



August 13, 2013

Rainer Lohmann, Ph.D.
Professor of Oceanography
University of Rhode Island, Narragansett, RI 02882

Response to questions for the record submitted by members of the U.S. House Energy and Commerce Subcommittee on Environment and the Economy hearing on ‘Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation’

Question from the Honorable Henry A. Waxman

- (1) Do you support placing the burden on manufacturers to demonstrate that their products do not pose risks to consumers, workers, hot spot communities, and vulnerable populations?**

Yes, it is the manufacturer’s responsibility to demonstrate the safety of their products.

- (2) Do you support reduce overclaiming of confidentiality and promoting transparency?**

Yes, absolutely. CBI has essentially been abused in the past by overclaiming confidentiality. It should be limited to a few years at maximum, and far stronger guidelines need to be attached to prevent abuse of this rule. Without knowing the chemical identity, little can be done with respect to the detection of worrisome compounds, their toxicity etc.

- (3) Should those important principles be included in any effort to reform TSCA?**

Yes, these principles need to be addressed in a reformed TSCA!

- (4) What other reforms are essential to include in TSCA reform if the statute is to be made effective and protective for everyone, including vulnerable populations?**

There are several important reforms to the current TSCA that should be included:

a) Any new TSCA that tasks EPA with conducting safety evaluations has to equip EPA with the financial and personnel resources to perform this task adequately and in a timely manner, preferentially with a fee on new chemicals to be tested.

b) High throughput *in vitro* screening assays that allow for the evaluation of many toxic endpoints should be developed and considered for mandatory testing of new chemicals.

c) TSCA reform should consider that potential effects of chemicals need to be evaluated over long periods of time (i.e. long-term chronic exposure studies), particularly for sensitive populations. TSCA should recognize these challenges and be less proscriptive and more holistic.

d) In the past, legislation has focused on a single chemical at a time. Yet environment exposures occur in complex mixtures. Studies have shown that a cocktail of many individual compounds each present at their no-effect levels can still result in significant adverse effects. TSCA and the Lautenberg-Vitter bill are designed to evaluate chemicals independently, but many chemical manufacturers sell their products as mixtures. Therefore, evaluations should be conducted not only on individual chemicals but also on the mixture as marketed.

e) TSCA does not limit the period during which a chemical and the associated data can be considered proprietary. This should change. The chemical industry should have only a few years during which information submitted to the U.S. EPA will be considered confidential. After this time, information should be publicly available, and this should include site-specific production data. By withholding information on the chemical identity, it becomes almost impossible for academic scientists to identify these chemicals in the environment and assess human exposure levels.

f) In addition, because research on many chemicals is hindered by a lack of authentic standards, samples of any chemical substance produced or imported into the U.S. should be archived in a national repository funded by the chemical industry. Both of these changes will open a dialogue among industry, academia, and non-governmental organizations to identify problem substances and to assess safer alternatives.

g) TSCA should be harmonized with chemical regulations in Europe, Japan, Canada, and Australia; the U.S. does not need to reinvent the wheel.

(5) Are those reforms included in the bill recently introduced in the Senate to reform TSCA?

Only partially. Legislation now before the Senate, called the Chemical Safety Improvement Act of 2013 (TSCA-II), makes some improvements over the original law. TSCA-II would require EPA to classify chemicals as high or low priority for safety assessment and to evaluate the safety of high-priority chemicals entering the marketplace and those already in commerce. Yet the bill introduced in the Senate lacks a stronger protection of consumers, workers, vulnerable populations and the environment by not doing enough to reduce the abuse of CBI. It also does not address the problem of the exposure to complex mixtures in the environment, nor does it attempt to harmonize with recent legislation in other major markets. A strategy to address long-term exposure to chemicals is also missing. These are major lost opportunities unless the bill is significantly improved. Lastly, the new bill needs to ensure that the EPA has the resources to do

a thorough and timely review. Ideally, having a repository for all compounds produced or imported would be a major step forward for scientists to being able to study all compounds on the market.

(6) Do you have concerns about that bill?

Yes - the bill introduced in the Senate lacks a stronger protection of consumers, workers, vulnerable populations and the environment by not doing enough to reduce the abuse of CBI. It also does not address the problem of the exposure to complex mixtures in the environment, nor does it attempt to harmonize with recent legislation in other major markets. A strategy to address long-term exposure to chemicals is also missing. These are major lost opportunities unless the bill is significantly improved. Lastly, the new bill needs to ensure that the EPA has the resources to do a thorough and timely review. Ideally, having a repository for all compounds produced or imported would be a major step forward for scientists to being able to study all compounds on the market.

(7) Do you agree with that statement?

No, current disclosures are completely inadequate for scientists, let alone consumers, to understand which compounds are produced and which effects it might have on the US population.

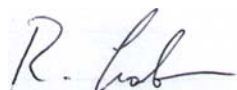
(8) Do these redacted notices provide enough information for consumers to make informed choices and avoid these chemicals if they so desire?

No, in the redacted notices there is so little information left that consumers are unable to make an informed choice.

(9) In your view, should a substantiation like this be sufficient?

No, the substantiation presented by the manufacturer is clearly insufficient. If a given chemical or product is harmful or toxic, consumers need to know so they can avoid it. In fact, such a product should not be marketed at all, or under severe restrictions of use so that the consumers are not exposed to such a produce that clearly has adverse effects.

Sincerely



(Rainer Lohmann)
Professor of Oceanography