



April 18, 2005

Mr. Joseph Tretler, Jr.  
ANSI Staff Liason for the U.S. Standards Strategy Committee  
American National Standards Institute  
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New York, NY 10036

Dear Mr. Tretler:

The Institute for Trade, Standards and Sustainable Development (ITSSD) is pleased to have the opportunity to submit comments concerning the contents of the draft revision to the United States Standards Strategy (USSS). The USSS appropriately emphasizes the increasingly important role served by international standards in facilitating global commerce. It also accurately reflects the ever-closer relationship that foreign governments have drawn between environment, health and safety (EHS) regulation and industry product, process and service standardization.

The Institute's comments are divided into two sections. The first section responds to several of the specific initiatives proposed. The second section discusses crosscutting issues which, though not addressed in the USSS, must nevertheless be adequately considered if the USSS is to preserve U.S. international economic interests.

#### Section 1:

Initiative #2 - Continue to address health, safety and the environment in the development of voluntary consensus standards

There is not much to disagree with concerning the need to ensure openness and inclusiveness within the standards development process and to air 'stakeholders'' views - this is quite elementary. Also, the necessity of gathering empirical evidence with a scientific foundation is consistent with WTO SPS and TBT agreement provisions and with much of U.S. federal regulatory law.

However, it is uncertain what is meant by the phrase 'widely embraced by the scientific community'. The ITSSD would appreciate clarification of this phrase, specifically, whether it is intended to mean 50% or more, more than 50%, more than two-thirds, or more than three-fourths, i.e., a supermajority of the scientific community. Furthermore, ITSSD believes that the USSS should explain how empirical data that is not 'widely embraced by the scientific community' will be treated where it is nevertheless based on good science and was derived from the application of scientific methodology. Since the failure of the scientific community to embrace empirical data can arise because of outside political pressures imposed by civil society and government refusal to address 'hot' issues that have nothing to do with science, ITSSD



believes that the minority scientific view still needs to be considered. Furthermore, the USSS does not indicate which scientific community is being referred to. Is it the U.S., European or global scientific community? This phrase needs to be better defined to protect the role of science in evaluating potential public EHS risks posed by industrial activities, advanced technologies and new products.

The ITSSD also believes that before international standards are adopted at the ISO/IEC, they should be subject not only to scientific and technical justification, but also to economic cost-benefit analysis. In other words, proposed international standards should be subject to an economic efficiency test after they have met technical performance and use requirements. This will ensure that a balanced and workable approach will be taken to secure EHS protection that considers the relative costs and benefits of doing so. The USSS does not expressly mention the need for economic cost-benefit analysis, although such requirement is incorporated into many U.S. food safety and environmental statutes and within federal regulatory law. It is usually performed on economically prior to the enactment of economically significant regulations by the Office of Information and Regulatory Affairs (OIRA) at OMB, and it is expressly required by the WTO SPS and TBT agreements. A requirement that international standards be subject to an economic cost-benefit analysis thus makes sense from a consistency perspective, insofar as the development of international standards would then be compatible with both U.S. and WTO treaty law. ITSSD believes that this would make technical regulations and standards more fluid, compatible and economically efficient.

Furthermore, the USSS fails to address the need to screen stakeholders *other than* ANSI, government, industry, and standards developers, for the purpose of identifying the appropriate parties that should be permitted to participate in one or more of the various stages of the international standards development process. ITSSD believes that it is absolutely necessary to ascertain which stakeholders have genuinely important interests at stake that are also relevant/germane to a particular standards work project or technical committee or subcommittee business plan. By establishing a framework for determining relevance / germaneness, it would be possible to avoid the risk of ISO/IEC work programs being obstructed by the political grandstanding of destructive 'civil society' elements that have no rightful place in the international standards development process to begin with.

ITSSD also believes that it is necessary to better define those stages of the international standards development process which should remain open and accessible to relevant civil society stakeholders. Many environmental and social groups, for instance, lack the requisite scientific, technical, business and/or legal understanding of the issues being addressed in technical committee, subcommittee and/or work group deliberations to make a meaningful contribution. And, it is these deliberations that may later serve as the bases of future international standards proposals. ITSSD believes that in those instances where the rendering of non-expert advice in such deliberations will not materially contribute to the standards development process, and may actually impede it, participation should be denied. The USSS framework should also take into account the underlying motivations of politically active and influential civil society members that



continually seek to broaden the scope of ISO technical committee and subcommittee mandates. In this regard, the USSS should consider the public statements and activities of particular civil society groups which have expressly endeavored to alter WTO rules and to reshape U.S. and international commerce. To admit such parties into the international standards development process will serve only to threaten long-term U.S. international economic interests.

