



## **Europe, China and the Use of Standards as Trade Barriers How Should the U.S. Respond?**

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Mr. Chairman, and ranking members of the Subcommittee, my name is Lawrence Kogan, and I am CEO and Co-Director of the Institute for Trade, Standards and Sustainable Development, Inc. (ITSSD). The ITSSD is an independent and non-partisan not-for-profit organization dedicated to the promotion of a positive paradigm of sustainable development consistent with World Trade Organization (WTO) principles. The ITSSD is pleased and honored to comment about the subtle, complex and significant challenge posed to U.S. global economic and technological competitiveness by the growing use of new market access barriers. During the past several years, it has become more obvious that such disguised trade barriers are typically cast as overly stringent and extra-territorial environment, health and safety (EHS) technical regulations and product and process standards, which have the effect of protecting underdeveloped, lagging or ailing industries in other countries.

Our research has revealed that most such measures are premised on an evolving European norm known as the precautionary ('better safe than sorry') principle. As employed by the European Union (EU) the precautionary principle severely restricts or altogether bans the introduction of a number of new and existing U.S. products, substances, processes and technologies into the marketplace, unless they have first satisfied rigorous pre-market authorization requirements that are in excess of relevant international standards, but which are not scientifically, economically or technically justified. Once permitted into the marketplace, they are then subject to overly stringent post-market testing requirements that are also in excess of relevant international standards. In addition to ignoring free market principles, such rules arguably also violate the terms of three WTO agreements: the Sanitary and Phytosanitary (SPS) Agreement; the Technical Barriers to Trade (TBT) Agreement; and the General Agreement on Tariffs and Trade (1994).

As requested, my testimony will respond to the following two sets of questions posed by the Subcommittee to the list of witnesses that testified during the May 11, 2005 hearing:

1. What has been China's and Europe's approach to the development and use of standards? How is this approach changing international standards development in organizations such as the International Standards Organization, and through bilateral relations with other countries? What are the implications for U.S. trade with China and the rest of the world?
2. Based on the U.S. Standards Strategy that ANSI has been developing, what should the Federal Government, States, U.S. standards development organizations, and companies be doing to reduce their vulnerability to the use of standards as trade barriers, and how could they promote the adoption of non-exclusionary standards in the global marketplace? How should these efforts be coordinated?

## I. Assessment of the Problems:

### 1(A) Europe and International Standards

The universe and importance of standards has broadened at a breathtaking pace since the completion of the Uruguay Round negotiations and the ratification of the TBT Agreement by WTO member countries. During the past 5-10 years, the EU, for one, has decided to link the adoption of technical regulations (government policymaking) concerning environment, health and safety (EHS) with the development of (industry) product and process standards, on both a regional and an international level. Within the U.S., standardization is primarily ‘market’-focused and industry-driven, and is generally treated separate and apart from government regulation. Food and drug regulations present an obvious exception to this general rule. One of the essential differences between the EU and U.S. standards systems is that, under the EU system, “when a European national standard is developed and approved, competing national standards must be withdrawn”, whereas in the U.S., there can be competing ‘national’ standards.<sup>1</sup>

As is evident from the EU model, however, regulations and standards have been increasingly developed pursuant to a ‘top-down’ process that spans multiple industry sectors based on the widely used ‘New Approach’ and ‘Global Approach’ to European regulation.<sup>2</sup> This has ensured that important EU political policy goals are achieved, often without reference to the WTO benchmarks of scientific risk assessment, economic cost-benefit analysis, technical use, quality and performance, and stakeholder transparency and notification. One European policy goal has been the elimination of all ‘technological and industrial risk’, even that which is not yet known, through use of the precautionary principle. Another has been the improvement of European industries’ global competitiveness - of ailing, underdeveloped or lagging European regional industries – consistent with the EU ‘Lisbon Agenda’, the primary objective of which is to make Europe “the most dynamic and competitive knowledge-based economy in the world [by 2010]”.

In other words, standardization, in the minds of European regulators and industry, is the ticket to global economic dominance. As stated by former EC Enterprise Commissioner Erkki Liikanen,

*“In the global marketplace Europe is in a very strong position because it has linked European standardization as closely as possible to international standardization... [The EU has]... realized the value of [using] national and regional standards as stepping-stones to international standardization... Cooperative agreements already exist between international and regional or national standards organizations... [This has]... offer[ed] [the EU] a systematic framework to take over international standards and/or to contribute to the international standards making process... 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 worldwide-standardization”*(emphasis added).<sup>3</sup>

And, Germany is largely the source behind Europe’s drive to dominate international standardization.

