide Europe.”¹⁰² The spillover cost of contamination and the transaction costs in negotiating between pro-GMO and anti-GMO states affect the EU in a unique way because the Member States physically neighbor each other and economically strive for uniformity. “If Member States can opt out of a product approval system simply

⁹⁹ John M. Broder, *U.S. Issues Limits on Greenhouse Gas Emissions from Cars*, N.Y. TIMES, Apr. 1, 2010, <http://www.nytimes.com/2010/04/02/science/earth/02emit.html>.

¹⁰⁰ *Id.*

¹⁰¹ See Coase, *supra* note 93, at 16 (“Within the firm individual bargains between the various cooperating factors of production are eliminated and for a market transaction is substituted an administrative decision. The rearrangement of production then takes place without the need for bargains between the owners of the factors of production.”). In the EU’s case, bargaining within the European Community would reduce the costs of bargaining between individual Member States.

¹⁰² TFEU, *supra* note 40, at pmbl.

because of political preference," however, "the result will be more uncertainty and less choice for farmers."¹⁰³ Once GMOs are cultivated in one area, there is little a neighboring state can do to avoid their effects. Centralization obligates the neighboring states to make the decision together.

4. THE CASE AGAINST DECENTRALIZED DECISION-MAKING OVER GMO CULTIVATION

The EU's proposal to decentralize GMO cultivation will encourage Member States to move forward under different economic and agricultural policies, dividing the EU's common marketplace and disincentivizing a cooperative, cohesive approach to agriculture. Additionally, the EU's proposal does not address the WTO's 2006 decision regarding GMO application approval. As such, although decentralized regulation may address concerns that centralization cannot, it is ultimately not an appropriate response to the particular issues raised by GMO cultivation in the EU.

4.1. *The EU's Proposal May Not Actually Allow Member States to Decide Whether to Cultivate GMOs*

In September 2011, the Court of Justice of the European Union ruled on Monsanto SAS's and other GMO companies' complaint regarding a French law that suspended the transfer, use, and planting of MON 810 maize seed varieties.¹⁰⁴ The Court held that Member States may not prohibit or suspend the sale of GMO seeds authorized for cultivation under Directive 90/220 and existing

¹⁰³ *EU Lawmakers Give Backing for National GM Crop Bans*, REUTERS, Jul. 5, 2011, available at <http://www.reuters.com/article/2011/07/05/us-eu-gmo-cultivation-idUSTRE7644UD20110705> (quoting Carel du Marchie Sarvaas of EuropaBio, an EU biotech industry association).

¹⁰⁴ See Joined Cases C-58/10 to C-68/10, *Monsanto SAS v. Ministre de l'Agriculture et de la Pêche*, EUR-Lex CELEX LEXIS 62010CJ0058, ¶ 2 (Sept. 8, 2011), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62010CJ0058:EN:HTML> (establishing the issues of the case). The French law was Article L.535-2 of the French Code de l'environnement, which allowed the government to suspend or withdraw a GMO's authorization, impose modifications, or order the destruction if a "new evaluation of the risks to public health or the environment caused by the presence of [GMOs] so justifies." *Id.* ¶ 24 (quoting Article L.535-2 of the French Code de l'Environnement, which is in force until June 27, 2008).

products under Regulation Number 1829/2003.¹⁰⁵ Member States could only prohibit the sale of authorized GMO seeds under “emergency measures” after demonstrating the “existence of a situation which is likely to constitute a clear and serious risk to human health, animal health or the environment.”¹⁰⁶ Once the EU approves a GMO material, in other words, a Member State cannot block the GMO without providing new and dependable information that the GMO is harmful.¹⁰⁷ As one commenter noted, “In principle, this judgement [sic] should therefore make it more difficult for Member States to unilaterally block approvals that have been granted at the EU level.”¹⁰⁸ While the full effect of this decision on the EU’s proposal and a Member State’s ability to ban the cultivation of a not-yet-approved GMO is still unknown, a Member State’s actual ability to independently regulate the movement of an approved GMO continues to be limited.¹⁰⁹ Although the proposal may allow Member States to initially decide whether or not to cultivate GMOs, the full legal impact of other GMO regulations may ultimately obstruct their decision.

