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Comments on S. 239

House Committee on Fish, Wildlife, and Water Resources
Representative Deen, Chair
Montpelier, VT

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My name is Thomas Osimitz. By way of background, I have a doctorate degree in toxicology and am certified in toxicology by the American Board of Toxicology and am also a European Registered Toxicologist.

For those of you who may not be familiar with the field of toxicology, toxicology is the study of the adverse effects of chemical, physical, or biological agents on people, animals, and the environment. Toxicologists are scientists trained to investigate, interpret, and communicate the nature of those effects.

I have spent over 30 years as a toxicologist examining the safety of a wide range of chemicals primarily used in products that consumers, including children, come into contact with. An important component of my work, in addition to understanding the hazard, or inherent toxicity of chemical and its potency, is the scientist estimation of exposure. I have experience with various ways to accomplish this and with the approaches that different regulatory agencies and governments have taken in this regard.

I am here to speak on behalf of the American Chemistry Council (ACC) and to discuss concerns regarding S. 239, "An Act Relating to the Regulation of Toxic Substances."

This is a complex bill dealing with an important, yet very complex topic. I believe that we have common ground in the mutual desire to protect human health and the environment. We all live in a world limited resources, both time and financial. Given this, how do we best focus our efforts for maximum public good?

I would like to discuss several aspects of S. 239:

- Accuracy of some of the "Findings;"
- Disharmony between S. 239 and other state and federal efforts;
- Complexity of the important tasks and resources required of the State by S. 239;
- Importance of keeping risks from chemical exposures in perspective.

1. Accuracy of some of the "Findings"

As a toxicologist, I must comment on some of the assertions made in the Finding sections section of S 239. I'll limit my comments to just a few, but many of the statements made here are incorrect, misinformed, or misleading.

Status of Knowledge about Toxicity of Chemicals

We often hear the number that certain tens of thousands of chemicals are used in the United States commercially and the impression is given that we know virtually nothing about the vast majority of these chemicals. That simply isn't true. With regard to the universe of chemicals, it's important to take a look at what that universe consists of.

The TSCA Inventory currently contains over 70,000 existing chemicals, many of which are produced or imported at low or negligible volumes, while others are polymers that, because of their physical size (e.g., high molecular weight) and other characteristics, are unlikely to present significant exposures and resulting risks. By excluding low volume chemicals (~25,000 chemicals produced or imported in amounts less than 10,000 pounds per year) and polymers (which tend to be poorly absorbed by organisms and therefore typically exhibit low toxicity), the remaining TSCA Inventory is comprised of about 15,000 non-polymeric chemicals produced/imported at levels above 10,000 pounds per year.

Of these 15,000 non-polymeric chemicals, there are 3,000-4,000 chemicals that are produced/imported in amounts over 1 million pounds per year; these chemicals are considered by EPA to be U.S. High Production Volume (HPV) chemicals. EPA has identified this 15,000 chemical subset as being the broad focus "universe" of the TSCA Existing Chemicals and Chemical Testing Programs with the primary focus placed on the 3,000- 4,000 HPV chemicals.

EPA has prioritized existing chemicals and has identified 83 Work Plan Chemical (existing chemicals) priorities that it is currently conducting targeted risk assessments on. The agency recently added approximately 20 flame retardants to its priorities for evaluation and assessment. The agency has regulated many more chemicals than identified in Finding #3. In fact, EPA's website demonstrates that as of 2006, more than 2,600 new chemicals were regulated using TSCA section 5(e) consent orders and/or section 5(a)(2) significant new use rules (SNURs). An additional 1,700 new chemicals were withdrawn by industry submitters (often this occurs in the face of EPA regulation) and EPA obtained voluntary testing on more than 300 new chemicals. In addition, all of the more than 11,000 TSCA section 5(h)(4) exemption chemicals are regulated and subject to the terms of the exemption. The figure noted in the finding that "EPA has required testing for approximately 200 chemicals" only refers to the TSCA section 4 testing EPA has required, but selectively ignores the significant testing required on new chemicals through section 5(e) consent orders as well as all the data and information on the approximately 2,200 High Production Volume (HPV) chemicals under the Challenge

Program.

EPA has issued more than 300 Significant New User Regulations (SNURs) on existing chemicals, including a number of Persistent Bioaccumulative Toxic (PBT) chemicals (e.g., 6 PBBs (polybrominated biphenyls, the brominated analogue of PCBs, 2 PBDEs (polybrominated diphenyl ethers), and over 270 perfluoroalkyl sulfonate (PFOS) derivatives, known or suspected carcinogens (including 24 benzidine dyes, the flame retardant "tris", and erionite (an asbestos-like fiber)), and others.

With regards to the remaining chemicals, although complete testing has not been done on all of these chemicals, much is still known about their potential toxicity. EPA's Office of Pollution Prevention and Toxics (OPPT) groups chemicals with shared chemical and toxicological properties into categories so that new chemical reviews are informed from data and regulatory determinations on similar chemicals. Detailed profiles of over 50 chemical categories have been made. EPA considers all new chemical submissions on a case-by-case basis and uses the most appropriate structural analogue to support any concerns for health or environmental effects.