Moreover, as the USSS recommends, it is essential that the U.S., federal, state and local governments actively participate with industry on standards development committees. This will ensure that the voluntary consensus-based standards so produced are compatible with governmental EHS public policy and regulatory objectives. The issue is more than that of trust; rather, synergies, efficiencies, redundancies, industry costs and potential legal liabilities all should be considered. These are all important reasons to foster greater government and industry cooperation, domestically, as well as, internationally.

In this regard, the ITSSD agrees with the USSS statement that ANSI should foster consideration of health, safety and environmental requirements in U.S. and international standards “where appropriate.” However, the USSS fails to define the phrase “where appropriate”, and does not discuss *how* it will foster such consideration. The USSS states only that, “*standards developers* should establish specific guidance to encourage participants to consider health, safety and environment as integral aspects of their work.” The ITSSD believes that ANSI, as U.S. national representative to the ISO/IEC, should take the lead in coordinating such an effort and in providing overall substantive and procedural guidance. ITSSD believes, furthermore, that the U.S. government should also play a leading advisory role in facilitating compatibility between U.S. EHS regulatory requirements and EHS technical products standards to the extent possible. Such coordination should strengthen the U.S. government’s negotiating position in intergovernmental regulatory standards bodies and also strengthen ANSI’s negotiating position at the ISO/IEC.

Initiative #3 Improve the responsiveness of the standards system to the views and needs of consumers

It is both advisable and necessary in today’s technologically connected global marketplace to periodically conduct consumer research to identify *who* the relevant consumers are in a particular market and *what* it is, in terms of products or services that they are looking for. Were standards developers to acquire such information, they would be better able to assess the criteria that must be used to develop the standards that underlie those products and services. The ITSSD agrees with the USSS in this regard.

The ITSSD, however, believes that the USSS definition of ‘consumer’ is too narrow, as it seemingly refers only to the ‘ultimate consumer’ – “those individuals who use goods or services to satisfy their individual needs *rather than* to companies, government agencies or other organizations that use goods or services”. Ultimate consumers come in all shapes and sizes and exist in both wholesale and retail markets. By too narrowly focusing on consumers as



individuals, the USSS misses the point, especially as regards EHS issues. Both wholesale and retailer consumers may be concerned about EHS issues, but for completely different reasons and in completely different ways.

The USSS makes reference to today's consumers being "more concerned about health, safety and the environment...and more socially conscious" than in prior eras. What ANSI seems to be alluding to without expressly saying so is the phenomenon of individuals wearing two hats – a 'consumer' hat AND a 'citizen' hat. What is meant by this dichotomy, is that people may look at products and services and the standards that underlie them one way from a consumption perspective, and then look at them entirely differently from a citizenship (civic) perspective. For example, consumers may be satisfied with a product's quality, durability, technical performance, safety and reliability and impressed with the science and technology that underlies it. In the case of services, they may be satisfied by the efficiency and competency with which a service is rendered. Yet, in each of these instances, consumers qua citizens may be dissatisfied with how that product or service potentially impacts their health or the environment. This latter consideration may depend wholly on the outside information such people receive from their governments and/or from civil society organizations.

ITSSD therefore believes that it is critical that each of these two dimensions – consumer AND citizen - be monitored and evaluated and any potential overlap or separation between them identified. Indeed, alleged citizen EHS preferences may actually represent the masked demands of politically motivated and agenda-based civil society organizations. As the USSS suggests, this information may best be gathered through company and trade association market *and* societal surveys, and then incorporated by ANSI and the broader standards development community within the international standards development process.

The USSS seems to suggest that U.S. standards outreach activities should be undertaken generally by the U.S. government. The ITSSD disagrees. U.S. government involvement in promoting U.S. standards internationally may be necessary, however, where non-U.S. governments intervene in their home country marketplace to shape consumer /citizen views and expectations about products and services – i.e., where such governments function as *market-makers* rather than as merely *market-facilitators*. The ITSSD believes, in this instance, that the effect is to create disguised market access barriers to trade that favor home country products and services. There is growing evidence that this has already occurred within the EU and European member states, and it is now increasingly occurring within European trading partner nations. Under these circumstances, the U.S. government should aggressively educate foreign citizens about how U.S. EHS regulatory requirements and related product/service standards ensure the health and environmental safety (harmlessness) of U.S. product and service exports. It should focus, in other words, on explaining how U.S. standards achieve EHS performance measures that can be scientifically and technically verified.

