



***The European Strategy
to Become the New Global Standards-Setter***

A Compendium©

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I. Introduction / General Observations

- A. *Europe Employs 'Economic and Legal Soft Power' to Project its Regional 'Higher Level of Consumer Protection' Regulation and Standardization Model Globally*
- B. *Europe Has Quickly Converted EU Cultural Preferences into Global Industry Standards by Coordinating its Regional & International Regulation and Standardization Efforts*
- C. *Europe's International Regulatory/Standardization Strategy Looks Beyond Ensuring Product Safety as a Matter of 'Risk Prevention'; Emphasizes Need to View the Market in Terms of Hazard/ 'Precaution'*
- D. *Europe's International Regulatory/Standardization Strategy Aims, in Part, to 'Protect' European Industries' Economic Interests and Prevent a 'Prisoners' Dilemma'*
- E. *Europe Encourages 'Naming and Shaming' Public Pressure Campaigns By Civil Society to Influence Private Sector Supply-Chain Standards-Based Compliance With EU Sustainable Development Policies*

II. Examples of Successful European Regulatory and Standards-Based Market Access Barriers Imposed on U.S. Food Exports

- A. *The European Ban of Growth Hormone-Treated U.S. Beef*
- B. *The European Ban of U.S. Genetically Modified Food, Feed and Seed*
- C. *The European Ban of Growth Promoting Antibiotics Used in U.S. Cattle and Poultry Feed*
- D. *The European Ban of U.S. Poultry Treated with Low-Concentration Chlorine as an Antimicrobial Treatment*
- E. *The European Ban of U.S. Wines Produced With non-EU Oenological Practices and Using EU Semi-Generic Names of Geographic Origin*
- F. *The European Ban of U.S. Produce Containing Pesticides Exceeding 'Approved' Maximum Residue Levels (MRLs)*
- G. *The European Ban of U.S. Seafood*

III. Potential New European Sustainable Agriculture and Organic Farming Trade Barriers in the Making

- A. *European Cap Reform Inspires Sustainable Agriculture and Trade Regulation and Standardization Policy Initiatives*

IV. Examples of Third Countries Adopting EU-Type Bans of U.S. Farm Exports

- A. *China*
B. *Russia*
C. *Turkey*

V. Private Agricultural Standards as Potential Trade Barriers

- A. *EU Governance Mechanisms May Facilitate Development of Private Standards that Promote European Community Environmental, Health and 'Food Safety+' Policies*
B. *Organization for Economic Cooperation and Development (OECD) Review of Private Food Sector Standards*
C. *Food and Agriculture Organization (FAO) Review of Private Food Safety Standards in Livestock Sector*
D. *Codex Alimentarius Commission Review of Private 'Food Safety+' Standards*
E. *Private Industry Standards Are Being Developed for Maximum Pesticide Residue (MRL) Levels*

VI. Hypotheses About Why Europe Has Succeeded in Becoming the Global Standard-Setter

- A. *An Effective Three-Prong Trade Strategy to Export EU Regional Sustainable Development Regulations and Standards Globally*
B. *Effective Liberal Interpretation of GATT/WTO Treaty Rules to Alter the Relationship Between Trade and Non-Trade Law*

1. The EU has endeavored to Glean from GATT/WTO Case Law Justification to Liberally Interpret the 'Like or Similar' Products standard of GATT Article III.4 and TBT Article 2.1, such that food, feed, and seed products produced, processed, or otherwise formulated consistent

with or pursuant to preferred EU sustainable development-based standardized methods, procedures and/or criteria would NOT be deemed by EU consumers as ‘like or similar’ to U.S. products not otherwise subject to such EU regulatory or standards benchmarks, especially where human, animal and plant health risks such products might be engendered and/or where EU consumer tastes/preferences and perceptions regarding the different food, feed and seed processing and production, cultivation and stewardship methods are shaped by point-of-sale labeling detailing the distinct process and production methods (PPMs)) employed by non-EU producers (e.g., U.S. exporters) for livestock, seeds and the crop or grazing land (i.e., whether or not they are subject to EU ‘sustainability’, ‘green’ or ‘CSR’ verification and certification standards) such that those differences render the U.S. exported end-products distinct from other products in the EU marketplace.

a. GATT/WTO Case Law on ‘Like or Similar’ Products:

2. The EU has endeavored to glean from WTO case law justification to liberally interpret the scientific risk assessment requirements of the Sanitary and Phytosanitary (SPS) Agreement, so that greater weight is placed on the “relevant processes and production methods” and “relevant ecological and environmental conditions” factors articulated by WTO case law, when assessing potential human, animal or plant *Safety Risks* or potential related *Ecological and/or Environmental Risks* that might be engendered by food, feed and seed products that fail to adhere to European process and production, cultivation and product/land stewardship methods (PPMs) as required by EU ‘sustainability’, ‘green’ or ‘CSR’ regulations or verification and certification standards.

a. WTO SPS Agreement Case Law:

3. The EU has endeavored to glean from WTO case law justification to liberally interpret the ‘purpose’ of particular Food ‘Safety’ Traceability and/or Packaging and Labeling’ and/or Certification measures so that they qualify as *non-Food Safety* (Environmental) or *non-Safety Food* ‘Consumer Information or Preference/Taste’ measures and/or Food ‘Quality’ measures (*which can be either or both*), subject to the less rigorous (Non-scientific) risk assessment requirements of the Technical Barriers to Trade (TBT) Agreement or of the GATT, rather than as Food ‘Safety’-focused ‘Sanitary or Phytosanitary Measures’ within the meaning of Annex (A)(1) of the SPS Agreement, which are subject to strict Scientific Risk Assessment requirements and economic cost-benefit analysis. Alternatively, the EU has endeavored to craft regulations or delegate authority to craft standards in such a manner as to include both SPS and a non-SPS ‘requirements’, to avail the EU and its Member States of the less rigorous scientific and economic justification provisions of the TBT Agreement.

a. SPS vs. TBT Agreement – It’s All About the ‘Purpose(s)’ of the Measure:

b. Conflating Food ‘Safety’ With Food ‘Quality’ for Product Certification, Packaging and/or Labeling Purposes:

C. *Since the EU Has Not Often Been Able to Fully Exploit its '27:1' Voting Advantage vis-à-vis the United States for Purposes of Shaping International Food Safety Standards because of the Requirement of 'Consensus-based Decision-making' (Which Favors the U.S. at the WTO and the Codex), the EU May be Seeking to Alter Voting Rules at the WTO via Promotion of New 'Critical Mass Decision-making' Procedures, and at the Codex via Introduction of New Stakeholders into the Consensus Decision-making Process*

1. World Trade Organization (WTO):
2. Codex Alimentarius Commission (CAC):
3. United Nations Economic Commission for Europe (UNECE):
4. Organization for Economic Cooperation and Development (OECD):

D. *Various Intergovernmental and Nongovernmental Organizations Continue to Compete at the Codex to Influence the Development or Introduction of 'Food Safety+' Standards Which Reflect EU Regional 'Green' and 'Consumer Information'-based Sustainable Development/Agriculture Process and Production Methods*

1. UNECE. *[Effort to push through EU-centric regional fruits & vegetables 'food safety +' standards as international Codex standards]*
2. International Organization for Standardization (ISO). *[Effort to push through Codex private EU-centric 'food safety+' and import-export certification conformity assessment standards implementing existing Codex standards developed in technical committees and subcommittees in which the EU participates as a 'liaison']*
3. Organization for Economic Cooperation and Development (OECD). *[Effort to push through EU-centric 'food safety +' pesticide MRLs via 'OECD MRL calculator' to replace currently used 'NAFTA MRL calculator']*

E. *Europe Encourages and Promotes Public and Private 'Food Safety +' Standards that Elevate Regional 'Green' and Consumer Information-based Regional Organic and/or Sustainable Agriculture Process and Production Methods Internationally Without Granting Mutual Recognition to Comparable U.S. Standards*

VII. Conclusion: This Complex Non-Linear Challenge Transcends Traditional Analysis

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I. Introduction / General Observations

A. Europe Employs ‘Economic and Legal Soft Power’ to Project its ‘Higher Regional Level of Consumer Protection’ Regulation and Standardization Model Globally

1. Brandon Mitchener, *Standard Bearers: Increasingly, Rules of Global Economy Are Set in Brussels—to Farmers and Manufacturers, Satisfying EU Regulators Becomes a Crucial Concern—from Corn to SUV ‘Bull Bars,’* WALL ST. J. (Apr. 23, 2002), at A1 (emphasis added).

“Because of differing histories and attitudes toward government, the EU...with... the world’s second-largest economy, regulates more frequently and more rigorously than the U.S., especially when it comes to consumer protection. So, even though the American market is bigger, ***the EU, as the jurisdiction with tougher rules, tends to call the shots for the world’s farmers and manufacturers...EU rules often cause particular friction in the high-tech fields, such as software, electronic commerce and biotechnology.***”

2. Mark Schapiro, *Brussels, Big Time, CondeNast Traveler - Truth in Travel* (Aug. 2006) at pp. 106-113.

“[There is a] changing power dynamic between the European Union (EU) and the United States[...]As the EU evolves from what was primarily a free trade zone of fifteen member countries to a political organism of twenty-five countries with the teeth to back up its actions, the lure of the market – the most affluent in the world – has made Europe an economic and political superpower. The United States seems slowly to be waking up to the fact that big money is at stake.

...Already some American companies have run afoul of the EU’s anti-trust laws. General Electric’s proposed merger and expansion was blocked and Microsoft was fined \$500 million. ***US manufacturers are also facing the EU’s tough environmental health standards. For instance, America’s chemical industry is discovering that products cannot be exported to the Europe and the cosmetics industry is finding that many of its most popular ingredients are not considered safe by the EU.***”

“...[European Commission representative Robert Donkers]...explains the EU’s environmental policies to American industry and government representatives. This extraordinary job puts him at the fulcrum of a changing power dynamic between Europe and the United States...***Donkers’ job is to deliver the news: Either adapt to these standards or risk losing the European market, 450 million people.***”

...Donkers cuts into his filet d’agneau, pungent with red curry...‘You know’, he quips, pausing to sip a glass of the fine Bordeaux he selected with relish, ‘You’re either writing the menu, or you’re on it’. Over the past five years, Donkers has been a key figure in rewriting the environmental part of the metaphoric ‘menu’ of Europe’s regulatory policy.”

3. *EU ‘Is World’s Green Product Standard Setter’*, ENDS Europe (Jan. 11, 2007) (emphasis added).

“The EU is increasingly replacing the United States as the de facto setter of global product standards,” say Henrik Selin and Stacy VanDeveer of Brown University in the latest issue of the academic journal Environment. ‘The centre of much global regulatory standard-setting is shifting from Washington, DC to Brussels.’ Meanwhile Europe has also ‘taken over the role as the leader in chemical policy development’ after the field was led by the US in 1970s and 1980s. The EU’s lead is mainly down to its adoption of directives on electroscrap waste recycling and substance bans (WEEE and RoHS) and the new Reach chemical policy framework... *‘Regulatory standards set in Brussels can have significant implications for international production and trade,’ the authors say. Though all three laws are relatively new, they have already persuaded many multinational corporations to make all their production lines compliant - even in markets where the EU standards do not apply. They have also prompted other countries, particularly in Asia, to adopt similar laws... ‘The importance of WEEE, RoHS and Reach extends far beyond the EU border through processes of international economic integration and trade,’ the academics say.* They cite an American engineer’s claim that the RoHS law, which took effect last July, is ‘probably the biggest change in electronics in 50 years’. In other observations *the authors say they expect the EU to continue efforts to ‘upload’ its product and chemicals standards into international agreements.* They also note that US firms have been unable to wield significant power in EU policy-making circles, citing their failure to influence Reach despite ‘extensive’ lobbying.”

4. Tobias Buck, *Standard Bearer: How the European Union Exports Its Laws*, FIN. TIMES (July 10, 2007) at p.9 (emphasis added).

Sometimes voluntarily, sometimes through gritted teeth and sometimes without knowing, countries around the world are importing the EU’s rules. It is a trend that has sparked concerns among foreign business leaders and that irritates US policymakers. But *whether they like it or not, rice farmers in India, mobile phone users in Bahrain, makers of cigarette lighters in China, chemicals producers in the US, accountants in Japan and software companies in California have all found that their commercial lives are shaped by decisions taken in the EU capital.*

...
The EU’s emergence as a global rulemaker has been driven by a number of factors, but none more important than the sheer size and regulatory sophistication of the Union’s home market... At the same time, the drive to create a borderless pan-European market for goods, services, capital and labour has triggered a hugely ambitious programme of regulatory and legislative convergence among national regimes. This exercise has left the Union with a body of law running to almost 95,000 pages—a set of rules and regulations that covers virtually all aspects of economic life Compared with other jurisdictions, the EU’s rules tend to be stricter, especially where product safety, consumer protection and environmental and health requirements are concerned. Companies that produce their goods to the EU’s standards can therefore assume that their products can be marketed everywhere else as well.

As...two US-based academics[] point out in a recent paper that examines the global impact of three recent EU laws on chemicals, electronic waste and hazardous substances: *‘The EU is increasingly replacing the United States as the defacto setter of global product standards and the centre of much global regulatory standard setting is shifting from Washington DC to Brussels’.*”

5. *Brussels Rules OK; How the European Union Is Becoming the World’s Chief Regulator*, ECONOMIST (Sept. 20, 2007) at p. 68 (emphasis added).

“Brussels is becoming the world’s regulatory capital. The European Union’s drive to set standards has many causes—and a protectionist impulse within some governments (e.g., France’s) may be one. But though the EU is a big market, with almost half a billion consumers, neither size, nor zeal, nor sneaky protectionism explains why it is usurping America’s role as a source of global standards. A better answer lies in transatlantic philosophical differences. The American model turns on cost-benefit analysis, with regulators weighing the effects of new rules on jobs and growth, as well as testing the significance of any risks. Companies enjoy a presumption of innocence for their products: should this prove mistaken, punishment is provided by the market (and a barrage of lawsuits). The European model rests more on the “precautionary principle,” which underpins most environmental and health directives. This calls for pre-emptive action if scientists spot a credible hazard, even before the level of risk can be measured. Such a principle sparks many transatlantic disputes: over genetically modified organisms or climate change, for example. In Europe corporate innocence is not assumed. Indeed, a vast slab of EU laws evaluating the safety of tens of thousands of chemicals, known as REACH, reverses the burden of proof, asking industry to demonstrate that substances are harmless. Some Eurocrats suggest that the philosophical gap reflects the American constitutional tradition that everything is allowed unless it is forbidden, against the Napoleonic tradition codifying what the state allows and banning everything else.

...One American official says flatly that the EU is “winning” the regulatory race, adding: ‘And there is a sense that that is their precise intent.’ He cites a speech by the trade commissioner, Peter Mandelson, claiming that the export of “our rules and standards around the world” was one source of European power. Noting that EU regulations are often written with the help of European incumbents, the official also claims that precaution can cloak “plain old-fashioned protectionism in disguise.”

B. Europe Has Quickly Converted EU Cultural Preferences into Global Industry Standards by Coordinating its Regional & International Regulation and Standardization Efforts

1. European Policy Principles on International Standardization, Commission Staff Working Paper SEC(2001) 1296, at pars. 9, 26 (July 26, 2001) (emphasis added).

“Generally, regional or national standards should be aligned to the greatest possible extent to international standards, but the value of national and regional standards as stepping-stones to international standardisation should also be recognised. It is also be considered helpful to have explanations from authorities for deviations from international standards as foreseen under the WTO TBT Agreement.

...Co-operative arrangements with international standards bodies offer a systematic framework to take over international standards and/or to contribute to the international standards making process.”

2. Implementing Policy for External Trade in the Fields of Standards and Conformity Assessment: A Tool Box of Instruments, Commission of the European Communities, Commission Staff Working Paper, SEC (2001) 1570 (Sept. 28, 2001), at pp. 5 and 8 (emphasis added).

“[T]he adoption overseas [by EU trading partners] of standards and regulatory approaches based on, or compatible with...European practices [is necessary] in order to improve the market access and competitiveness of European products...Developments in the Community’s legal framework have

propelled the EU towards improving the effectiveness of regulatory authorities in protecting an ever-increasing number of public policy interests such as health and safety, the environment, and consumer interests. In this respect, it is worth mentioning...the recent Commission Communication on the *precautionary principle*, where the Commission considers that the principle *has a scope to cover measures for protection of human, animal and plant health in addition to environmental aspects*".

3. Commission Marks World Standards Day With Focus on Environment and Standards, European Commission Press Release (IP/01/1408) (Oct. 12, 2001) (emphasis added).

"Pursuing environmental improvements through standards is also a top priority for the European Union... 'Doing business in the Single Market has become so much easier with European standards', says [former] Enterprise Commissioner Erkki Liikanen in charge of standardization policy. In the global market place Europe is in a very strong position because it has linked European standardization as closely as possible to international standardisation'... 'It is clear that standards are an important part of today's global society', Margot Wallstrom, [former] Commissioner for the Environment added. 'Standardisation is one way of working with the market to put the idea of environmental protection into practice'...Standards can play a crucial role from the design of products, through manufacturing and packaging to the end-of-life phase, including re-use, recycling and waste management.

...Quality and safety issues have long interested private experts who work together in standardization organizations. With the increasing use of standards, which is also linked to European legislation, other stakeholders such as consumer representatives have started to join in recent years. 'Today, the challenge before us is to ensure that environmental considerations are taken fully into account in the standards making process. This is why the Commission has put considerable emphasis on the full involvement of all relevant interested parties in the standards development process', says Mr. Liikanen.

... 'It is an important responsibility for the experts that develop standards to consider the environmental dimension on the same level as quality, safety and health', says Mrs. Wallstrom."

4. New Standards Guidelines for Europe, European Committee for Standardisation (CEN) Press Release (March 28, 2003) (emphasis added).

"European standardization policy has been brought up to date today as the result of the adoption of new guidelines between the European Commission (EC), the European Free Trade Association (EFTA), and the three official European Standards Organizations (ESOs).

... The guidelines replace the previous version established in November 1984, which laid down for the first time a common political understanding of the conditions under which the EC and the then two ESOs, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), would co-operate. Equivalent guidelines were signed between these ESOs and EFTA in 1985. Since then, many changes have taken place in Europe and beyond, economically, technologically, at a regulatory level and in standardization itself.

As an example, the creation of the European Telecommunications Standards Institute (ETSI) in 1988 contributed significantly to the restructuring of the European standardization process that was already under way (ETSI subsequently received official recognition as an ESO alongside CEN and CENELEC in

the EC Directive 98/34/EEC). This process has become increasingly open to all interested parties and considerably more responsive to the very tight timescales of today's technological developments, and the demands for technical quality. *As a result, European standardization is now extremely dynamic: for instance, over the last ten years the number of European Standards available has risen from 2000 to more than 14000 – and the number continues to grow by more than 1000 annually.*

These figures illustrate *the huge demand from industry in all sectors for standards that help ensure products and services are safe, fit for their purpose and compatible. European standards provide a powerful means of enhancing the competitiveness of companies in Europe and creating the single European market. This success also ensures Europe a very powerful position in world-wide standardization.*

The progressive widening of European policy since the original guidelines were first drawn up has created a role for standards in support of issues such as safety in the workplace, and protection of consumers and the environment. The new guidelines also recognize the EC/EFTA "New Approach", under which standards provide technical solutions for presumption of conformity with legal requirements: *the guidelines thus include a mutual commitment to use standardization to support legislation.*

These developments in policy have, in turn, encouraged wider participation in European standards-making by non-governmental economic and social interest groups, and has generated greater openness of the European standard-setting process. As a result, all sectors of society now benefit greatly from this efficient and well-structured European standardization framework, based upon the three independent ESOs..."

5. *Vademecum on European Standardisation*, Part IV - European Standardisation in the International Context, Chapter 1 - Strategy for the international promotion of standards, European Commission Working Document, Enterprise DG Standardisation Unit (Nov. 15, 2003) (emphasis added).

VII. It may be beneficial to channel standards, specifications and other deliverables that have reached a certain consensus outside international standards bodies into the international standardisation process. *Fairly balanced co-operative arrangements with international standards bodies offer a systematic framework to take over international standards and/or to contribute to the international standards making process.* The Vienna and Dresden Agreements between ISO and CEN, respectively the IEC and CENELEC are useful examples how to enable for input, to avoid double work or to speed up standardisation work. In this regard, *it is important to ensure that the maintenance of the international standard is considered first with the international standards body who may decide whether or not to delegate the maintenance responsibility to the originating body.* VIII. *The Community generally supports, in line with its political objectives, the development of a (preferably regional) infrastructure for standardisation. This would facilitate greatly the establishment of international standards since it would permit a reduction of "players".* The EC also promotes the creation of legal and economic conditions which facilitate trade and which are receptive to the use of voluntary consensus standards.

6. *Pascal Lamy, Co-existence Between Public Policy and Free Trade: Can We Achieve Good Protectionism?*, Conference of the Greens/European Free Alliance at the European Parliament, Brussels (5 March 2004) (emphasis added).

“Our dispute with the United States over its extra tariffs on steel...[which] were clearly designed to protect an uncompetitive industry...[should be contrasted with]...[o]ur refusal to import genetically-modified maize or soya that we have not authorized...[The latter]...is not protecting a European industry (we do import soya and maize that are not genetically modified) but reflects our society’s highly precautionary preference in this area...[W]e must be careful to make the distinction between protectionism, which means discriminating between imported and domestic products in a way that favours the latter, thus protecting domestic manufacturers, and the legitimate protection of social choices.

...Public policy is the expression of a particular country's social choices. Increasingly, trade in goods and services embodies these choices, making international trade today the point at which different collective preference systems intersect. These systems reflect the values of a given society, and in the EU's case they have been democratically defined in consultation with civil society and parliaments, giving them a solid legitimacy. *Public opinion in our countries – not as averse to globalisation as is sometimes claimed – is nevertheless highly aware of the potential dangers, and unequivocally insists that our social choices, and our public policies, must be preserved.* It is up to us to heed what they are saying.

...The WTO system is...an international instrument that should enable States to go on opening up their markets while still retaining the capacity to make public policy choices. It is up to us to help the system adapt as trade itself evolves...So what should be the relationship between the WTO's essentially commercial raison d'être, however open to a measure of collective preference, and rules set forth in other fora such as the ILO, UNEP or the multilateral environmental agreements (MEAs)? We need to improve the compatibility of the trade and non-trade elements and ensure they mesh more closely, as the report just brought out by the Commission under the ILO's aegis suggests.

Finally, let us imagine for a moment what might happen *if WTO members enjoyed an untrammelled right to adopt any measure they pleased, however unfair, unreasonable or unrelated to any agreed international framework. That would set us on a very dangerous road towards blinkered, selfish protectionism. That would not be “good protectionism”* at all, and the fact that we and other WTO members have spent 50 years building a system within which we renounce our freedom to follow such policies is, I submit, no bad thing”.

7. Bruce Stokes, *New Trade Barriers: National Preferences*, National Journal (April 24, 2004) (emphasis added).

“International commerce once comprised mainly of value-free economic transactions involving largely interchangeable commodities and manufactured products. Now, it increasingly involves trade in goods and services that are often laden with ‘ideological content,’ according to a [November 2003] European Union discussion paper, ‘The Emergence of Collective Preferences in International Trade’...In other words, Americans would argue that the trade in genetically modified foods, for example, should be affected only by the scientific facts, whereas Europeans would argue that the whole idea of such modifications makes them queasy...It is perceived threats to such collective preferences that drive much of the anti-globalization movement today. Indeed, the greatest challenge facing the international trade policy community in the years ahead, predicted E.U. Trade Commissioner Pascal Lamy in a

March 5 speech in Brussels, may be ‘how we can organize market-opening in such a way as to uphold the varying collective preferences of different societies.’”

8. European standards - International activities, European Commission Enterprise and Industry website (last referenced on Nov. 10, 2010) (emphasis added).

“It may be beneficial to channel standards, specifications and other deliverables into the international standardisation process that have reached a certain consensus outside international standards bodies. Co-operative arrangements with international standards bodies offer a systematic framework to take over international standards and/or to contribute to the international standards making process. The Vienna and Dresden Agreements between International Organisation for Standardisation (ISO) and the European Committee for Standardisation (CEN), respectively the International Electrotechnical Commission (IEC) and the European Committee for Electrotechnical Standardization (CENELEC) are useful examples how to enable for input, to avoid double work or to speed up standardisation work. In this regard, it is important to ensure that the maintenance of the international standard is considered first with the international standards body who may decide whether or not to delegate the maintenance responsibility to the originating body.”

C. Europe’s International Regulatory/Standardization Strategy Looks Beyond Ensuring Product Safety as a Matter of ‘Risk Prevention’; Emphasizes Need to View the Market in Terms of Hazard/ ‘Precaution’

1. Jeremy Rifkin, *A Precautionary Tale: The EU plans new regulations for scientific risk-taking, based on the principle of sustainable development. US big business is furious*, The UK Guardian (May 24, 2004) (emphasis added).

“Chances are that most people have never heard of ‘the precautionary principle’. This relatively new term is the most radical idea for rethinking humanity's relationship to the natural world since the 18th-century European Enlightenment. Its potential impact is already being felt within the business community and the halls of government, with profound implications for all of us.

Recently, a congressional committee released emails between the United States and Europe about the future of scientific research, technology innovation and entrepreneurial risk-taking. At issue is a proposed EU directive that would force companies to prove chemical products introduced into the marketplace are safe before being granted permission to market them. Existing laws allow most chemical-based products to be introduced without prior assurances by the company of their safety. The result is that 99% of the total chemicals sold in Europe have not passed through any environmental and health testing review process.

Under the proposed EU standards, companies would be required to register and test for the safety of more than 30,000 chemicals at an estimated cost of nearly €6bn (£4bn) to the industry. The new proposed standard is called Reach - registration, evaluation and authorisation of chemicals. The American chemical industry is furious.

...What's at stake here goes far beyond the chemical industry. The EU is attempting to establish a radical new approach to science and technology based on the principle of sustainable development and global stewardship of the Earth's environment.

In November 2002, the EU commission adopted a communication on the use of what it calls the "precautionary principle" in the regulation of science and technology innovation and the introduction of new products into the marketplace. *The precautionary principle is designed to allow government authorities to respond pre-emptively, as well as after damage is inflicted, with a lower threshold of scientific certainty than has been the rule of thumb in the past. "Scientific certainty" has been tempered by the notion of "reasonable grounds for concern".* The precautionary principle gives government the flexibility to respond to events in real time, so that potential adverse impacts can be forestalled or reduced while the suspected causes of the harm are being evaluated.

At the heart of the precautionary principle is a radical divergence in the way Europe has come to perceive risks compared to the US. In Europe, intellectuals are increasingly debating the question of the great shift from a risk-taking age to a risk-prevention era. That debate is virtually non-existent among American intellectuals. Risks of all kinds are now global in scale, open-ended in duration, incalculable in their consequences, and not compensational. Acid rain, the tear in the Earth's ozone layer, and the spread of virtual and biological viruses, are among the new genre of man-made threats. No one can escape their potential effects. When everyone is vulnerable, and all can be lost, then traditional notions of calculating and pooling risks become virtually meaningless. This is what European academics call a risk society.

The EU hopes that by integrating the precautionary principle into international treaties and multilateral agreements, it will become the unchallenged standard by which governments oversee and regulate science and technology. While the US has integrated aspects of the precautionary principle into some of its environmental regulations, for the most part its standards are far more lax than the EU's, though better than many countries. *But the US views Europe's tightening regulatory regime as a noose around US exports and is determined to thwart its efforts. America's National Foreign Trade Council warned that the EU's invocation of the precautionary principle 'has effectively banned US and other non-EU exports of products deemed hazardous' and stifled scientific and industrial innovation.'*

The precautionary principle is deeply at odds with the traditional Enlightenment idea about science. Risk taking is at the heart of modern science. To attempt to put limits on scientific pursuits, in lieu of greater certainty about their potential impacts on the environment, is, some scientists say, tantamount to squelching our very notion of progress...The old Enlightenment science is too primitive to address a world where the bar for risk has been raised to the threshold of possible extinction itself. When the whole world is at risk because of the scale of human intervention, then a new scientific approach is required that takes the whole world into consideration."

2. *Jeremy Rifkin, The European Dream: The new Europe has its own cultural vision -- and it may be better than ours, UTNE Reader (Sept./Oct. 2004) (emphasis added).*

"Though historians seldom allude to it, the American Dream is largely a European creation transported to American soil and frozen in time. The American Dream was born in the early modern era -- a period that saw the flowering of the individual, the development of a sophisticated private property regime, the invention of market capitalism, and the creation of the nation-state. The Protestant

Reformation and the Enlightenment idea of science as the relentless pursuit and exploitation of nature's secrets had begun to take hold in Europe. *While much of Europe eventually tempered its religious fervor, its scientific zeal, and its enthusiasm for unbridled market capitalism, preferring a compromise in the form of democratic socialism, America did not. Instead, successive generations chose to live out those older traditions in their purest forms, making us the most devoutly Protestant people on Earth and the most committed to scientific pursuits, private property, capitalism, and the nation-state.*

That difference is reflected in the American and European Dreams, which at their core are about two diametrically opposed ideas about freedom and security. For Americans, freedom has long been associated with autonomy. An autonomous person is not dependent on others or vulnerable to circumstances beyond his or her control. To be autonomous one needs to be propertied. The more wealth one amasses, the more independent one is in the world. One is free by becoming self-reliant and an island unto oneself. With wealth comes exclusivity, and with exclusivity comes security.

The new European Dream is based on different assumptions about what constitutes freedom and security. For Europeans, freedom is found not in autonomy but in embeddedness. To be free is to have access to many interdependent relationships. The more communities one has access to, the more options one has for living a full and meaningful life. It is inclusivity that brings security -- belonging, not belongings.

...Europe has articulated a new vision for the future that differs from our own in fundamental ways. These basic differences are crucial to understanding the dynamic that has begun to unfold between the early 21st century's two great superpowers.

...Europe's newly emerging dream is already threatening to create a schism with the United States in a number of areas.

...The growing divisiveness between the American and European dreams manifests itself in other ways. For instance, the U.S. government gave the green light to genetically modified foods in the mid-1990s, and by the end of the decade over half of America's agricultural land was given over to GM crops. No new laws were enacted to govern the potential harmful effects. With its commitment to the precautionary principle and reining in high-risk scientific enterprise, in the name of sustainable development and environmental protection, Europe responded quite differently. Massive opposition to GM crops led to a de facto moratorium and tough new EU protections covering this technology.

...The unexamined optimism that has been so characteristic of the American spirit has not always served us well. In a world of increasing global threats, tempered enthusiasm balanced against a realistic assessment of risks might be more appropriate.”

3. Jeremy Rifkin, *The European Dream: Building Sustainable Development in a Globally Connected World*, EMagazine (March-April 2005) (emphasis added).

In recent years, the European Union (EU) has turned upside down the standard operating procedure for introducing new technologies and products into the marketplace and society, much to the consternation of the United States. The turnaround started with the controversy over genetically engineered (GE) foods and the introduction of genetically modified organisms (GMOs)...The EU embarked on a lengthy review process to assess the environmental and health risks of introducing GE food products. In the end, it established tough new protections designed to mitigate the potential harm.

The measures included procedures to segregate and track GE grain and food products from the fields to the retail stores to ensure against contamination; labeling of GMOs at every stage of the food process to ensure transparency; and independent testing as well as more rigorous testing requirements by the companies producing GE seeds and other GMOs.

The EU is forging ahead on a wide regulatory front, changing the very conditions and terms by which new scientific and technological pursuits and products are introduced into the marketplace and the environment. Its bold initiatives put the EU far ahead of the rest of the world. Behind all of its newfound regulatory zeal is the looming question of how best to model global risks and create a sustainable and transparent approach to economic development.

