Trans Atlantic Consumer Dialogue

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Resolution on better regulation of chemicals, including nanomaterials, in light of the Trans-Atlantic Trade and Investment Partnership: What should policy makers agree on in the interest of consumers?

Executive Summary

In this new TACD resolution we call for aligning the regulatory frameworks for nanomaterials at the highest safety level as it should be the objective of negotiations for the Transatlantic Trade and Investment Partnership (TTIP) to reduce regulatory divergences without undercutting safeguards.

TACD Recommendations:
A desired outcome of the TTIP negotiations with regard to chemicals management including nanomaterials would be a regulatory framework which:

- puts health and safety of people and the environment at the center of TTIP negotiations;
- effectively lowers the exposure of consumers and the environment to harmful chemicals;
- takes due account of the precautionary principle;
- allows parties to the TTIP to take steps to protect their most vulnerable populations and environments from nanoparticles;
- manages chemicals based on hazard;
- takes into account consumer preferences and allows consumers informed choices
- enables each jurisdiction to adopt new initiatives aiming at improved safety
- provides for robust regulation of emerging technologies such as nanomaterials and biotechnologies
- requires adequate pre-market testing for all nanomaterials that will be in products used directly by consumers
- provides a public available inventory for all nanomaterials which are subject to pre-marketing research and already used in products.
- provides a public and consumer friendly register of all nano-products, which are on the market and available to consumers.

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[1]. While REACH has considerable potential 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]. Consumer organisations 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, will further increase if 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 TACD has called on policy makers on both sides of the Atlantic for better regulation of nanotechnologies and materials since 2009. We identified a lack of coherent definitions, lack of adequate and agreed testing methodologies, research gaps and transparency for consumers as stumbling blocks to effective regulation for consumer safety. 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[3].

Since 2009, 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[41], 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 (EC), only marginal proposals, such as updating the REACH Annexes, are currently discussed.

In the U.S., the Toxic Substances Control Act is a weak piece of legislation that regulates nano chemicals primarily through a provision of the law called “Significant New Use Rules” (SNUR) wherein the Environmental Protection Agency (EPA) negotiates a rule with the manufacturer or importer of a chemical. Many parts of the “consent” degree which can include conditions for worker and environmental protection are kept secret as confidential business information.[6] Recently, the EPA has approved a number of SNURs for carbon nanotubes.[7] The U.S. Congress is working on a re-write of the Toxic Substance Control Act, earlier drafts explicitly addressed nano-chemicals, but the latest draft introduced into the U.S. Senate, called the Chemical Safety Improvement Act, does not.

Nano-pesticides are regulated under a different law, the Federal Insecticide Fungicide and Rodenticide Act. Unfortunately, the EPA has been prohibited by the White House Office of Management and Budget from implementing a new regulation that would regulate nano-pesticides as unique pesticides. Several U.S. groups, including a number of TACD members, have filed a legal petition with the EPA to force it to follow the law on nano-pesticides, but the EPA has not yet responded to that petition.[8]

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 TTIP trade negotiations which focus primarily on removal of non-tariff barriers to trade (NTBT) to increase market access. According to a EC econometric projection, "two thirds of the total GDP gains of the Transatlantic Trade and Investment Partnership (TTIP)" would result from an ambitious NTBT removal scenario."[9] As is customary in trade negotiations, only entrepreneurial benefits, not social costs, are estimated under further trade liberalization scenarios.

While TACD appreciates 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, with a view to keeping regulation *a minima* in the hope to facilitate trade in 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, while possibly facilitating their trade, will result in consumer benefits whereas its costs to public health, the environment, worker safety and public confidence could prove to be very high indeed.

Ideally, TTIP should offer an opportunity to harmonise two differing standards at the level which provides better protection for consumers. Regrettably, having in mind the outcome of past trade negotiations , we rather fear that a deal will be made at the "lowest-common-denominator" and at a level which favors private interests of a few over public interests[10],[11].

In March 2013, the TACD stated therefore 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 we emphasized that trading partners must be afforded discretion to regulate 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[12].

In this paper, we discuss the potentials and risks through aligning the rules for sound chemicals management including nanomaterials and give recommendations to policy makers which should be considered when further negotiating the TTIP.

1. Ensuring public health and protecting consumers and the environment from exposure to hazardous chemicals 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.[13] Scientific evidence is an important factor to set appropriate regulatory requirements, and we are precisely concerned that with regard to emerging technologies such as nanomaterials and biotechnologies, evidence of harm is still inconclusive (no evidence of harm is not the evidence of no harm). Due to these uncertainties, we believe there is an urgent need to act on a preventive basis. One only has to look at the recent European Environment Agency publication "Late

Lessons from Early Warnings vol. II - science, precaution, innovation[142]", to find concrete examples of chemicals once thought to be non-problematic only to find out years on - after ignoring early warning signs - that the chemical was very harmful for nature and / or health.

