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Sinister partners: transatlantic trade agreement & toxic chemicals

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Chemicals are the sinister and little-recognized partners of radiation in changing the very nature of the world–the very nature of life.
– Rachel Carson.

On July 8, in Washington, D.C., trade negotiators from the United States and the European Union are expected to open the first round of talks for a Trans Atlantic free trade agreement (TAFTA) or as it is formally known, the Transatlantic Trade and Investment Partnership (TTIP). **The United States is pushing for a transatlantic deal that not only integrates the trade policies of the U.S. and E.U., but also deregulates their economies**.

Because tariffs are already relatively low between the U.S. and Europe, TAFTA negotiations will instead focus on regulatory "barriers" to transatlantic trade and investment.[i] This may result in dangerous deregulation of environmental and public health safeguards – including those related to toxic chemicals, and will likely have a chilling effect on any future efforts to enact similar protections. Specifically, the E.U.'s more precautionary approach to chemicals management system should not be "harmonized down" to low U.S. standards.

As Mark Schapiro explained in a 2007 story in Harper's: "Whereas U.S. regulators are forced to find scientifically improbable definitive evidence of toxic exposure before acting, [Europe's] REACH [regulation] acts on the basis of precaution. European authorities consider the inherent toxicity of a substance and, based on an accumulation of evidence, determine whether its potential to cause harm is great enough to remove it from circulation. Unlike [the U.S.'s Toxic Substances Control Act[ii]], REACH places the burden of proof on manufacturers, who must demonstrate that their chemicals can be used safely."

TAFTA threatens effective chemicals regulation

The U.S. Trade Representative has already targeted REACH[iii], Europe's chemicals regulation program. **The 2013 USTR report on Technical Barriers to Trade identifies many provisions of the REACH system as trade barriers.[iv] The United States also raised objections to REACH at the time the program was developed[v], as well as more recently in the World Trade Organization Committee on Technical Barriers to Trade[vi] and in other fora. Advocates for U.S. companies argue that registration,**

data gathering, and notification requirements under REACH impose higher costs on chemical products imported into the E.U., and detailed analyses have been prepared that, in effect, lay out the argument for why major elements of REACH are illegal trade barriers under international trade law.[vii]

In addition, the High Level Working Group report, the official document laying out the negotiating objectives for the transatlantic trade deal, proposed so-called "WTO-plus" provisions for the chapter on technical barriers to trade (TBT), which covers toxic chemicals regulation. The WTO TBT chapter does not have even a modest exception for environmental and public health measures[viii], and many TBT challenges to environmental and health measures before WTO tribunals have been successful (for example challenges related to dolphin safe tuna labels, country of origin meat labeling, and a ban on clove cigarettes).[ix] To go beyond the WTO TBT provisions, to "TBT-plus" is frightening in its implications.

All this would strongly encourage the downward harmonization of E.U. toxic chemicals regulation, moving toward the lowest common regulatory denominator – namely, the U.S. Toxic Substances Control Act. TSCA has been characterized by the President's Cancer Panel as perhaps "the most egregious example of ineffective regulation of chemical contaminates."[x] Similarly, the bi-partisan compromise bill introduced in May by U.S. Senators Lautenberg and Vitter, that allegedly makes some improvements in TSCA, falls far short of the European standard for safeguarding the public from dangerous toxic chemicals.

The failure of the U.S. chemical regulatory system

Regulation of toxic chemicals by the federal government in the United States, particularly TSCA, is widely regarded as a failure. The most significant gaps in TSCA are not filled by other federal laws regulating toxic chemicals, such as the Federal Food, Drug, and Cosmetics Act; the Federal Insecticide, Fungicide, and Rodenticide Act; The Clean Air Act and the Clean Water Act; the Consumer Product Safety Act; and the Occupational Safety and Health Act. These other laws, for the most part, merely regulate the release of chemicals into the environment.