In May of 2003, the EU proposed sweeping new regulatory controls on chemicals to mitigate toxic impacts on the environment and human and animal health. The proposed new law would require new companies to register and test for the safety of more than 30,000 chemicals at an estimated cost to the producers of nearly eight billion Euros... The “REACH” system—which stands for Registration, Evaluation and Authorization of Chemicals—requires the companies to conduct safety and environmental tests to prove that the products they are producing are safe. If they can’t, the products will be banned from the market.

The new procedures represent an about face to the way the chemical industry is regulated in the U.S. In America, new chemicals are generally assessed to be safe and the burden is primarily put on the consumer, the public or the government to prove that they cause harm. The EU has reversed the burden of proof. Former EU Environmental Commissioner Margot Wallstrom makes the point: ‘*No longer do public authorities need to prove they [the products] are dangerous. The onus is now on industry to prove that the products are safe.*’

...GMOs and chemical products represent just part of the new “risk prevention” agenda taking shape in Brussels. In early 2003, the EU adopted a new rule prohibiting electronics manufacturers from selling products in the EU that contain mercury, lead and other heavy metals. Another new regulation requires the manufacturers of all consumer electronics and household appliances to cover the costs for recycling their products. American companies complain that compliance with the new regulations will cost them hundreds of millions of dollars a year.

All of these strict new rules governing risk prevention would come as a shock to Americans who believe that the U.S. has the most vigilant regulatory oversight regime in the world for governing risks to the environment and public health. Although that was the case 30 years ago, it no longer is today.

The EU is the first governing institution in history to emphasize human responsibilities to the global environment as a centerpiece of its political vision. Europe’s new sensitivity to global risks has led it to champion the Kyoto Protocol on climate change, the Biodiversity Treaty, the Chemical Weapons Convention and many others. The U.S. government has refused, to date, to ratify any of the above agreements.

...In Europe, intellectuals are increasingly debating the question of the great shift from a risk-taking age to a risk-prevention era. That debate is virtually non-existent in the U.S., where risk-taking is seen as a virtue. ***The new European intellectuals argue that vulnerability is the underbelly of risks. A sense of vulnerability can motivate people to band together in common cause.*** The EU stands as a testimonial to collective political engagement arising from a sense of risk and shared vulnerability.

... The EU has already institutionalized a litmus test that cuts to the core of the differences between America and Europe. It's called "the precautionary principle" and it has become the centerpiece of EU regulatory policy governing science and technology in a globalizing world... n November 2002, the EU adopted a new policy on the use of the precautionary principle to regulate science and new products derived from technology innovations. *According to the EU, reviews occur in "cases where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU."* The key term is "uncertain." *When there is sufficient evidence to suggest a potential negative impact, but not enough to know for sure, the precautionary principle allows regulatory authorities to err on the side of safety. They can suspend the activity altogether, modify it, employ alternative scenarios, monitor the activity or create experimental protocols to better understand its effects. The precautionary principle allows governments to respond with a lower threshold of scientific certainty than in the past. "Scientific certainty" has been tempered by the notion of "reasonable grounds for concern."* The precautionary principle gives authorities the flexibility to respond to events in real time, either before or while they are unfolding...The precautionary principle has been finding its way into international treaties and covenants. It was first recognized in 1982 when the United Nations General Assembly incorporated it into the World Charter for Nature. The precautionary principle was subsequently included in the Rio Declaration on Environment and Development in 1992, the Framework Convention on Climate Change in 1992, the Treaty on EU (Maastricht Treaty) in 1992, the Cartagena Protocol on Biosafety in 2000 and the Stockholm Convention on Persistent Organic Pollutants (POPs) in 2001."

D. Europe's International Regulatory/Standardization Strategy Aims, in Part, to 'Protect' European Industries' Economic Interests and Prevent a 'Prisoners' Dilemma'

1. Lawrence A. Kogan, 'Unscientific 'Precaution': Europe's Campaign to Erect New Foreign Trade Barriers, Washington Legal Foundation WORKING PAPER Series No. 118 (Sept. 2003), at pp. 5-6 and fn 14, paraphrasing David Vogel, *Environmental Regulation and Economic Integration*, Presentation prepared for a Workshop on Regulatory Competition and Economic Integration: Comparative Perspectives, Yale Center for Environmental Law and Policy (October 1999), at pp. 23-25.

“'[G]reen' countries may seek to export their strict environmental standards to other jurisdictions for several reasons. Not only might such countries (e.g., the EU and its Member States) perceive economic and environmental benefits from doing so, but they may also fear that by not doing so they may trigger a 'prisoner's dilemma' for their own industries. In other words, green countries may believe that their industry could be left at a competitive disadvantage if they did not press other jurisdictions (which, left to their own devices would not be likely) to adopt such strict standards.

2. Andrew Jordan and Timothy O'Riordan, *The Precautionary Principle in Contemporary Environmental Policy and Politics, Paper delivered to the Wingspread Conference, Racine, Wisconsin, (Jan. 23-25, 1998) (emphasis added).*

“Initially precaution was [used] by German authorities in the early 1980’s to justify unilateral application of technology based standards to reduce acid rain. But once in place, *the Germans pressed the EU to adopt similar standards across the rest of Europe, to prevent its own industries being placed at a competitive disadvantage.* This was not enlightened environmentalism at work but the dictates of a competitive market of member states...‘The policy debate was more dominated by competitive considerations rather than environmental concerns...’ The *precautionary principle therefore helped to lay the conceptual and legal basis for a proactive environmental policy, which once spread into Europe, was also directed at ensuring ‘burden sharing’ in order that German industry did not lose its competitive edge, but rather gain new markets for its environment-friendly technology and products*” (emphasis added).

3. David Vogel, *Environmental Regulation and Economic Integration*, Prepared for a Workshop on Regulatory Competition and Economic Integration: Comparative Perspectives, Yale Center for Environmental Law and Policy (October 1999), at pp. 8-9, 10-11 (emphasis added).

“...*Some regulations create a competitive advantage for domestic producers by making it more difficult for foreign producers to sell their products. In fact, knowing or anticipating that the burdens of compliance will fall disproportionately on their international competitors may make domestic producers more willing to support stricter regulations than they would have in the absence of foreign competition.* Examples of alliances between environmentalists and domestic producers abound. For example, *the recycling requirements enacted by Denmark and the Canadian province of Ontario have both disadvantaged foreign beer producers while improving environmental quality. The strict automobile emission controls requirements supported by German environmentalists during the 1980’s protected the domestic market share of German automobile companies, since it was more difficult for French and Italian firms to comply with them.*

...*[F]oreign producers in nations with weaker domestic standards...are forced...to design products that meet those standards, since otherwise they will be denied access to its markets. This, in turn, encourages those producers to make the investments required to produce these new products as efficiently as possible. Moreover, having made these initial investments, they now have a stake in encouraging their home markets to strengthen the standards in part because their exports are already meeting them...[T]he relationship between product standards that disadvantage importers and those which prompt exporters to strengthen their own standards in order to maintain market access must be understood in dynamic terms.* The environmental regulatory agenda is a highly fluid one. In some cases, these may create only a temporary source of competitive advantage until other nations have adopted them, while in other cases this advantage may prove more enduring. But the result is similar: economic integration can promote the ratcheting upward of regulatory standards”

4. Jeremy Wall, *European Commission Views on Mutual Recognition Opportunities – A DG Enterprise View of Mutual Recognition Between SFM Certification Schemes in the Forestry Sector*, at p. 4 (June 7-26, 2000) (emphasis added).

“...EU forests are for their most part well managed, engendering higher costs to forest owners and to wood buyers, but no market advantage is accrued over competitors, many of whom do not always bear the full costs of SFM [sustainable forest management]. *Thus a key recommendation of the study [of the*

competitiveness of the European Union woodworking industries was to ‘export EU environmental (and social standards), in other words, to promote the raising of forest management standards world-wide – which is good for forests – and thereby enhance competitiveness – which is good for [EU] forest-based industries’.

5. European Business Position on the ‘White Paper on the Strategy for a Future Chemicals Policy, Eurochambres (Sept. 2001), at p. 6 (emphasis added).

“There must be a ‘level playing field’ for chemicals (particularly imported chemicals) as constituents of finished products (e.g., toys, textiles). Substances with potential impact on human health or environment imported to the EU as constituents of products must not be exempt from notification. Controls must be in place to ensure that finished products imported to the EU do not contain untested and unregistered substances. This should ensure that EU manufacturers remain competitive with finished products from outside the EU”.

6. Henning Christophersen, Some Aspects of Agricultural Trade – The Case of the European Poultry Industry, II Conference With Representatives from the European Civil Society, Business Community & Academic Community on EU-Mercosur & the EU-Chile Association Negotiations (Feb. 12, 2002) (emphasis added).

“Our view in A.V.E.C...concerning the EU-Mercosur negotiations is, given the current state of play, that the disadvantages for European poultry producers outweigh the advantages of a free trade agreement...If trade in poultry meat is liberalised, the EU poultry producers as well as its suppliers (animal feed, cereal) will be subject to fierce competition, which will be difficult to fend off...The Commission has indicated that whereas a liberalisation of trade cannot be achieved without detrimental effects on the the main interests of EU agriculture, the sensitivity of agricultural products, such as poultry meat, will be taken into consideration. I take the liberty of proposing some measures, which could ensure that the EU poultry industry’s interests are taken into consideration and that consumer safety is not jeopardized...First of all the EU should carry out a wide benchmarking exercise in the Mercosur countries in all the relevant fields (e.g., food safety, animal welfare, veterinary inspections, hygienic requirements) to compare the performance between these countries and the EU. For instance, the Commission is in the process of establishing minimum standards for animal welfare on the basis of information from third countries...Secondly, we should only introduce a greater liberalization of the poultry market through progressive concessions within preferential tariff quotas, to the extent these exports comply with requirements pertaining to food safety, animal welfare, hygiene and environment. It is important that written declarations are made and control mechanisms (export certification programmes) introduced to verify compliance. In situations of doubt, the EU should apply the precautionary principle...Thirdly, we should ensure that imported poultry products are clearly and indelibly labelled providing the EU consumers with sufficient information about the origin of the product, the characteristics of the product, ingredients, etc...”

7. EU Chemicals Policy Review – The View of European Mid-Sized and SME Chemical Manufacturers, CEFIC (the European Chemical Industry Council) (Nov. 28, 2002), at p. 4 (emphasis added).

*“The chemical industry is truly global. The EU industry needs a level playing field with the rest of the world in order to compete. There is not support for amending legislation in the USA or Asia, who are our main competitors, to take a parallel approach to REACH. There, REACH imposes a cost for chemicals testing and registration which our non-EU competitors will not have to bear. **WTO rules and administrative practicalities prevent EU legislation from banning the import of finished articles containing non-registered substances...It is essential that a solution compatible with WTO rules be found to create a level playing field between EU producers of both substances and finished articles, and non-EU manufacturers of the same finished articles who are excluded from the requirements of the REACH system”.***

8. Regulation of the European Parliament and of the Council, Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency and Amending Directive 1999/45/EC and Regulation (EC) on {Persistent Organic Pollutants}, European Commission Staff Working Paper, [Draft] Extended Impact Assessment {COM (2003) 644 final}, SEC (2003) 1171/3 (10/29/03), at pp. 22-23 (emphasis added).

*“As far as exports are concerned, there will be a potential risk of some loss of market share if prices of domestically produced chemicals are forced up due to REACH. **This namely holds for cases where competitors exist on third markets that totally neglect the important European market.** Indeed, it would be only these companies that would completely escape the REACH legislation and its testing and registration requirements and costs associated to this...**In the longer run, the balance of impacts on competitiveness on these third markets as well as on the European market will also depend on the extent to which the REACH regime is successful in establishing itself as a new international standard. This would give the EU chemicals industry a substantial boost in terms of international competitiveness”.***

9. Arthur D. Little, *New Proposals for Chemicals Policy: Effects on the Competitiveness of the Chemical Industry* - (Project EP/IV/A/2003/07/03-2), Study for the Directorate General for Research, (April 2004) (emphasis added).

*“The review of existing studies and the estimate on a European level shows that burdens by the new legislation on chemicals in Europe will potentially affect the Chemical Industry in a dramatic manner...Costs will burden mainly price-sensitive products. **Changes in time to market, duty of authorization and duty for disclosure are issues which touch the innovative power of the European chemical industry...Industry does not expect an immediate innovative push. For this to happen, global implementation of the EU substances policy would be a fundamental prerequisite.** In such a situation, all products would be manufactured under comparable conditions and every producer would be confronted with the effects of the new substances policy. Through this equal pressure on all competitors, the producer with the most innovative product would have a competitive advantage and so there would be an incentive for innovation. **However, as long as the global environment is not comparable and producers can manufacture their products outside Europe under easier conditions, then this hoped-for positive effect of an innovative push will tend to be transformed instead into the negative effect of a production loss...The fundamental aim of European legislation must be to achieve practical reform of the EU substances policy and so minimize the negative consequences for German industry”.***

10. Kym Anderson, Richard Damania and Lee Ann Jackson, *Trade, Standards and the Political Economy of Genetically Modified Food*, World Bank Development Research Group, World Bank Policy Research Working Paper 3395 (Sept. 2004), at pp. 3-4 (emphasis added).

“Our results suggest that heightened domestic consumer or environmentalist opposition to GM crops is not the only reason why there has been a moratorium on the production and sale of GM foods in regions like the EU. Rather, differences in comparative advantage in the adoption of GM crops may be sufficient to explain the trans-Atlantic difference in GM policies. On the one hand, it is rational for producers in the EU (whose relatively small farms would enjoy less gains from the new biotechnology than broad-acre American farms) to reject GM technologies if that enables them, with the help of consumer and environmental lobbyists, to argue for restraints on imports from GM-adopting countries...When faced with a more efficient competitor, the optimal response of farmers in countries with a comparative disadvantage in GM adoption is to lobby for (or at least not resist) more-stringent GM standards...”

E. Europe Encourages ‘Naming and Shaming’ Public Pressure Campaigns By Civil Society to Influence Private Sector Supply-Chain Standards-Based Compliance With EU Sustainable Development Policies

1. Palitha T.B. Kohona, *Implementing Global Environmental Standards: The Emerging Role of the Non-State Sector*, EIL Journal (Nov. 2004) (emphasis added).

“In particular, European Community directives and legislation in individual countries have played a major role in influencing the attitudes of private sector corporations. In some instances, corporations have responded to public pressure even in the absence of legislative rules. Increasingly, such legislation is being enforced, sometimes through action undertaken by civil society. Noncompliance with environmental legislation could lead to costly litigation and adverse publicity which corporations would very much like to avoid. Compliance with environmental standards also makes them less susceptible to public criticism...Not only would these assist in avoiding conflict with legal requirements in the target markets, it would help to avoid damaging protests by vigilant civil society groups.

...The reasons for the gradual conversion of the decision makers of some private sector institutions to adopting environmental friendly policy approaches are interesting given their traditional focus on profits and the obsession with year end bonuses. *The message that civil society groups and academics have been preaching for some time, that non-compliance with global environmental standards carries financially negative consequences, may be getting through finally. In fact, non-compliance with global environmental standards may actually result in the loss of profits and bonuses and this has been a powerful element in focusing the minds of those making critical corporate decisions.*

...The continuing pressure exerted by civil society lobby groups has had a significant impact. Groups such as Greenpeace, WWF, Rainforest Action Network (RAN) and Sierra have continued to highlight corporate shortcomings and attract public attention to these. The naming and shaming approach adopted by such pressure groups has had a critical impact in some cases. It could be assumed that the

negative publicity would harm not only the image of a company, but also its earnings. *Television images of prominent individuals cutting up their credit cards issued by Citibank at the instigation of RAN may have had an impact on this bank's decision to enter into a 'common understanding of key global sustainable development issues'*. Home Depot changed its wood sourcing policies following a campaign carried out by environmental groups including RAN.”

2. Lawrence A. Kogan, *Precautionary Preference: How Europe Employs Disguised Protectionism to Weaken American Free Enterprise*, International Journal of Economic Development (IJED), Vol. 7 No. 2-3 at pp. 241-242 (see also thru p. 264) (2005) (emphasis added).

“Whether U.S. small and medium-sized businesses export their U.S. manufactures to Europe, source and import their products from China, or are engaged exclusively in a domestic business, they are all likely to be affected by global supply chain management programs. These programs, which incorporate the precautionary principle, are being promoted by the EU Commission and prominent international environmental groups such as Greenpeace, Friends of the Earth, the World Wildlife Fund, the Natural Resources Defense Council, the Basel Action Network, the Rainforest Action Network, and the Sierra Club. In addition, these programs are championed by corporate governance and corporate social responsibility groups such as Business for Social Responsibility, Prince of Wales Business Leaders’ Forum, and the World Business Council for Sustainable Development, and the Rose Foundation.

Indeed, the EU institutions and these civil society groups have a symbiotic relationship. Pursuant to one or more alternative EU governance instruments, such as co-regulation or self-regulation, *Brussels financially underwrites, facilitates and promotes many environmental and corporate accountability campaigns that are consistent with and effectively implement EU policy frameworks. And, precaution-based regulations and product standards increasingly reflect the political influence wielded by such groups within the European Parliament and Commission* and now the International Organization for Standardization (ISO). These groups, together with international labor groups such as the International Labor Organization (ILO) and the Fair Labor Association in the United States, have continued to wage campaigns of intimidation (‘naming and shaming’) against U.S. multinationals and their key suppliers, in order to shape public opinion against them. *And, as these groups have become better recognized within the growing global civil society, their role and influence within the United Nations’ programs and agencies and national governments has expanded commensurately.*”

II. Examples of Successful European Regulatory and Standards-Based Market Access Barriers Imposed on U.S. Food Exports

“U.S. agricultural exports to the EU in calendar year 2009 totaled \$7.46 billion with tree nuts the largest category at \$1.28 billion followed by soybeans and products at \$1.0 billion. Fruits, vegetables and juices were the third largest at \$822 million and wine and beer at \$386 million was the fourth largest. The top six items were rounded out by tobacco at \$370 million and planting seeds at \$287 million. Red meat exports were \$239 million and poultry meat \$146 million. Wheat was the largest grain export at \$157 million.”

Ross Korves, *EU Agriculture and Trade Policy in the Midst of Financial Turmoil*, Truth About Trade and Technology (April 20, 2010) (emphasis added).

A. The European Ban of Growth Hormone-Treated U.S. Beef

1. R. W. Stephany, *Hormone Residue Testing: An Update in Research and Approaches*, National Institute of Public Health and the Environment, The Netherlands (Oct. 2001); R.W. Stephany, *Hormones in Meat? Are Only Natural! Laboratory for Residue Analysis (ARO), National Institute of Public Health and the Environment (RIVM), the Netherlands* (emphasis added).

“...[T]here is no such thing as hormone-free meat and...the meat of animals which have been treated with anabolics in an expert and controlled manner contains hardly any more hormones than are found naturally. Under these conditions there is no risk to the consumer”

2. Lawrence A. Kogan, *Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science*, National Foreign Trade Council, Inc. (May 2003), at pp. 10-11 and accompanying notes (emphasis added).

“The EU continues to ban (for more than ten years) U.S. beef exports derived from growth hormone-treated cattle notwithstanding a WTO panel’s decision, subsequently upheld [in 1998] by the WTO Appellate Body in the EC-Hormones case, holding that such measures lacked a ‘scientific justification’ (there was no scientific evidence of health risk and no scientific risk assessment had been performed) and were thus inconsistent with EU’s obligations under the SPS Agreement. The ban also continues despite the U.S. imposition of 100% retaliatory tariffs on \$116 million of EU agricultural products from mostly France, Germany, Italy, and Denmark, countries deemed the biggest supporters of the ban.”

3. Lawrence A. Kogan, *The Precautionary Principle and WTO Law: Divergent Views toward the Role of Science in Accessing and Managing Risk*, 77 Seton Hall Journal of Diplomacy and International Relations (Winter/Spring 2004) at pp. 81, 97 and accompanying endnotes (emphasis added).

“Since 1988, the EU has implemented a total ban to use any hormone growth promoters in livestock production. The EU has argued that six hormones—oestradiol-17-beta, progesterone, testosterone, zeranol, trenbolone, and melengestrol acetate—may potentially cause cancer in humans. In the United States, to the contrary, use of five of these hormones is legally permitted (17 beta-estradiol, testosterone, progesterone, trenbolone and zeranol)...In December 2002, the EU permanently banned the use of oestradiol-17-B, a growth-promoting hormone widely used in the United States, which was determined by the U.S. Food and Drug Administration to pose no health risk to consumers. The EU has since presented the results of new studies that it says are based on scientific evidence showing that the six hormones pose a significant risk to public health. The U.S. and Canadian governments have continued to reject these results as not presenting any new scientific evidence to support the EU ban. During October 2003, the EU reported that it had amended its ban, ‘in a way that should satisfy both the complainants (the United States and Canada) and the WTO,’ and that therefore, ‘the United States and Canada should lift their trade sanctions against the EU.’ The EU has refused to lift its amended ban, insisting

that it “was now fully backed up by scientific evidence proving the risks and dangers of the hormones that are widely used in North American beef production.”

4. Markus Böckenförde, *Hormone Ban in Dispute Again: The WTO Refuses to Reject Either the EC Ban or Canadian/US Trade Sanctions*, 12 ASIL Insight International Economic Law Edition, American Society of International Law (Dec. 18, 2008) (emphasis added).

“The [WTO Appellate Body] AB report resolves one of the puzzles of the WTO’s Dispute Settlement Understanding (DSU): What to do when the WTO Dispute Settlement Body (DSB) has authorized sanctions against the trade of a Member found to have failed to implement DSB recommendations, the Member then adopts an implementing measure, and the original complainant does not believe that the measure brings the implementing Member into compliance? The AB rejected the EC’s argument that sanctions had to cease when the EC unilaterally asserted compliance by notifying its new Directive. It clarified that sanctions under the DSU may continue until there is a multilateral dispute settlement finding that substantive compliance has occurred. ***The AB also rejected the panel’s conclusion that the new EC Directive was still noncompliant, and found numerous errors in the panel’s analysis of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).***

...The AB also made lengthy findings...reversing the Panel’s findings that the directive violates SPS Articles 5.1 and 5.7. It found that the panel misinterpreted these provisions, misallocated the burden of proof, conducted a de novo review of the science incompatible with the proper standard of review, and mishandled its consultation with scientific experts. As the AB was unable to complete its analysis on the basis of the existing factual record, it found that the prior DSB recommendations and rulings in the Hormones case remain operative. It recommended that the DSB request all parties to initiate Article 21.5 proceedings without delay to resolve their disagreement about compliance and about the legal validity of continued sanctions.

5. EU Prepares WTO Action Over US Trade Sanctions Law, European Delegation to the United States of America, Press Release EU NR 05/09 (Jan. 15, 2009) (emphasis added).

“Today, in a clear attempt to escalate the EU-US hormones dispute, the outgoing US administration has decided to suspend the so called “carousel” trade sanctions legislation and thereby allow the US to revise, every six months, the list of goods subject to sanction. It is more punitive than the current measure, which imposes duties of 100 percent on certain products. The value of the sanctions amounts to 116.8 million euros on a fixed list of goods. It is clear that exporters will face increased uncertainty as their goods could be subject to tough duties at short notice. The trade implications of this measure will be significant.”

6. EU and US Reach Provisional Agreement in Beef Dispute, Europa Press Release IP/09/707 (May 6, 2009) (emphasis added).

“Today EU Trade Commissioner Catherine Ashton and United States Trade Representative Ron Kirk agreed in principle on a way forward in the long-running dispute over hormone-treated beef. They issued the following statement after the call: ‘Following a very good discussion today, we have reached

an understanding that provides a pragmatic way forward in the long-running beef dispute. An agreement is in our mutual interest, and we will now discuss this with our respective stakeholders and constituencies in an effort to finalize it as soon as possible. Reaching an agreement on this issue will be a clear sign of our commitment to working through -- and, where possible, resolving -- the bilateral disputes in our trade relationship. We will continue our close cooperation on other outstanding issues in the future.'

Details of the agreement Under the terms of the agreement, *the U.S. would agree not to impose new so-called 'Carousel' sanctions* which were due to come into force this week and would affect a range of EU products including Italian mineral water, *Roquefort cheese* and a number of other food products. *The U.S. would maintain the currently reduced level of existing sanctions against EU products* (68% or USD 79 million lower), *and would eliminate all sanctions beginning in the fourth year of the agreement. In return, the agreement would provide additional duty-free access to the EU market for the type of high quality beef traditionally exported by the U.S. and produced from cattle that have not been treated with growth-promoting hormones.* The agreement would provide additional duty-free access for 20,000 tons of beef in the first three years, increasing to 45,000 tons beginning in the fourth year. Before the end of the four-year period, the two sides will seek to agree on the conditions for the settlement applicable beyond that period.

...The US and Canada rejected the evidence underpinning the 2003 Hormones directive and maintained their sanctions. In 2004 the EU challenged these sanctions. *In November 2008, the Appellate Body ruled that it was unable to complete the analysis of the WTO-compatibility of the EU legislation due to mistakes made by the Panel in gathering factual information, and consequently did not give a definitive view on the legality of the US and Canadian sanctions. It did however clarify certain aspects of the SPS agreement.* Furthermore, it recommended that the EU, US and Canada start compliance proceedings to see if the current EU legislation remedied the breaches of WTO had identified in 1998, and as a result the US and Canada should end their sanctions. Following that recommendation, *on 22 December 2008 the EU asked for consultations at the WTO in order to examine the legality of the EU restrictions on hormone-treated beef.*'

7. Teri Schultz, *Is the US Getting a Raw Deal?*, Global Post (May 7, 2009) (emphasis added).

“The European Union and the United States have agreed to take a breather in a decades-long transatlantic trade tiff. The two sides struck a temporary deal lowering Europe's trade barriers on U.S. beef and America's on some of the EU's most notable exports, such as Roquefort cheese...The truce has been a long time coming. Since the 1980s, the EU has been blocking meat from U.S. cattle fattened with growth hormones, which EU health authorities say pose health risks and can even cause cancer, in the case of one of the hormone estradiol 17...Now, the U.S. will maintain the existing sanctions on European products, which are much lower than the maximum allowed under the WTO decision, but will remove them after three years. For its part, the EU will allow 20,000 more tons of hormone-free beef into its market duty-free for the next three years and an extra 45,000 tons the fourth year. Both sides agree not to seek WTO mediation on the hormone-treated beef ban for at least 18 months and to try to find a longer-term settlement within four years.”

B. The European Ban of Genetically Modified Food, Feed and Seed

1. Peter Pringle, The U.S.-European Biotechnology Initiative, Workshop 3: Segregation, Traceability and Labeling of GM Crops; An Interpretative Summary of a Transatlantic Conversation About Biotechnology and Agriculture, The German Marshall Fund of the United States (April 29, 2002), at pp. 3-8.

“[T]hree workshops previously organized by the German Marshall Fund’s U.S.-European Biotechnology Initiative to discuss U.S. and EU views toward biotechnology explains a great deal about EU reliance upon the precautionary principle. An interpretative summary of this last dialogue (prepared by a European) is extremely revealing. “The EC official stressed that *the political purpose of the European rules [about GMOs] was indeed to restore consumer confidence...‘Anything less than the regulations now being proposed would not restore consumer confidence and GM crops in Europe could fail’...One NGO representative was quoted as saying that, ‘Why can’t the Americans understand that this is not specifically about health and safety and labels and traceability; it’s a rebellion against industrial agriculture. We need to be talking about the emergence of new ways of farming which take social and environmental concerns into account, not just GMOs’...An important factor often omitted from the U.S. interpretation of the European conundrum is concern over the Americanization of European agricultural practices and food habits. This concern embodies dislike and fear of globalization in general...As one European...said, ‘There is a difference in what we want our countries to look like, not only with food but with all that goes with it.’ This ‘way of life’ statement echoed similar thoughts...one European said, ‘GM food was a concrete thing that gave us the feeling that the world was going to change radically with respect to food, control of food, and ultimately democracy’...The European consumer attitude to GMOs has evolved, not out of one or two big events such as growth hormones or ‘mad cow’ disease, but for many reasons that traverse the interdisciplinary spectrum of politics, science, economics, culture and social ethics.”*

2. Lawrence A. Kogan, Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science, National Foreign Trade Council, Inc. (May 2003), at pp. 19-20 and accompanying notes (emphasis added).

“*Since October 1998, the EU has both facilitated and failed to resolve an EU-wide moratorium on any new approval of genetically engineered products. This de facto ban, which resulted from a breakdown in the EU approval process for GMO products, has halted \$300 million in U.S. corn shipments and threatens trade in soya as well. Dairy products derived from livestock fed GMO feed, such as eggs or beef, are also at risk, as are flour and flour-based exports, such as soy protein concentrate, grain-based products, vegetable oil derived from soy beans, and pet food products derived from any of the above.* There are 18 biotech food products approved for import by the EU and 13 more applications pending. As a result, ‘food processors and exporters are either reformulating or seeking non-biotech sources’...*The EU Member State ban on GM products has been precipitated by environmentalist forces that have stoked consumer fears about the ‘safety’ of GM foods. These forces have argued that, because not all of the long-term effects of GM foods on health and the environment are known, they pose an unascertainable, and consequently, an unacceptable risk of harm to human health and environment...* The moratorium on GMOs effectively began at the Member State level during the spring of 1998, and since that time, ‘no new GMOs have been authorized for planting or use in the EU.’”

3. Lawrence A. Kogan, *WTO Ruling on Biotech Foods Addresses 'Precautionary Principle'*, Washington Legal Foundation Backgrounder Vol. 21 No. 38, at pp. 1-2 (Dec. 8, 2006) (emphasis added).

“On September 29, 2006, the World Trade Organization (‘WTO’) released its final decision in the longstanding dispute between the United States and Europe over the regulation of genetically modified (‘GM’ or, ‘biotech’) food and seed. The WTO Dispute Resolution Panel found that because the European Community (‘EC’) and several European Union member states had acted primarily out of *political* rather than *scientific* concerns to justify their trade-restrictive food safety measures, they clearly violated the tightly drafted provisions of the WTO Sanitary and Phytosanitary (‘SPS’) Agreement. ***This decision is significant because it clarifies the central role of science in evaluating the presence of health and environmental risks prior to the adoption of national food safety regulations not otherwise based on relevant international standards...In its decision, European Communities – Measures Affecting the Approval and Marketing of Biotech Products (hereinafter ‘EC Biotech Products’),¹ the Panel reaffirmed that WTO member countries concerned about the safety of specific biotech food-related imports must follow the specific terms of the WTO SPS Agreement.*** Pursuant to the SPS Agreement, countries may restrict imports of certain products in order to safeguard human or animal health, or to protect the environment, provided the regulations they enact either are in accordance with existing relevant international standards, or are narrowly drafted in order to protect against a genuine ascertainable risk, as determined by the application of best available science. ***This most recent WTO Panel decision makes clear that in the absence of relevant international standards, or a national government’s refusal to adopt them, a concerned WTO member bears the burden of conducting an objective, empirically-based scientific risk assessment.*** And this must be done *before* a WTO member promulgates regulations that have the effect of denying or restricting market access to those products.”

4. *Right to National GMO Bans Upheld: European Commission Defeated*, Friends of the Earth Europe Press Statement (March 2, 2009) (emphasis added).

“***Today, the European Commission was defeated in its latest attempt to force two countries to drop bans on controversial genetically modified maize. It was the second and third time that Hungary and Austria respectively had come under attack by the European Commission for refusing to grow GM maize.*** Friends of the Earth has welcomed the vote...Under EU GMO laws, countries are allowed to ban individual GM crops for environmental and health reasons...***European Environment Ministers concluded last December that GMO risk assessment in the EU is not fulfilling legal requirements, that long term impacts are not been assessed, and that crops such as those being voted on today should also be assessed under EU pesticide laws because of the toxin they release.*** The European Commission’s proposal to lift the bans completely disregarded this recent agreement.”

5. *Cison Di Valmarino, Germany Sees No EU Legal Action on GMO Ban*, Reuters (April 18, 2009) (emphasis added).