The report also highlights nanotechnology as an emerging issue focusing on the lack of regulatory action as one challenge:

"Political decision-makers have yet to address many of the shortcomings in legislation, research and development, and limitations in risk assessment, management and governance of nanotechnologies and other emerging technologies. As a result, there remains a developmental environment that hinders the adoption of precautionary yet socially and economically responsive strategies in the field of nanotechnology."[15]

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/monitoring 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.

TACD 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

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)[16] 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[17]. With regard to nanomaterials used in cosmetics, manufacturers in the EU are obliged to send a notification to the EC prior to marketing. In case of safety concerns related to a nanomaterial, the EC 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.

The FDA has, however, issued a draft guidance for industry requiring improvements in the way it tests nanoparticles in cosmetics[18]: *"FDA recommends that the safety assessment for cosmetic products using nanomaterials should address several important factors such as: the physico-chemical characteristics,*

- *Agglomeration and size distribution of nanomaterials at the toxicity testing conditions which should correspond to those of a final product,*
- *impurities,*
- *potential product exposure levels, and the potential for agglomeration of nanoparticles in the final product,*
- *dosimetry for in vitro and in vivo toxicology studies,*
- *in vitro and in vivo toxicological data on ingredients and their impurities, dermal penetration, irritation (skin and eye) and sensitization studies, mutagenicity/ genotoxicity studies, and*
- *clinical studies to test the ingredient, or finished product, in human volunteers under controlled conditions.*

FDA expects that the science surrounding nanomaterials will continue to evolve."

Unlike many U.S. agencies, the FDA has not set a hard and fast definition of the size of nanomaterials that it will regulate and has requested manufacturers to use a general rule of submitting data on any chemicals smaller than 1000nm when size or other attributes will change the behavior of the chemical from the bulk scale. In this respect, the FDA guidelines are superior to the EU rules.[19]

TACD 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 are in favor of allowing these products on both markets as consumers will benefit.
- The EU and U.S. should not be forced to mutually recognize certain chemicals and nanomaterials as "safe" although they would not qualify as such under the respective regulatory framework

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

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 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 as to what "nanomaterials" are in cosmetics and food, as well as in other consumer products. Likewise in the U.S., federal regulatory agencies (FDA, EPA and USDA) use different definitions.

The intransparency is worsened by the industry who is not sharing relevant data, continues to question what exactly "nano" is and does not apply the same understanding of the term.

TACD Recommendations:

- The TTIP agreement should provide in the long term for agreeing on common definitions for regulatory purposes, (noting that it may be that slightly different definitions will be needed for drug applications and food applications of nanotechnology than might be used for industrial nano-chemicals used in batteries or auto parts):
    - which goes beyond a mere size range definition
    - is based on number of particles rather than mass
    - 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 manufacturers produces "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. Better information on chemicals and nanomaterials is no "red tape"

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[20]. 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 that apparently more than 1,000 every day products contain nanomaterials (cosmetics, sport equipment, electronic products, construction materials, paints, etc.)[21].

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 is not "red tape" as it provides important information about the uses and volumes that are commercialized and provides for traceability along the supply chain. Hence, such a scheme can contribute to collecting useful information with regard to human and environmental exposure.

TACD 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. Civil society should be consulted regarding the information which has to be reported and disclosed within such a reporting scheme.
- The EU and U.S. should establish an extensive inventory of all nanomaterials which are subject to pre-marketing research and which are already used in products. This inventory for scientists, risk assessors and legislators would have to be made publicly available.
- The EU and U.S. should also make publicly available a consumer friendly register of products containing nanomaterials.

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.

TACD Recommendation:

- Priority should be given to test methods which have been adopted at the OECD or through international standards bodies. In the absence of such internationally standardized methods, each jurisdiction should remain entitled to adopt suitable measures.

6. Coordinating scientific research agendas

In the area of nanomaterials there is still a large gap between research funds spent on commercial applications and research funds spent for independent research projects that focus on human health and environmental protection. While we believe that in general more public funds should be dedicated to the hazards of nanomaterials, better cooperation between the EU and U.S. could provide for useful synergies.

TACD Recommendations:

- The EU and U.S. 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.
- Independent scientific research which is valuable for regulatory purposes should be complementary rather than doubling the efforts.
- Policy making should keep up to date with the development of new chemicals and nanomaterials and include the findings of latest science as they emerge. Far too often, new science is being taken into account in bi-lateral cooperation with a considerable delay.

