

HARMONIZATION 2004 GUIDEBOOK

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GLOBAL STANDARD-SETTING IN  
INTERNATIONAL TRADE



## *Public Citizen's Global Trade Watch*

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Public Citizen is a non-profit membership organization in Washington, D.C., dedicated to advancing consumer rights through lobbying, litigation, research, publications and information services. Since its founding by Ralph Nader in 1971, Public Citizen has fought for consumer rights in the marketplace, for safe and secure health care, for fair trade, for clean and safe energy sources, and for corporate and government accountability. Visit our web page at <http://www.citizen.org>.

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## GUIDE TO COMMONLY USED ACRONYMS

ANEC	European Association for the Co-ordination of Consumer Representation in Standardisation
ANSI	American National Standards Institute
APHIS	Animal and Plant Health Inspection Service
ARAC	Aviation Rulemaking Advisory Committee
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CHIC	Cosmetic Harmonization and International Cooperation
CI	Consumers International
CODEX	Codex Alimentarius Commission
COPOLCO	Committee on Consumer Policy, International Organization for Standardization
DOE	Department of Energy
DOL	Department of Labor
EPA	Environmental Protection Agency
ETSI	European Telecommunication Standards Institute
FAA	Federal Aviation Administration
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FSC	Forest Stewardship Council
FSIS	Food Safety and Inspection Service
GHS	Globally Harmonized System for Chemical Classification and Labeling
GHTF	Global Harmonization Task Force for Medical Devices
IAEA	International Atomic Energy Agency
ICH	International Conference on Harmonization
IEC	International Electrotechnical Commission
ILO	International Labor Organization
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
ITU	International Telecommunication Union
JAA	Joint Aviation Administration
NAFTA	North American Free Trade Agreement
NGO	Nongovernmental organization
NHTSA	National Highway Traffic Safety Administration
NIST	National Institute of Standards and Technology
NRC	Nuclear Regulatory Commission

OECD	Organization for Economic Cooperation and Development
OIE	International Organization for Epizootics
OSHA	Occupational Safety and Health Administration
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TWG	Technical Working Group
UN	United Nations
UNECE	United Nations Economic Commission for Europe
UN ECOSOC	United Nations Educational, Scientific and Cultural Organization
USDA	United States Department of Agriculture
JAA	Joint Aviation Authorities
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products
WTO	World Trade Organization
WTO SPS	World Trade Organization Agreement on Sanitary and Phytosanitary
WTO TBT	World Trade Organization Agreement on Technical Barriers to Trade
WP.29	Working Party 29, World Forum for Harmonization of Vehicle Regulations
WIPO	World Intellectual Property Organization
WHO	World Health Organization

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## I. INTRODUCTION

This booklet is intended to assist citizens, policymakers, researchers, press and other interested parties in discovering where and how key regulatory policies are being shaped in the era of NAFTA and WTO. Both pacts require that domestic regulations governing products be “harmonized” (or made the same) on a global basis. These harmonized standards are then given a special new status under the pacts – as the world’s presumptively trade-legal standards. Other conflicting standards held by national governments can be challenged as “barriers to trade” in the powerful dispute resolution bodies accompanying these global trade agreements. Harmonization negotiations are taking place with regard to a myriad of issues of public interest – such as those governing food safety, pharmaceuticals, medical devices, chemicals, auto safety, aviation safety, consumer products, as well as animal and plant disease – in a variety of global institutions. Many of the results of these distant, often closed-door processes will affect the daily lives of citizens around the world, yet citizens are rarely consulted with regard to these negotiations. As there are dozens of multinational harmonization institutions and groupings, and perhaps hundreds more international industry groupings all developing harmonized standards, we are not able to cover all such bodies in this document. Instead, we have focused on significant harmonization institutions of broad public interest. This booklet is intended as initial survey of these institutions and their procedures which will initiate awareness in the most prominent harmonization venues for U.S. consumers and other interested parties. Much more research is necessary to fully understand the extent to which international harmonization is impacting U.S. law and regulation and to identify the venues where harmonization negotiations are occurring and what can be done to ensure open, accountable standard-setting and balanced stakeholder input is both required and maintained in the era of globalization.

### **NAFTA and WTO’s Harmonization Mandates**

New international trade and investment rules of unprecedented scope and power, coupled with massive changes in business practices and organization over the past several decades, have resulted in an astonishing transformation in the substance of and processes for developing economic and social policy around the world. This new arrangement is often labeled “economic globalization.” However, in addition to its economic consequences, globalization has a major effect on domestic governance, and thus on public health, economic development, and social and environmental policy. These implications are not well understood by policymakers, the media, academics, advocacy groups or the public at large.

For the past six years, Public Citizen’s Harmonization Project has worked to inform and engage potentially interested parties in an analysis of the impacts globalization can have on some of our most treasured public interest policies and the way in which they are developed. We have focused attention on the mechanisms of this interaction, specifically the way in which international harmonization of regulatory standards has the potential to undermine policies and standards set domestically that provide better consumer, environmental or other public interest protections than global norms.

Two major trade pacts intensified and politically and legally formalized the move toward globalization: the North American Free Trade Agreement (NAFTA), passed by Congress in 1993, and the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), passed in 1994. The GATT Uruguay Round established the World Trade Organization (WTO), a powerful new global commerce agency designed to enforce the expansive policies set forth in the Uruguay Round’s 17 major agreements.

Both pacts contain numerous provisions that go far beyond the usual purview of trade agreements, which traditionally focused on tariffs and quotas. NAFTA and key WTO agreements establish comprehensive and binding international rules constraining the domestic policy objectives member countries may pursue, and what policy tools member countries may use to obtain even the allowed objectives. Unlike prior trade agreements, NAFTA and the WTO agreements constrain the options that member governments may utilize when setting their domestic public health, food safety, consumer, worker and environmental policies – even when such policies treat domestic and

foreign goods, producers, services or investors the same. Under NAFTA and WTO, non-discriminatory regulations may still violate the constraints on regulatory action the pacts establish.

Together, NAFTA and the WTO constitute permanent institutional structures which serve as engines driving corporate economic globalization. Both NAFTA and the WTO are based on certain underlying premises, among them: domestic health, safety, and environmental policies must be designed in the "least trade restrictive" manner and national laws and standards should be homogenized internationally so as to maximize economic efficiency in cross-border trade. This process of global standardization has been dubbed "harmonization" by industry proponents.

For instance, Article 3 of the WTO's Sanitary and Phytosanitary Agreement, which sets criteria that WTO nations must follow regarding policies designed to protect human, animal or plant life or health from pests, diseases and toxins in food, beverages or animal feed, requires WTO member nations to "to harmonize sanitary and phytosanitary measures on as wide a basis as possible, members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist." The WTO's Technical Barrier to Trade Agreement, which sets parameters for the production, packaging and labeling of non-food products, states "where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations." The NAFTA text contains similar provisions.

NAFTA and the WTO permit countries to have food safety measures that achieve a higher level of consumer, environmental or health protection than relevant international standards only in limited circumstances. Indeed, the WTO's TBT Agreement states that the only allowable exception to the requirement that countries use international standards is if it would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued. Similar harmonization requirements are planned for the NAFTA-expansion to 31 governments of the hemisphere called the Free Trade Area of the Americas and for a new WTO negotiation covering the delivery of public and private services.

The potential problems related to the establishment of such internationally-harmonized rules in the food safety area or any other area of public health, consumer or worker safety, or environmental protection are multi-fold. Theoretically, international harmonization could occur at the lowest or highest levels of health, safety or environmental protection or somewhere in between. Unfortunately, the actual provisions in NAFTA and the WTO requiring harmonization, or providing incentives for harmonization, are likely to result in the lowering of the best existing domestic public health, social, economic justice, natural resource conservation and environmental standards around the world.

This is the case because, under NAFTA and the WTO, international standards serve as a ceiling which countries cannot exceed, rather than as a floor that all countries must meet. The agreements provide for the challenge of any domestic standards that go beyond international standards in providing greater citizen safeguards, but contain no provisions for challenging standards that fall below the named international standard. Thus, the provisions in NAFTA and the WTO promoting harmonization are likely to serve only as a one-way downward ratchet on the most progressive domestic standards. Challenges to domestic standards that exceed international standards are resolved in the binding dispute resolution system built into these agreements, which is closed to public participation or observation, and which can result in millions of dollars in punitive trade sanctions against the losing country. This is the "race to the bottom" that is built into WTO and NAFTA rules.

Traditionally, regulations have been defined as mandatory policy developed by governments, and standards as voluntary, "consensus-based," industry "guidelines" developed in a diversity of quasi-governmental, or even private-sector, standard-setting institutions. This distinction is blurred, however, by a number of new realities. One is that NAFTA and the WTO oblige member governments to base their regulations on harmonized international standards and on international standard-setting techniques. Moreover, as explained above, these international

standards become the presumptively “trade-legal” standards and the point of reference in any trade-related dispute. Thus, internationally harmonized standards and guidelines are given a whole new weight and meaning in international law.<sup>1</sup>

The second reality is that many nations such as the United States are requiring federal agencies to use international standards in lieu of binding regulations whenever possible. In addition, more and more nations, especially those in the developing world, are now adopting international standards wholesale as binding regulation, further blurring the distinction between voluntary standards and mandatory regulation. Thus, international standards are given a whole new weight and meaning in domestic law as well. Regulators, consumer groups and other concerned parties, ignore the development of international standards at their peril. The legitimacy of standards developed in these institutions rests on factors such as democracy, transparency, and balanced stakeholder participation in their initial stages of development as well as upon their adoption by nations.

NAFTA and the WTO set minimalist guidelines on what international standard-setting bodies or standards are presumed to be NAFTA or WTO compliant. The WTO SPS and TBT agreements specifically defer to the food safety standards of the Codex Alimentarius Commission (Codex) in Rome, the animal health standards of the International Organization for Epizootics (OIE) in Paris, the plant protection standards of the International Plant Protection Convention (IPPC) and the product standards of the International Organization for Standardization (ISO) in Geneva. However, the agreements also state that the standards of any other international institution may also apply as long as the institutions are open to participation by representatives of WTO member countries. While not all of the harmonization institutions reviewed in this brochure are currently open to full membership for representatives of all WTO nations, they are the preeminent global institutions of their kind. As such, it is unlikely that their recommendations will be ignored by a WTO dispute resolution panel. Moreover, nonmember nations often have observer status at these institutions and it is possible – even likely – that at some future date, these institutions may expand their membership to incorporate more WTO member nations. The WTO and NAFTA also contain language encouraging nations to participate in the activities of these international institutions.

The WTO SPS and TBT agreements also require member nations to officially notify the WTO whenever they develop standards that differ from international standards. WTO member nations must notify the WTO in advance and give WTO member countries a chance to comment within 60 days. Each WTO member nation maintains an “Enquiry Point” where other members can submit comments and ask for further information about laws, regulations and standards on the books or under development. In the United States, the Enquiry Point for WTO and NAFTA SPS measures is the Food Safety and Technical Service Division of the Food and Agriculture Service of the U.S. Department of Agriculture. For WTO and NAFTA TBT measures, the U.S. Enquiry Point is the National Center for Standards and Certification Information at the National Institute for Standards and Technology (NIST) which is part of the U.S. Department of Commerce. Many thousands of communiqués pass through these Enquiry Points on an annual basis.

## **U.S. Implementation of Harmonization Requirements**

When NAFTA’s implementing legislation and the Uruguay Round Agreements Act passed Congress in the early 1990s, the text of the agreements became binding federal law. In addition, the agreements’ lengthy implementing legislation rewrote huge swaths of U.S. domestic law and policy in one fell swoop in order to tailor it to the WTO and NAFTA requirements. The agreements were brought before Congress under the extraordinary

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<sup>1</sup> It is also notable that the terms technical regulation and standard are often used interchangeably by practitioners and are often conflated in the trade term “measure”. The WTO’s SPS Agreement, for instance, defines “measures” extremely broadly to include, “all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments...; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.”

requirements of the "Fast Track" trade voting procedure, which is a unique delegation of Congressional power and prerogatives regarding trade policy used only eight times in the history of the U.S. Congress. Under Fast Track rules, all normal democratic procedures are suspended. The normal hearings and 'mark ups' given to legislation in Congressional Committees are eliminated. Congress is only allowed limited time to read, debate and vote on lengthy trade agreements and their implementing bills written by the Executive Branch. No amendments are allowed to Fast-Track trade bills, meaning even the members of Congress who notice and understand the arcane details, such as the harmonization requirements, have no ability to fix the provisions that trouble them.

Many in Congress, the press and the public remain unaware that U.S. agency officials are currently engaged in innumerable harmonization negotiations around the world in an ever-increasing number of venues -- , some governmental, some private, some industry-government partnerships. U.S. agency officials are actively involved in the standard setting of the private-sector ISO as well as the UN-based Codex. Both the ISO, which sets global product standards, and Codex, which sets global food standards, are dominated by industry. Citizen input into these organizations is essentially non-existent, and significant participation by health or consumer groups is extremely limited. For instance, one part-time staffer at Consumers International currently attempts to cover a handful of the ISO's 2850 working groups, and only three U.S. consumer groups have been able to attain status to lobby within the Codex, which has 24 committees meeting all over the world on a regular basis.

When U.S. regulatory agencies develop regulations, standards, or guidance documents domestically, they are required do so in an open and participatory fashion. Citizen input into the policy generally is assured by an array of U.S. open-government laws including: the Administrative Procedure Act (APA), requiring public notice of any proposed regulation in the Federal Register (the official daily publication for rules, proposed rules, and notices of Federal agencies) and opportunity for public comment on proposed regulations or regulatory changes; the Freedom of Information Act (FOIA), permitting citizen access to the records of government agencies; the Government in the Sunshine Act, ensuring that important agency meetings are publicly announced; and the Federal Advisory Committee Act (FACA), requiring balanced representation on government advisory committees. Compliance with the U.S. standards by producers is secured through the monitoring and enforcement mechanisms of U.S. law.

In sharp contrast to this consultative, democratic process, internationally harmonized standards are negotiated overseas in closed-door, industry-dominated institutions. After years of negotiation, a final standard emerges which is often adopted by U.S. federal agencies. While these agencies may utilize the public notice and comment procedure laid out in U.S. law, at that point, all the details have been worked out, the deals have been cut and the agencies' ability or willingness to make any significant changes to the standard is significantly limited. Instead of consulting the American public as a first step in policymaking, the public is often consulted at the very end of the road after all the decisions have been made, and interested parties in the U.S. have little or no ability to secure changes in the text.