As indicated in the previous comment section, the extent to which ANSI should invite the participation of 'consumers'/'citizens' into the international standards development process



should be limited to their ‘stake’ in a particular project and the ‘relevance/germaneness of their concerns. Furthermore, any ‘consumer’/‘citizen’ education program recommended by ANSI, its members or non-ANSI standards developers should be targeted and goal oriented, to both prevent public information overload or misinformation and to effectively utilize the limited government resources available.

Initiative #4 Actively promote the consistent worldwide application of internationally recognized principles in the development of standards

As the USSS recommends, the U.S. standards community should work closely with a broad cross-section of domestic *and* international stakeholders (subject to the conditions previously noted) in markets where the relevant products are used. ITSSD believes that it is critical for the U.S. government to continue its support of the public-private partnership that has facilitated a consensus-based standards development process within the non-governmental international standards bodies (e.g., ISO/IEC). It is also important for that partnership to continue promoting the sectoral and ‘market-based’ U.S. standards model as a compliment to the balanced and science-based U.S. regulatory model being promoted within intergovernmental regulatory bodies (e.g., Codex, OECD, etc.) at which international regulatory harmonization issues arise, and as part of U.N. environmental treaty secretariat meetings and negotiations.

The ITSSD is especially concerned about the divergent approach to standardization that has emerged within other influential WTO members namely, the member states of the EU. This approach is now being promoted at international non-governmental fora such as the ISO/IEC and then exported abroad via technical assistance programs and bilateral trade capacity building agreements to third countries. It has been based on a *cross*-sectoral and government driven (*‘top-down’*) model of standards development that defines rather than responds to market demands. Pursuant to this model, public policy objectives (i.e., ‘essential requirements’) such as the protection of environment, health and safety (EHS) often lead to process-centric criteria that are superimposed on industry-based technical performance criteria and then incorporated into standards norms.

Given European governments’ (and the EU Commission’s) tendency to link regulation with standardization, the scientific and technical performance aspects of standards have been increasingly subordinated to design and manufacturing process-specific criteria. These criteria are usually not defined by technical experts but instead by politicians and civil society members. As a result, there is less and less consideration of the underlying science or of the costs and workability of the resulting European and international standards. Furthermore, there is little, if any, consideration of the feasibility of comparable U.S. market and technology-based standards that respond to strict U.S. regulatory requirements. For these reasons, ITSSD believes that it is imperative that the U.S. government, ANSI and the broader U.S. standards community coordinate their work efforts in international fora. This will help to ensure that the internationally recognized scientific and economic principles underlying the TBT agreement and within the WTO TBT Committee’s decision are consistently interpreted and applied as intended.



Yet, more must be done than simply this. The ITSSD wishes to emphasize that, in addition to linking regulation and standardization, European standards bodies (CEN, CENELEC and ETSI) are party to the Vienna and Dresden Agreements with the ISO/IEC. These agreements permit EU standards bodies to bootstrap EU standards embedded with regional EHS preferences into the ISO/IEC. Once there, they are then proposed and adopted in lieu of U.S. standards as ISO/IEC standards, and ultimately promoted to third countries. The USSS fails to address these circumstances and their potential impact on overall U.S. international economic competitiveness.

The ITSSD agrees with the USSS recommendation that U.S. stakeholders work toward ensuring that voting procedures in foreign national, regional and international standards development bodies do not limit U.S. active participation or the consideration of U.S. views. The ITSSD has found, however, that this is not likely to be easily accomplished. CEN and CENELEC membership procedures make it difficult if not impossible for U.S. standards development organizations or even ANSI to gain a membership with actual voting rights. And, where voting rights are available as in ETSI, they are circumscribed by detailed parliamentary rules such as ‘weighted voting’ and subject matter voting restrictions that effectively dilute the voting right itself. In light of these observations, the ITSSD is concerned that the USSS fails to set forth a strategy for addressing these problems.

