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**From the USA with Love: Sharing Home-Grown  
Hormones, GMOs, and Clones with a  
Reluctant Europe**

by

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# FROM THE USA WITH LOVE: SHARING HOME-GROWN HORMONES, GMOS, AND CLONES WITH A RELUCTANT EUROPE

BY  
CINNAMON CARLARNE\*

*The United States and the European Union (EU) disagree over the social, ethical, and environmental implications of producing, using, and trading the products of modern science. Since the 1990s, the United States and Europe have clashed heads in the World Trade Organization (WTO) over European regulations restricting imports of the products of modern biotechnology. In the first of these WTO disputes—the Beef Hormones dispute—the WTO upheld a United States challenge to EU regulations banning the importation of beef treated with hormones; this dispute is still ongoing. The scale of the Beef Hormones dispute pales in comparison to the pending row over genetically modified organisms (GMOs). The United States and the EU have adopted diametrically opposed regulatory regimes for the importation and use of GMOs, prompting yet another WTO trade dispute. In fall 2006, the WTO dispute settlement body found that Europe’s genetically modified (GM) regulations contradict international trade rules, thus fueling another epic transatlantic dispute.*

*In late 2006, the United States laid the groundwork for yet another biotechnology-trade conflict. On December 28, 2006, the Food and Drug Administration (FDA) released Animal Cloning: A Draft Risk Assessment. One of the practical consequences of the FDA’s report is that cloned food products will not have to be labeled as such when they enter the human food market. The EU has not yet established a framework for regulating the products of cloned animals, but it is unlikely to adopt such a laissez-faire approach.*

*This Article examines the beef hormones, GMOs, and cloned foods debates, focusing on whether cloned foods will incite American political and ethical debate or slide by without notice until the United States and the EU once again clash heads in the WTO. The Article concludes that the United States citizenry will likely continue to be, by and large, indifferent to food safety questions, but that the cloning debate will begin to turn the tide towards incorporating more public*

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*participation and scientific precaution into the U.S. regulatory decision-making process. Further, the Article finds that the stakes are too high and the human and environmental impacts too indefinite to allow global decision making on these issues to come down to the dialogue of a handful of developed nations, i.e., the United States and the EU, and the rules of an international organization, i.e., the WTO, that is monumental in task and influence but limited in scope and capacity.*

I. INTRODUCTION .....	302
II. DISCUSSION .....	303
A. <i>Hormones</i> .....	304
B. <i>GMOs</i> .....	308
1. <i>The Cartagena Protocol and the World Trade Organization</i> .....	309
2. <i>The WTO Debate</i> .....	310
3. <i>European Union and United States Regulations</i> .....	313
a. <i>European Union Regulations</i> .....	313
b. <i>United States Regulations</i> .....	316
4. <i>Consumer Preferences and the Future of the GM Debate</i> .....	318
C. <i>Cloned Products</i> .....	321
1. <i>The Cloning Process</i> .....	322
2. <i>Cloning in the European Union</i> .....	323
3. <i>Cloning in the United States</i> .....	326
4. <i>Cloning and Consumer Preferences</i> .....	330
III. CONCLUSION .....	333
A. <i>International Trade and Environment Tensions</i> .....	333
B. <i>Questions Defining the Future of the Debate</i> .....	336

## I. INTRODUCTION

Biotechnology, trade, and culture are the elements from which modern nightmares are made. In the case of relations between the United States and the European Union (EU),<sup>1</sup> these nightmares occur with increasing frequency, intensity, and consequences. From the disputes over the use of hormones in beef and the trade in genetically modified organisms (GMOs) to the ongoing deliberations over the marketing and trade of food products derived from cloned animals, the United States and the EU repeatedly clash over the social, ethical, and environmental implications of producing, using, and trading the products of modern science. Much has been said about the United States-EU hormone dispute and much is currently being written about the global dispute over genetically modified (GM) products. Yet, neither of these disputes is close

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<sup>1</sup> EU is used throughout the paper to refer to the European Union. It is also used to refer to the European Community, the political organization that the EU replaced in 1995, and which is still the legal entity recognized by the WTO.

to being resolved. A preliminary decision by the U.S. Food and Drug Administration (FDA)—concluding that meat and milk from cloned animals is safe and, thus, might soon enter the U.S. food market without the need for labeling—will exacerbate preexisting tensions between the United States and the EU.

This Article examines the impact of biotechnology on international trade relations between the United States and the EU. It focuses on how the introduction of meat treated with hormones, GMOs, and meat and dairy from cloned animals introduced into the streams of trade has affected United States-EU relations. The Article provides an overview of the beef hormones deliberations, examines the ongoing debate over GMOs, and analyzes how a final FDA decision regarding cloned meat and dairy products will influence current trade disputes. The Article reviews the disparate policies adopted by the United States and the EU. It then examines how and why consumer preferences in the United States and EU differ, and how these differences impact policy formulation. Finally, the Article considers whether the cloned foods debate is likely to shift the nature of the biotechnology-food debate and whether such a shift is desirable.

## II. DISCUSSION

In international relations, the United States and the EU are both *über*-allies and *über*-competitors. Since World War II, the United States and the countries that now form the EU have regularly acted together as a formidable force on international security issues—e.g., during the Cold War, the first Gulf War, and during other United Nations-sanctioned actions. In the realm of economics and international trade, the United States and the EU have worked jointly to liberalize international trade (e.g., General Agreement on Tariffs and Trade (GATT) and the World Trade Organization (WTO)) and increase global prosperity (e.g., Organization for Economic Cooperation and Development (OECD), World Bank, and International Monetary Fund (IMF)) while simultaneously competing ruthlessly for economic primacy.

United States-EU interaction in the GATT-WTO system best exemplifies the intensely competitive nature of this relationship. Disputes between the United States and the EU have continually dominated both GATT and WTO dispute settlement systems. From 1980 to 1985, nearly thirty percent of all GATT lawsuits (twelve of forty-two) were between the EU<sup>2</sup> and the United States;<sup>3</sup> ninety percent of all GATT lawsuits (thirty-eight of forty-two) involved either the EU or the United States as one of the parties;<sup>4</sup> since the creation of

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<sup>2</sup> The EC is the regional entity that participates in the WTO but, this Article uses the EU to refer to the EC to avoid any confusion or inconsistency.

<sup>3</sup> ANDRÉ SAPIR, OLD AND NEW ISSUES IN EC-US TRADE DISPUTES 3 (Apr. 11–12, 2002) (paper prepared for the Conference on “Transatlantic Perspectives on US-EU Economic Relations: Convergence, Conflict & Cooperation”), available at [http://www.ksg.harvard.edu/m-rcbg/Conferences/us-eu\\_relations/sapir\\_trade\\_international\\_investment.pdf](http://www.ksg.harvard.edu/m-rcbg/Conferences/us-eu_relations/sapir_trade_international_investment.pdf).

<sup>4</sup> *Id.*

the WTO in 1995 through 2002, disputes between the EU and the United States constituted nearly twenty percent (48 of 251) of all WTO disputes<sup>5</sup> and nearly seventy-five percent of all WTO disputes (184 of 251) have involved either the EU or the United States as one of the parties.<sup>6</sup> Competition and conflict define United States-EU economic affairs and international trade relations. Cultural disagreement over trade in the products of modern science is the newest and one of the most volatile areas of modern United States-EU economic conflict.

In the following sections, this Article analyzes two existing and one prospective United States-EU trade disputes. The three chosen cases are grouped together because they all involve the use of modern science to produce food products. In addition, all three cases highlight deep-rooted social and ethical—rather than primarily economic—reasons for policy differences. Thus, with each case, this Article examines the fundamental issue, the varying policy responses, and the underlying factors determining regional responses. In particular, the Article will highlight how concepts of precaution and risk, levels of consumer awareness and interest, and interpretations and support for international legal regimes impact policy choice.

### A. Hormones

The first case, the beef hormones dispute, involved the use of six natural and synthetic hormones in beef and beef products. The use, marketing, and trade of beef treated with synthetic and natural hormones highlights deep divisions between European and North American trade policy.

The battle between the United States and the EU over the use of growth promoting hormones is not a recent phenomenon. For almost twenty years, the two powers have argued over the safety of using natural and synthetic growth-promoting hormones in cattle. During the 1980s, tensions simmered and finally came to a head in 1989, when the EU first banned the importation of beef products containing growth-promoting hormones.<sup>7</sup> Tensions further escalated in 1996 when the EU enacted Council Directive 96/22 banning the importation of beef or beef products from cattle that had been treated with hormones for the purpose of growth promotion.<sup>8</sup> In effect, the EU law banned

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<sup>5</sup> *Id.* at 7.

<sup>6</sup> *Id.* at 8, 18.

<sup>7</sup> See Council Directive 81/602, art. 3, 1981 O.J. (L 222) 33 (EC) (prohibiting the marketing of “stilbenes, stilbene derivatives, their salts and esters and thyrostatic substances”); Council Directive 88/146, art. 4, 1988 O.J. (L 70) 17 (EC) (requiring producers to keep a register of hormones sold for pharmaceutical and veterinary products); Council Directive 88/299, art. 2, 1988 O.J. (L 128) 36 (EC) (detailing restricted uses for animals that have had hormones administered to them); see also EUROPEAN COMM’N, SCIENTIFIC COMM. ON VETERINARY MEASURES RELATING TO PUB. HEALTH, ASSESSMENT OF POTENTIAL RISKS TO HUMAN HEALTH FROM HORMONE RESIDUES IN BOVINE MEAT AND MEAT PRODUCTS 1 (1999), available at [http://ec.europa.eu/food/fs/sc/scv/out21\\_en.pdf](http://ec.europa.eu/food/fs/sc/scv/out21_en.pdf) (describing the 1989 directive that prohibited giving a farm animal growth hormones).

<sup>8</sup> Council Directive 96/22, 1996 O.J. (L 125) 3 (EC) (setting forth a total ban on the use of hormones where they are used for the specific purpose of growth promotion); see also Darrell Chichester, Note, *Battle of the Beef, the Rematch: An Evaluation of the Latest E.C. Directive Banning Beef Produced with Growth Hormones and the U.S. Refusal to Accept the Directive As*

virtually all imports of U.S. beef. After prolonged attempts to negotiate a compromise, in 1996, both the United States and Canada—whose imports were also affected—challenged the EU legislation in the WTO's Dispute Settlement Body.<sup>9</sup> The crux of the challenge was whether the EU ban could be justified on safety and human health grounds.<sup>10</sup>

The beef hormones dispute highlighted underlying disagreements between the EU, the United States, and Canada not only over the safety of using natural and synthetic hormones in the production of beef, but over food quality and safety in general. Following the European "hormone scandals" of the 1970s and 1980s and the bovine spongiform encephalopathy (BSE) and foot and mouth crises in the 1990s and new millennium, European consumers became increasingly suspicious of the use of hormones to produce beef and beef products. And, "[a]s a result many European Union consumers no longer trust science and demand higher levels of protection in a form of product bans or labeling requirements."<sup>11</sup> European distrust of food quality runs deep, so deep in fact that subsequent to these scandals, in 2002, the European Parliament responded to consumer concerns about food safety by forming the European Food Safety Authority.<sup>12</sup>

In the hormones case, prompted by feelings of distrust, consumers pressured the EU government to limit or ban the use and importation of growth hormones in cattle. The EU government responded to the pressure by banning the use of the six hormones in the EU (except for zootechnical and therapeutic reasons) and by banning the importation of all beef and beef products containing any of the six growth hormones.<sup>13</sup> While some of the EU's trade partners—e.g., Argentina and Australia—successfully accommodated the EU regulations by establishing systems for separating beef produced with and without hormones, both the United States and Canada refused to establish separate systems, citing the change as unnecessarily costly. Instead, the United States and Canada challenged the EU measures as contrary to WTO rules and regulations.

The United States and Canada based their primary challenge on the terms of the Sanitary and Phytosanitary Agreement (SPS)<sup>14</sup> to the WTO. The SPS

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*WTO Compliant*, 21 AM. U. INT'L L. REV. 221, 226–27 (2005) (discussing the impact of the directive on United States-EU relations).

<sup>9</sup> Chichester, *supra* note 8, at 227.

<sup>10</sup> *Id.* at 236.

<sup>11</sup> Krzysztof Kuik, *Recent Developments in EU/US Trade Relations*, 79 U. DET. MERCY L. REV. 433, 440 (2002) (discussing the relationship between the economies of the United States and EU).

<sup>12</sup> Commission Regulation 178/2002, art. 22, 2002 O.J. (L 31) 12 (EC) (laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and setting forth procedures in matters of food safety).

<sup>13</sup> See Council Directive 85/649 1985 O.J. (L 382) 228–31 (EC) (prohibiting interstate and trans-EU transportation of animals and meat administered substances with a "thyrostatic, oestrogenic, androgenic, or gestagenic action"); Kuik, *supra* note 11, at 440; Tim Josling, Donna Roberts & Ayesha Hassan, *The Beef-Hormone Dispute and Its Implications for Trade Policy* 4–6 (Stanford Forum on Contemporary Europe, Working Paper, 1999), available at <http://iis-db.stanford.edu/pubs/11379/HORMrev.pdf>.

