INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT

Comments on the Transatlantic Trade and Investment Partnership

Public Hearing before the US Trade Representative's Office, Trade Policy Staff Committee (TPSC) Washington DC

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The International Center for Technology Assessment was founded nearly twenty years ago to provide careful reviews of new technologies. The technologies that we are currently assessing include nanotechnologies and synthetic biology. We advocate that new technologies such as these should be governed by using regulations that are appropriate to the technology and take a precautionary approach when the science and data needed for precise regulation have not yet been well enough developed to adequately assess the environmental, public health, and social/economic effects of the new technologies.

We have worked with worldwide coalitions of environmental groups, consumer groups, scientific organizations, religious groups, labor unions and public health organizations to develop principles for the oversight of nanotechnology and synthetic biology. I am the US co-chair of the Transatlantic Consumers Dialogue Nanotechnology Taskforce. The Transatlantic Consumers Dialogue in June 2009 adopted the following principles for US-EU Nanotechnology Oversight:

"We urge the EU and US to convene intensive consultations among the relevant regulatory bodies on both sides of the Atlantic to exchange data and establish sound approaches to assessing and preventing risks. Regulatory systems regarding consumer and environmental protection must be updated in order to address the special characteristics of nanomaterials. The EU and US should take prompt action to address the following regulatory needs:

"1. Agree on definitions: It is crucial to ensure that there is agreement on definitions of what constitutes nanoparticles and other relevant nanotechnology-related terms so that lack of agreed definitions not further delay the establishment of effective regulation.

"2. Identify products: The EU and US should establish mandatory reporting schemes to keep track of the introduction into the marketplace of manufactured nanomaterials and exchange information obtained about products being introduced. In addition, the EU and the US should establish an extensive inventory of all current

and future nanomaterials used in products on the market. This inventory would have to be made publicly available.

"3. Develop testing methodologies adapted to nanoparticles: It is crucial to develop new testing methods and technology to adequately assess the safety of products containing nanoparticles, for both health and the environment, over the entire lifecycle of the product (including manufacturing, transport, product use, recycling and disposal). These methods ought to be adapted to the particular characteristics of each kind of nanoparticle.

"4. Address research gaps: The EU and US should direct and fund research into the extensive gaps in understanding about health and environmental risks, and coordinate their programs so as to make the most efficient use possible of available resources.

"5. Develop and adapt regulatory frameworks to address the special characteristics of nanomaterials:

This should include pre-market safety assessment and pre-approval of use of nanoparticles in consumer products to protect the public, workers, and the environment.

Both the EU and US need to establish regulatory frameworks that take into account the novel issues and risks presented by nanotechnologies and require the pre-market assessment and approval of substances and finished products that use manufactured nanoparticles. For some kinds of nano applications it may also be appropriate to obtain post-market assessment data to ensure product safety and efficacy. The nature and extent of the assessment may vary. For instance, products used on or in the body would require a full human health and environmental safety assessment. Other products, such as a washing machine containing nanomaterial, may require a more extensive environmental assessment.

These frameworks must be precautionary in nature and take into account the entire lifecycle of the material. Lack of data or evidence of specific harm cannot substitute for a reasonable certainty of safety. Safety data must be made transparent and available for public scrutiny. Regulatory approvals of products incorporating nanoparticles must state that their manufacturers retain liability for harm caused by the approved nanoparticles during the lifecycle of the product, in addition to being covered by general product liability law.

"6. Mandatory labeling: Consumer products containing nano-ingredients and with which consumers come in direct, close or regular contact must be labeled. Our call for mandatory labeling in protection of the public's fundamental right to know in no way vitiates or supersedes the need for full and mandatory pre-market assessment and, where appropriate, approval of nano-products. Mandatory labeling, at least until a coherent and effective policy approach is in place, would be consistent with governments' recognition of the public's right to know and of its obligation to assist consumer's ability to make meaningful choices, backed up by broader information about the issues raised by nanotechnologies. Moreover, product labeling facilitates documentation of potential environmental releases, human exposures, and accountability for adverse impacts. Labeling is a way that manufacturers can make information about in products available to the consumers. Consumer groups, likewise, can help consumers understand what it means when 'nano' is on the label of a product and why labeling is necessary.

"7. Regulate marketing claims: Frameworks are needed to ensure that claims made about the purported benefits of nanoproducts can be substantiated and independently verified. Governments should ensure that unverified claims are withdrawn and that these withdrawals are publicized. Governments should support a

center that collects and disseminates information to the public and especially the press about which products contain nanomaterials and what the nanomaterials are purported to accomplish in the products.

"8. The public should be consulted about their views on nanotechnologies not only concerning regulatory matters, but about governments' investments in and subsidies for nanotechnologies. The public's views should be meaningfully integrated into policymaking and the direction of research proceeding and informing policymaking.

"9. Governments should establish commissions to study the social and economic consequences of the displacement of existing industries and commodities by industries based in manufactured nanoparticles. Commissions to study ethical issues in nanotechnologies, e.g. uses of synthetic life forms in medicine and biofuels, should also be formed. Commission reports should inform the regulatory cost-benefit analysis and government decisions to invest or not in specific nanotechnologies."

ICTA is concerned that trade agreements should not under cut these principles through using arguments that that "Harmonization" of regulations is needed. In both the US and the EU, laws were not designed for the new kinds of products made possible by nanotechnologies. As we learn more about the special properties of nanomaterials, we are learning that we need to develop new regulations targeted to the properties of the nanomaterials. Even within the US federal regulatory agencies different definitions for what a nanomaterial are being used by the FDA, USDA, and the EPA. The US should not insist that Europe adopt a one-size fits all regulatory harmony when US agencies cannot and probably should not harmonize regulations. A nanomaterial being used as an antimicrobial in food contact substances can cause different health problems than the same material being used in bandages for diabetic patients and should be regulated accordingly.

Europe, moreover, is moving more quickly than the US in integrating new knowledge about nanomaterials into its existing regulatory structure. Efforts are underway to integrate nano chemicals into the major European regulatory chemicals law, REACH. Labeling of nano ingredients in cosmetics is already required in Europe, food labeling requirements are on the verge of the being implemented.

In the United States, amendments to the major US law regulating chemicals to include nanochemicals are delayed in the general re-write of the Toxic Substances Control Act. EPA's new regulations to control nano-pesticides have been held up by the White House Office of Management and Budget for the last two years. The US Department of Agriculture has not acted on the recommendations of the National Organic Standards Board that nanomaterials smaller than 300 nm should be excluded from organic products. The stalemate in the US regulatory process at the moment should not be forced on Europe through these negotiations. Nations should have adequate authority to regulate the health, worker safety and environmental aspects of these new chemicals even if their trading partners have a slower regulatory process.

Finally, we urge the texts of all of the negotiations related to nanotechnology and other emerging technologies such as synthetic biology, like other texts, should be made available for public scrutiny. The public deserves to know the particular elements of these agreements. Other negotiations that that include much detailed scientific material, such as the Codex Alimentarius negotiations are negotiated in the open so that public interest groups like ours can participate in the discussions, so should these agreements.