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**International Legal Issues Concerning Animal Cloning and
Nanotechnology – More of the Same or Are
“The Times They Are A-Changin’?”**

by

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I.

Introduction

In the global food system, emerging technologies spark methods of production that are both novel and engender controversy. These methods include the use of growth-promotion hormones for cattle, genetic modification for plants and animals and, in more recent times, animal cloning and nanotechnology. These technologies spawn debate over legal, ethical, social, moral, and religious issues. The divergent responses to these issues sharply divide the world’s trading partners have mushroomed into widely-followed, protracted disputes at the World Trade Organization (WTO). The emerging technologies of animal cloning and nanotechnology raise these same issues and threaten to further divide the world food community. The question is to what degree these issues will be cast in the same light as the issues raised in the debate over beef hormones and biotech-foods. Will these issues will be viewed differently by the public, the food industry, and governing officials?

On March 4, 2008, this author gave a presentation at the American Society of International Law in Washington, DC at which he introduced a list of twenty international law issues that may percolate with the advent of animal cloning and nanotechnology in global food production.³ The list makes no pretense at exhausting the issues involved in these new technologies as applied to the global food sector, but rather serves as a starting point for further issue development and analysis.

¹ Bob Dylan, *The Times They are a Changing* (Columbia Records, 1964).

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³ The event was titled *Regulating Animal Cloning and Nanotechnology in Food Production* and was hosted by The World Food Law Institute, the International Food & Agricultural Trade Policy Council (IPC) and the American Society of International Law. See *IPC Special Events*, <http://www.agritrade.org/events/Animalcloningandnanotechnology.html>.

This article outlines the international law framework that will deal with these issues, namely the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement) and the WTO Agreement on Technical Barriers to Trade (TBT agreement), a dual, multilateral construct that governs the trade and flow of food products. It article will also explain the factual and legal backdrop in the two food-production cases before the WTO that have created sharp divisions between the United States and Europe and agitated the world food community for years: *EC Measures Concerning Meat and Meat Products (“Hormone Beef”)*,⁴ the first WTO decision to substantively deal with the SPS agreement, and *European Communities-Measures Affecting the Approval and Marketing of Biotech Products (“Biotech Products”)*,⁵ a distinctly complex case that has generated world-wide scrutiny. This article also briefly summarizes the emerging technologies used in the production of food product – animal cloning and nanotechnology – and the developing national regulatory responses in the United States and Europe, and will pose the twenty (20) issues that help frame the debate over these emerging technologies.

II.

International Legal Construct

The global governance of food trade turns on the SPS and TBT trade agreements that were adopted at the end of the Uruguay Round of multilateral negotiations in 1994. These agreements were intended to set out transparent and fair trade rules and to eliminate policies that distort and reduce trade among countries.⁶ Established in 1995 as a replacement body to the Contracting Parties of the General Agreement on Tariffs and Trade (GATT), the WTO is responsible for administering the SPS and TBT agreements.⁷

A. SPS Agreement

To ensure that imported food products are safe and do not threaten human, animal, and plant health, countries impose regulations referred to as “sanitary measures” to protect human and animal health and “phytosanitary measures” to protect plant health.⁸ Examples of common sanitary and phytosanitary measures (SPS measures) include the regulation of food

⁴ WTO Report of the Appellate Body on EC Measures Concerning Meat and Meat Products (Hormones) WT/DS26, 48/AB/R (Jan. 16, 1998), at http://www.wto.org/english/tratop_e/dispu_e/hormab.pdf.

⁵ Panel Report, *European Communities--Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS/291/R, WT/DS/292/R, WT/DS/293/R (Sept. 29, 2006), at http://www.wto.org/english/news_e/news06_e/291r_e.html.

⁶ See, TIM JOSLING ET AL., FOOD REGULATION AND TRADE 40-56 (Peterson Institute 2004).

⁷ See generally, World Trade Organization at <http://www.wto.org/> (provides background, resources, and documents).

⁸ See WTO, SPS Agreement Training Module: Background, at http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/intro1_e.htm.

biotechnology, meat and poultry processing standards to reduce pathogens, residue limits for pesticides in foods, and restrictions on food and animal feed additives.⁹

The concern with SPS measures is that countries may use these measures as barriers to trade in food and other products. As stated more completely by the WTO:

Sanitary and phytosanitary measures, by their very nature, may result in restrictions on trade. All governments accept the fact that some trade restrictions may be necessary to ensure food safety and animal and plant health protection. However, governments are sometimes pressured to go beyond what is needed for health protection and to use sanitary and phytosanitary restrictions to shield domestic producers from economic competition. Such pressure is likely to increase as other trade barriers are reduced as a result of the Uruguay Round agreements. A sanitary or phytosanitary restriction which is not actually required for health reasons can be a very effective protectionist device, and because of its technical complexity, a particularly deceptive and difficult barrier to challenge.¹⁰

To resolve these concerns, the SPS agreement allows member countries to the WTO to adopt SPS measures provided that the measures meet certain conditions: the measures must be based on science, apply only to the extent necessary to protect health, and must not be arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.¹¹

The SPS agreement encourages members to use existing international standards, guidelines, and recommendations.¹² The SPS agreement recognizes three international standard-setting bodies as the official entities for developing these standards, guidelines, and recommendations: Codex Alimentarius Commission (Codex) for food safety standards,¹³ Office of International Epizootics (OIE) for standards related to animal health and zoonoses affecting both animal and human health,¹⁴ and the International Plant Protection Convention (IPPC) for

⁹ See WTO, SPS Agreement Training Module: Introduction, What is an SPS Measure?, at http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s3p1_e.htm.

¹⁰ WTO, Sanitary and Phytosanitary Measures: Introduction, at http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm.

¹¹ See WTO, Understanding the WTO: The Agreements – Standards and Safety, at http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm.

¹² See WTO Analytical Index: Dispute Settlement Understanding – Agreement on Sanitary and Phytosanitary Measures, at http://74.125.39.104/search?q=cache:mE51jwQKEcEJ:www.wto.org/english/res_e/booksp_e/analytic_index_e/sps_01_e.htm+sps+maintains+delicate+balance+encouraging+members+international+standards+allow+measures+higher+levels+health&hl=en&ct=clnk&cd=1.

¹³ See FAO/WHO Codex Alimentarius, at http://www.codexalimentarius.net/web/index_en.jsp.

¹⁴ See World Organization for Animal Health, at http://www.oie.int/eng/en_index.htm.

plant health measures.¹⁵ The standards set by these three international organizations set a basis for presumed compliance with the SPS agreement.¹⁶ Members may adopt SPS measures that result in higher levels of health protection than that provided by these standards only where the standards are proven scientifically justified.¹⁷

B. TBT Agreement

Although technical barriers (TBTs) are related to SPS measures, the TBT agreement treats TBTs as a different category of potential trade barriers.¹⁸ TBTs are technical regulations and standards for non-safety attributes that can take any of the forms available to safety regulations.¹⁹ This means that the TBT agreement covers technical requirements, standards, and procedures that are not covered by the SPS agreement.²⁰ Examples of TBTs that may affect trade in food products include labeling of composition or quality of food, nutrition claims, animal welfare rules, and packaging regulations (volume, shape, and appearance of packaging).²¹

The TBT agreement “protects the right of members to adopt measures which ensure the quality of exports; protect human, animal, or plant life; protect the environment; or prevent deceptive practices, as long as these measures do not breach the disciplines set forth in the [TBT] Agreement.”²² The TBT agreement also expresses a preference for product standards over standards for process and production methods.²³

The TBT Agreement sets down several principles for judging the legitimacy of a technical regulation. Members must ensure national treatment for products of international origin no less favorably than that accorded to like products of domestic origin, ensure that technical

¹⁵ See International Plant Protection Convention, at <https://www.ippc.int/IPPC/En/default.jsp>.

