TACD

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PRINCIPLES OF HARMONIZATION

International harmonization can occur at the lowest or highest level of public health, worker safety, or environmental protection. However, the TACD strongly believes that in the instances when international harmonization of standards is appropriate, it must result in the adoption of best available technology and embody the highest levels of consumer protection. Unfortunately, the actual provisions of the WTO requiring harmonization or providing incentives for harmonization generally promote the lowering of the best existing domestic public health, food safety, economic justice, natural resource conservation and product safety standards. For instance, under the WTO, international standards do not serve as a floor that all countries must meet. Rather, they serve as a ceiling. 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 lax standards. Thus, as outlined in its position paper in preparation for the Seattle Ministerial, the TACD is concerned that as currently written, the permanent WTO agreements and provisions will serve only as a one-way downward ratchet on domestic standards. In the wake of Seattle, TACD affirms that the review and repair of the WTO's Technical Barrier to Trade Agreement and the Sanitary and Phytosanitary Agreement is an urgent priority that is more attainable than ever.

Principles for International Harmonization:

1. **Standards that do not have a health and safety component should be the primary candidates for international harmonization.** We must distinguish between standards and procedures that do not directly involve health and safety concerns (i.e. the size of a floppy disk, credit card, or customs and accounting procedures) and those that impact health and safety (i.e. auto standards, medical device standards, and allowable pesticide residues in food.). Many standards, like pesticide residues, are impacted by factors such as cultural norms, dietary intake which make a "one size fits all" standard hard to achieve.

2. **Some issues must remain outside the scope of international commercial rules altogether.** We reject the movement fostered in the WTO to turn basic necessities or elements of life (like genetic materials) into commodities. Rather they should be recognized as common goods and precious resources for government to protect, distribute and regulate. For example, we reject the commodification of bulk water, and the patenting of life forms and seeds.

3. **TACD favors international standards being used as a floor rather than a ceiling.** The harmonization mechanisms in the TBT and SPS Agreements encourage the challenge of higher domestic standards but not the challenge of lower standards. The current

mechanism can only result in a ratcheting down of standards. At a minimum, the harmonization provisions of the SPS and TBT agreements need to be rewritten to ensure that the role of democratically-achieved international standards is not to discourage cutting-edge domestic innovations geared toward solving some of our most pressing problems.

4. **TACD is concerned about current WTO use of international standards in deciding disputes regarding health, safety and the environment**. TACD believes that international standards, while helpful in some contexts, should be voluntary and that the WTO SPS and TBT Agreements' current elevation of all such standards, regardless of the forum in which they are set or the level of protection provide, is inappropriate. For instance, international standards should not be used to undermine non-discriminatory domestic standards merely because those domestic standards provide a higher level of health, safety or environmental protection. TACD is particularly concerned at the practical application of international standards in the dispute resolution procedure. Not enough emphasis is being placed on the exception which allows nation states to adopt higher standards or requirements. This is compounded by the inability to challenge international standards themselves for not embodying a sufficiently high level of consumer protection.

5. **The Precautionary Principle should be incorporated more broadly in the international standards setting process**. Ironically, while the U.S. government challenges the EU beef hormone and genetically modified organisms (GMO) policies at the WTO, it undercuts the underlying basis for regulatory policy in the U.S. For example, the FDA's pharmaceutical safety rules, the burden of proof is on the producer to show a drug is safe. Until there is scientific evidence to make that showing, the drug is kept off the market. If a precautionary approach had been systematically applied, it might have prevented some of the recent and deadly food safety crises in Europe. Bringing such a principle to life is merely a matter of setting the right rules. The obvious test as to a standard's trade effect -- and the one that would have safeguarded the beef hormone policy -- is whether the measure is discriminatory as between domestic and foreign goods. The rule we demand is that standards based on the Precautionary Principle and applied equally to domestic and foreign producers are inherently permissible.

6. **Governments should only recognize or be involved in harmonization activities negotiated in open, accountable democratic fora**, with clear avenues for public input and transparent methods of rulemaking and record keeping. Non-transparent private industry groups for example, are not the place to be setting WTO-presumptively legal standards which impact public health, consumer safety or the environment. If differing regional and international standards are to be harmonized then this should take place within an open and transparent framework. This framework must allow for participation by consumer representatives at all levels and all stages of the standards-writing process. Greater co-operation between government officials is also required to agree on essential safety requirements, which should be applied to international standards. Provision should also be made for public and/or government review and possible challenge of the right of a particular international standard to give any presumption of compliance with legal requirements. Other, quasi-governmental organizations like the Codex Alimentarius must also be reformed to give consumers and equal voice with industry in the process.

7. **a. We reject the notion of functional equivalence**. In Europe, equivalency decisions have been a conspicuous failure that has eventually resulted in the writing of over 5,000 new European standards with some 8,000 more on the way. Standards provide a bright line test

whereby precise comparisons can be made. The very notion of equivalence allows for imprecise, subjective comparisons that are not appropriate when dealing with issues as important as public health and safety. However, given that equivalency decision between nations are moving forward with increasing frequency, we must develop strict rules for making equivalence determinations. A standard or a regulatory system should be determined equivalent only if it provides the same or greater level of substantive protection for health, safety or the environment. Criteria for determining equivalency should be clearly outlined and equivalency proposals should have substantive public input before they reached. (Thus, the NAFTA equivalence finding on Canadian beef that did not even review, much less compare, the varying regulatory systems and numerous standards, is unacceptable.)

b. Any equivalence decision or MRA must ensure that the procedural safeguards of the countries involved are equally strong -- meaning there is a democratic process that assures consumer input and redress and government enforcement. To this end we recommend readiness criteria under which potential MRA and equivalency agreement must be reviewed. We urge nations to adopt strong freedom of information provisions, on-the-record rulemaking procedures, laws providing for open meetings of governmental agencies and balance on advisory committees among other reform measures to encourage citizen input into trade-related and standards-related proceedings.

8. **Harmonization activities including MRAs and equivalency agreements are only ever appropriate if they enhance the well-being of the people of the nations involved**. If these agreements are not negotiated with the input of the citizenry and if there is not a clearly defined public benefit, there is no reason for governments to spend public resources to accomplish harmonization. The cost of harmonization which only benefits industry should be shifted back to the private sector to execute voluntary standards. (For example, the FDA estimates that the 1997 U.S.-EU MRA will cost them over $10 million and 125 full-time employees to implement.)

9. **We oppose the TABD's call for increased reliance on "suppliers declaration of conformity**," especially in sensitive areas including: public health, food, product and worker safety and the environment. Conformity assessment procedures are only one component of the framework which ensures that products actually comply with the appropriate standards. This framework includes the product liability regime and market surveillance in particular. The role that each of these components will play can legitimately differ from one jurisdiction to another. There is a danger that focussing on only one aspect i.e. conformity assessment will upset the balance of the whole framework. Some equivalency decisions and MRAs (i.e., 1997 U.S.-EU MRA on good manufacturing practices for pharmaceuticals) are leading to situations where one country is handing over federal regulatory authority to private entities in a second country. TACD believes it is entirely inappropriate to privatize key public safety functions via MRAs and equivalency decisions, even if national governments retain ultimate responsibility for the safety of products.