Only TSCA purports to regulate chemicals through the production and distribution cycle. The Act authorizes the Environmental Protection Agency to monitor chemicals to identify products and the use of products that may be a threat to public health or the environment. But many chemicals are not covered by TSCA if they are regulated by other federal laws. In addition, TSCA generally restricts EPA's authority by requiring the agency to employ the regulatory tool that is least burdensome on industry.

Among the many factors rendering TSCA ineffective are the grandfather problem, the burden of proof problem, the judicial review problem, and the secrecy problem:

- *The grandfather problem.* Over 62,000 chemicals were "grandfathered" at the time TSCA was enacted. Chemicals sold on the market prior to 1979 are exempt from the Act's primary provision for testing and safety review. As a result, most of the chemicals on the U.S. market today have never been tested.

- *The burden of proof problem.* TSCA requires the EPA to bear the burden of proof showing that a chemical is unsafe, rather than putting the burden on chemical companies to show that their products are safe. The U.S. Environmental Protection Agency is only allowed to regulate chemicals on the market before 1979 if it can meet a high evidentiary threshold demonstrating an "unreasonable risk to human health."The U.S. act, therefore, perversely discourages industry from innovating to develop safer chemicals. And, any safety measures imposed must be the "least burdensome" and take into consideration the costs to the chemicals company.
- *The judicial review problem.* U.S. courts generally will not challenge an agency's regulatory decision unless the decision is "arbitrary and capricious," but TSCA requires a tougher standard of judicial review of agency action. If the courts find that EPA has not demonstrated that its administrative action is supported by "substantial evidence," they are required under TSCA to strike down EPA rules requiring the development of chemical test data, determinations of safety, or restrictions on the use of chemicals Given the difficulty in meeting the "unreasonable risk" and "substantial evidence" tests, it is not surprising that EPA has banned only five chemicals under the provisions of TSCA. Even such highly hazardous chemicals as asbestos have escaped prohibition.
- *The secrecy problem.* The U.S. Environmental Protection Agency's own Office of the Inspector General admitted that given the strictures of TSCA, the EPA is "predisposed to protect industry information rather than to provide public access to health and safety studies." TSCA provisions protecting the industry's "trade secrets" stand in the way of effective safety testing of chemicals.

Because of the failure of TSCA, state governments have stepped into the breach to regulate toxic chemicals. Between 2002 and 2010, 18 states enacted 71 chemical safety laws. California, Maine, Minnesota, and Washington State have adopted comprehensive chemical policy reforms.

Illusory TSCA reform

So egregious are the shortcomings of TSCA that even the chemicals industry has called for "reform," but the industry's idea of reform falls far short of what is needed. An alleged "compromise" bill, the Chemical Safety Improvement Act (CSIA), S. 1009[xi], was introduced in the U.S. Senate with the industry's support by the late Democratic senator from New Jersey, Frank Lautenberg, and Republican Senator David Vitter of Louisiana.

As introduced, the CSIA does not provide a framework for effectively protecting people and the planet from toxic chemicals. The bill replicates many of the worst provisions of TSCA, and its provisions for broadly preempting state regulation of toxics and limiting personal injury lawsuits are substantially worse than the status quo. For example:

- *Preemption of state law*. Under CSIA, section 15 (a), (b), current and future state law regulating toxic chemicals would be broadly preempted. Preemption is particularly disturbing because more progressive environmental laws in California often set a national standard for chemical safety; it is often not economic for firms to manufacture and market different products for the huge California market than for the rest of the country.