¹⁶ Tim Josling et al., *supra* note 6, at 41-42.

¹⁷ See Analytical Index: Dispute Settlement Understanding – Agreement on Sanitary and Phytosanitary Measures, *supra* note 12.

¹⁸ See WTO, Understanding the WTO: The Agreements – Standards and Safety, *supra* note 11.

¹⁹ *Id.*

²⁰ See WTO, SPS Agreement Training Module: Chapter 9 – Health and other WTO Agreements, at http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c9s3p1_e.htm.

²¹ See WTO, SPS Agreement Training Module: Chapter 9 – Introduction to the SPS Agreement, at http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s4p1_e.htm. Examples of non-agricultural TBTs include cigarette labeling and standards and regulations for cordless phones, automobiles, toys, and pharmaceuticals. *Id.*

²² Geoffrey S. Becker, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*, CRS Report for Congress, (Jan. 10, 2008), at 13, at <http://www.nationalaglawcenter.org/assets/crs/RL33472.pdf>.

²³ The International Agricultural Trade Research Consortium, *Agriculture in the WTO: The Role of Product Attributes in the Agricultural Negotiations* (May 2001), at 30.

regulations are not more trade-restrictive than necessary to fulfill a legitimate objective, take account of the risks non-fulfillment would create, and ensure that international standards, when they exist, are used as a basis for national regulation except when they would be an ineffective or inappropriate means of fulfilling of the legitimate objectives pursued.²⁴ Legitimate objectives include national security requirements, the prevention of deceptive practices, and the protection of human, animal, or plant life health or safety, or protection of the environment.²⁵ In assessing risks, the member must consider available scientific and technical information, related processing technology, and intended end-uses of products.²⁶

C. Applicable Agreement

The determination of whether the SPS or TBT agreement is the applicable regulation depends on the objective of the measure. If a measure is adopted to safeguard human health, then it would trigger an SPS provision; if the measure is to ensure the compositional integrity of a product, it would be governed by the TBT agreement.²⁷ The question of which agreement applies is important as the SPS agreement is generally viewed as requiring a higher standard because the focus is more on the scientific justification for measures rather than their discriminatory trade effects.²⁸

II.

WTO Review of New Production Technologies Under SPS and TBT Agreements

By virtue of their membership in the WTO, members agree that if they believe fellow-members are violating trade rules, such as those contained in the SPS and TBT agreements, they will use the multilateral system of settling disputes instead of taking action unilaterally.²⁹ This accord was reached in 1994 when WTO members agreed on the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) annexed to the "Final Act" signed in

²⁴ See Agreement on Technical Barriers to Trade, Apr. 15, 1994, WTO Agreement, art. 2.

²⁵ *Id.* at art. 2.2.

²⁶ *Id.*

²⁷ See WTO, Sanitary and Phytosanitary Measures: Introduction – Question and Answers, at http://74.125.39.104/search?q=cache:v31DdAdOoDcJ:www.wto.org/english/tratop_e/sps_e/spsund_e.htm+How+do+you+know+if+a+measure+is+SPS+or+TBT%3F+Does+it+make+any+difference%3F&hl=en&ct=clnk&cd=1.

²⁸ Jacqueline Peel, *A GMO By Any Other Name . . . Might Be An SPS Risk!: Implications of Expanding the Scope of the WTO Sanitary and Phytosanitary Measures Agreement*, 17 Eur. J. Int'l L. 1009, 1011-1012 (2006).

²⁹ See WTO, Understanding the WTO: Settling Disputes – A Unique Contribution, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/displ_e.htm.

Marrakesh.³⁰ Dispute settlement via the DSU is regarded by the WTO as having made a "unique contribution to the stability of the global economy."³¹

Two instances of dispute settlement at the WTO that were widely followed concerned new food-production technologies to which consumers reacted strongly, one involving meat hormones and the other involving biotech food. Both disputes share common features: first, they encompassed highly controversial technologies in the development of food products; second, they engendered strong consumer reaction and concern; third, they pitted against each other the differing views of these technologies in the powerful trading members, the EU and the U.S.; fourth, they reflected differing cultural, political, ethical, and sociological perspectives; fifth, they resulted in findings by the WTO of violation of WTO rules; sixth, they are still unsettled long-standing disputes; and seventh, they deliver important lessons that can be applied to the possible trade controversies that concern the new food-product technologies of animal cloning and nanotechnology.

A. Meat Hormone Dispute

The enduring acrimony between the U.S. and EU over the meat hormone dispute has earned the controversial the title of "mother of all food safety trade disputes."³² The controversy involves six hormones. Three of the hormones – estradiol, progesterone, and testosterone – are naturally occurring hormones produced by humans and animals. The other three hormones – trenbolone acetate, zeranol acetate, and melengestrol acetate – are synthetic hormones.³³ The use of these hormones allows a treated animal to gain weight more rapidly, producing a more flavorful and tender product,³⁴ and reaching market weight quickly reduces the cost of beef production.³⁵

The regulatory bodies in the U.S. and Europe sharply disagree over the effects of the use of growth-promoting hormones. The U.S. Food and Drug Administration (FDA), which regulates animal drugs, holds that there is no difference between beef from animals raised using hormones and those raised without their use.³⁶ In contrast, the EU posits that there is not enough

³⁰ See Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, WTO Agreement, Annex 2, Legal Instruments – Results of the Uruguay Round vol. 31 (1994), 33 I.L.M. 1126 (1994).

³¹ WTO, Understanding the WTO: Settling Disputes – A Unique Contribution, *supra* note 29.

³² Tim Josling, Donna Roberts, & Ayesha Hassan, *The Beef-Hormone Dispute and its Implications for Trade Policy*, Forum on Contemporary Europe, Freeman Spogli Institute for International Studies, Stanford University (Sept 1999) at 1, at <http://iis-db.stanford.edu/pubs/11379/HORMrev.pdf>.

³³ *A Primer on Beef Hormones*, Embassy of the United States of America (Feb. 24, 1999), at <http://stockholm.usembassy.gov/Agriculture/hormone.html>.

³⁴ *Id.*

³⁵ *Id.*

³⁶ See 21 U.S.C. § 360b (2006).

data to conduct a valid quantitative risk assessment on the long-term health effects from consumption of beef from animals raised using hormones, especially for prepubescent children.³⁷

EU concerns over the health effects of the use of growth-promoting hormones date back to the 1970s.³⁸ Europeans became alarmed over well-publicized incidents involving the use of illegal growth hormones in Italy in school lunches and veal-based baby food. These food scares created a climate of consumer suspicion towards the use of growth hormones in animal production and fostered an active regulatory environment that spawned a series of bans and restrictions, then in the ban of the use of synthetic hormones altogether, and finally in 1989, a ban on the production and importation of meat from livestock treated with both synthetic and natural growth-promoting hormones.³⁹

The U.S. beef industry was convinced that the EU ban was a protectionist device aimed at restricting trade.⁴⁰ The U.S. in 1987 initially attempted but failed to resolve the issue under the GATT dispute settlement mechanisms.⁴¹ This dispute in part motivated negotiation of stronger disciplines on technical regulations in the GATT Uruguay Round and the adoption of the SPS agreement.⁴²

After the new Uruguay Round rules for dispute settlement procedures and for SPS measures, the U.S. renewed its complaint against the EU beef import ban.⁴³ In January 1996, the U.S. requested formal consultations with the EU, which were joined by Australia, Canada, and New Zealand. The U.S. argued that the EU ban violated basic GATT provisions and the SPS and TBT agreements.⁴⁴ The U.S. specifically asserted that the EU ban on growth hormones lacked any scientific justification, the EU failed to perform required risk assessments of the dangers posed by hormones before it implemented the ban, and the ban was intended to protect the EU cattle industry and was not really based on health dangers.⁴⁵ The EU disagreed with the U.S. position and replied that further studies were needed because the scientific data on the safety of

³⁷ See Mickey Parish, *Science Behind the Regulation of Food Safety: Risk Assessment and the Precautionary Principle*, CRS Report for Congress, Updated Aug. 27, 1999.