“***Germany does not expect the European Commission to seek to stop its ban on cultivation and sale of genetically modified (GMO) maize*, German Agriculture and Consumer Protection Minister said. ***But it does expect a legal action from U.S. biotech company Monsanto (MON.N) whose MON 810 maize will be affected by the ban which was announced this week***, Ilse Aigner told reporters on the sidelines of the**

farm ministers meeting in northern Italy. *'I do not think that the EU Commission is going to start legal proceedings now...they hinted at the fact that they are not going to do so,' Aigner said via an interpreter. 'But we are expecting legal proceedings from Monsanto,' she said without giving more details. Germany's decision contradicts the European Union rulings that the biotech grain is safe* and the EU Commission, the bloc's executive arm, said on Tuesday it would examine the German move. Monsanto has said it would consider legal options to enable GMO seeds to be planted for this year's harvest, if the ban was confirmed."

6. Tom Levitt, *GM-free Europe: How We Could Still Ban GMOs*, Ecologist (Oct. 21, 2009) (emphasis added).

"[U]nder proposals being put forward by the Netherlands, the objections of other member states to approving new varieties of GM may soon be bypassed. ***Once a particular GM crop has received EU health and safety approval, the Dutch want the final decision on whether to allow the crop to be cultivated to be left to individual member states: effectively, a re-nationalisation of GM policy. Member states can already block GM by invoking a so-called 'safeguard clause'. Under this rule they can ban the use and sale of a GMO if they have justifiable reasons to consider that it poses a risk to human health or the environment. Austria, France, Greece, Hungary, Germany and Luxembourg have all used the clause in recent years.*** GM-free Europe On the face of it the Dutch proposals go further by allowing individual countries to ban crops for social and economic reasons and not just health ones. ***It would allow a country to declare itself GM-free and bring an end to the current EU regulatory pressure to accept transgenic crops.*** Many regions in Italy and Germany are already declaring themselves GM-free. Only last week Ireland said it would ban all GM crop cultivation and the Welsh Assembly has had a long-standing policy against GM."

7. Brent Patterson, *NEWS: European Commission Seeks to End GMO Ban*, rabble.ca (July 15, 2010) (emphasis added).

"...*'The European Commission recommended sweeping new changes to the European Union's policy on the cultivation of genetically modified organisms (GMOs) on Tuesday, unveiling a proposal to grant individual member states the right to decide for themselves whether to allow their domestic farmers to grow the altered crops.'* ***The proposed 'amendment would not give countries the right to ban imports of GM products or to prohibit the marketing of those seeds within their borders'*** and has raised the concern that 'the European Commission would lean on EU member states to approve GM seeds at the bloc level' ... 'Before it can become law, the amendment will have to win the approval of both the European Parliament and a qualified majority of EU member states.' That said, Austria, Bulgaria, Germany, Greece, Hungary, Ireland and Luxembourg have banned the cultivation of GM seeds, while other countries including the Czech Republic, the Netherlands and the United Kingdom appear more open to GMO crops."

8. Doug Palmer, *U.S. Farmers Urge Sanctions Against EU's GM Crop Ban*, Reuters (July 28, 2010) (emphasis added).

“The largest U.S. farm group has urged the Obama administration to begin steps towards imposing sanctions on the European Union in a longrunning dispute over the EU's treatment of genetically modified crops. The American Farm Bureau Federation, in comments given to the administration on Monday, complained the EU still has not complied with a 2006 World Trade Organization ruling against its ‘de facto’ moratorium on approving new varieties of biotech crops for sale in the 27-nation bloc. ‘The inability of the EU to operate a timely and predictable regulatory process ended U.S. corn exports (to the EU) in 1998 and has reduced corn byproducts substantially,’ the Farm Bureau said in its recommendations for President Barack Obama's National Export Initiative. ‘If the EU does not immediately begin to make timely, science-based regulatory decisions on pending and future applications, soybean exports also are at serious risk,’ the farm group said. ‘USTR should initiate a retaliation proceeding against the EU to force compliance with the WTO ruling on GMOs (genetically-modified organisms),’ the group said...U.S. farmers have widely embraced genetically modified crops, which offer higher yields with reduced pesticides. But the technology is viewed with suspicion by many European consumers because of perceived safety concerns. The United States first challenged the EU's de facto moratorium and other policies that impeded sales of U.S. genetically modified crops at the WTO in 2003 and was joined by Canada and Argentina. The WTO's 2006 ruling largely backed the complaint brought by the three countries, who argued the EU was failing to apply its own scientific approval procedures to GM products. Since then, the United States has agreed at least twice to give the EU more time to comply with the ruling.”

9. *USTR Kirk Flags Problems With EU GMO Cultivation Policy On New Bans, World Trade Online (7/30/10) (emphasis added).*

*“U.S. Trade Representative Ron Kirk this week criticized the European Commission's new proposal to make it easier for member states to ban the cultivation of genetically modified organisms (GMOs) for reasons other than health and safety as being contrary to a predictable approval system based on science...The U.S. officials made clear that, in the U.S. view, the cultivation proposal does not appear to be consistent with the EU's stated goal of a science-based approach on GMO approvals, sources said. U.S. officials also asked detailed questions to better understand the details of the cultivation proposal, sources said...Kirk said he is ‘greatly encouraged’ by the fact that Dalli has publicly committed to a more transparent, science-based approval process on GMOs. **Dalli emphasized** the Commission's commitment to a science-based approach when unveiling the new GMO cultivation proposal. He did so when some members of the European Parliament pressed him on whether there was a trade-off between giving member states more power to ban a GMO for cultivation and getting easier approvals for GMO applications in return. He also said **the Commission is focused on strengthening the science-based elements of the EU GMO approval process by beefing up the environmental impact assessment of the European Food Safety Authority (EFSA)**, which will happen before the end of the year. **Dalli's proposal to give EU member states more leeway to restrict or ban GMO cultivation has one element that will go into effect immediately and a second one that will likely take years to implement. The first part is a new set of Commission guidelines on coexistence of GMO and non-GMO crops, which are not legally binding on member states. The second part will involve adding a new paragraph to Directive 2001/18 governing the release of GMOs into the environment, and this must be approved by the Council of Ministers and Parliament before taking effect...The proposal has no direct GMO trade implications except possibly for GMO seeds, which the U.S. does not now export to the EU. But critics say it could call into question the principle of the EU single market, which functions by all member states agreeing to the same set of rules.** Major EU members, including France and Germany, have responded critically to the GMO cultivation proposal, sources said. Asked to respond to a request by the*

American Farm Bureau Federation that the U.S. take the first step toward retaliation against the EU for failure to implement an earlier World Trade Organization that faulted the EU GMO approval process for undue delays, Kirk made it clear he prefers negotiation to litigation.”

C. **The European Ban of Growth Promoting Antibiotics Used in U.S. Cattle and Poultry Feed**

1. *Council and Parliament Prohibit Antibiotics as Growth Promoters: Commissioner Byrne Welcomes Adoption of Regulation on Feed Additives*, EU Institutions Press Releases, IP/03/1058 (July 22, 2003) (emphasis added).

Since 1997, the EU has banned five animal growth-promoting antibiotics administered in cattle feed on the basis of the precautionary principle. They include avoparcin, bacitracin, spiramycin, tylosin, and virginiamycin. Instead it has advocated therapeutic administration of antibiotics to individual heads of cattle to treat specific infections. During July 2003, the European Parliament and Council adopted a new regulation that “will strengthen the EU’s rules on the safety of animal feed and complete the EU ban on the use of antibiotics as growth promoters...Banning the use of antibiotics as growth promoters in feed is also vital to efforts to combat anti-microbial resistance. The Regulation will come into force later this year...”

2. *Mark Casell, Christian Friis, Enric Marco, et al., The European Ban on Growth-Promoting Antibiotics and Emerging Consequences for Human and Animal Health*, *Journal of Antimicrobial Chemotherapy* (July 2003) 52, pp. 159–161 (emphasis added).

“Experience in Sweden had already shown that the bans might have adverse consequences for animal health and welfare, and economic consequences [from reduced animal production] for farmers. There were also suggestions that human health is unlikely to benefit and that it might even be adversely affected...The driving forces behind these bans were consumer and political opinion, and a scientific concern that resistance in selected animals might be transmitted to humans to the detriment of their health. The efforts and expenditure involved in the imposition of the ban would have been better spent on achieving rational antibiotic use in humans and animals, and on much greater efforts to understand the complex epidemiology of resistant pathogens and resistance genes, as well as adequate risk assessments of both the ban, the ‘precaution,’ in parallel with the ‘threat,’ i.e., the continued use of growth promoters.”

3. *Ian Phillips, Mark Casewell, Tony Cox, et al., Does the Use of Antibiotics in Food Animals Pose a Risk to Human Health? A Critical View of Published Data*, *Journal of Antimicrobial Chemotherapy* (Sept. 2003) at p. 17 (emphasis added).

“Essentially antibiotics are used if they are known to be effective for their indicated purpose. They must cure or prevent infection, or in the case of growth promotion, must have a significant effect on food conversion parameters, and thereby improve the economic return to the animal producer, and they should not harm the animal...Almost every case made for or against antibiotics used in animals is complicated by the use of the same antibiotics in humans, which are equally able to give rise to resistance...What

has not happened in 50 years of antibiotic use in animals and man seems unlikely to happen at a rapid rate now. The banning of any antibiotic usage in animals based on the 'precautionary principle' in the absence of a full quantitative risk assessment is likely to be wasted at best and even harmful, both to animal and to human health".

4. Anna Wilde Mathews, *FDA Announces Policy Designed To Curb Animal-Antibiotics Use,*" Wall Street Journal (Oct. 24, 2003) p.A6 (emphasis added).

"[During October 2003,] the US Food and Drug Administration (FDA) announced a new review procedure designed to curb the use of animal antibiotics that may pose a risk to human health...Many countries, researchers and some in Congress have argued that the practice aggravates the problem of antibiotic-resistant bacteria and the practice should be halted...The European Union has stopped the use of many animal antibiotics for growth promotion...U.S. law forces [the agency] to look at products individually. 'We think it is far better to look at the real risk...instead of just disallowing a category of uses,' said Lester Crawford, deputy FDA commissioner...In its reviews, the agency will assess several different factors in deciding the risks to humans. One will be the likelihood that the drug could promote resistant bacteria in the animals that take it. The second major factor is the likelihood that humans would ingest the resistant bacteria. The third would weigh the chances that the exposure of people to the bacteria would have an effect on human health..."

5. *EU Imposes Total Ban on Use of Antibiotics in Animal Feed,* Red Orbit (Dec. 23, 2005) (emphasis added).

"The European Union (EU) will impose a complete ban on the use of antibiotics as growth promoters in animal feed as from Jan. 1, 2006. The last four antibiotics which have been permitted as feed additives to help fatten livestock will no longer be allowed to be marketed or used from this date, said the European Commission on Thursday. The ban is the final step in the phasing out of antibiotics used for non-medicinal purposes. It has already banned antibiotics used in human medicine from being added to animal feed. The total ban is part of the commission's overall strategy to tackle the emergence of bacteria and other microbes resistant to antibiotics, due to their over exploitation or misuse, said the commission, the executive body of the European Union (EU). 'This ban on antibiotics as growth promoters is of great importance, not only as part of the EU's food safety strategy, but also when considering public health,' said Markos Kyprianou, EU commissioner for health and consumer protection. 'We need to greatly reduce the non-essential use of antibiotics if we are to effectively address the problem of micro-organisms becoming resistant to treatments that we have relied on for years. Animal feed is the first step in the food chain, and so a good place to take action in trying to meet this objective.'"

6. John Wallace, *Plants and Plant Extracts to Replace Growth-Promoting Antibiotics in Farm Livestock Production,* KnowledgeScotland (Sept. 1, 2010) (emphasis added).

"Antibiotics were used as growth promoters in poultry, pig and ruminant livestock production for more than 40 years before their ban by the European Commission at the beginning of 2006. The ban followed one well documented instance in which a transmissible antibiotic resistance factor that

originated in livestock receiving a relatively new growth-promoting antibiotic (GPA) found its way into a human pathogen. Thus, human infection caused by this pathogen would no longer be treatable by vancomycin, one of the most potent antibiotics remaining in the clinician's armoury. While there is no suggestion that other GPA could compromise human health in this way, *the Commission responded to strong consumer pressure and banned all GPA, thus lessening the environmental load of widespread antibiotic use as well as eliminating specific health risks. Other nations, including those in North America, took a more pragmatic view, however, banning only those GPA where risk was identified. As a consequence, EU livestock producers could be considered to be at a competitive disadvantage compared with those other nations. Improved management practices can compensate at least partially for the absence of GPA. The Scandinavian countries, which banned GPA many years before the EU-wide ban was imposed, have pioneered the management approach. Alternative feed additives might provide a suitable alternative in less readily managed livestock systems. Among the most promising category of replacements is plant extracts.* Several projects led by scientists at RINH have explored the potential of the plant kingdom as 'feed additives' rather than simply for their nutrient content."

D. The European Ban of U.S. Poultry Treated With Low-Concentration Chlorine as an Antimicrobial Treatment

1. Processed Foods and Beverages: A Description of Tariff and Non-Tariff Barriers for Major Products and Their Impact on Trade U.S. International Trade Commission Report ('USITC Report'), Vol. 1: Executive Summary and Chapters 1-15, Report on Investigation No. 332-421 under section 332(g) of the Tariff Act of 1930 (Publ. 3455, Oct. 2001), at p. xvii (emphasis added).

"[T]he use of chlorinated water...which is the primary means employed in the U.S. to meet strict U.S. standards designed to ensure the safety of poultry products from microbial contamination...was rejected [by the EU]..."

2. Lawrence A. Kogan, Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science, National Foreign Trade Council, Inc. (May 2003), at pp. 11-12 and accompanying notes (emphasis added).

"[The EU has] continue[d] to prohibit the use of antimicrobial treatments (AMT) in poultry production to prevent transmission of bacteria such as salmonella [since 1997], despite the publication of an EU study which recommended that antimicrobial treatments, other than chlorination, could be used as part of an overall strategy for pathogen control throughout the production chain. The inconsistency of this ban with the terms of the SPS Agreement has become more apparent since recent European Commission audits uncovered that Member States are not complying with the EU ban on the domestic use of chlorinated water. These practices continue despite the existence of the 1999 U.S.-EU Veterinary Equivalence Agreement, which was designed to make trading in various livestock products, including poultry products, less restrictive."

3. Jane Byrne, EU Proposal to Allow Chicken Imports Faces Opposition, FOODProductiondaily.com (May 30, 2008) (emphasis added).

“A European Commission proposal announced this week to lift a ban on chicken imports rinsed with chemicals has been met with opposition by MEPs. The EU ban, in place since 1997, has effectively stopped all imports of US poultry meat, which is generally treated by a chemical process. The Commission's decision will have to be ratified or rejected in the coming weeks by the Standing Committee on Food Chain and Animal Health (SCoFAH). The EU's food safety regulator, the European Food Safety Authority (EFSA), recently adopted an opinion dismissing risks from treating poultry carcasses with chlorinated water. Threat to EU standards MEPs, speaking in the Parliament's Environment Committee, said the chlorination of chicken intended for human consumption is not acceptable for the EU and would threaten the community's entire set of food production standards. French Socialist MEP Anne Ferreira said that lifting the ban would be ‘totally absurd’. She was supported by John Bowis (EPP-ED, UK), who said it would be ‘outrageous’ and would degrade EU citizens to the status of ‘guinea pigs’

...The Commission also wants to allow the use of four currently banned antimicrobials in meat processing plants, citing EFSA endorsement of the chemicals at the start of this year. Scientific opinion, issued by EFSA in January, stated that the banned chemicals (phosphate, acidified sodium chlorite, chlorine dioxide or peroxyacid) posed no risk to human health and could be used to clean chicken carcasses. The decision was also one of the first applications of the bloc's new hygiene regulations in relation to removing contamination from meats. EU regulation No 853/2004, part of the package of hygiene laws that came into effect on 1 January, provides a legal basis to permit the use of a substance other than potable water to remove surface contamination from products of animal origin. Previously, such a legal basis did not exist in the bloc's legislation for red meat and for poultry meat.

...‘With the adoption of the hygiene package and the introduction of the hazard analysis and critical control points (HACCP) principles in the entire food chain, establishments are obliged to improve their hygiene and processing procedures,’ the EFSA stated. ‘Under such circumstances the use of antimicrobial substances on food of animal origin can be reconsidered.’ The EFSA scientific panel also noted that spraying poultry carcasses with antimicrobials, by comparison to dipping and immersion treatments, reduces the exposure to residues and by-products that might arise.”

4. Jane Byrne, *Farmers’ Over-Reliance on Antibiotics Affects Resistance, Says UK Organic Group*, FOODProductiondaily.com (Aug. 14, 2008) (emphasis added).

“UK farmers and veterinary surgeons are giving antibiotics to animals often to prevent rather than treat disease, which is contributing to the problem of antibiotic resistance through food, claims a UK organic group. Antimicrobials are chemicals such as antibiotics used in veterinary and human medicine. Resistance to antibacterials in animals is rising, meaning that the risk of animal-based food becoming contaminated is higher. At the same time, antimicrobials are also becoming less effective in fighting human infections. The Soil Association claims that an over-reliance on antibiotics in farming is resulting from the need to control potential disease problems in crowded environments: ‘Unfortunately, the congestion problems associated with intensive rearing of animals means that the conditions are ripe for the spread of bacteria among the livestock,’ said organic farmer and policy adviser to the Soil Association Richard Young. He claims that organic systems are designed with the objective of reducing the potential for disease but where antibiotics are used in UK organic farming to treat sick animals there is a long withdrawal period before the meat can be sold for consumption. Cost pressures Young told FoodProductionDaily.com that a growing pressure on intensive farmers, chicken

producers in particular, to meet consumer and retailer expectation on rock bottom prices is reducing their margins and encouraging the use of drugs so that they can meet delivery times. *‘The routine use of low-level antibiotics over a prolonged period in animals rather than a short, sharp one-off treatment is encouraging resistance in livestock,’ said Young.*”

5. Jane Byrne, *EU Ban Remains on US Chicken* – Report, News in Brief, FOODProductiondaily.com (Dec. 19, 2008) (emphasis added).

“European Union agriculture ministers have rejected attempts to lift a ban on US poultry which is washed in chlorine, according to media reports. The EU ban, in place since 1997, has effectively stopped all imports of US poultry meat. Agriculture ministers, meeting in Brussels, yesterday voted against the attempted move by the European Commission. The proposal from the Commission last May then met with opposition from numerous MEPs. MEPs, speaking in the Parliament’s Environment Committee at the time, said the chlorination of chicken intended for human consumption is not acceptable for the EU and would threaten the community’s entire set of food production standards.”

6. Jane Byrne, *US Contests EU Chicken Restrictions*, FOODProductiondaily.com (Jan. 19, 2009) (emphasis added).

“EU restrictions on US chicken imports have been challenged by Washington, which is demanding that the World Trade Organisation (WTO) intervene in the dispute. The EU ban, in place since 1997, has effectively stopped all imports of US poultry meat, which is generally treated by a chemical process aimed at pathogen reduction. Last month, European agriculture ministers decided to maintain the ban, rejecting efforts by EU Industry Commissioner Guenter Verheugen to lift the ban under certain conditions such as labelling to identify the process and pledges that the chicken would be rinsed. US trade officials filed a complaint with the WTO on Friday, claiming that ‘the poultry treatments at issue have been widely and safely used in the US for many years.”

7. Dan Flynn, *Russia Bans U.S. Poultry Over Chlorine*, Food Safety News (Jan. 7, 2010) (emphasis added).

“[T]he Office of the U.S. Trade Representative has...been unable to open the EU to U.S. poultry...The EU ban on bathing chicken in chlorine has been in effect since 1997. The US-EU dispute was a test case for the Transatlantic Economic Council, which was formed in 2007 to facilitate trade and business between the two economies. A plan to end the ban was vetoed by EU veterinary experts.”

E. **The European Ban of U.S. Wines Produced Pursuant to non-EU Oenological Practices and Using EU Semi-Generic Names of Geographic Origin**

1. Lawrence A. Kogan, *Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science*, National Foreign Trade Council, Inc. (May 2003), at pp. 14-16 and accompanying notes (emphasis added).

“The EU...has enacted regulations which ‘require imported wines to be produced with only those oenological practices that are authorized for the production of EU wines.’ The EU has continued to grant U.S. wine exports a ‘temporary’ exemption from these requirements under the terms of the 1983 US-EU Wine Accords, and this exemption has been extended until December 31, 2003. EU law is contrary to U.S. law which, absent a health or safety concern, effectively grants automatic acceptance of EU wine making practices. However, as required by these accords, the EU has failed to convert this temporary exemption for U.S. wine producers into a ‘permanent’ exemption, even though the EU has been unable to prove that U.S. oenological practices pose a ‘health’ or ‘safety’ risk. In fact, as recently as 1998, the EU prohibited the use of more than a dozen oenological practices and additives then currently approved for use in the U.S. and several other countries...Given the apparent difficulties encountered with these accords, the U.S. and the EU launched a new round of negotiations on a bilateral wine agreement in 1999, which continued throughout 2001. Notwithstanding this effort, the U.S. ‘continues to be concerned about the EU’s requirements for import certification and the review and approval of future wine making practices’.

... In addition to non-science based winemaking standards, *the EU has enacted new labeling regulations that are concerned more about the ‘consumer’s right to know’ than about risks to human health. The consumer’s right to know has been referred to within the EU as the ‘Fourth Criterion’. For example, these non-science-based regulations seek the phase-out in the U.S. of semi-generic names (e.g., burgundy, champagne, Chablis) on labels of non-EU wines. And it seeks to impose similar labeling restrictions for ‘traditional expressions’ (e.g., terms used with certain other expressions, often geographical indications, to describe wine or liqueur. These restrictions are contained within the April 29, 2002 adoption of EU wine labeling regulations (Commission Regulation 753/2002)...[which]...is not scheduled to be implemented until August 2003”.*

2. *EU-US Wine Agreement, US-EU Wine Trade Issues, Foreign Agricultural Service U.S. Mission to the European Union Update (Sept. 28, 2009) (bold italicized emphasis added).*

“On March 10, 2006, Commissioner Fischer-Boel and Ambassador Portman signed the US-EU wine trade Agreement, marking the end of a first phase in ongoing trade discussions, which began in 1983. The Agreement addresses several key issues, and sets a framework to facilitate future wine trade between the United States and Europe...Mutual acceptance of existing oenological (wine making) practices...This Agreement removes the continuous uncertainty of these temporary derogations, providing more stable market conditions for US wine exporters. The US continues to accept current EU oenological practices, and agrees to follow a formalized approval process for new wine making procedures...Certification: Under the terms of the Agreement, the EU has simplified its import certification requirements for US wine. All U.S. wine imports must be accompanied by certification and analysis documentation using the format specified...With the mutual acceptance of wine making practices, the US will exempt EU wine from new US certification requirements for imported wine...Semi-generic names: The US agrees to seek legislative changes to limit the use of 16 semi-generic names, as well as retsina used on wine labels. The names covered by the Agreement include: burgundy, chablis, champagne, chianti, claret, haute sauterne, hock, madeira, malaga, marsala, moselle, port, retsina, rhine, sauterne, sherry, and tokay. Legislation changing the legal status of these names was enacted by the Congress and signed by the President on December 20, 2006, as section 422 of the Tax Relief and Health Care Act of 2006. The new rules grandfather existing uses of these semi-generic names, but prohibit new brands from using these names on non-European wine... Labeling:

The Agreement addresses a number of additional labeling issues...*‘labels shall not contain false or misleading information in particular as to character, composition or origin.’* More specifically, *the Protocol on Wine Labeling sets specific conditions for the use of names of vines, vintage characteristics, production methods, product types and variety names.’*

3. Commission Communication concerning the Agreement between the European Community and the United States of America on trade in wine (2007/C 176/09) OJ L. 176 (July 28, 2007) p. 14 (emphasis added).

“By letter dated 7 February 2007, the US have notified the Community that in accordance with Article 6(3) of the Agreement between the European Community and the United States of America on trade in wine the change of legal status concerning ‘semi-generics’ referred to in the said Article has come into effect. The relevant US legislation is the ‘Tax Relief and Health Care Act of 2006 — Section 422’ which was signed by the US President and enacted as law on 20 December 2006. In accordance with Article 17(2) of the Agreement, Article 4 of the Agreement concerning wine making practises and specifications and Article 9 concerning the certification of wine and other marketing conditions are therefore applicable in the Community as of 1 April 2007.”

4. Hilde Brans, New EU Wine Labeling Rules, USDA Foreign Agricultural Service Global Agricultural Information Network (GAIN) Report Number E49061 (8/31/2009).

*“The second and final phase of the EU wine reform entered into force on August 1, 2009, and covers oenological practices, designations of origin and labeling...**OENOLOGICAL PRACTICES** Commission Regulation 606/2009 lays down detailed rules for implementing Regulation 479/2008 as regards permitted oenological practices. Annex I A sets out the oenological practices authorized in the EU and the conditions for their use...Annex I B sets out the maximum allowed sulphur dioxide contents: 150 mg per liter for red wines, 200 mg per liter for white and rosé wines. **LABELING** Framework Regulation 479/2008 provides for one type of labeling, i.e. similar mandatory and optional indications for all categories of wine. *Wines are now classified in two categories: wines without geographical indications and wines with geographical indications. For wines with geographical indications, two definitions apply: protected designation of origin (PDO) and protected geographical indication (PGI)...Designation of Origin* Chapter II of Regulation 607/2009 establishes *the application procedure for a designation of origin or a geographical indication.* Designation of origin or geographical indications which have been accepted will be entered in a ‘Register of protected designations of origin and protected geographical indications’ maintained by the European Commission...**Traditional Terms** Annex XII to Regulation 607/2009 establishes a list of protected traditional terms. *The use of expressions such as ‘style’, ‘type’, ‘method’, ‘as produced in’, ‘imitation’, ‘flavor’, ‘like’ or ‘similar’, in combination with a traditional term listed in Annex XII is not allowed...Annex XIII lists the terms referring to a holding. Terms referring to a holding such as ‘chateau’ and ‘clos’ are, under certain conditions, reserved for wines with a PDO or PGI.”**

F. The European Ban of Produce Containing Pesticides Exceeding ‘Approved’ Maximum Residue Levels (MRLs)

1. Luis Suguiyama, USEPA, *How a Dis-harmonized Pesticide MRL System Impacts Global Agricultural Trade*, Presentation at Alexandria, Egypt (March 30 – April 2, 2009) (emphasis added).

“Some countries set their own MRLs, and in many cases, with different numerical values for a certain pesticide in the same crop/crop group. Most countries defer to Codex MRLs But most countries will reject crops containing residues of pesticides that they have not explicitly approved (even if Codex MRLs have been established). MRLs are not harmonized internationally. This creates agricultural trade irritants...Countries routinely reject crops with pesticide residue levels higher than their national MRL values or when MRLs are absent...[The] Preferred Approach for MRLs[:] Global harmonization of MRLs. Cooperation (joint reviews) and transparency in risk assessments and establishment of MRLs. International data sharing and promoting regulatory efficiencies. Codex/JMPR to set MRLs for new and ‘reduced-risk’ pesticides prior to setting national MRLs.”

2. Rory Harrington, *EU Hails Success of New Food Safety Regime*, FoodProductiondaily.com (June 28, 2010) (emphasis added).

“The recent introduction of tougher border controls on fruit and vegetables and the outlawing of hundreds of pesticides have boosted food safety in European Union, said Brussels. The rules, which came into force at the start of the year, are already bearing fruit, said John Dalli, European Commissioner for Health and Consumer Policy. Since the new regime was introduced in January, some 13,600 consignments of imported and domestic fruit and vegetables have been checked – with 10 per cent of products being tested, as per the new regulation. As a result, 10 per cent of the fruit and vegetables tested have been rejected by European authorities.”

3. Harry Cline, *MRL Issue Clouds Ag Export Outlook*, Western Farm Press (July 1, 2010) (emphasis added).

“The U.S. Environmental Protection Agency registers agricultural chemicals and when it does, it sets pesticide residue allowances considered safe for people and animals. Many countries accept EPA’s tolerance. However, many do not and set their own tolerances called MRLs or abide by a multi-nation standard. One of those is called Codex. The USDA FAS also tracks MRLs. Individual buyers like supermarkets or wholesalers can set their own MRLs. This customized customer MRL tactic is growing. What this means is that ag chemical manufacturers must submit registration data to anyone who sets MRLs. If MRLs are not established for the customer receiving the product, the customer can refuse shipments of U.S. agricultural imports. If established MRLs are exceeded, the product can also be rejected...MRLs act as trade barriers that can significantly reduce accessibility of U.S. ag production, [Richard]Carver, [senior DuPont registration manager,] said...Forty-five countries default to Codex MRLs. However, major buyers like Canada, the European Union’s 27 member nations, Japan, Taiwan, Australia, Russia, New Zealand, Argentina and Brazil are among buyers of U.S. ag products who set their own MRLs. Mexico, another major buyer, accepts U.S. EPA tolerances. Matt Lantz, director of international market access and chemical and technical services for a Seattle company, Bryant Christie, Inc., has worked throughout the world on U.S. ag import issues. He told the seminar attendees MRLs will increase in importance to growers and shippers. ‘The challenge to growers is that they can be within tolerance in the U.S. and be illegal abroad,’ he said. ‘There are increasingly more rejections each year.’ Adding to this dilemma are new pests showing up in the U.S. that require

*aggressive chemical control, like the European grapevine moth that was found for the first time last fall in the U.S. in California grapes. Also, there are new, reduced risk compounds being introduced in the U.S. after going through EPA registration that cannot be used because countries like Japan and Taiwan have not established MRLs. This forces U.S. growers to use higher risk compounds with MRLs, if they want to ship into those markets. And there is the growing list of private sector MRLs where buyers say they want growers only to use a half or a third of the labeled rate — ‘for no reason’ if a grower or packer wants to sell them product. Educating buyers and consumers abroad is the key to use acceptance by food chains and others who are often setting unreasonable product use standards. Phil Brindle, senior regulatory manager for BASF agricultural solutions, called *the lack of MRL harmonization a ‘nightmare’*”*

4. *Public Comments of Susan Day, Vice President International Marketing, California Table Grape Commission on SPS National Trade Estimates Report on Foreign Trade Barriers: Fresh Table Grapes (HS 0806.10) USTR-2010-0020-002 (Oct. 4, 2010) (emphasis added).*

“I. E.U. Pesticide Residue Harmonization The United Kingdom (U.K.) is the California table grape industry’s largest export market in the European Union (E.U.) *Though the E.U. harmonized its member state pesticide maximum residue levels (MRLs) on September 1, 2008, many E.U. MRLs are established at levels significantly more restrictive than U.S. or Codex MRLs. The E.U.’s adoption of restrictive MRLs could also result in other barriers or disruptions in countries that adopt and defer to E.U. standards. The commission has additional concerns that new E.U. legislation covering pesticide authorizations will result in the withdrawal of certain pesticides. Some of these crop protection tools will remain in use in the U.S.* The commission requests that the U.S. government work with the European Commission to ensure that import tolerances remain in place in the E.U. even when a product has been withdrawn from active use in Europe. II. Estimate of Potential Increase in Exports if Barriers Were Removed *In 2009, the U.K. was California’s ninth largest table grape market by value, with exports worth approximately \$18.6 million. Exports to the E.U. as a whole total \$21 million. Should significant pesticide residue issues emerge in Europe, this entire market could be under threat”.*

5. *Pesticides and MRLs, Foreign Agricultural Service U.S. Mission to the European Union, (Oct. 21, 2010) (emphasis added).*

“The currently ongoing legislative initiatives in the area of pesticides are resulting in a drastic reduction of the number of active substances. Meanwhile, maximum residue levels (MRLs) are being harmonized throughout the EU... Regulation 1107/2009 sets out rules for the authorization of plant protection products (PPPs). It entered into force at the end of December 2009 and it will become fully applicable as from June 14, 2011. This Regulation establishes a list of approved active substances. Only PPPs containing active substances included in the list may be authorized for use in the EU. Member States (MS) can approve PPPs containing the active substances. According to the new Regulation, the EU is divided in three different zones. Once a MS approves the PPP it can be mutually recognized and thus authorized within the same EU zone as set out in Annex I of the Regulation. The Maximum Residue Levels (MRLs) for substances not on the list will be set at default level: 0,01 mg/kg. The legislation allows exporters to request an ‘import tolerance’ for active substances not yet evaluated or in use in the EU. Since September 2008 all MRLs in the EU have been harmonized by Regulation 396/2005 on food or feed of plant and animal origin. Pesticide MRLs for processed or composite products are based on the MRLs of the raw agricultural ingredients. Harmonized sampling methods

are established for the official control of residues in and on products of plant and animal origin by Commission Directive 2002/63/EC. Commission Regulation 915/2010 requires Member States to take and analyze samples for product and pesticide residue combinations in food of plant and animal origin. Annex I to the Regulation sets out the pesticide and product combinations to be monitored. Annex II sets out the number of samples that need to be taken for each combination. The Member States must submit results of the sample tests to the EU by 31 August 2012, 2013 and 2014 for samples tested in 2011, 2012 and 2013 respectively. If there is no EU legislation in place in the importing Member State, then the exporter can seek to obtain an "import tolerance" for active substances that have not been evaluated or used in Europe before. Applications for import tolerances must be submitted to the 'Rapporteur Member State' (RMS). The Commission assigns a Member State, if no RMS exists. The RMS reviewed dossiers are evaluated by the European Food Safety Authority (EFSA) before being forwarded to the Commission for consideration... Since September 2, 2008 all MRLs, including import tolerances, apply EU wide."