<sup>14</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994,

provides regulations for evaluating measures that deal with the use of additives, contaminants, toxins, and disease-carrying organisms in food, beverages, and feeds-stuffs.<sup>15</sup> Under the SPS, WTO members can adopt SPS measures that are “necessary for the protection of human and animal health” subject to six primary restrictions.<sup>16</sup> The measures must: 1) be no more trade restrictive than required to achieve an appropriate level of protection,<sup>17</sup> 2) be applied “only to the extent necessary,”<sup>18</sup> 3) be based on “scientific principles” and “sufficient scientific evidence,”<sup>19</sup> 4) be based on a risk assessment,<sup>20</sup> 5) meet the requirements of the *Chapeau*,<sup>21</sup> and 6) and meet the obligation to at least consider adopting international, rather than unilateral, SPS standards.<sup>22</sup>

The hormones case turned on whether the EU ban was based on scientific evidence, as required by the SPS. Accordingly, the EU was required to show that its decision was based on “scientific principles” and “sufficient scientific evidence”<sup>23</sup>—i.e., the EU was not able to base its decision on considerations of consumer preference. Both the WTO Dispute Settlement Body Panel (Panel) and the Appellate Body found the ban to be incompatible with the EU’s responsibilities under the WTO, with particular reference to the terms of the SPS.

In the first instance, the Panel found that the EU’s measures were arbitrary and unjustifiable and were not based on risk assessments, as required by the SPS.<sup>24</sup> The Panel further found that the EU relied on measures that were not based on international standards and that the EU had not provided adequate justification for this derivation from common practice,

1867 U.N.T.S. 493 [hereinafter SPS Agreement].

<sup>15</sup> *Id.* arts. 4, 6. Under the SPS: 1) members may choose their own levels of protection but must be prepared to justify them, 2) the precautionary principle cannot be used to override specific provisions of SPS, 3) harmonization and adoption of international standards is encouraged but not required, and 4) only the *means* chosen to implement domestic policies will be subject to WTO review and test will balance national interests and need to police disguised trade restrictions. *Id.* art. 2.

<sup>16</sup> *Id.* art. 3.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.* art. 4.

<sup>20</sup> *Id.* The SPS does not define “sufficient risk assessment;” member countries are free to consider “available scientific evidence” and “relevant economic factors” but must show that there is a rational relationship between the trade measure they have adopted and the risk assessment that they have performed. *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.* art. 3. Members may choose the international SPS standard, base their standard on the international standard without conforming to all its requirements, or set a level of protection wholly their own. Each standard has a different test. International standards carry a rebuttable presumption of SPS conformity. *Id.* Partially enforced international standards have no presumption in their favor, but the complaining party must make a prima facie case of inconsistency. *See id.* (stating members have the right to choose higher measures as long as they are not inconsistent). State-created standards must be based on a “risk assessment” and “sufficient scientific evidence.” *Id.* arts. 3–4.

<sup>23</sup> *Id.* art. 3.

<sup>24</sup> Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, ¶ 6(i)–(ii), WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998).

according to the terms of the SPS.<sup>25</sup> For these reasons, the EU measures were held to be inconsistent with the SPS.

On appeal, the Appellate Body reversed, upheld, and modified the Panel decision.<sup>26</sup> Of particular relevance, the Appellate Body found that the EU measures were inconsistent with the SPS and, despite the EU's arguments to the contrary, the precautionary principle did not override the specific wording of the SPS.<sup>27</sup> In its decision, the Appellate Body suggested that the EU could justify its hormone ban by providing convincing scientific evidence that the hormones in dispute presented a danger to human health.<sup>28</sup> The European Commission, however, failed to supply the requisite scientific evidence to establish danger within the set period of time. The EU also refused to bring its measure into compliance with the WTO ruling. As a consequence, the United States and Canada requested compensation from the EU.<sup>29</sup> In response, the WTO authorized the United States and Canada to levy tariffs on specific categories of EU exports. Accordingly, the United States and Canada suspended existing concessions on EU items, including Roquefort cheese, foie gras, and Perrier water.<sup>30</sup> In total, the compensation amounted to approximately \$117 million in concessions for the United States and approximately \$8 million for Canada.<sup>31</sup>

The Appellate Body decision and the consequent countermeasures did not bring an end to the United States-Canada-EU hormone dispute. On November 8, 2004, the EU requested consultations with both Canada and the United States concerning the continued imposition of countermeasures in the hormone dispute. The challenge turned on the EU's implementation of new hormones legislation—Directive 2003/74/EC.<sup>32</sup> The EU claimed that it had adopted new provisions based on revised risk assessments and that the new provision brought the EU into conformity with all WTO obligations.

Based on these new provisions, the EU is now challenging the United States' and Canada's decision to continue imposing countermeasures against the EU.<sup>33</sup> First, the EU is challenging the United States' continued suspension

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<sup>25</sup> *Id.* ¶ 6(iii).

<sup>26</sup> *Id.* ¶ 253.

<sup>27</sup> *Id.* ¶ 253(c).

<sup>28</sup> *See id.* ¶¶ 205–08 (finding the issue to be whether the EU in fact submitted a risk assessment with relevant documentation to base the import prohibition on, as required by the SPS, and concluding that the EU had not submitted a risk assessment since the scientific studies presented by the EU did not actually assess the potential impacts related to noncompliance with practice).

<sup>29</sup> Kuik, *supra* note 11, at 441.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> Commission Decision 2003/74, 2003 O.J. (L 28) 45 (EC). On the basis of the studies reviewed by the Scientific Committee on Veterinary Matters relating to Public Health (SCVPH), on May 5, 2000, the European Commission adopted a proposal to amend the "hormones directive." The new proposal calls for a permanent ban of 17- $\beta$ -oestradiol, on the basis that new studies show that this hormone has carcinogenic and genotoxic effects, and a provisional ban for the remaining five hormones in dispute. The new directive entered into force on October 14, 2003. *Id.*

<sup>33</sup> World Trade Organization, Dispute Settlement: Dispute DS321, Canada—Continued



of obligations and its continued imposition of import duties in excess of bound rates on imports from the European Communities despite the fact that EU claims to have removed the inconsistent measures.<sup>34</sup> Second, the EU is challenging what it claims is the United States' unilateral determination that the new EU legislation continues to violate WTO obligations.<sup>35</sup> Third, the EU is challenging the United States' failure to refer the present hormone disputes to dispute settlement proceedings so that the WTO Dispute Settlement Body can properly settle the question of whether the EU's new hormone legislation is consistent with its obligations under the WTO.<sup>36</sup> Following the breakdown of consultations, and in response to the EU's complaint, on June 6, 2005, the WTO Director-General established a new Dispute Settlement Body Panel.<sup>37</sup> The Panel has not yet issued a report on this dispute.

Throughout the hormones disputes, conflict between the United States and the EU has hinged on two main questions. First, the debate focuses on the scientific and technical aspects of the hormone ban and its validity under the terms of the SPS. Second, the disputes revolve around the differing social and ethical perspectives shaping regional policies and the ability of sovereign nations and regional organizations to protect social and ethical beliefs from the forces of international trade while continuing to participate in the international trade regime.

The hormones disputes highlight the beginning of a new era of international trade tensions between the EU and the United States. In this era, the EU has consistently responded to consumer pressure by adopting a precautionary approach to regulating the products of modern science while the United States, without fail, has fought EU attempts to restrict trade based on precautionary concerns. The hormones disputes set the stage for the escalating debate between the United States and the EU over trade in GMOs.

### B. GMOs

The burgeoning dispute between the United States and the EU over the use of hormones in beef and beef products foreshadowed the commencement of an even more intense and far-reaching debate over trade in GMOs. GMOs are "organisms that have received a selective transfer of

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Suspension of Obligations in the EC—Hormones Dispute, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds321\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds321_e.htm) (last visited Apr. 15, 2007); World Trade Organization, Dispute Settlement: Dispute DS320, United States—Continued Suspension of Obligations in the EC—Hormones Dispute, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds320\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds320_e.htm) (last visited Apr. 15, 2007).

<sup>34</sup> See World Trade Organization, Dispute Settlement: Dispute DS320, United States—Continued Suspension of Obligations in the EC—Hormones Dispute, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds320\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds320_e.htm) (last visited Apr. 15, 2006) (describing EU complaint regarding United States' failure to remove retaliatory measures, United States' unilateral determination that EC legislation is a WTO violation, and failure of the United States to allow follow the appropriate dispute settlement procedures).

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

genes from another organism (even another natural species) via advanced procedures, as opposed to the more traditional genetic manipulation of cross-fertilization.<sup>38</sup> The United States has used, released, and exported GMOs since the 1980s, basing its policy decisions on principles of “sound science.”<sup>39</sup> The EU has taken a more cautious approach to the use and release of GMOs, basing its regulatory strategy on the “precautionary principle.”<sup>40</sup> The different regulatory approaches adopted by the United States and the EU have sparked an ongoing international trade dispute.

The GMO debate has been further exacerbated by the existence of two potentially conflicting international legal regimes, the Cartagena Protocol to the Convention on Biological Diversity (Cartagena Protocol) and the WTO. Both the Cartagena Protocol and the WTO regulate the trade and movement of GMOs, but they are guided by different principles and have different aims.

### 1. *The Cartagena Protocol and the World Trade Organization*

The Cartagena Protocol<sup>41</sup> creates a multilateral regime governing the transnational movement of GMOs.<sup>42</sup> The objective of the Cartagena Protocol is to

contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.<sup>43</sup>

The Cartagena Protocol, as a constituent part of the Convention on Biological Diversity, regulates the movement of GMOs for the primary purpose of biodiversity protection.

The WTO, in contrast, promotes trade liberalization and seeks to diminish or eliminate impediments to free trade.<sup>44</sup> As demonstrated by the hormones disputes, the WTO discourages the use of any regulations that limit trade in new products absent clear evidence that the regulations

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<sup>38</sup> Susana Borrás, *Legitimate Governance of Risk at the EU Level? The Case of Genetically Modified Organisms*, 73 TECHNOLOGICAL FORECASTING & SOC. CHANGE 61, 62 (2006).

<sup>39</sup> Joseph Murphy, Les Levidow & Susan Carr, *Regulatory Standards for Environmental Risks: Understanding the US-European Union Conflict over Genetically Modified Crops*, 36 SOC. STUD. OF SCI. 1, 133 (2006).

<sup>40</sup> *Id.*

<sup>41</sup> Convention on Biological Diversity, The Cartagena Protocol on Biosafety (2000), Feb. 23, 2000, 39 I.L.M. 1027, available at <http://www.biodiv.org/biosafety/protocol.shtml> [hereinafter Cartagena Protocol]. The Cartagena Protocol is also commonly referred to as the Biosafety Protocol.

<sup>42</sup> The Cartagena Protocol uses the term Living Modified Organisms (LMOs) rather than GMOs. For purposes of this Article the terms are interchangeable.

<sup>43</sup> Cartagena Protocol, *supra* note 41, art.1.

<sup>44</sup> World Trade Organization, What is the World Trade Organization?, [http://www.wto.org/English/thewto\\_e/whatis\\_e/tif\\_e/fact1\\_e.htm](http://www.wto.org/English/thewto_e/whatis_e/tif_e/fact1_e.htm) (last visited Apr. 14, 2007).

comport with international standards or are based on sound science and risk assessments.

The aims and objectives of the Cartagena Protocol and the WTO establish potentially conflicting regimes that the United States and the EU can refer to in support of their disparate GMO policies. Consequently, it is not surprising that the United States and the EU are teetering on the brink of a long-term dispute over trade in GMOs.<sup>45</sup>

## 2. *The WTO Debate*

GMOs instigate trade disputes when international players, such as the United States and the EU, enact conflicting regulatory regimes concerning the testing, use, labeling, identification, and approval procedures required to allow GMOs and GMO products to reach domestic markets. During the early days of the emerging GMO debate, the EU enacted a de facto ban on the import and sale of all GMOs. The United States, on the other hand, placed relatively few restrictions on the approval and sale of GMOs. In fact, GMOs already constitute a large part of U.S. agricultural production and the United States is the leading exporter of GMO products.<sup>46</sup> Further, while the EU supports its regulations on the basis of precautionary concerns, the United States insists that bans, strict regulations, and labeling requirements for GMOs are unnecessary and constitute arbitrary and unjustified impediments to free trade.

The WTO Dispute Settlement Body has only recently issued its first decisions in a GMO dispute.<sup>47</sup> This decision is too new to have elicited a comprehensive response. However, it stands to reshape and prolong the current United States-EU GMO dispute. Within the WTO, GMOs are viewed as the “next battlefield”<sup>48</sup> and the long-anticipated dispute is quickly taking concrete form.

The recently decided GMO case was brought to the WTO on May 13, 2003, when the United States and Canada requested consultations with the EU regarding regulations adopted by the European Community and its member states regarding food and agricultural imports from the United States and Canada. Specifically, the United States and Canada challenged a

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<sup>45</sup> Anais Kedgley Laidlaw, *Is It Better to Be Safe Than Sorry? The Cartagena Protocol Versus the World Trade Organisation*, 36 VICT. U. WELLINGTON L. REV. 427, 429–30 (2005).

<sup>46</sup> See Sakika Fukudo-Parr, *Introduction: Global Actors, Markets and Rules Driving the Diffusion of Genetically Modified (GM) Crops in Developing Countries*, 2 INT'L J. TECHNOLOGY & GLOBALISATION 4–5 (2006) (noting that the United States accounted for 59% of the world total of GM foods in 2004); CHANTAL POHL NIELSEN, SHERMAN ROBINSON & KAREN THIERFELDER, *TRADE IN GENETICALLY MODIFIED FOOD: A SURVEY OF EMPIRICAL STUDIES 3–4* (2002), available at <http://www.ifpri.org/divs/tmd/dp/papers/tmdp106.pdf> (examining the factors that affect GMOs economic effect and its benefits to diverse nations).