³⁸ Tim Josling et al., *supra* note 32 at 3.

³⁹ *See id.* at 3-8.

⁴⁰ *See id.* at 9.

⁴¹ *See id.* at 8.

⁴² *See id.* at 9; see also Gavin Goh, *Precaution, Science and Sovereignty – Protecting Life and Health Under the WTO Agreements*, J. WORLD INTELL. PROP. (May 2003), 441, 446, at <http://www.blackwell-synergy.com/action/showPdf?submitPDF=Full+Text+PDF+%281%2C851+KB%29&doi=10.1111%2Fj.1747-1796.2003.tb00224.x>.

⁴³ TIM JOSLIING et al, *supra* note 6 at 120.

⁴⁴ *Id.*

⁴⁵ Tim Josling, et al., *supra* note 32 at 13.

beef hormones was inadequate, that controls necessary to ensure safe administration of the hormones were not in place in the U.S., and that the ban was justified by the EU's historical use of the concept of international customary law known as the precautionary principle, which provides that if something is potentially dangerous, then, in the face of scientific uncertainty, the prudent thing for the regulatory body to do is intervene and limit the risk.⁴⁶

Unable to reach a settlement, the U.S. followed the dispute settlement procedures and asked that the WTO establish a panel to hear the dispute.⁴⁷ The amount of trade involved was roughly \$100 million dollars, a small fraction of the billions of dollars of trade each year, but the hormones dispute became a lightning rod for differences in trade relations.⁴⁸ The controversy also served as a test for the new SPS agreement.

Following intensive briefing by all parties involved, the WTO dispute settlement panel in a report issued in August 1997 agreed with the complainants that the EU ban on beef treated with growth promotion hormones was inconsistent with its obligations under the SPS agreement.⁴⁹ The panel found that the EU did not present scientific evidence in which potential adverse effects on human health of these growth hormones residues was evaluated.⁵⁰ The panel held that the ban was not based on risk assessment or on international standards and that the EU had not provided scientific evidence to support the ban.⁵¹

All three parties to the dispute – U.S., Canada, and the EU – requested a review of the procedural and substantive panel findings.⁵² After reviewing the panel's decision and report, the WTO Appellate Body released a report in January 1998 that overruled the panel on several points but concurred with the panel that the EU measure did not conform to SPS disciplines.⁵³ While affirming the right of each country to determine its own level of acceptable risk, the

⁴⁶ See Cass R. Sunstein, *Irreversible and Catastrophic*, 91 *Cornell L. Rev.* 841, 849 (2006) (discussing various permutations of the Precautionary Principle).

⁴⁷ Tim Josling, et al., *supra* note 6 at 13.

⁴⁸ *Id.* at 115.

⁴⁹ See WTO Report of the Panel: EC Measures Concerning Meat and Meat Products (Hormones), (Aug. 18, 1977), 1997 WL 569984.

⁵⁰ *Id.* at 184-87.

⁵¹ *Id.*

⁵² See WTO Report of the Appellate Body on EC Measures Concerning Meat and Meat Products (Hormones), *supra* note 4. The Appellate Body was established in 1995 pursuant to the DSU. It hears appeals from reports issued by panels in disputes brought by WTO Members. The Appellate Body can uphold, modify or reverse the legal findings and conclusions of a panel, and Appellate Body Reports, once adopted by the Dispute Settlement Body, must be accepted by the parties to the dispute. WTO, Dispute Settlement: Appellate Body, at http://www.wto.org/english/tratop_e/dispu_e/appellate_body_e.htm.

⁵³ See WTO Report of the Appellate Body on EC Measures Concerning Meat and Meat Products (Hormones), *supra* note 4.

Appellate Body found that the SPS agreement requires that any measures imposed to reach that level of risk must be based on scientific evidence.⁵⁴ A member may act in a precautionary manner in the absence of sufficient science, but the SPS agreement requires that member to seek to obtain the science.⁵⁵ The Appellate Body determined that the panel correctly found that the EU ban failed to provide a risk assessment and that the risk assessments that were available indicated that there were no ascertainable risks to human health.⁵⁶

The Appellate Body decision did not bring an end to the now twelve-year-old hormone saga.⁵⁷ A breakdown in consultations led to a new Dispute Settlement Body Panel's being instituted on June 2005.⁵⁸ A WTO panel decision made public in March 2008 permits the U.S. and Canada, if there is no scientific basis for the EU ban, to maintain sanctions worth tens of millions of dollars a year on European products like Roquefort cheese, truffles, and Dijon mustard.⁵⁹ The EU is considering appealing the panel decision.⁶⁰

B. Biotechnology Food Dispute

The beef hormone WTO dispute foreshadowed an even more divisive trade battle over food and science -- biotech food.⁶¹ The biotech food dispute was one of the most complex and

⁵⁴ *Id.* at 45.

⁵⁵ *See id.* at 31-32.

⁵⁶ *See id.* at 60-61. Similarly, in the WTO *Japanese Agriculture* case, where imports of various fruits from the United States and elsewhere were banned because of a concern that they could spread disease through codling moth unless they met various stringent border tests, both the panel and the Appellate Body found that these border requirements were based on no risk assessment at all and were thus in violation of the SPS Agreement. WTO Appellate Body Report, *Japan-Measures Affecting Agricultural Products*, AB-1998-8, WT/DS76/AB/R (February 22, 1999). In the *Australian Salmon* case, a ban on the importation of fresh, chilled or frozen salmon was found to violate the SPS Agreement both because the ban was based on no risk assessment and because, inconsistently, it allowed imports of other kinds of fresh, chilled or frozen fish that presented at least as high a risk of spreading disease. WTO Appellate Body Report, *Australia-Measures Affecting Importation of Salmon*, AB-1998-5, WT/DS18/AB/R (October 20, 1998).

⁵⁷ *See generally*, WTO Dispute Settlement: Dispute DS26 – European Communities – Measures Concerning Meat and Meat Products (Hormones), at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm. (overview of procedural history).

⁵⁸ *See id.*

⁵⁹ WTO Report of the Panel: United States Continued Suspension of Obligations in the EC – Hormones Dispute, WT/DS320/R, (Mar. 31, 2008), at [http://www.worldtradelaw.net/reports/wtopanelsfull/us-hormonessuspension\(panel\)\(full\).pdf](http://www.worldtradelaw.net/reports/wtopanelsfull/us-hormonessuspension(panel)(full).pdf).

⁶⁰ *See* Neil Merrett, *EU Mulls Appeal Over WTO Growth Hormone Decision*, foodproductiondaily.com, at <http://www.foodproductiondaily.com/news/ng.asp?id=84359-wto-growth-promoting-hormones-eu>.

⁶¹ Cinnamon Carlarne, *From the USA with Love: Sharing Home-Grown Hormones, GMOs, and Clones With a Reluctant Europe*, 37 *Env'tl. L.* 301, 308 (2007).

wide-ranging in the history of the WTO. It took three years for the WTO panel to resolve the issues and resulted in a 1,000-plus page report.

