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American® Chemistry Council

August 14, 2013

The Honorable John Shimkus
Chairman
House Subcommittee on Environment
and the Economy
2125 Rayburn House Office Building
Washington, D.C. 20515

Via email to: Nick.Abraham@mail.house.gov

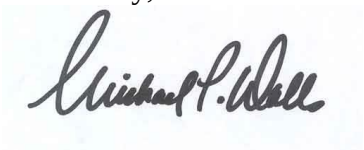
Re: Responses of Mr. Craig Morrison, President, CEO and Chairman, Momentive Performance Materials Holdings, LLC, to Questions for the Record dated August 1, 2013

Dear Mr. Chairman:

Mr. Craig Morrison testified before your Subcommittee at its July 11, 2013 hearing "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation" on behalf of the American Chemistry Council. On behalf of both Mr. Morrison and ACC, I am providing responses to the additional questions for the record provided by you and Mr. Waxman.

If we can provide any additional information, please feel free to contact me.

Sincerely,



cc: The Honorable Paul Tonko
Ranking Member
Subcommittee on Environment and the Economy

Attachments

The Honorable John Shimkus

1. What are the strengths of TSCA's New Chemicals Program?

Response: The two greatest strengths of the TSCA New Chemicals Program are the scientific basis of EPA's Pre-Manufacturing Notice (PMN) reviews and the efficiencies inherent in EPA's PMN review.

- Scientifically Robust Review: EPA has developed scientifically robust Structure-Activity-Relationship (SAR) analyses to predict physical-chemical properties, environmental fate and human and environmental effects of new chemicals. EPA is recognized as a world leader in the use of SAR analysis. EPA has also developed other tools to identify chemicals with Persistent, Bioaccumulative and Toxic (PBT) characteristics enabling EPA to readily flag materials with PBT characteristics for more extensive PMN reviews. In addition, other applicable similar chemical data are accepted as part of the review process.
- EPA Review Meets the Demands of the Marketplace: The EPA review allows U.S. companies the advantage of getting their new chemistries to market in a way that is responsive to customer demand and the global marketplace. The system is also flexible enough to accommodate EPA's review needs. If EPA raises questions about a chemical that cannot be answered based on the information it has, the 90 day review clock can be suspended until the submitter either provides EPA the necessary data/information or withdraws the PMN. The Polymer, Low Volume, and R&D exemptions are valuable and scientifically valid processes under TSCA which bring value to the marketplace.

2. How can EPA get more data about a new chemical once a new chemical is on the market?

Response: Under TSCA today, EPA obtains data and information through several methods to make science based decisions about new chemicals that are under review. These methods help protect against unreasonable risks from exposures to these substances. For example, in the PMN review process, EPA uses "read across" information from analog chemicals; it uses structure activity relationship analysis; and it uses other sophisticated models for predicting a chemical's properties, potential effects and exposures. EPA's approach is scientifically rigorous, efficient, and workable within the marketplace.

In addition, EPA can approve the PMN but condition it upon proposal of a Section 5(e) consent order under which EPA can impose restrictions on the chemical, including requirements for testing. The 5(e) consent order takes effect at the end of the PMN review period. These consent orders are specific to the original manufacturer. EPA has also used its section 5 authority to promulgate Significant New Use Rules (SNURs) that can include a requirement applicable to all later manufacturers of the substance to provide new data or information in the event that a new use (beyond that assessed in the new chemical review process). These new uses can include significant increases in volume manufactured. EPA can also halt the PMN review process until additional data or information is provided by the submitter. In these cases, the manufacturer can either provide the data or withdraw the PMN.

EPA also has the authority at any time under section 4 of TSCA to pursue a test rule (or negotiations leading to a consent agreement) for the generation of new data or information.

The practical reality is that if a manufacturer has a significant commercial interest in a new chemical substance, the company will make every appropriate effort to address EPA's concerns, including generating new data.