<sup>47</sup> 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), available at [http://www.wto.org/english/news\\_e/news06\\_e/291r\\_e.htm](http://www.wto.org/english/news_e/news06_e/291r_e.htm).

<sup>48</sup> Daniel Kalderimis, *Problems of WTO Harmonization and the Virtues of Shields over Swords*, 13 MINN. J. GLOBAL TRADE 305, 324 (2005).

de facto EU moratorium on approving biotech products.<sup>49</sup> The United States and Canada claimed that the moratorium impermissibly restricted or delayed approval of imports and was inconsistent with EU obligations under the SPS, Agreement on Technical Barriers to Trade (TBT), and Agriculture Agreements, as well as with the provisions of GATT itself.<sup>50</sup>

In August 2003, the United States, Canada, and Argentina requested that the WTO establish a Dispute Settlement Body panel. This request was deferred and a panel was established on August 29, 2003. Due to difficulties determining the composition of the Panel, on February 23, 2004, the United States, Canada, and Argentina requested that the WTO Director-General determine the composition of the Panel. On March 4, 2004, the Director-General did so.<sup>51</sup> The Panel did not, however, follow its six month time schedule, citing the parties' requests for additional time to prepare their rebuttals and the Panel's desire to request scientific and technical advice. After numerous delays and requests for extra time to seek further information, on August 11, 2005, the Panel suggested that it would attempt to issue its final report to the parties by the end of December 2005. On December 21, 2005, however, the chairman of the Panel issued a communication indicating that, "[d]ue to the large number of issues to be addressed" the Panel would not be able to issue a final report by the end of December 2005.<sup>52</sup> The chairman estimated that the final report would instead be issued by the end of March 2006.<sup>53</sup>

On September 29, 2006, the Panel finally circulated its report to WTO members—all 1000 plus pages of it.<sup>54</sup> In relevant part, the Panel found that the EU had, in fact, "applied a general de facto moratorium on the approval of biotech products between June 1999 and August 2003."<sup>55</sup> The Panel held that the EU moratorium constituted, in large part, a violation of the SPS because it "led to undue delays in the completion of EC approval procedures" for new products.<sup>56</sup> Further, regarding the product-specific EU

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<sup>49</sup> See *infra* notes 61–86 and accompanying text (discussing the EU strategy in more detail).

<sup>50</sup> See World Trade Organization, Dispute Settlement: Dispute DS291, European Communities—Measures Affecting the Approval and Marketing of Biotech Products, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds291\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm) (last visited Apr. 15, 2007) (summarizing the dispute between the EU and the United States and Canada regarding the marketing of biotech products).

<sup>51</sup> Argentina, Australia, Brazil, Canada (with respect to the United States' and Argentina's complaints), Chile, China, Colombia, El Salvador, Honduras, Mexico, New Zealand, Norway, Paraguay, Peru, Chinese Taipei, Thailand, Uruguay, and the United States (with respect to Canada's and Argentina's complaints) reserved their third-party rights.

<sup>52</sup> World Trade Organization, *supra* note 50.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

The Panel further found that, by applying this moratorium, the European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, and Article 8 of the SPS Agreement because the de facto moratorium led to undue delays in the completion of EC approval procedures. The Panel, however, found that the European Communities has not acted inconsistently with its obligations under other provisions

measures at issue, the Panel again found that the EU had “acted inconsistently with its obligations” under the SPS in relevant part, reemphasizing that the EU measures resulted in undue delays.<sup>57</sup> Finally, when considering EU member state safeguard measures:

the Panel found that the European Communities acted inconsistently with its obligations under Articles 5.1 and 2.2 of the SPS Agreement with regard to all of the safeguard measures at issue, because these measures were not based on risk assessments satisfying the definition of the SPS Agreement and hence could be presumed to be maintained without sufficient scientific evidence.<sup>58</sup>

The Panel decision has not yet been approved by the WTO Dispute Settlement Body. However, as with the decision in the beef hormones dispute, the Panel decision finds that the EU measures at issue violate provisions of the WTO, here the SPS. The primary consequence of this decision is the finding that the EU is out of compliance with its international obligations. Ultimately, if adopted, the decision means that the EU will have to bring its measures into compliance with the SPS or risk being subject to costly countermeasures.

The EU will, doubtless, appeal the Panel decision to the WTO Dispute Settlement Body Appellate Panel—possibly arguing that the EU moratorium has already been replaced by internationally consistent measures and providing empirical evidence to demonstrate that the EU carried out the proper risk assessments.<sup>59</sup> At first glance, however, the Panel decision closely mirrors the earlier conclusions in the beef hormones case, suggesting that the EU again faces a long, drawn out trade dispute with the United States—i.e., the United States won victory in the first stage but the battle between “sound science” and “precaution” wages on.<sup>60</sup>

raised by the complaining parties, including Articles 5.1, 5.5, 5.6, 2.2 or 2.3 of the SPS Agreement.

*Id.*

<sup>57</sup> *Id.*

With regard to the product-specific EC measures, the Panel found that the European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, and Article 8 of the SPS Agreement in respect of the approval procedures concerning 24 out of 27 biotech products identified by the complaining parties because there were undue delays in the completion of the approval procedures for each of these products. The Panel found, however, that the European Communities has not acted inconsistently with its obligations under any other provisions raised by the complaining parties, including Articles 5.1, 5.5 and 2.2 of the SPS Agreement, with regard to any of the products concerned.

*Id.*

<sup>58</sup> *Id.*

<sup>59</sup> See *infra* notes 67–85 and accompanying text.

<sup>60</sup> The EU most likely also faces disputes with third parties, including Argentina, Australia, Brazil, Canada, Chile, China, Chinese Taipei, Colombia, El Salvador, Honduras, Mexico, New Zealand, Norway, Paraguay, Peru, Thailand, and Uruguay. See World Trade Organization, *supra* note 50.

The WTO is not the only stage for the GMO conflict. There is also considerable conflict over the use and handling of GMOs in other international forums. Most international institutions, including the Biosafety Protocol and the United Nations Development Programme, advocate caution in creating regulatory frameworks for the use, handling, and transport of the products of biotechnology. There is not, however, any consensus about what type of regulatory framework is necessary and valid. Consequently, even once the WTO Dispute Settlement Body has adopted a final decision, the issue will not be settled as there will inevitably—and properly—be continuing international debate both inside and outside of the international trade forum.

### 3. *European Union and United States Regulations*

#### a. *European Union Regulations*

At the heart of the GMO debate is the fact that modern biotechnology is still a new field, and there are many potential unknowns associated with introducing GMOs into both the human food chain and the natural environment. Europeans are particularly concerned about the “unknowns” associated with GMOs.<sup>61</sup> This stands in direct contrast to the U.S. public.

In the United States, by and large, the public has accepted the use and marketing of GMO products almost seamlessly, or at least without widespread coordinated resistance. In contrast, European consumers are wary of how the widespread use of GMOs will affect biodiversity and human health.<sup>62</sup> Specific concerns include “the evolution of genetically modified organisms (GMOs) into ‘super weeds,’ cross-pollination introducing herbicide resistance into existing weeds or introducing undesirable genetic traits into neighboring crops, and harm to nontarget populations caused by toxins introduced to create insect resistance.”<sup>63</sup> Meanwhile, in the United States, “roughly 75 percent of U.S. processed foods—boxed cereals, other grain products, frozen dinners, cooking oils and more—contain some genetically modified, or GM, ingredients”<sup>64</sup> and all of the products are sold

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<sup>61</sup> Sylvie Bonny, *Why Are Most Europeans Opposed to GMOs? Factors Explaining Rejection in France and Europe*, 6 ELECTRONIC J. BIOTECHNOLOGY 50, 56 (2003), <http://www.ejbio.technology.info/content/vol6/issue1/full/4/4.pdf> (last visited Apr. 15, 2007).

<sup>62</sup> Cf. Alex Kirby, *UK Doctors Alter Tack to Back GMs*, BBC NEWS, Mar. 9, 2004, <http://news.bbc.co.uk/2/hi/science/nature/3545717.stm> (last visited Apr. 15, 2007) (explaining the British Medical Association’s opinion that “huge public concern over the impact of GM foods” necessitates further research “to allay remaining concern about the potential risks to human health and the environment”).

<sup>63</sup> Carl H. Nelson, *Risk Perception, Behavior, and Consumer Response to Genetically Modified Organisms: Toward Understanding American and European Public Reaction*, 44 AM. BEHAV. SCIENTIST 1371, 1371 (2001).

<sup>64</sup> *Americans Clueless About Gene-Altered Foods: Few Aware of How Many Genetically Modified Products They Eat, Study Finds*, ASSOCIATED PRESS, Mar. 23, 2005, available at <http://www.mindfully.org/GE/2005/Americans-Clueless-GMOs23mar05.htm> [hereinafter *Americans Clueless*].

without any type of mandatory labeling and without many consumers even being aware of the presence of GM products in their food. For example, in the United States, in excess of eighty percent of soy crops and forty percent of corn crops are GM varieties.<sup>65</sup> As of 2004, global reliance on GM crops expanded to roughly 200 million acres, with the United States accounting for two-thirds of that cropland.<sup>66</sup>

The EU has responded to growing concerns by adopting a stringent regulatory regime for controlling the use and trade of GMOs. According to the provisions of the *White Paper on Food Safety* released by the European Community on January 12, 2000, as a basic prerequisite, all decisions on GMOs and food safety will be made based on the precautionary principle.<sup>67</sup>

EU legislation on GMOs consists of four key elements: 1) Directive 2001/18/EC on the deliberate release of GMOs into the environment, 2) Regulation (EC) 258/97 on novel food and food ingredients, 3) Regulation (EC) 1829/2003 on GM food and feed, and 4) Regulation (EC) 1830/2003 on traceability and labeling of GMOs and GM products.<sup>68</sup> According to the terms of the white paper, the EU regulations are founded on the precautionary principle, as enunciated in Principle 15 of the Rio Declaration and the Cartagena Protocol on Biosafety, which urged that cost-effective measures to prevent environmental degradation should not be avoided because of a lack of scientific certainty.<sup>69</sup> The shape of the EU regulatory regime is largely a “response to consumer demand for protection from the potential threats posed by GMOs.”<sup>70</sup> For example, in England, there have been recorded incidents of protestors destroying GMO test fields, while in France citizens have protested GMOs as introducing “contaminants” into the food chain.<sup>71</sup>

Reflecting these concerns, between 1999 and 2003, the European Commission enforced a de facto moratorium<sup>72</sup> on the authorization and marketing of any GM products within the EU.<sup>73</sup> Despite this firm early stance, in July 2003, the European Commission responded to mounting

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> *Commission White Paper on Food Safety*, at 9, COM (1999) 719 final (Jan. 12, 2000), available at [http://ec.europa.eu/dgs/health\\_consumer/library/pub/pub06\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf).

<sup>68</sup> Theofanis Christoforou, *The Regulation of Genetically Modified Organisms in the European Union: The Interplay of Science, Law and Politics*, 41 COMMON MKT. L. REV. 637, 639 (2004); Council Directive 90/220/EE, 2001 O.J. (L 106) (EC); Commission Regulation 258/97, 1997 O.J. (L 043) (EC); Commission Regulation 1829/2003, 2003 O.J. (L 268) (EC); Commission Regulation 1830/2003, 2003 O.J. (L 268) (EC).

<sup>69</sup> Nelson, *supra* note 63, at 1383. See generally THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY: LATE LESSONS FROM EARLY WARNINGS (Poul Harremoës & David Gee et al. eds., 2002) (discussing several historical examples of when intervention was necessary before the exact dangers were identified with scientific certainty, such as asbestos and mad cow disease); INTERPRETING THE PRECAUTIONARY PRINCIPLE (Tim O’Riordan & James Cameron eds., 1994) (providing an in-depth discussion of the interpretation and implementation of the precautionary principle).

<sup>70</sup> Nelson, *supra* note 63, at 1372.

<sup>71</sup> *Id.* (quoting D. Moisi, *Meat of the Matter Is Mistrust*, FIN. TIMES, Oct. 29, 1999).

<sup>72</sup> See *supra* notes 55–58 and accompanying text (discussing WTO Panel findings regarding moratorium).

<sup>73</sup> World Trade Organization, *supra* note 50.

international pressure by recommending new legislative guidelines<sup>74</sup> for the “development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming.”<sup>75</sup> The recommended legislation includes a “revised directive on deliberate release into the environment, and two very recent regulations, on GM food and feed, and on traceability and labeling.”<sup>76</sup> Confirmation of the end of the moratorium and the adoption of the new legislation came into force on May 19, 2004, when the European Commission approved the import and marketing of a GM sweet corn—an insect-resistant GM corn made by Syngenta.<sup>77</sup>

The primary components of the new EU framework regulating GM products are “pre-marketing safety assessments; and a single ‘one-stop’ authorization procedure to achieve the internal market.”<sup>78</sup> Regarding the safety assessments, the EU is focusing on process rather than product-oriented analysis<sup>79</sup> and is analyzing GM products using case-by-case risk assessment.<sup>80</sup> The EU decision to focus on analyzing the process by which GMs are created, rather than focusing on the end product, will be a continuing point of contention between the EU and the United States. The U.S. regulatory process focuses on analyzing end products rather than processes.<sup>81</sup> Similarly, the WTO currently supports end product rather than process analysis as the proper method for evaluating and comparing “like products.”<sup>82</sup> Thus, the EU’s focus on process promises to be a sticking point with the United States and similarly minded trading partners. The decision to emphasize process rather than product analyses reflects the EU’s attempt to build precaution into its new legislation.