Biotech food is food that consists of genetically modified organisms (GMOs) or is produced from genetically modified organisms. Conventional breeding methods have been employed to develop food products for several thousands of years.⁶² Newly-developed scientific methods are now used, however, to create a vast array of products by altering the genetic makeup of organisms and producing unique traits that are not easily obtained through the conventional breeding methods.⁶³ These products are commonly referred to as “transgenic,” “bioengineered,” or “genetically modified” because they contain foreign genetic material.⁶⁴ This article will refer to these products simply as “biotech food.”

The U.S. position towards biotech foods is defined by the doctrine of “substantial equivalence”⁶⁵ that distinguishes between process and the end product and holds that unless scientific evidence establishes that the physical characteristics of the biotech food product are different from the conventional counterpart, a biotech food product is subjected to the same regulatory oversight as the conventional product to which it is deemed equivalent.⁶⁶ Modification of the genetic makeup is an inconsequential process that does not concern regulators.⁶⁷

The result of the U.S.’s adoption of the doctrine of substantial equivalence is that biotech foods do not require special procedures for the approval or marketing, and there is no specialized regulatory law or agency having sole authority over biotechnology.⁶⁸ The regulatory approach instead consists of a coordinated approach to regulating food biotechnology, with multiple agencies – the FDA, the Environmental Protection Agency (EPA), and U.S. Department of Agriculture (USDA) – all reviewing biotech food products under the purview of their jurisdiction with the same standards as conventional products.⁶⁹ The FDA evaluates the safety

⁶² See Biotechnology: An Overview, National Agricultural Law Center, at <http://www.nationalaglawcenter.org/assets/overviews/biotechnology.html>.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. Mich. J.L. Reform 403, 429 (2002).

⁶⁶ See Gregory N. Mandel, Gaps, *Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 Wm. & Mary L. Rev. 2167, 2242 (2004).

⁶⁷ Douglas A. Kysar, *Preferences for Process: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 Harv. L. Rev. 525, 557-558 (2004).

⁶⁸ See Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22984; see also FDA’s Statement of Policy; Foods Derived From New Plant Varieties, U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition Q & A Sheet (June 1992), at <http://www.cfsan.fda.gov/~lrd/bioqa.html>.

⁶⁹ See generally Doug Farquhar and Liz Meyer, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 Drake J. Agric. L. 439, 445 (2007).

and marketing of biotech foods intended for human or animal consumption under the Food Drug and Cosmetic Act.⁷⁰ The USDA, acting through the Animal and Plant Health Inspection Service (APHIS), monitors the growth and safety of biotech crops under the Plant Protection Act.⁷¹ The EPA regulates environmental risks posed by organisms modified to contain insecticidal properties under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)⁷² and the Toxic Substances Control Act (TSCA).⁷³ Under this coordinated framework, these federal agencies overseeing biotech food products presume the products are safe so long as the biotech food product is substantially equivalent to the original.⁷⁴

The effectiveness that this cooperative arrangement has had in appeasing consumers in the United States is difficult to measure. While industry estimates suggest that as many as sixty percent of all processed food items on U.S. supermarket shelves contain undisclosed GM ingredients,⁷⁵ public awareness and understanding of biotech foods remains relatively low and has declined in recent years.⁷⁶ Americans in general support regulation of biotech foods, with forty-one percent feeling that there is too little regulation in this area.⁷⁷ Whatever the level of American animosity there is towards biotech foods, it has not translated into the cautious regulatory approach that marks the EU.

Such caution in the EU over biotech foods is born out of widespread consumer opposition in Europe to the spread of genetically modified foods.⁷⁸ A series of unrelated food crises during the 1990s created consumer apprehension about food safety in general, eroded the public trust in government oversight of the food industry, and left many EU consumers unwilling to consider “science” to be a guarantee of quality.⁷⁹

⁷⁰ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et al.

⁷¹ 7 U.S.C. §§ 7701-7786 (2006).

⁷² *Id.* §§ 136-136y.

⁷³ 15 U.S.C. §§ 2601-2692 (2006).

⁷⁴ Thomas O. McGarity, *supra* note 65 at 429 (asserting how the presumption of safety is an extension of the doctrine of substantial equivalence).

⁷⁵ See Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 Ann. Surv. Int'l & Comp. L. 129, 131 (2000).

⁷⁶ See Review of Public Opinion Research, Memorandum from The Mellman Group to Pew Initiative on Food and Biotechnology (Nov. 16, 2006), at <http://pewagbiotech.org/research/2006update/2006summary.pdf>.

⁷⁷ *Id.* at 5.

⁷⁸ See Cinnamon Carlarne, *supra* note 61 at 319.

⁷⁹ See Gregory A. Baker, *The Battle for Biotech Foods: The United States and European Union*, 4 Santa Clara J. Int'l L. 61 (2006).

The EU's cautious regulatory approach to biotech foods rests on the precautionary principle.⁸⁰ Consistent with its implementation in the beef-hormone case, the precautionary principle provides that if something such as a genetically modified food product is potentially dangerous, then, in the face of scientific uncertainty, the prudent thing for the regulatory body is to intervene and limit the risk.⁸¹ The potential danger in biotech foods perceived in the EU derives from concerns about the "unknown" in terms of food safety and the natural environment.⁸²

These concerns translated into EU regulations that rely on "pre-marketing safety assessments" and focus on process rather than on the end product.⁸³ The practical effect of these pre-market, process-oriented assessments starting in 1998 was what was popularly termed a "de facto ban or moratorium" from the EU market of biotech food products from the U.S. and other major GM producer countries such as Canada and Argentina.⁸⁴

In May 2003, the U.S., along with Canada and Argentina, responded by challenging the EU's de facto moratorium on biotechnology product approvals.⁸⁵ Although the EU claimed to have lifted the moratorium in May 2004 by approving a genetically engineered corn variety, the three complainants pursued the case, in part because a number of EU member states continued to block biotech products, even those the EU itself deemed acceptable.⁸⁶ The moratorium reportedly costs U.S. corn growers some \$300 million in exports to the EU annually.⁸⁷

⁸⁰ See 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).

⁸¹ See Sunstein, *supra* note 46 at 849.

⁸² See e.g., *Genetically Modified Organisms*, EurActive.com, at http://209.85.135.104/search?q=cache:5Rh_eqG4KvcJ:www.euractiv.com/en/biotech/genetically-modified-organisms/article-117498+why+eu+opposed+to+gm+food+unknown&hl=en&ct=clnk&cd=1.

⁸³ 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).

⁸⁴ See Geoffrey S. Becker and Charles Hanrahan, *European Moratorium on Biotech Crops, Congressional Research Service Agriculture Policy Briefing Book*, at <http://209.85.135.104/search?q=cache:Iy22Yd4AxCIJ:www.cnie.org/nle/crsreports/briefingbooks/Agriculture/European%2520Union%2520Moratorium%2520on%2520Biotech%2520Crops.htm+crs+eu+ban+gmo&hl=en&ct=clnk&cd=3>.

⁸⁵ World Trade Organization, Request for Consultations by the United States, European Communities-Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/1 (May 20, 2003).

⁸⁶ See Charles E. Hanrahan, *Agricultural Biotechnology: The U.S.-EU Dispute*, CRS Report for Congress (Mar. 10, 2006) at 2.

⁸⁷ *Id.* at 1.