The WTO and NAFTA trade harmonization mandate has been taken up with enthusiasm by many U.S. agencies. For example, the U.S. Food and Drug Administration (FDA) has a harmonization policy which calls for prioritizing internationally harmonized standards over domestic standards. (See, 60 Fed. Reg. 53077, Oct. 11, 1995). FDA officials participate in a number of harmonization bodies described in this booklet including the Codex (food safety standards), International Conference on Harmonization (new drug products), the Global Harmonization Task Force (medical devices), and Cosmetics Harmonization and International Cooperation (cosmetics). USDA has also been an active participant in the international food standard setting at the Codex, and in that capacity has repeatedly agreed to the setting of international standards that are weaker than U.S. standards, opening the door to trade challenges against U.S. measures. The U.S. Animal and Plant Health Inspection Service (APHIS) participates in the activities of Geneva-based Office of International Epizootics and the International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Products (VICH), which harmonize standards relating to animal diseases and veterinary drugs. APHIS also participates in the International Plant Protection Convention which develops standards for handling plant diseases and invasive species. Moreover, all U.S. agencies are impacted by a White House Office of Management and Budget policy which requires agencies to rely on international standards and

report on why they are not using them. (See, 1998 OMB Circular A-119).

The result of these activities is nothing less than a profound shift of regulatory decision-making away from a relatively open and accountable process under the U.S. Administrative Procedures Act to unaccountable international institutions which have few requirements guaranteeing a diversity of stake-holders, transparency in proceedings, or public participation in the standard-setting process.

Over the past decade, many parties have recognized that in order for these global standard-setting institutions to have legitimacy in the public eye, they need to overhaul their procedures to make them more democratic and transparent, and incorporate an array of stakeholders in their deliberations. Some of these institutions have responded to the calls of civil society groups to improve their performance in this area, others have not. Yet, even in an ideal world where all such institutions opened their doors to public participation and balanced stakeholder representation, it is likely that extremely few people outside of industry would be able to participate. Only industry lobbyists and technical experts are paid as part of their normal nine-to-five professions to participate in standard-setting activities and are reimbursed for their international travel. The vast majority of public interest nongovernmental organizations (NGOs), academics, citizens or other interested parties do not have these kinds of funds. This situation has led to some to question the appropriateness and legitimacy of relying on these institutions to set global policy, especially in sensitive consumer, environmental and worker-related areas, and the appropriateness of the harmonization mandates included in an ever-increasing number of trade agreements.


## II. GLOBAL RULEMAKING INSTITUTIONS

### American National Standards Institute

[www.ansi.org](http://www.ansi.org)

The American National Standards Institute (ANSI), founded in 1918, is a non-profit U.S.-based organization that administers and coordinates standardization and conformity assessment systems for the United States. ANSI itself does not develop standards, but facilitates the development of American National Standards by accrediting the procedures of over 200 industry standards developers. More than 10,000 standards have been approved by ANSI as American National Standards. ANSI promotes the use of U.S. standards internationally and encourages the adoption of international standards domestically. ANSI represents the United States in ISO and IEC and tracks international standards development in other international standard-setting bodies.


#### Hot Topics

- Medical electrical equipment
- Sterilization of health care products
- Cooking appliances 
- Performance tests for radioactivity of solid waste products

#### Membership

ANSI has six types of memberships: 1) Company Members (corporations, partnerships or other legal entities created under the laws of the United States); 2) Educational Members (domestic, non-profit institutions of higher learning); 3) Government Members (departments or agencies of the U.S. government or any state, interstate, regional authority or agency or any local or county subdivision of such entities); 4) Organization Members (non-profit scientific, technical, professional, labor, consumer, trade or other association involved in standards, certification or related activities); 5) International Members (entities engaged in the activities of an organizational, company or educational member but that are not created under the laws of the United States or any state), and; 6) Individual Members (U.S. citizens interested in the development of standards or related activities, who are not eligible for membership under any membership categories). Even if membership dues are waived for public interest participants, it is extremely difficult for them to participate in standards development due to the cost of travel and the resource demand of repeated meetings that are necessary to provide a meaningful contribution to standards development discussion. In an attempt to address this profound imbalance, ANSI developed a Consumer Interest Forum, to educate consumers regarding the activities of ANSI and to facilitate the representation of consumers in ANSI policy discussions and standardization activities. However, this group does not systematically review ANSI standards prior to their adoption. Additionally, only a handful of the 26 members represent independent consumer organizations. Others represent industry trade associations, federal government agencies, testing organizations, professional societies and retailers.

#### Governance

ANSI is headed by a Board of Directors, which has industry, government, organizational, consumer group and at-large representatives. Currently, ANSI has three board committees, six policy committees and six program oversight committees. Of particular importance is the Board of Standards Review, which consists of  ANSI members and is responsible for the approval and withdrawal of American National Standards. Also of significance is the Appeals Board, which is responsible for considering all final appeals by companies who believe that they have been or will be adversely affected by an American National Standard. ANSI members meet once during every fiscal year to discuss and vote on standards.

## Process

The development of ANSI standards begins with a project initiations notification (PINS) announcement submitted to ANSI by an accredited industry Standards Developer representing a specific industry grouping. The PINS includes a statement of need and identification of stakeholders likely to be impacted by the standard. This announcement is published for comment in the ANSI weekly publication called *Standards Action*. If the PINS is approved by the Board of Standards Review, a draft text is developed and Subject Matter Experts convened to develop the standard. After the standard is written, it is sent to companies that may be affected by the proposed standard and noticed in *Standards Action*. Comments are submitted and reviewed, and an attempt is made to incorporate them into a new draft. If the draft changes significantly, another notification in *Standards Action* may be called for. After all comments have been reviewed and ballots have been tabulated, the standard developer submits a certification statement to ANSI for final approval. ANSI's Board of Standards Review checks the material to ensure that the standard was developed in accordance with ANSI procedures. Upon approval, the standard is listed in *Standards Action* and in ANSI's Catalog of American National Standards. Affected persons, which include organizations, companies, governments, agencies and individuals, may appeal first to the standards developer then to the ANSI Board of Standards Review, then the ANSI Appeals Board.

## Transparency

ANSI standards are developed and approved largely by industry representatives. However, ANSI does solicit wider participation in standards committees and public comment on draft standards via its publication *Standards Action*. Because this process is not well known or understood by the general public, usually only industry groupings that are members of ANSI and are familiar with the standards process comment on draft standards. In addition, many draft standards must be purchased from the developer before interested parties can comment. Standards that are proposed for adoption by federal agencies as policy are sometimes given public notice and an opportunity for public comment in the official federal agency publication called the Federal Register. However, it is difficult to determine how often standards are adopted by U.S. federal agencies or if the public notice and comment requirements of the Administrative Procedures Act are being utilized by agencies in all cases. Final American standards are available for purchase via the industry standards developer and via the ANSI webpage for a fee.

## Funding

ANSI receives funding from the sale of publications, membership fees, from International Standards Programs, government grants, and conformity assessment.

## U.S. Point of Contact

American National Standards Institute, 1819 L Street, NW, Suite 600, Washington, DC 20036; Phone: (202) 293-8020; Fax: (202) 293-9287, Website: [www.ansi.org](http://www.ansi.org)

### Codex Alimentarius Commission

[www.codexalimentarius.net](http://www.codexalimentarius.net)

The Rome-based Codex Alimentarius Commission (Codex) is the primary international standard-setting organization focusing on food-related standards, including those for individual food commodities, food contaminants, food labels and pesticide residues. Two UN agencies, the Food and Agricultural Organization (FAO) and the World Health Organization (WHO) established the Codex in 1962 as a means to facilitate international trade in food by setting international commodity and food safety standards. In pursuit of this objective, the Codex has produced an international food code, known in Latin as the *Codex Alimentarius*, which provides over 200 standards by which countries are encouraged to conform as a means of facilitating international trade of food and agriculture. The Codex is formally recognized by the NAFTA and WTO Sanitary and Phytosanitary Agreement as setting the world's presumptively trade-legal food safety standards.

### Hot Topics

- Irradiated food
- Genetically modified foods
- Meat Inspection
- International food inspection systems
- Toxins in food
- Pesticide residues

### Governance

The work of the Codex is fulfilled by twenty-four committees, each responsible for a particular food commodity or area of food safety. Additionally, six Coordinating Committees assist in addressing issues peculiar to different geographic regions. The highest decision-making body of the Codex is the General Assembly, called the Codex Alimentarius Commission (CAC), which meets once every two years. The Codex Executive Committee, made up of members representing the various geographic regions, oversees Codex work between CAC meetings and wields a great deal of influence over committee and CAC decisions.

### Membership

Codex membership is open to delegations from all Member Nations and Associate Members of the FAO and WHO. There are currently 165 member countries; however, a smaller subset regularly participate in Codex activities, since developing nations generally do not have the funds to send multiple country delegations to the demanding schedule of meetings which take place around the globe. Recently, Codex has undertaken an effort to create a trust fund for developing country participation. Over the protests of consumer groups worried about increased industry influence in the Codex, the trust fund will be accepting industry donations. Member Nations appoint government employees to attend Codex meetings. In the past, these government officials have generally been food safety officials, but increasingly trade officials are being sent to represent a nation's interest in the Codex. In addition, some governments such as the U.S., Japan and Australia bring industry advisors to Codex meetings as an official part of their delegation. Non-member countries and internationally -incorporated NGOs may apply for Observer Status. NGOs and other interested individuals can sometimes participate as part of their government delegation by invitation of the government. However, U.S. government delegations are made up overwhelmingly of industry food representatives.

### Process

Codex employs an eight-step procedure for developing standards. Initially, a Member Nation or a Codex subsidiary committee (sub-committees work on a specific food issues) submits a standard to be developed and then the CAC determines whether to begin standards development. The CAC Secretariat then arranges for a subsidiary committee composed primarily of government and industry to compose a proposed Draft Standard, which, upon completion, is circulated to member countries for comment. The subsidiary committee considers the comments and then presents the text to the CAC as a Draft Standard. If the CAC adopts the standard, it is re-circulated to member countries for acceptance and then, once accepted, the standard is added to the *Codex Alimentarius*. Often, this procedure is accelerated, in which case the number of steps may be between five and eight. Decisions regarding standards throughout the process are supposed to be consensus-based; however, votes have taken place on controversial issues such as standards regarding hormone residues in meat, the topic of a successful WTO suit against the European Union by the United States.

### Transparency

The general public has no ability to participate in Codex standards development unless member governments make Codex draft documents available to their citizens for public comment in a timely fashion. In the United States, the U.S. Codex Office is housed in the Department of Agriculture. It sponsors public meetings prior to Codex committee or CAC meetings and sometimes makes draft documents available to interested parties via email and the official publication for proposed regulations, the Federal Register. However, this effort has been sporadic and inconsistent, and draft standards are rarely made available in the Federal Register in a timely fashion. All Codex standards are available free of charge on its web site. Because the Codex's 30-plus committees meet continually in

different countries, even non-profit NGOs with considerable resources cannot effectively participate. Thus, there is little public awareness of, or involvement in, Codex activities in the United States.

## Funding

The Joint FAO/WHO Food Standards Programme funds the operating expenses of the Codex.

## U.S. Point of Contact

U.S. Manager, U.S. Codex Office, Food Safety Inspection Service/USDA. Room 4861, South Building Washington, DC 20250-3700, Phone : (202) 205-7760, Fax: (202) 720-3157, E-mail: [scodex@fsis.usda.gov](mailto:scodex@fsis.usda.gov), Website: [www.fsis.gov/OA/codex](http://www.fsis.gov/OA/codex)

## Cosmetics Harmonization and International Cooperation (CHIC)

<http://www.cfsan.fda.gov/~dms/cos-toc.html>

Cosmetics Harmonization and International Cooperation (CHIC) is currently an informal international standard-setting initiative of the U.S. Food and Drug Administration (FDA) that works on developing international standards in the field of cosmetics. The FDA formed CHIC in part because it considered ISO an inappropriate venue for the harmonization of cosmetic regulations and standards. CHIC was launched in 1999 and includes cosmetics regulators from the United States, the European Union, Japan and Canada. To date, CHIC has not produced any rules of governance, procedures for standard setting or standards, and CHIC activities have been stalled over the past few years as it evaluates its scope and potential. ISO Technical Working Group 271 also works on cosmetic harmonization.

## Hot Topics

- Animal Testing
- Labeling/Nomenclature
- Sunscreen
- Alert notification for dangerous products

## Membership

Government regulatory bodies of the United States, EU, Japan and Canada are parties to CHIC. They include: U.S. FDA, Japan's Ministry of Health, Labour and Welfare (MHLW), Health Canada and Enterprise, Directorate General SANCO of the European Commission. Although CHIC has still not been formally organized, it will likely follow the ICH model and become an industry-government partnership. Already at the CHIC meetings since 1999, industry representatives have been invited but not consumer or health groups or other potentially interested parties.

## Governance

There are no specific committees and subgroups established by CHIC, but the assistance of the European Union Scientific Committee for Cosmetics and Non-Food Products (SCCNFP) is sought in certain areas, such as basic safety substantiation, labeling or allergenicity. Ad hoc committees may be formed for specific issues. Additionally, a multilateral Memorandum of Cooperation is under consideration for the purpose of promoting the cooperation and exchange of information, including non-public information, among CHIC participants. The last CHIC meeting was in 2000.

## Process

CHIC has yet to develop a process for finalizing standards. CHIC activities have focused on the exchange of data and information which allows for the comparison of various regulatory systems in a variety of countries. Some of the topics that are under discussion are: harmonizing the list of permissible color additives in cosmetics, new animal testing requirements in the EU and harmonizing the approaches to sunscreen and UV protection (sunscreens are classified as cosmetics in Europe and as more highly regulated over-the-counter drugs in the United States). In

addition, parties discussed the possible harmonization of nomenclature cosmetics including a proposal to harmonize nomenclature for botanical ingredients included in cosmetics. Europe has a harmonized nomenclature system that relies on Latin labeling of such products, while the United States relies on a "common language" system as required by U.S. law. Obviously, U.S. consumers that may have an allergy to certain botanical ingredients benefit from this common language system. To date, no final standards have been issued by CHIC.

### Transparency

As CHIC is still in its formative stages, there is very little information available to the public about planned CHIC activities. To date there has been no public notice of CHIC meetings, and only industry and governments have participated. CHIC has not finalized any standards, and there is limited information available about the organization on the internet or in the public arena.