6. Maximum Residue Levels, CropLife International website, (last updated Nov. 10, 2010) (emphasis added).

"Under the Sanitary and Phytosanitary (SPS) agreement, the World Trade Organization (WTO) proposed globally-recognised MRLs as world wide trading standards. However, neither the USA nor the EU approve Codex MRLs or generally rely on MRLs. Instead, they independently set their own standards. However, this is not to say that MRLs are ignored. For example, the European MRL regulation 396/2005 states that MRLs set at the international level by the Codex Alimentarius Commission should also be considered when Community MRLs are being developed. In addition, in the absence of European MRLs for an active substance/ crop combination an existing Codex MRL might help the inspection services to decide whether imported agricultural products containing traces of residues are considered to be safe and can be further traded. In the USA, the law states clearly that food is considered adulterated if pesticide residues exceed established US standards. The existence of a different Codex level does not influence this acceptability decision at the time of importation. However, if a Codex level already exists when a US tolerance is being set, the Environmental Protection Agency (EPA) may choose to set the same level where possible. *Codex MRLs are hardly ever used to solve trade disputes at the WTO level, probably because of the administrative hurdles and costs involved in filing a WTO complaint. Codex MRLs are acknowledged by countries which might not have an own legislation in place, nor capacity to set MRLs, or they might use them in addition to their own nationally established MRLs, especially as Import Tolerances...The lack of acceptance of Codex MRLs by national governments and regional authorities reduces the value of MRLs as a tool for well-regulated international trade. As a consequence food companies are forced to use national or import MRLs which devalues Codex MRLs as an international standard for public health. Also, growers are forced to comply with many different national MRLs instead of one internationally accepted standard. This increases costs for industry without increasing food safety."*

G. The European Ban of U.S. Seafood

1. Alexander Higgins, No Wonder Europe Banned US Sea Food After BP Gulf Oil Spill; Feds Say Fish Exposed To Oil Safe To Eat In Weeks, Alexander Higgins Blog (Aug. 5, 2010) (emphasis added).

“Beginning July 1, 2010, a European Commission Regulation allowing import of ANY molluscan shellfish and certain marine invertebrates (not only live and fresh product) from the United States expired. This is expected to halt the import of these products into the European Union (EU) at that time. Until the products are again allowed to enter, the NOAA Seafood Inspection Program will not issue export health certificates for these products. The Regulation includes, live and fresh bivalve mollusks, echinoderms, tunicates, and marine gastropods from all U.S. states. Shellfish from the five states bordering the Gulf of Mexico are already not allowed into the EU for other reasons. Wild scallop meats, fresh or frozen, will be allowed entry; whole scallops or scallop adductor muscles with the roe attached will not be allowed. The U.S. Food and Drug Administration (FDA) and the European Union have been in discussion about the reciprocal equivalence between the nations for live mollusks. The EU agreed to a six month temporary authorization allowing U.S. exports to continue through July 1, 2010. The differences have not been resolved...European Commission Decision (2009/951/EU; 14 December 2010)...Specifically the European Union gave the US 6 months in December of 2009 to comply with regulations assuring that sea food harvested from the Gulf of Mexico was safe for human consumption. Then along came the BP Gulf Oil Spill and needless to say and the US did not comply.”

III. Potential New European Sustainable Agriculture and Organic Farming Trade Barriers in the Making

A. European Cap Reform Inspires Sustainable Agriculture and Trade Regulatory and Standardization Policy Initiatives

1. *A Common Agricultural Policy for European Public Goods: Declaration by a Group of Leading Agricultural Economists*, Harvest a Better Europe blog (Nov. 2009) (emphasis added).

*“Europe’s Common Agricultural Policy (CAP) is in need of reform. The imminent negotiation of a post-2013 budget settlement for the EU offers a real opportunity to undertake the necessary changes. A broad public debate is vital if Europe is to make the right choices. We wish to contribute to this debate...The time has come to redesign the CAP to strengthen its positive effects. Only if the CAP efficiently helps promote society’s interests will it be legitimate in the eyes of our citizens and viable in the long run. The EU should only be involved in financing and regulating the sector to the extent that it serves these wider goals, and in particular when the effects of agricultural policies spill across national borders. Otherwise, policies should reflect the principle of subsidiarity. Social and redistribution policies should be left to national and sub-national authorities that are better placed to pursue local preferences with financial responsibility. Fair competition on the internal market can be obtained through EU oversight and does not warrant significant EU financing. **The objectives of the future CAP. Four classes of potential objectives for the CAP can be identified: enhancing economic efficiency and competitiveness, ensuring food security, changing income distribution, and promoting public goods. However, only the last objective provides a sustainable basis for the future CAP.***

4. Rural public goods: *Farmers often create public goods valued by society but not sufficiently remunerated on the market. These public goods may include environmental protection, conservation of biodiversity, soil fertility and water quality, landscape preservation, food safety, animal and plant health, and rural development. Some of these public goods are more global by nature, such as biodiversity, and do call for EU action. Others, like landscapes, are local in nature, and would more appropriately be addressed by national or local authorities. **Environmental protection:** Some*

environmental public goods could justify EU support. An obvious one is the fight against climate change, which is a global challenge justifying a supranational response. Monitoring greenhouse gas emissions in order to apply cap-and-trade schemes or carbon taxes is difficult in agriculture. Payments for climate-friendly farming practices may well be needed to induce farmers to go beyond minimum legal requirements. The protection of biodiversity also warrants EU support because animals, ecosystems and biodiversity-threatening pollution cross borders. Similarly, keeping water clean and preventing water scarcity as well as floods is an EU concern because Europeans share rivers, lakes and seas... **Food standards:** It is sometimes suggested that subsidies are warranted to enable EU farmers to meet Europe's more demanding legislation on food safety, without driving agricultural production to foreign, low-standard suppliers. Imported foods do, however, have to meet the EU's food safety standards, and in that regard face the same costs. *There are, nonetheless, difficult issues relating to environmental, animal welfare, and other ethical aspects of production methods, which are not easily resolved. The EU should be more forceful in international negotiations, in ensuring products can be appropriately labelled for example, and in seeking international harmonization of ethical and environmental production standards. If European voters decide to apply higher standards to Europe's farmers, then European consumers need to be adequately informed of the attributes of imported goods.*

2. *MEPs Want Farm Policy to Ease Climate Change*, EurActiv.com (Jan. 28, 2010; Updated Feb. 5, 2010) (emphasis added).

“An EU White Paper on the challenge posed by climate change to European agriculture and a Working Document on the role of agriculture in climate change mitigation (April 2009) states that the farming sector will suffer in the long term unless structural and technological changes are made and adaptation measures are implemented. *The document also acknowledges the sector's contribution to total emissions alongside its mitigation potential, and underlines the importance of developing synergies between the two.* A recent report by the Worldwatch Institute, a think-tank, stresses the climate change mitigation potential of agriculture too. It argues that agriculture and land management have not received enough attention from scientists and politicians, while a number of innovations in food production and land use could help to fight global warming (EurActiv 09/06/09). *As the EU prepares for a major revamp of its farm policy for the post-2013 era, the EU executive stresses that European farmers must slash agricultural greenhouse gas emissions by at least 20% by 2020, primarily by producing biomass and storing carbon in the soil* (EurActiv 16/09/09). *The future CAP may well make support for farmers subject to delivering on biodiversity, sustainable farming practices and CO2 reduction goals* (EurActiv 27/10/09). *The recent CAP health check showed that current EU farm policy does not take climate change into account enough, even though ‘agriculture is part of the solution to fight climate change,’ said Paolo de Castro, chairman of the House's committee on agriculture and rural development, in a public hearing on the matter.* Stéphane Le Foll (S&D), French draftsman of the Parliament's own initiative report on EU agriculture and climate change, regretted that ‘the EU currently deals with agriculture and environment separately,’ and that different directives only create a lot of administrative hurdles for farmers. Presenting his draft report, *Le Foll called for agriculture to be addressed across the policy spectrum, using farm policy to combat climate change, tackle water and soil quality and sustainable natural resource management.* ‘I propose that we use EU agriculture to reduce fossil energy use, emit less and capture more CO2, and for sustainable management of natural resources,’ Le Foll said. *The future CAP should be used ‘to ensure a transition towards sustainable agriculture that is economically viable,’ he added. The draft report, to be adopted later this spring, currently states that ‘the CAP must be turned into an agricultural, food and environmental policy’ and*

that climate change, water management, renewable energies and biodiversity ‘must be addressed through all the CAP instruments, not just the second pillar subsidies’.

3. *An Appraisal of the Leaked Communication from DG Agriculture, Reform the Cap, Harvest a Better Europe blog (2010) (emphasis added).*

“The communication from DG Agri that prepares the CAP community for the legislative proposal next summer and which aims to channel the debate has [been] leaked. Its title reads ‘The CAP towards 2020: Meeting the food, natural resources and territorial challenges of the future’... Less than one year ago, agricultural economists from across Europe called for an ambitious CAP reform. Here is a comparison between the communication from DG Agri and the expert declaration. The contrast couldn’t be more stark...The communication pays ample lip service to environmental protection and climate change mitigation. But it is almost silent when it comes to concrete policy instruments to promote these objectives. It does not admit that there is competition for money within the CAP: every Euro that is spent on untargeted farm income support cannot be spent on more efficient measures. The communication upgrades ‘territorial balance’ to one of the explicit key objectives of the CAP. This creates the possibility for even more spending of the social-and-regional-policy kind that should neither be centralized at EU level nor be part of agricultural policies.”

4. *EU Eyes Increased Role for Organic Farming, EurActiv.com (April 22, 2010) (emphasis added).*

“With the EU’s future farm policy expected to have an increased focus on protecting biodiversity, promoting sustainable farming and achieving CO2 reduction goals, organic farming may be worth a closer look, EU officials said. Organic farming is a method of production which emphasises environmental protection and animal welfare considerations. It avoids or drastically reduces the use of synthetic chemical inputs such as fertilisers, pesticides, additives and medicinal products. When the EU’s Common Agricultural Policy (CAP) was created, there was no such thing as organic farming. Organic agriculture received official recognition in 1991 when the first EU regulation on organic farming and a corresponding labelling system were adopted. In response to ‘the rapid increase in the number of farmers producing organically and strong demand from consumers,’ the European Commission adopted an EU action plan for organic food and farming in June 2004. The action plan set out initiatives aimed at developing the market for organic food and improving standards by increasing efficiency, transparency and consumer confidence. ‘There is a growing interest in organic farming, particularly in the context of talks on ecosystem services,’ said Ladislav Miko, director at the European Commission’s environment directorate, addressing a seminar on the role of organic farming in combating climate change on 20 April. His comments come as the EU is preparing a major overhaul of the Common Agricultural Policy (CAP) for the post-2013 era, in a bid to tap into the increasingly recognised potential of agriculture to mitigate climate change and deliver various other environmental benefits, such as improved soil and water quality (EurActiv 26/01/10; EurActiv 28/01/10). A Commission staff working document accompanying the 2004 EU action plan on organic farming underlines that its main benefits include the protection of soil, nature, biodiversity and habitats. Restricted use of pesticides also improves water quality, it notes. According to the EU executive, only 4% of EU farmland is currently used by organic farming. However, in some countries organic farming covers up to 15-20%. Anna Barnett from the Commission’s environment directorate stressed that the focus should be on reducing pollution from the 96% of farm land currently used for conventional farming. She noted that 50% of France’s drinking water, for example, needs to be cleaned of

pesticides before it is fit to drink. ‘We also need more money for rural development measures, for organic farming as well as fairer distribution of payments,’ Barnett said.”

5. Foreign Trade Association (FTA) Reply to the Public Consultation on a Future Trade Policy Launched by the European Commission, DG Trade, (July 28, 2010) (emphasis added).

“Sustainable trade Q: How can trade policy best support green and inclusive growth around the globe including through Sustainability Impact Assessments?”

R: Many FTA member companies have included the principle of sustainability into their corporate philosophy. ***The FTA welcomes a sustainable trade policy as long as it does not lead to a discrimination of goods and services, certain countries and economic operators or means of transport. However, incentives such as duty reductions or exemptions which do not have a discriminative effect should be maintained.*** The GSP+ deserves particular mention in this context. ***The sometimes discussed exemption from duty for environmentally friendly products or products produced in environmentally responsible conditions does follow the same goal, however, must be rejected because of the inevitable problem of eligibility and the danger of abuse. Moreover, proposals aiming at giving preference to goods which were produced in good social conditions should not be pursued further. In this case, problems with regard to determining eligibility as well as the danger of abuse cannot be avoided.*** The Business Social Compliance Initiative (BSCI) is an initiative of the FTA which enables companies to successfully practice Corporate Social Responsibility in the international supply chain. It is important to generate favorable framework conditions at the political level which support companies in their social responsibility activities. ***Sustainability Impact Assessments may contribute to identify measures having a sustainable impact on global trade. For example, if a trade measure would result in considerable traffic relocations which would be harmful to the environment, it has to be weighed carefully whether such a measure should be implemented or not.***

Q: Given the forthcoming revision of the Common Agricultural Policy and the continuing need to foster a sustainable agricultural sector in Europe, how should EU trade policy develop in this area consistently with the overall objectives of the Lisbon Treaty?

R: The Foreign Trade Association understands the need to integrate environmental concerns into the ***Common Agricultural Policy. Environmental degradation is an issue and encouraging sustainable agricultural practices would benefit the consumers. Nevertheless, sustainable agriculture and environmental concerns should not be used as a pretext for setting trade barriers for the import of agricultural products.*** The FTA supports free and open trade, and a demand- driven agricultural policy. The EU agricultural policy is still based on quotas and subsidies distorting the market. This has a considerable impact on both multilateral and bilateral international trade negotiations. ***We expect the EU to dramatically reduce agricultural protective measures and allow free and open trade of agricultural products.***”

6. Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, *The CAP towards 2020: meeting the food, natural resource and territorial challenges of the future* COM(2010) at pp. 1-2, 4-10 (9/29/10) final (emphasis added).

“The Common Agricultural Policy (CAP) is confronted with a set of challenges, some unique in nature, and most unforeseen, that invite the ED to make a strategic choice for the long term future of its agriculture and rural areas. In preparation for this Communication, the Commission organised an extensive public debate earlier in 2010 that concluded with a conference in July 2010...In broad terms, the views expressed recommended the following strategic aims: To preserve the food production potential throughout the ED, so as to guarantee long-term food security for European citizens and to contribute to growing world food demand...***Recent incidents of increased market instability, often exacerbated by climate change***, further highlight these trends and pressures...***To support farming communities that provide the European citizens with quality and diversity of food produced sustainably, in line with our environmental, water and animal welfare ambitions. The active management of natural resources by farming is a key lever to maintain the rural landscape, to combat biodiversity loss and contributes to mitigating climate change...******To maintain viable rural communities, for whom farming is a core economic activity creating local employment***; this delivers multiple economic, social, environmental and territorial benefits. A significant reduction in local production would also have implications with regards to greenhouse gases (OHO), characteristic local landscapes as well as more limited choice for the consumer.

...Reform of the CAP must also continue, to promote greater competitiveness, efficient use of taxpayer resources and effective public policy returns European citizens expect, with regard to food security, the environment, climate change and social and territorial balance. The objective should be to build more sustainable, smarter and more inclusive growth for rural Europe. To achieve this, the future CAP should contain a greener and more equitably distributed first pillar and a second pillar focussing more on competitiveness and innovation, climate change and the environment with a view to releasing the latent productivity potential, notably in the new Member States, thus contributing to the Europe 2020 objectives. Targeting support exclusively to active farmers and remunerating the collective services they provide to society would increase the effectiveness and efficiency of support and further legitimize the CAP...3. **WHAT ARE THE CHALLENGES?**...3.2 **Environment and climate change** ***Although GHG emissions from agriculture have decreased by 20% since 1990, further efforts will be required to meet the ambitious ED energy and climate agenda, to reduce GHG emission, to adapt and make a positive contribution through carbon sequestration and biomass production based on innovation. The environmental challenges, such as depletion of soil, water and air quality as well as habitats and biodiversity need to be addressed too.***

...4. **WHY DO WE NEED A REFORM?** The CAP has evolved, but further changes are necessary in order ***to respond to the new challenges notably: to address rising concerns regarding both EU and global food security; to enhance the sustainable management of natural resources such as water, biodiversity and soil; to deal with both the increasing pressure on agricultural production conditions caused by ongoing climatic changes, as well as the need for farmers to reduce their contribution to climate change;***...By facing these challenges, the CAP will also contribute to the ***EU 2020 Strategy in terms of: Smart growth -by increasing resource efficiency through technological knowledge and innovation, developing high value added and quality products; developing green technologies***, investing in training and providing incentives for social innovation in rural areas; ***Sustainable growth -by maintaining the food, feed and renewable production base, ensuring sustainable land management, providing environmental public goods, addressing biodiversity loss, promoting renewable energies, further reducing emissions*** and fully developing the potential of rural areas;

...5. **OBJECTIVES OF THE FUTURE CAP** ***The three main objectives for the future CAP would thus be: Objective 1: Viable food production...In addition European farmers face competition from the world market while also having to respect high standards relating to environmental, food safety,***

quality and animal welfare objectives... **Objective 2: Sustainable management of natural resources to guarantee sustainable production practices and secure the provision of environmental public goods as many of the public benefits generated through agriculture are not remunerated through the normal functioning of markets; to foster green growth through innovation which requires adopting new technologies, developing new products, changing production processes, and supporting new patterns of demand; to pursue climate change mitigation actions -and also enable agriculture to adapt to climate change.** Because agriculture is particularly vulnerable to the impact of climate change, enabling the sector to better adapt to the effects of extreme weather fluctuations, can also reduce the negative effects of climate change.

... **6. REFORM ORIENTATION 6.1. Future instruments** All potential options of the future CAP imply changes in present CAP instruments. This section explores how instruments could be defined in order to respond in a more efficient way to the above objectives. The future design should be based on a two pillar structure, which was the overwhelming view expressed in the public debate and which is also clearly favoured by the Council, the EP and the CoR. **The first pillar should contain the support paid to all farmers on a yearly basis, whereas the 2nd pillar is the support tool for community objectives** giving the Member States sufficient flexibility to respond their specificities... **Direct payments... The future of direct payments to be granted to active farmers could be based on the following principles**, taking up the concept proposed by the European Parliament: ... Basic income support through the granting of a basic decoupled direct payment, providing a uniform level of obligatory support to all farmers in a Member State (or in a region) based on transferable entitlements that need to be activated by matching them with eligible agricultural land, plus fulfillment of cross-compliance requirements... **Enhancement of environmental performance of the CAP through a mandatory 'greening' component of direct payments by supporting environmental measures applicable across the whole of the ED territory. These could take the form of simple, generalised, non-contractual and annual agri-environmental actions (e.g. permanent pasture, green cover, crop rotation and ecological set-aside). In addition, the possibility of enhancing certain elements of GAEC standards should be analysed. Promotion of the sustainable development of agriculture in areas with specific natural constraints by providing an additional income support to farmers in such areas in the form of an area-based payment with optional national top-ups on a voluntary basis.** The existing support for LFAs granted in the 2nd pillar would come to an end... **Rural Development As an integral part of the CAP, rural development policy has proved its value by reinforcing the sustainability of the ED's farm sector and rural areas - economically, environmentally and socially.** There are strong calls for the policy to continue to fully integrate the constraints of the environment and climate change and to deliver a wide range of benefits for farming, the countryside and wider society and contribute to: the competitiveness of agriculture, by promoting innovation and restructuring and by enabling the farm sector to become more resource efficient; **the sustainable management of natural resources, by taking care of the environment and the countryside, and maintaining the production capacity of the land;**

Within this framework, environment, climate change and innovation should be guiding themes that steer the policy more than ever before. For example, investments should lift both economic and environmental performance; environmental measures should be more closely tailored to the individual needs of regions and even local areas; measures to help unlock the potential of rural areas should pay close attention to innovative ideas for business and local governance. Support for developing direct sales and local markets should also be important.”

IV. Examples of Third Countries Adopting EU-Type Bans of U.S. Farm Exports

A. China

1. Country Strategy Paper 2002-2006 & China and National Indicative Program 2002-2004, Commission Working Document, European Commission IP/02/349 (Brussels, Mar. 1, 2002), at pp. 4-5 (emphasis added).

“Europe should offer its environmental energy know-how to China to help develop efficient and clean industrial processes and energy production. The EC should in particular help China integrate environmental priorities such as the prevention of industrial pollution and greenhouse gas emissions, and the conservation of biological diversity further into national economic policy-making processes...[C]ollaborative projects to support future policies and integration into China of EU technical standards, in such areas as the environment, energy, transport, food safety and consumer protection may be supported”.

J. Sanders, EU Science Counsellor Beijing, EU-China S&T Relations (Nov. 2002).

“...In the last two years...EU-China S&T relations have made a large step forward – both in terms of policy and of its operational consequences...*Our S&T relations clearly contribute to the overall positive political relations between the EU and China...The INCO programme has successfully supported selected policies like health, environment, food security and safety, sustainable agriculture, and overall policy development research. It has contributed to move China towards European models: China has a de facto moratorium on GMO food, uses European car emission standards, supports bio-energy and sustainable agriculture, and even China tries to copy elements of our way to manage the Framework Programme...Our projects already show an impact on regulatory activity in China...*Trade issues are increasingly reliant on scientific support, like radiation emissions of mobile phones, certified BSE-free cosmetics, or hormones in chicken meat...*China’s policies for GMO food follow the EU positions closely* and are subject to strong pressures from the US”.

B. Russia

1. Dan Flynn, Russia Bans U.S. Poultry Over Chlorine, Food Safety News (Jan. 7, 2010) (emphasis added).

“*With as much as 30,000 tons of American poultry in the pipeline to Russia, the government in Moscow imposed a ban on future U.S. poultry imports on New Year's Day. Russia joins the European Union in prohibiting the use of chlorine as an anti-microbial treatment in poultry production, which is commonly used in the United States...* The U.S. Department of Agriculture defended the use of chlorine by the American poultry industry. ‘*Since chlorine has been used as an anti-microbial treatment for more than 25 years, this resolution effectively blocks U.S. exports of poultry to Russia, has a devastating impact on the U.S. poultry industry and trade, and raised the costs of poultry products for Russia's consumers,*’ says USDA spokeswoman Katie Gorscak. She said there is overwhelming scientific evidence that chlorine is safe and effective as a disinfectant for poultry.”

2. BCI Monitor, A Report for the California Pear Advisory Board, at p. 1 (June 25, 2010) (emphasis added).

“Russia Aligns Some MRLs with EU Levels. The European Commission announced on June 24, 2010 that Russia has aligned some MRLs with European Union (EU) levels. The new MRLs entered into force earlier in June. The European Commission subsequently published a translation of a new Russian MRL amendment on its website. The amendment contains MRLs for 49 pesticides. A full review to determine the extent of harmonization with EU MRLs has not been conducted, but after a cursory review of the amendment it is clear that not all new MRLs match their European equivalents. According to the translation, Russia has established a new MRL for captan on pome fruit at 3 ppm. This is much more restrictive than the U.S. MRL of 25 ppm. Russia has also established a new MRL for chlorpyrifos on pome fruit at 0.5 ppm, which is less restrictive than the U.S. MRL of 0.05 ppm for pears.”

C. Turkey

1. *Turkey to Ban GMO Import below EU Standards, Xinhua (Jan. 21, 2010) (emphasis added).*

“Turkey’s Agriculture and Rural Affairs Ministry said Wednesday it would ban the import of those genetically modified organisms (GMOs) that do not meet European Union (EU) standards, Turkish media reported. Changes were made to a regulation on GMOs, which Turkey adopted in October 2009, to clear previous public confusion regarding the import of GMOs, the semi-official Anatolia news agency reported...After the regulation came into effect, some claimed it completely left the GMO import unchecked while others said it prohibited the import, according to Turkish media reports. The revised regulation made it clear that import of GMOs below the EU standards would not be allowed, the ministry said. There have been arguments in Turkey over producing and importing food and feed containing GMOs, with the opponents voicing safety and ecological concerns, Anatolia reported.”

V. Private Agricultural Standards as Potential Trade Barriers

A. EU Governance Mechanisms May Facilitate Development of Private Standards that Promote European Community Environmental, Health and ‘Food Safety+’ Policies

1. Lawrence A. Kogan, *Discerning the Forest From the Trees: How Governments Use Ostensibly Private and Voluntary Standards to Avoid WTO Culpability*, Global Trade and Customs Journal, Vol. 2., No. 9 (2007) at p. 330.

“Pursuant to one or more alternative EU governance instruments, the EU Commission has increasingly delegated legislative or regulatory authority to expert or specialized NGOs for purposes of directly or indirectly carrying out Community policies. Such delegations have been disproportionately focused on creating environment, health and food safety standards that require application of the extra-WTO Precautionary Principle. Reliance on the hazard-based Precautionary Principle satisfies civil society demands for industry accountability and transparency even where it is only suspected that industry products, technologies and/or activities might possibly give rise to health or environmental harm. Indeed, these delegations have tended to reflect the growing role that private standards play in

promoting official regulatory policy. In many cases, the EU Commission has promoted industry accountability and transparency by encouraging greater public participation in Community policy-making and implementation. It has done so by expanding the number of specialized NGOs that it recognizes as falling within the broader universe of standardizing bodies to which it may ultimately delegate authority. The Commission may have gone beyond the intent of the TBT Agreement in making some such designations, although this is uncertain. And, depending on the circumstances, a given delegation of EU authority to a particular NGO may or may not entail a transfer of some of its legal powers to enforce a technical regulation or directive. Therefore, whether the Commission has retained for itself the sole legal authority of enforcement in a given situation is a question of fact.

The primary methods of EU delegation are ‘co-regulation’ and ‘self-regulation’. By definition, co-regulation is the more formal method of delegation, and it is used to authorize recognized EU technical standards bodies to develop EU environmental and food safety product standards that implement Community environmental legislation. Co-regulation entails ‘a Community legislative act [that] entrusts the attainment of the objectives defined by the legislative authority to [economic operators, the social partners, non-governmental organizations, European associations or other recognized parties]’. Co-regulation combines government action with private action by concerned actors, with legislation and regulation focused on ‘overall objectives, basic rights, enforcement and appeal mechanisms, and conditions for monitoring compliance...[drawn] on the experience of interested parties, particularly operators and social partners.’ Self-regulation is a comparatively less formal means of delegation, not involving direct Commission participation because of its ostensibly private and voluntary nature. By its very definition, self-regulation invites voluntarily ‘economic operators, the social partners, non-governmental organizations or associations to adopt amongst themselves and for themselves common guidelines’, without recognizing any particular stance or approach. Given the nature of self-regulation, it is uncertain whether the EU Commission is sufficiently indirectly involved in the private standards-setting process that the standards and their effects on trade can be attributed to it. Yet, it is clear that the Commission is empowered to scrutinize self-regulation practices for compliance with the environmental provisions of the EC (Maastricht) Treaty and to report to Parliament those practices ‘contributing to the attainment of the Treaty objectives and...being compatible with the Treaty provisions emphasis added.’ Furthermore, the Commission is charged with not making regulatory actions where self-regulation ‘of this kind already exists and can be used to achieve the objectives set out in the Treaty’ (emphasis added). ‘Voluntary agreements can also be concluded on the basis of a legislative act, i.e., in a more binding and formal manner in the context of co-regulation, thereby enabling parties concerned to implement a specific piece of legislation’. Arguably, the EU Commission’s discrete use of these mechanisms has thus far enabled it to escape GATT/WTO challenge. Non-EU WTO members, including developing countries, have long suspected disguised protectionism at work but have been unable to prove it. However, this may soon change.”

B. Organization for Economic Cooperation and Development (OECD) Review of Private Food Sector Standards

1. Linda Fulponi, Summary of the OECD Final Report on Private Standards and the Shaping of the Agro-Food System, agrifoodstandards.net (12.5.06) (emphasis added).

“1. The study examines the role of private voluntary standards in shaping the agro-food system, with a focus on product sourcing. It discusses the main economic incentives for the development of such standards as well as their likely evolution from the perspective of lead retailers in OECD countries. It

also provides information on the views of agricultural producers regarding to the importance of private voluntary standards for market entry and effects on revenues, competitiveness, farm efficiency worker safety and the environment. *The information presented is based on interviews and surveys of lead retailers and a survey of farmer organizations in OECD countries.*

2. The study identifies three key developments in private standards schemes in the food sector over the past decade: 1) a move to voluntary management systems in the food industry for the monitoring of product and process attributes; 2) the emergence of coalitions of firms for setting private collective voluntary standards and 3) an increased use of private standards in the context of global business tobusiness (B2B) practices.

3. Results from interviews with retailers suggest that the development and use of private standards schemes is closely linked to the economic environment as well as institutional and legal frameworks in which the firms operate. Among the main factors characterising the economic environment are the strengthening of consumer demands and expectations regarding food, in particular food safety and to some extent production methods affecting the environment, labour conditions and animal welfare. *The interviews revealed the reasons for the development of private standards, whose compliance can be verified through third-party audits and certifications...Firm reputation, in terms of food quality and safety was voiced as a key concern of retailers. Failure to meet consumer expectations, in particular for food safety, was viewed as damaging to firm reputation, which in turn could lead to a loss in earnings and consumer loyalty.*

4. Institutional and legal frameworks in which firms operate were also considered to be an extremely important determinant in *developing private standards schemes which not only ensure compliance with given food safety regulations but also provide a margin of defence against possible outcome failures. Thus the development and use of private standards on a B2B basis with emphasis on process management were seen to correspond both to the importance of reputation as well as to the requirements imposed by the new food economy.*

...7. The study found that *for agricultural food products the private standards required by retailers focused above all on the management process used to achieve a given outcome in addition to the traditional product control. These procedures, coupled with reporting requirements, make private standards more demanding than government requirements...Social and labour conditions of workers were seen as the next most important issue to be tackled in co-operation between firms in the food sector.*

8. Survey results of farmer associations confirmed *the high emphasis on food safety but also on other production process characteristics, particularly agri-environmental practices. Meeting private standards was considered a condition to do business with both manufacturers and retailers.* However many responses noted the overlap of requirements among standards and expressed the wish for harmonization among standards.