The ITSSD, moreover, wishes to draw the attention of ANSI and the broader U.S. standards development community to the issue of voting procedure and the need for more aggressive U.S. parliamentary tactics at the ISO/IEC. It has been alleged by ANSI members that the EU member states have been able, from time to time, to effectively vote as a bloc on particular standards proposals that favor EU regional preferences. Thus far, however, ANSI and its members have been unable to confirm whether such a pattern exists on a broad level spanning many different technical committees. The ITSSD believes that they might be more successful at identifying the existence of such a pattern if they focused on a narrower subset of standards containing an EHS (precautionary principle/sustainable development) component. Considering the primarily technical focus demanded of ISO/IEC technical committee and subcommittee participants, the ITSSD believes that ANSI and the broader U.S. standards development community would likely benefit if they could rely on the U.S. government to serve as U.S. parliamentarian/ adviser/tactician at the various ISO/IEC standards voting processes.

Initiative #5 Encourage common governmental approaches to the use of voluntary consensus standards as tools for meeting regulatory needs

The ITSSD is pleased that the USSS has acknowledged the growing linkages between government regulations and product standards. Indeed, government established regulatory policy frameworks are often transposed by national / regional standards development organizations into compatible, understandable and workable technical rules with which industry product and service providers can comply. Governments’ setting of EHS policy and regulatory norms serves as a prime example. Considering the increasingly global nature of commerce, to



the extent that EHS standards are developed to meet compatible EHS regulatory frameworks, any divergence among different national government regulatory policy objectives will likely result in a similar divergence among different nations' product and service standards. The ITSSD is concerned that this can significantly raise the costs of doing international and domestic business. As previously discussed, the ITSSD is concerned that this often creates market access barriers that severely restrict or ban foreign products and services for nonscientific reasons. While the goals of achieving international regulatory harmonization and global relevance are important, they should not override the basic principles of sound science, cost-benefit analysis, transparency and inclusiveness that ensure that national and international regulatory and standards-setting activities are workable, pragmatic and balanced.

The USSS rightly recommends that governments should be encouraged to adopt an approach that uses standards to meet regulatory needs based on the U.S. model. However this is more easily said than done. For one thing, it depends on the cooperation of the national foreign government with which the U.S. is dealing. For example, it would be easier to persuade transitional market and developing country governments (including those WTO members that wish to more fully benefit from their membership and those acceding to WTO membership) than EU member state governments to adopt the U.S. model of regulation and standardization. To this end, the USSS recommends improving the understanding among international stakeholders of the superiority of the U.S. standards model, including its ability to improve the quality of individual citizens' lives and the opportunities for national economic growth. The ITSSD believes that, while this is a worthy objective, the USSS fails to adequately identify specific deliverables that may be 'sold' to these countries.

It is clear that what the USSS is recommending will take years to accomplish. And, it will require vision and a *long-term* outlook. The ITSSD questions however, whether ANSI and the broader U.S. standards community have the patience and determination necessary to achieve this goal. The ITSSD also questions whether individual industry members have the ability to look beyond their own quarterly profits to consider the long-term costs and benefits of preserving the U.S.-based standards model, and along with it, U.S. international economic competitiveness. Furthermore, the ITSSD questions whether these constituencies can overcome 'first-mover' syndrome so that they may pool their individual interests in furtherance of a collective private *and* public good. And, ITSSD questions whether they possess the discipline and fortitude to weather the popular resistance they are likely to encounter from EU governments and a growing European-incited anti-globalization movement suspicious and critical of American industry, the U.S. market economy and the WTO. In other words, a detailed game plan is needed to implement these objectives, but the USSS has failed to articulate one.

Initiative #6 Work to prevent standards and their application from becoming technical trade barriers to U.S. products and services

The ITSSD supports any initiatives that prevent the use of standards as disguised technical barriers to trade. The USSS recommends that the U.S. government work within



*intergovernmental* bodies to encourage the recognition of all relevant U.S. standards that support U.S. regulations. It states that this will help to prevent the use of standards as trade barriers.

The ITSSD believes that such activities by themselves constitute an ambitious but unrealizable goal. There are many *intergovernmental* bodies in which the U.S. government participates. They include the Codex Alimentarius Commission (Codex), the Organization of International Epizootics (OIE), the International Plant Protection Convention (IPPC), the Organization of Economic Cooperation and Development (OECD) and its Global Harmonization System (GHS) and SIDs programs, the United Nations (UN) and its many agencies and programs. Within the UN, for example, there is the UN Environment Program (UNEP), which oversees the UN multilateral environmental treaty secretariats and the Strategic Approach to International Chemicals Management program (SAICM). And, there is the UN Commission on Sustainable Development, the UN Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the joint UN International Program on Chemical Safety (IPCS). Each of these agencies and programs focus, to various degrees, on developing EHS regulatory standards norms which are then transposed into understandable technical product or service standards at the ISO/IEC.