### U.S. Point of Contact

Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3836, Phone: (202) 418-3412, Fax: (202) 208-6937, E-mail: [LKATZ@cfsan.fda.gov](mailto:LKATZ@cfsan.fda.gov), Website: <http://vm.cfsan.fda.gov/~dms/cos-intl.html>

<p><b>European Committee for Electrotechnical Standardization</b> <a href="http://www.cenelec.org">www.cenelec.org</a></p>
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The European Committee for Electrotechnical Standardization (CENELEC), located in Brussels, Belgium, was founded in 1973 as a non-profit, technical standard-setting organization comprised of European National Electrotechnical Committees. Specifically, CENELEC's work entails developing standards for product quality and safety and service quality and safety in the fields of electricity, electronics and associated technologies. CENELEC works very closely with the International Electrotechnical Commission (IEC) under an agreement known as "the Dresden Agreement" which aims to expedite the standard-setting process through synchronized planning of new work and parallel CENELEC and IEC voting concerning technical standards. CENELEC has published over 4000 standards. Although CENELEC does not accept delegations from all WTO countries, as one of the three major harmonization institutions of Europe along with the European Committee for Standardization (CEN) and the European Telecommunication Standards Institute (ETSI), it help sets a global agenda on standards within its purview.

### Hot Topics

- Safety of toys
- Personal protective equipment
- Safety of machinery
- Medical devices

### Membership

The only bodies eligible for membership in CENELEC are the 28 National Electrotechnical Committees of European nations, which are non-profit industry-sponsored organizations. CENELEC has an additional non-membership category called "Co-operating Partners" largely made up of Europe-wide industry associations, such as the European Computer Manufacturers Association. Few public interest NGOs have the resources to participate in CENELEC activities. The EU consumer group ANEC (European Association for the Coordination of Consumer Representation in Standardization) has Observer Status. As an observer, ANEC has the right to attend meetings and submit written comments regarding draft standards. However, ANEC is not permitted to vote.

## Governance

The highest governing body of CENELEC is the General Assembly, which is comprised of National Committees and makes all of the policy decisions. An Administrative Board serves as an executive board and supervises the work that takes place at CENELEC. The Technical Board establishes the Technical Committees, which prepare standards. The Secretariat in Brussels coordinates the work program.

## Process

The standards development process at CENELEC typically begins when the IEC, a CENELEC committee or a industry partner submits a request. When a draft is completed in a technical working group (largely comprised of industry technical experts), it is submitted to the National Committee for public comment (referred to as “CENELEC inquiry”). The comments are then studied by the technical body assigned to the draft and incorporated into the document or rejected. Once completed, the 28 National Committees vote on the standard. The vote usually takes three months. Countries are allowed a specific number of votes, depending upon the size of the country. For example, larger countries such as Germany, France and the UK have 10 votes, while smaller countries have one or two. In order for the standard to pass muster, a majority of the National Committee must vote in favor of the document, and at least 71% of member votes must be positive.

## Transparency

There is typically a three to six month national comment period for draft standards, for the purpose of including the public and accepting public comment. However, the success of the comment period depends upon the rules of procedure of the particular national standardization organization. Generally, the process is not very visible and attracts little public input. CENELEC standards are only available to the public for a fee.

## Funding

Approximately 70% of the CENELEC budget comes from member contributions. The remaining income comes from the sale of standards publications and other sources.

## Point of Contact

CENELEC, 35, Rue de Stassartstraat, B-1050 Brussels, Belgium, Phone: +32 2 519 68 71, Fax: + 32 2 519 69 19, E-mail: [info@cenelec.org](mailto:info@cenelec.org), Website: [www.cenelec.org](http://www.cenelec.org)

**European Committee for Standardization**  
[www.cenorm.be](http://www.cenorm.be)

The European Committee for Standardization (CEN), located in Brussels, Belgium, is a non-profit standardization body founded in 1961 and made up of the 28 European national standards bodies. It has produced a broad range of technical product standards and, more recently, service-sector and environmental standards. Its stated mission is to promote technical harmonization in Europe in conjunction with worldwide bodies such as ISO and CEN's partners in Europe. CEN has 8,474 standards and approved documents. Although CEN does not accept delegations from all WTO countries, as one of the three major harmonization institutions of Europe along with CENELEC and ETSI, it helps sets the global agenda in matters under its purview.

## Hot Topics

- data protection
- cigarette lighters
- detection and enumeration of salmonella or listeria
- detection of irradiated food
- waste management
- safety of toys

### **Membership**

CEN has three types of membership. National Members are comprised of the 28 national standards bodies of European countries, which are non-profit industry sponsored organizations. National Members elect the Secretary General, furnish secretariats of CEN technical committees and develop and vote on the ratification of European Standards. Associate Members are broad-based European organizations representing industry, consumers, environmental groups and workers. Counsellors are representatives from European industries who participate in the General Assembly and also attend the Administrative Board when policy issues are discussed. They participate in the General Assembly, the Administrative Board and the Technical Board; however, they have no voting rights. In total, there are eight Associate Members, consisting of five industry federations, one worker group, one consumer group (ANEC) and one environmental group.

### **Governance**

CEN is headed by a President and the Secretary General. It is governed by the General Assembly of its National Members in accordance with its legal statutes. The Assembly is responsible for the budget, membership and appointment of officers. The Administrative Board is the authorized agent of the Assembly for the direction of CEN's operations. It prepares the annual budget and membership applications. The Administrative Board is advised by two committees – the Consultative Committee for External Policy and the Consultative Committee for Financial Affairs. The Technical Board, made up of National Members, is responsible for the development of technical policies and for the overall management of technical activities. Therefore, it monitors the progress of standards work, examines proposals for new projects and erects and disbands new technical committees.

### **Process**

Standards are prepared in a technical working group comprised largely of industry technical experts at the request of industry or the European Commission or upon submission of a proposal from one of its members. The formal adoption of European Standards is decided by a majority vote of all CEN National Members. Electronic voting is commonly used with a two month voting period.

### **Transparency**

There is typically a three to six month national comment period for draft standards, which is for the purpose of including the public and accepting public comment. However, the success of the comment period depends upon the rules of procedure of the particular national standardization organization. Generally the process is not very visible and attracts little public input. CEN standards are available to CEN members and affiliates. A catalogue of standards is available on the CEN website – however, members of the public must purchase the actual standards from CEN national members.

### **Funding**

Funding for the CEN annual budget comes from the European Commission, membership fees, contracts and sale of standards by CEN national members.

### **Point of Contact**

CEN Infodesk, 36 rue de Stassart, B-1050 Brussels, Belgium, Phone: +32 2 519 68 71, Fax: +32 2 550 08 19, E-mail: [infodesk@cenorm.be](mailto:infodesk@cenorm.be), Website: [www.cenorm.be](http://www.cenorm.be)

## European Telecommunication Standards Institute

[www.etsi.org](http://www.etsi.org)

The European Telecommunication Standards Institute (ETSI), located in Sophia Antipolis, France, is a non-profit, private-sector organization founded in 1988 that develops standards for telecommunication, broadcasting and information technology. This encompasses all electrotechnologies including electronics, magnetics and electromagnetics, electroacoustics, multimedia, telecommunication, and energy production and distribution, as well as associated general disciplines such as terminology and symbols, electromagnetic compatibility, measurement and performance, dependability, design and development, safety and environmental issues. ETSI, along with CEN and CENELEC, is one of the three major harmonization bodies of Europe, and helps set the global agenda for matters under its purview. Although only European firms can be Full Members, firms from other parts of the world can participate in the work program as Associate Members. ETSI has developed over 8, 300 standards.

### Hot Topics

- electronic signatures
- smart cards
- aeronautical radios
- maritime radios

### Membership

Membership in ETSI is comprised primarily of industry representatives, specifically listed as telecommunications manufacturers, network operators and service providers. Full Membership and Associate Membership may be obtained by associations, companies, organizations or public authorities of European nations. Full Members have the right to attend meetings of the Technical Bodies where standards are developed and to participate in their work with the right to vote. Associate Members, which may include companies outside of Europe, have the right to attend meetings of Technical Bodies and to participate in their work with the right to vote on all matters except those concerning short range devices (radio devices designed to operate over short ranges at low power levels) or matters concerning documents exclusively intended for regulatory use by the European Union. Observer Status may be obtained by an organization entitled to become a Full or Associate Member. Observers do not have the right to attend meetings of a Technical Body, but may attend the General Assembly meetings without the right to vote. Most of ETSI's 752 members are companies from approximately 60 nations. ANEC, the European consumer voice in standardization, is a full member of ETSI and served on the ETSI Board between 2000 and 2002 as a representative of consumers until they were voted off in 2003 and replaced with a business group.

### Governance

The highest decision-making body of ETSI is the General Assembly, which meets twice a year. It has the right to vote and make or ratify acts and standards of ETSI. The ETSI Board acts on behalf of the General Assembly and is appointed by the General Assembly. The election is ad personam, as Board members must attend personally all meetings without possibility of being replaced by a colleague. 16 Technical Bodies, staffed by industry representatives, prepare standards for the organization.

### Process

A proposal for a new standard is submitted by industry. A Technical Body may approve the motion for work on a new standard if at least four ETSI members volunteer to support the work. The Technical Body then forms a Working Group to organize the drafting of the standard. The Working Group assigns the actual drafting to a Rapporteur Group (a subcommittee of the working group designated for a specific purpose). The Rapporteur Group then submits the draft to the Working Group for approval, which is then submitted to the Technical Body for approval or adoption. Once the Technical Body approves the standard, it is then made available to the ETSI membership to be voted upon at the General Assembly. If at least 71% of the membership votes in favor of the draft, it is adopted. Once adopted, it is published and posted on the ETSI web site.

### Transparency

According to the ETSI rules of procedure, ETSI standards must be given a 120 day national comment period for soliciting public comment. However, the success of the comment period depends upon the rules of procedure of the particular national standardization organization. Generally the process is not very visible and attracts little public input. The public comment procedure is only used for standards; however, it is not mandatory for ETSI's other "deliverables" such as guides and technical specifications. Some ETSI standards are available online and may be accessed free of charge.

### Funding

ETSI's budget is funded by member contributions, European Commission and European Free Trade Association and commercial sale of ETSI documents.

### Point of Contact

European Telecommunication Standards Institute, 50 route des Lucioles, Sophia Antipolis Cedex, France, Phone: +33 (0)4 92 94 42 00, Fax: +33(0) 4 93 65 77 16, E-mail: [infocentre@etsi.org](mailto:infocentre@etsi.org), Website: [www.etsi.org](http://www.etsi.org)

### Forest Stewardship Council

[www.fsc.org](http://www.fsc.org)

The Forest Stewardship Council (FSC), a non-profit organization located in Bonn, Germany, was founded in 1993 by environmental groups and timber traders with the specific objective of developing a system to identify well-managed forests for the purpose of improving conservation and reducing deforestation. This is accomplished through a system of forest certification, whereby a third party certifies whether a particular forest or woodland is being managed according to an agreed set of standards. Wood products harvested from FSC-certified forests are then permitted to bear the FSC label, which provides a guarantee that the products come from a sustainable, well-managed forest. FSC has affiliated groups in 66 countries around the world, including FSC-U.S. FSC affiliates have certified over 39 million hectares of forest as sustainably managed. The FSC label is recognized by major forest product retailers, including IKEA and Home Depot.

### Hot Topics

- Genetically modified plants and organisms
- Maintenance and conservation of biological diversity
- Use of pesticides
- Management of exotic species

### Membership

FSC International and many FSC affiliates divide their membership into three categories: the Economic Chamber, Environmental Chamber and Social Chamber. The Economic Chamber consists of members with a commercial interest in forestry, such as industry and trade associations. The Social Chamber is intended for indigenous organizations and social movements with an interest in forest stewardship. The Environmental Chamber includes non-profit NGOs and research, academic and technical institutions and individuals that are primarily concerned with environmentally viable stewardship, such as Friends of the Earth and the World Wildlife Fund.

### Governance

The FSC International is governed by a General Assembly, which consists of all three sectors of its membership and meets every three years to make major decisions and elect FSC's nine-member Board of Directors. Non-members such as individuals and other NGOs may attend the General Assembly at the discretion of the Board. A Secretariat is headed by an Executive Director, who is considered the chief executive of FSC. The Executive Director ensures the implementation of policies and is responsible for the finances, accounting, legal matters and administration of the FSC.

## Process

The FSC itself does not certify forests but authorizes independent certification organizations to certify forests, based upon the assumption that third-party certification will ensure consistent and unbiased certification. There are three types of FSC certification: Forest Management Certification certifies that the forest maintains the essential characteristics of a natural forest before and after a timber harvest; Chain of Custody Certification certifies that wood products that the FSC endorses actually do come from well-managed forests; Group Certification allows resource managers such as cooperatives and owners' associations to certify portfolios of land under their management. Industry pays for the certification, and certified forest products receive a certificate and the right to bear the FSC logo.

Certification of forests is based upon FSC principals and specific regional standards. FSC has developed 10 global principles that guide the development of forest management standards. National FSC groupings implement these principles by developing forest management standards in their respective countries (called National Indicators) accompanied by specific regional certification standards. The FSC-U.S., for instance, established a Standards Committee to develop a set of National Indicators which are slated to be reviewed every three years. These serve as baseline standards for 9 sets of regional standards — from the Pacific Coast to the Mississippi Valley to the Appalachian Mountains — which measure sustainably managed forests in these diverse biospheres. U.S. national and regional standards are developed by regional working groups, then approved by the FSC-U.S. Board, then endorsed by the FSC International Board, which makes decisions based upon a super-majority vote. The FSC also develops “Chain of Custody” Standards for manufacturers and processors of wood products to ensure credible tracking of sustainably-harvested forest products.

## Transparency

All standards and draft standards are posted on the international and national FSC web sites, and the organization welcomes comments from the public during the standards development process. For example, in the United States, standards are posted on the FSC-U.S. website for comment, and notices are also mailed to interested parties soliciting comments.

## Funding

FSC is funded by charitable donations, government donors, membership subscriptions and accreditation fees.