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<sup>74</sup> Comm’n of the European Union, Commission Recommendation of 23 July 2003 on Guidelines for the Development of National Strategies and Best Practices to Ensure the Co-Existence of Genetically Modified Crops with Conventional and Organic Farming 3 (2003), available at [http://ec.europa.eu/agriculture/publi/reports/coexistence2/guide\\_en.pdf](http://ec.europa.eu/agriculture/publi/reports/coexistence2/guide_en.pdf).

<sup>75</sup> *Id.* at 1.

<sup>76</sup> Elsa Tsioumani, *GMOs in EU Public Attitudes and Regulatory Developments*, 13 REV. EUR. COMMUNITY INT’L ENVTL. L. 279, 279 (2004); see also Press Release, EU Legislation: Commission Press Release, European Legislative Framework for GMOs Now in Place (July 23, 2003), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/03/1056&format=PDF&aged=1&language=EN&guiLanguage=en> (noting that Council of Ministers formally adopted two European Commission proposals related to GMOs).

<sup>77</sup> See Tsioumani, *supra* note 76, at 279–80 (stating that, despite authorization, Syngenta decided not to commercialize the sweet corn in the EU due to market considerations); see also James F. Oehmke & Monika Tothova, *Is Europe Moving from Cleansing Genetically Modified Foodstuffs to Peaceful “Co-Existence”?*, 5 J. PUBL. AFF. 275, 275–76 (2005) (stating that authorization of Syngenta’s sweet corn signals a shift in European policy). This suggests that the EU will likely argue that its new legislation brings it into compliance with international obligations under the WTO.

<sup>78</sup> Tsioumani, *supra* note 76, at 284.

<sup>79</sup> See, e.g., Council Directive 2001/18, 2001 O.J. (L 106) 5 (EC) (establishing procedures for authorization and supervision of deliberate releases into the environment of GMOs).

<sup>80</sup> *Id.* art. 4.

<sup>81</sup> Oehmke & Tothova, *supra* note 77, at 277.

<sup>82</sup> *Id.* at 276.



In regards to the precautionary principle, “pursuant to the jurisprudence of the European Court of Justice, the [European] Commission has suggested extending the applicability of this principle from the area of environmental protection to the area of consumer and health protection while clarifying the guidelines for its implementation.”<sup>83</sup> Thus, while:

science-based risk assessment is at the heart of EU biotechnology regulation, and efforts have been made to improve and coordinate better the provision of scientific advice both at the Community and the Member State level, the precautionary principle plays an important role in the development and implementation of legislation, as well as in the risk-assessment process itself.<sup>84</sup>

In this way, the EU is both heeding the WTO Dispute Settlement Body decisions and dicta in the WTO beef hormones case while continuing to respond to consumer concerns and respecting the many scientific unknowns still associated with the development, use, and consumption of GM foods and crops. The EU framework is distinct in its reliance on consumer choice (e.g., labeling and traceability requirements) and on its sophisticated use of and distinction between risk assessment, risk management, and risk communication.<sup>85</sup>

Despite the new, more moderate legislation, recent surveys reveal that EU consumers remain skeptical about the benefits of GM foods and crops and continue to resist GM food products.<sup>86</sup> Thus, while EU legislation has changed, it appears that consumer opinions and preferences have not. The recent Panel decision is not likely to be well received by the EU government or EU civil society.

#### *b. United States Regulations*

In contrast to the EU, genetically altered corn and soybeans have entered the feed and food system in the United States without widespread public concern or even noticeable public awareness. Transgenic crops move through standard grain supply channels and have been substituted for traditional crops in the production of a wide variety of food products and animal feeds. To date, however, public concern about GMOs appears to be limited to a small number of interest groups. Based on the lack of coordinated social and political response, the larger American citizenry still appears to be largely apathetic about the use and consumption of GMOs in food.<sup>87</sup>

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<sup>83</sup> Borrás, *supra* note 38, at 65.

<sup>84</sup> Tsioumani, *supra* note 76, at 285.

<sup>85</sup> Borrás, *supra* note 38, at 65.

<sup>86</sup> Tsioumani, *supra* note 76, at 280.

<sup>87</sup> See, e.g., Wenn S. Chern & Kyrre Rickertsen, *Consumer Acceptance of GMO: Survey Results from Japan, Norway, Taiwan, and the United States* 9–12 (Dep't. of Agric., Envtl. & Dev. Econ., Ohio State Univ., Working Paper No. AEDE-WP-0026-02, 2002) (noting the United States government's rejection of mandatory biofood labeling and the lack of considerable consumer

Further, in the United States, GM food products are regulated in much the same way as traditional and conventional food products.<sup>88</sup> Regulatory control over GM foods is divided between the FDA,<sup>89</sup> the Environmental Protection Agency (EPA),<sup>90</sup> and the United States Department of Agriculture (USDA).<sup>91</sup> These three agencies share responsibility for regulating different aspects of GM products such that the USDA regulates plant and plant pests, the EPA regulates “microbial/plant pesticides, new uses of existing pesticides [and] novel microorganisms,” and the FDA regulates “products that are used as food, feed, food additives, veterinary drugs, human drugs and medical devices.”<sup>92</sup> The general roles of the agencies are as follows: 1) the “FDA ensures that novel food products are just as safe as traditional food products;”<sup>93</sup> 2) the Animal and Plant Health Inspection Service (APHIS) of the USDA oversees the “agricultural environmental safety of planting and field testing genetically engineered plants;”<sup>94</sup> and 3) the EPA is responsible for ensuring that “biologically produced pesticides are safe, . . . set[ting] tolerance levels” for pesticides, and regulating “microorganisms intended for commercial use that contain or express new combinations of traits.”<sup>95</sup>

The FDA, USDA, and EPA derive their regulatory authority from the Federal Food, Drug, and Cosmetic Act,<sup>96</sup> the Federal Plant Protection Act,<sup>97</sup> the Federal Insecticide, Fungicide, and Rodenticide Act,<sup>98</sup> and the Toxic Substances Control Act.<sup>99</sup> The current system was created under the 1986 Coordinated Framework for Regulation of Biotechnology.<sup>100</sup>

opposition to the sale of GM foods).

<sup>88</sup> Specifically, the FDA “focuses on how the new GM food product compares and meets ‘the same safety standards as traditional foods.’” Sara J. MacLaughlin, *Food for the Twenty-First Century: An Analysis of Regulations for Genetically Engineered Food in the United States, Canada and the European Union*, 14 IND. INT’L & COMP. L. REV. 375, 396 (2003) (citing Carol Lewis, *A New Kind of Fish Story: The Coming of Biotech Animals*, FDA CONSUMER MAG., Jan.–Feb. 2001, available at <http://www.cfsan.fda.gov/~dms/fdbiofish.html>).

<sup>89</sup> For example, the FDA is responsible for evaluating food safety risks. MacLaughlin, *supra* note 88, at 391.

<sup>90</sup> For example, EPA is responsible for reviewing environmental risks, specifically ensuring that biologically produced pesticides are safe. *Id.* at 393.

<sup>91</sup> For example, USDA regulates such GM products as plant pests, plants, and veterinary biologics. *Id.* at 390.

<sup>92</sup> *Id.*; see *id.* 390–96 for a detailed discussion of how FDA, USDA, and EPA regulate GM food products including such issues as food safety, environmental concerns, and transgenic animals.

<sup>93</sup> *Id.* at 391.

<sup>94</sup> *Id.* at 393.

<sup>95</sup> *Id.*

<sup>96</sup> See 21 U.S.C. § 334(h)(1)(A) (Supp. IV 2004) (explaining that “[a]n officer . . . of the Food and Drug Administration may order the detention . . . of any article of food that is found during an inspection”); see also *id.* U.S.C. § 381(i)(3) (explaining that “[i]n providing for research under paragraph (1), the Secretary shall as appropriate coordinate with . . . the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture”).

<sup>97</sup> Federal Plant Protection Act of 2000, 7 U.S.C. §§ 7701–86 (Supp. 2003).

<sup>98</sup> Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 (2000).

<sup>99</sup> Toxic Substances Control Act, 15 U.S.C. §§ 2601–92 (2000).

<sup>100</sup> Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986); see also 7 C.F.R. §§ 340.0–340.9 (2006).

Thus, while these three agencies participate in regulating GM products, regulatory authority is fragmented and no single agency has clear or decisive control.<sup>101</sup> Due to its complexity, the U.S. regulatory regime lacks the type of clarity and coordination necessary to effectively handle such a weighty issue.

The lack of clear control or coordination among these agencies results in a convoluted, incomprehensible regulatory regime that makes it difficult for the general public to either understand or participate in the regulatory process.<sup>102</sup> Consequently, GMOs are largely treated in the same fashion as traditional food items. That is, food products produced with or containing GMOs are not required to carry any special labeling, making it impossible for consumers to express their preferences for or against GMOs through their purchasing powers. The U.S. experience is, thus, very different from the EU experience, where the regulatory process is organized and transparent, and consumers have more knowledge about GMOs<sup>103</sup> and have expressed their preferences through coordinated political pressure and food purchasing choices.

#### *4. Consumer Preferences and the Future of the GM Debate*

In the EU and the United States, consumer responses to the marketing and consumption of GMOs vary. At a basic level, European consumers are more informed about and more opposed to the unregulated marketing and consumption of GM products.

According to Lisa Lorenzen, who is a "liaison to the biotech industry at Iowa State University," citizens in the United States are not concerned about genetically modified foods because they have faith in the American regulatory system; whereas, "many Europeans oppose GM foods because they don't trust governments that wrongly insisted for years that the beef supply, tainted by mad cow disease, was safe."<sup>104</sup> This is an oversimplified assessment of the political, cultural, and regulatory environments of the two places. Aside from faith, or lack thereof, in the regulatory system, factors contributing to the different regional responses to GM foods include levels of consumer awareness, cultural perceptions of risk and precaution, and the influence of media, industry, and consumer groups on the social construction and regulation of GM products. There is an extensive body of literature reviewing consumer responses to and perceptions of the risks associated with GMOs.<sup>105</sup> This Article does not attempt to present a

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<sup>101</sup> MacLaughlin, *supra* note 88, at 390-91.

<sup>102</sup> See generally Nelson, *supra* note 63 (discussing consumer difficulty in assessing risks).

<sup>103</sup> European consumers are generally better informed about food quality and risks, due in part to a heightened sense of awareness resulting from previous health scares, e.g., mad cow disease, foot and mouth disease. Thus, Europeans are more apt to seek detailed information about products such as GMOs and to resist government inaction and to demand transparent and responsive regulatory processes.

<sup>104</sup> *Americans Clueless*, *supra* note 64.

<sup>105</sup> For a full discussion of consumer response to GMOs, see Bonny, *supra* note 61 (discussing the lower acceptance of GMOs among EU, as compared to U.S., consumers and

comprehensive review of this research or of all of the surveys that have measured consumer responses to GM products, but rather to highlight key differences between European and U.S. conditions.

One of the primary distinctions between the U.S. and EU regulatory approaches revolves around general consumer awareness about GM food products. A Rutgers survey in the United States revealed that “less than half the people interviewed were aware GM foods are sold in supermarkets.”<sup>106</sup> Meanwhile, in Europe, awareness, education, and concern about GM foods are widespread. In Europe, consumers have played a key part in ensuring that European policies prevent the entrance of GM foods into the market. A majority of European consumers continue to oppose the use or consumption of GM food. If GM food products were to become available on the market, polled Europeans:

believed that *labels should state if food or ingredients have been genetically modified, that processed food derived from GM crops should be labeled, and that GM and non-GM crops should be kept separate at all stages of processing.* In particular, people thought that even foods containing GM ingredients through accidental contamination during processing should be labelled.<sup>107</sup>

At a basic level, simple interaction with Europeans and Americans reveals the difference, with many Americans unaware that much of their food already contains either growth hormones or genetically modified products and equally unaware of either the positive or negative implications of this reality.<sup>108</sup> Meanwhile, most Europeans are not only aware of the debate but are also hyper-conscious both of the government policies

using France as a case study for considering the factors that have led to European mistrust of GMOs). See also Chern & Rickertsen, *supra* note 87 (summarizing and discussing survey results on the knowledge and acceptance of GMOs among university students in the United States, Norway, Japan, and Taiwan and among a more representative cross section of U.S. and Norwegian societies and examining how variation in several factors relates to the societies' willingness to pay equal prices for GM foods, ultimately concluding that substantial price reductions for GM foods are necessary to achieve public consumption equal to that of non-GM foods).

<sup>106</sup> *Americans Clueless, supra* note 64.

<sup>107</sup> INST. OF FOOD RESEARCH, PUBLIC PREFERENCE FOR LABELING OF GM FOODS (2002), available at [http://www.ifr.ac.uk/science/sciencebriefs/public\\_pref.html](http://www.ifr.ac.uk/science/sciencebriefs/public_pref.html).