In February 2006, the WTO dispute panel issued a report that agreed in large part with the complainants' arguments.⁸⁸ The panel found that the EU "safeguard measures" fell within the definition of the SPS Measures" in Annex A of the SPS agreement and that there was a failure to conduct appropriate risk assessment measures before the imposition of these measures in violation of the SPS agreement.⁸⁹ The panel further found that the EU failed to ensure that its approval procedures were conducted without "undue delay."⁹⁰ Disposing the claims under the SPS agreement alleviated the need for the panel to assess the complaints under the TBT agreement or the GATT.⁹¹

The panel also disposed of the EU's argument that the precautionary principle provides that lack of full scientific certainty should not be used as a reason to preclude measures to minimize unproven risks of serious or irreversible harm. The precautionary principle was treated by the panel as an interpretive tool according to norms of treaty interpretation via the Convention on Biological Diversity (also commonly referred to as the "Biosafety Protocol"), which recognizes the precautionary principle in its preamble.⁹² The panel acknowledged that Article 31.3(c) of the Vienna Convention on the Law of Treaties mandated the panel to take into account any relevant rules of international law *only if* these rules are "applicable" to parties concerned.⁹³ The panel found that of the parties to the *EC-Biotech* dispute, only the EC is a party to the Biosafety Protocol (although both Argentina and Canada are signatories), and the U.S. had no meaningful involvement in it.⁹⁴ As to the broad question of whether the precautionary principle belongs to general principles of law, the panel noted that it need not address such a "complex" and "unsettled" issue in this specific dispute.⁹⁵

⁸⁸ See Panel Report, European Communities--Measures Affecting the Approval and Marketing of Biotech Products, WT/DS/291/R, WT/DS/292/R, WT/DS/293/R (Sept. 29, 2006), at http://www.wto.org/english/news_e/news06_e/291r_e.html.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ The WTO Panel's decision not to consider the TBT or GATT claims with respect to the non-SPS measures was viewed by many as not resolving the dispute with respect to non-SPS objectives and one of the bases for asserting that it could be appealed. See e.g., Alice Palmer, *The WTO GMO Dispute: The Implications for Developing Countries and the Need for an Appeal*, (Nov. 2006), available at http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/WTO_Biotech_case_dcsummaryfinal_1.pdf.

⁹² Panel Report, European Communities--Measures Affecting the Approval and Marketing of Biotech Products, *supra* note 88 at para. 7.68.

⁹³ *Id.*

⁹⁴ On January 29, 2000, the representatives of 129 countries met in Montreal and adopted the Cartagena Protocol on Biosafety, an act capping over five years of negotiations regarding the international transport of GMOs. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, U.N. Doc. UNEP/CBD/ExCOP/1/3, reprinted in 39 I.L.M. 1027, at <http://www.biodiv.org/biosafety/protocol.asp>.

⁹⁵ *Id.*

The EU decided not to appeal the panel report, and the WTO Dispute Settlement Body adopted the panel's report in November 2006. The WTO's decision has not, however, ended the debate over biotech food.⁹⁶ The debate has shifted in certain respects from the approval of biotech food products to the right to make an informed choice, an issue that burns strongly for many Europeans. With the same passion, but on the other side of the spectrum, Robert B. Zoellick, the U.S. trade representative at the time, opined that the European position toward biotech food was "immoral" since it could lead to starvation in developing countries as some famine-threatened countries refused to accept U.S. aid because it contained biotech food.⁹⁷

C. Lessons Learned

Several important lessons can be gleaned from the beef hormone and food biotech controversies and applied to new food technologies to help predict issues, frame legal analyses, and anticipate consumer and political reaction. First, new technologies in food production, coupled with a lack of confidence in the government, can create a crisis in consumer confidence in the government, science, and the ability of regulators. Second, it is a challenge to balance consumer safety based on science with consumer safety based on public sentiment. Third, there is a practical limit to what the WTO dispute settlement cases can do to provide politically acceptable solutions on powerful countries. Fourth, considerations of consumer preference do not die easily, as the debate shifts from science-based issues to a "right-to-know." Fifth, it remains unclear how to square differing social, religious, and ethical perspectives within the whole debate over trade, as what is not strictly rational or scientific is demoted in the regulatory process. Sixth, the impact of the TBT agreement on the regulation of other quality attributes remains unresolved, which is troubling given the rise in interest in quality standards and labeling to achieve a wide variety of objectives. Seventh, it is not clear whether the process/product distinction intelligently accounts for the growing cultural and political significance attached to the consumptive function.

D. Private Standards: A Wrinkle in the Works

Extending the lessons learned from the beef hormone and food biotech controversies to the emerging technologies of animal cloning and nanotechnology in the global food sector belies a clean analytical framework. Adding to the complexities of factors is the growing practice of food companies in the global food supply chain that adopt private standards.⁹⁸ This embracement has led to the development and proliferation of private standards in the forms of codes and

⁹⁶ See WTO Secretariat, *European Communities--Measures Affecting the Approval and Marketing of Biotech Products*, Action by the Dispute Settlement Body, WT/DS291/33 (Nov. 29, 2006), at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm.

⁹⁷ Elizabeth Becker, *U.S. Threatens to Act Against Europeans Over Modified Foods*, *The New York Times* (Jan. 10, 2003), at <http://query.nytimes.com/gst/fullpage.html?res=9D06E3DA1E3EF933A25752C0A9659C8B63>.

⁹⁸ See Johyn W. Miller, *Private Food Standards Gain Favor*, *The Wall Street Journal* (Mar. 11, 2008) at B1.

supply-chain contracts that permeate international boundaries.⁹⁹ As a result, a privatized sustainability governance scheme has emerged in a food supply world that has traditionally been regulated by state and international standard-setting public institutions.¹⁰⁰

The number of private standards has grown at a surprising pace as manufacturers, retailers, and non-governmental organizations develop their own criteria to address safety, quality, sustainable development, and labor conditions.¹⁰¹ Supermarkets from time to time have banned genetically modified food from their shelves or advocated a consumer's right to know what products contain genetically modified ingredients.¹⁰²

Will private standards regulate de facto food technologies, such as those applied to biotech foods? Will private standards regulate future emerging technologies? These questions have alarmed the food industry and some constituencies. For example, the Biotechnology Industry Organization and major commodity trade associations have expressed concern that a draft "sustainable agriculture" standard under development by the American National Standards Institute would exclude farms from growing biotech crops.¹⁰³ Developing countries are also concerned that private standards impose significant burdens on poor farmers to meet compliance standards that are often higher than those set by the public bodies.¹⁰⁴ There is ongoing investigation as to whether these private standards fall within the scope of the SPS and TBT agreements, as developing countries rue that private standards impose significant burdens on poor farmers to meet compliance standards that are often higher than those set by the public bodies.¹⁰⁵

⁹⁹ See WTO Committee on Sanitary and Phytosanitary Measures, *Private Standards and the SPS Agreement* (Jan. 2007) G/SPS/GEN/746 at 1.

¹⁰⁰ See generally, Maki Hatanaka, Carmen Bain, and Lawrence Busch, *Third-Party Certification in the Global Agrifood System*, Food Policy (June 2005) (discusses how private standards and third-party certification reflect broader shift from public to private governance).

¹⁰¹ See WTO Committee on Sanitary and Phytosanitary Measures, *supra* note 99 at 4.

¹⁰² See e.g., *Whole Foods Market Genetic Engineering Position Statement* (May 2000) at http://209.85.135.104/search?q=cache:ji_1UPusGQwJ:www.mindfully.org/GE/Whole-Foods-GMO-Statement.htm+private+standards+genetically+modified+food+gmo&hl=en&ct=clnk&cd=8; Melinda Fulmer, *Two Chains Ban Engineered Foods*, Los Angeles Times (Dec. 31, 1999).