## U.S. Point of Contact

Forest Stewardship Council-U.S, 1155 30<sup>th</sup> Street, NW, Suite 300, Washington, DC 20007, Phone: (202) 342-0413, Website: [www.fscus.org](http://www.fscus.org)

## **Globally Harmonized System for Chemical Classification and Labeling**

[www.unece.org/trans/danger/publi/ghs/histback.html](http://www.unece.org/trans/danger/publi/ghs/histback.html)

The Globally Harmonized System for Chemical Classification and Labeling (GHS) is a harmonized regulatory schema developed by the UN and recommended for adoption by UN nations. It was initiated in 1992 at the UN Conference on Environment and Development. The GHS includes harmonized criteria for classification of the physical and health hazards of chemicals; labeling elements, including harmonized symbols, hazard warning statements, and signal words for each type of hazard; and a harmonized format for safety data sheets. The definition of “chemicals” includes pesticides, pharmaceuticals and consumer products. During its development, overall coordination of the GHS was spearheaded by the UN-based Interorganization Programme for Sound Management of Chemicals (IOMC), which coordinated the efforts of seven international institutions. The IOMC coordinated the technical work related to the harmonization mandate, and included governmental representatives from the chemical

classification and labeling systems of the United States, European Union, Canada. The OECD was responsible for classifying acute health hazards (such as irritation, sensitization and acute toxicity), chronic health hazards (such as carcinogenicity and reproductive toxicity) and environmental hazards through a series of expert committees. The UN Committee on the Transport of Dangerous Goods was responsible for harmonizing criteria for classification of physical hazards, including flammability and reactivity (explosive hazards). Finally, the International Labor Organization was responsible for hazard communication, including rules regarding labeling and material safety data sheets.

The system, as well as an implementation plan, was finalized and approved by appropriate UN bodies in 2002. It is now available for worldwide implementation with a goal of achieving implementation by 2008. The GHS is officially classified as a "non-mandatory recommendation" of the UN. It is anticipated that nations wishing to adopt the recommendations will make the domestic regulatory or legal changes that are necessary to comply with the international harmonization effort.

### Hot Topics

- Classification of chemical mixtures
- Harmonized safety data sheets
- Hazard warning statements
- Hazard signal words

### Governance

A management committee has been set up by the UN Economic and Social Council (ECOSOC) to assist nations in adopting the GHS system. In 1999, ECOSOC decided to enlarge the mandate of the UN Committee of Experts on the Transport of Dangerous Goods to create a new Sub-Committee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS Sub-Committee). The GHS Sub-Committee, composed of governmental, intergovernmental and industry advisors, will serve a coordinating function to assist in the adoption, implementation, amendment and maintenance of the harmonized system by governments. The operations of the sub-committee are governed by very brief terms of reference passed by the UN ECOSOC in 1999.

### Membership

ECOSOC approves membership in the GHS-Subcommittee. Currently, there are 36 governmental members and observers, along with 16 industry representatives and representatives from specialized agencies of the UN and intergovernmental organizations. While public interest NGOs may apply to participate, there appear to be none at the current time.

### Process

In addition to the GHS Sub-Committee, seven working groups have been set up, comprised of both industry and government representatives, to develop guidance documents to assist in the implementation and monitoring of the system. Notably, a representative from the International Council of Chemical Associations sits on every single working group. The seven groups are working on further developing data sheets, precautionary statements, labeling, and other technical issues as well as developing and refining the sub-committee process. All work is supposed to be conducted by consensus. The agenda, minutes of meetings and membership of these committees is available on the UN webpage above.

### Transparency

This UN Sub-Committee does not directly solicit public input into the ongoing process, but relies on governments to utilize domestic processes where they exist. Agendas and working papers of the GHS are available at the web page above. During the 10-year negotiation of the GHS, the U.S. Department of Labor's Occupational Health and Safety Division (OSHA) occasionally convened public meetings via the Federal Register to notify interested parties of the negotiations and to garner public input on the discussions. These meetings were largely attended by U.S. chemical industry representatives. No public health or environmental groups were consistently involved except for union representatives via the related work program of the ILO. Now that the recommendation is completed, new transparency issues arise. If the United States were to adopt this UN recommendation, it may result

in legal or regulatory changes for four U.S. agencies: the Consumer Product Safety Commission; the Department of Transportation; the Environmental Protection Agency, and the Occupational Health and Safety Commission. These agencies are currently reviewing the recommendation and deciding what statutory and regulatory changes may be needed to implement it. Any such changes would follow normal Congressional or regulatory procedures for public comment and public involvement. However, now that this major international negotiation has been finalized, the most significant aspects of the GHS system will be difficult to modify.

### U.S. Point of Contact

Directorate of Standards and Coordination, U.S. Department of Labor, OSHA, Room N3609, 200 Constitution Avenue, NW, Washington DC 20210, Phone: (202) 693 1982, Fax: (202) 693 1663, Website: [www.osha-slc.gov/SLTC/hazardcommunications/global\\_questions\\_answers.html](http://www.osha-slc.gov/SLTC/hazardcommunications/global_questions_answers.html)

## Global Harmonization Task Force for Medical Devices

[www.ghtf.org](http://www.ghtf.org)

The Global Harmonization Task Force (GHTF) is a grouping of government medical device regulatory authorities and industry trade associations formed in 1992 to promote international harmonization in the regulation of medical devices. GHTF publishes and disseminates harmonized guidance documents which can then be adopted and/or implemented by member national regulatory authorities. GHTF's work includes identifying medical device product requirements and auditing processes for harmonization, market surveillance and adverse event reporting. The GHTF was formed by the medical device regulatory bodies and trade associations of Japan, the European Union, the United States, Canada and Australia. The secretariat of the organization rotates between the regulatory bodies. It has published 15 standards, with many more proposed standards under consideration.

### Hot Topics

- Labeling for Medical Devices
- Principles of Safety and Performance of Medical Devices
- Audit Standards
- Reporting User Error

### Membership

GHTF has four types of memberships. 1) Founding Members are regulatory or industry representatives from one of the countries that initiated the formation of the GHTF: They may participate in all regular GHTF proceedings and serve on any study group or other working group, provided that the representative possesses the relevant expertise; 2) Participating Members, which include representatives of medical device regulatory authorities and medical device trade associations, may participate in or attend GHTF conferences and may participate in Study Groups and expert working groups upon invitation; 3) Liaison Members are representatives of public health organizations, international standard-setting bodies and other similar groups who can assist with GHTF undertakings, and 4) Observer Status is granted on a case-by-case basis, at the discretion of the GHTF Chair or Study Group Chair. Like ICH, GHTF is an industry–government partnership. As such, if a public interest NGO wanted to participate, it would apply to the Steering Committee for permission, and if approved, would likely be granted Observer Status.

### Governance

The GHTF is headed by a Steering Committee, which consists of up to four regulatory and up to four industry representatives. The Steering Committee provides policy direction and strategic planning, and assigns and provides oversight of technical work initiatives. The Secretariat role rotates between the governments involved in GHTF. The work of the GHTF is performed by Study Groups, which are formed for the purpose of evaluating specific areas for harmonization. The Study Groups, largely comprised of industry and government representatives, work by

consensus. The Steering Committee may form or dissolve a Study Group at any time. There is a U.S. point of contact for each of the four current study groups. (This information is available at [www.ghtf.org](http://www.ghtf.org).) The GHTF meets at least once every 18 months in various international locations. Study Groups meet two to three times a year. The four current study groups are:

- SG1 – Operational medical device regulatory systems
- SG2 – Adverse event reporting, post-market surveillance
- SG3 – Quality systems requirements in countries having developed device regulatory systems
- SG4 – Quality system auditing practices and developing guidance documents determining harmonized principles for the medical device auditing process

### Process

Any work undertaken by the Study Groups must first be approved by the GHTF Steering Committee. Alternatively, the Steering Committee can direct the Study Group to undertake specific work. After a Study Group has been assigned or initiates a specific standard, the Study Group must develop a working draft document. Once the document is reviewed and approved by the GHTF Chair and Steering Committee, it is advanced to the proposed document stage. It is then posted on the GHTF web site, commencing a three month public comment period for any interested party. The Study Group presents a proposed final document to the Steering Committee, which has eight weeks to review the document. Once the GHTF Chair endorses the final document, it is published and posted on the GHTF web site. All documents are developed by consensus. Since ISO has a committee that also addresses medical devices (Technical Committee 210), the two bodies have entered into a memorandum of understanding to work together and not duplicate work.

### Transparency

The GHTF makes standards in development available for public comment at least once in the process by posting them on its web site for a three month period. Once the Final Document is completed and approved, it is again posted on the GHTF web site. In the United States, FDA has no uniform process for adopting GHTF standards and guidance documents. GHTF standards are sometimes adopted by the FDA after a notice and comment period in the Federal Register, but draft standards under development at GHTF are generally not posted. FDA sometimes adopts certain GHTF standards and rejects others or adopts only portions of GHTF guidance documents. This is in contrast to FDA's policy regarding ICH, in which FDA plays a dominant role in determining the standard-setting agenda and intends to adopt each guidance produced.<sup>1</sup>

### Funding

Major GHTF meetings are funded by participant fees. Governments generally provide funding for their governmental representatives to participate in GHTF activities.

### U.S. Point of Contact

International Staff, Center for Devices and Radiological Health, HFZ-220, 1350 Picard Drive, Rockville, MD 20850, Phone: (301) 443-6597, Fax: (301) 443-8818, Website: [www.fda.gov/cdrh](http://www.fda.gov/cdrh)

### **U.S.-EU Aviation Harmonization Work Program**

[www.faa.gov/avr/arm/araac/index.cfm](http://www.faa.gov/avr/arm/araac/index.cfm)

In the United States, the Federal Aviation Administration (FAA) sets and administers safety and aircraft design standards; the Joint Aviation Authorities (JAA) similarly sets standards for aircraft manufactured for use in Europe. In 1988, the FAA and the JAA began early harmonization efforts, and in 1999, under the Fast Track Harmonization Program, the FAA and JAA began to accelerate the harmonization of United States and European aviation standards. The body working on these efforts is the Harmonization Working Group, and the joint U.S.–EU effort is designated as the Harmonization Work Program.

## Hot Topics

- Flight crewmember licensing
- Aging airplane safety
- Aircraft and aircraft engine noise emissions
- Civil aviation security rule

## Membership

The membership of the Harmonization Working Group includes representatives from the FAA, JAA, and a copious list of U.S. and EU aviation industry organizations including Boeing, Airbus, Fokker, Dassault, Eurocopter and European Association of Aerospace Industries (AECMA) and many others.

## Governance

The Harmonization Work Program is managed by a Harmonization Management Team (HMT). The HMT, which is made up of FAA and JAA management personnel, meets twice annually, and additional meetings may be scheduled on an ad hoc basis. The HMT consists of an Operations and Maintenance Harmonization Group (OHG) and a Certification Codes Harmonization Group (CCHG). The OHG is responsible for monitoring the harmonization process for requirements and associated material regarding operations and maintenance of civil aircraft and related products and parts, and licensing of flight crews. The OHG also identifies issues for harmonization, prioritizes the issues, establishes levels of coordination and identifies necessary resources. The CCHG is responsible for monitoring the harmonization process for requirements and associated material regarding design and manufacture of civil aircraft and related products and parts, noise and emission of aircraft and aircraft engines. Similar to the OHG, the CCHG is responsible for further identifying areas of harmonization, prioritizing these issues, establishing levels of coordination and identifying necessary resources. The Harmonization Working Group meets once a year. Other interested civil aviation authorities are invited to attend as observers.

## Process

Any person or organization may propose a subject for harmonization. The JAA and FAA technical staffs then consult with designated United States and European industry users to determine whether the harmonization proposal has merit. If further research is warranted, a Term of Reference (TOR) is completed within 60 days by either the FAA or JAA contact point, detailing the merit of the harmonization proposal and outlining the technical work program. The TOR is then sent to both the JAA and FAA for Executive Review. There must be a joint decision to approve and finalize a TOR. If a TOR is approved, it is then the responsibility of the FAA and JAA to initiate harmonization by notifying their respective rulemaking systems.

In the United States, the FAA has tasked the Aviation Rulemaking Advisory Committee (ARAC), a formal standing advisory committee of the FAA, with the international harmonization effort. ARAC consists of the Full Committee, the Executive Committee, Issue Areas and multiple technical Working Groups. The Full Committee is made up of all of the member organizations of ARAC, which include government, industry, as well as a few aviation union and NGO representatives. In the EU, the JAA assigns tasks to a JAA Study Group, which then nominates a Chairman to act as the contact point for the harmonization initiative. When ARAC accepts a harmonization task, a notice is published in the Federal Register, announcing the topic and soliciting the public participation in the working group. The public cannot attend working group meetings. Once a working group is formed, a draft recommendation document is prepared and then presented to the Issue Area for acceptance. The Issue Area may hold open meetings to discuss a recommendation. ARAC must accept a working group proposal before presenting the proposal to the FAA as an advisory committee recommendation, after which the document is sent to the FAA, posted on its web site, and the agency proceeds with normal domestic rulemaking procedures.

## Transparency

This joint US-EU harmonization work effort relies heavily on a coordinated regulatory policymaking by FAA and JAA. There is not a free-standing institution doing the work with its own web page listing harmonized standards. As a formal federal advisory committee, ARAC is governed by U.S. open government laws requiring balance and open meetings. Currently, unions and public interest organizations and individuals serve on the dual committee. However, the multiple technical working groups are heavily dominated by industry representatives largely from the

two major aircraft manufacturers, Boeing (U.S.) and Airbus (EU). Draft aviation harmonization rules are posted in the Federal Register for public comment before being adopted as U.S regulations or standards. ARAC regulatory standards are available for free on the ARAC web site.

### **U.S. Point of Contact**

Aviation Rulemaking Advisory Committee, Federal Aviation Administration, 800 Independence Avenue, S.W. Room 810, Washington, DC 20591, Phone: (202) 967 9677, Website: [http://www1.faa.gov/avr/arm/arac\\_index.cfm?nav=6](http://www1.faa.gov/avr/arm/arac_index.cfm?nav=6)

### **International Atomic Energy Agency**

[www.iaea.org](http://www.iaea.org)

The International Atomic Energy Agency (IAEA) was established under the UN in 1957 as an intergovernmental forum for scientific and technical co-operation in the use of nuclear technology. Located in Vienna, Austria, the IAEA houses multiple conventions such as the Nuclear Non-Proliferation Treaty and provides inspectors for related verification work. The organization works to safeguard nuclear materials to make sure that they are not used for militaristic purposes, promotes nuclear technologies and nuclear energy, and develops international standards for the safe handling and transportation of nuclear materials and radioactive waste. IAEA has 138 member states.