The proposal to decentralize the decision to cultivate GMOs, furthermore, may be ineffective because it does not address the

¹⁰⁵ *Id.* ¶ 63. Directive 90/220 provides for the European Community’s authorization of GMOs that will be intentionally released into the environment, such as occurs during cultivation. *Id.* ¶ 5. Regulation Number 1829/2003 provides for authorization of GMO products to be used as source material for the production of feed. *Id.* ¶ 11.

¹⁰⁶ *Id.* ¶ 81.

¹⁰⁷ See Press Release, Sidley Austin LLP, Court of Justice Affirms Primacy of EU in Suspending GMO Approvals (Sept. 27, 2011), available at <http://m.sidley.com/court-of-justice-affirms-primacy-of-eu-in-suspending-gmo-approvals-09-27-2011/> (summarizing the Court of Justice’s decision and its interpretation of emergency measures as referring to “significant risk which clearly jeopardizes human health, animal health or the environment”) (emphasis in original).

¹⁰⁸ *Id.*

¹⁰⁹ See Council Directive 2002/53, art. 16, 2002 O.J. (L 193) 6, 7 (EC) (forbidding Member States from placing marketing restrictions on a variety of approved agricultural plant species except GMOs, for which limitations are allowed only if the variety could be “harmful . . . [to] plant health,” does not correspond to the original approved species, or if there is another valid reason based on “a risk for human health or the environment”); see also Press Release, EUROPA, GM Feed Ban: Commission Takes Poland to the EU Court of Justice (March 14, 2011), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/292> (announcing the EU’s decision to bring Poland to the Court of Justice for passing a law that will prohibit the production and marketing of GMO animal feed in violation of Regulation No. 1829/2003).

WTO's 2006 decision or comply with the SPS Agreement.¹¹⁰ The July 5, 2011 amendments enumerated several reasons Member States may exclude GMOs, including "other grounds that may include land use, town and country planning, or other legitimate factors."¹¹¹ The SPS Agreement, however, dictates that "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence"¹¹² To comply with the SPS Agreement, any basis for excluding GMO cultivation must still be based on sufficient scientific principles, regardless of the EU's enumerated reasons.¹¹³

U.S. Trade Representative Ron Kirk recognized the shortcomings of the EU proposal well before the non-scientific reasons were listed in the amendment.¹¹⁴ Kirk notes: "[w]hat we want in every case is an open, transparent process that conforms with international, scientific standards, and you're not going to be able to do that if you have member states all coming up with their

¹¹⁰ See *supra* Section 2.1 (discussing the WTO panel report and the SPS agreement).

¹¹¹ 2011 Amended Proposal, *supra* note 39, amend. 16. See *supra* notes 39–46 and accompanying text (providing a detailed discussion of the amendments to the 2001 Directive); see also *Brussels Supports Decentralised GM Crop Proposal*, INT'L CTR. FOR TRADE & SUSTAINABLE DEV. (July 11, 2011), <http://ictsd.org/i/news/biores/110309/> (observing that "[c]ritics fear that the legislation will lead to fragmentation of internal EU policies, uncertainty for farmers and incompatibility with WTO law").

¹¹² SPS Agreement, *supra* note 10, art. 2(2) (emphasis added). The SPS Agreement further notes:

In assessing the risk to animal or plant life or health . . . Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

Id. art. 5(3).

¹¹³ This is assuming that Member States will be held to the SPS Agreement by other signatories, such as the United States, Argentina, and Canada, regardless of whether the country provides non-sanitary reasons for banning GMOs.