These chemical structural similarities within chemical classes form the basis for the use of non-testing methods such as quantitative structure-activity relationships, read-across, and modeling tools. EPA has an entire suite of hazard and exposure tools at its disposal and which are publicly available on its website for use by others to assess and evaluate chemicals

Presence of Chemicals in Biomonitoring Samples

The detection of a chemical (in humans, in the environment, or in consumer products) does not equal harm. The U.S. Center for Disease Control (CDC) has stated clearly:

> "The presence of an environmental chemical in people's blood or urine does not mean that it will cause effects or disease."

In the addition, the State of Washington clearly points out that with respect to their list of chemicals of high concern to children that:

> "As required by the law, chemicals on the list are toxic and have either been found in children's products or have been documented to be present in human tissue (blood, breast milk, etc.). However, the mere presence of these chemicals in children's products does not necessarily indicate that there is a risk of harm."

Chemicals are Responsible for a Rising Level of Adverse Health Effects

The Annual Report to the Nation on the Status of Cancer, 1975-2008, published by CDC reports that death rates from all cancers combined for men, women, and children continued to decrease in the United States between 2004 and 2008; breast cancer incidence rates among women decreased from 1999 through 2004, and remained level

from 2004 through 2008; for more than 30 years, excess weight, lack of physical activity, and an unhealthy diet have been considered second only to tobacco use as preventable causes of disease and death in the United States. Other reports by authoritative bodies reach similar conclusions.

2. Disharmony between S. 239 and other state and federal efforts

It is laudable that the bill highlights the need to harmonize efforts with other states and jurisdictions. But a closer look show disharmony in two important respects. First, the bill's reporting and information requirements are more extensive than those in the other states mentioned. These need to be carefully compared so that an entire separate scheme need not be developed for Vermont. Perhaps the Washington State process can serve as a model here? On April 1, 2008, the Children's Safe Products Act was passed in Washington and significant resources have gone into implementing in.

The second aspect, one which, as a toxicologist concerns me the most, establishes a process by which the State of Vermont embarks upon an exercise to establish a list of Chemicals of High Concern. Given that such efforts that have been undertaken in states such as California and Washington, this is akin to reinventing the wheel, although the result will likely be a different wheel. Differences in lists between states results in more confusion and complications for manufacturers trying to comply. Thus, while the spirit of harmonization is expressed in S 239, more detail is needed to be sure that it actual takes place.

3. Complexity of the important tasks and resources required of the State by S. 239

The processes outlined in the bill can only be considered to be high level outlines and either glosses over or completely omits many key steps that need to be taken and the significant resources needed to accomplish them. The processes are complex and require significant scientific and technical capacity to accomplish. Doing this properly is a scientific exercise, not a multi-stakeholder Working Group process and sufficient resources need to be allocated to accomplish this. It is unlikely that the relevant Vermont state agencies have the resources to do this. None of assessments to be made are simply tasks. That doesn't mean that they should not be undertaken, but it is critical to acknowledge that doing them should be a rigorous exercise whose assessment criteria and resulting assessments should be subject to scientific review and comment.

4. Importance of keeping risks from chemical exposures in perspective

Risk to humans and/or the environment is a function of both toxicity, a property inherent to the chemical, and the extent of exposure that a human or environmental species receives. We are exposed to many chemicals, both natural and synthetic, every day that have inherent toxicity, but because of the level of exposure and our body's ability to detoxify many of these chemicals, risk is low or nonexistent.

Understanding and mitigating risk is something that we all do every day in daily life. Few human activities, whether it's driving a car or flying are without some element of risk. The same is true for exposure to chemicals. Regulation clearly on the basis of hazard, or inherent toxicity will result in the elimination or de-selection in the market of chemicals for which the actual risk to human based on exposure, is very low. I support the inclusion of language that stresses the importance of examining exposure pathways and assessing risk.

I mentioned that we all form our own risk assessments every day, whether knowingly or otherwise. Various commonly ingested foods cooked and otherwise (exempt from the proposed legislation) contain known rodent carcinogens, naturally occurring. Many of these chemicals were tested the animal studies for carcinogenicity and on that basis may likely qualify as a chemical of high concern by the Commissioner of Health. In this case many of these chemicals not only have been shown to cause cancer in toxicology studies, but also are likely to be found in biomonitoring of human fluids and tissue. Most of the people in this room are exposed to these chemicals from oral ingestion. The resulting direct oral exposure to these chemicals is likely much greater than exposure to other chemicals of high concern where exposure is intermittent and by coming into physical contact with articles that may contain such chemicals.

As referred to within the flame retardant legislation passed last year by the legislature, the Vermont Statutes provide an important standard against which exposures evaluated:

> "Significant public health risk" means a public health risk of such magnitude that the commissioner or a local health officer has reason to believe that it must be mitigated. The magnitude of the risk is a factor of the characteristics of the public health hazard and the degree and the circumstances of exposure to such public health hazard."

The key term here is "significant public health risk." This term should be the ultimate determinant of whether a given product-related exposure should be mitigated.

Thank you very much for the opportunity to testify today and I would be glad to answer any questions.