...9. *Overall the study finds that private voluntary standards schemes can contribute to improving food system efficiency so as to deliver and ensure specific product and process attributes at reasonable cost to consumers. Nevertheless, these standards may also be exclusionary for certain producers. Compliance with private voluntary standards schemes may exclude those producers who, due to lack of potential scale economies or otherwise can not easily meet the standards. requirements and remain economically viable.”*

C. Food and Agricultural Organization (FAO) Review of Private Food Safety Standards in Livestock Sector

1. FAO. 2010. *Draft report on a global survey on private standards, codes of conduct and guidelines in the livestock sector*. Working document (emphasis added).

“In recent decades private standards have become a key element of governance in global agro-industrial food chains, progressively influencing both domestic business and international trade. To obtain an overview of private standards addressing the livestock sector, in 2010 FAO circulated a global questionnaire, which was replied by 105 respondents, mostly belonging to governmental organizations, not-for-profit non governmental organization, business organization (representing several sub-sectors of the food or livestock business), and others. In a preliminary analysis, the replies reveal that beyond food safety, animal and public health and animal welfare, a wide range of societal objectives such as food quality, environmental sustainability, poverty and equity issues is targeted in the standards. These objectives go beyond SPS-related measures and seem to confirm that the private standards aim to fill gaps left by international standards and agreements regarding these multiple objectives.

Most standards were said to be based on other existing national or international regulation or standards (e.g. OIE or Codex Alimentarius), thus indicating that the large majority of the standards may possibly exceed, but unlikely be inconsistent with the internationally negotiated ones. The replies to the questionnaire highlight that often a multiplicity of costs could be compensated by an equally broad set of benefits. Costs related to the standards are about one quarter related to initial investments, with the majority of costs occurring continuously as record keeping or related to certification. The standards seem to provide economic benefits, not only in premium prices or stabilized or increased market opportunities, but also in productivity increases and more reliable production. This indicates that the implementation of certain standards may be beneficial even without certification. Adherence to the standards is mostly certified by independent organizations.”

D. Codex Alimentarius Commission Review of Private Food Safety Standards

1. Spencer Henson and John Humphrey, *The Impacts of Private Food Safety Standards on the Food Chain and on Public Standard-Setting Processes* - Paper Prepared for FAO/WHO, Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission 32nd Session ALINORM 09/32/9D-Part II (June 29-July 4, 2009) (emphasis added).

3. Private standards have become increasingly important in global agri-food value chains, progressively pervading both domestic business and international trade. *These standards may relate to food safety and the integrity of food safety systems, but can also refer to aspects of food such as provenance, environmental impact, animal welfare, etc. One of the defining characteristics of private standards, particularly as they relate to food safety, is an increasing focus on the processes by which food is produced. In this respect, they mirror the increasing importance of process standards in public regulations...*

5... *Codex is primarily concerned with standard-setting and with establishing meta-rules for governments to follow when introducing national regulations. Much of the work of private standards schemes is concerned with detailed rules concerning implementation and conformity assessment.*

6. Within the broad array of private standards relating to food safety, the *WTO has distinguished between three types of standard. This classification is based on who sets (defines and codifies) the standard. Individual company standards* are set by individual firms, predominantly large food retailers, and adopted across their supply chains. *Collective national standards are set by collective organisations* that operate within the boundaries of individual countries, *including industry associations and non-governmental organisations (NGOs)*. Some of these standards are specifically designed to establish claims about food from particular countries or regions. Others, however, have international impacts through their application to globalised value chains. *A third set of standards, collective international standards, are designed to be adopted (required or used) by organisations in different countries.* This frequently means that the organisation that sets the standard has international membership.

... 8. *There are four key drivers for increasing control in agri-food value chains.* These must be situated within wider processes of regulatory change and the restructuring of global agricultural and food markets.

First, reforms of food safety regulatory systems respond to real and/or perceived risks in food production, transport and processing which are the result of a series of food safety crises and increasing consumer anxiety.

Second, heightened interest among consumers and businesses in food production processes and changes in their conceptions of food safety and quality are reinforced by company competitive strategies around provenance, environmental and social impact, etc.

Third, the globalisation of food supply and increased role of coordination economies in defining competitiveness create new risks and new challenges for value chain coordination and control.

Fourth, responsibility for ensuring food safety has been devolved from the state towards the private sector.

10. *Private standards are frequently characterised as going beyond the requirements of public standards. This 'going beyond' involves at least three different elements.*

First, private standards may set a higher standard for particular food product attributes. In other words, private standards may be seen as more stringent or more extensive than public standards. This is probably the most widely-held perspective on the relationship between private and public standards.

Second, private standards may increase the scope of activities regulated by the standard. Standards coverage can be extended both vertically and horizontally. Increased vertical coverage means extending the span of control up and down the value chain. Increased horizontal coverage relates to including new elements to be regulated by the standard. *Food safety standards, for example, frequently include additional elements such as environmental and social impacts.*

Third, private standards are much more specific and prescriptive about how to achieve the outcomes defined by standards than is the case with public standards. In many cases public mandatory standards

lay down the basic parameters of a food safety system, while private standards elaborate on what this system should 'look like' in order to be effective. It should be noted that some public regulations also perform this function when they specify particular procedures to be adopted by food producers and processors to assure food safety.

11. *In addition to reducing risk, private standards also provide businesses with a basis for product differentiation*, although this is not common in the arena of food safety. *Standards can be adopted to support claims to consumers that products have certain extrinsic characteristics that reflect the way in which they have been produced. Generally speaking, claims about credence characteristics – attributes of a product that neither the retailer nor the consumer can verify through direct examination of the product or through consumption unlike so-called 'experience attributes' – are backed up by standards which aim to provide a credible basis for making the credence claims.*

...16. *At the heart of the on-going debate about the role and implications of private food safety standards are questions about their 'legitimacy', both in general and in comparison to the standards elaborated by established international organisations in the area of food safety, notably Codex Alimentarius and ISO...* The paper discusses the following indicators of legitimacy: extent to which the standards-setting process is transparent; influence of agri-food value chain stakeholders on the standards-setting process; extent to which developing country interests are taken into account in the standards-setting process; speed of the standards-setting process and responsiveness to the demand for new or revised standards; harmonisation; scientific basis for standards.

19. Public and private standards differ considerably in their speed of response to new challenges. One feature of Codex, and of other international standards organisations, is the time and resources expended in elaborating new or revised standards... It should be noted that the difference in scope between science-based standards in support of health outcomes and other standards (e.g. quality standard) is an important factor to also consider in this context.

20. *A challenge for both public and private standards is harmonisation.* Evidence suggests that the harmonisation of national food safety regulations around international standards has been slow. Further, *an important criticism of private food safety standards is that they undermine this process of harmonisation, introducing a new layer of governance* that further fragments national markets according to the food safety requirements with which exporters must comply...

21. *A key concern in on-going debates about the legitimacy of private food safety standards, predominantly in the WTO, is whether they are 'science-based'.* Although there is little compelling evidence that private food safety standards come under the purview of the SPS Agreement, there are concerns that the requirements of private food safety standards do not provide appreciably higher levels of protection against food safety hazards. Intuitively, private firms would not engage in the setting and/or adoption of standards that impose costs on the value chains in which they operate unless some greater level of protection was afforded than prevailing food safety controls. *The one exception relates to the use of standards to differentiate products, although it would appear that food safety is rarely used as a differentiator. At the same time, it is argued in the paper that one of the primary functions of private food safety standards is to define a set of requirements and associated systems of conformity assessment directed at regulatory compliance.*

... 27. In practice, there is a substantial overlap between public and private standards and their impacts on food production and processing and developing countries. *Private standards for food safety are often responses to government regulations that build on the framework of public standards. In so doing,*

private standards are able to reduce the cost of standards formulation and enforcement, for example by providing a detailed ‘road map’ for compliance and conformity assessment. By defining rules for the elaboration of public and private standards by other entities - member governments, firms and NGOs - Codex plays an important role in guiding the development of private standards.

E. Private Industry Standards Are Being Developed for Maximum Pesticide Residue (MRL) Levels

1. Cary Blake, Confusion Over Private MRL Regulations, Western Farm Press (July 17, 2010) (emphasis added).

“U.S. food companies are throwing a monkey wrench into the growing complexity of pesticide maximum residue levels (MRLs) in crops. McDonald’s and Wal-Mart are stirring the MRL pot by considering private regulations far more stringent than the MRLs developed by the U.S. Environmental Protection Agency (EPA). The regulations are creating more confusion for production agriculture on allowable pesticide tolerances. A MRL is the maximum pesticide residue level legally permitted in or on food or animal feed. The MRL is an enforcement tool for products in trade. Cindy Baker says the evolution of private company regulations is aimed at protecting company brands and ensuring food safety. ‘Companies have a lot at stake with their brand,’ said Baker, president of Exigent, part of the Gowan Group of companies. Gowan is a registrant and marketer of crop protection products based in Yuma, Ariz...Baker says companies are hunkering down to further reduce or eliminate pesticide MRLs in crops to boost market share by marketing their products as free of pesticide residues....Baker’s credentials on the MRL issue include her involvement as a member of the U.S. Environmental Protection Agency’s (EPA) Pesticide Program Dialogue Committee. Baker is the registrant on the U.S. delegation for Codex, an international body that sets tolerances for countries without their own MRL levels...‘They’ve started to look at whether they can get a better market advantage by eliminating pesticide residues in food or eliminating classes of chemistry including organophosphates used in crop production,’ Baker said.

Wal-Mart, for example, is evaluating a stewardship index initiative for specialty crops grown in the West. Growers would be rated according to a matrix of factors; comparing practices by Grower X, Grower Y and Grower Z. Growers could be graded on efforts to reduce pesticide and water use, plus worker protection from pesticide exposure. The matrix would be on top of stringent EPA regulations. Baker shared a McDonald’s effort where a stakeholder resolution proposed the company discontinue the purchase of crops containing any pesticide residue. The company chose to test the concept on potatoes. The idea was to create a common matrix for potato production at every location where potatoes are grown for McDonald’s. Baker says these matrixes can be problematic since integrated pest management (IPM), production costs, and other resources are not given full consideration. ‘Growing potatoes in different areas of the U.S. and Canada is very different due to various nematode and insect pressures, weed management challenges, and weather conditions,’ Baker said. ‘IPM procedures for potato production in Boise, Idaho are different from those in Canada.’ ‘Whether the issue is food safety, sustainability or pesticide use, the core principals of IPM should be incorporated into crop production. We need to grow a crop affordably, safely, and effectively.’ Private regulation for pesticides is among the emerging MRL issues.

Also on the front burner is the growing practice by individual countries or blocks of countries, the European Union (EU) for example, to create individual MRL levels for each pesticide, crop and

country. Globally, the practice is extremely complicated for production agriculture where keeping track of multiple MRLs generates confusion.”

VI. Hypotheses About Why Europe Has Succeeded in Becoming the Global Standard-Setter

A. An Effective Three-Prong Trade Strategy to Export EU Regional Sustainable Development Regulations and Standards Globally

1. Lawrence A. Kogan, ‘Unscientific ‘Precaution’: Europe’s Campaign to Erect New Foreign Trade Barriers, Washington Legal Foundation WORKING PAPER Series No. 118 (Sept. 2003), at p.6.

“...[T]he EU has been inspired by such environmental movements to pursue a three-dimensional strategy that seeks to define and employ the precautionary principle globally. The EU has sought to inject it within the WTO system at large through creative interpretation of the SPS and TBT Agreements and The EU has sought to inject it within the WTO system at large through creative interpretation of the SPS and TBT Agreements and through incorporation within them of obligations assumed under multilateral environmental agreements. In addition, the EU has sought to incorporate the precautionary principle within international standards through active and skilled participation in the international standards development process. Furthermore, the EU has begun to incorporate it within bilateral and regional free trade and aid agreements and within EU trade capacity-building initiatives offered to developing countries. Apparently, the EU is attempting to elevate the status of the precautionary principle from a limited (provisional) WTO exception to a ‘norm’ of general customary international law equal in importance to general principles of international trade law.”

2. Lawrence A. Kogan, *Exporting Europe’s Protectionism*, The National Interest, Issue 77, 91-98 at pp. 93-94 (2004) (emphasis added).

“As Agrifood News reported on November 26, 2002: ‘*Spending twice as much on research and development, and employing twice the number of people, the U.S. is creating more biotechnology products and services than Europe...[In 2001], market capitalization of U.S. [biotech] firms was five times that of EU companies.*’ That alone would provide the commission with ample incentive to protect the relatively undeveloped European biotech industry from competition. By saddling American GMO exporters with market access hurdles more onerous and costly than those imposed within the United States, the EU ‘levels’ the economic playing field—that is, tilts the playing field to the advantage of European companies. The EU Commission goes to some effort to deny this obvious fact. It contends that the higher environmental standards imposed on EU businesses pursuant to the precautionary principle actually enhance their competitiveness in world markets, because of the more sophisticated technologies they are forced to employ. Other things being equal, that might be true. *But the EU’s rationalization ignores the reality that the more expensive technologies needed to satisfy those standards raise industry costs and make EU companies less competitive. Rather than being absorbed by such companies, the higher technology costs are almost always reflected in higher product prices. The negative competitive advantage they impose is roughly equivalent to the added cost of going beyond average international production costs to satisfy the higher EU market standards.*

Hence the commission seeks to level the playing field again by exporting its costly precaution-based regimes abroad to other countries along the global product supply chains, such as China. Examples include the regulation on GMO traceability and labeling, the proposed REACH regulation on management of high-volume chemicals, and the combination of the directives preventing waste from electrical and electronic products and restricting the use of hazardous substances in consumer electrical and electronic products...Thus, the EU seeks to export its standards (and costs) to foreign producers directly.

Increasingly, however, it employs a more subtle and even covert method: It subsidizes NGOs in other countries that then seek to reproduce EU-style rules at home through political pressure. This remote-control policy is hard to trace, because often the EU (and sometimes individual EU countries) give subsidies to European NGOs that pass on the money to their subsidiaries abroad. What makes this policy so effective is that the sums of money are often large by local standards, but they arrive in the semi-disguise of humanitarian outreach. Some of the most outrageous examples of this practice concern the campaign against GMOs in countries with large malnourished populations. As the New York Times noted in a February 21, 2003 article, one such country, the Philippines, has recently become the target of a sustained campaign by anti-GMO activists. The reason? The Philippines is home to the International Rice Institute, which is attempting to develop a strain of rice fortified with vitamin A, called ‘golden rice.’ But this has not gone unnoticed in Europe, and the NGO community, flush with EU grants, has responded. The South Asia Regional Institute for Community Education (SEARICE), the Philippines’ main anti-biotech NGO, has received substantial funding from the Development Fund of Norway, including an anti-GMO, anti-biotech propaganda campaign. SEARICE has also received funding and support from the Swedish Society for Nature Conservation and the Swedish International Development Cooperation Agency, the Swedish government’s aid agency. And the Humanist Institute for Development Cooperation, a Dutch NGO and recipient of EU and Dutch government largesse, also provides support to SEARICE, as well as to hundreds of other local organizations in dozens of developing countries. While the EU has publicly declared GM foods to be ‘safer than conventional plants and foods’, its member states (and the EU itself) generously fund antibiotech groups like Greenpeace, Friends of the Earth and Consumers International. Each of these groups has actively opposed the provision of GM food aid to the developing world. *As the Center for Consumer Freedom noted, ‘the Director of the European Union Commission on Consumer Protection [has] admitted that Europe funds the very environmental organizations that stirred up anti-biotech hysteria in sub-Saharan Africa, prompting Zambia’s president to reject’ millions of dollars of U.S. food aid.’*

3. Henrik Selin and Stacy D. VanDeveer, *Raising Global Standards: Hazardous Substances and E-Waste Management in the European Union*, “Environment” Vol. 48, No. 10, pages 6–17, at pp. 7-8 and 15 (Dec. 2006) (emphasis added).

“Three recent EU policy developments—two ‘directives’ and one ‘regulation,’ in EU terms—are of particular significance to the future management of hazardous chemicals and e-waste. The first directive covers waste electrical and electronic equipment (WEEE), and the second outlines restrictions on the use of certain hazardous substances in electrical and electronic equipment (RoHS). WEEE and RoHS entered into force in February 2003. Finally the regulation on the registration, evaluation, and authorization of chemicals (REACH) will soon be finalized and will become legally binding in 2007. ***WEEE, RoHS, and REACH are noteworthy for several reasons. All are critical for EU sustainable development efforts. Furthermore, aspects of the new hazardous substances and e-waste standards are***

the highest in the world. As such, they are drawing considerable attention from policymakers, regulators, company managers, and environmental activists from around the globe. Because of growing international trade and the diffusion of policy ideas and information, producers and users of chemicals, heavy metals, and manufactured goods in markets such as the United States, Japan, and China will be affected by EU policy. In effect, new, higher EU regulatory and product standards are likely to push many global standards upward through a process that political scientist David Vogel calls ‘trading up.’

...European actors also want other jurisdictions to adopt similar chemical and waste policies. Now that EU standards have increased, European officials, European environmental organizations, and European firms have shared interests in exporting EU standards to other countries and in uploading such standards into international agreements. Political scientist David Vogel argues that such shared interests lead to coalitions of environmental actors and firms—‘Baptists and bootleggers’—that use market forces to ‘trade up’ regulatory standards. This is consistent with a long-standing EU strategy, dating from the first Environment Action Programme in 1973, of active engagement in international forums to achieve goals that could not be obtained solely at a regional level. As such, the EU can be expected to pursue the uploading of its new chemical and waste management policies in a host of international forums.”

B. Effective Liberal Interpretation of GATT/WTO Treaty Rules to Alter the Relationship Between Trade and Non-Trade Law

The European Union and the World, European Commission (March 2001) at p. 12, referenced in *Trade: Removing Barriers, Spreading Growth – The European Union: A Global Player*, The European Commission Delegations to Lithuania and Barbados and the Eastern Caribbean websites; *Implementing Policy For External Trade in the Fields of Standards and Conformity Assessment: A Tool Box of Instruments*”, Commission of the European Communities, Commission Staff Working Paper, SEC (2001)1570 (9/28/01), at p. 5 (emphasis added).

“...[T]he WTO must be reformed...Its rulebook needs to be rewritten and civil society more closely involved so that environmental and social concerns can be considered alongside trade and development issues...In the EU’s view...a new round of WTO negotiations should...address a number of civil society concerns, by clarifying WTO rules on trade and the environmental agreements, labeling, public health and the application of the precautionary principle...”

Lawrence A. Kogan, *Polluting the Future of the WTO*, Institute for Trade, Standards and Sustainable Development (2006) (emphasis added).

*“The Wall Street Journal recently reported about the European Commission’s latest bid to promote United Nations sustainable development (SD)-based ‘global governance’ (See *EU Trade Chief Poses WTO Rules in Energy* – WSJ 6/23/06). Although EU Trade Commissioner Mandelson has recommended that WTO Member States negotiate an energy treaty under WTO auspices to ensure global energy security and to enhance international ‘economic harmonization’, his appeal should be stripped of its rhetoric and recognized for what it truly is – an attempt to subject global energy production and distribution to EU SD regulation.*

...Mr. Mandelson's appeal is conspicuously consistent with the thinking of *WTO Director General Pascal Lamy, who recently delivered two very important speeches during this past May (on 5/19 and 5/30). In them, he outlines one possible future course for the WTO as a multilateral institution, along with its 'special' relationship to the UN network of international organizations. Specifically, Mr. Lamy speaks of the relationship of trade to non-trade law. Although he focuses on the need to harmonize international trade, environment and health treaty law, which is now governed largely by the GATT (1994) and the WTO Sanitary and Phytosanitary (SPS), Technical Barriers to Trade (TBT), and TRIPS Agreements, he also aspires to articulate broader ideas. One such idea is to gradually transfer a portion of the WTO's jurisdictional and governance responsibilities to the UNEP, the WHO, the UNHCHR, etc., so that other than pure trade-related science, technology, intellectual property and innovation related issues may fall increasingly under less technical and commercial UN auspices. Alternatively, he suggests that it is necessary to expand the jurisdictional and governance responsibilities of the WTO so that it may encompass and address all trade and non-trade crosscutting issues together under one roof.*

In his May 19th speech, in particular, Mr. Lamy focuses on this latter possibility. Specifically, he discusses how the available GATT Article XX chapeau and exceptions from the WTO Agreements' general trade principles permit WTO Member States to pursue non-trade policies without fear of violating WTO rules. He argues that, 'WTO Members' trade restrictions imposed to implement non-trade considerations, will be able to prevail over WTO market access obligations so long as they are not protectionist...Absent protectionism, a WTO restriction based on non-WTO norms, will trump WTO norms on market access'. Obviously, the Director General has stepped out on a limb to candidly acknowledge that the WTO treaties and accompanying jurisprudence place important substantive technical limitations on the ability of WTO Member governments to utilize non-trade measures (environment, health and safety (EHS) regulations and standards) to 'protect' home-country industry competitiveness..."

1. The EU has endeavored to Glean from GATT/WTO Case Law Justification to Liberally Interpret the 'Like or Similar' Products standard of GATT Article III.4 and TBT Article 2.1, such that food, feed, and seed products produced, processed, or otherwise formulated consistent with or pursuant to preferred EU sustainable development-based standardized methods, procedures and/or criteria would NOT be deemed by EU consumers as 'like or similar' to U.S. products not otherwise subject to such EU regulatory or standards benchmarks, especially where human, animal and plant health risks such products might be engendered and/or where EU consumer tastes/preferences and perceptions regarding the different food, feed and seed processing and production, cultivation and stewardship methods are shaped by point-of-sale labeling detailing the distinct process and production methods (PPMs)) employed by non-EU producers (e.g., U.S. exporters) for livestock, seeds and the crop or grazing land (i.e., whether or not they are subject to EU 'sustainability', 'green' or 'CSR' verification and certification standards) such that those differences render the U.S. exported end-products distinct from other products in the EU marketplace.

a. **GATT/WTO Case Law on 'Like or Similar' Products:**

GATT Article III.4 obliges a contracting party to accord to imported products

“*treatment no less favorable than* that accorded to *like products* of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation distribution or use” (emphasis added).

The choice of the word ‘AFFECTING’ in the text of GATT Article III(4) suggests that *the drafters of the Article intended to cover NOT ONLY the laws and regulations which directly governed the conditions of sale or purchase, BUT ALSO ANY laws or regulations which might adversely modify the conditions of competition between the domestic and imported products on the internal market. Italian Discrimination Against Imported Agricultural Machinery* (GATT Panel Rpt Adopted (1959)

The *Report of the Working Party on Border Tax Adjustments* [BISD 18S/97 (1970)], “set out the basic approach for interpreting ‘like or similar products’ generally in the various provisions of the GATT 1947:

“...[T]he interpretation of the term should be examined on a case-by-case basis. This would allow for a fair assessment in each case of the different elements that constitute a ‘similar’ product. *Some criteria were suggested for determining, on a case-by-case basis, whether a product is ‘similar’: the product’s end-uses in a given market; consumers’ tastes and habits, which change from country to country; the product’s properties, nature and quality.*” [Id., at par. 18, cited in *Japan-Taxes on Alcoholic Beverages*, WT/DS8, 10 & 11/AB/R, Appellate Body Report adopted by the DSB 11/1/96] (emphasis added).

In *Japan-Taxes on Alcoholic Beverages* [WT/DS8, 10 & 11/AB/R], the Appellate Body indicated that the meaning of *the phrase ‘like’ products’ must be considered in light of “the broad and fundamental purpose of Article III, [which] is to avoid protectionism in the application of internal tax and regulatory measures.*

“...Toward this end, Article III obliges Members of the WTO *to provide equality of competitive conditions* for imported products in relation to domestic products. ‘*[T]he intention of the drafters of the Agreement was clearly to treat the imported products in the same way as the like domestic products once they had been cleared through customs. Otherwise indirect protection could be given.*’ Moreover, it is irrelevant that the ‘trade effects’ of the tax [(or regulatory)] differential between imported and domestic products, as reflected in the volumes of imports, are insignificant or even non-existent; *Article III protects expectations not of any particular trade volume but rather of the equal competitive relationship between imported and domestic products. Members of the WTO are free to pursue their own domestic goals through internal taxation or regulation so long as they do not do so in a way that violates Article III or any of the other commitments they have made in the WTO Agreement*” (emphasis added). [Id., at 16, quoting *Section 337*, para. 5.10; *Superfund*, para. 5.1.9; and *Italian Agricultural Machinery*, par. 11] (emphasis added).

The Appellate Body followed the *Border Tax Adjustment Report’s* framework in analyzing whether... liquor items were ‘like products’. However, when considering the broader focus of the second sentence of Article III.2 [dealing with internal taxes or charges], it undertook a more expansive evaluation to define the phrase ‘directly competitive or substitutable products’ found in *Ad Article III.2. The Panel emphasized the need to look not only at such matters as ‘physical characteristics, common end-uses,*

and tariff classifications, but also at the ‘market place’, including ‘the elasticity of substitution’ (i.e., the ability to substitute one product for another).

“In the Panel’s view, *the decisive criterion in order to determine whether two products are directly competitive or substitutable is whether they have common end-uses, inter alia, as shown by elasticity of substitution*” (emphasis added) [Id., at pars. 6.28-6.32].

Once a measure has been found to constitute a technical regulation, it is assumed by the TBT Agreement to fall under the auspices and responsibility of a central or local government body, or a non-governmental body possessing (i.e., that has been delegated) the legal authority to enforce it. [TBT Arts 2 and 3; Annex 1.7 and 1.8]. Accordingly, **TBT Article 2.1** imposes upon such body a ‘national treatment’ obligation that prohibits discrimination as between domestically produced goods and the same or ‘like’ imported goods. **“Members shall ensure that...products imported from...any other [WTO] member shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country”** (emphasis added).

While the meaning of these terms is nowhere defined in *the TBT Agreement*, the Appellate Body, in *EC Measures Concerning Meat and Meat Products (Hormones)* [WT/DS26 & 48AB/R, Appellate Body Report adopted by DSB (2/13/98)], determined that they **should be construed consistent with the directly parallel language of GATT Article III.4.**

“The term ‘like product’ was not defined in the TBT Agreement, but given the direct parallel between the language of Article 2.1 of the TBT Agreement and Article III:4 of GATT, the GATT approach to ‘like product’ should apply. Similarly, given the direct parallels between Article 2.1 of the TBT Agreement and Articles I and III of GATT, a technical regulation that was inconsistent with Articles I or III of GATT should also be inconsistent with Article 2.1 of the TBT Agreement” (emphasis added). [*EC Hormones* at par. 241].

In *EC-Asbestos*, the Appellate Body noted how **“the general purpose of Article III is to prevent Members from applying internal taxes and regulations in a manner which affects the competitive relationship in the marketplace between the domestic and imported products involved, ‘so as to afford protection to domestic production’”**(emphasis added) [WT/DS135/AB/R, at par. 98]. In light of this broad purpose, it reasoned that “the word ‘like’ in Article III.4 [must] be interpreted to apply to products that are in such a competitive relationship. **Thus a determination of ‘likeness’ under Article III.4 is, fundamentally a determination of the nature and extent of a competitive relationship between and among products”** (emphasis added) [Id., at par. 99]. Since such a relationship will vary from case-to-case, the Appellate Body concluded that the ‘accordion’ of ‘likeness’ (product scope) of Article III.4 can be at least as narrow as the *first* sentence of Article III.2, but no broader than the *combined* product scope of both sentences of Article III.2.

The Appellate Body, furthermore, indicated that **the four general ‘likeness’ criteria** outlined in *Border Tax Adjustments* and *Japan-Taxes on Alcoholic Beverages* “comprise **four categories [or groupings] of ‘characteristics’ that the products might share: i) the physical properties of the products; ii) the extent to which the products are capable of serving the same or similar end-uses; iii) the extent to**

which consumers perceive and treat the products as alternative means of performing particular functions in order to satisfy a particular want or demand; and iv) the international classification of the products for tariff purposes” [Id., at par. 101].

It noted that, while each grouping addresses a different aspect of the products involved and should therefore be examined separately, they are nevertheless interrelated. For example,

“the physical properties of a product shape and limit the end-uses to which the products can be devoted, Consumer perceptions may similarly influence-modify or even render obsolete-traditional uses of the products. Tariff classification clearly reflects the physical properties of a product” (emphasis added) [Id., at par. 102].

When undertaking an evaluation of ‘likeness’, the Appellate Body, however, recommended that the physical properties of products be reviewed separately so that they are not confused with the examination of end-uses. It noted, for example, how “[t]he physical properties of a product may influence how a product can be used, consumer attitudes about the product, and tariff classification” [Id., at par. 111]. Yet, it warned how a product’s end-uses cannot, similarly, alter that product’s physical properties. “Products with quite different physical properties may, in some instances be capable of performing similar or identical end-uses”; however this end-use equivalence does not change their physical properties, which remain different [Id., at par. 112].

The Appellate Body, relying on this reasoning, emphasized that health risks posed by products, such as carcinogenicity or toxicity, can constitute a defining aspect of the physical properties of a product [Id., at par. 114]. In this particular case, it found that the different health risks posed by chrysotile asbestos fibers and polyvinyl alcohol, cellulose and glass fibers (PCG) (“the evidence indicates that PCG fibers do not share these properties”) likely arose from the differing structures or chemical compositions of such substances [Id., at par. 115]. Given this information, the Appellate Body could “not see how this highly significant physical difference cannot be a consideration in examining the physical properties of a product as part of a determination of ‘likeness’ under Article III.4” [Id.].

The Appellate Body, furthermore, highlighted the importance of including health risk considerations in the determination of whether “all [of] the relevant evidence...as a whole, indicates that the products in question are ‘like’ in terms of the legal provision at issue” [Id., at par. 103]. As concerns Article III.4, this means “whether and to what extent the products involved *are—or could be*—in a competitive relationship in the marketplace” [Id.].

In this regard, the Appellate Body noted how “the second and third [Border Tax Adjustment] *criteria involve certain of the key elements relating to the competitive relationship between products:* first the extent to which products are capable of performing the same, or similar, functions (end-uses), and, second, *the extent to which consumers are willing to use the products to perform these functions (consumer tastes and habits)*” [Id., at par. 117]. Taking these elements into account, the Appellate Body concluded that *evidence relating to consumers’ tastes and habits establish that the health risks*

associated with chrysotile asbestos fibers in the present case would likely influence consumers' behavior with respect to the different fibers at issue. In other words,

“[C]onsumers' tastes and habits regarding fibers, even in the case of commercial parties, such as manufacturers, are very likely to be shaped by the health risks associated with a product which is known to be highly carcinogenic...[although] the influence known dangers have on consumer tastes and habits is unlikely to be uniform or predictable” (emphasis added) [Id., at par. 122; fn 2].

The Appellate Body emphasized that *“since 1977, chrysotile asbestos fibers have been recognized internationally as a known carcinogen because of the particular combination of their molecular structure, chemical composition, and fibrillation capacity”* [Id., at par. 135]. The concurring opinion went a bit further. *“Considering the nature and quantum of the scientific evidence showing that the physical properties and qualities of chrysotile asbestos fibers include or result in carcinogenicity...there is ample basis for a definitive characterization, on completion of the legal analysis, of such fibers as not ‘like’ PCG fibers”* (emphasis added) [Id., at par.152].

The EC had made a ‘prima facie’ case for the existence of a ‘health risk’ in connection with the ‘use’ of chrysotile, and for the non-existence of a reasonably available alternative to the banning of the chrysotile and chrysotile cement products AND recourse to substitute products. The risk, in particular, concerned lung cancer and mesothelioma in the occupational sectors downstream of production and processing. It also concerned the public in general, in relation to chrysotile cement products. Canada did not rebut the prima facie case.

2. The EU has endeavored to glean from WTO case law justification to liberally interpret the scientific risk assessment requirements of the Sanitary and Phytosanitary (SPS) Agreement, so that greater weight is placed on the “relevant processes and production methods” and “relevant ecological and environmental conditions” factors articulated by WTO case law, when assessing potential human, animal or plant Safety Risks or potential related Ecological and/or Environmental Risks that might be engendered by food, feed and seed products that fail to adhere to European process and production, cultivation and product/land stewardship methods (PPMs) as required by EU ‘sustainability’, ‘green’ or ‘CSR’ regulations or verification and certification standards.

a. WTO SPS Agreement Case Law:

Lawrence A. Kogan, *Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science*, National Foreign Trade Council, Inc. (May 2003), at pp. 16-18 and accompanying notes (emphasis added).