¹⁰³ See Industry "antsy about ANSI" Sustainable Agriculture Standard, Food Chemical News (Jan. 2008) at 1.

¹⁰⁴ See WTO Committee on Sanitary and Phytosanitary Measures, *supra* note 99.

¹⁰⁵ See *id.*

II.

Emerging Technologies

A. Animal Cloning

Animal cloning first generated a public storm in 1997 when the birth of Dolly, the world's most famous sheep, was announced.¹⁰⁶ Since Dolly's birth, scientists have used cloning technology to breed dairy cows, goats, beef cattle, poultry, hogs, and other livestock species.¹⁰⁷ The cloning technology is a multi-step procedure that involves the insertion of a nucleus into an enucleated egg, the initiation of development, and the implantation of the egg into a surrogate dam where it completes gestation.¹⁰⁸

Supporters view cloning as beneficial to consumers, animals, environment, and producers.¹⁰⁹ Breeders may create animals with preferred genetic characteristics without the uncertainties of natural breeding.¹¹⁰ For example, there is a claim that cloning would allow for fewer superior dairy cows to produce the same quantity of milk while making less animal waste.¹¹¹ Another advantage is that breeders will be able to predict better the characteristics of the offspring and can propagate superior genetics into future generations and provide consumers with a better product.¹¹² Cloning also has the potential to produce disease-resistant animals.¹¹³

¹⁰⁶ See Elizabeth Weise, *Dolly was World's Hello to Cloning's Possibilities*, USA Today (July 4, 2006), at http://www.usatoday.com/tech/science/genetics/2006-07-04-dolly-anniversary_x.htm.

¹⁰⁷ *Id.*

¹⁰⁸ See Human Cloning and Human Dignity, The President's Council on Bioethics (July 2002) (Chapter 4), at <http://209.85.135.104/search?q=cache:xBXLVRKtU5UJ:bioethics.gov/reports/cloningreport/background.html+cloning+procedure+insertion+nucleus+enucleated+egg+implantation+surrogate+gestation&hl=en&ct=clnk&cd=1>.

¹⁰⁹ Linda Bren, *Cloning: Revolution or Evolution in Animal Production?*, 37 FDA Consumer 3, May-June 2003, at http://www.fda.gov/fdac/features/2003/303_clone.html

¹¹⁰ Center for Food Safety Fact Sheet, Cloning and Food Safety (Oct. 2005), at <http://www.centerforfoodsafety.org/pubs/cloned%20meat%20and%20dairy%20factsheet10.19.2005.pdf>.

¹¹¹ Barbara Ingham, *Safety of Meat and Milk Derived From Animal Clones*, Food Facts For You, at http://www.foodsafety.wisc.edu/assets/foodfacts_2007/wffFeb2007.htm.

¹¹² Linda Bren, *supra* note 109.

¹¹³ *Id.*

Despite these claimed advantages, the cloning of animals has its detractors. Concerns involve food safety, animal welfare, ethics, and genetic diversity (leading animals to being susceptible to a single disease).¹¹⁴ There is also a large concern over the transfer of this technology to humans, where issues such as biological determinism, individuality, and the redefinition of family arise.¹¹⁵ The same September 2006 PEW report referred to earlier in this article concerning biotech foods found that animal cloning “evinces much stronger opposition than does the modifications of plants.”¹¹⁶ According to the report, American consumers claim to have heard more about animal cloning than about biotech food.¹¹⁷ Although they are not well informed about animal cloning, Americans are very uneasy about the technology. The PEW report shows that 64% of Americans are uncomfortable with animal cloning (46% “strongly uncomfortable”), compared to just 22% who say they are comfortable with animal cloning.¹¹⁸

The general distrust from the American public has not dissuaded the FDA from paving the way for products derived from cloned animals and their offspring to be made available to consumers. On December 28, 2006, the FDA released a report, *Animal Cloning: A Draft Risk Assessment*, which 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.¹¹⁹ Despite this regulatory green-light from the FDA, the USDA has instituted a voluntary moratorium on the sale of products from cloned animals, including milk and meat from animal clones.¹²⁰ It also should be noted that the financial costs of cloning are still high,¹²¹ and the science of cloning animals must be improved.¹²²

¹¹⁴ See Chad West, *Economics and Ethics in the Genetic Engineering of Animals*, 19 Harv. J.L. & Tech. 413, 425-31 (2006).

¹¹⁵ On March 8, 2005, the General Assembly of the United Nations adopted a declaration on human cloning that is rather ambiguous, as it does not ban cloning altogether, including cloning for reproductive purposes. The negotiation leading up to the declaration was replete with discussions on human rights, cultural, and religious issues. The purpose of the declaration was to “develop an international framework for responsible societal governance of human genetic technology.” Resolution Adopted By The General Assembly. 59/280. United Nations Declaration on Human Cloning, U.N. GAOR 6th Comm., 59th Sess., Agenda Item 150, U.N. Doc. A/RES/59/280 (2005). However, it fails to implement the framework as intended. Channah Jarrell, Article, *No Worldwide Consensus: The United Nations Declaration on Human Cloning*, 35 GA. J. INT’L & COMP. L. 205, 208 (Fall 2006).

¹¹⁶ The Melman Group, Memorandum to The Pew Initiative On Food And Biotechnology (Nov. 16, 2006), at 1, available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Public_Opinion/Food_and_Biotechnology/2006summary.pdf.

¹¹⁷ *Id.* at 7.

¹¹⁸ *Id.* at 9.

¹¹⁹ FDA, Center for Veterinary Medicine, A Risk-Based Approach to Evaluate Animal Clones and Their Progeny – Draft, at <http://www.fda.gov/cvm/Cloneriskassessment.htm>.

¹²⁰ Bruce I Knight, Under Secretary for Marketing and Regulatory Programs, Animal Cloning: Transitioning from the Lab to the Market, Speech Before Washington D.C. Advisory Committee on Biotechnology and 21st Century Agriculture, March 5, 2008.

¹²¹ James D. Murray and Gary B. Anderson, *Genetic Engineering and Cloning may Improve*

The EU has not approved any cloned animals or animal products for sale in the human food supply. Not surprisingly, there is grave public concern over the prospects of cloned animal products entering the market.¹²³ European public opinion polls show strong resistance to the cloning of animals.¹²⁴ If the recommendations from the United Kingdom's Department for Environment, Food, and Rural Affairs (DEFRA) are any indication of how the EU may respond to animal cloning, then a strict regulatory regime is to be expected.¹²⁵ DEFRA's twelve recommendations incorporate concerns of preserving the precautionary principle, consumer choice, and animal and human health.¹²⁶ Denmark and Norway have already passed restrictive animal-cloning legislation.¹²⁷ It is likely that countries outside the EU will follow suit.¹²⁸ There is also the concept of consumer rights – the right to be informed and the right to self-determination or free choice – that may very well be incorporated by the EU in its regulatory approach to these emerging technologies.¹²⁹

In March 2007, the European Commission requested guidance from the European Group of Ethics and from the European Food Safety Authority (EFSA). EFSA is responsible for conducting scientific risks assessments for proposals for novel foods that would enter the EU food chain.¹³⁰ EFSA published its final paper in July 2007 and concluded that there is no

Milk, Livestock Production, California Agriculture (July-August 2000), 57-65, at http://californiaagriculture.ucop.edu/0004JA/pdf/geneng_clon.pdf. For supporters of animal cloning, costs have been cited as a barrier especially for developing countries, whom it is argued, need animal cloning to ensure the survival of rare cattle breeds that are well suited to cope with harsh conditions. Calestous Juma, *Developing Nations Need Cloning*, BBC News, January 25, 2007, at <http://news.bbc.co.uk/2/hi/science/nature/6288941.stm>.