### **Hot Topics**

- Radioactive Waste Management
- Nuclear terrorism
- Chernobyl +15
- Depleted Uranium

### **Membership**

All UN member nations and any country that signed the IAEA statute (which is the document establishing the organization) within 90 days of its approval are automatically members of the IAEA. Membership is additionally open to any country, whether or not it is a member of the UN, provided that its membership is approved by the General Assembly of the IAEA, which is called the General Conference. Therefore, NGOs, industry representatives and individuals cannot be IAEA members. The consultants who draft the IAEA standards largely consist of industry and government representatives.

### **Governance**

The General Conference, which is comprised of all IAEA members, meets once a year to consider the report of its Board of Governors for the previous year, and to approve the program, budget, and any new standards and applications for membership. The IAEA is headed by a Director General and a Board of Governors and approved by the General Conference. The Board of Governors, which is comprised of 35 member governments, approves safeguards agreements and the publication of the IAEA's safety standards.

### **Process**

The IAEA Secretariat, four Safety Standards Committees (nuclear safety, radiation safety, radioactive waste safety and safe transport of radioactive material) and a Commission on Safety Standards prepare and review safety standards. IAEA standards are initiated or revised when the Secretariat prepares an outline and work plan, which is then subject to the approval of the IAEA Committees and the Commission. The Secretariat and consultants then draft the safety standard, which is reviewed by the four Safety Standards Committees and submitted to Member States and the Secretariat for comment and review. Finally, it is approved by the Commission on Safety Standards. Five years after publication, standards are reviewed to determine whether revision is necessary.

## Transparency

There is no process for the public to participate in the development of IAEA standards unless members of the government facilitate a process domestically. In the United States, through Federal Register notices, it appears that the public is permitted to comment on standards in development through participation in public meetings and the submission of written and oral comments.

## Funding

The IAEA operating budget comes from member contributions per a scale of assessment for each country.

## U.S. Point of Contact

Office of International Programs, Nuclear Regulatory Commission, Washington DC 20555, Phone: (301) 415-2336, Web Site: [www.nrc.gov/what-we-do/international.html](http://www.nrc.gov/what-we-do/international.html)

Office of Non-Proliferation and International Security, Department of Energy, 955 L'Enfant Plaza SW, Washington, DC 20585, Phone: (202) 586-2108, Website: [www.nnsa.doe.gov/na-20/](http://www.nnsa.doe.gov/na-20/)

## International Organization for Standardization

[www.iso.org](http://www.iso.org)

The International Organization for Standardization (“ISO”) is a private, non-profit organization, composed of national standards bodies from 146 countries located in Geneva, Switzerland. Formed in 1947, ISO promotes the development of international product standards in an effort to promote international trade. The name “ISO” is not intended to be an acronym for the International Organization for Standardization, but instead, a tribute to the Greek word *isos*, which means “equal.” ISO is officially recognized by the WTO Technical Barrier to Trade Agreement as setting the world’s presumptively trade-legal product standards. To date, ISO has developed over 12,000 international standards. When ISO focused primarily on product standards, such as those governing the standardization of light bulbs, floppy disks and bank cards, their work was relatively non-controversial. But, in the last decade, ISO began developing “management” standards which could conflict with domestic regulations. ISO has two “families” of management standards that are being widely adopted – ISO 9000 and ISO 14,000. ISO 9000 deals with quality management, which encompasses all features of a product or service that are required by the customer. ISO 14,000 concerns environmental management, which describes ways that an organization can minimize harmful effects on the environment caused by its activities. New ISO service standards, such as proposed standards on water services management, have raised new concerns about ISO creating standards likely to conflict with domestic regulatory standards.

## Hot Topics

- meat inspection quality management and foodborne illness testing
- mechanical contraceptives
- water quality and service management standards
- ecommerce
- surgery implants & medical devices
- cosmetics
- safe toys
- smart cards

## Membership

ISO’s membership is made up of the national standards bodies from each country represented. There are three levels of ISO membership: 1) A Member Body is a national standards body most representative of the standards efforts of a nation with a fully developed standardization process; 2) A Correspondent Member represents a country without a fully developed national standard body, and 3) A Subscriber Member represents a country with a very small economy. Only Member Bodies can vote and give conclusive input on the development of standards.

Individuals, businesses and NGOs cannot be members of ISO, but can sometimes participate as members of their national standards body delegations. As ISO standards are industry-driven, ISO relies upon “experts on loan from industrial, technical and business sectors”<sup>2</sup> to participate as part of the national standards body delegation. Because few NGOs have the resources to donate staff to such an endeavor, representation by public interest groups in ISO is extremely limited. For instance, Consumers International struggles to cover only a handful of the 2,850 ISO working groups and committees, and consumer group participation in national standards bodies is also very limited. To address this profound imbalance, ISO established a Committee on Consumer Policy (COPOLCO). COPOLCO promotes the integration of consumer groups into the ISO process by coordinating participation of consumer representatives in ISO technical committees and organizing workshops on specific issues. However, COPOLCO does not systematically review ISO standards prior to adoption in an effort to promote a consumer perspective.

### **Governance**

The highest governing body of ISO is the General Assembly, which meets once a year to review annual reports, strategic plans and finances. The ISO Council, made up of 18 elected national standards bodies, serves as the executive board and meets annually. The ISO Technical Management Board, comprised of national standards body representatives, also exercises a great deal of influence by approving the formation of new committees. The General Secretariat in Geneva is responsible for all of the administrative paperwork. The core work of ISO is performed by approximately 2,850 technical committees, subcommittees and working groups, comprised largely of industry experts who develop international standards.

### **Process**

ISO standards are developed using a three-step process. Typically, an industry requests the initiation of a specific standard, then working groups define the technical scope of the future standard. Secondly, the members of the working group negotiate the detailed specifications within the standard. Finally, the standard has to be approved by a paper ballot vote of two-thirds of the members involved in developing the standards and 75% of all of the members who vote. All standards must be reviewed at least every five years.

### **Transparency**

The general public has no opportunity to comment on ISO standards as they are being developed unless a process is developed domestically. In the United States, ANSI, the U.S. national standards body which represents U.S. interests in ISO and serves on 80% of ISO committees, is not a governmental organization but a non-profit, private-sector organization that coordinates industry standard-setting activities. ANSI uses its weekly publication *Standards Action* to solicit public input on draft ISO standards and American standards. Because this process is not well known or understood by the general public, usually only industry groupings that are members of ANSI and are familiar with the standards process comment on draft standards. Standards that are proposed for adoption by federal agencies as policy are sometimes given public notice and an opportunity for public comment in the official federal agency publication called the Federal Register. However, it is difficult to determine how often standards are adopted by U.S. federal agencies or if the public notice and comment requirements of the Administrative Procedures Act are being utilized by agencies in all cases. ISO standards are catalogued on its web site for interested parties to purchase.

### **Funding**

ISO receives 80% of its funding through member subscriptions and 20% through the sale of ISO standards and other publications. Subscriptions are calculated based upon the basis of economic factors such as gross national product and the value of imports and exports of the member's country.

### **U.S. Point of Contact:**

American National Standards Institute, 1819 L Street, NW, 6th floor, Washington, DC 20036, Phone: (202) 293-8020, Fax: (202) 293-9287, Website: [www.ansi.org](http://www.ansi.org)

## International Conference on Harmonization

[www.ich.org](http://www.ich.org)

The Geneva-based International Conference on Harmonization on Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a private sector, non-profit organization formed in 1990 for the purpose of harmonizing the technical requirements for new pharmaceuticals or innovator drugs. ICH is an industry-government partnership made up of governmental agencies regulating drugs and pharmaceutical industry associations. ICH's purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration and thereby reduce duplicative testing carried out during the research and development of new medicines.

### Hot Topics

- Impurities in new drugs
- Duration of chronic toxicity
- Testing in animals
- Carcinogenicity in pharmaceuticals
- Biotechnological products

### Membership

The six parties to the ICH consist of its government and industry founding members: the European Union (EU), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Ministry of Health, Labor and Welfare, Japan (MHLW), the Japan Pharmaceutical Manufacturers Association (JPMA), the U.S. Food and Drug Administration (FDA) and the Pharmaceutical Research and Manufacturers of America (PhRMA). The founding members are referred to as co-sponsors. There are also three observers – The World Health Organization (WHO), The European Free Trade Area (EFTA) and Canada. The International Federation of Pharmaceutical Manufacturers Association (IFPMA), the Geneva-based industry association, serves as the Secretariat for the organization. The ICH generally meets twice a year. NGOs and individuals cannot be members or observers, or serve on the governing body of this industry-government partnership.

### Governance

The ICH is administered by a Steering Committee, which determines the policies and procedures for ICH, selects topics for harmonization and monitors the progress of harmonization initiatives. The Steering Committee members consist of representatives of the six ICH founding members. ICH Coordinators, which are comprised of government representatives, are the main contact point with the ICH Secretariat, and ensure that ICH documents are distributed to the appropriate persons. The ICH Secretariat is responsible for preparing and documenting the meetings of the Steering Committee, as well as coordinating meetings for expert working groups and drafting groups.

### Process

In order to initiate the ICH harmonization process, a formal proposal in the form of a concept paper must be submitted to one of the six parties to the ICH or one of the observers on the Steering Committee. If the Steering Committee decides to adopt a topic for harmonization, an Expert Working Group consisting of government and industry personnel is convened, and reviews the differences in requirements between the co-sponsor's regions and develops a consensus required to reconcile those differences. The members of the Expert Working Group then reach a consensus on an initial draft of a guideline or recommendation and submit it to the Steering Committee, which decides either to continue or abandon the project. If the Steering Committee opts to continue harmonization efforts on the topic, guideline or recommendation, it is submitted for regulatory consultation in the United States as a draft guideline in the Federal Register. An ICH Regulatory Rapporteur, which is either a government or industry representative member, submits a final document and obtains agreement from the experts representing the regulatory parties. This draft is then adopted by the Steering Committee. Finally, the revised text is submitted for

regulatory implementation domestically and is reported to the Steering Committee and published by the Secretariat. In the United States, FDA regularly adopts ICH guidance as U.S. policy.

### Transparency

ICH working groups are staffed by the pharmaceutical industry and government employees. There is no avenue for public input into the ICH standards under development, unless a process exists domestically. In the United States, the FDA generally allows the public to comment on draft ICH guidance documents and on final ICH guidance documents before adoption via the Federal Register. ICH standards are available on the ICH web page free of charge.

### Funding

The ICH secretariat is an industry association. ICH is funded by its members. FDA activities are funded by the FDA.

### U.S. Point of Contact

Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 827-0864, E-Mail: [wmail@oc.fda.gov](mailto:wmail@oc.fda.gov), Website: [www.fda.gov/cder/audiences/iact/iachome.htm#ICH](http://www.fda.gov/cder/audiences/iact/iachome.htm#ICH)

**International Cooperation on Harmonisation of Technical  
Requirements for Registration of Veterinary Products**  
[vich.eudra.org](http://vich.eudra.org)

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products, better known as VICH, consists of governmental and industry representatives from the European Union, Japan and the U.S. VICH meets twice a year, and its activities are carried out under the auspices of the Paris-based Office of International Epizootics, which develops animal health and disease prevention standards for international trade in animals and animal products. Launched in 1996, the purpose of the VICH is to create globally-harmonized technical requirements for veterinary products and product registration.

### Hot Topics

- Ecotoxicity
- Testing of residual formaldehyde
- Impurities in drug substances
- Antimicrobial resistance

### Membership

VICH has four classes of membership – Full Members, Associate Members, Observers and Interested Parties. The only Full Members of VICH are the parties to the program – the industry and animal health regulatory bodies of the EU, Japan and the United States. Associate Members and Observers may contribute to VICH discussions, but they do not have the right to vote. Interested Parties may apply to attend VICH sessions, but cannot vote, speak or contribute in any way unless requested by the chair. While it may be possible for public interest NGOs to participate in VICH in one of these latter categories, currently it appears that only industry associations and governments participate in the VICH process.

### Governance

The VICH Steering Committee determines the working procedures and prioritizes the work agenda. It is composed of member representatives from governmental and industry groups, including the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health, Committee on Veterinary Medicinal

Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries. The Steering Committee also has observers from the government and industry of New Zealand and Australia. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the industry association Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings. VICH has nine expert working groups consisting of government and industry representatives.

## Process

The VICH procedure for developing standards involves a nine-step process. First, the Steering Committee defines a priority item from a concept paper submitted by a member and assigns it to a Working Group. The Working Group develops a draft recommendation, which is then submitted to the Steering Committee for approval. A national comment period may ensue. If comments are submitted, the Working Group prepares a revised draft, and it is submitted to the Steering Committee for final approval.

## Transparency

There is no process for the public to participate in the development of VICH standards unless member governments implement a process domestically. In the United States, draft and final VICH standards are posted in the Federal Register for public comment. VICH standards are available on the organization's website free of charge.

## Funding

The VICH secretariat is an industry association. Members of VICH pay for their own participation in the harmonization effort.

## U.S. Point of Contact

Food and Drug Administration MPN-2, HFV-1, Center for Veterinary Medicine, 7519 Standish Place, Rockville, MD 20855, Phone Number: (301) 827-4108, Fax: (301) 827-3957, Website: [www.fda.gov/cvm/default.html](http://www.fda.gov/cvm/default.html)

## International Electrotechnical Commission

[www.iec.ch](http://www.iec.ch)

The International Electrotechnical Commission (IEC), located in Geneva, Switzerland, is a non-profit standard-setting organization comprised of industry and government representatives, which publishes international standards for electric, electronic and related technologies. This includes all electrotechnologies including electronics, magnetics, electromagnetics, electroacoustics, multimedia, telecommunication, and energy production and distribution, as well as associated general disciplines such as terminology and symbols, electromagnetic compatibility, measurement and performance, dependability, design and development, safety and the environment. Since commencing work in 1906, the IEC has published 4553 international standards. These standards serve as the basis for national standards and are referenced in the preparation of international purchases and contracts.

## Hot Topics

- Overhead Lines (TC 11)
- Plugs, Socket-Outlets and Switches (SC 23C)
- Insulating Materials (TC 15)
- Fuses (32C)

### Membership

There are two forms of membership: Full Membership is reserved for national committees, which represent a country's interest in IEC. National Committees can be composed of manufacturers, providers, distributors, consumers, government agencies, professional societies and standards developers, but are often comprised of industry and government technical experts. Full IEC Members have full voting rights. Associate Membership is reserved for countries with limited resources. Associate Members have Observer Status and can participate in all IEC meetings, however, they have no voting rights. If an individual or NGO is a member of a country's National Committee, then they can participate in standards development. However, there is no other vehicle by which individuals or NGOs can participate in the standards development process or comment on draft or final standards.