*As the export “world champion”, and the leading exporter of technology, Germany needs an effective standardization body. Standards play an extremely important role both*

economically and politically...Standardization helps the rapid dissemination of technical knowledge and innovation, increasing the business competitiveness...[S]tandardization is also extremely relevant for the individual participants in economic processes, *since whoever makes the standards controls the market*. In times of increasing globalization and rapid technological development, the role of standardization in opening up new markets will become increasingly important (emphasis added).<sup>4</sup>

In addition, EHS regulations and standards premised on the precautionary principle, are being used to further the EU's global economic agenda under the guise of 'sustainable development' as articulated by the various agencies and programs of the United Nations.<sup>5</sup>

Precautionary principle-based regulations and standards focus on *hazard* rather than *risk* assessment. This means that they do not look to specific scientific evidence (context) of harm - empirical data of actual or predictable/probabilistic toxicity (high dosage) *and* exposure (human or environmental exposures) - to *individual* products and substances. Rather, they are primarily concerned with identifying intrinsic hazardous characteristics and inherent qualities of *groups* of products and substances determined by reference to sweeping criteria (long and seemingly arbitrary checklists) defining categories of products and substances bearing similar traits, *without regard to scientific context*. These categorizations or 'groupings' of products and substances are then incorporated into administrative and legal presumptions of hazard which will have significant legal and economic consequences for U.S. industry and national global competitiveness.

"The EU is [now] 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 (emphasis added)...*By championing a host of global environmental treaties and accords taking the precautionary approach to regulation...* [i.e., invoking]...**the precautionary principle**...the EU has shown a willingness to act on its commitment to **sustainable development** and global environmental stewardship" (emphasis added).<sup>6</sup>

"The **precautionary principle** is designed to allow government authorities to respond **preemptively, 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'...* 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...*The precautionary principle is deeply at odds with the traditional Enlightenment idea about science. Risk taking is at the heart of modern science...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*" (emphasis added).<sup>7</sup>

Originally, evidence suggested that the EU's use of precautionary principle-based measures was regionally focused, in part, intended to protect its industries from more advanced and lower cost U.S. product and technology exports. However, increasing evidence has shown that the EU is exporting such measures to other countries besides the U.S., multilaterally *and* bilaterally. For example, the EU has embedded precaution within regional technical regulations, which are then



projected into *treaty-based intergovernmental 'regulatory' bodies* such as the Codex Alimentarius Commission, the International Plant Protection Convention, the OECD, the United Nations Environment Program (UNEP) (which hosts the multilateral environmental treaty secretariats) and the World Health Organization (etc.) for consideration and adoption as international regulatory frameworks or treaty norms. The EU also embeds precaution within EU regional industry product and process standards pursuant to a non-transparent and non-inclusive process from which ANSI and U.S. standards developers have been largely excluded.<sup>8</sup> And they are then projected into the ISO/IEC, a *non-governmental non-treaty-based* standards body, for consideration and adoption as 'voluntary' international industry standards.

Because the relationship between these different kinds of international bodies is not very clear, the EU has exploited that 'unknown' in two ways. First, the EU works to define and develop global precaution-based regulatory frameworks modeled after those within the European region within the intergovernmental bodies noted above. These globally focused frameworks are intended to identify, assess and manage public EHS *hazards* (as opposed to risks). These regulatory frameworks are then transposed into complimentary and more comprehensible international technical product standards by and for global industry at the ISO/IEC. This parallel track is pursued much in the same way that the EU Commission and EU regional standards bodies cooperate within the EU at a regional level. Second, the EU chooses to advance particular precaution-based EHS agenda items within whichever of these international bodies (regulatory and/or standards) it sees a strategic opportunity arise – i.e., it forum shops.

While it is relatively well known (and, to some extent, controlled) how the EU utilizes the processes and procedures within the intergovernmental bodies to advance the precautionary principle as an international regulatory framework norm, it is either not as well known or as controlled *how* they go about doing so within the ISO/IEC. Evidence strongly suggests, however, that the EU relies to a large extent on the Vienna and Dresden Agreements executed between the European regional standards bodies (CEN and CENELEC) and the ISO/IEC. These agreements enable those bodies to 'bootstrap' particular EU precaution-embedded EHS standards into the ISO/IEC without notifying or otherwise providing non-EU technical committee, subcommittee or working group members with the opportunity to protest (e.g., ANSI, consortia and U.S. industry participants) the 'transfer' of such European standards.<sup>9</sup> This fast-track procedure, which entitles standards to skip several stages of review, is mentioned below.

In addition, increasing evidence also suggests that the EU Commission has served and continues to serve as a 'liaison' ('advisory') organization to the ISO. In this role, the EU has been actively assisting European ISO members to further European economic and technology interests, i.e., by using the ISO process to incorporate the precautionary principle and EU sustainable development notions within a growing number of proposed and adopted *international* standards. For example, the EU Commission currently serves as an organization in liaison to **91** technical committees *and to* multiple subcommittees thereof, where most of the work at ISO is known to be performed. It is common knowledge that technical committees possess the discretion to engage accredited liaison organizations as they deem necessary. The U.S. Government, by contrast, is not listed as a liaison



organization to the ISO. Currently, certain individual U.S. Government employees from a handful of federal agencies diligently participate in only some of the voluminous ISO technical work relevant to their jurisdiction. However, their ISO work is being performed only indirectly, as they serve through and within ANSI's International Policy Forum. Unfortunately, this forum/mechanism is hardly a match for direct and extensive EU Commission involvement.