7. Mandatory labeling and/or exclusion of nano chemicals in consumer products

Consumer products containing nano-ingredients and with which consumers come in direct, close or regular contact must be labeled to enable informed choices. Consumers have a fundamental right to know which is currently not respected with regard to nanomaterials. Moreover, product labeling facilitates documentation of potential environmental releases, human exposure, and accountability for adverse impacts. In the area of organic food certification, European organic certifying authorities,

such as the Soil Association of the UK, have excluded nanoparticles smaller than 200 nm from organic foods. In the U.S., the National Organic Standards board has recommended the exclusion of nanoparticles smaller than 300nm. In the Nordic ecolabelling scheme (Swan), nanoparticles are not allowed in cosmetics[22]. Such authorities should not be prevented from prohibiting certain sizes of nanoparticles by the TTIP.

In the context of international trade negotiations, labeling requirements are regularly being challenged as obstacles to market products in other jurisdictions. We insist however that regulatory convergence should result in labeling requirements being extended, not reduced.

TACD Recommendation:

- Products containing nanomaterials with which consumers come in direct, close or regular contact must be labeled;
- Where mandatory labeling requirements exist (e.g. for food and cosmetics in the EU), these should not become obsolete due to the TTIP negotiations. If there is a need for harmonization, the labeling requirements should rather be extended to cover also products in other jurisdictions.
- In some areas, such as food products and food packaging, as well as products that infants might put into their mouths, exclusion of added nanoparticles should be permitted.

8. Regulating marketing claims

Better regulation is needed to ensure that claims made about the purported benefits of nanoproducts can be substantiated and independently verified. Unsubstantiated claims should be prohibited.

TACD Recommendation:

- Governments should ensure that unsubstantiated and not verifiable claims are withdrawn and that these withdrawals are publicized.

9. Taking account of civil society's views on nanotechnologies

The success or failure of new technologies depends largely on consumer acceptance. For instance, consumers may not accept a new technology such as nanomaterials if they perceive the application to be unnatural or assume there is a lack of control combined with uncertainty about future consequences of the technology[23].

TACD Recommendation:

- We see an urgent need to consult consumers not only concerning regulatory matters, but also about governments' investments in and subsidies for nanotechnologies. The public's views should be meaningfully integrated into policymaking.
- All texts of the TTIP negotiations related to nanotechnology and other emerging technologies, such as synthetic biology, should be made available for public scrutiny.

ENDNOTES

[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 prove 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.

[2] Human biomonitoring studies show that consumers in industrialised 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] 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

[4] Currently 1,236 products are registered in the Danish "Nanodatabase" – http://nano.taenk.dk/

[5] David Azoulay: 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] http://www.epa.gov/oppt/newchems/pubs/cnosnurs.htm

[7]http://www.gpo.gov/fdsys/pkg/FR-2013-06-26/html/2013-15032.htm

[8] http://www.centerforfoodsafety.org/files/cta_nano-silver-petition__final_5_1_08.pdf

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

[10] 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.

[11] 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.

[12] TACD open letter to Ambassador Kirk and Commissioner De Gucht "EU and US 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.

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

[14] http://www.eea.europa.eu/publications/late-lessons-2

[15] Late Lessons from Early Warnings vol. II - science, precaution, innovation, page 530).
[16] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

[17] 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 bring considerable improvements as it foresees 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

[18] ttp://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ucm300886.htm

[19] Ibid. Note that in the Background section of this guidance, the FDA says that it is using this expanded definition of what constitutes a nanomaterial:

„FDA recently issued draft guidance to industry titled "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology" (Ref. 1). As described in that guidance, when considering whether an FDA-regulated product contains nanomaterials or otherwise involves the application of nanotechnology, FDA will ask: (1) whether an engineered material or end product has at least one dimension in the nanoscale range (approximately 1 nm to 100 nm); or (2) whether an engineered material or end product exhibits properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer. Once the guidance is finalized, the agency intends to apply these considerations broadly to all FDA-regulated products, including cosmetic products."

[20] Belgium notified the EU Commission on 4 July 2013 about a legislative proposal for a reporting scheme. See: http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa_notif_overview&sNlang=EN&iyear=2013&inum=369&lang=EN&iBack=3. Also in Denmark such a reporting scheme is under way. See: http://www.endseurope.com/32869/denmark-pushes-ahead-with-nano-register and http://www.nanotechia.org/news/news-articles/danish-epa-starts-public-consultation-national-nanomaterial-product-register

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

[22] http://www.ecolabel.dk/kriteriedokumenter/090e_2_6_1.pdf

[23] Gupta, Nidhi; Fischer, Arnout R.H.; George, Saji and Lynn J. Frewer: Expert views on societal responses to different applications of nanotechnology: a comparative analysis of experts in countries with different economic and regulatory environments, in: Journal of Nanoparticle Research (2013) 15:1838, http://link.springer.com/article/10.1007/s11051-013-1838-4.