“WTO case law, which has interpreted many of the provisions within the SPS Agreement, has essentially created a roadmap that helps to discern when a sanitary and/or phytosanitary measure constitutes a disguised trade barrier. SPS Article 2.2 requires each WTO member (including the EU and its Member States) to base its measures on ‘scientific principles’ and to maintain those measures with ‘sufficient scientific evidence’. ‘From this general duty flows *the obligation to base SPS measures either on*

*‘international standards’, to the extent they exist, pursuant to Articles 3.1 and 3.2, or on other [, or even, its own] scientific justification’, pursuant to Article 3.3.’ Scientific evidence has been deemed to be ‘sufficient’ if there exists “a sufficient or adequate relationship between two elements, in casu, between the SPS measure and the scientific evidence...there [must] be a rational or objective relationship between the SPS measure and the scientific evidence...Sufficiency is to be determined on a case-by-case basis, depending on the particular factual circumstances, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence.’ [See, e.g., Appellate Body’s decision on *Japan -- Measures Affecting Agricultural Products*, (hereinafter referred to as “the *Japan-Varietals* case”), adopted on March 19, 1999, WT/DS76AB/R].*

Where international standard setting bodies have not established ‘relevant international standards’ that specifically relate to a particular food product, or such standards are ‘not sufficient to achieve a WTO member’s appropriate level of SPS protection, that member is required to base its SPS measures on its own ‘scientific justification’, pursuant to SPS Article 3.3. ***Scientific justification must be established on the basis of an examination and evaluation of all available scientific information. Consistent with the requirement that an SPS measure must be based on scientific principles, SPS Article 5.1, requires that a WTO member’s SPS measure must be based on an assessment of the risks to human, animal or plant life or health. Such a risk assessment must be appropriate to the circumstances and must take into account risk assessment techniques developed by the relevant international organizations. There are three international standards organizations charged with harmonizing food safety regulations; they are the Codex Alimentarius (Codex), the International Plant Protection Convention (IPPC), and the International Office of Epizootics (OIE).***

When undertaking a risk assessment, SPS Article 5.2 requires that the following factors be taken into account: 1) available scientific evidence; 2) relevant processes and production methods; 3) relevant inspection, sampling and testing methods; 4) prevalence of specific diseases or pests; existence of pest or disease-free areas; 5) relevant ecological and environmental conditions; 6) quarantine or other treatment. In assessing risks to health or animal or plant life, SPS Article 5.3 requires the EU to also take into account economic factors: 1) the potential damage in terms of loss of production or sales in the event of entry; 2) establishment or spread of a pest or disease; 3) the costs of control or eradication in the territory of the importing Member; and 4) the relative cost-effectiveness of alternative approaches to limiting risks.

WTO case law has articulated certain standards relating to risk assessments that a WTO member such as the EU must follow. First, “the risk evaluated must be an ‘ascertainable risk’. Theoretical uncertainty should not be assessed. The existence of unknown and uncertain elements does not justify a departure from the risk assessment requirement.” [See e.g., *EC Hormones* case]. In addition, ‘the risk to be evaluated in a risk assessment under SPS Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist – the actual potential for adverse effects on human health in the real world where people live and work and die.’ [See e.g., *EC Hormones* case]. Furthermore, a “qualitative assessment of risk is sufficient; a quantitative assessment is not required...In other words, a risk assessment does not require the establishment of a certain magnitude or threshold level of risk.’ [See e.g., *EC Hormones* case]. Moreover, a risk assessment must be specific as to each substance evaluated and must evaluate each potential risk presented. In other words, ‘a separate risk assessment must be conducted for each substance – a generic risk assessment for a class of substances is not enough...[And,] the studies part of a risk assessment must be specific enough to address the particular kind[s] of risk[s] at stake; general studies showing the existence of a general risk of harm [are] not enough.’ [See e.g., *EC Hormones* case]. Accordingly, ‘if a measure is not based on a ‘risk assessment’, it can be presumed not to be based

either on ‘scientific principles’, or to be maintained without ‘sufficient scientific evidence’ [Report of the Appellate Body on Australia - Measures Affecting the Importation of Salmon (hereinafter referred to as “the Australia Salmon case), adopted on November 6, 1998].

Lastly, a WTO member such as the EU must demonstrate that the SPS measures it has adopted are ‘objectively based on the risk assessment – it must not involve a subjective or procedural examination into the regulator’s decision-making process. There must be a rational relationship between the measure and the risk assessment... Even minority scientific opinions can justify this rational relationship... The risk assessment could set out both the prevailing view representing the mainstream of scientific opinion, as well as the opinions of scientists taking a divergent view... coming from qualified and respected sources’ [See, e.g., *EC-Hormones*].”

Lawrence A. Kogan, *World Trade Organization Biotech Decision Clarifies Central Role of Science in Evaluating Health and Environmental Risks for Regulation Purposes*, Global Trade and Customs Journal Vol.2 No.3, at pp. 149-151 (2007) and accompanying notes (emphasis added).

*“In its decision *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (hereinafter *EC – Biotech Products*), the Panel reaffirmed that WTO member countries concerned about the safety of specific biotech food-related imports must follow the specific terms of the WTO SPS Agreement. Pursuant to the SPS Agreement, countries may restrict imports of certain products in order to safeguard human or animal health, or to protect the environment, provided the regulations they enact either are in accordance with existing relevant international standards, or are narrowly drafted in order to protect against a genuine ascertainable risk, as determined by the application of best available science.* This most recent WTO Panel decision makes clear that, in the absence of relevant international standards, or where a concerned national government refuses to adopt them, a WTO member bears the burden of conducting an objective empirically based scientific risk assessment of identified or ascertainable potential health or environmental risks posed by specific products. And this must be done before a WTO member promulgates regulations that have the effect of denying or restricting market access to those products.

The Panel then proceeded to explain in more detail how the EC and EU Member States had failed to undertake an ‘adequate risk assessment’ of their own. While doing so, it also clearly distinguished between the environmental and health concerns of scientists, which are typically substantiated through application of scientific method, and those of legislators, which are often based on unverifiable facts, public fears and a need to politically address them. In the Panel’s view, legislators’ concerns are relevant primarily for managing potential product risks whose degree of ‘safety’ scientists have already assessed in gauging how to arrive at the ‘appropriate level of regulatory protection’ (i.e., fulfilling the legislators’ protection goals). Legislators’ concerns may even ‘have a bearing on the question of which risks a Member decides to assess with a view to taking regulatory action, if necessary’ on safety grounds. Scientists’ concerns, on the other hand, are relevant for identifying and evaluating (i.e., assessing), in the first instance, the existence and magnitude (severity) of potential health and/or environmental safety risks posed by a specific product. In effect, the Panel rejected the EC’s and EU Member States’ argument, and focused on how neither the language of the SPS Agreement, nor relevant WTO jurisprudence ‘suggest[s] that a risk assessment had to be adequate for the purposes of a Member’s legislator’.

According to the Panel, there is ‘only one relevant relationship: that between the scientific evidence and the obligation to perform a risk assessment under Article 5.1’. ‘[T]he definition of the term “risk assessment” in Annex A(4) does not indicate that a Member’s appropriate level of protection is pertinent to an assessment of the existence and magnitude of risks....Also, Annex A(5) to the SPS Agreement states that the concept of the appropriate level of protection is referred to by some Members as the concept of the ‘acceptable level of risk’. We do not think that scientists need to know a Member’s ‘acceptable level of risk’ in order to assess objectively the existence and magnitude of a risk.’

Consequently, the WTO Panel, by raising this issue, once again reaffirmed that a science-based risk assessment and a politics-based risk management decision are indeed two distinct but related disciplines involving different experts and considerations. It also clarified that only science-based risk assessments are relevant for purposes of determining whether a WTO member has satisfied SPS Article 5.1 and Annex (A)(4).”

3. The EU has endeavored to glean from WTO case law justification to liberally interpret the ‘purpose’ of particular Food ‘Safety’ Traceability and/or Packaging and Labeling’ and/or Certification measures so that they qualify as non-Food (Environmental) Safety or non-Safety Food ‘Consumer Information or Preference/Taste’ measures and/or Food ‘Quality’ measures (which can be either or both), subject to the less rigorous (Non-scientific) risk assessment requirements of the Technical Barriers to Trade (TBT) Agreement or of the GATT, rather than as Food Safety-focused ‘Sanitary or Phytosanitary Measures’ within the meaning of Annex (A)(1) of the SPS Agreement, which are subject to strict Scientific Risk Assessment requirements and economic cost-benefit analysis. Alternatively, the EU has endeavored to craft regulations or delegate authority to craft standards in such a manner as to include both SPS and a non-SPS ‘requirements’, to avail the EU and its Member States of the less rigorous scientific and economic justification provisions of the TBT Agreement.

a. **SPS vs. TBT Agreement – It’s All About the ‘Purpose(s)’ of the Measure:**

The TBT Agreement does not primarily require Member states to conduct a scientific risk assessment to evaluate actual human, animal and plant health risk, as the basis of a technical regulation the objective of which is to reduce or eliminate non-food safety or non-safety food risks, unlike Articles 5.1 and 5.2 of the SPS Agreement which address only food-safety risks. TBT Article 2.2 includes available scientific and technical information, related processing technology or intended end-uses, inter alia, as equal considerations in assessing the non-food safety risks posed to human, animal or plant life or health or to the environment, which a technical regulation was enacted to reduce or eliminate (e.g., consumer confusion or misrepresentation) consistent with a legitimate state objective. Consequently, the risk assessment required to be undertaken by TBT Article 2.2 to evaluate human, animal or plant health, which can include an ecological risk assessment or a sustainability or environmental impact assessment focusing on science and non-science considerations, is not as strict as the scientific risk assessment required by SPS Articles 5.1 and 5.2. Furthermore, the TBT Agreement Article 2.2’s “technical regulations shall not be more trade-restrictive than necessary” language, which is modeled on the GATT Article XX Chapeau, appears weaker than the “shall take into account as relevant economic factors...” language of SPS Article 5.3.

In other words, SPS Article 5.3 requires a more rigorous economic cost-benefit analysis than does TBT Article 2.2.

Michael J. Trebilcock and Robert Howse, *The Regulation of International Trade*, 2nd Edition, at pp. 142-143, Rutledge (1999)

“In terms of assessing risks, Art[icle] 2.2 [of the TBT Agreement] states that relevant elements of consideration are, inter alia, available scientific and technical information, related processing technology or intended end-uses of products. ***This may allow differentiation based on how a product is made, as opposed to the final product itself.*** Art[icle] 2.2 includes factors for consideration for determining whether products are ‘like’ or not that support an argument that measures which distinguish between products on the basis of production processes could be now validly justified as national treatment as well.” (pp. 142-143).

SPS Agreement – Food ‘Safety’ ‘Purpose’ of the Measure:

Annex (A)(1) of the SPS Agreement: An SPS measure is “Any measure applied: (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements, and procedures, including inter alia, end product criteria; processes and production methods;...certification and approval procedures;...provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.

TBT Agreement – Non-Food ‘Safety’ or Non-Safety Food Purpose’ of the Measure:

Pursuant to Article 1.5 of the TBT Agreement, “The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement of Sanitary and Phytosanitary Measures.”

Robert L. Howse and Henrik Horn, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, World Trade Review (2009), 8: 1, 49–83, at pp. 66-69 (emphasis added).

[TBT Agreement - No Scientific Justification Requirement:]

“[U]nder SPS the very scope of an SPS measure is defined in terms of the measure’s purposes. If a measure does not correspond to any of those purposes, then the specific additional disciplines (i.e. additional to the GATT) of SPS do not apply to it. The question then becomes whether the measure falls within the scope of the TBT Agreement. If not, then GATT Article III :4, which applies generally to domestic ‘laws, regulations, and requirements’ will likely be the applicable law, along with any defenses available for example under Article XX. It should be noted that the disciplines of SPS and TBT are not cumulative, so that *if a measure is considered an SPS measure, the disciplines of TBT do not apply. Under TBT, WTO Members are not required to base their measures on scientific principles or scientific risk assessment.* (p. 66)

Only to the extent that a measure serves the purposes articulated in Annex A(1) of SPS, must it be required to be justified scientifically. Thus, in the case of GMOs, if a WTO Member were to enact a ban or some less stringent measure for other purposes, such as to address ethical, religious, or lifestyle concerns about GMOs, there is no question that it could enact such a measure without the requirement of scientific justification. Indeed, it would be incoherent to require scientific evidence in such a case, because the measure is motivated by considerations that are not amenable to scientific analysis.

[Measures Bearing Both Food ‘Safety’ and ‘Non-Food Safety’ ‘Purposes’]

The question becomes whether the right of a WTO Member to enact such a measure without scientific justification is qualified or attenuated where the measure is also enacted to serve the purposes in SPS. If the measure fails the SPS requirements of scientific justification, does it become impermissible per se, despite the fact that had it been enacted purely for non-SPS purposes it would not be WTO-illegal?

Here is the Panel’s answer to this important question:

‘7.151 The European Communities argues that the SPS Agreement has a limited scope of application and that the scope is defined by reference to the objective, or purpose, of the measure at issue, that is the reasons justifying the measure. *The European Communities considers that if a WTO Member acts for two different reasons, one of which falls within the scope of the SPS Agreement, and the other of which does not, there are in effect two different measures for WTO purposes. According to the European Communities, this is so even if the two different objectives are sought to be achieved by a measure reflected in a single document.* The measure (or part thereof) taken for any of the reasons enumerated in the SPS Agreement falls within the scope of that Agreement. The measure (or part thereof) taken for other reasons falls outside the scope of the SPS Agreement.’ (p.67)

‘...7.165 *In our assessment, the better and more appropriate view is that of the European Communities. Hence, we consider that to the extent the requirement in the consolidated law is applied for one of the purposes enumerated in Annex A(1), it may be properly viewed as a measure which falls to be assessed under the SPS Agreement; to the extent it is applied for a purpose which is not covered by Annex A(1), it may be viewed as a separate measure which falls to be assessed under a WTO agreement other than the SPS Agreement.* It is important to stress, however, that our view is premised

on the circumstance that *the requirement at issue could be split up into two separate requirements which would be identical to the requirement at issue, and which would have an autonomous raison d'être, i.e., a different purpose which would provide an independent basis for imposing the requirement.*'

'7.166 *We recognize that, formally, the requirement at issue constitutes one single requirement.* However, neither the WTO Agreement nor WTO jurisprudence establishes that a requirement meeting the condition referred to in the previous paragraph may not be deemed to embody two, if not more, distinct measures which fall to be assessed under different WTO agreements. *We note that Annex A(1) of the SPS Agreement, which defines the term 'SPS measure', refers to '[a]ny measure' and to 'requirements'. But these references do not imply that a requirement cannot be considered to embody an SPS measure as well as a non-SPS measure.*' (p.68)

'...7.167 We note the United States' and Argentina's argument that Article 1.5 of the TBT Agreement supports a different conclusion. *To recall, Article 1.5 states that the provisions of the TBT Agreement 'do not apply' to SPS measures as defined in Annex A(1) of the SPS Agreement.*' (p.68)

'The operation of Article 1.5 is best illustrated by reference to the specific case of our hypothetical requirement contained in the consolidated law. To that end, *we assume that the consolidated law qualifies as a technical regulation within the meaning of Annex 1(1) of the TBT Agreement. We have stated above that to the extent the requirement in the consolidated law is applied for one of the purposes enumerated in Annex A(1) of the SPS Agreement, it can be viewed as an SPS measure. As such, it falls to be assessed under the SPS Agreement, provided the measure may affect international trade. Article 1.5 makes clear that to the extent the requirement at issue qualifies as an SPS measure, the provisions of the TBT Agreement would 'not apply', even though the requirement at issue is contained in a law which meets the definition of a technical regulation. We have also said that to the extent the requirement at issue is applied for a purpose not covered by Annex A(1) of the SPS Agreement, it can be viewed as embodying a non-SPS measure.* By its terms, Article 1.5 is not applicable to non-SPS measures. However, *given that the requirement is assumed to be part of a technical regulation, it falls to be assessed under the TBT Agreement, to the extent it embodies a non-SPS measure.* As the foregoing considerations demonstrate, *our view that a requirement may in certain cases incorporate more than one measure is consistent with, and gives meaning and effect to, the provisions of Article 1.5.* Therefore, we do not agree that Article 1.5 compels a different view.' (p. 69)

b. Conflating Food 'Safety' With Food 'Quality' for product certification, packaging and/or labeling purposes:

Food Safety and Quality Assurance Issues, Section V, "Improving the Safety and Quality of Fresh Fruits and Vegetables: A Training Manual for Trainers", Joint Institute for Food Safety and Applied Nutrition at pp. V-2 thru V-4 (©2002 University of Maryland) (emphasis added).

"Safety vs. Quality...

FOOD SAFETY. *Food safety is defined as the assurance that the food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use (FAO/WHO, 1997). Thus food safety assurance involves the reduction of risks* which may occur in the food. Implementation of

Good Agricultural Practices and Good Manufacturing Practices...are primary steps in reducing the risks associated with fresh fruits and vegetables.

...FOOD QUALITY. *[Food] Quality is defined by the International Organization for Standardization (ISO) as ‘the totality of features and characteristics of a product that bear on its ability to satisfy stated or implied needs.’ In other words, good quality exists when the product complies with the requirements specified by the client (van Reeuwijk, 1998). This means quality is a term defined by the consumer, buyer, grader, or any other client based on a number of subjective and objective measurements of the food product. These may include measures of purity, flavor, color, maturity, safety, wholesomeness, nutrition, or any other attribute or characteristic of the product.*

Using these definitions, safety is a component of quality. In fact, *many experts have argued that safety is the most important component of quality since a lack of safety can result in serious injury and even death for the consumer of the product. Safety differs from many other quality attributes since it is a quality attribute that is difficult to observe.* A product can appear to be of high quality, i.e. well colored, appetizing, flavorful, etc. and yet be unsafe because it is contaminated with undetected pathogenic organisms, toxic chemicals, or physical hazards. *On the other hand, a product that seems to lack many of the visible quality attributes can be safe.* Obvious quality defects can result in consumer rejection and lower sales, while safety hazards may be hidden and go undetected until the product is consumed. *Since assuring safety is vital to public health, achieving safety must always take precedence over achieving high levels of other quality attributes.*

Smith, G. (2009), *Interaction of Public and Private Standards in the Food Chain*, OECD Food, Agriculture and Fisheries Working Papers, No. 15, OECD Publishing at pp. 4-6 (emphasis added).

“1. This paper discusses a number of issues arising from the contiguous development of public and private quality standards, predominately in developed countries. The paper is an exploratory examination of the ways in which public and private food quality standards interact with each other in modern food systems...*The focus of the report is on food quality standards which are defined here as including the full array of food product and process attributes required by consumers and society as well as food safety. Food safety is clearly an integral part of food quality at least to the extent that food safety is a basic prerequisite for any quality attribute. However, food safety has very different requirements than other food quality attributes. Food safety is essentially a “public good” because safe food is a basic requirement of any food system to ensure trust in the food supply.* It is traditionally seen as a sovereign responsibility of the government to provide regulations, usually compulsory food safety standards as a basis for guaranteeing that food on offer is safe when delivered to consumers. Due to the presence of externalities, informational asymmetries and public goods characteristics, markets alone will generally not provide the socially desirable amount of food safety. *Hence it is assumed here that the competence for food safety standards remains a public sector responsibility and outside the ambit of the discussion in the paper concerning the interaction of public and private food quality standards.*

...3. At the same time, public food standards are being subject to closer scrutiny in the WTO and elsewhere in terms of their scientific justification and economic efficiency, which, in turn, is influencing the course of the progression. Historically, the public sector was involved with setting standards for product grades, weights and measures used in arms length transactions for mass markets composed of largely homogenous agricultural commodities. Grades and standards in these markets have many of the characteristics of public goods and will remain predominately in the public domain. *Public food quality*

regulations are, in general, becoming more performance and process based, placing greater responsibility on private food companies to implement effective food quality controls. In turn, private food quality standards have emerged to mitigate regulatory and reputational risks faced by private food businesses, and are increasingly being employed to facilitate competitive positioning in higher value food markets, through product differentiation based on an increasing array of food quality attributes.

*4. As advances in science, increases in wealth and evolving societal concerns with respect to the environment, sustainability and animal welfare put greater focus on a wider range of food quality attributes, both private firms and public institutions find themselves responding increasingly to consumer and societal demands for higher food quality. However, private and social interests are often distinct and an efficient food quality control system operated from a private business perspective may not yield socially efficient outcomes. Firms have incentives to provide high quality food in order to gain competitive advantage, but in cases where information available to consumers on which to judge food quality is imperfect, market and legal incentives may be insufficient to give consumers the level of quality and protection that society as a whole would like. In such cases of information asymmetries and externalities, governments continue to play an important role in correcting market failures by enacting minimum food quality regulations. In the case of experience and credence goods, consumers rely to a large extent on public standards and quality signalling to ensure the quality of food products provided in the market. This reflects both the difficulty they face to evaluate food product quality in such instances or to take recourse against suppliers if the product turns out not to meet their expectations. However, this does not necessarily imply that mandatory regulations or quality standards are required in all circumstances. Governments may instead introduce voluntary standards and seek compliance with such quality standards. **For a voluntary standards approach to be successful, the government must be prepared to follow up by imposing mandatory standards if adequate food quality compliance is not achieved with voluntary standards.** But where practices by producers can have serious effects on the well-being of consumers, governments often decide to take preventive action to rule out such possibilities. In these incidences, the government will choose mandatory standards.*

5. In circumstances where adequate information is available to consumers or can be found by them on the quality attributes of a food product, the role of mandatory standards is more questionable. For search attributes of food quality, the market will normally provide efficient incentives for producers to provide food quality even in the absence of mandatory standards or a well-functioning product liability system.

*10. From this brief review of the literature it would appear that while private food quality standards are often higher, more flexible and agile in responding to a wide range of continually evolving consumer preferences for food quality than public quality standards enforced by single nations on their domestic food supply or as a result of international negotiations (Codex); overall, public and private food quality standards tend to be complementary. **In many cases private standards build on the existing public standard infrastructure to provide an element of competition through quality differentiation.** Public standards are still necessary to correct market failures associated with information asymmetries or consumption externalities and where standards have clearly public good characteristics. **Public standards will, therefore, continue to play a dominant role in establishing basic grades and standards for mass markets composed of largely homogenous agricultural products to create economies of scale and for ensuring minimum standards of a safe food supply as well as to prevent fraud or quality deception of consumers. They also have a global role in assuring that basic standards are consistent across countries and with those that are required to be met (SPS, TBT) in cross border trade.** Private standards may play a substitute role in situations where there is an absence of effective public standards*

to provide a measure of food quality for consumers. *Alternatively, private standards have emerged despite the existence of strong public food quality standards as a means to differentiate products, reflecting the growing role of quality as the mode of competition in agricultural and food markets, as well as to facilitate effective coordination of expansive buyer supply chains.* In certain circumstances, private standards can also act to facilitate compliance with public standards to allow for better targeting of scarce compliance resources. *In markets for differentiated products and to meet requirements of niche markets (including for product liability), food companies may choose to exceed public standards with higher private standards.* In this way, private and public standards can be mutually reinforcing, contributing to total system efficacy and resulting in higher quality food being available in national and global markets.”

C. Since the EU Has Not Often Been Able to Fully Exploit its ‘27:1’ Voting Advantage vis-à-vis the United States for Purposes of Shaping International Food Safety Standards because of the Requirement of ‘Consensus-based Decision-making’ (Which Favors the U.S. at the WTO and the Codex), the EU May be Seeking to Alter Voting Rules at the WTO via Promotion of New ‘Critical Mass Decision-making’ Procedures, and at the Codex via Introduction of New Stakeholders into the Consensus Decision-making Process

1. World Trade Organization (WTO):

Article IX, Decision-making, and Accompanying Notes2-3, URUGUAY ROUND AGREEMENT, Marrakesh Agreement Establishing the World Trade Organization (emphasis added).

1. *The WTO shall continue the practice of decision-making by consensus followed under GATT 1947(1). Except as otherwise provided, where a decision cannot be arrived at by consensus, the matter at issue shall be decided by voting. At meetings of the Ministerial Conference and the General Council, each Member of the WTO shall have one vote. Where the European Communities exercise their right to vote, they shall have a number of votes equal to the number of their member States(2)which are Members of the WTO. Decisions of the Ministerial Conference and the General Council shall be taken by a majority of the votes cast, unless otherwise provided in this Agreement or in the relevant Multilateral Trade Agreement(3).”*

...FN1. *The body concerned shall be deemed to have decided by consensus on a matter submitted for its consideration, if no Member, present at the meeting when the decision is taken, formally objects to the proposed decision.*

2. *The number of votes of the European Communities and their member States shall in no case exceed the number of the member States of the European Communities.*

The European Union and the WTO, Member Information, WTO website (emphasis added).

“...The European Union (until 30 November 2009 known officially in the WTO as the European Communities for legal reasons)...has been a WTO member since 1 January 1995. *The 27 member States of the EU are also WTO members in their own right. The EU is a single customs union with a single*

trade policy and tariff. The European Commission — the EU's executive arm — speaks for all EU member States at almost all WTO meetings.

Patrick Low, *WTO Decision-Making for the Future*, prepared for Round Table 5: WTO Decision-Making for the Future at the Inaugural Conference of Thinking Ahead on International Trade (TAIT): Challenges Facing the World Trade System, Graduate Institute Geneva (Sept. 10, 2009).

*“The standard decision-making modality of the WTO is consensus, or unanimity. Vested interests, inertia and conservative risk preferences often militate against change and impart a strong preference for the status quo. This makes experimentation more difficult, calls for convincing arguments about why change is needed and requires a higher degree of certainty that changes will be effective...**These are challenges facing any attempt to modify the WTO's decision rules.**” (p.1)*

...Three main considerations suggest themselves. One relates to efficiency and the notion that the veto implicit in unanimity in decision-making imparts a bias towards lowest-common-denominator outcomes. Progress, when made, comes at a slow pace. *The history of how the European Communities started to move away from exclusive reliance on unanimity in the Council from the 1987 Single European Act onwards is instructive of how pressures for progress clashed with a cumbersome decision-making culture...* Much of the rest of this paper will be devoted to developing a framework for “critical mass” decision-making. Critical mass decision-making requires a relaxation of the unanimity rule, suitably embedded in a series of checks and balances that could make for a more vibrant and flexible multilateral trading system.” (p.2)

...*[F]or most of the GATT's existence and all of the WTO's the default rule has been unanimity or consensus (Pauwelyn, 2005). The original GATT has nothing to say about consensus. Instead it sets out voting rules varying with circumstance from unanimity to a two-thirds majority. As GATT membership multiplied there was increasing resort to consensus as the de facto decision rule in practically all matters. Rarely in recent years has voting been resorted to. The practice of consensus in the GATT/WTO has always been taken to mean that no party objects rather than that all parties must agree.” (p.3)*

... *Article IX of the WTO Agreement spells out detailed decision-making rules. The starting point is adherence to the ‘practice’ of consensus decision-making, with a possibility of voting on the basis on one vote per Member in cases of disagreement, with a simple majority carrying the day unless otherwise specified. Interpretations of provisions, amendments of provisions or waivers require super-majorities of two-thirds or three-quarters of Members, depending on the case at hand, and in the absence of consensus.*

In practice one might well interpret consensus decision-making as a hidden system of weighted voting, simply in terms of the reality that larger countries with more power would find it easier to influence voting outcomes than smaller ones. It would be more costly for smaller countries to challenge an outcome popular with large countries than vice-versa. Similarly, blocking a consensus with a veto is much more difficult for less powerful countries. Large countries have been willing to accept a one-country one-vote arrangement on the assumption that voting would not be used and that the veto would only be applied with great moderation. With opacity and pragmatism, then, parties to the GATT and WTO arguably found a broadly acceptable decision-making equilibrium over the years that responded to underlying power relationships...The equilibrium is increasingly one of inaction. (p.4)

... *Two interesting aspects of the critical mass decision-making are worth noting at the outset. First, critical mass decision-making is itself a form of de facto or implicit voting* and... Second, even though the EU has succeeded in establishing voting arrangements, it has still felt the need for its own critical mass approach to decision-making, referred to both as enhanced cooperation and flexible integration. We can learn useful lessons from the EU experience with this approach. **A critical mass, as defined for the present purpose, may be said to exist when a sufficient number of parties that do not represent the entire membership agree upon a common course of cooperative action to be taken under the auspices of the WTO.** (pp. 4-5)

... *[T]here are the critical mass agreements on telecommunications and financial services, and the Information Technology Agreement, all of which were negotiated subsequent to the completion of the [WTO] Uruguay Round.* These agreements embody the feature that benefits accruing from them apply on a non-discriminatory basis to signatories and non-signatories alike. (p.6)

... In considering areas in which critical mass decision-making could be an option, it is useful to distinguish between market access negotiations and negotiations about trading rules. *In the case of negotiations on trade opening measures – that is, reductions in tariffs and non-tariff barriers to trade in goods or market access and national treatment barriers to trade in services – it is arguable that elements of critical mass are already embedded both in the negotiations and their results. No two Members have the same market access obligations.* The baseline for market access negotiations is the individual tariff schedules of each Member, initially set at the time of accession and modified on the basis of negotiations in subsequent rounds. Members have participated more or less intensively in these negotiating rounds, largely as a function of their development status. *The examples of critical mass negotiations that have taken place since the creation of the WTO have for the most part involved market access, such as in the ITA, telecommunications and financial services negotiations. The fact that these were sectoral negotiations is what made a critical mass threshold – that is, a focus on the minimum necessary level of participation –* such an important point of focus. Future sectoral market access negotiations could well involve a similar approach, but for the present purposes we are more interested in critical mass negotiations involving the establishment of new or modified rules.

EU experience with critical mass – Enhanced Cooperation

The institutional and procedural arrangements surrounding enhanced cooperation are worth exploring in some detail for the lessons they may offer the WTO in contemplating similar arrangements. (p.7)

*A proposal must be made to the Commission by at least eight Member States (nine under the impending Lisbon Treaty) and if accepted by the Commission, is subject to qualified majority voting (QMV) in the Council, following consultation with, or consent from if appropriate, the European Parliament. An enhanced cooperation proposal must further the objectives of the EU and reinforce the process of integration, respect the treaties and single institutional framework of the EU, respect *acquis communautaire* and measures adopted under other provisions.* Proposals must remain within the limits of power of the EU and not fall within areas of exclusive community competence. They must not undermine the Single Market or economic and social cohesion, and must not constitute a barrier to, or discrimination in, trade between Member States, or distort competition. They must also respect the competence, rights and obligations of non-participating Member States, and the arrangements must be open to all Member States. All Council members may take part in deliberations, but only those participating in enhanced cooperation are permitted to take part in the adoption of decisions. *Enhanced cooperation does not form part of *acquis communautaire* but is binding on participants and should not*

be impeded by non-participants. The Council and Commission are responsible on a continuing basis for ensuring the consistency of enhanced cooperation initiatives.