The United Nations Environment Program (UNEP), which is largely funded by the European Union and EU Member State national governments, is also listed as an ISO liaison organization. It advises several technical committees: TC22 (road vehicles); TC147 (water quality); TC207 (environmental management – “*Standardization in the field of environmental management systems and tools in support of sustainable development*”); REMCO (reference materials). And, several other United Nations programs and agencies serve as liaisons, besides UNEP. They include the UN Industrial Development Organization (UNIDO), the UN Development Program (UNDP), UN Conference on Trade and Development (UNCTAD), UN Commission on International Trade Law (UNCITRAL), UN Educational, Scientific, and Cultural Organization (UNESCO), UN Economic and Social Commission for Europe (UNECE). Arguably, TC 207 is one of the broadest and largest technical committees of ISO.

Furthermore, there is the issue of voting. ANSI, U.S. standards development organizations (‘SDOs’), U.S. industry participants, and consortia members have long complained about the one-country, one vote rule, which arguably poses a significant disadvantage to the U.S. and its non-EU allies where ‘block voting’ is observed to occur.<sup>10</sup> And that disadvantage is only exacerbated by the ‘fast-track’ process, which skips the preparatory and committee stages of the standards development process to arrive at an ‘enquiry draft’ vote. Pursuant to that practice a participating member of an actively engaged liaison organization of a concerned technical committee may propose that an existing standard from any source be submitted for a vote as an enquiry draft. An international standardizing body recognized by ISO/IEC also may propose that a standard developed by that body be submitted for vote as a final draft international standard (‘FDIS’). And an organization that has entered into a formal technical agreement with ISO/IEC (e.g., CEN, CENELEC) may propose that a Draft standard developed by that organization be submitted for vote as an enquiry draft.

Moreover, a careful examination of the business plans defining the scope of the work for each of the ISO technical committees is also instructive. It reveals that these business plans incorporate, to varying degrees, direct and indirect references to EU notions of ‘sustainable development’, ‘sustainability’ (‘for future generations’), ‘environmental friendliness’ and ‘social’, environmental, or ‘cultural’ language that refers to process-based environmental product stewardship/life cycle assessment requirements and the need to conduct a hazard assessment of substances and products. However, there is little, if any, mention of economic cost benefit analysis. These listed notions arguably run counter to the bedrock WTO principles of sound science, economic cost-benefit analysis and technical performance. In addition, some of these business plans draw express linkages between current EU regulatory and standards regimes, United Nations programs and agencies (e.g., UNEP/SAICM, UNIDO, UNCED, Agenda 21, GHS, UNECE) and international standardization. Others are based on proposed or adopted EU regulatory regimes and EU



Commission reports. And, still others are based on disputed OECD studies and (CSR) guidelines, U.N. Global Compact Principles and UNEP treaties (e.g., Basel Convention, Rotterdam PIC Convention).

While it promotes these activities, the EU Commission is well aware that developing countries, including China, look to each of these bodies for guidance when developing national regulatory and standards systems. Indeed, the ISO's Developing Country Policy Development Committee ('DEVCO'), which focuses on rendering technical assistance and/or capacity-building services to developing countries<sup>11</sup>, is most likely being utilized to promote EU-centric sustainable development objectives that incorporate the precautionary principle. The EU has also embedded precautionary principle requirements directly within its bilateral aid, trade, technical capacity-building and science and technology (S&T) agreements with developing countries. (See discussion below regarding China).

An interesting compliment to DEVCO's *capacity-building* standards activities is the UNEP and UNDP-GEF Project on Development of National Biosafety *regulatory* Frameworks.<sup>12</sup> The purpose of that program, which is targeted towards developing countries, is "to provide a practical 'how-to' guide for countries to assist them in developing and implementing a project aimed at preparing their draft National Biosafety Frameworks (NBF)...[T]his toolkit provides a resource for countries that want to ensure that their NBF reflects their obligations under the Cartagena Protocol on Biosafety as a minimum, but may wish to go beyond the Cartagena Protocol in developing their regulatory regimes"<sup>13</sup> (emphasis added).<sup>14</sup> And, as with other EU-centric sustainable development agenda items that go beyond relevant international standards, it refers expressly to the precautionary principle.<sup>15</sup> It is arguable that this 'regulatory' toolkit is complimentary to the food product 'safety' standards being prepared by ISO technical committee 34, Work Group 7, specializing in genetically modified organisms (GMOs) and GMO-derived products (food and feed).