### Governance

The highest governing body of the IEC is the Council, which is the general assembly of all of the National Committees. The Council sets IEC policy and long-term strategic and financial objectives, elects officers and approves IEC standards. The Standardization Management Board (SMB) is responsible for the management of standards work including the creation, dissolution and scopes of the 179 IEC technical committees and 700 project teams comprised primarily of industry representatives. The Conformity Assessment Board (CAB) is responsible for the overall management of conformity assessment activities. Lastly, an Executive Committee comprised of members of the national committee implements Council's decisions concerning the operation of the IEC Central Office.

### Process

A proposed IEC standard is usually submitted by industry via a National Committee to the appropriate technical committee or subcommittee. A simple majority vote then commences the development process. After the committee has agreed to work on a specific standard, it must prepare a working draft, which is then submitted to the National Committees for comment, after which it may be amended. Next, the draft is submitted to all National Committees for a five-month long voting period. The final draft is then circulated for a two-month voting period and is considered accepted, if approved, by National Members by a supermajority vote.

### Transparency

There is no role for the public to participate in the creation of IEC standards, unless a process is developed domestically. The U.S. National Committee (USNC) for the IEC is housed in ANSI and is in charge of representing the United States on IEC committees. The USNC works through ANSI to adopt IEC standards as "American National Standards." Prior to adoption, proposed national standards are published in the weekly on-line ANSI publication *Standards Action*. It appears that IEC standards are rarely adopted as U.S. regulatory requirements, but IEC testing, evaluation and accreditation standards on complex technical and conformity assessment issues are sometimes adopted by reference. For instance, the United States has incorporated IEC standards regarding maritime communication and noise certification standards for aircrafts after posting notice in the Federal Register. Such IEC standards are only available by purchase, which can be done online.

### Funding

The IEC is financed through the sale of published standards and membership dues.

### U.S. Point of Contact

U.S. National Committee for the International Electrotechnical Commission, American National Standards Institute 1819 L Street, NW, Suite 600, Washington, DC 20036, Phone: (202) 293-8020, Fax: (202) 293-9287, Website: [www.ansi.org/standards\\_activities/iec\\_programs/overview.aspx?menuid=3](http://www.ansi.org/standards_activities/iec_programs/overview.aspx?menuid=3)

## International Labor Organization

[www.ilo.org](http://www.ilo.org)

The International Labor Organization (ILO), is a UN organization located in Geneva, Switzerland, which addresses an array of issues related to workers rights, worker health and safety and human rights. The ILO is a tripartite agency made up of government labor officials, industry and labor union representatives. The ILO develops labor standards in the form of conventions and recommendations, which its member countries are urged to ratify and adopt domestically. The ILO sets international standards concerning a variety of topics such as the right to organize, abolition of forced labor, equality of opportunity and treatment and collective bargaining.

### Hot Topics

- Forced labor
- Occupational safety and health
- Child labor
- Right to organize

### Membership

ILO membership is open to government, industry and union delegations from any country. NGO's other than labor unions may not become members of the ILO. However, internationally incorporated NGOs may participate as experts, advisors or consultants if they have been granted Observer Status by the Economic and Social Council of the UN. There is also a Special List of NGOs, which are deemed either employer or worker organizations, which participate in ILO activities. Upon obtaining Observer Status, NGOs can be given limited access to specific ILO meetings depending on a demonstrated particular interest, but have no voting powers. For example the International Confederation of Free Trade Unions, an association comprised of national labor federations, has observer status within ILO.

### Governance

The ILO operates through three bodies: The International Labor Conference, the Executive Council and the International Labor Office. Delegations from ILO member states meet under the auspices of the International Labor Conference once per year, where they establish and adopt international labor standards, elect the governing body and adopt the budget. At the conference, each country is represented by two government delegates, a worker delegate, an employee delegate and technical advisors. The governing body of the ILO is the Executive Council. Comprised of 28 government members, 14 employer members and 14 worker members, the Executive Council establishes policy, the work program and the budget. The International Labor Office is the Secretariat of the ILO. It serves an administrative function and is also the venue where research is conducted and work is published.

### Process

The ILO formulates three types of initiatives: conventions, recommendations and codes of practice. Conventions and codes of practice are developed the same way. They are proposed by the Conference and then drafted by the Secretariat. Afterwards, the draft is presented for review to a Committee of Experts including six employers, six employees and six government representatives. Once the draft is reviewed and revised, it is presented for majority vote by the Conference. Recommendations typically accompany conventions as a supplement and may be approved or refused independent of the outcome of the convention. Once the recommendation or convention is adopted, it is communicated to all member states, which are obligated to present it to their domestic legislative bodies for implementation. The member states must take such action no later than one year from the closing of the session of the conference or in exceptional circumstances, this time period may be extended to 18 months. Members must then inform the Director-General of the actions which its country has taken to fulfill the convention or recommendation.

### Transparency

There is no avenue for citizens to comment on conventions or other initiatives being considered by the ILO unless a process is developed domestically. In the United States, the Executive Branch sends conventions to be ratified by the U.S. Senate. Congress is then required to conform domestic legislation to comply with the convention. The United States has ratified only 14 of a possible 1400 ILO conventions, one of the worst ratification rates in the world. Most recently, the Senate ratified the ILO convention on the worst forms of child labor in 1999. Some ILO standards and publications are available for purchase on the ILO web site while others are available free of charge.

### Funding

ILO is financed through membership dues.

### U.S. Point of Contact

Bureau of International Labor Affairs, Office of International Labor Policy, U.S. Department of Labor, Room S-5303, 200 Constitution Avenue, NW, Washington, DC 20210, Phone: (202) 693-4785, Fax: (202) 693-4784  
Email: [Contact-OFR@dol.gov](mailto:Contact-OFR@dol.gov), Website: [www.dol.gov/ILAB/programs/ofr/main.htm](http://www.dol.gov/ILAB/programs/ofr/main.htm)

### International Organization of Epizootics

[www.oie.int](http://www.oie.int)

The Paris-based International Organization of Epizootics (OIE) was founded in 1924 for the purpose of developing animal health and disease prevention standards for international trade in animals and animal products. OIE is an intergovernmental organization made up of national veterinary regulatory agencies from 162 countries. OIE collects and analyzes scientific information on animal disease control, disseminates an annual report on the global incidence of animal diseases and designates the disease-free status of member countries. Along with Codex and ISO, the OIE is officially recognized by the WTO and NAFTA's Sanitary and Phytosanitary Agreements as setting the world's presumptively trade-legal animal health and animal disease standards.

### Hot Topics

- Mad Cow Disease or bovine spongiform encephalopathy (BSE)
- Hoof and Mouth disease
- Avian Influenza

### Membership

OIE is comprised of national governmental delegates, usually the chief veterinary officer of the 162 member countries. As a consequence there is no process for NGOs or industry representatives to become members or obtain observer status. However, the U.S. delegate has occasionally brought representatives from groups such as the American Veterinary Medical Association along as technical advisors to OIE meetings. Certain member governments exercise a great deal of influence over OIE proceedings. For instance, the U.S. government succeeded in weakening the animal health code to facilitate trade in beef and live cattle with countries with indigenous cases of BSE after mad cow disease was found in Canada and later in the United States.

### Governance

The International Committee is the highest authority of the OIE. It is comprised of all of the delegates and meets once per year during the OIE's annual General Session. The obligations of the International Committee are to adopt international standards and resolutions and elect the members of the governing bodies of the OIE. The Administrative Commission is composed of the President of the International Committee, the Vice-President, the Past President and six Delegates. The Administrative Commission's duty is to examine technical and administrative matters, the working program and proposed budget. There are also four specialist commissions erected for the purpose of studying problems of epidemiology and control of animal disease and issues related to the harmonization

of international regulations, including: the International Animal Health Code Commission, Foot and Mouth Disease and Other Epizootics Commission, Standards Commission and Fish Diseases Commission. Standards are approved by consensus.

### Process

OIE working groups undertake the initial preparation of draft standards, which are then circulated to member countries for review and comment. Draft standards are then revised and presented to the OIE General Session for adoption by consensus.

### Transparency

There is no process for the public to participate in the OIE unless member governments implement a process domestically. In the United States, APHIS posts draft standards on a web page for public comment [www.aphis.usda.gov/vs/ncie/oie/#Terrestrial](http://www.aphis.usda.gov/vs/ncie/oie/#Terrestrial). OIE standards are often posted in the Federal Register prior to their adoption by federal agencies. OIE standards are available for purchase and some are available free of charge online.

### Funding

The OIE is funded by regular annual contributions and voluntary contributions by member countries.

### U.S. Point of Contact

USDA, APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road, Unit 38, Riverdale, MD 20737-1231, Phone: (301) 734-3577, E-mail: [michael.j.david@aphis.usda.gov](mailto:michael.j.david@aphis.usda.gov), Website: [www.aphis.usda.gov/vs/ncie/oie/](http://www.aphis.usda.gov/vs/ncie/oie/)

## International Plant Protection Convention

[www.ippc.int](http://www.ippc.int)

The International Plant Protection Convention (IPPC) is an international agreement implemented to promote plant health, to prevent the spread of plant pests and to promote appropriate measures for their control. The IPPC is a UN convention that came into force in 1952 after it was negotiated under the auspices of the UN Food and Agriculture Organization (FAO). In 1997, the convention underwent an overhaul to create a more efficient standard-setting process. The new convention created the (Interim) Commission on Phytosanitary Measures ICPM, which is comprised of representatives from all IPPC nations and meets annually for the purpose of developing standards. The standards the ICPM develops, which include measures covering containers, soil, packing material and other conveyances that may harbor pests, become International Standards for Phytosanitary Measures (ISPMs), which other IPPC member countries are expected to adhere to. To date there are 14 ISPMs. The IPPC is officially recognized by the WTO and NAFTA's Sanitary and Phytosanitary Agreements as setting the world's trade-legal plant health and pest control standards. The IPPC Secretariat is based in Rome, Italy.

### Hot Topics

- Invasive species
- Treatment of packaging crates for pests
- Pest reporting and eradication
- Guidelines for equivalency

### Membership

A country may become a party to the IPPC by depositing its signature with the Director-General of the FAO. NGOs, businesses and individuals cannot become parties to the IPPC. The IPPC is comprised of national and regional plant protection organizations, which are government bodies. Industry and NGOs can participate as observers in the IPPC, provided they are granted Observer Status by the Secretariat of the FAO. Greenpeace, for instance, has Observer Status in the IPPC.

### Governance

The ICPM is composed of representatives from the National Plant Protection Organizations of contracting parties to the IPPC, and FAO members. All members of the FAO, as well as other countries who notify the Director-General of the FAO of their interest in the organization are eligible for membership in the ICPM. Countries with a special interest in the IPPC may also be eligible for associate membership or observer status, but may not enjoy the voting rights of a full member. The ICPM is headed by a chairperson, two vice-chairpersons, and a rapporteur. The IPPC and the ICPM jointly share a Secretariat, who in addition to coordinating the annual workplan of the ICPM has a significant role in the standard-setting process. The chairpersons are elected by the Commission and the Secretariat is appointed by the Director-General of the FAO.

### Process

Suggestions for standardization topics are made by Regional or National Plant Protection Organizations, the IPPC Secretariat or the WTO SPS Committee as proposals for global harmonization. Industry and other interested parties can also suggest topics for harmonization via the Secretariat. The ICPM decides which ideas have merit and refers the matter to the Standards Committee which oversees the standard-setting process by agreeing on the specifications for draft standards. The Standards Committee is made up of 20 members drawn from seven FAO regions. Members are senior government experts. These senior members designate a working group to undertake detailed work on a draft standard. Once a draft standard has been completed by a working group and approved by the Secretariat and the Standards Committee, there is a 120 country consultation period. Comments are incorporated in consultation with the Secretariat and the Standards Committee. A final standard is submitted to the ICPM for approval by consensus. The standard is then published and distributed by the Secretariat.

### Transparency

There is no avenue for public involvement in IPPC decision-making unless one is provided domestically. In the United States, IPPC standards have been adopted after public notice and comment in the Federal Register. For instance, the United States recently proposed the adoption of IPPC guidelines for wood packing crates that some environmental groups have criticized as too lax to prevent the introduction of invasive species and exotic pests into the United States. Some IPPC standards are available on the web site for free and others are only available in hard copy, also for free.

### Funding

The IPPC is funded by the FAO.

### U.S. Point of Contact

Program Director, International Standards, Plant Protection and Quarantine, APHIS, 4700 River Road, Unit 140, Riverdale, MD 20737, Phone: (301) 734-8469, Fax: (301) 734-7639, E-mail: [Nancy.G.Klag@aphis.usda.gov](mailto:Nancy.G.Klag@aphis.usda.gov)  
Website: [www.aphis.usda.gov/ppq/index.html](http://www.aphis.usda.gov/ppq/index.html)

### International Telecommunication Union

[www.itu.int](http://www.itu.int)

The International Telecommunication Union, located in Geneva, Switzerland, was established in 1865. The ITU is a UN organization comprised of industry and government telecommunication regulatory representatives that standardizes all aspects of the telecommunication industry. The ITU is divided into three sectors that deal with specific topics in the telecommunication arena: Telecommunication Standardization (ITU-T), Radiocommunication (ITU-R) and Telecommunication Development (ITU-D).

## Hot Topics

- Global positioning systems
- Software application
- Optical and transport networks
- Telephone service

## Membership

There are three types of membership – State, Sector and Associate. State Membership is open to governments exclusively. Sector Membership is open to private organizations such as equipment manufacturers, funding bodies, research and development organizations and international and regional telecommunication organizations. However, Sectoral Members are typically corporations and industry associations and include members such as NEXTEL, Hewlett Packard, Verizon, Sprint, Lucent Technologies, Microsoft and NOKIA. Associate Members are recognized operating agencies, scientific or industrial organizations, financial or development institutions or telecommunication organizations. Associate Membership entitles organizations to take part in study groups, however, they have no voting rights.

## Governance

The highest governing body of the ITU is the Plenipotentiary Conference, which is composed of delegations that are comprised of industry representatives and government employees from the ITU's Member States. Plenipotentiary conferences, held every four years, determine the direction of the ITU and its activities, and make decisions relating to the structure of the organization. In the interim period between Plenipotentiary Conferences, the ITU Council acts as the ITU's governing board. A third governing body within the ITU is the World Telecommunication Assembly, which approves work programs and ITU recommendations for standards.