3. What are some types of trade secrets in the chemical industry?

Response: A confidential chemical identity is a trade secret. Chemical formulations may also be trade secrets. For example, the formulation that makes paint shinier or more chip resistant; or the concentration of a substance in a mixture that conveys special, unique characteristics may be trade secret. Customer lists and specific information about the use, function, volume, market, process, or application of a substance or mixture in a process, mixture, or product are also examples of trade secrets.

4. Why is trade secret protection of confidential chemical identity important to your company and to the chemical industry?

Response: Trade secret protection is crucial to the competitiveness of my company and the U.S. chemical industry. Much of the innovation in chemistry depends on protection for trade secret chemical identities. In the chemical industry, confidential chemical identities are among the most valuable intellectual property. Chemical identities can provide information on chemical structure, composition, formulation, manufacturing process, raw materials, and generally disclose information that puts significant investment in new product development at risk to competitors. Protecting chemical identities from disclosure can be critical for technological innovation. Companies would be reluctant to invest the significant sums of money they dedicate to research and development of new, "greener" or more effective or less costly substitutes if their "secret ingredient" would be freely available to any foreign or domestic competitor once the chemical is on the market.

5. Some critics, and some supporters of strong CBI protections, claim that industry had made excessive CBI claims over the years and that many of those claims are not legitimate, how do you respond?

Response: The charge that industry made excessive claims in the past is due to several factors. First, industry may have made too many claims in some instances. In addition, until recently EPA was not actively reviewing and evaluating CBI claims that were made by industry. Third, there was no mechanism in place to look at past claims and declassify them when those claims could no longer be substantiated.

In 2010, EPA announced a CBI Declassification Challenge requesting industry support in reviewing 22,000 submissions for health and safety studies that EPA believed may include CBI claims for chemical identity. Industry is actively participating in this Challenge and to date, between EPA and industry, 15,700 cases have been reviewed. The vast majority (11,553) do not contain any CBI claims in the health and safety studies. This review has

resulted in 895 health and safety study claims being declassified and 3,304 CBI claims stand. There are 7,675 cases left to be reviewed between now and the end of 2014. EPA has also begun requiring upfront substantiation of CBI claims made on the 2012 Chemical Data Reporting to update the TSCA Inventory, which it had not done in previous years.

In addition, EPA has the authority to challenge any CBI claims as submitted. For instance, EPA has challenged the generic naming used for describing the chemical identity to reveal more details.

6. **You maintain that the current EPA process for reviewing new chemicals under Section 5 of TSCA is sufficiently strong and that it fully protects the American people from any adverse health risks. Do you think that the chemicals that your company manufactures would be approved for manufacturing today if they were submitted to EPA for Pre-manufacturing notification (PMN) review?**

Response: I am very confident that the chemicals my company produces would be approved if they were submitted for PMN review today.

7. **At our last hearing on TSCA a former EPA chemicals office director, Mr. Auer, testified that rules for significant new uses of chemicals provide a flexible regulatory approach for EPA to get "another bite at the apple" for new chemicals that exceeded their SNUR triggers. Do you agree?**

Response: I agree. EPA has several ways to obtain more data and information on a new chemical. A SNUR can allow limited production and use, and require new data to be generated when changes to production volume or uses are significant. The limited use allows revenue to be generated to pay for the testing. In short, under a SNUR, once a new chemical PMN is approved and once manufacture begins, EPA can impose a wide variety of requirements on the chemical based on any changes in uses that EPA deems "significant," even changes in production volume.

8. **Should TSCA be revised to enhance the information requirements for new chemicals?**

Response: No, TSCA should not be revised to impose mandatory minimum information requirements on new chemicals. Such a requirement would have a significant negative impact on innovation, including substantially slowing the pace of innovation. More importantly, a minimum data set does not in and of itself enhance EPA's ability to make judgments on new chemical substances.

In addition, a minimum data requirement would impose an enormous workload on EPA and the industry, for questionable benefit. Despite what some may think, EPA has a very solid understanding of the chemicals and chemistry in commerce today, so not all chemicals in commerce today require a minimum data set in order to assure that EPA can appropriately review them. Today, EPA can appropriately and efficiently tailor its information needs in reviewing a new chemical.