Furthermore, this toolkit's reference to socio-economic criteria indicates how the EU is actually using its considerable market size as leverage ('soft power') to subtly persuade, through the exercise of its 'soft' power, non-EU countries to reject GMO imports and to refuse authorization of GMOs domestically. As even American organic farmers have discovered, the EU's 0% GMO detectability threshold has been brandished as a precondition to obtaining EU market access. It has also actually served as a market access barrier where U.S. organic exports have been detected to have *any* GMO content at all.

"In establishing criteria for decision-making, countries may wish to consider other issues such as...*socio-economic, ethical, cultural or religious considerations*...Examples of socio-economic considerations might include the impact of the approval on particular communities (e.g., livelihoods of poor farmers) in the country; *the economic impacts on organic farmers of the potential loss of 'GM-free' status; the potential loss of export markets for agricultural produce*; and concerns about the potential impact of a particular GMO on food security" (emphasis added).<sup>16</sup>

Sub-Saharan African countries know all too well how 'subtle' EU market pressures have prompted African organic farmers to lobby against and African governments to refuse U.S. GMO food aid.



And, as the ITSSD’s forthcoming study reveals, the EU regulatory policy on GM food and feed has also encouraged U.S. organic farmers in a number of U.S. states to join with environmentalists to lobby state legislators to enact anti-GM or GM liability legislation.

1(B). China and International Standards:

The ITSSD has noted the testimony of Mr. Deutsch of Oracle concerning the Chinese imposition of a compulsory national Wireless Local Area Network (‘WLAN’/‘WAPI’) licensing standard on U.S. technology exports to China. Apparently, this requirement was imposed for the purpose of differentiating and protecting the nascent marketplace for Chinese technologies and products from more advanced and encroaching U.S. technologies and products. It also likely serves as a disguised means of extracting sensitive proprietary information (trade secrets) and other intellectual property from U.S. technology companies, without adequate compensation or I/P protections, for competitive advantage. And, these disguised trade barriers have had only to do with purely ‘technical performance’ and technical ‘know-how’ product standards.

The ITSSD wishes to emphasize that, in addition to such technical requirements, Chinese regulators have been incorporating within their regulatory and standards systems environmental, health and safety (EHS) requirements that, in many cases, mirror similar EU regulations and standards. As in Europe, public policy EHS requirements are increasingly being utilized to create new artificial market distinctions between domestic and foreign products. These distinctions, unfortunately are being justified other than by reference to sound science, economic cost-benefit analysis or technical performance and workability requirements.

China has come to be viewed as the ‘factory of the world’ and is now widely recognized as the base of the global supply chain for many types of manufactured products and processes. It is for this reason that the pace of joint EU-China regulatory and standards initiatives has increased in recent years. Unfortunately, those activities may also have a significant adverse impact on the China-based imports *and* exports of U.S. companies. For example, there is increasing evidence that the Chinese Government is looking to the EU for inspiration on environmental policy, and that this has resulted in China’s initiation of several environmental policies based on EU models.

According to two experts on Chinese standardization, China’s interest in the European regulatory and standards model, especially as concerns environmental policy, has likely arisen for two reasons. First, it is most likely due to China’s post-WTO accession need to develop science-based and market responsive national standards to facilitate its continuing technological and economic development. In other words, WTO accession has not only “obligated China to redesign its own domestic standards regime, but [it] has also provided incentives to pursue distinctive Chinese technical standards in its technology policy as a way of managing the increasing competition from foreign firms.”<sup>17</sup> Second, it is most likely attributable to a systemic bias that it shares with Europe (and even Japan) towards top-down, state-directed economic activity and formal international institutions.<sup>18</sup>

Not surprisingly therefore, Europe has been eager to oblige, especially if it disadvantages American industry and keeps American economic and political power in check.<sup>19</sup> Indeed, since 2000, the EU has maintained a science and technology (S&T) exchange program<sup>20</sup> (the ‘INCO Programme’) based in China to promote EU health, environment and food security and safety research. By comparison, the U.S. Department of Commerce only recently (2004) appropriated monies to fund *non-governmental* standards outreach activities in China by U.S. industry, which began this year.

The goal of the INCO Programme has been to move China towards European precaution-based regulatory rules in order to impose them throughout the global product supply chains. In many ways, the EU has already achieved considerable progress.