- *Toxic tort suits severely limited.* As 34 prominent legal scholars have noted, CSIA "takes the extraordinary step of making safety determinations by EPA admissible in any federal or state court and dispositive [or conclusive] of whether a chemical substance is safe." CSIA section 15 (e) would provide sweeping immunity from tort liability for the chemicals industry "even when subsequent evidence calls into question the agency's reasoning."
- *Overwhelming administrative burdens on EPA in assessing new chemicals.* Under the CSIA, the U.S. Environmental Protection Agency would continue to be overwhelmed by the task of assessing the risks of thousands of new chemical submissions, especially given that most submissions will lack complete health and safety data.
- *Chemicals in the market before testing.* CSIA would likely allow chemicals to be manufactured before they are tested or determined to be safe. EPA, also, would be required to justify any calls for safety testing.
- *Weak safety standard.* CSIA section 3(16) provides a weak safety standard: not a true health-based standard. It would essentially replicate TSCA's requirement that EPA demonstrate an "unreasonable risk" to human health before the agency could act. EPA would be required to balance economic costs against public health benefits in a way that could survive judicial review of whether EPA's decision was supported by "substantial evidence."
- *Value of human life discounted.* In effect, an administratively burdensome cost-benefit analysis could be required by CSIA before EPA imposes risk management measures, particularly as TAFTA comes into play with a regulatory coherence chapter based on the Trans Pacific Partnership model as expected. Cost-benefit calculations should not be used in this way to value corporate profits over public health, and to allow economists literally to "discount" the value of a human life, by estimating the present value of lifetime earnings or by similar attempts at quantitative measurement of the immeasurable.

What is left out of CSIA is as disturbing as what it includes. For example:

- *Failure to fix the burden of proof problem.* The EPA would still be required to meet a high burden of proof in order to restrict use of any one of the 84,000 chemicals already on the market. An effective approach, by contrast, would put the primary burden of proof on the manufacturer to demonstrate the safety of a chemical or its use. CSIA fails to hold companies responsible for demonstrating the safety of chemicals, or ensure that safety assessments meet an appropriate set of minimum standards based on the best science and assessment methodologies available. The bill also fails to require that companies pay for the assessment of their products' safety.
- *Failure to adequately fix the secrecy problem.* With few exceptions, CISA section 14 continues to protect "confidential business information" related to chemicals and chemical identities. Health professionals would still be denied information about "secret chemicals" necessary to identify and treat people who have been injured.
- *No effective environmental justice provisions.* The bill does not adequately address issues of environmental justice for especially vulnerable groups including children, the elderly, women of childbearing age, workers exposed to chemicals, and communities of color and low-income communities subject to multiple exposures.
- *No nanotechnology provisions.* CSIA fails to expand the EPA's authority over nanotechnology, as was provided in earlier legislative proposals by Senator Lautenberg. Nanotechnology is a powerful emerging

technology for taking apart and reconstructing nature at the atomic and molecular level. And, the field is being commercialized largely outside of public view or debate, with few regulations to protect workers, the public and the environment. Nanotechnology poses novel and poorly understood risks to human health and the environment. If there was ever an area where the precautionary principle should apply, it is this one.

With Senator Lautenberg's death, it is hard to handicap the prospects for U.S. Senate passage of CSIA this year. Action in the Republican-controlled House of Representatives is even less predictable. This raises the question of why the chemicals industry is pushing so hard for CSIA at this time.

Some observers have speculated that Republican and chemical industry support for at least the appearance of TSCA reform is influenced by their desire to see a transatlantic trade deal. In other words, U.S. negotiators and pro-TAFTA corporations like Dow, Eastman and other big U.S. chemical companies[xii] must at least a provide a "fig leaf" of reforming U.S. toxic chemical regulation, if the industry is to achieve its goal of harmonizing standards across the Atlantic, and thereby substantially weakening REACH.

The superiority of the E.U. system of chemicals regulation

In marked contrast to TSCA's reputation, the E.U.'s REACH program for chemicals regulation, while not perfect, is widely admired by environmentalists and public health advocates. REACH regulates not only manufacturers and importers, but also so-called "downstream users." As Mark Schapiro explains, "REACH also extends to the endless array of consumer goods that utilize these compounds; thus, tens of thousands of 'downstream users,' from construction companies to tennis-shoe manufacturers and fashion houses, will be forced to find out and report what chemicals are in their products and what effects they have on human health and the environment."

REACH stands for **R**egistration, **E**valuation, and **A**uthorization of **Ch**emicals: it is a comprehensive system[xiii] for the regulation of new and existing chemicals administered by the European Chemicals Agency in Helsinki.[xiv]

Registration means that a manufacturer or importer must register any chemical entering the E.U. market in amounts over one ton per year.[xv] A registration dossier must be prepared by the chemical company that includes hazard data and risk assessments.

