INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT

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Any Trade Agreement Should Result in Better Regulation of Chemicals, Including Nanomaterials and Not Undermine Efforts to Regulate Nanomaterials

Introduction

The EU and U.S. approach towards regulating chemicals based on the U.S. Toxic Substances Control Act (TSCA) and the EU REACH Regulation are quite different.

While REACH has considerable potential[1] to achieve a higher level of safety for consumers and the environment in the future, both systems ought to be improved as they currently fail to protect human health and the environment effectively[2]. Neither can adequately address nanochemicals as they both rely on weight limits to trigger regulation that are too large to capture most nanochemicals. Consumer organizations in the EU and U.S. are concerned that chronic and severe diseases such as cancer, allergies and asthma, as well as reproductive disorders, which may be linked to the exposure to hazardous chemicals, including nanochemicals, will further increase if all chemicals are not brought under control.

A common feature of both regulatory systems is also an insufficient capacity to adequately tackle emerging technologies such as synthetic biology and nanotechnologies. The International Center for Technology Assessment has been studying nanotechnology regulation since 2005. We identified a lack of coherent definitions, absence of adequate and agreed testing methodologies, research gaps and transparency for consumers as stumbling blocks to effective regulation for consumer safety.[3] We urged the EU and U.S. governments to develop and adapt regulatory frameworks which would ensure a pre-market safety assessment and pre-approval of use of nanoparticles in consumer products to protect the public, workers and the environment[4].

Since 2005, little has been achieved in the EU and the U.S. to ensure that nanoparticles and nanotechnologies are safe and beneficial to consumers. Although more and more consumer products containing nanomaterials appear on the market, there is neither pre-market safety testing of those products nor post-market surveillance to ensure they do not lead to new human health and environmental risks.

For example, REACH is currently failing to control nanomaterials as consumer products continue to enter the EU market with little or no information on their potential risks, thereby violating the principle "no data no market"[5]. Despite vocal criticism from the European Parliament concerning the insufficient regulatory approach of the European Commission, only marginal proposals, such as updating the REACH Annexes, are currently discussed and only a few products are subject to consumer labeling, namely food and cosmetics, and food labeling is not enforced yet.

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Recent drafts of revisions of the Toxic Substance Control Act in the U.S. have dropped provisions included in earlier drafts that would have provided better regulations for nanochemicals. The Federal Rodenticide, Insecticide and Fungicide Act should be used to regulate nanopesticides, but the EPA's new proposed regulations for nano pesticides have been delayed for more than two years by the Office of Management and Budget.

In this current situation of unresolved major public health issues that are linked to inadequate hazardous chemicals management, the EU and U.S. entered the current trade negotiations of the Transatlantic Trade and Investment Partnership (TTIP). These negotiations focus primarily on removal of non-tariff barriers to trade (NTBT) to increase market access. According to a European Commission econometric projection, "two thirds of the total GDP gains of TTIP" would result from an ambitious NTBT removal scenario."[6] As is customary in trade negotiations, only economic benefits, not costs, are estimated under further trade liberalization scenarios.

While we appreciate that trade negotiators hope to contribute to economic recovery, following the crisis triggered by the deregulation of financial services, it would be a major strategic error to negotiate TTIP chapters in sanitary and phytosanitary measures (SPS), technical barriers to trade (TBT) and regulatory coherence, in order to facilitate trade in the unregulated products of emerging technologies. "Light touch" regulation enabled the greatest economic crisis since the Great Depression: there is no reason to believe that "light touch" regulation for trade in the products of emerging technologies will result in consumer benefits. And the costs to public health, the environment and worker safety of the ongoing failure to regulate these products, while allowing their commercialization, could prove to be very high indeed.

The outcome of past trade negotiations rather suggests that a deal is made at the "lowest-common-denominator" and at a level which favors private interests of a few over public interests[7,8].

In March 2013, the TransAtlantic Consumer Dialogue (I am the U.S. Co-Chair of their Nanotechnology Policy Committee) stated that the TTIP must focus on consumer well-being. We voiced our skepticism that a trade partnership built around regulatory convergence will serve consumer interests. Moreover, we called on EU and U.S. policy makers to allow both trading partners the autonomy to adopt stronger non-discriminatory protection measures. With regard to emerging technologies, like nanotechnology, we emphasized that trading partners must be afforded discretion to regulation products of emerging technologies. Non-discriminatory regulations that meet the objectives of consumer protection and environmental or ethical protections, including those addressing labeling, should not be subject to threat of investor state lawsuit challenge under a Transatlantic Trade agreement[9].

1. **Ensuring public health and protecting consumers and the environment from exposure to hazardous chemicals, including nanochemicals, must remain the ultimate responsibility of governments, and not be compromised or qualified by TTIP commitments to removal of "trade irritants" such as NTBT rules.**

Industry often calls for regulation to be based on "sound science", ironically a public relations term used to justify the cigarette industry denial that smoking in the presence of others had harmful health effects.[10] While scientific evidence is an important factor to set appropriate regulatory requirements, we are concerned that with regard to emerging technologies such as nanomaterials and biotechnologies there is an urgent need to act on a preventive basis, even in the absence of final scientific evidence or due to uncertainties. It is important to underline that no evidence of harm is not the evidence of no harm.