...Our S&T [science and technology] 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...* [concerning]...radiation emissions of mobile phones, certified BSE-free cosmetics, or hormones in chicken meat...European companies are rapidly building up research facilities in China. Sectors especially interested to extend the Framework Programme into China are: IT, aeronautics, automotive, pharmaceutical, and biotechnology... (emphasis added).<sup>21</sup>

During 2002-2003, for example, the Chinese Government had enacted strict rules implementing EU-like regulations on agricultural biotechnology safety, testing and labeling. In addition, the Chinese had issued proposed regulations to eliminate the use of lead in electronics products based on the EU RoHS and WEEE regulations, which require U.S. hi-tech companies and their suppliers to eliminate the use of certain hazardous substances in their products and to ‘take-back’ and recycle waste.<sup>22</sup> In addition, Chinese government agencies are focusing more on chemicals management issues, and are now believed to be considering the adoption of an EU REACH-type regulation for chemicals management<sup>23</sup>, despite their previous public criticisms of the EU REACH proposal.<sup>24</sup> And, back during 2001, “China introduced a product quality law that contained a number of different provisions, including *a specific provision on liability compensation for damage, [that was] identical to the European Directive [on Products Liability]*. It even include[d] a development risk defen[s]e, since China wished to protect their nationalized business entities through this means...”<sup>25</sup>The ITSSD’s forthcoming paper analyzes the impact of this EU directive.

Furthermore, consistent with current EU development policy, Europe is offering to China “its environmental energy know-how to help it develop efficient and clean industrial processes and energy production...to prevent climate change”.<sup>26</sup> And these efforts have been complimented by those of the environmental NGO community, which is involved in developing China’s environmental regulatory framework so that it incorporates the precautionary principle and impacts global supply chains. The U.S.-based Natural Resource Defense Council (NRDC), for example, has embarked on a program to help China draft and enforce air pollution laws and to reshape its energy infrastructure by, among other things, promoting western (presumably, European) industry’s



transfer of greenhouse gas emissions mitigation technology to China. According to the NRDC, since China is the second largest consumer of energy in the world, the leading producer of coal in the world and the second greatest emitter of (coal-based) greenhouse gases in the world, once the Kyoto Protocol goes into force China's ratification of it will "ensur[e] [that] official CDM [clean development mechanism] projects [encouraged by the treaty] will soon be launched on its soil."<sup>27</sup>

What has concerned American companies even more regarding China's growing cooperation with Europe on regulatory and standards issues, however, is its willingness to emulate Europe's use (implementation) of strict top-down (precautionary principle-based) environmental regulations as disguised trade barriers in order to protect its nascent commercial and technology industries. Also unsettling, is the question surrounding how U.S. international business activities, technologies and products may be affected in the longer term by the common view shared by Europe and China that, "global institutions, particularly the United Nations, need to be strengthened...as a further check against a unipolar hegemon [the United States]", and for the purpose of addressing the "various challenges of global governance" – namely, sustainable development.<sup>28</sup> According to a recent report, the different ways in which Europe and the U.S. perceive an evolving China can be summarized as follows:

"Although European and U.S. companies are locked in intense competition for market share in China, at the governmental level the difference in investment of resources is indicative of the divergent approaches to managing a rising China. The United States invests its resources primarily to monitor the growth of China's hard power and to deter potentially aggressive Chinese behavior beyond its borders, whereas the *EU is investing in initiatives inside of China to increase the country's soft power and facilitate its sustainable development*" (emphasis added).<sup>29</sup>

## II. **Recommendations:**

### 1. The U.S. Standards Strategy and Recommendations:

On April 18, 2005, the ITSSD submitted comments and recommendations to the American National Standards Institute (ANSI), in response to their draft revision of the 5-year United States Standards Strategy (USSS). These comments are already in the possession of certain members of this Subcommittee and should be considered as part of this record.

Besides the recommendations contained therein, the ITSSD wishes to proffer the following additional recommendations which, assuming adequate funding was made available, could be initiated within the foreseeable future:

### 2. ISO/IEC:

A. The ITSSD proposes to undertake an in-depth study of the composition and operations of the various organs of the ISO/IEC with an eye toward stemming the exportation of precautionary principle-based ISO/IEC standards, and improving the overall functionality

and efficiency of this international non-treaty-based non-governmental institution in furtherance of American interests. Such a study would among other things:

- i) Focus on how the ISO/IEC international standards development and adoption processes and procedures could be made more transparent and inclusive so that international standards ultimately adopted better reflect the global marketplace;
- ii) Seek to evaluate specific technical committee and working group parliamentary protocols and procedures, including voting rights and voting records, and their impact on ANSI's ability to promote U.S.-based standards as international standards;
- iii) Review the definitional requirements for becoming a liaison organization to the ISO/IEC, the different statuses of and roles played by various governmental and intergovernmental liaison organizations in the work of technical committees and working groups and projects. Assess the extent to which the increased participation of such entities within the ISO/IEC standards development process impairs achievement and/or realization of U.S. strategic goals. Identify meaningful and achievable cost-efficient ways to increase direct U.S. governmental participation within the ISO/IEC standards development process. Identify specific technical committees, sub-committees and working group projects where direct U.S. government participation will further U.S. strategic interests.
- iv) Consider how the 'fast-track' procedure for bringing non-ISO standards into the ISO can be made fairer, more transparent and inclusive, and subject to more advanced notification requirements, consistent with those contained within Article 2.9 of the TBT Agreement. As part of this inquiry, consider how the Vienna and Dresden Agreements between EU regional standards bodies and the ISO/IEC have disadvantaged ANSI's ability to promote U.S. standards for adoption at the ISO/IEC interests, and whether it is in the U.S. interest and control to execute an analogous agreement of similar scope with the ISO/IEC;
- v) Examine the feasibility of establishing new institutional benchmarks (i.e., 'checks and balances') within the ISO/IEC to which all international standards, *before* they can be adopted, as either draft or final standards, would be subject. Such benchmarks would need to be consistent with and complimentary to established benchmarks already found within the SPS and TBT WTO Agreements, namely: a) Specificity – Product and process standards must relate to specific products or substances rather than to broad categories of products, substances and/or production processes; b) Scientific Justification – Product and process standards must be subject to a rigorous risk analysis comprised primarily of a risk assessment of specific health and/or environmental risks based on actual or probabilistic exposure and toxicity scenarios; c) Economic Justification – Product and process standards must be subject to a detailed economic cost-benefit analysis that looks not only to the environmental, health, and safety benefits to be obtained from implementation of the standard in a national and international setting, but also the

economic and social costs such implementation would engender – i.e., the likely costs imposed on industry, consumers and society at large, taking into account the particularities of each national situation. d) Technical Justification – Product and process standards must satisfy rigorous technical ‘fitness-for-use’, quality, durability, and performance requirements; e) Non-Discrimination – Product and process standards must not arbitrarily discriminate between otherwise identical or substantially similar products and substances based on *how* they are produced; f) No Unnecessary Obstacles to Trade – Product and process standards must reflect the least trade restrictive alternative available to addressing non-trade national public policy objectives; g) Global Relevancy – Product and process standards must be capable of being used and implemented internationally as broadly as possible, without favoring specific national norms that differ materially from international norms, i.e., the ‘essential differences’ in the mandatory requirements of the standard from nation to nation must be recognized as ‘equivalent’, and each of the conditions noted above must first be satisfied. As described by ANSI, this term “emphasizes the value of a single international standard that can be used and implemented as broadly as possible by affected industries in countries around the world...ISO approved its global relevance policy in 2003. Its policy recognizes both differing *technical* requirements as well as differing *market* requirements. The goal of the ISO policy is to achieve the objective of ‘one standard, one test, accepted worldwide’” (emphasis in original).<sup>30</sup>

- B. The ITSSD proposes to undertake an audit of the business plans of each of the ISO/IEC technical committees to identify and evaluate the degree to which such business plans contain direct or indirect references to EU precautionary principle-based standards and/or regulations and UN programs, agencies relating to sustainable development, and whether the scope of activities that have been undertaken thus far have been impacted by these references.
- C. The ITSSD proposes to undertake aggressive outreach to developing countries participating at the ISO/IEC, beyond that envisioned by the ISO DEVCO program. Such outreach would initially assume the form of educational seminars and workshops that identify, discuss and explain the key benchmarks noted above that are contained within the relevant WTO Agreements, as well as, how to employ them at the national level. Such a program would also compare and contrast the U.S. risk-based vs. the EU hazard-based approaches to addressing potential environment, health and safety matters, and the differences between the U.S. market-based and EU regulatory-based approaches to standardization.
- D. The ITSSD proposes to actively tie in such outreach and training with U.S. Government trade capacity-building initiatives contemplated or underway with specific countries. Such initiatives would seek to promote bilateral and/or regional approaches to standardization consistent with the U.S. interpretation of the WTO Agreements. They would focus on the EHS dimension of the standards and regulatory provisions of existing Trade Investment Agreements (TIFAs), Bilateral Investment Treaties (BITs) and Free Trade Agreements (FTAs).
3. ISO/IEC / Codex Alimentarius Commission/ OECD/ United Nations Coordination:



The ITSSD proposes to undertake a study that reviews and analyzes how to improve coordination between U.S. Government, SDO and industry activities within the intergovernmental regulatory bodies noted above and the ISO/IEC standardization bodies.

These are but a few of the issues and proposals that the Institute for Trade, Standards and Sustainable Development stands ready to discuss in further detail. Thank you once again, Mr. Chairman, and the ranking members of this Subcommittee, for providing us with the opportunity to comment about these important matters.

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<sup>1</sup> See: William P. Kelly, “Resolving Standards Conflicts Key to U.S.-Europe Foreign Trade”, Washington Legal Foundation Legal Backgrounder Vol. 18, No. 36 (9/5/03), at p. 4, at: (<http://www.wlf.org/upload/9-5-03kelly.pdf>).