<sup>108</sup> See, e.g., PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, PUBLIC SENTIMENT ABOUT GENETICALLY MODIFIED FOODS: NOVEMBER 2005 UPDATE (2005), <http://pewagbiotech.org/research/2005update/1.php> (last visited Apr. 15, 2007) (findings of a recent study reveal that 58% of Americans are unaware of genetically modified foods and only 25% of Americans believe they have eaten genetically modified foods); WILLIAM K. HALLMAN ET AL., PUBLIC PERCEPTIONS OF GENETICALLY MODIFIED FOODS: A NATIONAL STUDY OF AMERICAN KNOWLEDGE AND OPINION at i (2003), available at <http://www.foodpolicyinstitute.org/docs/reports/NationalStudy2003.pdf> (findings of the 2003 study reveal that “[o]nly half of Americans are aware that foods containing genetically modified (GM) ingredients are currently sold in stores, . . . only one-quarter of Americans believe they have eaten them, . . . [l]ittle more than a third of Americans have ever discussed biotechnology”); *U.S., Europe React Differently over Modified Foods*, CNN, July 8, 1999, <http://www.cnn.com/NATURE/9907/08/genetics.enn/> (examining potential explanations for why “genetically modified foods get[] so much attention in Europe while Americans seem to be going about their grocery shopping as usual”).

regulating hormones and GMOs and of their ability to choose whether or not to purchase food products containing these products.<sup>109</sup> The most recent Euro-barometer surveys reveal this phenomenon, finding that most Europeans exhibit a “high level of mistrust of GMOs,” with the “most commonly encountered attitude [being] the demand to be able to choose and the demand for information.”<sup>110</sup> For example, “95% of Europeans want to have the right to choose when it comes to genetically modified foods. . . . Secondly, people want information: 86% of those asked wanted ‘to know more about this type of food before eating it.’”<sup>111</sup>

In contrast, in the United States, surveys reveal that only 16.4% of Americans were “extremely unwilling” to purchase GM foods.<sup>112</sup> As Chern and Rickertson note, “[s]o far, there has not been notable consumer opposition to GM foods in grocery stores, however, some consumer groups have strongly supported the consumer’s right to know.”<sup>113</sup>

Consumer group activities in Europe and the United States reflect cultural differences in levels of awareness and concern over GM foods. In Europe, consumer groups such as Greenpeace, Friends of the Earth, and other environmental and consumer non-governmental organizations (NGOs) “have fought a well-publicized battle against the introduction of genetically modified corn and soybeans there.”<sup>114</sup> On the contrary, “one of the most vocal food-related consumer groups in the U.S., the Center for Science in the Public Interest, has no official position on the genetic engineering of foods.”<sup>115</sup> This is not to suggest that there are not many consumer and environmental groups actively lobbying the U.S. government to more stringently regulate GMOs. Many NGOs are actively addressing these issues. However, these groups have been less successful than their counterparts in Europe in gaining either widespread public support or governmental respect and response.<sup>116</sup> Similarly, while GMO stories are a favorite topic among the European news media, studies of the news media in the United States reveal that coverage of GMO-related issues is limited.<sup>117</sup>

<sup>109</sup> See, e.g., EUROPEAN UNION DIRECTORATE-GENERAL FOR PRESS AND COMMUNICATION, EUROBAROMETER 55.2: EUROPEANS, SCIENCE AND TECHNOLOGY 40 (2001) (finding that 94.6% of Europeans “want to have the right to choose” genetically modified foods and 85.9% want to know more about genetically modified food before consuming those foods).

<sup>110</sup> Bonny, *supra* note 61, at 51.

<sup>111</sup> *Id.* at 51–52.

<sup>112</sup> Chern & Rickertson, *supra* note 87, at 23.

<sup>113</sup> *Id.* at 4.

<sup>114</sup> Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 536 (1998).

<sup>115</sup> *Id.* at 536–37.

<sup>116</sup> See, e.g., Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 735 (2003) (noting that, despite NGO complaints, the United States continues to develop more GM products).

<sup>117</sup> Joan Thomson & Laura Dininni, *What the Print Media Tell Us About Agricultural Biotechnology: Will We Remember?*, 20 CHOICES 247, 248 (2005), available at <http://www.choicesmagazine.org/2005-4/GMOs/2005-4-07.pdf>; see also Eric A. Abbott et al., *Riding the Hoopla: An Analysis of Mass Media Coverage of GMOs in Britain and the United States: 1997–2000* (Aug. 2001) (unpublished paper presented at the Association for Education in

While most U.S. citizens are not opposed to buying GM foods, surveys increasingly reveal that consumers are incrementally learning about GM foods and demanding labeling mechanisms.<sup>118</sup> Of course, this issue is currently moot in the United States since GM food products are already prevalent in the food chain without any type of labeling. Overall, U.S. citizens exhibit moderate reservations towards GM foods. The level of opposition and, certainly, the level of coordinated response pales in comparison to the widespread public opposition in Europe, where “GMOs are the subject of a strong hostility.”<sup>119</sup>

### C. Cloned Products

Policymakers and consumers continue to wrangle over the use of growth hormones and GMOs in food products. Looming on the horizon, however, is an even larger and potentially more explosive subject—human consumption of cloned meat and milk products. In the United States, the FDA appears to be nearing safety approval of cloned meat and milk products.<sup>120</sup> Of particular importance, on December 28, 2006, the FDA released *Animal Cloning: A Draft Risk Assessment*.<sup>121</sup> In this draft report, the FDA finds that meat and milk from cloned animals and their progeny are safe for human consumption and that no special system of labeling is needed to introduce cloned meat and milk products into the food market.<sup>122</sup>

If the FDA issues a final decision that permits unlabeled cloned products to be sold on the U.S. market, both domestic and international upheaval is sure to follow. Thus, another biotechnology-food dispute is pending.

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Journalism and Mass Communication Convention) (using three models of content analysis—social amplification of risk, hoopla, and triggering effects—to develop and test predictions about coverage of genetically modified organisms in the New York Times, London Times, and London Daily Mail from 1997–2000, and revealing that while scientists have declined significantly as sources over time and citizens’ groups have remained constant, themes or frames for articles shifted in response to triggering events. In addition, positive themes declined over time while negative ones remained relatively constant.).

<sup>118</sup> Chern & Rickertson, *supra* note 87, at 10 (revealing that 87.1% of consumers said they would want labeling).

<sup>119</sup> Bonny, *supra* note 61, at 58.

<sup>120</sup> CTR. FOR VETERINARY MEDICINE, U.S. FOOD & DRUG ADMIN., ANIMAL CLONING: A DRAFT RISK ASSESSMENT 15 (2006), available at [http://www.fda.gov/cvm/Documents/Cloning\\_Risk\\_Assessment.pdf](http://www.fda.gov/cvm/Documents/Cloning_Risk_Assessment.pdf) (“Edible products derived from the progeny of clones pose no additional food consumption risk(s) relative to corresponding products from other animals based on underlying biological assumptions, evidence from model systems, and consistent empirical observations . . .”).

<sup>121</sup> *Id.*; see also Press Release, U.S. Food & Drug Admin., FDA Issues Draft Documents on the Safety of Animal Clones: Agency Continues to Ask Producers and Breeders Not to Introduce Food from Clones into Food Supply (Dec. 28, 2006), available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01541.html>. The Draft Risk Assessment excludes sheep clones from the list of animals considered to be safe due to a lack of data. *Id.*

<sup>122</sup> CTR. FOR VETERINARY MEDICINE, *supra* note 120, at 285; see also CTR. FOR VETERINARY MEDICINE, U.S. FOOD & DRUG ADMIN., ANIMAL CLONING FAQs ABOUT CLONING FOR CONSUMERS, available at [http://www.fda.gov/cvm/cloningRA\\_FAQConsumers.htm](http://www.fda.gov/cvm/cloningRA_FAQConsumers.htm).

Genetically engineered food products dominate U.S. markets and complicate United States-EU relations. The attention hormones and GMOs receive often overshadows the fact that the entrance of biotechnology into the realm of human food products is a relatively recent phenomenon, and that there are still many health and safety unknowns associated with the production and consumption of biotech food products. Despite this fact, the biotech industry is charging ahead with new and enhanced food products—cloned meat and milk products vividly demonstrate this trend. Monsanto, “the world’s leading producer of gene altered crops” confirmed this trend when it “recently predicted that cloning and genetic engineering will soon be routine practices for creating ‘designer cows’ for food production.”<sup>123</sup>

Cloned food products raise many of the same environmental, health, and ethical issues as GMOs and growth hormones. The debate over cloned food products, however, has the potential to ignite a livelier debate in the United States due to the heightened religious, moral, and ethical implications associated with animal cloning. Thus, cloned products are liable to do what neither hormones nor GMOs have been able to accomplish—bring the biotechnology-food debate to the attention of the American public, with unknown but potentially detrimental ramifications for the previously burgeoning U.S. biotech market.

### *1. The Cloning Process*

Animal cloning has been in the news since the birth of the world’s most famous sheep, Dolly, in 1997.<sup>124</sup> Since Dolly’s birth, scientists have used animal cloning, otherwise known as somatic cell nuclear transfer, to breed dairy cows, beef cattle, poultry, hogs, and other species of livestock.<sup>125</sup> In somatic cell nuclear transfer:

the nucleus (which contains DNA) of an unfertilized egg is removed, and replaced with the nucleus from an adult (somatic) cell from a donor animal. In place of fertilization with a male animal’s sperm, an electric current is used to kick-start cell division, and the embryo is then transferred to the uterus of a surrogate female animal.<sup>126</sup>

Cloning appeals to the livestock industry because it provides a way to use technology to “regenerate identical copies of prized animals with favorable characteristics, without the uncertainties of natural breeding or even other assisted reproduction techniques.”<sup>127</sup> In this way, breeders hope to create

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<sup>123</sup> See Ctr. for Food Safety, Center for Food Safety Fact Sheet (Oct. 2005), <http://www.centerforfoodsafety.org/pubs/cloned%20meat%20and%20dairy%20factsheet10.19.2005.pdf> (last visited Apr. 15, 2007) (describing a speech by “Dr. Tom Bailey, a veterinarian with Monsanto” at the National Holstein Convention).

<sup>124</sup> See *Dolly the Sheep Is Cloned*, BBC NEWS, Feb. 22, 1997, [http://news.bbc.co.uk/onthisday/hi/dates/stories/february/22/newsid\\_4245000/4245877.stm](http://news.bbc.co.uk/onthisday/hi/dates/stories/february/22/newsid_4245000/4245877.stm) (last visited Apr. 15, 2007).

<sup>125</sup> Ctr. for Food Safety, *supra* note 123, at 1.

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

animals with preferred genetic characteristics, i.e., dairy cows that produce high quality milk.<sup>128</sup> Currently, the costs associated with selling cloned animals are still prohibitive. Thus, the primary “appeal of cloned animals to the livestock industry largely lies in their role as breeders or milk producers, not in selling the meat of cloned animals . . . . Already, cloned bulls’ sperm is shipped all over the [United States] to sire offspring with particularly desirable traits.”<sup>129</sup>

Early animal cloning, however, revealed health problems associated with cloned animals, e.g., arthritis and lung disease. And, while many industry-produced studies suggest that modern cloning processes have eliminated animal health problems,<sup>130</sup> there are still very few comprehensive studies analyzing the long-term health and safety of animal cloning—and even fewer studies on the implications of human consumption of cloned animals and animal products.<sup>131</sup> Thus, there is considerable scientific uncertainty associated with animal cloning.

## 2. Cloning in the European Union

EU law relating to health, consumer protection, and animal welfare abounds. As a baseline, European countries must comply with the animal welfare provisions of the Treaty of Amsterdam,<sup>132</sup> which “recognizes that animals are sentient beings and obliges European institutions to pay full regard to the welfare requirements of animals when formulating and implementing EU legislation.”<sup>133</sup>

Owing to their relatively new development, human food products derived from cloned animals and animal products escape precise regulatory control. Cloned food products do not fall within the reach of regulations relating to GMOs.<sup>134</sup> At present, cloned animals, the offspring of cloned

<sup>128</sup> See PUB. CITIZEN, CLONED ANIMALS ON THE DINNER PLATE 1 (Mar. 8, 2005), available at <http://www.citizen.org/documents/clonefactsheet.pdf> (noting that “[a]pproximately 200 beef cows, 150 dairy cows and 200 pigs [have] been cloned in the United States”).

<sup>129</sup> *Id.* (noting that “[t]hese ‘half-clones’ (offspring of cloned animals) are possibly reaching the marketplace, with no consumer awareness as to their ancestry. One semen broker who has sold the sperm of cloned bulls, said that these offspring are ‘going to be slaughtered [for food], and the FDA can’t do anything about it.’”).

<sup>130</sup> See, e.g., Biotechnology Indus. Org., *Demystifying Animal Cloning: The Facts on Health, Regulatory and Safety Issues* (2006), <http://www.bio.org/foodag/animals/animalcloning.asp> (last visited Apr. 15, 2007) (noting that “decades of research has proven that cloned animals are just as healthy as non-cloned animals”).

<sup>131</sup> See Ctr. for Food Safety, *supra* note 123, at 1.

<sup>132</sup> Treaty of Amsterdam Amending the Treaty on European Union, the Treaties Establishing the European Communities and Certain Related Acts—Protocol Annexed to the Treaty of the European Community—Protocol on Protection and Welfare of Animals., Oct. 10, 1997, 1997 O.J. (C 340) 110 (EC).

<sup>133</sup> F. De Simone & J. Serratos, *Biotechnology, Animal Health and Animal Welfare Within the Framework of European Union Legislation*, 24 SCI. & TECHNICAL REV. 89, 93 (2005), available at [http://www.oie.int/eng/publicat/rt/2401/A\\_R240108.htm](http://www.oie.int/eng/publicat/rt/2401/A_R240108.htm).