¹²² D.N. Wells, *Animal cloning: problems and prospects*, Rev. Sci. Tech. Off. Int. Epiz., 24 (1), 251-264 (2005), available at <http://www.oie.int/eng/publicat/RT/2401/24-1%20pdfs/22-wells251-264.pdf>.

¹²³ See Public Perceptions of Farm Animal Cloning in Europe, Danish Centre for Bioethics and Risk Assessment, at <http://www.sl.kvl.dk/cloninginpublic/index-filer/CloninginPublicEthicalReport.pdf>.

¹²⁴ *Id.*

¹²⁵ See Cinnamon Carlarne, *supra* note 61 at 314-315.

¹²⁶ Department for Environment, Food, and Rural Affairs, Animal Welfare: Government Response to FAWC's Report on the Implications of Cloning for the Welfare of Farmed Livestock (Feb. 5, 2003), at <http://209.85.135.104/search?q=cache:M1TAWSh2PRAJ:www.defra.gov.uk/animalh/welfare/farmed/cloning-resp.htm+Government+Response+to+Animals+and+Biotechnology&hl=en&ct=clnk&cd=2>.

¹²⁷ See Christian Gamborg, Jennifer Gunning & Mette Hartlev, *Farm Animal Cloning: The Current Legislative Framework*, Danish Centre for Bioethics and Risk Assessment, 21-24 (2005).

¹²⁸ See *id.* at 34.

¹²⁹ See generally, John H. Murphy, *Mandatory Labeling of Food Made From Cloned Animals: Grappling With Moral Objections to the Production of Safe Products*, 63 Food & Drug L.J. 131 (2008) (dealing with right-to-know issue and mandatory labeling relative to cloned animals).

¹³⁰ See Cinnamon Carlarne, *supra* note 61 at 325.

indication that differences exist in food safety for meat and milk of clones and their progeny compared with those from conventionally bred animals.¹³¹ EFSA also noted that the health and safety of a significant proportion of clones, mainly within the juvenile period for cattle and prenatal period for pigs, were adversely affected, often severely and fatally, and recommended that the health and welfare of clones be monitored.¹³² EFSA noted as well that uncertainties in the risk assessment are due to limited studies and data and recommended additional investigation and studies.¹³³

Shortly after EFSA's draft opinion in December 2007, the European Group on Ethics and Science and New Technologies released a report that stated there is no ethical justification to use clones in the food supply, called for more scientific study, and said if cloned foods are allowed in the food supply, they should be labeled.¹³⁴

If product from cloned animals is allowed in the EU market only if they are labeled as such, then it is possible that a trade showdown with the U.S. would ensue that could be as lengthy and costly as the beef-hormone and biotech-food disputes. Complicating the dispute would be the heightened moral, ethical, and religious concerns with the cloning of animal products.

B. Nanotechnology

Defining nanotechnology is difficult. The term "nanotechnology" was first coined in a 1986 book by K. Eric Drexler titled, *Engines of Creation: the Coming Era of Nanotechnology*.¹³⁵ Nanotechnology is generally defined as the "ability to do things – measure, see, predict and make – on a scale of atoms and molecules," usually in the realm of 1-100 nanometers.¹³⁶ A nanometer is a billionth of meter and a sheet of paper is 100,000 nanometers thick.¹³⁷ It is this

¹³¹ See European Food Safety Authority, *Scientific Opinion on Food Safety, Animal Health and Welfare and Environmental Impact of Animal Derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals, Endorsed for Public Consultation on Dec. 19, 2007*, at http://www.efsa.eu.int/EFSA/Scientific_Opinion_op_ej767_animal_cloning_summary_en.pdf?ssbinary=true.

¹³² See World Food Regulation Review, European Union Final Opinion on Animal Cloning 6-7 (August 2008).

¹³³ See *id.*

¹³⁴ See The European Group on Ethics in Science and New Technologies to the European Commission, *Ethical Aspects of Animal Cloning for Food Supply*, (Jan. 16, 2008).

¹³⁵ K. ERIC DREXLER, *ENGINES OF CREATION: THE COMING ERA OF NANOTECHNOLOGY* (4th ed. 1994).

¹³⁶ Peter D. Hart, Research Associates, Inc., Report Findings, Woodrow Wilson International Center for Scholars for Project on Emerging Nanotechnologies (Sept. 19, 2006), 8, at <http://www.cst.gov.uk/cst/business/files/ww3.pdf>.

¹³⁷ National Nanotechnology Initiative, Frequently Asked Questions, <http://209.85.135.104/search?q=cache:xWWrtSiBisMJ:www.nano.gov/html/facts/faqs.html+nanometer+is+a+billionth+of+meter+and+a+human+hair+is+about+100,000+nanometers+in+width&hl=en&ct=clnk&cd=2>.

small size, even at the atomic level, coupled with an extremely high ratio of surface area to volume, that gives nanotechnology materials chemical, physical, or biological properties that are different from those of their larger counterparts.¹³⁸

These novel properties portend great potential for nanotechnology materials to be used in a variety of ways for food product. For example, intelligent packaging could forewarn a consumer if a product goes by its sell-date or has become contaminated.¹³⁹ Other applications concern the food directly, for example, where food ingredients are released only if and when the body is in need of them, such as vitamins in winter time.¹⁴⁰ In addition to the food industry, nanotechnology materials also promise novel application to a vast array of exciting products, such as pesticides, sunscreens, tennis balls, cosmetics, digital cameras, just to name a few.¹⁴¹ New nanotechnology products are coming on the market at the rate of three or four a week.¹⁴² The nanotechnology industry by some accounts is expected to grow to \$2.6 trillion in manufactured goods by the year 2014.¹⁴³ It is a technology that promises dramatic change.

Nanotechnology, like all emerging technologies, does have its detractors. Critics attribute much of the euphoria about nanotechnology to hype.¹⁴⁴ Whether nanotechnology will change the world's approach to food and everything else remains to be seen. Critics also worry about the application of nanotechnology. Concerns about nanotechnology are especially grave when it comes to the packaging and processing of food.¹⁴⁵ The driver for these concerns is ironically the same special properties of nanotechnology materials that hold such promise. These special properties are viewed as posing new and different risks for humans and the environment. It is not clear, for example, that the evidence used to assess the safety of larger materials

¹³⁸ Food and Drug Administration-Regulated Products Containing Nanotechnology Materials; Public Meeting, 71 Fed. Reg. 46232 (Aug. 11, 2006).

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ For a full range of product inventory incorporating nanotechnology compounds, *see* Project on Emerging Nanotechnology, Woodrow Wilson International Center for Scholars, A Nanotechnology Consumer Product Inventory, <http://www.nanotechproject.org/inventories/consumer/>. For the category of food and beverage products, specifically, *see* Project on Emerging Nanotechnology, Woodrow Wilson International Center for Scholars, Food and Beverage, http://www.nanotechproject.org/inventories/consumer/browse/categories/food_beverage/.

¹⁴² Project on Emerging Nanotechnology, Woodrow Wilson International Center for Scholars, News, New Nanotech Products Hitting the Market at the Rate of 3-4 Per Week, <http://www.nanotechproject.org/news/archive/6697/>.