What is not widely known, however, is that these intergovernmental organizations, along with regional governmental bodies, actively serve as liaison organizations to the ISO/IEC, which is a non-treaty *non-governmental* organization. In such capacity, they apparently advise and influence the work of many ISO/IEC technical committees, subcommittees and work groups responsible for developing international standards. Since these liaison organizations include the European Commission and many United Nations agencies and programs, it is not surprising that a growing number of ISO/IEC standards reflect EU regulatory and UN ‘soft’ law norms. The ITSSD is very concerned about the extent to which these organizations have successfully injected precautionary principle/sustainable development goals and initiatives within the business plans of ISO/IEC technical committees. Indeed, a review of the business plans of a number of ISO technical committees will reveal many references to specific regional EU standards and regulations, the precautionary principle and sustainable development doctrines and specific UN programs and agencies. Even the UN’s FAO and Codex Alimentarius Commission, the WHO and the OECD in which the U.S. government participates serve as liaison organizations to the ISO/IEC.

Oliver Smoot, current President of ISO and past chairman of ANSI, claimed in a recent December 2004 presentation that it is within ISO’s 184 technical committees “where it all happens” at the ISO/IEC. If this is true, the ITSSD believes that it is incumbent upon ANSI, as U.S. national representative to the ISO/IEC, to keep the relevant U.S. government agencies informed about activities engaged in by foreign governmental (e.g., the EU Commission) and intergovernmental liaisons (e.g., the United Nations) that threaten U.S. international economic interests. Similarly, individual U.S. government agencies should be interested in participating in ISO/IEC activities. The ITSSD believes that U.S. government agencies with interests in particular ISO technical committee and subcommittee work projects must coordinate and





cooperate amongst themselves, with ANSI and with the broader U.S. standards development community participating at the ISO/IEC. To this end, the ITSSD believes that the U.S. government should register its agencies immediately as liaison organizations within the ISO/IEC so that they may monitor how the activities of other governments and intergovernmental bodies impact the ISO standards development process.

Lastly, the USSS correctly recognizes that the U.S. government and industry must work together closely in order to prevent the adoption, use and implementation of technical standards as disguised barriers to trade. The ITSSD believes, however, that this will most likely necessitate that the USTR commence WTO dispute settlement negotiations against the European Union to clarify the meaning of disputed WTO EHS language. At the outset, such negotiations would focus on the enforcement of various TBT provisions, including its Code of Good Standards Practice. These provisions collectively hold WTO member state governments responsible for the standards development, adoption and implementation activities of recognized standards bodies operating within their sovereign borders, to the extent those activities result in or have the effect of creating barriers to trade. These TBT agreement provisions do not require the USTR to prove that another WTO member government was directly and intentionally involved in facilitating, supporting or encouraging any of those activities. According to prior GATT case law, indirect government involvement will suffice, as well as government failure to act with knowledge that such activities are taking place. The ITSSD recommends that ANSI and the broader U.S. standards community seriously consider assisting the USTR in these endeavors. The ITSSD believes that such assistance were rendered it would improve ANSI's chances of securing additional future funding.

Initiative #7 Strengthening international outreach programs to promote understanding of how voluntary consensus-based, market-driven, sectoral standards can benefit businesses, consumers and society as a whole

It seems that the type of initiatives being recommended to help stakeholders in developing countries to understand the U.S. standards development process and its many benefits involve primarily educational outreach programs and workshops. While this may serve as a good first step to introduce the U.S. standards model to foreign standards development organizations, much more is required. The USSS suggests that private and public resources be devoted to the promotion of such policies and procedures generally, but fails to make any *specific* recommendations or to identify any particular *deliverables*.

One important deliverable that the USSS did not mention is the provision of technical assistance. The ITSSD did not find any discussion within this USSS concerning how ANSI, the broader U.S. standards development community and U.S. industry could work collaboratively with the U.S. government to provide technical assistance to key emerging developing country markets. Any obvious goal of any such activity would be the establishment of a national standardization system that mirrors or is compatible with the U.S. standards model. The ITSSD believes that such technical assistance could be provided as part of U.S. government (USTR/USAID) trade



capacity building efforts that precede or are incident to a Trade and Investment Framework Agreement (TIFA) or a more formal Free Trade Agreement (FTA) being entered into with a particular developing country.