Taking further urgently needed regulatory steps for public health prevention from harmful chemicals is needed, such as for example pre-market safety assessments and pre-approval of use of nanoparticles in consumer products to protect the public, workers and the environment. 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.

Recommendations:

- Policy makers on both sides of the Atlantic must retain the right to set the level of protection from hazardous chemicals and nanomaterials. This right to adopt more ambitious measures regarding health, safety and environmental protection should include the right for EU Member States and states of the U.S. to go beyond the regulator determined "appropriate level of protection" allowed in the WTO SPS Agreement.
- Both, the EU and U.S. need to establish regulatory frameworks which adequately take into account the novel issues and risks presented by nanotechnologies as well as the legitimate expectations of consumers regarding the products they use every day. These frameworks must be precautionary and take into account the entire lifecycle of the material.
- Pre-market safety assessments and pre-approval of use of nanoparticles in consumer products must become mandatory.
- Regulatory approvals of products containing nanoparticles must state that their manufacturers retain liability for harm caused by the approved nanoparticles during the lifecycle of the products, in addition to being covered by the general product liability law.
- Safety data must be made transparent and available for public scrutiny.
- Labeling of nanochemicals in consumer products is essential for consumer confidence and for tracking the use of nanochemicals for possible product recalls.

2. Products have to fulfill all applicable legal requirements

We emphasize that increased mutual market access must not undermine current human health and environmental protection standards.

With regard to safe use of chemicals in consumer products, the EU and U.S. follow different regulatory approaches. For example, the EU Cosmetics Regulation (EC 1223/2009)[11] prohibits 1.328 chemicals and lays down specific restrictions for a wide range of substances. By contrast, cosmetics marketed in the U.S. are barely regulated[12]. With regard to nanomaterials used in cosmetics, manufacturers in the EU are obliged to send a notification prior to marketing to the EU Commission. In case of safety concerns related to a nanomaterial, the EU Commission may adopt additional legal requirements. In the EU, consumers are informed about nanomaterials in cosmetics due to mandatory labeling in the list of ingredients. Similar provisions are missing in the U.S.

Recommendations:

- All consumer products have to fulfill as a minimum requirement the legislation which is applicable in the respective jurisdictions. In case one jurisdiction has rules in place which provide for a higher level of safety, we support allowing the jurisdiction to enforce stronger regulations for these products as their consumers will benefit.
- The EU and U.S. should not be forced to mutually recognize certain chemicals and nanomaterials as "safe" if they do not meet the safety standards of the other territory's regulations.

3. Agreeing on definitions is an important pre-condition for effective regulation

It is crucial to ensure that there is basic agreement on definitions of what constitutes nanoparticles and other relevant nanotechnology-related terms so that lack of agreed definitions does not further delay the establishment of effective regulation. The EU recommendation for the term "nanomaterial" which was published in 2011 has so far not been implemented in product specific legislation and is not binding. Hence, legal clarity is missing what "nanomaterials" are in cosmetics and food as well as in other consumer products. In the U.S., federal regulatory agencies (FDA, EPA and USDA) use slightly different definitions, but the "size" of nanomaterial to be regulated might be justifiably different for different applications.

Recommendations:

- The EU and U.S. should in the long term agree on common definitions for regulatory purposes, noting that it may be that slightly different definitions will be needed for drug applications that for food applications of nanotechnology:
  - which goes beyond a mere size range definition,
  - is based on number of particles rather than mass. One of the problems of REACH and TSCA is that they require rather large mass amounts before regulation. The approach of France and other EU nations that are attempting to track all producers of nanomaterials should be encouraged by any trade agreement.
  - includes internal structures such as aggregates and agglomerates,

- clarifies that all nanoparticles which are present in a material are covered by the definition and not only the ones that manufactures produce “intentionally”,
- which takes into account latest science.

- In the absence of a consensus regarding definitions, no jurisdiction should be forced to repeal their definition and all consumer goods would need to comply with those definitions which are a precondition for marketing products in the respective market.

4. Requiring better information on chemicals and nanomaterials and their effects is not a barrier to trade

Through REACH, the EU adopted substantial information requirements for manufacturers. As the REACH information requirements related to nanomaterials are not functioning well, some EU Member States have or are planning to complement REACH with mandatory reporting schemes for nanomaterials. Since 1 January 2013, the French scheme requires manufacturers, distributers and users of nanomaterials to notify authorities about the uses, quantities and condition of nanomaterials. The French authorities indicate apparently more than 1000 every day products contain nanomaterials (cosmetics, sport equipment, electronic products, construction materials, paints etc.)[13].

In the U.S., the EPA has been blocked by the Office of Management and Budget of the White House from issuing new regulations on nano-pesticides, but has begun a product by product “data call-in”, beginning with nano-silver, wherein it requests data from manufacturers on how they are using nano-silver. Other nano chemicals will be subject to such “data call-ins” later. The original regulations proposed by the EPA would be better than these “data call-ins”. The regulations would have made it mandatory for nano-pesticide manufacturers to send health and safety data to the EPA.