Evaluation is performed by the E.U. Chemicals Agency, which makes thorough annual assessments of chemicals flagged as high risk, based on the registration data. There are two types of evaluation. Dossier evaluation requires the E.U. Chemicals Agency to review all testing proposals submitted at registration. A small percentage of registration dossiers are audited for full legal compliance. Under substance evaluation, the E.U. member states and the European Commission agree on an annual list of chemicals to be assessed in depth to determine if new control measures are required.

Authorization requires that chemicals of very high concern, such as carcinogens, mutagens, persistent bioaccumulatative toxins, and endocrine disruptors, must be authorized for entry into the market. Authorization will be granted if the risks are under "adequate control" or, if there is no safer

alternative, on socio-economic grounds even if adequate control is impossible. Chemical companies, however, must attempt to find safer substitutes for substances of very high concern.

The superiority of REACH in protecting public health and the environment is put in stark relief by comparing it to TSCA.[xvi] For example:

TSCA rarely requires companies to do more than submit available safety information, while REACH requires chemical companies to accept responsibility for gathering data and conducting risk assessments. TSCA does not generally require chemical companies to **develop** information about new or existing chemicals. Most often, companies are merely required to submit information that is already available. Under the European REACH system, chemical companies must submit and **develop** information on the effects of both new and existing chemicals on human life and the environment.

TSCA provides minimal testing and safety review, even for particularly hazardous chemicals, while REACH has a comprehensive system for testing and safety review. TSCA does not generally require companies to test new chemicals. Worse, TSCA exempts thousands of chemicals from the law's primary provision for testing and safety review, if they were on the market prior to 1979.

TSCA provides that EPA, by issuing a test rule, can require development of information about such particularly hazardous chemicals on a case-by-case basis, but the TSCA's test rule provision and its data-gathering requirements are so expensive and time consuming that EPA has great difficulty in promulgating test rules through the formal administrative process and relies primarily on voluntary efforts by chemical companies to gather more risk data on suspect chemicals. The vast majority of chemical in use in the United States have never been tested by the government to determine their effect on human health and the environment.

Under REACH, European regulators look at the inherent toxicity of a chemical and systematically accumulate of evidence about its safety to determine whether it should be allowed in the marketplace.

TSCA generally requires EPA to demonstrate that chemicals on the market before 1979 will cause unreasonable risk, while REACH requires chemical companies to demonstrate the safety of both new and existing chemicals. As noted above, the U.S. Environmental Protection Agency may only regulate pre-1979 chemicals by meeting an almost impossible showing that they pose an "unreasonable risk" to human health, while also showing safety measures are the "least burdensome" on chemical companies. **REACH generally treats new and existing chemicals the same and puts the burden of proof on companies to show that chemicals are safe.**

TSCA imposes no specific requirements on downstream users, while REACH requires them to them to develop and keep available information about how a chemical has been used for at least 10 years. For example under REACH, manufacturers, construction companies, and other downstream users must prepare a chemical safety report for use outside conditions described in an "exposure scenario" or any use that a supplier advises against. *TSCA does not specifically impose requirements on finding safer alternatives for chemicals, while REACH requires an analysis of possible safer alternatives to chemicals of "very high concern."* **Under**

REACH, chemical companies are required to attempt to find safer substitutes for chemicals of high concern under the "authorization" process.

TSCA allows chemical companies to claim protection for "confidential business information" covering almost all information provided to EPA, while REACH places limits on what kinds of information may be claimed as confidential. Under TSCA, EPA is limited in its ability to share data provided by chemical companies. **REACH provides greater disclosure. For example, a company may not claim confidentiality for information about a chemical's safe use or a chemical's trade name.**

Why we should care about the transatlantic trade deal threat to chemicals regulation?