9. What one or two things do you think could be done to improve the public's confidence in EPA regulation of new chemicals or new uses of existing chemicals?

Response: Momentive has confidence in EPA's new chemicals program and believes that the public should have confidence in EPA's regulation of chemicals. To improve confidence, EPA could make its decision-making processes under TSCA more transparent to the public. Enhanced transparency in how EPA reviews new chemicals, and what data and information it considers, would help the public better understand the scientific basis on which EPA makes its decisions.

The information requirements of the new chemicals program of TSCA today have proven to be sufficient for the review of new chemical substances. They balance well the policy need for EPA to assure a new chemical will not present an unreasonable risk to health and the environment, and the need for EPA to promote innovation in new and improved chemistries.

Although ACC believes that major changes in section 5 are not necessary, we agree that EPA's evaluation of a new chemical would be improved if submitters would provide appropriate hazard, use and exposure information that puts hazards and uses into context. Finally, EPA should be able to gather that basic information through a variety of means (e.g., read-across; structure activity analysis; modeling). We agree that EPA should be able to obtain additional information efficiently, when necessary in the review process.

10. Does Momentive produce any chemicals classified as Persistent Bioaccumulative and Toxic or PBT?

Response: Momentive is a significant producer of various silicones, including polymers that contain volatile cyclic methlysiloxanes ("VMS"). There are some studies on several VMS' indicating those VMS' have a potential to bioaccumulate in certain portions of the aquatic environment. Studies indicate, however, that these substances do not bioconcentrate and do not pose a risk to aquatic organisms or humans. Momentive and other siloxane producers are conducting voluntary studies to look further into this question. Siloxane producers are also in discussions with EPA to implement additional voluntary monitoring to gather data that will assist the agency in characterizing any ecological risk posed by these materials.

11. Please explain a bit more the challenges of introducing new chemicals into commerce.

Response: A major challenge in bringing a new chemical to market is understanding if a market exists for the particular innovation. Under TSCA commercial production is only allowed after PMN approval. In many cases our customers need to test the market for their products commercially which requires the chemicals used to manufacture their products to be approved under TSCA, The PMN review process may result in delaying or limiting feasibility of production in response to EPA action on the PMN.

a. Why do only 50 percent of them get notices of commencement?

Response: The fact that some 50% of PMNs are subsequently commercialized reflects two major considerations: First, TSCA requires early contact with the Agency about new chemicals, well before markets are firmly established. Second, TSCA creates a system that is responsive to the demands of the highly competitive chemical market, in effect creating an incentive to go to EPA early before the commercial potential of a substance has been completely assessed.

b. How easy it is to have a chemical's production stopped or curtailed in the early going?

Response: New chemicals are developed through Research and Development activities (R&D). TSCA exempts R&D chemicals and activities from notification to EPA. There are also exemptions for "low volume" and "low release" chemicals. However, once a company decides to pursue commercial production beyond these exemptions, TSCA requires manufacturers to submit a PMN to EPA. Because commercial production cannot be "ramped up" prior to PMN approval, it may be possible to halt or curtail production if necessary in response to EPA action on the PMN. This is an important aspect of U.S. chemical regulation – the United States employs a "pre-manufacturing" system of review, while other systems generally apply a "pre-marketing" review process. There are regulatory risks inherent in a pre-marketing review assuming that significant investments have been made to manufacture the substance.

12. **How critical to your business is protection of CBI?**

Response: Protection of CBI information is vital to Momentive specifically and to the U.S. chemical industry generally. Momentive relies heavily on the ability to use our expertise in specialty chemicals and materials to innovate. CBI protections can prevent competitors from reaping the benefits of the R&D that the innovator has conducted to put the new chemical on the market. Protection of CBI allows businesses to remain competitive and differentiate their products from other companies, so it is not only critical to our business, it is critical to the U.S. economy.