¹¹⁴ See *supra* note 43 and accompanying text.

own rules.”¹¹⁵ Member States have also raised concerns regarding the proposal. The Italian Agricultural Minister Giancarlo Galan said that “Italy opposes the ‘each on his own’ logic that involves fragmenting Europe’s common agricultural policies . . . [t]he GMO theme is too important to be left up to the decisions of individual countries.”¹¹⁶ France’s Minister of Food, Agriculture and Fishing, Bruno Lemaire, has agreed: “[d]ecisions taken at a national level are not reassuring either for [EU] citizens or for Europe.”¹¹⁷ France has furthermore “expressed the worry that the proposal could leave” Member States vulnerable to WTO challenges,¹¹⁸ and the European Council’s internal legal service has noted that “the proposal may violate the national treatment principle in the General Agreement on Tariffs and Trade”¹¹⁹

Representative Kirk and the Member States’ concern may be well founded. A shadow draftsman of the 2011 amendment, Bart Staes (Belgium), has stated: “clearly an EU-wide moratorium would give the greatest certainty to the member states and clear majority of citizens that are opposed to GMO cultivation. However, this vote would give greater legal certainty to countries or regions wishing to introduce bans and, as such, is a step forward.”¹²⁰ It is difficult to imagine that the WTO’s decision—that the EU’s *de facto* moratorium on GMOs was an “across-the-board marketing ban” and violated the SPS Agreement¹²¹—can be remedied with a proposal that makes it easier for Member States to introduce bans.

Lastly, the EU’s proposal has yet to address the WTO’s mandate to the EU to process GMO applications “without undue

¹¹⁵ USTR Kirk Flags Problem with EU GMO Cultivation Policy on New Bans, 16 INSIDE WASHINGTON’S FDA WEEK (Inside Health Policy, Washington, D.C.), Aug. 6, 2010, at 12.

¹¹⁶ Italian Agriculture Minister Argues Decisions on GMOs Must be EU-Wide, BBC MONITORING EUROPE, Sept. 28, 2010.

¹¹⁷ *Id.*

¹¹⁸ Commission ‘Opt-Out’ Proposal on GMO Cultivation Largely Deadlocked, 29 INSIDE U.S. TRADE, Oct. 7, 2011.

¹¹⁹ *Id.*

¹²⁰ European Parliament Paves Way for GMO Crop Bans, ACTMEDIA (Dec. 7, 2011), <http://www.actmedia.eu/2011/07/12/top+story/european+parliament+paves+way+for+gmo+crop+bans/34643>.

¹²¹ Panel Report, *supra* note 2, at 41.

delay.”¹²² While the EU’s legislative process is certainly a necessary “delay,” the proposal is just that – a proposal – five years after the WTO’s decision. As EuropaBio complained in October 2011 to EU policymakers: “[t]he EU authorization process for GM products takes substantially longer than comparable systems, despite the fact that government processes around the world to assess the safety and impact of GM products are essentially the same”¹²³ Since 2007, the number of GM crops awaiting approval has risen from around fifty to seventy-two, including twenty-one applications for cultivation, and is expected to be over ninety pending approvals by 2015.¹²⁴

4.2. Decentralization May Run Counter to the Common Market

At its core, decentralization of GMO cultivation “runs counter to the principle of a unified EU market”¹²⁵ and EU competition principles. The Common Market demands “concerted action in order to guarantee steady expansion, balanced trade, and fair competition.”¹²⁶ The debates surrounding GMOs and GMO labeling laws, however, indicate that certain Member States and markets will be inherently discriminatory towards GMO and non-GMO products.¹²⁷ GMOs do provide certain benefits that make them cheaper to grow and more affordable to buy. For example,

¹²² See Council Conclusions on Genetically Modified Organisms, *supra* note 34, at 2 (stating that improvement of the implementation of the legal framework in order to better meet the objectives of the EC legislation necessitates continuing processing applications without undue delays).