<sup>2</sup> See: Lawrence A. Kogan, “EU Regulation, Standardization and the Precautionary Principle – The Art of Crafting a Three-Dimensional Trade Strategy that Ignores Sound Science”, at pp. 20-27, fns 62-63, 68-84; p. 33, fn 99; p. 41, fn 128, at: (<http://www.itssd.org/White%20Papers/WLFfinaldocumentIII.pdf>).

<sup>3</sup> Comments of European Enterprise Commissioner Erkki Liikanen, “Commission Marks World Standards Day With Focus on Environment and Standards”, EU Institutions Press Release, IP/01/1408 (Oct. 12, 2001), at: (<http://europa.eu.int/rapid/start/cgi>); “Report From the Commission to the Council and the European Parliament on Actions Taken Following the Resolutions on European Standardization Adopted by the Council and the European Parliament in 1999”, COM (2001) 527 final (Sept. 26, 2001), at par. 49 at 20; “European Policy Principles on International Standardization”, Commission Staff Working Paper, Commission of the European Communities, SEC (2001) 1296 (July 7, 2001), at par. 9 and 26 at pp. 5 and 10.

<sup>4</sup> See, Wolfgang Clement, *German Standardization Strategy, Standardization in Germany Helps Business and Society Strengthen, Develop and Open Up Regional and Global Markets*, “Opening Statement”, at p. 4, at: ([http://www2.din.de/sixcms\\_upload/media/1345/DNS\\_english%5B1%5D.pdf](http://www2.din.de/sixcms_upload/media/1345/DNS_english%5B1%5D.pdf)).

<sup>5</sup> “EU Regulation, Standardization and the Precautionary Principle – The Art of Crafting a Three-Dimensional Trade Strategy that Ignores Sound Science”, at pp. 30-31, fn 90; p. 41, fn 127.

<sup>6</sup> See: Jeremy Rifkin, “The European Dream: Building Sustainable Development”, *E/The Environmental Magazine* (March/April 2005), at: (<http://www.emagazine.com/view/?2308>).

<sup>7</sup> See: Jeremy Rifkin, “A Precautionary Tale”, *The Guardian* (May 12, 2004), at: (<http://www.guardian.co.uk/analysis/story/0,3604,1214638,00.html>).

<sup>8</sup> Lawrence A. Kogan, “‘Unscientific Precaution’: Europe’s Campaign to Erect New Foreign Trade Barriers”, Washington Legal Foundation (Sept. 2003) at p. 23-26, at: (<http://www.itssd.org/White%20Papers/WLFKoganArticle2.pdf>).

<sup>9</sup> However, the Dresden Agreement between CENELEC and the IEC does provide the IEC with the ostensible ‘right of first refusal’ on all new work proposals, as compared to the Vienna Agreement between CEN and the ISO, which does not.

<sup>10</sup> Professor Kelly noted how apparent EU ‘block voting’ served to “reject the adoption of a draft ISO standard on criteria for recognition of international pressure equipment codes and standards...” William P. Kelly, “Resolving Standards Conflicts Key to U.S.-Europe Foreign Trade”, at p. 3.

<sup>11</sup> DEVCO has four main objectives: “[1] To identify the needs and requirements of developing countries in the fields of standardization and related activities (i.e. conformity assessment including accreditation, quality and metrology) and to assist the developing countries, as necessary, in defining these needs and requirements; [2] [T]o recommend actions to assist the developing countries in meeting them; [3] To monitor the implementation of the ISO Action Plan for [D]eveloping [C]ountries, and [4] To provide a forum for the discussion of all aspects of standardization and related activities...” See: “How ISO Helps: DEVCO”, at: (<http://www.iso.org/iso/en/comms-markets/developingcountries/iso+developingcountries-03.html>). Chief among the ISO Action Plan for Developing Countries objectives is the following: “Improve awareness of key stakeholders in developing countries of the role of standardization in economic growth, world trade and sustainable development.” See: ISO Action Plan for Developing

Countries 2005-2010”, at: (<http://www.iso.org/iso/en/comms-markets/developingcountries/iso%2Bdevelopingcountries-05.html#actionplan> ).

<sup>12</sup> See: “UNEP-GEF Project on Development of National Biosafety Frameworks – Phase 3 Toolkit Module PART (i): Developing The Regulatory Regime”, at:

(<http://www.unep.ch/biosafety/development/devdocuments/ToolkitBSF3RegEN.pdf> ). \*See, also: UNEP World Conservation Monitoring Centre, “Capacity Building for Biological Diversity – A Situation and Needs Analysis”, for the Environment Management Group (EMG)” (11/8/04), at: ([http://www.unemg.org/download\\_pdf/EMG9/DOC\\_9\\_8.pdf](http://www.unemg.org/download_pdf/EMG9/DOC_9_8.pdf) ).