... It is noteworthy that the EU's enhanced cooperation provisions have not led to any decisions so far of the kind we would equate to the critical mass decision-making we are contemplating here. It is beyond the scope of this study to explain why the enhanced cooperation provisions have not been used. Perhaps the EU's voting provisions are sufficient, or maybe the institutional and procedural constraints surrounding enhanced cooperation render its use impractical in the eyes of Member States. Moreover, enhanced cooperation is seen as a last resort in the EU, in circumstances where a more inclusive approach has failed to yield results. (p.8)

Proposing a critical mass approach

... First, presumably a prior understanding would be necessary that such arrangements required to support of a sufficient number of Members to warrant further consideration. Second, proposers would be expected to justify their desire to resort to a critical mass mode. Third, ***abstracting from market access sectorals, rules-related critical mass proposals might be about enhanced obligations in existing areas of WTO law*** – just as the Tokyo Round non-tariff measure accords (except for government procurement) were in the GATT context. (pp.8-9)

... A critical mass exists when those prepared to go ahead with an agreement consider the agreement has sufficient support and commitment among the membership. Given the view, strongly embedded in the GATT/WTO manner of doing business, that free riding is the dominant unconstrained mode of behaviour in situations of potential international cooperation, it would be expected that potential participants in a critical mass agreement would be very attentive to the question of who else was participating...***The starting point of a critical mass agreement is that not all parties will participate.*** (p. 9)

... When the critical mass has defined itself (as above) those left outside it are presumably considered too small in the market to undermine the agreement. In this sense, the outsiders cannot meaningfully be considered free-riders. ***This brings us to the conclusion that the economist's "small country" assumption should apply here. A free-rider is only a party whose non-participation in an agreement can destabilize that agreement.*** The rest should be left alone. A conclusion from this line of reasoning would seem to be that ***there is no justification for refusing to apply the MFN rule in respect of all the benefits accruing from a critical mass agreement – to signatories and non-signatories alike.*** In many cases this may be irrelevant if countries external to the agreement are not in a position economically speaking to benefit from the commitments of others under the agreement. If anything, this merely reinforces the case for a MFN default.

A consideration of some importance is what happens if today's small countries become tomorrow's free-riders. A concern often expressed about an MFN approach to critical mass is precisely this – ***dynamic developing economies will face no pressure to make commitments down the road if they can enjoy the benefits of the commitments of others in a non-reciprocal manner, even though they have become free-riders in the eyes of the members of a critical mass agreement. This point should not be taken lightly.*** (p.10)

... The somewhat obvious point to be made here is that ***for critical mass agreements to remain part of a multilateral structure they will need to be held to the standards that applied at their inception. This means that multilateral reporting and review arrangements would be part of the package.***

Decision points requiring consensus

Three decision points seem to arise in respect to the question as to when consensus decision-making should apply to critical mass initiatives. The first is at the launch of a proposal, the second is during the actual negotiation of the substance of an agreement and the third is upon adoption of results.

... There does not seem to be any justification for requiring that substantive negotiation of critical mass agreements be subject to a consensus decision-making process. This would be cumbersome, inefficient and costly. The consensus requirement would better be left to the time when the results of a negotiation are adopted and an agreement is to enter into force. This would be an indispensable accompaniment of keeping a critical mass agreement within the ambit of the multilateral system... In sum, then, of the three decision points, *the conclusion here is that consensus might or might not be required at the entry point, would not be required at the negotiation stage, and would be required at the adoption stage.*" (p.11)

2. Codex Alimentarius Commission (CAC):

Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission Report, 26th Session (June 30-July 7, 2003) (emphasis added).

“AMENDMENTS TO THE PROCEDURAL MANUAL (Agenda Item 4) Proposed Amendments to the Rules of Procedure...“***Proposed Amendments to the Rules of Procedure concerning the Membership of Regional Economic Integration Organizations***...The 18th Session of the Committee on General Principles...considered ***an amendment proposed by the Delegation of the United States to delete the clause allowing Member States of a Regional Organization to develop or support the position of the Member Organization in the Commission and its subsidiary bodies.*** (par. 19)

The Delegation of the United States...stressed the need to clarify the application of mixed competence between the European Community and its member states, and ***reasserted its earlier position that only the Regional Organization should participate in debates concerning questions within its competence.*** (par. 20)

Several delegations however expressed the view that the member states of a Regional Organization should have the possibility to intervene to support the position of that Organization from a technical point of view. They pointed out that it was essential to retain the diversity of the debate, and that this would also facilitate discussions in order to reach consensus. ***Some delegations referred to regional economic integration in their regions and noted that the Membership of Regional Economic Integrations Organizations in Codex might also facilitate such integration in the future.*** (par. 21)

...[T]he Commission proceeded to a roll-call vote on the amendment with the following results... **Tally: 85 votes cast, 73 in favour, 12 against, 13 abstentions** (majority required 57)

Result: The amendment was adopted.”

Appendix II – Amendments to the Rules of Procedure of the Codex Alimentarius Commission, Clarification of Rule VI.4 (Voting and Procedures), Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission Report, 26th Session (June 30-July 7, 2003) (emphasis added).

“[The Commission added]...*a new Rule 1.3 to the Rules of Procedure...‘Membership shall also comprise regional economic integration organizations members of either FAO or WHO that notify the Director-General of FAO or WHO of their desire to be considered Members of the Commission.’*”

[The Commission also added]... *new ‘Rule II - Member Organizations’*

1. *A Member Organization shall exercise membership rights on an alternative basis with its Member States that are Members of the Commission in the areas of their respective competence.*

2. *A Member Organization shall have the right to participate in matters within its competence in any meetings of the Commission or its subsidiary bodies in which any of its Member States is entitled to participate. This is without prejudice to the possibility for the Member States to develop or support the position of the Member Organization in areas within its competence.*

3. *A Member Organization may exercise on matters within its competence, in any meetings of the Commission or any subsidiary body of the Commission in which it is entitled to participate in accordance with paragraph 2, a number of votes equal to the number of its Member States which are entitled to vote in such meetings and present at the time the vote is taken. Whenever a Member Organization exercises its right to vote, its Member States shall not exercise theirs, and conversely.*

...5. Before any meeting of the Commission or a subsidiary body of the Commission in which a Member Organization is entitled to participate, the Member Organization or its Member States shall indicate in writing which, as between the Member Organization and its Member States, has competence in respect of any specific question to be considered in the meeting and which, as between the Member Organization and its Member States, shall exercise the right to vote in respect of each particular agenda item. Nothing in this paragraph shall prevent a Member Organization or its Member States from making a single declaration in the Commission and each subsidiary body in which a Member Organization is entitled to participate for the purposes of this paragraph, which declaration shall remain in force for questions and agenda items to be considered at all subsequent meetings, subject to such exceptions or modifications as may be indicated before any individual meeting.

... 7. **In cases where an agenda item covers both matters in respect of which competence has been transferred to the Member Organization and matters which lie within the competence of its Member States, both the Member Organization and its Member States may participate in the discussions. *In such cases the meeting, in arriving at its decisions,² shall take into account only the intervention of the party which has the right to vote.³***

2 *The word ‘decisions’ should be understood to mean both voting and situations where a decision is taken by consensus.*

3 *The above is without prejudice to the question of whether or not the views of the party not having the right to vote shall be reflected in the report of the meeting.* Where the views of the party not having the right to vote are reflected in the report, the fact that they are the views of the party not having the right to vote shall also be reflected in the report.

8. ***For the purpose of determining a quorum***, as specified in paragraph 6 of Rule IV, ‘*the delegation of a Member Organization shall be counted for a number equal to the number of its Member States which are entitled to participate in the meeting and are present at the time the quorum is sought*, to the extent that it is entitled to vote under the relevant agenda item.’”

Explanatory Note on Procedure and Voting: Election of the Chairperson and Vice-Chairpersons, Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission 33rd Session CX/CAC 10/33/16 (July 5-10, 2010) (emphasis added).

“Each Member of the Commission has one vote. Members of the Commission are those Member Nations of FAO or WHO which have notified either the Director-General of FAO or of WHO of their wish to be Members of the Commission... Rule II.3 of the Rules of Procedure of the Commission provides as follows: ‘*A Member Organization may exercise on matters within its competence, in any meetings of the Commission or any subsidiary body of the Commission in which it is entitled to participate in accordance with paragraph 2, a number of votes equal to the number of its Member States which are entitled to vote in such meetings and present at the time the vote is taken. Whenever a Member Organization exercises its right to vote, its Member States shall not exercise theirs, and conversely*’. Rule II.4 of the Rules of Procedure provides that a ‘*Member Organization shall not be eligible for election or designation, nor to hold office in the Commission or any subsidiary body. A Member Organization shall not participate in voting for any elective places in the Commission and its subsidiary bodies*’”. (par. 2 and fn. 2)

...Rule VI.7 [of the Rules of Procedure of the Commission provides:] ‘*The majority of the Members of the Commission shall constitute a quorum for the purposes of making recommendations for amendments to the Statutes of the Commission and of adopting amendments of, or additions to, the present Rules* in accordance with Rule XV.1. *For all other purposes the majority of the Members of the Commission attending the session shall constitute a quorum, provided that such a majority shall be not less than 20 percent of the total membership of the Commission, nor less than 25 Members. In addition, in the case of amendment or adoption of a proposed standard for a given region or group of countries, the quorum of the Commission shall include one third of the Members belonging to the region or group* of countries concerned.

Codex Alimentarius Commission Procedural Manual 19th Edition, World Health Organization and Food and Agriculture Organization of the United Nations (2010) (emphasis added).

“Rule XII Elaboration and Adoption of Standards

1. Subject to the provisions of these Rules of Procedure, the Commission may establish the procedures for the elaboration of worldwide standards and of standards for a given region or group of countries, and, when necessary, amend such procedures.
2. *The Commission shall make every effort to reach agreement on the adoption or amendment of standards by consensus. Decisions to adopt or amend standards may be taken by voting only if such efforts to reach consensus have failed.*

...GUIDELINES TO CHAIRPERSONS OF CODEX COMMITTEES AND AD HOC INTERGOVERNMENTAL TASK FORCES...

Consensus *The chairpersons should always try to arrive at a consensus and should not ask the Committee to proceed to voting if agreement on the Committee's decision can be secured by consensus.* The Procedure for the Elaboration of Codex Standards and Related Texts allows for full discussion and exchange of views on the issue under consideration, in order to ensure the transparency of the process and arrive at compromises that would facilitate consensus. Much of the responsibility for facilitating the achievement of consensus would lie in the hands of the Chairpersons.”

3. United Nations Economic Commission for Europe (UNECE):

About UNECE, United Nations Economic Commission for Europe website (emphasis added).

“The United Nations Economic Commission for Europe (UNECE) was set up in 1947 by ECOSOC. It is one of five regional commissions of the United Nations...***Its major aim is to promote pan-European economic integration.*** To do so, UNECE brings together 56 countries located in the European Union, non-EU Western and Eastern Europe, South-East Europe and Commonwealth of Independent States (CIS) and North America. All these countries dialogue and cooperate under the aegis of the UNECE on economic and sectoral issues.

To this end, it provides analysis, policy advice and assistance to governments, it gives focus to the United Nations global mandates in the economic field, in cooperation with other global players and key stakeholders, notably the business community.

The UNECE also sets out norms, standards and conventions to facilitate international cooperation within and outside the region.

The area of expertise of the UNECE covers such sectors as: economic cooperation and integration, energy, environment, housing and land management, gender, population, statistics, ***timber, trade, and transport.*** UNECE has 56 member States. However, all interested UN member States may participate in its work.”

... Member States and Member States Representatives

United States of America

28 March 1947

H.E. Mrs. Betty E. KING

Terms of Reference and Rules of Procedure of the Economic Commission for Europe Fifth revised edition E/ECE/778/Rev.5 (2009) (emphasis added).

“Rules of Procedure of the Commission

... CHAPTER VIII
CONDUCT OF BUSINESS

Rule 27

A majority of the members of the Commission shall constitute a quorum.

... Rule 36

If two or more amendments are moved to a proposal, the Commission shall vote first on the amendment furthest removed in substance from the original proposal, then, if necessary, on the amendment next furthest removed and so on, until all the amendments have been put to the vote.

Rule 37

The Commission may, at the request of a representative, decide to put a motion or proposal to the vote in parts. If this is done, the text resulting from the series of votes shall be put to the vote as a whole.

CHAPTER IX VOTING

Rule 38

Each member of the Commission shall have one vote.

Rule 39

Decisions of the Commission shall be made by a majority of the members present and voting.

... Rule 43

If a vote is equally divided upon matters other than elections, a second vote shall be taken. If this vote also results in equality, the proposal shall be regarded as rejected.”

4. Organization for Economic Cooperation and Development (OECD):

Convention on the Organisation for Economic Co-operation and Development (emphasis added).

“PARIS 14th December 1960

...*Article 1*

The aims of the Organisation for Economic Co-operation and Development (hereinafter called the ‘Organisation’) *shall be to promote policies designed:*

- (a) to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries*, while maintaining financial stability, and thus to contribute to the development of the world economy;
- (b) to contribute to sound economic expansion in Member as well as non-member countries in the process of economic development; and*
- (c) to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.*

Article 2

In the pursuit of these aims, the Members agree that they will, both individually and jointly:

- (a) promote the efficient use of their economic resources;*
- (b) in the scientific and technological field, promote the development of their resources, encourage research and promote vocational training;*
- (c) pursue policies designed to achieve economic growth and internal and external financial stability and to avoid developments which might endanger their economies or those of other countries;*
- (d) pursue their efforts to reduce or abolish obstacles to the exchange of goods and services and current payments and maintain and extend the liberalisation of capital movements; and*

(e) *contribute to the economic development of both Member and non-member countries in the process of economic development by appropriate means* and, in particular, by the flow of capital to those countries, having regard to the importance to their economies of receiving technical assistance and of securing expanding export markets.

Article 3

With a view to achieving the aims set out in Article 1 and to fulfilling the undertakings contained in Article 2, the Members agree that they will:

- (a) keep each other informed and furnish the Organisation with the information necessary for the accomplishment of its tasks;
- (b) consult together on a continuing basis, carry out studies and participate in agreed projects; and
- (c) co-operate closely and where appropriate take co-ordinated action.

Article 4

The Contracting Parties to this Convention shall be Members of the Organisation.

Article 5

In order to achieve its aims, the Organisation may:

- (a) take decisions which, except as otherwise provided, shall be binding on all the Members;
- (b) make recommendations to Members; and
- (c) enter into agreements with Members, non-member States and international organisations.

Article 6

1. Unless the Organisation otherwise agrees unanimously for special cases, decisions shall be taken and recommendations shall be made by mutual agreement of all the Members.
2. Each Member shall have one vote. If a Member abstains from voting on a decision or recommendation, such abstention shall not invalidate the decision or recommendation, which shall be applicable to the other Members but not to the abstaining Member.
3. *No decision shall be binding on any Member until it has complied with the requirements of its own constitutional procedures.* The other Members may agree that such a decision shall apply provisionally to them.

Article 7

A Council composed of all the Members shall be the body from which all acts of the Organisation derive. The Council may meet in sessions of Ministers or of Permanent Representatives.”

Jean-H. Guilmette, Peer Pressure Power: Development Cooperation and Networks, Making use of methods and know-how from the Organisation for Economic Co-operation and Development (OECD) and the International Development Research Centre (IDRC) at pp.18, 73, 76, 82-83, 86, 91 (2004) (emphasis added).

“The OECD process for promoting international economic cooperation is predicated on a consensus with respect to basic political values, most notably human rights, multiparty democracy, transparency in government, freedom of expression, and reliance on market rules for management of the economy. These values were highlighted in clear and unambiguous language in the opening paragraphs of the OECD Convention signed in 1961. (See Statement of Preliminaries table). **OECD partners are expected**

to accept and implement these core values in order for the process of international cooperation to succeed and to become effective.

From the outset, it is important to emphasize the pragmatic character of the OECD negotiation process. *The OECD approach to negotiations is designed to lead to an agreement upon policies or policy options and structures that may be implemented by all member countries, since they arise from a consensus-building process. In essence, the OECD process produces outcomes that are seen – by member countries - to be reasonable and acceptable.* These policy outputs are generally considered relevant and timely, and can be readily adapted to the specific needs of the concerned member countries. *The possibility of adapting policies adopted through consensus is the essence of the very subtle OECD process.* If a country adapts a policy in a manner that seems contrary to the spirit of the common policy, the perceived misadaptation will give rise to discussions at the occasion of Peer Review. The process can only be described as intensively iterative; for some it sounds slow and tedious, but it should be argued that it results in resilient and sustainable agreements in the end.

Over the years, OECD members have enlarged the subjects of their analyses. In many cases their concern for reducing trade barriers and creating a level playing field for business transactions has been expanded to include sharing knowledge about “promising or best practices” on matters that do not involve mutual competition. This is the case for studies on health or education, for example. In such cases the pursuit of consensus and the negotiation process is less critical; sharing “intelligence” on these matters becomes the real essence of their cooperation.

... OECD functions through its governing body, the Council, chaired by the Secretary General, and its network of about 120 Committees and Working Groups, which are issue-related. One deals, for example, with maritime transport, another focuses on competition law and policy, while another was formed to deal with scientific and technological policy. *The OECD Secretariat carries out work mandated by the Council and the Committees. The Council approves decisions and recommendations. Generally, decisions of Council require unanimity (consensus).*

...Subsection 1.5 – OECD’s Basic Rules of Conduct

The methodologies deployed by OECD are not well understood, and have rarely been discussed in the professional and scholarly literature.

The success of OECD rests on a “blueprint” for international and regional cooperation consisting of three elements: (1) promulgation of a supra-national policy regime based on respect for human rights, democratic government, and the market economy; (2) enforcement of certain basic rules of inter-state conduct; and (3) application of certain unique techniques for making and negotiating collective choices among member countries.

The rules for OECD meetings and procedures include agreement on an agenda leading to a practical and defined outcome. This has a practical operational mission that is expected to lead to tangible objectives and real, demonstrable progress. The basic principles of OECD procedures include: (1) respect for ethics; (2) confidence and trust in the other partners; (3) frankness, blended with courtesy; (4) a commitment to respect agreements as they are reached and not to reopen them to obtain advantage at later stages; and (5) a consensus based on objectivity and common standards (these will be described in more detail later).

...In addition, OECD has developed its own know-how on reconciling diverse opinions and consensus building. This is achieved through (1) iterative peer review, (2) application of common standards, (3) well structured meetings, and (4) transparent processes.

...The primary commitments of states (to work together; to submit their economic policies to peer review; to provide all information needed by OECD) have produced what we might call the OECD 'etiquette.'

Working together

- The dominant ethical code in the organization resembles somewhat that of an old style English 'gentlemen's club.'

- ...• *All decisions are taken on the basis of unanimity, or consensus.*

- ...• *The consensus rule, however, is subject to certain exceptions and accommodations in order to make it less constraining.*

- *Formal decisions are rare:* since 1961 there have been perhaps 50 at most (this does not include annual budget resolutions for the functioning of the Secretariat). For the most part, the results of OECD's work are reflected in a range of commitments that are progressively less formal and constraining.

- ...• *Respect for consensus is enforced by peer pressure,* i.e. a kind of moral and political constraint that can be highly effective but is quite different from that flowing from formal agreements.

...For a concept, an idea or a policy to be agreed to and to be transformed into a general practice, each and every participant in the network must recognize and accept its intrinsic merit. At the very least, it should see it as in its interest to stay with the group or be swayed through other arguments. *Occasionally, a majority may decide to proceed and leave a few laggards behind, thereby suspending the consensus rule in hopes that the holdouts will eventually join the consensus;* such situations, however, are the exception and are not intended to last very long.

...Rule of exception to the consensus

In all cases, the meeting chair will allow the discussion to continue (perhaps over several months) until there are no further formal objections. A member may then simply sit silent so as not to prevent a consensus from being reached. This approach is sometimes less binding than a formal vote. *On the other hand, a member may formally abstain. In this case, the 'decision' (or the 'recommendation') will not apply to that member,* a situation that differs from the rules of the European Union, where a majority vote (in certain fields) is equally binding on all members."

Supplementary Protocol No. 1 to the Convention on the OECD (emphasis added).

"14 December 1960

THE SIGNATORIES of the Convention on the Organisation for Economic Co-operation and Development;

HAVE AGREED as follows:

1. *Representation in the Organisation for Economic Co-operation and Development of the European Communities* established by the Treaties of Paris and Rome of 18th April, 1951, and 25th March, 1957, *shall be determined in accordance with the institutional provisions of those Treaties.*

2 . The Commissions of the European Economic Community and of the European Atomic Energy Community as well as the High Authority of the European Coal and Steel Community shall take part in the work of that Organisation.”

Sieglinde Gstöhl, ‘Patchwork Power’ Europe? The EU’s Representation in International Institutions, paper presented at the GARNET conference The European Union in International Affairs at pp. 7-8, 11 (April 2008) (emphasis added).

“*[B]oth the Commission and the member states speak when the same trade issues are discussed in the OECD...EU member states are more reluctant to create a 'single voice', if the institution deals with a broadly defined area of cooperation and an exchange of information and best practices rather than binding agreements, and if only a few of them actually are members of the institution. For example, Reiter claims that the EU member states in the OECD are reluctant to agree to speak with one voice in view of the ‘broad scope of the OECD, the organization’s focus on best practices and soft law, as well as the dominance of EU countries in the total membership and the fact that not all EU members are part of the organization’...*

The scope of *the OECD* is not limited to trade issues, and *its focus is not on binding rules but rather on the exchange of information, best practices and soft law*. Art. 304 TEC [Treaty of the European Community] states that ‘[t]he Community shall establish close cooperation with the Organisation for Economic Cooperation and Development, the details of which shall be determined by common accord’. *A supplementary protocol to the OECD Convention provides for the Commission’s participation in its work, which goes beyond that of a mere observer and is similar to a ‘full participant’ in the UN system.* Like the EU member states, *the Commission* maintains a Permanent Delegation to the OECD in Paris.⁵² Its ambassador *is a member of the OECD Council but without a right to vote when legal acts are being adopted*. Other Commission representatives sit on the various specialised committees alongside the national representatives. Even though the Commission often takes a leading role, EU member states retain the right to engage in the deliberations in most OECD meetings.”

D. Various Intergovernmental and Nongovernmental Organizations Continue to Compete at the Codex to Influence the Development or Introduction of ‘Food Safety+’ Standards Which Reflect EU Regional ‘Green’ and ‘Consumer Information’-based Sustainable Development/Agriculture Process and Production Methods

1. UNECE. [Effort to push through EU-centric regional fruits & vegetables ‘food safety +’ standards as international Codex standards]

European Community Comments on Codex Circular Letter Cl 2008/13-FFV, Part B – Point 5: Proposals for Amendments to the Priority List for the Standardization of Fresh Fruits and Vegetables (Para. 108 and Appendix VI), CODEX - EC Position Paper (June 26, 2009), reported to Codex Committee on Fresh Fruit and Vegetables (CCFFV) 15th Session (Oct. 19-23, 2009) (emphasis added).

“The European Community would like to highlight the need for a very close cooperation between the Codex Committee and the UNECE and for continued harmonization efforts to avoid duplication of commercial quality standards.

Therefore, the ECMS see no priority for developing Codex-Standards for products where already UNECE standards exist (Kiwi, Pears, Pineapple, Strawberry, Garlic, Onion (Chanterelle is in progress)). If developing Codex standards in this field the ECMS would prefer to use the existing UNECE standards as a work basis and only add the Codex specific requirements on hygiene and contaminants.”

Report of the U.S. Delegate, Codex Committee on Fresh Fruits and Vegetables, Codex Alimentarius Commission 15th Session (Oct. 2009), accessible on US Department of Agriculture Food Safety and Inspection Service website (emphasis added).

“The 15th Session of the Codex Committee on Fresh Fruits and Vegetables (CCFFV) was held in Mexico City, Mexico, from 19 to 23 October 2009. The Session was attended by delegates from 51 Member countries, one Member Organization and an observer from an international organization...Below are some of the highlights of the meeting:

...Matters Arising From Other International Organizations on the Standardization of Fresh Fruits and Vegetables

The most important matter discussed under this agenda item came from the United Nations Economic Commission for Europe (UNECE).

The Committee also noted the decision of the Working Party to remove the reference to the ‘UNECE’ from the cover pages of the standards, thereby changing the nomenclature from the title of ‘UNECE’ standards to ‘UN’ standards.

Some delegations questioned the international coverage of the standards developed by the Working Party, expressing concern that the UNECE Working Party operates under the terms of reference of the UNECE, a regional commission of the United Nations, and works for the economic development and integration of a particular region. Among the points raised in support of that view included was the “Codex standards might require different provisions from those of the UNECE to accommodate the needs of Codex broader membership and in view of the different mandates and goals of Codex and UNECE.”

*The Codex Secretariat drew the attention of the Committee to previous discussions on this issue in the Codex Alimentarius Commission and the Codex Committee on Fresh Fruits and Vegetables **and the decision of the 54th Session of the Working Party to withdraw the proposal to change the title of the ‘UNECE standards’ to ‘UN standards’ in response to the Legal Counsel of the United Nations concerns on the global status of Codex standards as related to UNECE standards.**”*

2. International Organization for Standardization (ISO). [Effort to push through Codex private EU-centric ‘food safety+’ and import-export certification conformity assessment standards implementing

existing Codex standards developed in technical committees and subcommittees in which the EU participates as a 'liaison']

Relations Between the Codex Alimentarius Commission and Other International Organizations, Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission 28th Session (July 4-9, 2005) (emphasis added).

“Relations between Codex and the International Organization for Standardization (ISO)

14. *The Executive Committee at its 53rd session agreed that the Codex Secretariat establish preliminary contact with the ISO to obtain information on the current status of food safety-related work within the ISO and present its findings to the Executive Committee, together with the implications to the work being undertaken by Codex*⁷.

15. The 27th Session of the Commission agreed that the Secretariat should maintain its contacts with ISO and report to the Executive Committee and the Commission on ISO activities of relevance to Codex work.

16. The 55th Session of the Executive Committee was informed that in accordance with the decisions of the Executive Committee and the Commission, contacts for information exchange were maintained between the Codex Secretariat and ISO. *The Committee noted that Technical Committee 34 (Food products) of ISO was currently working on three items of relevance to Codex: food irradiation (ISO/AWI 22810), traceability in feed and food chain (ISO/CD 22519), and food safety management systems (ISO/DIS 22000).*

17. *The Executive Committee noted that the Codex Secretariat had sent written comments to the Secretariat of ISO/TC 34 regarding ISO/CD 22519 and ISO/DIS 22000 in September and November 2004 respectively to draw the attention of ISO/TC 34 to the existing and on-going work of Codex in the areas in question.*

18. *The Executive Committee was informed that the General Assembly of ISO had adopted in September 2004 the ISO Strategic Plan 2005-2010, of which Objectives 4 and 5 called for increased collaboration between ISO and intergovernmental standard setting bodies such as Codex.*

19. *The Executive Committee agreed that contacts should be maintained between the Secretariats of Codex and ISO. It was also agreed that in order to minimise duplication of work and to increase consistency of normative guidance between Codex and ISO, national Codex Contact Points should be encouraged to strengthen communication and coordination with the respective national focal point for ISO*⁸.

20. An information paper on ISO work, submitted by the ISO Central Secretariat, will be provided to the Commission separately. The information provided by the Secretariat of ISO/TC 34, on selected work items of interest to Codex, is summarised in Table 1 below.

21. *The Commission is invited to note the information provided, identify those areas where coordination of work between Codex and ISO should be maintained or strengthened and make proposals on practical modalities for implementing such coordination, as appropriate.”*

Discover ISO, ISO's International Partners, International Organization for Standardization website (emphasis added).

“ISO collaborates with the United Nations (UN) Organization and its specialized agencies and commissions, particularly those involved in the harmonization of regulations and public policies, *such as: CODEX Alimentarius, on food safety measurement, management and traceability...ISO's technical committees have formal liaison relations with over 600 international and regional organizations...*”

Tim Büthe, The Politics of Food Safety in the Age of Global Trade: The Codex Alimentarius Commission in the SPS-Agreement of the WTO, RWJF Scholars in Health Policy Research Program Working Paper (Aug. 2009) (emphasis added).

“*Codex's centrality today, however, is unsuitable as an explanation for why Codex was selected as the international standard-setter, since causation runs the other way: Codex today is in numerous ways a function of the prominence that it acquired by being selected as the designated food safety standard-setter in the SPS-Agreement* (e.g., Tarullo 2000; Veggeland and Borgen 2005). *At the launch of the Uruguay Round negotiations in 1986, Codex had a 23-year history of rather modest achievements and faced an uncertain future; some characterized it as “moribund.”*” (p.2)

...*Codex attained its current prominence by being designated the international standard-setter in the SPS-Agreement...[T]he authority to set international food safety standards...was delegated to Codex in the SPS-Agreement.* This prominent delegation of regulatory authority is puzzling not only because food safety issues are politically sensitive but also because there were at least four international bodies that had for decades set food and food safety standards when the Uruguay Round negotiations were launched, but only one of them was written into the treaty. I have argued that, to explain the selection of Codex as the designated source of ‘international standards’ for food safety under the SPS-Agreement, we must examine and take seriously the informational constraints of GATT negotiators' strategic calculations, as well as their perceptions of the available standard-setting bodies' legitimacy—perceptions that could be influenced by those international bodies, understood as actors rather than mere institutional structures. *I have found that the SPS standard-setting organizations with geographically limited scope (UN/ECE and OECD) lacked legitimacy in the face of universal/global alternatives and were therefore opposed by developing countries. They stood little chance of being designated international standard-setters for purposes of the SPS-Agreement, although their inclusion was repeatedly suggested. Among the two global bodies, Codex had a much stronger organizational imperative to seek designation as the official international standard-setting organization, and it sought this designation forcefully, shaping perceptions of its technical capacity and legitimacy while building on strategic support from the U.S.* As a consequence, Appendix A of the SPS Agreement defines ‘international standards ... for food safety’ as ‘the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice.’” *It is one of the most robust and near-exclusive cases of international delegation of regulatory authority.*

...*Would the actual standards, developed by Codex since the SPS-Agreement came into force, have differed if they had been developed by ISO instead?...*[T]here are several reasons to think that the choice mattered: First, the decision-making procedures differ. *Both organizations have consensus norms, but*

when consensus cannot be achieved, Codex allows for adopting an international standard by simple majority, whereas ISO standards adoption requires large supermajorities. This suggests that the most politically contentious standards, adopted by Codex with a bare majority, would not have become international standards in ISO—leaving food-important countries with greater leeway to address food safety concerns through divergent national measures. Second, in other research on global governance, I have found that the traditional power resources of states are far less usable in international non-governmental organizations than in inter-governmental organizations (Büthe and Mattli 2010a, 2010b). This suggests that delegation to the inter-governmental Codex rather than non-governmental ISO was detrimental to the interests of the small highly developed countries, who often play a prominent role in ISO, but quite beneficial to large developed countries, such as the United States, whose government has a wealth of power resources at its disposal.

Whose interests, however, are represented by the U.S. government? One of the key concerns about Codex in recent years has been the over-representation of industry and the under representation of consumer interests. In fact, my research suggests that this skewed representation of stakeholders contributed to the attractiveness of Codex to U.S. government negotiators since it largely replicated the domestic political power structure within the United States... In part, the imbalance in favor of commercial interests (especially food industry multinationals) is simply a function of the uneven distribution of technical expertise—a general constraint on any policies or procedures to make standard-setting more inclusive (Mattli and Büthe 2005). The under-representation of non-commercial stakeholders in U.S. delegations to Codex technical committees, however, is also a function of the long-standing U.S. policy to treat willingness to pay as the "true" measure of the seriousness of any stakeholder's interest. Non-governmental appointees to Codex committees therefore pay their own way. Since Codex standard-setting stretches over multiple years and involves attending meetings in various countries around the globe, the lack of any public support for noncommercial participants is bound to reinforce the under-representation of consumer safety advocates and other non-commercial stakeholders. Subsidies for non-commercial participants thus hold greater promise for a better balance of interest representation than shifting standard-setting to another organization or boosting the transparency of the Codex process through increased use of administrative law procedures.” (p. 12-13)

Communication from ISO (report of activities relevant to Codex work), Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission 33rd Session (July 5-9, 2010) (emphasis added).

“1. ***The International Organization for Standardization (ISO) has prepared this information paper as part of ongoing updates and communication between the Codex Alimentarius Commission (CAC) Secretariat and the ISO Central Secretariat.*** It provides a summary of current work undertaken by ISO that may be of interest to the CAC and is intended to support and enhance dialogue and coordination between the two organizations.