Ineffectively regulated toxic chemicals exact a devastating cost on human health and ecosystems. **Therefore, the threat that TAFTA presents to the E.U. system of chemicals regulation, and ultimately to any future reform of the U.S. system based on the REACH model is cause for significant concern.**

The effect of TAFTA's chapter on technical barriers to trade could be profound as it would likely limit regulators' access to the tools they need to effectively regulate the roughly 85,000 chemicals in commerce and to effectively protect human health and the environment. A growing body of scientific evidence is demonstrating that many chronic illnesses on the rise in the industrialized world are linked to exposure to toxic chemicals, including many cancers, learning disabilities, asthma, Alzheimer's and Parkinson's disease, and fertility problems.[xvii] For example, 216 chemicals are associated with increases in breast cancer, including 73 found in consumer products or food. Among the many chemicals suspected of causing learning and developmental disabilities are organophosphate pesticides, such as melaththion. Everyday solvents such as methanol and trichloroethylene (TCE) are associated with Parkinson's disease. Endocrine disruptors, such as BPA found in plastic and the linings of cans and other food packaging, interfere with hormones and may be associated with adverse health impacts including infertility, early puberty and breast cancer, just to name a few.

The effects on wildlife could be similarly profound.[xviii] For example, synthetic chemicals are causing hormone disruption in animals as diverse as alligators, polar bears, and some species of fish, impacting their ability to reproduce. PFOS (Perfluorooctanesulfonic acid) used in stain repellants is a cancer-causing chemical that has been found in European dolphins, tuna, and birds like the common cormorant. The list goes on.

Neonicotinoid pesticides are a key factor in the global die-off of bees, which threatens not only their survival but also a vast array of plants and commercial crops that depend upon bees for pollination. Neonicotinoid pesticides have been restricted by the E.U, and this important regulation is potentially at risk from TAFTA. [xix]

Lisa Archer, director of the food and technology program at Friends of the Earth, U.S., sums it all up: "The transatlantic free trade agreement will give chemical companies and other multinational companies the ultimate weapon, via a secretive, undemocratic process, to destroy the progress we have made over the last decade in the E.U. and in states across the U.S. to protect human health and the environment from toxic chemicals—the

stakes couldn't be higher. It's time for politicians on both sides of the Atlantic to stand up and oppose this fundamental attack on our health, our environment and our democracies."

This post is a "first cut" analysis, and will be refined, expanded, and corrected in a definitive issue report to be released later this summer. If you have comments, concerns, or corrections to suggest, please contact Bill Waren at wwaren@foe

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SELECTED ENDNOTES

[i] According to a European Commission statement on the launch of U.S.-E.U. trade talks: "In today's transatlantic trade relationship, the most significant trade barrier is not the tariff paid at the customs, but so-called "behind-the-border" obstacles to trade, such as, for example, different safety or environmental standards for cars." European Commission, European Union and United States to Launch negotiations for a Transatlantic Trade and Investment Partnership, 13 February 2013, available at, http://trade.ec.europa.eu/doclib/press/index.cfm?id=869.*See generally*, Final Report of the U.S.-E.U. High Level Working Group on Jobs and Growth, February 11, 2013, available at http://www.ustr.gov/about-us/press-office/reports-and-publications/2013/final-report-us-eu-hlwg.

[ii] 53 U.S. C. §§ 2601–2629, available at, http://www.law.cornell.edu/uscode/text/15/chapter-53

[iii] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, available at, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1907:EN:NOT

[iv] U.S. Trade Representative, 2013 Report Technical Barriers to Trade, available at, http://www.ustr.gov/sites/default/files/2013%20TBT.pdf.

[v] The Congressional Research Service reports that:' The U.S. Government was actively engaged throughout the development of REACH. The Bush Administration expressed concerns about its trade implications for U.S.-produced chemicals. Specific concerns included, increased costs of and time lines for testing chemicals exported to the EU; placement of responsibility on businesses (as opposed to governments or consumers) to generate data, assess risks, and demonstrate the safety of chemicals; possible inconsistency with international rules for trade adopted by the World Trade Organization (WTO); and the effect of the legislation on efforts to improve the coherence of chemical regulatory approaches among countries in the Organization for Economic Cooperation and Development (OECD).Some U.S. chemical industry representatives believe that REACH is "impractical." Industry has expressed objections to the proposed list of "high concern" chemicals, some of which areessential building blocks for the manufacture of other chemicals." Linda-Jo Schierow, Chemical