In the past, the usefulness of such reporting schemes has been questioned by the industry. However, we underline that such information provides important data about the uses and volumes that are commercialized and provides for traceability along the supply chain. Such a scheme contributes useful information with regard to human and environmental exposure.

Recommendations:

- The EU and U.S. 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. To reduce the burden for industry, the information requirements could be standardized. The public should be consulted regarding the information which has to be reported and disclosed by such a reporting scheme.
- The EU and U.S. 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. In the U.S., organizations such as the Wilson Center and the International Center for Technology Assessment have developed data bases on consumer products on the market, but government, not NGOs should be responsible for developing and maintaining such databases.

5. Developing testing methodologies adapted to nanoparticles

It is crucial to develop new testing methods and technology to adequately assess the safety of products containing nanomaterials, for both health and the environment, over the entire lifecycle of the product (including the manufacturing, transport, product use, recycling and disposal). These methods ought to be adapted to the particular characteristics of each kind of nanoparticle. Measurement techniques, even if required for the import of products, should not be considered barriers to trade.

Recommendation:

- Priority should be given to testing methods which have been adopted at the OECD, ISO standards, or the Codex Alimentarius level. In the absence of such internationally standardized methods, each jurisdiction should remain entitled to adopt suitable measures.

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[1] REACH is based on hazard, shifts the burden of proof for safety on manufacturers, encourages the substitution of hazardous chemicals with safer alternatives and lists chemicals which pose unacceptable burden on society as Substances of Very High Concern. By contrast, TSCA follows a risk-based approach and placed considerable burden on the authorities to proof a risk as a precondition for its regulation which leads to many unregulated toxic substances being continuously marketed. The proposed Chemical Safety Improvement Act currently does not sufficiently propose a change of approach and does not have nano-specific provisions.

[2] Human biomonitoring studies show that consumers in industrialized countries are exposed to a wide range of similar pollutants such as brominated flame retardants (BFRs), perfluorinated compounds (PFCs), phthalates and phenols including bisphenol A. While exposure levels vary, the presence of these chemicals in newborns shows that they are not adequately managed. Latest science shows evidence that these chemicals may have additive effects in our bodies and that their combined effects may be more detrimental then of a single substance alone. With regard to human biomonitoring results see for example: http://www.eu-hbm.info/democophes ; http://www.chemsec.org/news/news-2011/808-%20mix-of-hazardous-chemicals-under-your-bed-EU-needs-to-act; http://www.cdc.gov/

[3] We worked with a large coalition of environmental, scientific, religious and consumer groups to develop the Principles for the Oversight of Nanotechnologies and Nanomaterials. Available at: http://www.centerforfoodsafety.org/issues/682/nanotechnology/reports/961/principles-for-the-oversight-of-nanotechnologies-and-nanomaterials

[4] TACD Resolution on Consumer Products Containing Nanoparticles, June 2009 & TACD Resolution on the need for a mandatory reporting scheme and inventory for nanomaterials, June 2011, http://tacd.org/index.php?option=com_docman&task=cat_view&gid=75&Itemid=40

[5] David Azoula: Nanomaterials "Just Out of REACH" of European Regulations, 6 February 2012, CIEL – The Center for International Environmental Law, http://www.ciel.org/Chem/JustOutofREACH_Feb2012.html.

[6]European Commission: Reducing Transatlantic Barriers to Trade and Investment, March 2013, Table 17. http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf

[7] See also Center for International Environmental Law, Statement of Carroll Muffett before the U.S. House of Representatives Committee on Energy and Commerce, Sub-Committee on Commerce, Manufacturing and trade, hearing on the E.S. – EU Free Trade Agreement: Tipping over the regulatory barriers, 24 July 2013, http://www.ciel.org/Publications/Muffett_Statement_24July2013.pdf.

[8] Koivusalo, Meri; Labonte, Ronald and Scott Sinclair (2011): The proposed EU-Canada trade agreement raises health concerns in both Canada and European Union,

http://www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2011/07/CETA%20and%20Health%20in%20Europe.pdf.

[9] TACD open letter to Ambassador Kirk and Commissioner De Gucht "EU and U.S. consumer groups' initial reaction to the announcement of a Transatlantic Trade and Investment Partnership", 5 March 2013, http://www.tacd.org/index2.php?option=com_docman&task=doc_view&gid=354&Itemid=40.

[10] Sheldon Rampton, „Tobacco Industry Spins Sound Science," PR Watch, November 2001. http://www.prwatch.org/spin/2001/11/818/tobacco-industry-sponsors-sound-science

[11] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

[12] The Safe Cosmetics and Personal Care Products Act of 2013 (H.R. 1385), introduced on March 21, 2013 by Reps. Jan Schakowsky, D-Ill. and Ed Markey, D-Mass., could have brought considerable improvements as it foresaw giving the U.S. Food and Drug Administration authority to ensure that personal care products are free of harmful ingredients and that ingredients are fully disclosed. See: Campaign for safe cosmetics, http://safecosmetics.org/section.php?id=74

[13] http://www.developpement-durable.gouv.fr/spip.php?page=article&id_article=30578