<sup>134</sup> See Council Directive 2001/18, preamble 2001 O.J. (L 106) 1 (EC) (repealing Council Directive 90/220/EEC, which dealt with the “deliberate release into the environment of genetically modified organisms”).



animals, and food products derived from cloned animals fall within the remit of Regulation 258/97, *Concerning Novel Foods and Novel Food Ingredients*.<sup>135</sup> The novel foods regulation requires that foods “not present a danger for the consumer,” not “mislead the consumer,” and not “differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.”<sup>136</sup>

The EU has not approved any cloned animals or animal products for sale in the human food supply.<sup>137</sup> Despite the fact that the EU has not yet adopted any legislation specifically regulating the development, approval, or sale of cloned animals, public concern is growing as the likelihood of cloned animal products entering the food market increases. Given its strict GM regulatory regime, the EU is likely to develop similar regulatory controls for cloned products.

Recent recommendations by the United Kingdom’s Department for Environment, Food, and Rural Affairs (DEFRA) highlight growing European concern over food products derived from cloned animals and suggest how specific European states and the EU might develop a regulatory regime for these products. DEFRA recommends that a “new strategic advisory body should be set up by statute to examine issues raised by the use of genetic biotechnology on farm animals in the context of its use on other animals and current livestock farming practices.”<sup>138</sup> DEFRA recommends, in relevant part, that the government should: 1) focus on providing new methods of funding to engage the public in the decision-making process, 2) regulate cloned animals under the same policy scheme as GM and conventional animals, 3) establish a post market monitoring program to review animal welfare and animal and human health concerns, 4) create a regulatory regime that “maintain[s] consumer choice about whether to purchase meat

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<sup>135</sup> Commission Regulation 258/97, *Concerning Novel Foods and Novel Food Ingredients*, 1997 O.J. (L 43) 2 (EC), *available at* [http://www.fsai.ie/legislation/food/eu\\_docs/Novel\\_Foods\\_and\\_Ingredients/Reg258.97.pdf](http://www.fsai.ie/legislation/food/eu_docs/Novel_Foods_and_Ingredients/Reg258.97.pdf). This regulation requires that novel foods are safe when consumed at foreseeable levels, not misleadingly presented, and nutritionally comparable when used as replacements for conventional foods. The regulation applies to foods that: 1) contain or consist of GMOs, or are produced from GMOs though they do not contain them, 2) have a new or intentionally modified primary molecular structure, 3) consist of or are isolated from micro-organisms, fungi or algae, 4) consist of or are isolated from plants or (for ingredients) animals, unless they are obtained by traditional propagating or breeding practices and have a history of safe food use, or 5) have been subjected to a production process not currently used, which gives rise to significant changes in their composition or structure, affecting their nutritional value, metabolism or level of undesirable substances. *Id.* art. 1.

<sup>136</sup> *Id.* art. 3.

<sup>137</sup> Press Release, European Union, Questions and Answers on the Regulation of GMOs in the EU (Mar. 22, 2005), <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/05/104&format=HTML&aged=0&language=EN&guiLanguage=en> (last visited Apr. 15, 2007) (responding to questions regarding the regulation of GMOs in the EU).

<sup>138</sup> DEP’T FOR ENV’T FOOD & RURAL AFFAIRS, GOVERNMENT RESPONSE TO *ANIMALS AND BIOTECHNOLOGY*: A REPORT BY THE AEBC 2 (2002), *available at* [http://www.defra.gov.uk/environment/gm/noncrop/aebc-response/pdf/aebc\\_animals\\_response.pdf](http://www.defra.gov.uk/environment/gm/noncrop/aebc-response/pdf/aebc_animals_response.pdf) (setting out the government’s response to the recommendations of the Agriculture and Environment Biotechnology Commission’s report *Animals and Biotechnology*).

or other products from GM and cloned animals,” 5) prohibit commercial production and sale of certain GM fish due to remaining uncertainty about environmental consequences, and 6) monitor the “international movement of GM and cloned animals and reproductive material.”<sup>139</sup>

DEFRA’s recommendations reflect current EU GMO policies, which take a precautionary approach to regulating new technologies and integrating consumer preferences and maintaining consumer choice. At present

all cloning for research or medical purposes in the UK must be approved by the Home Office under the strict controls of the Animals (Scientific Procedures) Act 1986. This safeguards animal welfare while allowing important scientific and medical research to go ahead.<sup>140</sup>

Despite heavy reliance on the precautionary principle, the Group of Advisors to the European Commission on the Ethical Implications of Biotechnology has recognized that “cloning may well be able to contribute to human wellbeing” and can specifically contribute to medical research, agriculture, and improving animal welfare, to “reduce, replace and, when possible, refine research experiments that use animals.”<sup>141</sup> The group also emphasizes that cloning research must take place against a specific background that recognizes that humans have a “responsibility for animals, nature and the environment, including biodiversity” and they must “pay[] particular attention to the need to preserve genetic diversity.”<sup>142</sup> European public opinion polls, however, reveal that “[i]n terms of overall support, Europeans are . . . opposed to both GM foods and the cloning of animals.”<sup>143</sup>

Most recently, the release of the previously mentioned FDA Draft Risk Assessment on Animal Cloning and reports that European countries were beginning to raise cloned animals has intensified the tenor and pace of the animal cloning debate in the E.U. In an effort to move forward on the question of how to regulate cloned animals and their products, on March 8, 2007, the European Commission requested guidance from the European Group of Ethics and the European Food Safety Authority (EFSA)—the body responsible for conducting scientific risk assessments for proposals for novel foods that would enter the EU food chain—on the “food safety, animal health, animal welfare and environment implication”, associated with cloned animals and their offspring.<sup>144</sup> The EFSA has said that it will produce a

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<sup>139</sup> *Id.* at 2–6.

<sup>140</sup> RDS, Animal Cloning (2004), [http://www.rds-online.org.uk/pages/page.asp?i\\_ToolbarID=5&i\\_PageID=162](http://www.rds-online.org.uk/pages/page.asp?i_ToolbarID=5&i_PageID=162) (last visited Apr. 15, 2007).

<sup>141</sup> Simone & Serratos, *supra* note 133, at 91–92.

<sup>142</sup> *Id.*

<sup>143</sup> George Gaskell, Agricultural Biotechnology and Public Attitudes in the European Union, AgBioForum University of Missouri (Spring–Summer 2000), <http://www.mindfully.org/GE/EU-Attitudes.htm> (last visited Apr. 15, 2007).

<sup>144</sup> Ahmed ElAmin, *EU Considers Allowing Cloned Meat, Milk on Market*, <http://www.foodnavigator-usa.com/news/printNewsBis.asp?id=74840> (last visited Apr. 15, 2007).

report for the European Commission within six months.<sup>145</sup> Accordingly, both the United States and the EU are moving forward to develop regulatory regimes for the meat and milk products of cloned animals. The final form of regulatory regimes will have considerable consequences for consumer health and safety and for trade debates in the United States and the EU.

### 3. Cloning in the United States

Despite the fact that scientists have made many advances in cloning technology and succeeded in cloning numerous species of animal, there are still many unknowns associated with animal cloning, and the financial costs of cloning are still high. The United States has not yet approved any transgenic animals or animal products for sale in the human food chain.<sup>146</sup> Currently, U.S. meat and dairy producers are “observing a voluntary moratorium on the sale of their products, while waiting for guidance on marketing cloned products from the U.S. Food and Drug Administration (FDA).”<sup>147</sup>

The FDA is the U.S. agency with primary responsibility for regulating “in whole or in part, diverse animal biotechnology products.”<sup>148</sup> As with genetically modified products, FDA derives its primary regulatory authority from the Federal Food, Drug, and Cosmetic Act.<sup>149</sup>

With the voluntary moratorium pending, the FDA’s Center for Veterinary Medicine has been analyzing the implications of animal cloning for human food safety, animal health, and the environment.<sup>150</sup> The FDA analyzes and regulates transgenic cloned animals in the same way that it regulates any other food or pharmaceutical products.<sup>151</sup> While FDA evaluates the safety of animal cloning, it has asked farmers and livestock producers to respect a voluntarily moratorium on the introduction of cloned animals, meat, or milk into the food chain. The livestock industry has not opposed FDA’s temporary, voluntary moratorium; however, FDA has not implemented a monitoring program and it is suspected that cloned products have already quietly slipped into U.S. food supplies.<sup>152</sup>

On October 31, 2003, FDA took the first step towards making a final decision when it released a *Draft Executive Summary of Its Assessment of*

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<sup>145</sup> *Id.*

<sup>146</sup> MacLaughlin, *supra* note 88, at 394. While no transgenic animal products are approved for consumption in the human food chain, “a limited number of transgenic animals have been approved for use as components in animal feed.” *Id.*

<sup>147</sup> FOOD & DRUG ADMIN., ANIMAL CLONING AND THE PRODUCTION OF FOOD PRODUCTS: PERSPECTIVES FROM THE FOOD CHAIN 1 (2002), available at <http://pewagbiotech.org/events/0924/proceedings2.pdf> [hereinafter ANIMAL CLONING].

<sup>148</sup> U.S. Food & Drug Admin., Ctr. for Veterinary Medicine, Information for Consumers: Questions and Answers About Transgenic Fish, <http://www.fda.gov/cvm/transgen.htm> (last visited Apr. 15, 2007).

<sup>149</sup> Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301–97 (2000).

<sup>150</sup> ANIMAL CLONING, *supra* note 147, at 1.

<sup>151</sup> PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, BIOTECH IN THE BARNYARD: IMPLICATIONS OF GENETICALLY ENGINEERED ANIMALS 27 (2002), available at <http://pewagbiotech.org/events/0924/proceedings1.pdf>.

<sup>152</sup> See PUB. CITIZEN, *supra* note 128, at 1.

*Safety of Animal Cloning*.<sup>153</sup> In this report, FDA considered the risks that somatic cell cloning pose to animals and to food consumption. FDA concluded that the risks somatic cell cloning posed to animals were not “qualitatively different from those encountered by animals involved in modern agricultural practices . . . although the frequency of the risks appears to be increased in some species during the early portions of the life cycle of animal clones.”<sup>154</sup>

Concerning the food consumption risks clones pose to humans, the FDA report emphasized that:

Information on the composition of clone meat or milk is extremely limited. Very few of the bovine clones are old enough to have been bred, given birth, and begun lactating. One study has been identified on the composition of milk from clone cows; no studies on the composition of meat from clones have been identified.<sup>155</sup>

Based on the information available, FDA concluded that the food consumption risks were negligible, stating that:

The current weight of evidence suggests that there are *no biological reasons*, either based on underlying scientific assumptions or empirical studies, to indicate that consumption of edible products from clones of cattle, pigs, sheep or goats poses a greater risk than consumption of those products from their non-clone counterparts. . . . Edible products from the progeny of healthy clones are likely as safe to eat as similar products from the progeny of non-clone animals, based on underlying biological assumptions, compelling evidence from the mouse model system, and limited data in the species evaluated. The one study of the composition of milk from bovine clones does not indicate any food safety concerns.<sup>156</sup>

The report analyzes the safety of animal cloning, acknowledging the fact that there is still limited scientific information available to use in the risk analyses. In fact, the FDA report concedes that the findings are derived from a “single study of milk from cloned animals, and no data at all on cloned meat.”<sup>157</sup> Of particular relevance, FDA itself has not sponsored any research specifically addressing the safety of animal cloning; most of the

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<sup>153</sup> Press Release, Food & Drug Admin., FDA Issues Draft Executive Summary of its Assessment of Safety of Animal Cloning; Current Voluntary Moratorium on Releasing Animal Clones Remains in Effect (Oct. 31, 2003), *available at* <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00968.html>.

<sup>154</sup> FOOD & DRUG ADMIN., ANIMAL CLONING: A RISK ASSESSMENT: DRAFT EXECUTIVE SUMMARY 5 (2003), *available at* <http://www.fda.gov/cvm/Documents/CLRAES.doc>.

<sup>155</sup> *Id.* at 7.

<sup>156</sup> *Id.* at 10.

<sup>157</sup> See Ctr. for Food Safety, *supra* note 123, at 1. The National Academy of Science also highlighted this dearth of reliable data in 2004, saying: “There are to date no published comparative analytical data assessing the composition of meat and milk products of somatic cell clones, their offspring, and conventionally bred individuals.” *Id.* (quoting NAT’L ACAD. OF SCIS., ANIMAL BIOTECHNOLOGY: SCIENCE BASED CONCERNS, 8-9, 64-65 (2002)).

currently available information comes directly from the potentially regulated industry itself.<sup>158</sup> The report suggests that there is no apparent health risk associated with animal cloning, but the brevity of the report and the paucity and reliability of available data leaves many questions unanswered.

FDA had promised the ensuing release of its final cloning policy since issuing this 2003 preliminary report. Despite this promise, until December 2006, FDA failed to issue even a preliminary ruling on the safety of cloned animal products. Consumer safety groups and biotechnology companies alike persistently prodded FDA to make a decision. Impatient livestock producers went so far as to “dub[] the FDA the ‘Food Dragging Administration.’”<sup>159</sup>

Finally, as previously mentioned, on December 28, 2006, the FDA released *Animal Cloning: A Draft Risk Assessment*.<sup>160</sup> In this long awaited document, the FDA addresses the issue of human consumption of cloned animals and animal products. After many years of industry and consumer groups waiting with bated breath, the FDA did what everyone expected it to do—it found that “meat and milk from clones of adult cattle, pigs and goats, and their offspring, are as safe to eat as food from conventionally bred animals.”<sup>161</sup> Similarly, in draft guidance issued to the food and feed industry, the FDA stated that it “does not recommend any special measures relating to human food use of offspring of clones of any species.”<sup>162</sup>

In the 678 page report, the FDA concludes in relevant part that:

Edible products from perinatal bovine clones may pose some very limited human food consumption risk.

