



2008 Open Forum for
Standards Developers



NIST

**National Institute of
Standards and Technology**
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Intersection of Standards and Public Policy

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Current Cases and Actions

Setting the Stage

Relationship between standardization and public policy

- ❑ Voluntary standards have long served to support public policy initiatives
 - Examples: medical devices and environmental protection

- ❑ Public sector reliance on voluntary standards is highlighted in law and policy
 - National Technology Transfer and Advancement Act
 - *United States Standards Strategy*

- ❑ There has been a steady increase in the number of new fields of standardization that have a public policy impact

Cases of Concern

- ❑ U.S. stakeholders have recently raised concerns regarding three specific cases:
 - ISO Social Responsibility Standard
 - ISO Exploration of New Opportunities for Biotechnology Standardization
 - ANSI-Accredited SDO the Leonardo Academy and the Sustainable Agriculture Draft Standard for Trial Use (DSTU)

- ❑ Though there may be some overlap of stakeholders, the concerns in each case are unique and require different solutions



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Case Study One: Social Responsibility

A WG reporting to the ISO/TMB
is developing an ISO standard on SR (WGSR)

ISO Social Responsibility Standard

U.S. Stakeholder Concerns

- ❑ Globally, participation in the WGSR is very broad
- ❑ Concerns about both process and content have been expressed by members of the U.S. TAG as well as non-TAG members
 - All stakeholder categories have concerns about WGSR processes
 - Government and industry stakeholders have particular concerns about the proposed content of the standard

ISO Social Responsibility Standard

U.S. Stakeholder Concerns (continued)

□ Examples

- Some content reinterprets or misrepresents international trade policy, international law and international treaties
- Some content seeks to drive the direction of public policy globally, including areas such as Genetically Modified Organisms (GMOs)
- Concern with effective WGSR transition from stakeholder expert positions at the working draft stages to national body positions at the approval stages
- Concern with how the WGSR is handling expert comments and addressing issues pertaining to transparency, documentation and accountability

ISO Social Responsibility Standard

ANSI actions to address concerns

- The U.S. TAG to the WGSR is submitting comments on drafts of the ISO SR standard to ensure that priority areas of concern from each stakeholder category are addressed and that resolution is attempted within the WGSR commenting processes
 - Networking with other countries to gain support for our concerns
- ANSI and other ISO/TMB representatives are working constructively with the WGSR leaders to identify and resolve priority concerns
 - Targets: July 2008 WGSR CAG meeting
 September 2008 WGSR meeting

ISO Social Responsibility Standard

ANSI actions to address concerns (continued)

- ISO Council has accepted an ANSI proposal to develop a set of principles that would serve as ISO's formal posture for its standards relative to public policy initiatives
 - ISO/TMB and IEC/SMB have agreed to form a joint group to further develop these principles
 - The goal is to produce a recommended document for approval at fall 2008 TMB and SMB meetings

ISO Social Responsibility Standard

DRAFT Principles

- The intent of the proposed ISO principles is two-fold:
 - To provide direction and guidance to ISO committees that are drafting standards that relate to public policy to enhance consideration, acceptability and use of the standards by public authorities.
 - To ensure consistent messaging for external communications and promotion.

ISO Social Responsibility Standard

DRAFT Principles (continued)

□ Context

- ISO can be an effective provider of standards that support public authorities
- ISO is not directly representative of government interests
- ISO reflects agreement across a range of stakeholders at the standard drafting level and at the national body position level

□ Implementation

- ISO committees, leaders and participants should actively support and promote the WTO/TBT principles
- NSBs should ensure that government representatives are aware of ISO's portfolio and are engaged in ISO standards development whenever appropriate

ISO Social Responsibility Standard

DRAFT Principles (continued)

- ❑ **ISO committees** shall create standards based on solid technical input; these standards shall provide credible technical tools that can support the implementation of regulation and public policy initiatives.
- ❑ **ISO committees** in their work shall not assume roles appropriate to governments. The development of regulation, public policy and/or the development and interpretation of international treaties are properly the role of governments or treaty organizations.
- ❑ **ISO standards** shall not seek to establish regulations or public policies, nor shall they seek to drive or motivate social and political agendas.
- ❑ **ISO standards** supporting regulation and public policy are best developed within ISO structures and under operational approaches and participation models that have been proven successful and that are detailed in the ISO directives. The use of special committee structures, processes or participation models may compromise the credibility and suitability of the resulting ISO standards supporting regulation and public policy.