¹²³ Charlie Dunmore, *Biotech Firms Warn EU Over Pace of GM Crop Approvals*, REUTERS, Oct. 11, 2011, available at <http://www.reuters.com/article/2011/10/11/us-eu-gmo-approvals-idUSTRE79A3G520111011>; see also Damien Geradin, *The European Community: Environmental Issues in an Integrated Market*, in THE GREENING OF TRADE LAW: INTERNATIONAL TRADE ORGANIZATIONS AND ENVIRONMENTAL ISSUES 117, 129 (Richard H. Steinberg ed., 2002) (“Inconsistent member state product standards may fragment the market, increase transaction costs, and generate diseconomies of scale for all producers.”).

¹²⁴ Dunmore, *supra* note 123.

¹²⁵ *Commission ‘Opt-Out’ Proposal on GMO Cultivation Largely Deadlocked*, *supra* note 118 (noting Germany and Spain’s opposition to the European Commission’s opt-out proposal on GMO cultivation).

¹²⁶ TFEU, *supra* note 40, pmb1.

¹²⁷ For an example of this debate as highlighted by differing laws between two neighboring countries, see discussion *supra* Section 3.3 (contrasting Hungary’s firm anti-GMO legislation with Romania’s pro-GMO legislation).

GMO cultivation can increase crop production and productivity,¹²⁸ and some GMO varieties can thrive under adverse conditions.¹²⁹ Moreover, many GMOs are bred pesticide-ready or pesticide-resistant,¹³⁰ and can be engineered to have lower fungal toxins or an increased shelf life.¹³¹ Because GMO producers have more control over pests and yield numbers, their products can be cheaper than their non-GMO counterparts.

As such, imported GMO products will most likely be less expensive than their traditionally grown local counterparts in countries that ban GMO cultivation. Importing cheaper GMO foods (which Member States must allow)¹³² inherently undercuts domestic products and unfairly competes with local agriculture, which would be legally barred from growing the less expensive GMO. As GMO domestic markets develop, the products of countries that do not cultivate GMOs will be more expensive than their imported counterparts from pro-GMO countries.

This expected price discrepancy may lead to competition issues between Member States in violation of several principles laid out in the Treaty on the Functioning of the European Union. Notably, any "restriction or distortion of competition within the internal market" is prohibited by Article 101.¹³³ Although Article 101 is

¹²⁸ Panel Report, *supra* note 2, at 28–29 (quoting *FAO Statement on Biotechnology*, U.N. FOOD & AGRIC. ORG., <http://www.fao.org/biotech/fao-statement-on-biotechnology/en>).

¹²⁹ See Katharine A. Van Tassel, *Genetically Modified Plants Used for Food, Risk Assessment and Uncertainty Principles: Does the Transition from Ignorance to Indeterminacy Trigger the Need for Post-Market Surveillance?*, 15 B.U. J. SCI. & TECH. L. 220, 226 (2009) (noting that a GM tomato plant has been engineered to grow in high salinity soil in which ordinary plants would not otherwise grow).

¹³⁰ See, e.g., *id.* at 232–33 (discussing GM peas that were engineered to contain a green bean protein which "inhibits weevils from digesting starch which causes the weevils to starve to death").

¹³¹ See Valery Federici, *Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws*, 35 BROOK. J. INT'L L. 515, 523–24 (2010) (noting that certain genetic modifications "have produced many important benefits, including lower average levels of fungal toxins on produce [and] increased shelf life").

¹³² See *supra* note 6 and accompanying text (noting that the adopted EU Proposal of 2010 regarding GMO foods prohibits Member States from interrupting the free flow of GMOs).

¹³³ TFEU, *supra* note 40, art. 101(1). See also *id.* pmbl (recognizing a desire to promote fair competition throughout the Common Market).

traditionally read to concern companies and undertakings,¹³⁴ the treaty prohibits *all* “concerted practices which may affect trade between Member States . . . which have as their object or *effect* the prevention, restriction or *distortion of competition*.”¹³⁵ A Member State’s decision to cultivate GMOs would inherently distort competition of its domestic goods and domestic companies. While all regulations affect competition on some level, decentralized decision-making over GMO cultivation would acutely harm competition in the Common Market. Member States that do not allow GMO cultivation would be forced to accept dissimilar conditions between locally grown traditional crops and imported GMOs, which will put local agriculture perpetually at a competitive disadvantage.¹³⁶