The ITSSD has observed how the European Commission has skillfully utilized this method to export its precautionary principle/sustainable development regulatory and standards norms to developing countries. The ITSSD therefore believes that it would provide a similar opportunity for the U.S. to export its science and economics-based standards abroad as part of an overall effort to help developing countries establish an U.S.-compatible market relevant national regulatory system. It would also enable the U.S. to secure new foreign markets for U.S. exports and to establish reliable manufacturing, assembly and/or distribution platforms for eventual U.S. imports. Furthermore, it would serve as a defensive measure to counter EU efforts to export precautionary principle/sustainable development-based EHS regulations and standards to a particular developing country. Unfortunately, the USSS fails to identify which developing countries would be good candidates for educational outreach efforts or for more involved trade capacity building initiatives.

The ITSSD believes that ANSI is well aware that ISO is now in the business of training developing country standards bodies how to implement ISO standards. The USSS proposal seems to borrow somewhat from the ISO Action Plan for Developing Countries 2005-2010, which emphasizes the need to educate developing country standards bodies about the importance of international standards and the need to provide them with technology and information tools to do so. The stated goal is to increase their participation in the ISO standards development process. However, since the focus of the Developing Country Policy Development Committee (DEVCO) program is on ISO rather than U.S. standards, it emphasizes EHS-centric *sustainable development* objectives that incorporate the precautionary principle rather than purely technical performance, technological development and economic growth objectives. It also focuses on the need to render technical assistance or capacity-building services to assist such countries in implementing such standards. The ITSSD questions why the USSS fails to make any mention of how the DEVCO program may potentially threaten the primacy of U.S. standards and U.S. industrial competitiveness. The ITSSD also questions why the USSS does not seek specific funding from the U.S. government to address this potential threat.

The ITSSD agrees that ANSI should play a significant role in promoting dialogue with developing country standards organizations for purposes of promoting U.S. standards. The ITSSD believes, however, that ANSI must coordinate its efforts with U.S. government activities at the regulatory level. In other words, the transfer of U.S. standards to developing countries should, where possible, be part of a bilateral or regional U.S. government technical assistance and/or trade capacity building program, the goal of which is also to establish in particular countries an U.S. compatible national regulatory *and* standardization system.

Initiative #11 Maintain stable funding models for the U.S. standardization system

The ITSSD agrees that the U.S. government should provide additional funding to ensure that ANSI and the broader U.S. standards development community can vigorously participate in the international standards development process at the ISO/IEC. The ITSSD also agrees that the U.S. government should promote policies internationally that protect the intellectual property rights (e.g., copyrights and trademarks) of U.S. standards developers that are embedded within U.S. standards adopted either at the ISO/IEC or by developing country national governments.

### Section #2:

This section is devoted to commenting about those aspects of international standardization that the USSS does not address.

#### Comment #1 A Focus on Terminology Alone Will Not Effectively Counter EU Efforts to Reinterpret the General Principles Underlying International Standards Development

The USSS touches upon the fundamental differences between the competing U.S. and European models of standardization (i.e., ‘bottom-up’ vs. ‘top-down’), and for the need for more educational outreach to ensure that the U.S. standards model predominates internationally. It also touches upon the need to promote greater public-private coordination between the U.S. governmental agencies, and ANSI and the broader U.S. standards community.

The ITSSD also believes in the need to better coordinate the activities of governmental agencies participating within intergovernmental bodies that develop international EHS regulatory standards and the activities of ANSI and the broader U.S. standards community that participate within the non-governmental ISO/IEC, where related international technical product and services standards are developed. The ITSSD is concerned, however, that the USSS does not offer specific, concrete proposals, strategies or initiatives for achieving these goals. Rather, the USSS primarily emphasizes adherence to terminology, i.e., internationally recognized principles for standards development, and the historical superiority of U.S. ‘market-based’ and ‘globally relevant’ standards. By doing so, the ITSSD believes that the USSS overlooks and underestimates Europe’s skillful reinterpretation of these terms, and its ability to embed and implement their reinterpretations within other countries’ regulatory and standards systems. In the opinion of the ITSSD, a purely legalistic focus on terminology and historical education alone, without more, will not likely preserve the predominant role that U.S. standards have served in the global marketplace since the end of World War II.