....

Edible products from juvenile bovine clones pose no additional food consumption risk(s) relative to corresponding products from contemporary conventional comparators.

....

Edible products derived from adult bovine clones pose no additional risk(s) relative to corresponding products from contemporary conventional comparators.

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<sup>158</sup> Press Release, Consumer Fed'n of Am., CFA's Carol Tucker Foreman on FDA's Risk Assessment on Animal Cloning (Oct. 31, 2003), available at [http://www.consumerfed.org/releases2.cfm?filename=103103\\_cloning.txt](http://www.consumerfed.org/releases2.cfm?filename=103103_cloning.txt).

<sup>159</sup> Justin Gillis, *Clone Generated Milk May Be Approved: Favorable FDA Ruling Seen As Imminent*, WASH. POST, Oct. 6, 2005, at A1.

<sup>160</sup> CTR. FOR VETERINARY MEDICINE, *supra* note 120. The Draft Risk Assessment excludes sheep clones from the list of animals considered to be safe due to a lack of data. Press Release, U.S. Food and Drug Admin., *supra* note 121.

<sup>161</sup> Press Release, U.S. Food & Drug Admin., *supra* note 121.

<sup>162</sup> *Id.*

Edible products from adult swine clones pose no additional risk(s) relative to corresponding products from contemporary conventional comparators.

....

Except by relying on underlying biological assumptions, and by inference from other species, there is insufficient information on the health status of sheep clones to draw conclusions with respect to potential risks that could be posed from the consumption of food products.

....

Edible products from goat clones pose no additional food consumption risk(s) relative to corresponding products from contemporary conventional comparators.

....

Edible products derived from the progeny of clones pose no additional food consumption risk(s) relative to corresponding products from other animals.

....

Extensive evaluation of the available data has not identified any food consumption risks or subtle hazards in healthy clones of cattle, swine, or goats. Thus, edible products from healthy clones that meet existing requirements for meat and milk in commerce pose no increased food consumption risk(s) relative to comparable products from sexually-derived animals. The uncertainties associated with this judgment are a function of the empirical observations and underlying biological processes contributing to the production of clones. There is less uncertainty about the health of clones as they age and have more time to exhibit the full range of functionality expected of breeding stock.

Edible products derived from the progeny of clones pose no additional food consumption risk(s) relative to corresponding products from other animals based on underlying biological assumptions, evidence from model systems, and consistent empirical observations.<sup>163</sup>

The practical consequence of the findings in the FDA's Draft Assessment is that cloned food products will not have to be labeled as such.<sup>164</sup> In fact, meat and milk from cloned animals or the progeny of cloned animals will be virtually indistinguishable from conventional meat and milk products. Following the release of the Draft Risk Assessment on Cloning, the FDA initiated a 90 day comment period, during which time any member of

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<sup>163</sup> CTR. FOR VETERINARY MEDICINE, *supra* note 120, at 9–15.

<sup>164</sup> See CTR. FOR VETERINARY MEDICINE, U.S. FOOD & DRUG ADMIN., ANIMAL CLONING FAQs ABOUT CLONING FOR CONSUMERS, available at [http://www.fda.gov/cvmm/cloningRA\\_FAQ\\_Consumers.htm](http://www.fda.gov/cvmm/cloningRA_FAQ_Consumers.htm) (noting that the "FDA is not recommending any additional measures relating to food derived from adult clones and their offspring, including labeling").

the public could submit electronic comments on the draft documents.<sup>165</sup> The FDA will assess the comments and then release a final decision on animal cloning.

#### 4. Cloning and Consumer Preferences

Controversy is sure to follow the release of FDA's final policy. On the one hand, the regulated industries are already showing signs of impatience with the slow pace at which FDA is moving and emphasizing independent studies confirming the safety of cloning.<sup>166</sup> On the other hand, consumer advocacy groups and public health groups are urging "the US government to recognize and address moral, ethical and social concerns raised by animal cloning" and protesting that while "FDA prides itself on being a science driven agency . . . in this case it seems to have been [more] driven by political pressure to promote animal cloning than to protect public health."<sup>167</sup>

In the U.S. debate thus far, FDA has avoided addressing the social, moral, and ethical questions associated with animal cloning by maintaining that its sole role is as a scientific agency. Public opinion polls, however, suggest that concern over the ethical implications of cloning will prevent FDA and the Bush Administration from being able to overlook these issues entirely. Opinion polls administered in the United States reveal that the majority of Americans know very little about animal biotechnology, desire more information once they become aware of the practice, and have decidedly mixed feelings about the morality of both cloning animals and consuming the products of cloned animals.<sup>168</sup> For example, the Pew Agricultural Biotechnology Project found that 58% of Americans oppose genetic modification of animals, with 46% of the surveyed population being strongly opposed to this type of genetic modification.<sup>169</sup> Similarly, an

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<sup>165</sup> Press Release, U.S. Food & Drug Admin., *supra* note 121. The comment period closed on April 2, 2007. *Id.*

<sup>166</sup> See, e.g., Press Release, Xiangzhong (Jerry) Yang et al., Are You Ready for Cloned Beef and Milk? Comprehensive Analyses on Pioneered Clones Shows They Are Safe and No Different from the Meat and Milk Already on the Table (Apr. 11, 2005), available at <http://web.uconn.edu/crb/word%20documents/clonesafety-newsrelease-3-6-05.doc> (reporting favorable study results comparing milk and meats of cloned and naturally reproduced animals).

<sup>167</sup> Press Release, Consumer Fed'n of Am., *supra* note 158 (criticizing government timetable, scope of research, and motivation in pursuing animal cloning).

<sup>168</sup> See, e.g., JENNIFER SOSIN & MARK DAVID RICHARDS, WHAT WILL CONSUMERS DO? UNDERSTANDING CONSUMER RESPONSE WHEN MEAT AND MILK FROM CLONED ANIMALS REACH SUPERMARKETS (2005) (detailing in-depth consumer opinion research concerning cloning and related issues); Lorraine Heller, *Most Consumers Would Consider Cloned Meat, Says Study*, FOOD NAVIGATOR USA, Nov. 9, 2005, available at <http://www.foodnavigator-usa.com/news/ng.asp?n=63804-fda-viagen-cloned> (revealing that: "One third of consumers said they would buy meat and milk from the offspring of cloned animals, one third said they would consider buying it once they found out more, and one third said they would never buy it, according to research commissioned by animal breeding firm ViaGen.").

<sup>169</sup> Memorandum from the Mellman Group, Inc. & Public Opinion Strategies, Inc. to the Pew Initiative on Food and Biotechnology (Sept. 15, 2003), available at <http://pewagbiotech.org/research/2003update/2003summary.pdf> [hereinafter Mellman Memorandum].

August 2001 ABC News poll revealed that 60% of Americans were opposed to animal cloning.<sup>170</sup>

The public's general lack of awareness of animal cloning mirrors the public's lack of knowledge concerning genetically modified organisms. Opinion polls, however, reveal strong public curiosity about and opposition to cloning and genetic modification of animals. This contrasts with public opinion towards genetically modified organisms, which is more ambivalent. Confirming this variation, opinion polls reveal that "genetically modified plants [are] . . . considerably more accepta[ble] than genetically modified animals."<sup>171</sup>

Public opinion disfavors food derived from cloned animals. Nevertheless, the American public might not be given the opportunity to choose whether or not to consume cloned animal products. If FDA gives cloned meat and milk products the thumbs up, these products will be able to enter the food chain without any type of labeling, mimicking the current GM foods regime.<sup>172</sup> Consumers will not be able to differentiate between conventional foods and foods derived from cloned animals. In fact, many people believe that the products of cloned animals and their offspring are already sneaking into the marketplace, "making people unwitting consumers of meat and milk they want to avoid."<sup>173</sup> Responding to growing concerns, consumer organizations have begun protesting the ensuing absence of choice, arguing that "there should be public discussions about the related ethical issues, since there is such widespread opposition to this technology."<sup>174</sup> On the other hand, livestock and biotechnology industry advocates continue to maintain that fears about the safety of animal cloning are overblown, but "absent compelling evidence of a problem, it's not clear the FDA or any other government agency would have the legal power to keep cloned animals out of the food supply."<sup>175</sup>

The debate has not escaped the notice of Congress. Legislation has been proposed in both the House of Representatives and the Senate that would require the creation of a mandatory labeling regime for food from cloned animals and their progeny and that would prevent cloned products

<sup>170</sup> ABC News, Majority Opposes Human Cloning, Similar Response to Animal and Therapeutic Uses, [http://abcnews.go.com/sections/scitech/DailyNews/poll010816\\_cloning.html](http://abcnews.go.com/sections/scitech/DailyNews/poll010816_cloning.html) (last visited Apr. 15, 2007).

<sup>171</sup> Mellman Memorandum, *supra* note 169, at 1.

<sup>172</sup> On December 24, 2006, FDA made a move in this direction indicating the agency's concurrence with recent studies by U.S. scientists which found meat and milk from cloned animals safe for consumption. Karen Kaplan, *Meat, Milk from Cloned Animals Ok'd*, BOSTON GLOBE, Dec. 24, 2006, available at [http://www.boston.com/news/nation/articles/2006/12/24/meat\\_milk\\_from\\_cloned\\_animals\\_okd](http://www.boston.com/news/nation/articles/2006/12/24/meat_milk_from_cloned_animals_okd) (detailing FDA reaction to recently published studies). Four days later, FDA released a 678 page draft report assessing the risks of these products, largely agreeing with the assessment of the scientific reports released earlier in the week. CTR. FOR VETERINARY MED., *supra* note 120.

<sup>173</sup> PUB. CITIZEN, *supra* note 128, at 2.

<sup>174</sup> *Id.*

<sup>175</sup> PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, CLONED FOOD PRODUCTS NEAR REALITY, <http://pewagbiotech.org/buzz/display.php3?StoryID=80> (last visited Apr. 14, 2007).



from ever being allowed to be designated as organic.<sup>176</sup> When proposing the Cloned Food Labeling Act in the Senate on January 31, 2007, Senator Barbara Mikulski (D-Md.) expressed growing concerns over the consumption of cloned food products and the absence of a labeling regime, saying: "The American people don't want this. They find it repugnant."<sup>177</sup> The fact that legislation has been proposed in the House and the Senate prior to the release of a final FDA decision suggests that the cloned foods debate is beginning to spark growing public and political awareness and concern over the biotechnology decision-making process in the United States.

The United States is not alone in nearing approval of the unlabeled sale of foods derived from cloned animals. Other countries, including Japan, are moving towards lifting bans and approving the sale of such products.<sup>178</sup> Thus, this issue is poised to ignite public debate across multiple continents.

The possibility of introducing cloned products into the human food chain amplifies existing tensions between the United States and Europe over the use, trade, and consumption of growth hormones and GMOs in food products. The United States' decision on cloned food products will have a ripple effect on bilateral and multilateral trade relations and will almost certainly spark new WTO conflicts. In this way, the cloned food products debate is merely another link in the chain of United States-EU food safety clashes. It does, however, have the potential to change the nature of the debate.

Previously, the food safety disputes between the United States and the EU have largely escaped the notice of the general American public. Questions over growth hormones and GMOs have attracted widespread attention among European politicians and citizens alike. In the United States, however, while environmental and health and safety NGOs, the academic sector, and certain consumer groups have avidly followed the debate, these issues have largely remained within the political realm rather than trickling down into the public conscience. Only slowly are questions about hormones and GMOs filtering into the American media dialogue and, thus, permeating the general public conscience. Because cloning touches upon issues central to current American political discourse—religion, science, and the moral and ethical questions that bind the two—the debate over cloned food products stands to change the pace and nature of the current food safety trade debates.

If FDA issues a final decision effectively approving the unlabeled sale of food products derived from cloned animals, more than just NGOs and

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<sup>176</sup> See Pallavi Gogoi, *The Case Against Cloning*, BUS. WEEK, Mar. 7, 2007, [http://www.businessweek.com/bwdaily/dnflash/content/mar2007/db20070306\\_592550.htm](http://www.businessweek.com/bwdaily/dnflash/content/mar2007/db20070306_592550.htm) (last visited Apr. 15, 2007) (describing legislation proposed in response to loophole in USDA regulations "which prohibit cloning in organic production, but which do not address the issue of the offspring of cloned animals"); Lorraine Heller, *Bill to Ensure Strict Separation of Cloning and Organics*, FOODUSANAVIGATOR.COM, Feb. 13, 2007, <http://www.foodnavigator-usa.com/news/ng.asp?n=74168-cloning-organics> (last visited Apr. 15, 2007) (noting that proposed legislation would ban food coming from clones from "entering the organic food stream").

<sup>177</sup> Gogoi, *supra* note 176 (quoting Senator Mikulski, D-Md.).