The potential risks posed by GMOs further exacerbate this competitive disadvantage. While it is beyond the scope of this Comment to explore the scientific theories or the full economic advantages or disadvantages of GMOs, conducting a cost-benefit analysis pertaining to use of GMOs is an important consideration when evaluating competitive advantages. Countries that allow GMO cultivation are not only gaining potential advantages,¹³⁷ but are also exposing themselves and their neighbors to potential risks of cross-contamination.¹³⁸ Decentralization of cultivation allows a country that chooses to cultivate GMOs to reap the benefits while exposing neighboring nations to the costs. Such costs, for example, include reported incidents in which pesticide and herbicide-ready GMOs have actually increased the need for stronger chemicals as pests and weeds become resistant or are contaminated with GMO

¹³⁴ See, e.g., *Application of Articles 101 and 102 TFEU (Formerly Articles 81 and 82 of the EC Treaty)*, EUROPA, http://europa.eu/legislation_summaries/competition/firms/126092_en.htm (last updated Mar. 14, 2011) (summarizing “the new arrangements for applying the antitrust procedures . . . introduced by Council Regulation (EC) No. 1/2003 . . . in the interests of consumers and businesses, while easing the administrative burden of firms doing business in Europe”).

¹³⁵ TFEU, *supra* note 40, art. 101(1) (emphasis added).

¹³⁶ Article 101 expressly prohibits application of “dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage.” TFEU, *supra* note 40, art. 101(1)(d).

¹³⁷ See *supra* notes 119–22 and accompanying text (describing proposed moratoria on GMO cultivation in order to limit potential gains by countries that allow GMO cultivation).

¹³⁸ See discussion *supra* Section 3.1 (discussing spillover effects of GMO transboundary contamination).

genes.¹³⁹ Resistant weeds and pests not only affect farmers using biotechnology, but also jeopardize the natural insecticides used by organic farmers.¹⁴⁰ Other risks include allergic or toxic reactions to GM foods,¹⁴¹ reactions of cross-breeding high allergen foods with low allergen foods,¹⁴² and antibiotic resistance in people and animals caused by widespread consumption of GMOs containing antibiotic marker genes,¹⁴³ all of which could be incorporated into the genes of traditionally grown crops via cross-pollination. Finally, cross-pollination contamination between GMOs and non-target organisms, such as wild plants or neighboring crops, could drastically reduce biodiversity.¹⁴⁴ The eradication of target and non-target pest populations may harm the ecosystem in unknown ways,¹⁴⁵ and some studies have suggested that GMOs may have a

¹³⁹ See *First Documented Case of Pest Resistance to Biotech Cotton*, SCI. DAILY, (Feb. 7, 2008), <http://www.sciencedaily.com/releases/2008/02/080207140803.htm> (reporting that bollworms, a major cotton pest, were discovered in Missouri and Arkansas to have evolved resistance to Bt, a toxin engineered in certain GM crops to kill insects); see also William Neuman & Andrew Pollack, *Farmers Cope with Roundup-Resistant Weeds*, N.Y. TIMES, May 3, 2010, <http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?%ED%AF%80%ED%B2%AB> (describing the proliferation of ten species of pesticide-resistant weeds over twenty-two states and the need to spray pesticide-ready fields with more toxic chemicals).

¹⁴⁰ See Van Tassel, *supra* note 129, at 226-27 (listing various risks that are posed to ecosystems by the use of GM plants).

¹⁴¹ See, e.g., *GM Peas Cause Immune Response – A Gap in the Approval Process?*, GMO COMPASS (Jan. 3, 2006), http://www.gmo-compass.org/eng/news/stories/175.gm_peas_australia_cause_immune_response.html (noting that an Australian private research facility discovered that a protein in GM peas produced an allergic reaction in mice, which could potentially produce an allergic reaction in humans). Notably, there are no reports proving the existence of these types of reactions in humans.