By linking regulation with standardization and acting as a ‘market-maker’ rather than as a ‘market-facilitator’ of consumer and industry preferences and expectations, European governments are effectively redefining through practice what is market relevant for national, regional and international regulation and standardization purposes. Ever since the completion of the Uruguay Rounds and the entering into force of the WTO agreements in 1995, Europe has designed and promulgated sustainable development/precautionary principle-based EHS



regulations and product/ process standards at the European regional and international levels. And, via the Vienna and Dresden Agreements previously discussed, European regional EHS product and service standards have been quietly projected into the ISO/IEC without the knowledge of ANSI or the broader U.S. standards development community. It is only after the standards have been circulated among the ISO/IEC's technical committees and subcommittees and formally proposed that U.S. national standards representatives first become aware. The ITSSD believes that ANSI and the broader U.S. standards development community can no longer afford to be outside of the loop. Indeed, ANSI's failure to remain abreast of evolving international trends can no longer be tolerated since it places the U.S. at a significant competitive disadvantage.

As previously discussed, during the past several years, efforts have been launched at several intergovernmental bodies (e.g., the Codex and the OECD) and at the ISO/IEC non-governmental standards bodies to assist developing countries. Such programs seek to make the international regulatory and standards development processes more accessible to developing countries, and to make it easier for developing countries to adopt and implement at a national level international regulations and standards. The USSS appears to rely primarily upon the promotion of educational outreach programs that extol the virtues of the U.S. standards model to developing countries to prevent the diffusion of EU precautionary principle/sustainable development-based standards pursuant to these programs. The ITSSD questions whether such an approach, without more, could be effective.

Comment #2 The Expansion of the Scope of ISO/IEC Work to Include Non-Technical Standards – The Mischief Underlying ISO's New Corporate Social Responsibility Standards Program

During July-August 2004, the ISO Committee on Consumer Policy (COPOLCO), which includes the IEC, announced that the ISO would undertake its first effort to develop non-technical standards. These standards would focus on establishing ostensibly voluntary corporate social responsibility (CSR) 'soft' law norms that could supplement, extend the scope of, or replace existing laws. The ITSSD believes that such standards could ultimately serve as the basis for national CSR legislation in different countries. The ITSSD has observed how CSR standards initiatives have been utilized within the EU region to 'black label' companies that do not comply with EU notions of sustainable development and precaution or if they simply fail to subject themselves to third party stakeholder audits and inspections - public accountability. The ISO CSR standards project would appear to duplicate already existing model CSR standards previously developed at the OECD.

The ITSSD believes that it is clear that the EU had long considered adopting its own regional CSR legislation following the release of its Green Paper on this subject. EU CSR standards already exist, despite the similar but less rigorous OECD CSR standards. However rather than enact regional EU CSR legislation, the EU Commission and European civil society have opted to promote their CSR model through the ISO/IEC in order to broaden the potential users of their

more rigorous standards beyond the EU region. This should be of serious concern to ANSI, the broader U.S. standards development community and to U.S. industry in general. The notion of CSR that will likely be promoted at the ISO/IEC will be compatible with that now being promoted at the UN, which incorporates precautionary principle/sustainable development EHS concerns. There is already evidence that CSR initiatives currently being promoted by the UN Global Compact Office and enforced by global stakeholders (civil society) have already negatively impacted the brand reputations and stock values of certain non-compliant companies. When displeased, civil society actors have embarked upon negative social labeling campaigns that adjudge companies socially irresponsible if they fail to adhere to broadly defined UN social and political norms, including the precautionary principle and sustainable development. These CSR initiatives have already adversely impacted U.S. companies operating along the global supply chains. ANSI and the U.S. standards development community should do all within their power to shape these standards so that they do not threaten the U.S. enterprise system.

Comment #3 ANSI and the Broader U.S. Standards Development Community Need to Focus on Agricultural Standardization at the ISO/IEC

The ITSSD has observed that the USSS fails to make any reference of the need to monitor agricultural standards activities at the ISO/IEC. This result obtains, even though as U.S. national representative, ANSI has the obligation to remain abreast of these issues and to immediately communicate them to the U.S. government. This is a significant omission.

The ITSSD has observed that the EU Commission has vigorously participated in various *intergovernmental* bodies for the purpose of developing international regulatory standards that ensure food safety, plant and plant product safety, and animal and human health - e.g., to prevent against animal borne food diseases. Such bodies include the Codex Alimentarius Commission ('Codex'), the International Plant Protection Convention ('IPPC'), and the International Organization of Epizootics ('OIE'), each of which is expressly referenced within the WTO's Sanitary and Phytosanitary (SPS) Agreement. Unbeknownst to ANSI or the broader U.S. standards development community, however, EU standards bodies participating at the ISO/IEC have been increasingly advised by the EU Commission to engage in technical committee and subcommittee work involving biotech and food and plant safety issues.