## Process

The ITU standards development process begins when a member submits a Question on a particular topic within telecommunication standardization. A Question is the study of a particular subject and defines the work to be undertaken. For each Question that is presented, a Study Group is formed, which consists of industry representatives and government employees, and appoints a Rapporteur to manage the work. The Rapporteur is supported by a collection of experts on the subject, known as the Rapporteur Group. Based on the guidance of the Study Group, the Rapporteur Group will determine what recommendations are required and after considering comments from members, develop the text of a recommendation in response to the Question. After developing the text, the Rapporteur Group will appoint an editor to manage the development of the text. All draft recommendations must be formally approved by the Study Group which initiated the work. Once the draft recommendation is complete, it can be submitted during a study group or working party meeting. It is then posted on the ITU website for a four-week electronic comment period. If no comments are received, the recommendation is automatically approved by the study group at the next meeting. Any substantive comments received on the draft recommendation are made available to ITU members. In such cases, the draft recommendation is not automatically approved, but instead considered at a subsequent Study Group meeting where the comments are considered and the revised draft recommendation is re-posted. On average, recommendations are approved within six months of initiation. The World Telecommunications Assembly has a final majority vote on all standards.

## Transparency

As membership is restricted to countries and telecommunications companies, NGOs and private citizens have no access to the development of ITU standards unless a process is created domestically. In the United States, the U.S. State Department has created a formal federal advisory committee to advise the U.S. government on ITU and other international telecommunications issues. The U.S. International Telecommunications Advisory Committee is comprised of three sectors - telecommunications standardization, telecommunications development and radio communication – and numerous study groups. Per the requirements of U.S. open government law, the meetings of ITAC are noticed in the Federal Register and open to the public. It is unclear how frequently the U.S. government adopts ITU standard, however the Federal Communications Commission has on occasion adopted ITU standards after providing public notice. ITU standards are catalogued online and available for sale.

### Funding

The ITU is financed through contributions from member states. Other sources of financing include income from services such as the sale of publications, project execution and satellite notification.

### U.S. Point of Contact

U.S. International Telecommunications Advisory Committee, U.S. Department of State, 2201 C Street, NW, Washington, DC 20520, Phone: (202) 647-2592, E-mail: [ebcipma@state.gov](mailto:ebcipma@state.gov), Website: [www.state.gov/e/eb/adcom/c668.htm](http://www.state.gov/e/eb/adcom/c668.htm)

### NAFTA Technical Working Group on Pesticides

[www.epa.gov/oppfead1/international/naftatwg](http://www.epa.gov/oppfead1/international/naftatwg)

There are dozens of committees and working groups established under the North American Free Trade Agreement, which work on harmonizing rules and procedures between the three NAFTA nations. The U.S. government has failed to make even basic information about these committees and their U.S. contact points available via the Federal Register or the internet. As an annex to this document we make available to the public for the first time a list of NAFTA technical working groups and their contact persons. (See, p. 40). Only one U.S. agency has worked to keep the public apprised of its NAFTA harmonization activities – the U.S. Environmental Protection Agency which coordinates activities for the Technical Working Group on Pesticides. The purpose of the NAFTA Technical Working Group (TWG) on Pesticides is to develop a coordinated pesticides regulatory framework among NAFTA parties to address trade irritants (largely caused by national differences in allowable uses of pesticides and allowable levels of pesticides on food products), build national regulatory/scientific capacity, share the review burden and coordinate scientific and regulatory decisions on pesticides. The intended method of achieving this objective is to harmonize data requirements, test protocols, data submissions and study report formats, data review and risk assessment practices, regulatory decision-making and administrative processes and procedures in all NAFTA countries. There was a bilateral effort under the Canada-U.S. Trade Agreement (CUSTA) to initiate pesticide regulatory harmonization in the early 1990's. This effort was expanded to include Mexico in 1996 through NAFTA's Technical Working Group on Pesticides. Thus, the primary objective of the working group is to reduce trade barriers relating to pesticide regulation.

### Hot Topics

- Trade irritants such as differing registrations for controversial pesticides such as Lindane
- NAFTA pesticide label
- Lack of agenda on occupational health and safety
- Lack of agenda on children's health and risk

### Membership

The Pesticide TWG, which was officially established in 1996, is comprised of the Canada Pest Management Regulatory Agency (PMRA), the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP) and a consortium of Mexican agencies responsible for pesticide regulation, called Commission Intersecretarial para el Control del Proceso y Uso de Plaguicidas, Fertilizantes y Sustancias Toxicas (CICOPLAFEST). Industry groups and NGOs may attend meetings and participate. While few public interest groups have had the resources to attend meetings which take place in the three NAFTA countries, there is a more formal role for achieving industry input into the discussions. In June 1998 the NAFTA Industry Technical Working Group on Pesticides was established. The Industry Technical Working Group includes representatives of the three national pesticide industry associations: Crop Protection Institute, Canada, CropLife America, and *Asociacion Mexicana de la Industria Fitosanitaria* (AMIFAC) of Mexico. These organizations represent pesticide developers, manufacturers, formulators and distributors. Examples of some of the members of the American trade group include Monsanto Company, BASF Corporation and Dupont Crop Protection.<sup>3</sup>

## Governance

The full Pesticide TWG meets once per year and a detailed progress/status report on its activities is published every six months. The Pesticide TWG has established Technical Subcommittees in four areas. The first, the Joint Review of Pesticides develops review programs to facilitate routine sharing of the pesticide regulation work. The second, Food Residues, creates a process for establishing North American MRLs or tolerances for pesticide residues on food, thereby helping to reduce agricultural impediments to trade. Third, Risk Reduction coordinates work on alternative approaches to pest management, including facilitating access to biopesticides through harmonization of data requirements and joint reviews and supporting integrated pest management. Finally, the fourth, Regulatory Capacity Building, works on projects which contribute to the infrastructure necessary to achieve work sharing and creating a North American market for pesticides.

## Transparency

EPA has done a superior job of making the activities of this NAFTA TWG accessible to the public than other U.S. agencies involved in NAFTA TWGs. EPA maintains a public docket on NAFTA TWG activities, occasionally places finalized NAFTA guidance documents in the Federal Register for public comment, and maintains a list serve for interested parties. However, EPA does not regularly have public meetings in advance of NAFTA TWG meetings and therefore does not give interested parties who cannot afford to fly to TWG meetings systematic input into the negotiations. Only a few public interest groups such as the World Wildlife Fund of Canada and the U.S.-based Farm Worker Justice Fund have occasionally participated in Pesticide TWG meetings. The Pesticide TWG posts all meeting reports and proposals on its web site.

## U.S. Point of Contact

U.S. Environmental Protection Agency, Government and International Services Branch, Field and External Affairs Division, Office of Pesticide Programs (7506 C), Ariel Rios Building, 1200 Pennsylvania Ave. NW, Washington, D.C. 20460, Phone: (703) 308-9359, Fax: (703) 305-1850, E-mail: [soltero.vera@epamail.epa.gov](mailto:soltero.vera@epamail.epa.gov), Website: [www.epa.gov/oppfead1/international/naftatwg/](http://www.epa.gov/oppfead1/international/naftatwg/)

## Organization for Economic Cooperation and Development

[www.oecd.org](http://www.oecd.org)

The Organization for Economic Cooperation and Development (OECD), founded in 1961, is a Paris-based organization made up of 30 of the world's most developed nations. OECD's membership consists of the wealthiest countries in the world, providing two-thirds of the world's goods and services. Although not a classic standard-setting institution, nor open to membership by all WTO nations, its research, publications and policy formulation are highly influential on debates in the WTO and many other multilateral institutions. Specifically, OECD focuses on issues such as trade, macroeconomics, education, employment, energy, electronic commerce, biotechnology and food safety. The OECD is also known for developing what is termed, "soft law," which are non-binding instruments. In total, OECD publishes approximately 250 reports and statistical analyses a year.

## Hot Topics

- Biotechnology
- Competition policy
- Environment and trade
- Finance and investment
- Money laundering
- High production volume chemicals


### Membership

Any country that seeks to gain admission to OECD must conform to the OECD ideology, which includes a commitment to an open market economy, democratic pluralism and human rights. A country seeking admission to the OECD must provide its position to the OECD Secretariat and Committees on the 160 Decisions, Recommendations Codes and Declarations adopted within the OECD, stating whether it is willing to apply them in its own country. OECD has a formal structure for representation of business, (BIAC), and labor/trade unions, (TUAC), who have permanent representations at the OECD in Paris, and automatic Observer Status on all the OECD working committees. There is no such formal, criteria-based structure for other civil society stakeholders, such as environment, consumer groups or academic institutions. Each OECD committee decides on its own whether to incorporate such stakeholders. Participation in selected consultations, workshops or conferences is more common than a permanent seat at the table during committee sessions.

### Governance

The OECD is headed by the Council, which is composed of one representative of each member country, as well as a representative of the European Commission. The Council holds the decision-making power and meets once a year. Specialized committees meet to discuss ideas and review progress in more specific areas, such as economic policy, trade, science and technology, development assistance or financial markets. There are about 200 committees, working groups and expert groups in the OECD. The Secretariat supports the work of these groups by providing research and analysis on specific issues. The Secretary-General chairs the Council and serves as the liaison between the national delegations and the Secretariat.

### Process

OECD's work includes data collection and analysis and discussion of a wide variety of issues. Most of the material accumulated is then collected and analyzed at the OECD by its more than 2000 employees and used to develop policy and internationally agreed instruments, decisions and recommendations. Each committee proposes a work program, which is then approved by the OECD Council. The work programs reflect the priorities of member governments or other bodies such as the G8. In addition, the OECD also produces conventions such as the 1999 Convention on Combating the Bribery of Foreign Officials. Such conventions must be ratified and implemented by nations utilizing their domestic processes. Finally, in certain OECD issue areas, OECD has developed a standards-like process. For instance, the OECD's Global Initiative on High Production Volume Chemicals (HPV) is an industry-backed effort to collect and assess health and environmental data on hazardous chemicals about which little is known. The OECD program focuses on "high production volume chemicals" (those produced or imported at levels greater than 1,000 tons per year). A voluntary program with working groups comprised of industry and government representatives, HPV has only resulted in complete information for a small number of chemicals since the program's inception in 1998. While not a standard-setting  in the classic sense, the OECD chemicals program has been pointed to as the prevailing international standard in the context of the dispute over a new proposed chemicals policy in Europe called REACH.

### Transparency

Occasionally, OECD does use its website to invite public comment on policies being discussed, but this is not required or standard operating procedure. Most OECD publications must be purchased through its website, while a small number of documents may be accessed for free, but only when they are declassified. Many documents are classified and only available to governments while work is in process.

### Funding

The OECD is funded by its member countries. The amount of the contribution is based upon the size of the country. Additionally, countries may contribute to specific programs or projects of interest.

## U.S. Point of Contact

Dozens of U.S. federal agency officials participate in OECD meetings, working groups and events. In addition, OECD maintains an office in Washington DC. OECD Washington Center, 2001 L Street, N.W., Suite 650, Washington, DC 20036-4922, Phone (202) 785-6323 Website: [www.oecdwash.org/](http://www.oecdwash.org/)

## World Forum for Harmonization of Vehicle Regulations (WP.29)

[www.unece.org/trans/main/welcwp29.htm](http://www.unece.org/trans/main/welcwp29.htm)

The World Forum for Harmonization of Vehicle Regulations, also known as Working Party 29 (WP.29), an intergovernmental body located in Geneva, Switzerland, was first established in 1952 as the Working Party on the Construction of Vehicles. It was housed in the UN Economic Commission for Europe (UNECE) and focused on auto and road safety standards in Europe. WP.29 is responsible for two mutual recognition agreements, referred to as the 1958 Agreement and the 1998 Agreement. The purpose of the 1958 Agreement is to establish mutual recognition of governmental certifications based upon the UNECE regulations, while the purpose of the 1998 Global Agreement is to internationally harmonize the regulations. A total of 112 regulations have been published under the 1958 agreement. The 1998 Global Agreement formally expanded WP.29 to include non-European members and gave the organization new tasks to develop globally-harmonized vehicle standards. Under the terms of the Global Agreement, any party that joins a consensus vote for the establishment of a new harmonized standard must initiate the process for adopting the harmonized standard into its own domestic legislation – a unique and powerful harmonization mandate.

## Hot Topics

- Heavy-duty diesel emission test cycles
- Tire noise testing methods
- Pedestrian protection
- Vehicle crashworthiness
- Child restraints
- Airbags

## Membership

All nations that are members of the UNECE or the UN and any regional economic integration organization set up by the UN are eligible for participation in WP.29. However, many developing countries are not represented due to inadequate domestic infrastructure and funding. In order for a country to become a party to the Global Agreement, it must sign, accept or accede to the agreement using its domestic process for ratification. International NGOs and industry representatives may participate in WP.29 in a consultative capacity if they have been accredited and granted consultative status by the Economic and Social Council of the UN. This enables them to serve as experts, advisers and consultants to governments and the Secretariat. For example, Consumers International and ANEC are public interest NGOs with consultative status. Industry organizations such as the Association of European Wheel Manufacturers and the International Organization of Motor Vehicle Manufacturers also have consultative status.

## Governance

The work required to develop standards is undertaken by the Working Parties of Experts which is comprised of six government and industry representatives. This group of Working Party Experts deals with a variety of issues including noise (GRB), pollution and energy (GRPE), brakes and running gear (GRRF), lighting and light-signaling (GRE), passive safety (GRSP), and general safety (GRSG). The Global Agreement also sets up an Executive Committee, made up of governmental representatives of all contracting parties, which has the final word on all standards. The UNECE Secretariat provides administrative support for all WP.29 sessions which are held three times a year. The coordination of work is managed by a steering committee, entitled the Administrative Committee for the Coordination Work (WP.29 AC.2) which is also staffed by governmental representatives.

### Process

The first step in the development of a new regulatory standard under the Global Agreement is the submission of a written proposal by a country who is a party to the agreement to the Administrative Committee for the Co-ordination Work. If the proposal is consistent with WP.29's criteria for safety, environmental protection and anti-theft mandates and its permanent program of priorities, it is placed on a work agenda. Thereafter, it is assigned to the appropriate Working Party of Experts, which will address the development, harmonization or amendment of regulations. The Working Party of Experts then submits a final recommendation for a new, harmonized or amended regulation to the Executive Committee which determines whether the regulation comports with the objectives of the Global Agreement. The Executive Committee must vote and if a consensus is reached, the standard is established and published in a Global Registry.