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Standards Developers

Case Study Two: Biotechnology

ISO Council's Standing Committee on Strategies (ISO CSC/STRAT) is conducting an examination of possible opportunities for ISO standardization in the field of biotechnology

Biotechnology Standardization

U.S. Stakeholder Concerns

- ❑ On January 10 and March 31, 2008, ANSI convened meetings for U.S. stakeholders regarding ISO standardization discussions pertaining to biotechnology
- ❑ Stakeholders have expressed to ANSI that ISO's consideration of biotechnology standardization needs to:
 - exclude agricultural applications*
 - give proper consideration to, and avoid duplicating or conflicting with, existing standards serving global needs

*Rationale:

There have been years of highly politicized, problematic and difficult international trade negotiations related to agricultural food products.

Biotechnology Standardization

ANSI actions to address concerns

□ **By June 30, 2008**

Collection of U.S. stakeholder input on:

- existing biotechnology standards,
- the possible scope of ISO's biotechnology exploration and the prospects for ISO standards, and
- relevant international organizations with which ISO should consult on this subject.

□ **Tuesday, July 8, 2008**

ANSI meetings to review input and begin developing the ANSI positions and input to ISO. Also, development of strategies for networking with other countries to gain support.

Biotechnology Standardization

ANSI actions to address concerns (continued)

- ❑ **By Monday, August 1, 2008**
Completion of draft ANSI positions and input to ISO

- ❑ **Monday, August 4, 2008 through Friday, September 5, 2008**
Networking with contacts in other countries to gain support

- ❑ **Tuesday, September 9, 2008**
ANSI meetings to fine-tune ANSI positions and input based on information gathered networking with other countries

- ❑ **October 14 & 18, 2008**
Joe Bhatia advocates ANSI positions and input at the ISO meetings



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Case Study Three: Sustainable Agriculture

Leonardo Academy,
an ANSI-Accredited Standards Developer,
has announced a Draft Standard for Trial Use
on Sustainable Agriculture

Sustainable Agriculture

Definition: DSTU

- A Draft Standard for Trial Use (DSTU) is
 - governed by Annex B of the *ANSI Essential Requirements*
 - a preliminary document, subject to change
 - not an American National Standard (ANS)

- If a DSTU is eventually submitted to ANSI for approval as an ANS, it:
 - must satisfy all defined requirements for DSTUs, as well as
 - *ANSI's Essential Requirements* for openness, adequate notification, balance, due process and consensus.

Sustainable Agriculture

U.S. Stakeholder Concerns

- ❑ Many stakeholders in the sustainable agriculture industry have contacted ANSI to voice their concerns about the content of the DSTU and to request that ANSI intervene to modify or halt the standards development activity

- ❑ Concerns address both process and content issues, such as:
 - Inadequate notice to stakeholders
 - Lack of opportunity to contribute to the drafting of the DSTU before it was announced as such
 - Content is overly broad
 - Equates sustainable with “organic”
 - Rejects the use of biotechnology

Sustainable Agriculture

ANSI actions to address the concerns

- ANSI is responding to concerned stakeholders
 - Explaining the integrity of the process and encouraging respect for the procedures
 - Encouraging all interested stakeholders, including policy makers, to submit their written comments to the Leonardo Academy
 - Explaining the appeals process
 - An appeal must first be conducted and concluded at the Leonardo Academy before it may be filed with ANSI
 - As appropriate, multiple opportunities to appeal to ANSI exist after appeals to the Leonardo Academy have been concluded

Conclusions

- ❑ There has been a steady increase in the number of new fields of standardization that have a public policy impact
 - At both the national and international levels
- ❑ Some of the new fields present challenges to stakeholders that are outside of the historical ANSI constituencies
 - Both private sector and government
- ❑ ANSI is committed to maintaining the integrity of the U.S. standards system and to addressing challenges in a proactive manner