The ITSSD believes that the EU Commission has also stepped up its efforts to establish its regional precautionary principle/sustainable-based SPS standards as ISO standards and to assist developing countries in adopting them. This poses a real risk that the EU's SPS ISO activities could undermine the U.S. negotiating position at the Codex, the IPPC and the OIE. Examples of potentially conflicting EU ISO activities include: 1) ISO/TC34/WG9 N.4 – "*Traceability Systems in the Agricultural Food Chain – General Principles for Design and Development*"; 2) ISO/TC/34 N.1107 - "*Food Safety Management Systems – Requirements*"; and 3) ISO/TC/34/WG7 – Proposed standard on "*Genetically Modified Organisms and Derived Products*".

In addition to the threat discussed above, the ITSSD believes that the EU is utilizing the international standards development process also as a means of exporting precautionary principle/sustainable development-based product standards to developing countries, which will then use them as non-tariff trade barriers against U.S. agricultural exports. One need only recall the negative response given by certain sub-Saharan African governments to U.S. genetically modified food aid to see this policy in action. More disturbing yet, these activities seem to compliment efforts now being undertaken at the UN FAO and WHO to administer Codex training packages. Such packages have been developed for the purpose of helping poor countries satisfy Codex food safety standards.

One package provides information about the Codex process and guidance on how to establish effective national Codex programs. Its overall aim is to enhance developing country participation in the Codex process through improvement of national food control systems, thereby allowing them to define their countries' positions and policies on issues debated in Codex. A second package assists developing countries to assess their food safety capacity building needs, and aid food safety regulators and 'others' to introduce 'risk analysis' in all their food safety related activities. The ITSSD is concerned that these packages are intended to link EU-style precautionary principle/sustainable development food safety regulatory standards with more technically oriented ISO food product safety standards.

#### Comment #4 Greater U.S. Government Participation at the ISO/IEC is Necessary

The USSS strongly recommends that there should be greater U.S. government participation in the national and international standards development processes. The ITSSD has observed that there is currently little or no direct U.S. government participation at the ISO/IEC. The ITSSD questions whether the government's prior lack of information about and involvement in that body was due to government's or ANSI's failure. The ITSSD also questions the nature and degree of government participation that ANSI and the broader U.S. standards development community are now seeking. Is it merely pecuniary in nature? Or, is it advisory or strategic in nature? Would ANSI and the SDO community truly be comfortable with greater and more active U.S. government involvement at the ISO/IEC?

It bears repeating that, based on increasing European government activity in the areas of international regulation and standardization, the need for U.S. government involvement at the ISO/IEC is now inescapable, from both a financial and strategic perspective. The ITSSD believes that ANSI and its membership are facing greater standardization challenges from the EU than they alone can handle. ANSI and the SDO community had not even been aware of these issues or Europe's external standards strategy until after they had been presented with a detailed analysis of them approximately two years ago by this author.

As the sole U.S. national representative at the ISO/IEC, ANSI, a private non-profit organization, was granted a virtual monopoly by the U.S. government to protect U.S. interests in the field of international standardization and to project abroad the bedrock values and principles underlying



the U.S. standardization system. Incident to this delegation of authority, ANSI had also assumed the responsibility to remain abreast of evolving issues that could impact the field of international standardization and related U.S. interests, and to communicate to the U.S. government any known or potential threats posed by foreign sources thereto. Judging from the limited strategy articulated within this USSS, the ITSSD is truly concerned that ANSI and its membership do not fully appreciate the gravity of the threat posed by the EU to U.S. international economic interests. The ITSSD believes that, if the EU and its member states are successful in incorporating precautionary principle/sustainable development norms within ISO/IEC standards and then facilitating their adoption and implementation by developing country governments via ISO/IEC technical assistance programs, they could effectively displace U.S. global dominance in the field of international standardization. This, in turn, would pose an even more serious challenge to the long-term economic competitiveness of U.S. industries operating at the many levels of the global supply chains.

Conclusion:

The USSS represents a first attempt to articulate a comprehensive plan that addresses a growing number of challenges posed to the global dominance of U.S. standards and to U.S. global economic competitiveness in general. As currently drafted, however, the ITSSD believes that the USSS falls short of achieving this goal, and therefore, should be extensively revised.

Thank you once again for the opportunity to submit comments in response to the draft of the newly revised U.S. Standards Strategy. We hope that our comments will be seriously considered and look forward to receiving your organization's thoughtful response to them.

Very truly yours,

Lawrence A. Kogan, Esq.

Chief Executive Officer