¹⁴² See, e.g., Federici, *supra* note 131, at 540 (highlighting voluntary labeling statements and indicating that cross-breeding a food a consumer is not allergic to, such as a tomato, with a food the consumer is allergic to, such as a Brazil nut, may produce a GM tomato to which the consumer is allergic).

¹⁴³ See Panel Report, *supra* note 2, at 32 (noting that the European Communities food safety concerns about GMOs affected the EC's approval regime).

¹⁴⁴ See *id.* at 66 ("Potential harmful effects on the environment . . . include non-target effects, invasiveness and development of resistance, unintended effects arising through GMO related management practices, and effects on biodiversity.")

¹⁴⁵ See Lee Stockhorst, Note, *Super Crops or a Super Problem? The Battle Over Bt Corn*, 15 MO. ENVTL. L. & POL'Y REV. 531, 545 (2008) ("While Bt products are created to target specific crop-destroying insects, there is nothing to say that other, non-target insects, will not ingest the Bt toxin. This process could threaten the

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reduced or negative nutritional impact.¹⁴⁶ In short, the decision to cultivate GMOs is not an easy one, and allowing Member States to independently decide whether or not to cultivate GMOs creates two separate markets with distinct cost-benefit frameworks.

If the EU's proposal does prove to be an effective vehicle by which Member States can decide whether or not to cultivate GMOs on their soil, the Common Market will split between GMO goods and non-GMO goods, creating unfair competition between imported GMO and local non-GMO goods in countries that choose to ban cultivation. Given the potential advantages and disadvantages that GMOs present Member States, coupled with the spillover effect of cross-pollination, only a centralized decision-making body can fully weigh EU-wide costs and benefits of cultivating GMOs and protect the free movement of European foodstuffs.

5. CONCLUSION

Although a decentralized system of government may more simply address GMOs and the scientific uncertainty surrounding their long-term effects, a centralized approval system would best address the unique concerns of the EU while still complying with the WTO's 2006 decision. Centralization reduces the risk of one country being harmed by another country's decision whether to cultivate GMOs. If Member States are acting together, the costs associated with the spillover effect of cross-pollination could be uniformly allowed or discouraged, depending on the EU-wide policy on that GMO. A consistent position on cultivating a GMO, furthermore, will decrease transaction costs by reducing the potentially incalculable information, inspection, and import and export costs, as well as discourage discrimination between GMO and non-GMO crops. By continuing a unified GMO policy, the EU as a whole will be better armed to confront pressures from the international community and address issues of contamination.

survival of hundreds of insect species, not to mention the potential unbalance in the ecosystem that could result from an insect species being eradicated in a particular area.").

¹⁴⁶ See Strauss, *supra* note 1, at 779 (discussing the potential risks of GMOs and the substantial scientific uncertainty surrounding biotechnology).

It is important to note that the WTO decision only determined that the EU was not in compliance with one article and one annex of the SPS Agreement and did not make substantive findings regarding GMOs.¹⁴⁷ By establishing clear, non-arbitrary standards based on the precautionary principle¹⁴⁸ in order to approve or disapprove GMOs without undue delay, the EU may satisfy the WTO while also responding to the issues surrounding GMOs.

A Communitywide approval system may find that, contrary to European public opinion, GMOs are acceptable and should be approved for cultivation in all or parts of the EU despite the risks. A unified front on GMOs, however, will best preserve the structure of the EU and the Common Market, and will allow for more comprehensive regulation of GMO trade and cultivation. By identifying and remedying possible issues surrounding GMOs, the EU can present a united front against outside pressures and better regulate and protect at home.

¹⁴⁷ See generally Panel Report, *supra* note 2, at 1067-69 (concluding that while the Panel did not examine the safety of biotech products, it did examine whether European Communities acted inconsistently as to the requirements of the SPS Agreement).

¹⁴⁸ See TFEU, *supra* note 40, art. 191(2) ("Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.").