<sup>13</sup> See: UNEP-GEF Project on Development of National Biosafety Frameworks, at Sec. 1.2.2 at p. 3. The toolkit refers to four levels of legally binding and non-legally binding instruments. Id., at Sec. 3.2, at pp. 14-15.

<sup>14</sup> Id., at Sec. 1.1, at p. 2. This toolkit module complements the Implementation Guide produced by the UNEP-GEF Implementation Project: ([http://www.unep.ch/biosafety/Implementation/impdocs.ntm#A\\_draft\\_guide](http://www.unep.ch/biosafety/Implementation/impdocs.ntm#A_draft_guide) ).

<sup>15</sup> Id., at pp. 34-35.

<sup>16</sup> Id., at p. 35.

<sup>17</sup> See: “Prepared Statement of Richard P. Suttmeier – China’s ‘Technology Trap’ and the Reconstruction of the Chinese National Innovation System”, Presented at the Hearing on China’s High Technology US-China Development Economic and Security Review Commission, Stanford California (April 21-22, 2005), at p. 6.

<sup>18</sup> See: Richard P. Suttmeier and Yao Xiangkui, “China’s Post-WTO Technology Policy: Standards, Software and the Changing Nature of Techno-Nationalism”, The National Bureau of Asian Research, No. 7 (May 2004), at p. 25.

<sup>19</sup> See “Unscientific ‘Precaution’: Europe’s Campaign to Erect New Foreign Trade Barriers” at p. 55, at fn 161.

<sup>20</sup> See: COM (2004) 38 final, “Communication From the Commission to the Council and the European Parliament – Stimulating Technologies for Sustainable Development: An Environmental Technologies Action Plan for the European Union” (1/28/04), at: p. 23. See: Discussion, *infra*.

<sup>21</sup> See: J. Sanders, EU Science Counsellor Beijing, “EU-China S&T Relations” (Nov. 2002), at: (<http://europa.eu.int/comm/research/iscp/countries/china/cn-doc5.pdf> ), cited in “‘Unscientific Precaution’: Europe’s Campaign to Erect New Foreign Trade Barriers”, at p. 53, fn 156.

<sup>22</sup> See: “Unscientific ‘Precaution’: Europe’s Campaign to Erect New Foreign Trade Barriers”, at pp. 47-51.

<sup>23</sup> See: “Environment, Health and Safety Trends in China – Shanghai PCOG Working Group Discusses Chemical Industry Regulations”, EuroBiz Chamber Event Report (Dec. 2004), at: (<http://www.sinomedia.net/eurobiz/v200412/event0412.html> ).

<sup>24</sup> See: “Chinese Comments on the EU REACH System”, submitted by the Ministry of Commerce, P.R. China, General Administration of Quality Supervision, Inspection and Quarantine of P.R. China (AQSIQ), (2003). See, also: “Association of Petroleum and Chemical Industries of China Comments to ‘The European Union Strategies on the Policies of Chemicals in the Future’” (July 4, 2003), discussed in Lawrence A. Kogan, “Enlightened Environmentalism or Disguised Protectionism? Assessing the Impact of EU Precaution-based Standards on Developing Countries, for the National Foreign Trade Council, at pp. 76-81, at: (<http://www.itssd.org/White%20Papers/L%20Kogan%20NFTC%20White%20Paper%203.pdf> ).

<sup>25</sup> See: Comments of Chris Hodges, “Part Two: Content and Future of the Green Paper: A European Perspective”, Green Paper and the Future of Product Liability Litigation in Europe”, Global Liability Issues, at pp. 3-4.

<sup>26</sup> See: “Commission Working Document – Country Strategy Paper 2002-2006 & China and National Indicative Program 2002-2004”, European Commission, IP/02/349 (Brussels, Mar. 1, 2002), at p. 30.

<sup>27</sup> See: Barbara A. Finnemore and Tauna M. Szymanski, “Taming the Dragon Heads: Controlling Air Emissions From Power Plants in China – An Analysis of China’s Air Pollution Policy and Regulatory Framework”, 32 ELR 11439-458 (Dec. 2002).

<sup>28</sup> See: David Shambaugh, “The New Strategic Triangle: U.S. and European Reactions to China’s Rise”, The Washington Quarterly, by the Center for Strategic and International Studies and the Massachusetts Institute of Technology (28:3, Summer 2005) at pp. 12-13, at: ([http://twq.com/05summer/docs/05summer\\_shambaugh.pdf](http://twq.com/05summer/docs/05summer_shambaugh.pdf) ).

<sup>29</sup> Id., at p. 15.

<sup>30</sup> See: Gary Kushnier, “The Impact of Globalization on ABMA [American Bearings Manufacturer Association] Standards Setting” (May 20, 2004), presentation made at the ABMA 2004 Spring Product Section Meeting, at: (<http://www.abma-dc.org/publications/Kushnier.pdf> ).