¹⁴³ Letter from William L. Kovacs, Vice President, Environment, Technology and Regulatory Affairs, Chamber of Commerce of the USA (Nov. 10, 2006) (citing The Nanotech Report, 4th Edition, by Lux Research, Inc., 2006), at <http://www.uschamber.com/NR/rdonlyres/e6rxplrxhh72c4kue3i7vkscoe6m442s5krj5gmhcdbuy16y2nd3rltr6kbcmnxwu4vintt274kbzrab7aezq6pm5ah/110206tmCOMMENTSChambercommentstoFDAPetition.pdf>.

¹⁴⁴ *See generally*, DAVID M. BERUBE, NANO-HYPE, THE TRUTH BEHIND THE NANOTECHNOLOGY BUZZ (Jan. 2006).

¹⁴⁵ *Id.* at 366.

demonstrates the safety of the corresponding nanomaterials.¹⁴⁶ There is also the complexity of determining which nanomaterials are hazardous and which ones are not when engineering materials with precise nanoscale structures.¹⁴⁷ This again reinforces the point that “judgments about the safety of any particular engineered nanomaterial cannot be based either on the safety of larger-scale versions of the same material or on easy generalizations about nanomaterials as a class.”¹⁴⁸

It is not clear how the U.S. and the EU will regulate the application of nanotechnology to the food sector. In a report that has been presented in various venues, including the FDA, Michael R. Taylor, former general counsel to the FDA and Commissioner to the USDA’s Food Safety and Inspection Service, has warned that FDA is not prepared to regulate nanotechnology because it lacks the legal tools and resources necessary to deal with the complexities of nanotechnology.¹⁴⁹ Taylor suggests that the consequences of the FDA’s failure to adequately regulate nanotechnology are that the agency could miss a food safety problem and thereby trigger a public health crisis and dissipate public support.¹⁵⁰

Just as in the U.S., in the EU there is no encompassing review of the applicability of existing laws to nanotechnology in the food sector. The Commission of the European Communities (EC) has reviewed the regulatory landscape for nanotechnology and acknowledges regulatory gaps and shortcomings.¹⁵¹ The potentially conflicted regulatory objective of the EC is to protect public safety, health, and the environment and to ensure that innovation for the development of nanotechnology is not chilled.¹⁵² Possibly applicable is an EC directive on the classification, packaging, and labelling of dangerous substances, that defines “substances” as “all kinds of chemical elements and their compounds in the natural state or obtained by any production process”¹⁵³ Substances are classified as dangerous if they fit within any of the fifteen categories, including toxicity, harmfulness, and danger to the environment. There is a high probability that the EU’s Novel Food Regulation would apply.¹⁵⁴ Also, biotech food

¹⁴⁶ Michael R. Taylor, Woodrow Wilson Int’l Ctr. for Scholars, Project on Emerging Nanotechnologies, *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?* 16-17 (2006), at http://www.nanotechproject.org/process/assets/files/2705/110_pen5_fda.pdf

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *See id.* at 7.

¹⁵⁰ *See id.*

¹⁵¹ *See* Commission of the European Communities, *Nanosciences and Nanotechnology: An Action Plan for Europe 2005-2009* (2005).

¹⁵² *See id.*

¹⁵³ Council Directive 67/548/EEC, of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, 196 O.J. 16.8.1967, at 1.

¹⁵⁴ *Id.*

regulation may be a useful benchmark for predicting what EU law will become concerning nanotechnology, especially its application of the precautionary principle.¹⁵⁵ These directives in combination with the EU's precautionary principle and other related directives, may apply in varying degrees to nanotechnology.¹⁵⁶

A big question concerning nanotechnology is when to regulate? A concern is that nanotechnology will turn into another biotech food controversy, where the technology is too stigmatized by public opinion to be repaired. On the other hand, regulating now may be problematic in terms of making sure that the law is effectively regulating what it should be regulating. For now, it seems that nanotechnology is a moving target and regulators in the U.S. and EU are not sure which way to aim.

IV.

International Legal Issues

Given the backdrop of the international disputes of beef-hormone and biotech-food technologies, one can list a number of international law issues connected to the emerging technologies of animal cloning and nanotechnology.

Preliminary Issues

1. What are the definitions of animal cloning and nanotechnology?
2. What are the concerns connected to animal cloning and/or nanotechnology (food safety and security, animal welfare, animal rights, biodiversity, sustainability, public perception, social acceptability, consumer-right-to-know, slippery slope)?
3. What are the international institutions and instruments relevant to the regulation of animal cloning and nanotechnology?
4. Given that these technologies, especially nanotechnology, may evolve in a number of distinct phases, each progressing with its own legal, regulatory, societal, and political issues, should international standards be developed now or should they be delayed?
5. To what extent should animal cloning and nanotechnology be treated differently to existing scientific and commercial advances in related arenas (i.e., biotechnology)?
6. What are the lessons learned (successes and failures) in the international regulation of other food production technologies (i.e., beef hormones, biotechnology) that apply to animal cloning and nanotechnology?
7. Will the issues involved in these new technologies that encompass religious, science, moral, and ethical concerns, change the international regulatory paradigm for food safety and labeling?

Issues Underlying Application of SPS and TBT Agreements:

¹⁵⁵ See generally, Geert van Calster, *Regulating Nanotechnology in the European Union*, 3 *Nanotechnology L. & Bus.* 359 (2006).

¹⁵⁶ See *id.*

8. Would the SPS Agreement and the TBT Agreement apply to measures regulating trade in animal cloning and nanotechnology?
9. Which agreement – SPS (measures to protect humans, other animals, and plants from diseases, pests, toxins, and other contaminants) or TBT (food ingredient or labeling requirements, nutrition claims, quality attributes, animal welfare rules, and packaging regulations) – is more likely to apply to regulation of animal cloning and nanotechnology?
10. Would the SPS Agreement provide an objective balance between the risks and benefits of trading in nanotechnologies and cloned animals?
11. Will animal cloning and/or nanotechnology provide the next test of SPS rules (i.e., beef hormones, biotechnology)?
12. How would the effectiveness and flexibility of the SPS and TBT rules be tested by animal cloning and nanotechnologies?
13. Do the SPS and TBT agreements provide the foundation for developing transparent, science-based trade guidelines, as well as an effective framework for resolving disputes in the areas of animal cloning and/or nanotechnology?
14. Should the process/product distinction employed by the WTO SPS/TBT construct apply to animal cloning and/or nanotechnology?
15. Should and/or can the WTO and SPS/TBT construct respond to the political, ethical, and moral nuances raised in animal cloning and nanotechnology?

Overarching Value Issues:

16. Should the process of animal cloning or the process of nanotechnology lack conceptual significance, just as the process of genetic manipulation carries no significance under the “substantial equivalence” doctrine?
17. What should be the role of consumer concerns in connection with these emerging technologies in a world where consumers increasingly view themselves as purchasing not only products, but also shares of responsibility in the moral and ecological economy that produces them?
18. What will and should be the role of private standards in the international regulation of animal cloning and nanotechnology?
19. How should these emerging private standards be viewed within the context of the WTO SPS/TBT construct?
20. Will a sharp public divide over these emerging issues coupled by ignoring consumer concerns provide further impetus to legal pluralism in the global food sector, effectively bolstering the role of private standards at the expense of a vibrant public international food law scheme?

IV.

Conclusion

Will the emerging issues of animal cloning and nanotechnology in the global food system go the way of biotech foods and beef hormones? If not, how will issues affecting animal cloning and nanotechnology differ from the issues involved in the legal and policy controversies surrounding biotech foods and beef hormones? These questions help frame the list of

international legal issues that are raised specifically in this article concerning these new technologies. The debate over these questions will no doubt be as complex as the debate surrounding the conflicts of biotech foods and beef hormones. Whether the answers will be as slow in coming or as convoluted remains to be seen.