2. ISO is the International Organization for Standardization (<http://www.iso.org/>). ***ISO is a non-governmental organization*** established in 1947 with members consisting of the leading and recognized national standards organizations of 159 countries, on the basis of one member per country.

... 7. ***ISO has a specific status with many UN agencies, including the WHO and FAO. It is also an observer at the WTO Committee on Trade and Environment (CTE), the Committee on Technical Barriers to Trade (WTO TBT) and the Committee on Sanitary and Phytosanitary Measures (SPS).*** In

the area of technical assistance, ISO regularly cooperates with the WTO and ITC, and has entered into a Memorandum of Understanding with UNIDO.

...ISO status in Codex

10. ISO's observer status to the CAC provides an opportunity for the coordination of issues related to a variety of ISO standards that are adopted and used by Codex in its work. According to document “*Recommended methods of analysis and sampling*” (CODEX STAN 234-1999), approximately 310 methods refer to ISO/TC 34 standards (Food products) (representing approximately 60 different ISO/TC 34 standards); 21 methods refer to ISO/TC 147 standards (Water quality); 5 methods refer to ISO/TC 47 standards (Chemistry), and 1 standard each refers to ISO/TC 24, Sieves and other sizing methods, ISO/TC 61, Plastics and ISO/TC 93, Starch. This list is also complemented by CCMAS recent endorsement of methods for the detection of 21 different commodities (representing 28 different standards developed by ISO/TC 147) and Codex's adoption of the CASCO standard ISO/IEC 17025 for testing and calibration laboratories.

11. The priority areas of mutual interest on which ISO would like to maintain and nurture dialogue with the CAC are the work of ISO/TC 34 on food products and the generic work of the ISO Committee on conformity assessment (ISO/CASCO). It should however be noted that other ISO Technical Committees are working in fields that could be of interest for CAC:

- ISO/TC 54, *Essential oils* for which CAC has a liaison;
- ISO/TC 147, *Water quality* for which CAC has a liaison with its SC 2 and SC 4 (more details in point 41)

(see Annex 4 for the structure of ISO/TC 147);

- ISO/TC 234, *Fisheries and aquaculture* (created in February 2007) for which CAC has a liaison (more details in point 37) (see Annex 3 for the structure of ISO/TC 234).

Codex and ISO/TC 34 Cooperation

12. There is a long history of collaboration between the Codex Committees and ISO/TC 34, Food products. ISO/TC 34 supports the establishment of an ongoing and sustainable framework for collaboration between Codex and ISO, in order to enhance the mutual coordination of work and the elimination of duplication and contradictions. This also includes interest to support any joint or collaborative communication on each others' work.

13. Codex and ISO activities are complementary. Codex, as a governmental organization, prepares documents to assist governments in their statutory and regulatory work to protect their citizens from health hazards caused by food consumption. ISO, as a non-governmental organization, prepares standards in particular on test methods to assist stakeholders along the whole food chain to fulfil both the statutory and regulatory requirements, as well as the requirements of consumers of these products.

14. Since its creation in 1947, ISO/TC 34 has published 756 ISO deliverables (International Standards, Technical Specifications and Technical Reports). 65 % of these documents are test methods. See [Annex 1](#) for the structure of ISO/TC 34 and a list of projects/publications of interest to Codex.

Remaining unchanged for quite a long time, **the structure of ISO/TC 34 was modified in 2008 and 2009 with the establishments of dedicated Subcommittees on biomarkers, SC 16, and on Management systems for food safety, SC 17 (see Annex 1).**

... 20. **During the last year, after a general review of its Business Plan, the following 4 main objectives were identified:**

- *Safety of food products*
- *Fair practices in trade*
- *Quality of products*
- *Sustainable development*

... 28. **ISO/TC 34/SC 17, Management systems for food safety**

The ISO 22000 series are now under responsibility of the new SC 17. These documents of particular interest to the

CAC are:

- ISO 22000:2005, *Food safety management systems — Requirements for any organization in the food chain*
- ISO/TS 22004:2005, *Food safety management systems — Guidance on the application of ISO 22000:2005*
- ISO/TS 22002-1:2009 *Prerequisite programmes on food safety — Part 1: Food manufacturing*
- ISO/TS 22003:2007, *Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems*
- ISO 22005:2007, *Traceability in the feed and food chain — General principles and basic requirements for system design and implementation*
- ISO 22006:, *Guidelines on the application of ISO 9001 for crop production*

ISO 22000, and its associated conformity assessment, should have a positive impact on the harmonization and proper implementation of voluntary and mandatory food import and export requirements, inspection and certification systems. ISO 22000 underwent a systematic review process in 2008 and was confirmed.

29. New work was published at the end of 2009: ISO/TS 22002-1:2009, Prerequisite programmes on food safety — Part 1: Food manufacturing.

This document specifies requirements for establishing, implementing and maintaining prerequisite programmes (PRP) to assist in controlling food safety hazards. ISO/TS 22002-1:2009 is applicable to all organizations, regardless of size or complexity, which are involved in the manufacturing step of the food chain and wish to implement PRP in such a way as to address the requirements specified in ISO 22000:2005, Clause 7.

ISO/TS 22002-1:2009 specifies detailed requirements to be specifically considered in relation to ISO 22000:2005, 7.2.3: a) construction and layout of buildings and associated utilities; b) layout of premises, including workspace and employee facilities; c) supplies of air, water, energy, and other utilities; d) supporting services, including waste and sewage disposal; e) suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance; f) management of purchased materials; g) measures for the prevention of cross-contamination; h) cleaning and sanitizing; i) pest control; j) personnel hygiene.

In addition, ISO/TS 22002-1:2009 adds other aspects which are considered relevant to manufacturing operations:

- 1) rework; 2) product recall procedures; 3) warehousing; 4) product information and consumer awareness; 5) food defence, biovigilance, and bioterrorism.

30. In addition to the "ISO 22000 family", it should be noted that the ISO standard ISO 22006, ***Guidelines on the application of ISO 9001 for crop production*** was developed. **This International**

Standard contains the text of ISO 9001 and adds additional elements for agricultural production operators and for documents associated with a Farm Plan. It was published in December 2009.

31. ISO/TC 34 will continue to offer its full support and cooperation to the Commission with a view to avoiding duplication of work and will adopt, for its own documents, the conclusions of the Commission on all matters concerning food hygiene requirements.

Food safety — ISO publication

32. ISO and ITC have jointly published “*ISO 22000, Food safety management system, An easy-to-use checklist for small business, Are you ready?*”. This handbook on ISO 22000 will be of benefit to small businesses, especially in developing countries and transition economies, in their effort to improve their market share of food and agricultural products in the global market. French and Spanish versions of the publication are also available. ISO has used this publication in various workshops it has conducted for developing countries.

... **Codex and ISO/TC 147** (See structure in Annex 4)

41. CAC maintains a category A liaison with ISO/TC 147 "Water quality", and especially with sub-committee SC 2 "Physical, chemical and biochemical methods" and sub-committee SC 4 "Microbiological methods".

As water plays an important role in food processing (for all kinds of cleaning purposes, preparation of half-finished food products, production of beverages like beer and lemonades), many International Standards elaborated in ISO/TC 147/SC 2 and SC 4 are, or should be, taken into account.

42. Topics covered by ISO/TC 147/SC 2 range from metal determinations (single or multicomponent methods), anions, cations, to methods for organic substances such as plant treatment agents, or methods for ubiquitous pollutants like phthalates or polycyclic hydrocarbons, PAH.

... 43. In respect to microbiological methods (ISO/TC 147/SC 4), special importance is given to existing standards on the determination of salmonella, coliforms (E.coli and other substances), or e.g. methods on the investigation of microorganisms by culture. Special emphasis is laid on the preparatory work for a standard on the estimation of uncertainty in microbiological analysis.

The scope of all standards from ISO/TC 147/SC 4 does not exclude bottled water, so all standards can, in principle, be applied to analysis of bottled water.

... **ISO's conformity assessment standards and their use in food safety**

46. ISO is an International Standards developer and does not itself undertake assessments of conformity of products, management systems, processes or services against the requirements of the standards it produces.

47. ISO does however produce International Standards and Guides on how assessment of conformity should take place – this is the role of the ISO Policy Committee on Conformity Assessment (ISO/CASCO). It is this body within ISO that is closest to covering the same subject matter as the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS).

48. In relation to ISO/CASCO, most of the conformity assessment Guides have been, or are in the process of being, turned into International Standards. Annex 5 gives a list of documents and ongoing work.

49. Since its session in June-July 2008 in Geneva, the Codex Alimentarius Commission (CAC) has obtained the status of A-liaison. This new status allows Codex to participate in all ISO/CASCO working groups. To date, Codex has the following memberships:

- CASCO STAR (Strategic Alliance and Regulatory Group);
- CASCO WG 29 (Requirements for certification bodies certifying products (including services) and processes, revision of ISO/IEC Guide 65).

Apart from its participation in ISO technical work (WG 29), Codex attended four important ISO/CASCO meetings:

- a CASCO workshop entitled "The role of International Standards in managing the global supply chain and traceability" (11 November 2009);
- the 4th CASCO STAR meeting (9 November 2009);
- the 25th CASCO plenary meeting (12-13 November 2009).

...Conclusion

52. It is recognized that the Commission's members, as governments, have the authority to regulate at the national level and that ISO, as a producer of voluntary International Standards, does not. In the framework of good regulatory practice, as promoted at international and regional levels, *International Standards and Guides may be considered useful by regulators as effective and efficient tools to achieve important regulatory mandates, manage risk and address market confidence.*

53. ISO considers that by using its International Standards, regulatory authorities will achieve their aims in public health and safety at less cost to manufacturers and consumers. Using International Standards also assists countries to meet their WTO TBT and SPS Agreement obligations."

Codex Alimentarius Commission and European Commission, Organizations in Cooperation with ISO, About ISO, ISO website (emphasis added).

“Codex Alimentarius Commission, Liaisons

Total number of liaisons: 25

A liaisons: 18

B liaisons: 7

C liaisons: 0

...European Commission, Liaisons,

Total number of liaisons: 171

A liaisons: 100

B liaisons: 71

C liaisons: 0

[The EC and Codex served as liaison on 19 of the same TCs and SCs. The EC served on 2 food-related TCs and 4 food-related SCs without Codex. The EC did not serve on 4 food-related TCs on which Codex served, and did not serve on 2 food-related SCs on which Codex served.]

...**Liaisons A:** *Organizations that make an effective contribution to the work of the technical committee or subcommittee for questions dealt with by this technical committee or subcommittee.*

Liaisons B: *Organizations that have indicated a wish to be kept informed of the work of the technical committee or subcommittee.”*

ISO/IEC Directives, Part 1:2009 (Procedures for the technical work) (emphasis added).

“1.18.2 Liaisons at the technical committee/subcommittee level

1.18.2.1 *Category A and B liaison*

The categories of liaison are the following.

□ **Category A:** *Organizations that make an effective contribution to the work of the technical committee or subcommittee for questions dealt with by this technical committee or subcommittee. Such organizations are given access to all relevant documentation and are invited to meetings. They may nominate experts to participate in a WG/PT* (see 1.12.1 and 1.13).

□ **Category B:** *Organizations that have indicated a wish to be kept informed of the work of the technical committee or subcommittee. Such organizations are given access to reports on the work of a technical committee or subcommittee.*

1.18.2.2 Acceptance criteria

The liaison organizations shall be international or broadly based regional organizations working or interested in similar or related fields. Technical committees and subcommittees shall seek the full and, if possible, formal backing of the organizations having liaison status for each document in which the latter is interested.

1.18.2.3 Establishment of liaisons

Liaisons are established by the Chief Executive Officer in consultation with the secretariat of the technical committee or subcommittee concerned. They are centrally recorded and reported to the technical management board.

1.18.2.4 Review of liaisons

Technical committees and subcommittees shall review all their liaison arrangements on a regular basis, at least every 2 years, or at every committee meeting.

1.18.3 Liaisons at the working group/project team level

1.18.3.1 *Category D liaison*

The category of liaison is as follows:

□ **Category D:** *Organizations that make a technical contribution to and participate actively in the work of a working group, maintenance team or project team.*

1.18.3.2 Acceptance criteria

Liaison organizations can include manufacturer associations, commercial associations, industrial consortia, user groups and professional and scientific societies. Liaison organizations shall be multinational (in their objectives and standards development activities) with individual, company or country membership and may be permanent or transient in nature.

A liaison organization shall be willing to make a contribution to ISO or IEC as appropriate.

A liaison organization shall have a sufficient degree of representativity within its defined area of competence within a sector or subsector of the relevant technical or industrial field.

1.18.3.3 Management of liaisons

Category D liaisons shall be submitted for approval to the technical management board by the committee secretary, with a clear indication of the WG/PT/MT concerned. The submission shall include a rationale for the setting-up of the liaison, as well as an indication of how the organization meets the acceptance criteria given in 1.18.3.2. The committee secretary is responsible for administering D-liaisons.

1.18.3.4 Review of liaisons

Technical committees and subcommittees shall review all their liaison arrangements on a regular basis, at least every 2 years, or at every committee meeting.

1.18.3.5 Rights and obligations

Category D liaison organizations have the right to participate as full members in a working group (see 1.12.1) or project team (see 1.13).

Category D liaison experts act as the official representative of the organization by which they are appointed.

l) Category C liaison is reserved for ISO/IEC JTC 1.”

***[Arguably, U.S. governmental agencies could serve through their employees in a liaison capacity via a newly formed international NGO or through a regional organization such as NAFTA.]**

3. Organization for Economic Cooperation and Development (OECD). [*Effort to push through EU-centric ‘food safety +’ pesticide MRLs via ‘OECD MRL calculator’ to replace currently used ‘NAFTA MRL calculator’*]

Maximum Residue Levels, Issues, CropLife website (emphasis added).

“The Codex Committee on Pesticide Residues (CCPR) develops and maintains acceptable pesticide Codex maximum residue limits (MRLs) for food commodities in international trade. *Although these could, in principle, form the basis of globally-accepted standards, the major trading blocs in practice set their own independent standards...* Via the so called ‘Codex Step Procedure’ new MRLs are developed and agreed. *Member State governments nominate compounds to be evaluated by the Joint Meeting on Pesticide Residues (JMPR), if these compounds meets specific agreed criteria.* This is done in close co-operation with the manufacturer since they are the usual source of the necessary data. *JMPR evaluates compounds, which have measurable residues in internationally traded commodities.* Such residues are a legitimate matter of public health concern and could create problems in international trade unless properly regulated. The compound/product to be evaluated must be registered in at least one Member State and be available for commercial use.

Joint Meeting on Pesticide Residues (JMPR)

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is an international scientific expert group administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). It serves as an independent scientific advisory body to FAO, WHO, and their member governments, as well as to the Codex Alimentarius Commission. *Advice on pesticides is provided to the Commission via the Codex Committee on Pesticide Residues (CCPR).*

... Acceptance of Codex MRLs

Under the Sanitary and Phytosanitary (SPS) agreement, the World Trade Organization (WTO) proposed globally-recognised MRLs as world wide trading standards. However, neither the USA nor the EU approve Codex MRLs or generally rely on MRLs. Instead, they independently set their own standards.

Accomplishments Report for the Period of 2003–2008, North American Free Trade Agreement Technical Working Group on Pesticides at p. 3 (2008) (emphasis added).

“Many of the MRLs and tolerance issues among the NAFTA countries have been resolved, and the NAFTA TWG will continue to work toward resolving remaining differences. *For example, NAFTA governments developed and implemented a NAFTA guidance to set tolerances/MRLs through a statistics-based methodology (MRL calculator). This standard methodology can be used by governments as part of the joint review program so that the same or similar data sets will result in the same recommendation for tolerance/MRL levels.* The development of the MRL calculator and the guidance document on residue trial efficiencies contributed significantly to addressing MRL/tolerances issues.

... The MRL Calculator

Pesticide Maximum Residue Limits (MRL) or pesticide tolerances are an important means of ensuring that food crops being imported into a country do not contain quantities of pesticides above the amount allowed by regulations. *MRLs/tolerances are determined based on pesticide levels resulting from field trials of pesticide applications to crops. Creating MRLs which are common between countries is an important means of reducing trade irritants that can prevent the trade in fruits and vegetables.* Two important achievements of the TWG have facilitated the likelihood of common MRLs in the future:

- The development of a SOP for determining pesticide MRLs (or tolerances)* which will help ensure that the same or similar data sets will result in the same or similar recommendation for MRL levels in each regulatory program; and

- The development of a “NAFTA MRL spreadsheet,” (MRL Calculator) which is a spreadsheet that incorporates the decision algorithm and automates the statistical calculations that are outlined by the SOP.*

The draft SOP and calculator are intended for use by residue chemistry reviewers in the U.S. and Canada as part of the joint review program. The SOP and accompanying spreadsheet are intended to reduce reviewer bias and enhance the reproducibility of MRL/tolerance determination through adherence to agreed upon methods and assumptions. Through development and use of the SOP and the MRL calculator the regulatory communities in both Canada and the U.S. have made a great advancement toward establishing harmonized MRLs between the two regulatory programs. *The calculator and related methodology are also being considered for use in other regulatory jurisdictions (i.e., Europe) which could further reduce trade barriers with other markets.*

G. Jeffrey Herndon, *Safe Food: Global Harmonization of Pesticide Regulation*, USEPA, presentation made at Duke Global Health Institute at pp. 14, 20 and 22 (Feb. 20, 2009) (emphasis added).

“Specific Initiatives: NAFTA MRL Calculator

Conventional method Based on the highest residues from field trials reflecting the most conservative use pattern(s). Highly dependent on professional judgment of individual scientists

New Statistical Method (MRL Calculator)

Provides a defined method

Should result in consistent decisions on tolerance setting

NAFTA endorsed in 2005

JMPR recognizes and is using the procedure

Actively promoting its use with other groups (OECD and JMPR) (p.14)

... **Specific Initiatives: OECD**

• **OECD has adopted a vision that by the end of 2014, through the cooperation of OECD member countries working with relevant stakeholders, it will ensure that:**

Levels of risk arising from pesticide use is minimized;

Regulatory system for agricultural pesticides is harmonized and data reviews are in the OECD format;

Preparation of dossiers is coordinated globally by industry and work sharing opportunities are maximized;

Work sharing arrangements between regulatory authorities in OECD countries are routine;

Generation of single monograph for each active substance becomes commonplace;

Countries ensure that benefits derived from work sharing are taken into other international fora (e.g., JMPR); (p. 20)

... **Specific Initiatives: Codex**

JMPR/CCPREPA staff chair JMPR/FAO committee (residues) and participate in JMPR/WHO (toxicology) committee

EPA heads US delegation to CCPR

US promoting initiative to accelerate setting of MRLs for new active ingredients – risk assessment and risk management work

Consideration of Codex MRLs in domestic decisions

Codex Crop Grouping Revision

Promote work sharing – JMPR utilizes reviews done by national authorities

Promote dialogue between stakeholders within US as well as with stakeholders in other countries.” (p. 22)

Report of the 41st Session of the Codex Committee on Pesticide Residues (April 2009) of the Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission 32nd Session (June-July 2009) (emphasis added).

“30. The 40th Session of the Committee requested the JMPR to provide brief explanations of the derivation of each MRL estimate and to publish a calculation summary table in the JMPR report.

31. *The Committee was informed that the JMPR had been using the NAFTA spreadsheet as a tool and not as the primary determinant of estimations, since NAFTA spreadsheet was not a statistical model for the accurate estimation of maximum residue levels but it was rather a decision-tree logic that utilized statistical calculations to arrive at a reasonable MRL that should be acceptable to different parties considering the same data set.* The FAO JMPR Secretariat emphasized that the estimation was

not a simple matter of entering the residue trial numbers into a spreadsheet and recording the output but that JMPR looked at both the numbers and the basis of those numbers and considered all relevant aspects in arriving at its MRL estimates.

... 34. *JMPR welcomed a harmonized statistical calculation method and agreed to use the ‘OECD calculator for MRLs’ as a trial in the 2009 evaluation, if this method was available for the upcoming JMPR meeting.* However, it was difficult for JMPR to provide a table to explain every recommended MRL, in particular at the testing stage of ‘OECD calculator for MRLs’.

35. The Delegation of the USA indicated that the explanations contained in the table of 2008 JMPR Report were not sufficient because they did not explain the derivations of MRLs, but only why the NAFTA calculator was not used. The Delegation requested that a statistical calculation method be used as the first estimation of an MRL and the MRL recommended by the statistical procedure would be rejected only if it was clearly unreasonable. The Delegation indicated that there was a need to develop calculation procedures that all members could support and strive for a harmonized commodity grouping scheme because their analysis showed that those were two of the main reasons that different MRLs are derived from the same data set. The Delegation reiterated that it would be useful if JMPR could include a brief description on how the MRL was derived, when the calculator results are not used.

36. Other delegations stressed the importance of improving transparency of the MRLs establishment process and were of the view that a short explanation why one or the other decision was taken should be provided.

37. To the proposal that JMPR participate actively in the OECD work, the FAO JMPR Secretariat pointed out that JMPR was continually striving for the development and utilization of a statistical calculation method and that JMPR experts actively took part in the development of relevant OECD Guidelines, including the calculation method.

38. The Committee recommended that JMPR participate in the ongoing efforts of the OECD Residue Chemistry Expert Group and provide their input into the development of a revised statistical calculation method.

39. After some discussion it was recommended that for the 2009 JMPR meeting the OECD statistical calculation method would be used, if available, and if not available the NAFTA calculator method would continue to be used and reported and, to the extent possible, brief explanations of derivation of the MRLs would be provided when the calculator was not used.

40. *The Committee noted the need for testing the “OECD calculator” for establishment of MRLs and suggested JMPR to test it when it became available.*

... 42. *The Committee also noted that the ‘OECD calculator for MRLs’ is still in development and there were some questions regarding MRL setting policies which needed to be solved in order to finish this work.*

43. The Committee noted that a questionnaire containing questions regarding these MRL setting policies had been distributed to OECD countries (CRD 20). Some delegations suggested that this questionnaire be distributed to all Codex Members in order to have more inclusiveness in the development of this calculator since OECD had limited participation and proposed that replies to this

questionnaire could be evaluated by an electronic working group in order to prepare a paper for consideration by the next session of the Committee.”

European Union Positions on Items 4 and 5, 42nd Session of the Codex Committee on Pesticide Residues (April 2010) (emphasis added).

“Agenda Item 4(a) JMPR Report 2009, Section 2. General Consideration, Mixed Competence European Union Vote

2.1 TRANSPARENCY IN THE MAXIMUM RESIDUE LEVEL ESTIMATION PROCESS: FURTHER CONSIDERATIONS

The EUMS welcome the development of the OECD MRL calculator and the exploration of its use by JMPR. However, the EUMS agree that the evaluation of residue data is a complex task that requires the consideration of factors and parameters additional to the numerical residue values, and that MRL estimates cannot be based solely on automatic calculation using any currently available ‘statistical’ method.

U.S. Delegate's Report, 42nd Session, Codex Committee on Pesticide Residues, Recent Delegation Reports, Codex Alimentarius Commission (April 2010), accessible on US Department of Agriculture Food Safety and Inspection Service website (emphasis added).

“Transparency in JMPR Derivation of MRLs

The U.S. delegation expressed its appreciation for the continued efforts of JMPR/FAO to make more transparent the derivations of the JMPR MRL recommendations as it assists national authorities in determining the most appropriate MRL for their needs and increases the understanding of CCPR risk managers of the basis of JMPR MRL recommendations.

Regarding the MRL calculator, the U.S. noted there still seems to be a lack of recognition of its usefulness for MRL harmonization. Advancing the MRL calculator into the Codex MRL-setting methodology would increase the science-based transparency in the establishment of MRLs. The MRL calculator would be used as a starting point and its result would be used, unless otherwise justified and explained in writing. **The FAO JMPR secretary emphasized that the calculator tool is helpful, but that currently no appropriate international calculator had been available for use by JMPR.** JMPR will continue to strive to improve the explanations of the MRL derivations.

OECD MRL Calculator

Under this topic, **the MRL calculator being developed through the OECD was discussed. United States, as chair of the Codex Electronic Working Group, informed the Committee that the approach of the calculator group had substantially changed over the last year based on the input received and the ongoing OECD work.** Details of the new approach were released in April, and the approach will be discussed at the OECD for the first time in May.

The FAO JMPR Secretariat noted that the JMPR was continually striving for the development and utilization of a statistical calculation method and that JMPR experts were involved in the development

of OECD Guidelines related to the calculation method. The Committee agreed to circulate to Members any OECD requests for input on the calculator. Comments would be submitted to the United States with a copy to the Codex Secretariat. Further actions of the CCPR on the OECD calculator will be determined at a later stage when the final version of the OECD calculator becomes available.”

Kathy Monk, *EPA Partnerships and Progress on MRL Issues—A Regulatory Perspective*, USEPA, presentation at “2010 MRL Workshop – Global Regulations”, at p.11 (May 2010) (emphasis added).

“Joint Meeting on Pesticide Residues (JMPR)

Work sharing

- Extensive use of work sharing established in JMPR as direct result of work sharing being used for joint reviews
- Examining the toxicological endpoints selected by governments that have already reviewed a chemical is now an established first step for JMPR

MRL Calculator

- Routinely using NAFTA calculator as a tool*
- Has resulted in much greater transparency in JMPR MRL recommendations*
- JMPR will test new ‘OECD’ calculator and has had significant input in its development”.* (p.11)

E. Europe Encourages and Promotes Private ‘Food Safety +’ Standards that Elevate Regional ‘Green’ and Consumer Information-based Regional Organic and/or Sustainable Agriculture Process and Production Methods Internationally Without Granting Mutual Recognition to Comparable U.S. Standards

1. Organic Trade Association Receives \$750,000 Grant, Press Release (Oct. 14, 2008) (emphasis added)

“OTA envisions that this funding will go a long way towards understanding the hurdles that impede the trade of organic products and finding solutions to opening trade options for U.S. organic producers,” said David Gagnon, OTA's Chief Operating Officer and OTA leader on U.S. organic export projects. *With the funding, OTA member Sustainable Strategies: Advisors in Food and Agriculture, based in Boalsburg, PA, will conduct various comparative GAP analyses and overviews of international markets for U.S. organic products. Comparative GAP analyses are detailed, side-by-side comparisons of the U.S. national organic standards and those of designated countries. Each analysis identifies the barriers to exporting U.S. organic products to specific international specialty markets.*

... In their project proposal to FAS, OTA and Sustainable Strategies pointed out that U.S. organic producers are at an unfair trade disadvantage because various foreign nations, certifiers and their producers enjoy full access to the 50-state U.S. market while U.S. organic producers have no reciprocal access to their markets. As a result, U.S. companies often must negotiate with sovereign nations on an inherently uneven playing field.

‘As organic production and trade expand around the world, requests from countries for recognition and equivalence of standards grow, as does the need to compare standards. *OTA's previous work on side-by-side comparisons of organic standards and strategic analyses to support trade policy using TASC*

funds has provided vital information for USDA in negotiations with other countries and in determining when trade in organic products will be affected,’ according to Kelly Strzelecki, agricultural economist with the Processed Products and Technical Regulations Division within FAS.”

2. Matthew Holmes, *One Year Later: A Practical Guide to the Canada-U.S. Equivalency Agreement*, Organic Processing Magazine (May-June 2010) (emphasis added).

“When U.S. Deputy Secretary of Agriculture Kathleen Merrigan announced *the Canada-U.S. equivalency arrangement* last June... cell phones, blog sites, and international meetings became abuzz with *the world’s first full trade deal between two organic systems. The equivalency arrangement established full reciprocity—essentially free trade—between the Canada Organic Regime (COR) and U.S. National Organic Program (NOP), recognizing a common approach to organic agricultural production and processing. Many now hope that this will be the first domino to fall in what has become a long line of global organic non-tariff trade barriers... The historic agreement* between the United States Department of Agriculture (USDA) and the Canadian Food Inspection Agency (CFIA) *offers a new model for further expansion of North American organic products into the significant European and Asian markets*, and the continued growth of the global organic movement.

...[T]he agreement allows the smooth flow of organic products between the two countries, without requiring farmers or manufacturers to certify twice to two separate standards and compliance systems. Although there are some small differences between what is required of a certified organic producer in Canada and the United States (see “variances” below), the guiding principles of the two organic standards, the basic methods of production, and the governments’ enforcement of those standards are effectively the same.

... The “Variances” and How to Comply

During their negotiations on equivalency and in consultation with their domestic sectors, the USDA and CFIA determined that certain technical differences (“variances”) between the two standards needed to be maintained by the importing country. Therefore, to be deemed ‘equivalent’ under this trade arrangement, organic products traded between the U.S. and Canada must meet their domestic certification but also be verified to the following additional requirements (italics denote text from the actual agreement).

Regarding products entering the U.S. under COR certification:

- *‘Agricultural products derived from animals treated with antibiotics shall not be marketed as organic in the United States.’* Although Canada allows a limited application of antibiotics to dairy cows in certain situations, no products from these cows can be sold as organic in the U.S.

Regarding products entering Canada under NOP certification:

- *‘Agricultural products produced with the use of sodium nitrate shall not be sold or marketed as organic in Canada.’* As described earlier, USDA has taken immediate action to adhere to this requirement.
- *‘Agricultural products produced by hydroponic or aeroponic production methods shall not be sold or marketed as organic in Canada’...*

- *‘Agricultural products derived from animals must be produced according to livestock stocking rates as set out in CAN/CGSB-32.310-2006 (amended October 2008).’* The USDA has indicated to CFIA that it does not currently have the necessary information in order to assess its stocking densities in organic livestock operations and so has instructed certification agencies to collect this information and will provide it to CFIA by August 2010, at which time the variance will be reviewed.

... Not described in the actual agreement, but relevant, is *the difference in scope of the two systems. Currently, Canada only regulates organic food, feed, livestock and primary crops. Therefore, personal care or other items that qualify for the USDA organic seal or third-party organic claims may continue to be marketed in Canada but will not be eligible to bear the ‘Canada Organic’ logo.*

... The singularity of this agreement is that it’s a system-to-system equivalency rather than simply a country-to-country equivalency... [T]his arrangement allows NOP- or COR-equivalent products from any country to flow into either market. The importance of this “third-country” aspect of the equivalency agreement between Canada and the U.S. cannot be understated: it makes Canadian and U.S. organic products among the world’s most accessible, and it brings the world’s organic supply within reach of our processors, while maintaining the controls and requirements of our domestic regulatory systems and standards. Therefore, if you are NOP-certified by a USDA-accredited certifier anywhere in the world, and your certifier has also reviewed your ingredients and production methods to be in compliance with the terms of the arrangement, then you can send your product to Canada without any additional certification. The same goes for COR-certified products destined for the U.S.

... Labeling

Unique to this agreement is that NOP or COR organic products deemed equivalent can use either or both organic seals interchangeably (the ‘USDA Organic’ seal is available from the NOP, while the ‘Canada Organic’ logo must be provided by the certifier of the product)... Note that Canada does not permit a ‘100 percent organic’ claim, while the U.S. ‘made with’ claim for products containing 70 to 95 percent organic ingredients is treated as a percentage claim in Canada. That is, products must state ‘XX percent organic ingredients’ rather than name specific ingredients in the product which are organic.

... A final labeling difference relates to wine. *As Canada has no labeling provision to indicate wine products that are ‘made from organically grown grapes,’ this claim is not possible within Canada.* Therefore, any imported wine should be certified at both the production and processing stages.

... What It All Means

... Since the agreement was announced, the U.S. and the European Union (EU) have reinitiated long-stalled talks towards a possible equivalency. And negotiations between Canada and the EU have advanced considerably since the arrangement was reached with the U.S.—the two sides have already reviewed each other’s standards and will hold a final peer-assessment soon. Meanwhile, a number of other regulated markets are beginning to talk to both Canada and the U.S. about direct equivalency arrangements, signaling a possible end to the considerable trade barriers we’ve built for ourselves.”

VII. Conclusion: It’s Far More Complicated Than You Think; But There’s a Way Out!