<sup>178</sup> PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 175.

academics will pay attention. Just as stem cell research has piqued the political ire of conservatives and democrats alike and divided political parties down non-traditional lines, cloning and the consumption of cloned animals has the elements necessary to make a large percentage of the U.S. population—and the U.S. Congress—take notice of the debate.<sup>179</sup>

Citizens in the EU are already skeptical of the “benefits of modern biotechnology and are not willing to consume GM food” or meats treated with growth hormones.<sup>180</sup> While the American public is far from adopting the Europeans’ suspicious and precautionary approach to modern biotechnology, Americans are gradually becoming more concerned about the quality of their food and the quality of the regulatory process making food quality decisions. If food products derived from cloned animals are approved for unlabeled sale,<sup>181</sup> the public response could trigger more active citizen debate and participation in food quality decision making.

### III. CONCLUSION

The debate over the regulation of cloned foods is poised to do what neither hormones nor GMOs have succeeded in doing—turn U.S. food safety debates into a more highly politicized topic that sparks the interest of the American public. This shift could change the nature of domestic and international food safety trade debates. What remains to be seen is whether cloned foods will fan the flame of American political and ethical debate or slide by without notice until the Europeans and the Americans, once again, bump heads in the metaphorical hallways of the WTO.

#### *A. International Trade and Environment Tensions*

At the international level, an equally serious question looms: is the WTO the correct international organization for making significant health, safety, and environmental decisions? This question plagues environmental law across the board. The dispute over GM foods and the potential dispute over food products derived from cloned animals highlights existing divisions between countries, scientists, and environmental advocates over the ability—or, arguably, inability—of a “pure” trade organization to handle a

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<sup>179</sup> See, e.g., Rick Weiss, *Clash over Stem Cell Research Heats up: Scientists Dispute Claims of Leading Foe of Bill to Ease Embryo Restrictions*, WASH. POST, July 15, 2006, at A4, available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/07/14/AR2006071401380.html> (detailing the heated political and scientific debate over embryonic stem cell research and its potential alternatives); Rachel Benson Gold, *Embryonic Stem Cell Research—Old Controversy; New Debate*, THE GUTTMACHER REP. ON PUB. POL’Y, Oct. 2004, at 4, available at <http://www.guttmacher.org/pubs/tgr/07/4/gr070404.pdf> (revealing the drawn out history of the stem cell debate).

<sup>180</sup> Tsioumani, *supra* note 76, at 280.

<sup>181</sup> See *U.S. Will Rule Cloned Food Safe*, BBC NEWS, Oct. 31, 2003, <http://news.bbc.co.uk/2/hi/americas/3229941.stm> (last visited Apr. 15, 2007) (predicting that FDA will not require special labeling for the sale of milk and meat from cloned animals).

question that impacts the health and safety of humans and environmental biodiversity worldwide.<sup>182</sup>

Thus far, WTO has played a central role in the international regulation of the products of modern biotechnology. This is due to many factors. First, WTO is one of the most powerful and authoritative international institutions, trade or otherwise.<sup>183</sup> Second, WTO has one of the most diverse and inclusive memberships of international institutions.<sup>184</sup> Third, and probably most importantly, the structure of the WTO Dispute Settlement Body is uniquely appealing among international systems because it more closely resembles a traditional state dispute settlement system.<sup>185</sup> That is, instead of relying on traditional international dispute settlement techniques, such as consultation, mediation and arbitration, the WTO dispute settlement system is compulsory and binding for its members.

The WTO system is based on the voluntary submission of disputes by member states. Once a dispute has been submitted by one member state to the Dispute Settlement Body, the submission initiates court-like proceedings, incorporating short timetables, a right of appeal, and strict implementation and enforcement procedures.<sup>186</sup> The character of the WTO Dispute Settlement Body differs significantly from that of existing international health and environmental dispute settlement systems. For example, most multilateral environmental agreements have dispute settlement systems that are ill-defined and lack teeth and enforceability. Even the International Court of Justice's (ICJ) environmental chamber has failed to attract key international environmental disputes, both because the ICJ process is perceived to be administratively cumbersome and because ICJ decisions on environmental issues are virtually non-existent.<sup>187</sup> Thus, the

<sup>182</sup> See, e.g., Cinnamon Carlarne, *The Kyoto Protocol and the WTO: Reconciling Tensions Between Free Trade and Environmental Objectives*, 17 COLO. J. INT'L ENVTL. L. & POL'Y 45, 52–53 (2005–06) (examining the tensions between the free trade and trade related environmental measures with reference to interaction between the WTO and Kyoto Protocol as a case study).

<sup>183</sup> David Barnhizer, *Waking from Sustainability's "Impossible Dream": The Decisionmaking Realities of Business and Government*, 18 GEO. INT'L ENVTL. L. REV. 595, 603–04 (2006) (quoting Global Exchange, WTO, <http://www.globalexchange.org/campaigns/wto/> (last visited Apr. 15, 2007)).

<sup>184</sup> World Trade Organization, *Understanding the WTO—Whose WTO Is It Anyway?*, [http://www.wto.org/English/thewto\\_e/whatis\\_e/tif\\_e/org1\\_e.htm](http://www.wto.org/English/thewto_e/whatis_e/tif_e/org1_e.htm) (last visited Apr. 15, 2007).

<sup>185</sup> See Carlarne, *supra* note 182, at 52–53 (noting that the WTO's unique structure for settling disputes makes it an appealing international institution for dispute resolution).

<sup>186</sup> Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125, 1226–28, 1236–39 (1994); see also Peggy Rodgers Kalas & Alexia Herwig, *Dispute Resolution Under the Kyoto Protocol*, 27 ECOLOGY L.Q. 53, 68–69 (2000–01) (describing the structure of the Dispute Resolution Understanding that established WTO's Dispute Settlement Body).

<sup>187</sup> See Markus Ehrmann, *Procedures of Compliance Control in International Environmental Treaties*, 13 COLO. J. INT'L ENVTL. L. & POL'Y 377, 381–83 (2002) (comparing diplomatic and judicial procedures of international dispute resolution, opining that the “international court proceedings are regarded as too costly and slow,” and noting that the ICJ has not yet decided a single case dealing with international environmental law, prompting the need for and creation of a Chamber for Environmental Matters). The Environmental Chamber was established in 1993 under Article 26(1) of the Statute of the International Court of Justice; however, no cases have

WTO, by default, has become the frequent forum of choice for trade disputes with key health and environmental components.

Despite the WTO's attractiveness as a dispute settlement forum, the marriage between trade and environmental norms is nothing if not tumultuous. While trade policymakers and trade institutions, such as the WTO, primarily focus on liberalizing trade and promoting economic goals and short-term economic gains, environmental policymakers focus on protecting natural resources from the forces of economic development in both the short- and long-term. Consequently, trade and environmental policymakers rely on different core principles and policy evaluation tools and promote different end goals. The WTO dispute settlement system highlights these existing tensions. The WTO Dispute Settlement Body, for example, has already heard cases ranging from extraterritorial mammal protection<sup>188</sup> to automobile fuel standards<sup>189</sup> and food quality.<sup>190</sup>

Despite the breadth of the cases that the WTO Dispute Settlement Body has decided, the WTO is a trade liberalization institution and uses trade liberalization rules to determine the outcome of its disputes. Thus, many policymakers, scholars, and activists question the aptitude and the

yet been brought to the environmental chamber. *Id.* at 383. Pursuant to article 35 of the Statute of the Court, though, the Court decided a dispute between Hungary and Slovakia over whether potential environmental harm constitutes a circumstance precluding wrongfulness sufficient to justify unilateral termination or breach of a treaty. Case Concerning the Gabčíkovo-Nagymaros Project (Hung. v. Slov.), 1997 ICJ 7 (Sept. 1997). The case was decided on procedural grounds not related to the environmental issues. In its decision, however, the ICJ found that there was a duty upon states to carry out "continuing environmental impact assessment." *Id.* at 214.

<sup>188</sup> See, e.g., Panel Report, *United States—Restrictions on Import of Tuna*, ¶ 5.18 WT/DS21/R (Sept. 3, 1991) (determining that provisions of the United States' Marine Mammal Protection Act (MMPA), 16 U.S.C. §§ 1361–1421h (2000), prohibiting the importation of certain tuna products caught using commercial fishing technology that could lead to incidental takings of marine mammals, namely dolphins, violate certain provisions of GATT); Panel Report, *United States—Restrictions on Imports of Tuna*, ¶ 5.42 WT/DS29/R (June 16, 1994) (concluding that parties to the GATT, upon agreeing to take trade measures necessary to protect the health of plants, animals and persons and to conserve natural resources, had *not* agreed to confer upon each other the right to impose trade embargoes for such purposes, and so the MMPA failed to meet the requirements of GATT); Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 7.62 WT/DS58/R (Oct. 12, 1998) (*adopted* Nov. 6, 1998) (concluding that the United States' Section 609 of Public Law No. 101-162, which prohibited the importation of shrimp products from all countries that did not have plans certified by the President to prevent the incidental taking of sea turtles, an endangered species under the Endangered Species Act, 16 U.S.C. §§ 1531–44 (2000), was not in conformity with certain provisions of GATT).

<sup>189</sup> Report of the Panel, *United States—Taxes on Automobiles*, DS31/R (Oct. 11, 1994), 33 I.L.M. 1397, 1397–1400 (1994).

The GATT Dispute Settlement Panel was convened in 1992 to consider dispute DS31/2 between the United States and European Community regarding United States Corporate Average Fuel Economy (CAFE) regulations, gas guzzler tax, and car luxury tax. The panel concluded that these laws did not discriminate against European luxury car manufacturers. *Id.*

<sup>190</sup> See World Trade Organization, Dispute Settlement: Dispute DS320, United States—Continued Suspension of Obligations in the EC—Hormones Dispute, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds320\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds320_e.htm) (last visited Apr. 15, 2007) (summarizing the current status of WTO Dispute DS320, regarding hormones in meat exports from the United States to the European Community).

appropriateness of the WTO settling disputes raising far-reaching environmental and human health concerns.<sup>191</sup> Commentators both stress that the WTO decision-making process lacks transparency and favors corporate interests and emphasize that the Dispute Settlement Body lacks the expertise necessary to decide international environmental, health, and safety questions.<sup>192</sup>

In spite of persistent critiques about the capability and suitability of the WTO as a forum for deciding far reaching international questions, by default the WTO dispute settlement system has been and continues to be the forum of choice for key trade-environment, trade-health disputes. The questions now facing U.S. citizens and the international community alike are two-fold: (1) are we using the appropriate analytical tools and asking the right questions when we develop the regulating regimes for the products of modern biotechnology, and (2) is it proper to emphasize the trade dimensions and rely on international trade institutions to decide complex international environmental, health, and safety issues? These questions define ongoing trade and environmental deliberations.<sup>193</sup>

### *B. Questions Defining the Future of the Debate*

Will the U.S. citizenry change its tune? In the short term, U.S. citizenry will likely continue to be, by and large, indifferent to food safety questions. Cloning, however, will likely play a significant role in gradually turning the tide towards incorporating more public participation and more scientific precaution into the regulatory decision-making process. Gradually, politicians and the public are beginning to take notice and take action to raise the profile of biotechnology and food safety decision making.

Can the WTO appreciate and respond to the nuances of such complicated interdisciplinary questions? No. The WTO is reaching the outer edges of its ability to handle such complex and far reaching global problems.<sup>194</sup> The international community, through the World Health

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<sup>191</sup> See, e.g., Gregory C. Shaffer, *The World Trade Organization Under Challenge: Democracy and the Law and Politics of the WTO's Treatment of Trade and Environment Matters*, 25 HARV. ENVTL. L. REV. 1, 2, 4 (2001) (examining the role that the WTO's Committee on Trade and Environment in addressing the intersection of international trade and environmental law); Supachai Panitchpakdi, *The Evolving Multilateral Trade System in the New Millennium*, 33 GEO. WASH. INT'L L. REV. 419, 443 (2001) (advocating the creation of a World Environmental Organization to better align international trade and environmental protection agreements).

<sup>192</sup> See, e.g., Gregory Shaffer, *Symbolic Politics and Normative Spins: The Link Between U.S. Domestic Politics and Trade-Environment Protests, Negotiations, and Disputes*, 31 ENVTL. L. REP. 11,174, 11,174-75 (2001) (summarizing the Seattle, Washington anti-WTO protestors' two primary concerns as the WTO's "closed, trade-biased, anti-democratic" procedures and its systemic favoritism of "large corporate interests").

<sup>193</sup> See, e.g., Carlarne, *supra* note 182, at 76-84 (describing the ongoing effort to address the relationship between WTO and multilateral environmental agreements, initiated at the WTO's Ministerial Conference in Doha, Qatar in 2001).

<sup>194</sup> This is exemplified by the July 2006 breakdown in the most recent round of WTO trade talks in Geneva. See, e.g., Evan Davis, *The Death of the WTO's Doha Talks*, BBC NEWS, July 25, 2006, <http://news.bbc.co.uk/2/hi/business/5215318.stm> (last visited Apr. 15, 2007) (blaming the

Organization, the Convention on Biological Diversity, and other international institutions, must begin a more comprehensive dialogue about how to handle the use and regulation of modern biotechnology. The stakes are too high and the human and environmental impacts too indefinite to leave global decision making to a handful of developed nations and the rules of an international organization that is monumental in task and influence but limited in scope and capacity.

Food products derived from cloned animals are another link in the chain of biotechnology conflicts binding the EU and the United States. This time, however, the link may be too hot to handle. And, if dropped, where it falls and who it burns could turn the tide of domestic and international trade debate.