Regulation in the European Union: Registration, Evaluation, and Authorization of Chemicals, Congressional Research Service, March 1, 2012, p.3, available at,. http://www.fas.org/sgp/crs/row/RS22673.pdf

[vi] USTR, 2013 Report TBT, supra, p. 62-64

[vii] Lawrence Kogan, Is REACH a Trade Barrier? Chemical Watch, Global Business Briefing, December 2012-January 2013, pp 20-21, available at. http://www.koganlawgroup.com/uploads/CW53_December12_Kogan.pdf; Lawrence Kogan, REACH Revisited: A Framework for Evaluating Whether a Non-Tariff Measure Has Matured into an Actionable Non-Tariff Trade Barrier, American University International Law Review, Vol. 28, No. 2, September, 2012, available at,http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2149756.

[viii] The TBT agreement contains no exception for environment and public health measures. It might be argued that the article XX exception in GATT should apply to the TBT, but there is no holding to that effect. The TBT contains only some precatory, somewhat self-cancelling, and presumably non-binding language in the preamble: "... *Recognizing* that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade. ..."available at , http://www.wto.org/english/tratop_e/envir_e/issu4_e.ht

[ix] The WTO Appellate Body found that the U.S. dolphin safe labeling program violates the WTO TBT agreement. US-*Tuna II*, available at, http://www.worldtradelaw.net/reports/wtoab/us-tunamexico(ab).pdf Plaintiffs have recently succeeded in a WTO TBT challenge to U.S. measures related to country of origin labeling..US-COOL, available at, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds384_e.htm.The Clove cigarettes case *is available athttp://www.wto.org/english/tratop_e/dispu_e/cases_e/ds406_e.htm.*

[x] The President's Cancer Panel Report, available at, http://www.saferchemicals.org/resources/presidents-cancer-panel.html

[xi] Chemical Safety Improvement Act, as introduced, S.1009, available at, http://www.gpo.gov/fdsys/pkg/BILLS-113s1009is/pdf/BILLS-113s1009is.pdf.

[xiii] Europa, summaries of European legislation, Regulatory framework for management of chemicals (REACH), European Chemicals Agency, at http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/l21282_en.htm

[xiv] European Chemicals Agency homepage, available at http://echa.europa.eu/about-us;jsessionid=5F4EA8A4BC2F2065FB6F57EBBA78FE06.live1

[xv] Chemical Registration and Inspection Service, REACH registration process, http://www.cirs-reach.com/reach/REACH_Registration_Process.html.

[xvi] U.S. Government Accountability Office, Chemicals Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals, August 2007, available at , http://www.gao.gov/new.items/d07825.pdf

[xvii] See generally, Safer Chemicals Healthy Families, health report, Chemicals and Our Health, available at, http://healthreport.saferchemicals.org/.

[xviii] See generally, WWF, Chemical Contamination in the Mediterranean,: The Case of Swordfish, 2006, available at http://wwf.fi/mediabank/1092.pdf,and WWF, Causes for Concern: Chemicals and Wildlife, December 2003,available at, http://www.wwf.eu/?10921/WWF-report-highlights-new-chemical-concerns;

[xix] Tom Philpott**,** Europe Bans Bee-Harming Pesticides; US Keeps Spraying, Mother Jones, May. 3, 2013**,** available at**,** http://www.motherjones.com/tom-philpott/2013/05/eu-ban-bee-harming-pesticides-puts-pressure-us-epa**;** Lisa Archer, Worst bee die-off in 40 years**,** Friends of the Earth, U.S. Blog, Posted May. 14, 2013, available at**:** http://www.foe.org/news/archives/2013-03-worst-bee-die-off-in-40-years#sthash.Z4Mjppch.dpuf**.**
- See more at: http://www.foe.org/news/archives/2013-06-sinister-partners-transatlantic-trade-agreement--tox#sthash.pta4jIFG.dpuf