### Transparency

There is no process for accepting public comment into the work of WP.29 unless one is developed domestically. In the United States, draft WP.29 standards and notices of meetings are published in the Federal Register by the National Highway Traffic and Safety Administration (NHTSA) and EPA for public comment while they are under negotiation or under consideration for adoption as a U.S. standard. In 1998, NHTSA published a policy on how it will engage in international harmonization activities within WP.29 and the process by which the public can have input.<sup>4</sup> Meetings of WP.29 and subsidiary bodies are open to the public. However, individuals may not participate or act in a consultative capacity without accreditation. WP.29 standards are available free of charge on the UNECE website listed above.

### Funding

The UNECE is funded by member countries through the UN system from UN dues.

### U.S. Point of Contact

Director of International Policy and Harmonization, National Highway Transportation Safety Administration, Room 5208, 400 Seventh Street, SW, Washington DC 20590, Phone: (202) 366-2114, Fax: (202) 366-2559, Web Site: [www.nhtsa.dot.gov/cars/rules/international/Adopt/](http://www.nhtsa.dot.gov/cars/rules/international/Adopt/),

Office of Air and Radiation, Environmental Protection Agency, Ariel Ross Building MC 610 3A, 1200 Pennsylvania Avenue, NW, Washington DC 20460, Phone: (202) 564-1679, Fax: (202) 564-1554, Website: [www.epa.gov/air/](http://www.epa.gov/air/)

### World Health Organization

[www.who.int](http://www.who.int)

The World Health Organization (WHO), located in Geneva, Switzerland was established in 1948. It is a UN organization, the purpose of which is the attainment by all people of the highest level of health. WHO defines health as "a state of complete physical and social well-being and not merely the absence of disease or infirmity."<sup>5</sup> WHO facilitates the achievement of this objective by using a variety of measures including directing and coordinating governmental, health and safety authorities on international health work, assisting governments in strengthening health services, stimulating work to eradicate epidemic, endemic and other diseases and promoting research in particular fields of health.



## Hot Topics

- Bioterrorism
- Essential medicines
- Tobacco convention
- Disease eradication
- Environmental pollution
- Avian flu

## Membership

WHO membership is open to all states. There are two types of membership – Full Membership and Associate Membership. Associate Members do not have the right to vote within the Assembly, but may vote and hold office in other committees and sub-committees of the Assembly. An NGO may be admitted into “official relations” with WHO if the organization is international in nature and does work that is health-related and not of a commercial or profit-making nature. In order to be admitted into official relations with WHO, the NGO also must have the same purposes and principles of WHO relating to the health field, a constitution or similar document and governing structure and must have had at least two years of successfully completed working relations. In rare instances, a non-international NGO may enter into official relations with WHO if the major part of its work is related to international health, or if it has a program of collaborated activities with WHO and WHO wishes to draw upon its expertise. An NGO with official relations does not have the right to vote, but has the right to appoint a representative to participate in WHO’s meetings and committees.

## Governance

The World Health Assembly is the primary decision-making body for WHO. WHO is headed by the Director General. The Assembly determines policies of the organization, appoints the Director General, supervises the financial policies of the organization and reviews and approves the proposed program budget. Additionally, the Assembly has the authority to adopt conventions or agreements with respect to any matter within WHO as well as the ability to adopt rules concerning sanitary and quarantine requirements, nomenclatures related to diseases, cause of death and public health practices, standards for diagnostic procedures, standards relating to pharmaceuticals in international commerce and advertising and labeling of pharmaceuticals. The Secretariat, comprised of health and other experts and support staff, conducts the administrative work. An Executive Board’s duty is to give effect to the decisions and policies of the Assembly, to advise and facilitate the work at WHO. The Assembly meets once annually and for special sessions, as necessary.

## Process

Proposals for new activities to be undertaken by WHO are placed on the agenda before the annual session. The Director-General must report to the Assembly on the technical, administrative and financial implications of all items on the meeting agenda. No proposal may be considered absent these reports. Copies must be sent to all of the Members and Associate Members, representatives of the board and intergovernmental organizations and appropriate reports and documents are sent to NGOs with official relations. All decisions concerning the consideration of WHO conventions, agreements and approval agreements bringing WHO into relation with the UN and inter-governmental organizations require a two-thirds majority vote of the members of the Assembly present and voting. WHO rarely negotiates binding legal conventions, but did so in 2003 with the Framework Convention on Tobacco Control. The United States is a signatory to this convention, but has not yet ratified the convention. In addition, a diversity of subdivisions of WHO develop materials that could be considered international standards. For example, the Assembly has developed conventions specific to pertinent health topics such as its Essential Drugs and Medicine Policy, which provides global guidance on essential drugs and medicines and addresses the implementation of national drug policies that ensure equal access to essential drugs, drug quality and safety and rational use of drugs. This is done through the dissemination of global guidance materials, including operational research, management tools, training materials and training programs, and through technical advice and support to national governments and NGO’s. More information about WHO Essential Drugs and Medicines including the list of essential medicines and related standards such as those for ensuring quality, safety and efficacy of medicines can be found at: <http://www.who.int/medicines/>.

### Transparency


WHO has established a Civil Society Initiative in an effort to respond to the growing number of NGOs interested in working with the organization. The purpose of the initiative is to initiate more effective collaboration, information exchange and dialogue with Civil Society Organizations. WHO's global guidance documents and standards are generally available free of charge on its website.

### U.S. Point of Contact

Office of Global Health Affairs, U.S. Department of Health and Human Services, 200 Independence Ave., S.W. Room 639 H, Washington, D.C. 2020, Phone: (202) 690-6174, Fax: (202) 690-7127, Website: [www.globalhealth.gov](http://www.globalhealth.gov)

### World Intellectual Property Organization

[www.wipo.int](http://www.wipo.int)

The World Intellectual Property Organization (WIPO), located in Geneva, Switzerland, is a UN organization established for the purpose of ensuring the rights of creators and owners of intellectual property. WIPO is an intergovernmental body that was founded in 1970 and became a specialized agency of the UN system of organizations in 1974. Among the tasks that WIPO undertakes, is the administration of 23 international treaties and monitoring of international intellectual property developments. United States industry frustration with WIPO's inability to effectively enforce its treaties and conventions lead to the U.S. government's push to establish an Agreement on Trade Related Intellectual Property Rights (TRIPs) within the WTO in the mid-1990s and even more expansive intellectual protections in NAFTA. The WTO TRIPs agreement contains binding international intellectual property rules backed by the powerful and self-executing dispute resolution system of the WTO, making it the premier intellectual property agreement in the world. TRIPs incorporates many WIPO entions by reference.

### Hot Topics

- Scope of patent protection
- Enforcement of intellectual property rights
- Protection of traditional knowledge, folklore and access to genetic resources
- Trademark protection for domain names

### Membership

Membership is open to any UN country that abides by the WIPO bylaws. In addition, more than 170 international NGOs, mostly industry associations, have Observer Status, but no vote. International NGOs may obtain permanent Observer Status, provided that they submit reams of documentation regarding articles of incorporation, membership, and objectives. There is no method for individuals to participate in the development of WIPO standards.

### Governance

The highest governing body of WIPO is the General Assembly, which consists of representatives from all of the member states and meets once every two years. The General Assembly approves measures concerning international agreements, appoints the Director General and reviews and approves all of reports submitted by the Director General. The General Assembly makes its decisions by a supermajority vote. WIPO is additionally governed by the Conference, which consists of delegates from member countries. The Conference adopts the budget, approves applications for Observer Status and adopts amendments to the convention. The International Bureau is the Secretariat of the Organization and the Director General is the Chief Executive. Currently the WIPO Standing Committee on the Laws of Patents is involved in an effort to harmonize the patent laws of different nations of the world. The effort would result in a treaty which would allow for uniform treatment of patent applications and patent grants.

## Process

In total, WIPO houses approximately 23 treaties, each with a unique process for approval and amendment. The approval of measures concerning the administration of intellectual property international agreements requires a supermajority vote of the General Assembly.

## Transparency

WIPO standards are available online for a fee. The general public has no opportunity to comment on WIPO matters unless a process is developed domestically. The United States is party to many WIPO treaties and conventions. In addition, the U.S. government has been involved in the WIPO Standing Committee on the Laws of Patent's effort to harmonize substantive requirements of patent laws which could result in changes to U.S. regulatory and legal requirements. The U.S. Patent Office has occasionally placed notices and requests for public comment on these negotiations in the Federal Register, but has not used the Federal Register to any great extent to incorporate the U.S. public in WIPO activities.

## Funding

WIPO is primarily self-financed, deriving approximately 90% of its income from international intellectual property registration and other services.

## U.S. Point of Contact

International Liaison Staff, U.S. Patent and Trademark Office, Alexandria, VA 22313, Phone: (703) 308-6853, Website: [www.uspto.gov/web/offices/pac/dapp/ilsmain.html](http://www.uspto.gov/web/offices/pac/dapp/ilsmain.html)

## **ANNEX A: U.S. CONTACTS FOR NAFTA TECHNICAL WORKING GROUPS**

There are dozens of committees and working groups established under NAFTA, which work on harmonizing rules and procedures between the three NAFTA nations. The U.S. government has failed to make even basic information available about these committees or their U.S. contact points via the Federal Register or the internet. As an annex to this document we make available for the first time a list of NAFTA Technical Working Groups (TWGs) and their contact persons. Only one U.S. agency has worked to keep the public apprised of its NAFTA harmonization activities – the U.S. Environmental Protection Agency which coordinates activities for the TWG on Pesticides. The activities of the TWG on Pesticides is discussed at length above. Below we list the U.S. contact person for the other NAFTA TWGs, no other information is publicly available about the work of these groups.

**U.S. NAFTA Coordinator:** John Melle, Office of the Americas, Office of the U.S. Trade Representative, 600 17th Street, N.W., Washington, D.C. 20508

Land Transportation Standards Subcommittee (Article 913(5)) and Annex 913.5.a-1	Contact: Mr. David DeCarme U.S. Department of Transportation 400 7th St., S.W. Washington, D.C. 20590
Telecommunications Standards Subcommittee (Article 913(5)) and Annex 913.5.a-2	INACTIVE
Automotive Standards Council (Article 913(5)) and Annex 913.5.1-3	<p>Chair: Ms. Julie Abraham Office of International Harmonization National Highway Traffic Safety Administration Room 5220-NOA-05 U.S. Department of Transportation 400 Seventh Street S.W. Washington, D.C. 20590</p> <p>Chair: Mr. Ken Feith U.S. Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Avenue, NW Washington, DC 20460</p> <p>Contact: Mr. Martin Koubek National Highway Traffic Safety Administration U.S. Department of Transportation 400 Seventh Street, S.W. Washington, D.C. 20590</p>
Subcommittee on Labelling of Textile and Apparel Goods (Article 913(5)) and Annex 913.5.1-4	Chair/Contact: Ms. Caroyl Miller Office of Textiles Office of the U.S. Trade Representative

	600 17th Street, N.W. Washington, D.C. 20508
Committee on Small Business (Article 1021)	INACTIVE
Financial Services Committee (Article 1412)	Contact: Mr. Wilbur Monroe U.S. Department of the Treasury 1500 Pennsylvania Avenue, N.W. Washington, D.C. 20220
Advisory Committee on Private Commercial Disputes (Article 2022(4))	Chair / Contact: Mr. Jeffrey Kovar Office of the Legal Advisor U.S. Department of State Washington, D.C. 20520
<b>Working Groups</b>	
Working Group on Rules of Origin (Article 513)	Chair/Contact: Mr. Kent Shigetomi Office of the Americas Office of the U.S. Trade Representative 600 17th Street, N.W. Washington, D.C. 20508
Customs Subgroup (Article 513(6))	Chair/Contact: Ms. Cathy Saucedo Customs and Border Protection Department of Homeland Security 1300 Pennsylvania Avenue, NW Washington D.C. 20229
Working Group on Agricultural Subsidies (Article 705(6))	INACTIVE
Bilateral Working Group on Agricultural Grading and Marketing Standards (U.S.-Mexico) (Annex 703.2(A)(25))	INACTIVE
Working Group on Trade and Competition Policy (Article 1504)	INACTIVE
Temporary Entry Working Group (Article 1605)	Chair: Ms. Jacquelyn Bednarz Border and Transportation Security U.S. Department of Homeland Security
Working Group on Emergency Action (Established by the Supplemental Agreement on Import Surges under Article 2001(2)(d))	INACTIVE
Working Group on Government Procurement (Established by the NAFTA Trade Ministers on January 14, 1994)	Chair/Contact: Ms. Jean Grier Office of WTO and Multilateral Affairs Office of the U.S. Trade Representative 600 17th Street, N.W. Washington, D.C. 20508

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<p>Working Group on Services and Investment (Established by the NAFTA Trade Ministers on January 14, 1994)</p>	<p>INACTIVE</p>
<p>Investment Experts Group</p>	<p>Chair/Contact: Mr. David Weiner Office of Services, Investment and Intellectual Property Office of the U.S. Trade Representative 600 17<sup>th</sup> St. N.W. Washington, D.C. 20508</p>
<p>Article 10(6) Committee</p>	<p>Co-Chair: Mr. Mark Linscott Assistant U.S. Trade Representative for the Environment And Natural Resources Office of the U.S. Trade Representative 600 17th Street, N.W. Washington, D.C. 20508</p> <p>Co-Chair: Mr. Jerry Clifford Deputy Assistant Administrator for International Affairs U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460</p> <p>Contact: Ms. Darci Vetter Office of Environment and Natural Resources Office of the U.S. Trade Representative 600 17th Street, N.W. Washington, D.C. 20508</p> <p>Contact: Mr. Kent Shigetomi Office of the Americas Office of the U.S. Trade Representative 600 17th Street, N.W. Washington, D.C. 20508</p>

## **ENDNOTES**

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<sup>1</sup> Mary Bottari, Public Citizen, interview with Chris Nelson, FDA re: GHTF Aug 7, 2003.

<sup>2</sup> International Organization for Standardization, About ISO, Introduction, "Why Standards Matter," Sept. 5, 2003 available at: <http://www.iso.org/iso/en/aboutiso/introduction/index.html#two>.

<sup>3</sup> A USDA database for a comparison of the tolerances for 43 countries is being created with a grant to CropLife.

<sup>4</sup> 49 CFR §553.

<sup>5</sup> Preamble to the Constitution of the World Health Organization (1946) available at: <http://www.who.int/msa/qol/q1.htm>.