13. What other types of confidential commercial information, other than confidential chemical identities, is protected?

Response: Any information of a commercial or financial nature that is held confidentially and the disclosure of which would result in competitive harm is generally considered confidential information. This can be specific information that describes or reveals how a substance, mixture, or article is manufactured, processed, or distributed; marketing and sales information, information identifying suppliers or customers, the identity of constituents in a mixture and the respective percentages of those constituents; specific information about use, function, or application of a substance or mixture in a process, mixture, or product; and specific production or import volumes. These are all examples of CBI.

14. Is confidential information always disclosed to EPA?

Response: Yes, information claimed confidential under TSCA is always disclosed to EPA.

15. What is the purpose of the generic name?

Response: A generic name can be provided in lieu of a confidential chemical identity in order to permit the public to have sufficient knowledge of the chemical structure as to allow an understanding of the intrinsic properties. With a structurally-descriptive generic name, the public can access toxicological information on the potential health and environmental effects of similarly structured chemicals, while not revealing the confidential aspects of the confidential chemical. As noted above, confidential information is always disclosed to EPA.

16. What suggestions would you have to improve the Confidential Business Information provisions in a modernized TSCA?

Response: Improvements to the CBI provisions in a modernized TSCA should include:

a) Requiring upfront substantiation of the CBI claim;
b) Requiring structurally-descriptive generic names in lieu of confidential chemical identity;
c) Regular EPA review and approval CBI claims (or subsets of claims, as appropriate);
d) Authority for EPA to share CBI with state governments in appropriate circumstances as long as adequate protections are in place to protect the CBI from disclosure; and
e) Disclosure of CBI to medical professionals in the case of an emergency and in non-emergencies with confidentiality agreements.

17. Heather White's testimony, on behalf of EWG, suggested there was no incentive for companies to test chemicals under TSCA Section 5's new chemicals program. How does this statement compare with your companies' experiences under TSCA Section 5?

Response: Ms. White's statement does not reflect the realities of manufacturing chemical substances. U.S. law – including tort and product liability law – establish significant incentives for manufacturers to know of and understand the hazards, uses and exposures of the substances they manufacture. The fact that new testing is not required initially for a new chemical under TSCA does not mean that applicable testing has not been done or will not be provided. Companies do understand the hazards, uses, and exposures of their products, and this can often provide EPA with appropriate and adequate information to review and assess a new chemical.

TSCA requires all available information to be provided to EPA, including any available test data. Companies have an incentive to understand the hazards and potential exposures to their substances and provide EPA sufficient information for the Agency to make decisions on them. Generally speaking, a company decides whether to test a chemical based on its potential uses and exposures. For example, if a substance is being developed for a consumer product, there's obviously strong motivation for a company to develop test data. The volume

at which production of a substance is anticipated could also motivate a company to conduct testing.

18. The Center for International Environmental Law (CIEL) recently released a new report, entitled "Driving Innovation," which examined the impact of chemical regulation on innovation. The final report, cited by some Members of this committee, claims that more stringent rules for chemicals foster the creation of safer alternatives, and it encourages global economies to adopt stricter policy on chemical regulation.

a. Can you please discuss how the CIEL report's conclusions compare with the conclusions of a study conducted by the Center for Strategy and Evaluation Services regarding REACH?

Response: The CIEL report concludes, on the basis of information about the increased number of patented inventions for phthalate alternatives between 1999 and 2008, and on the basis of the substitution/reformulation impact of the REACH candidate list of SVHCs, that "regulation" spurs innovation. This conclusion is based on very limited examples, however, since the "regulations" in question are regulations that threaten bans of the chemicals. It shouldn't be surprising that "innovation" into alternatives would be promoted by threats of bans/phase-outs of certain chemicals. The CIEL report does not make clear that a hazard based approach to "regulating" chemicals may produce little ultimate benefit to health/environment, but at huge cost. Chemical ban regulations, based solely on hazard, have a significant adverse economic impact, especially as there may not be appropriate substitutes for the banned substance or alternatives may not be effective to address the hazards.

The study conducted by the Center for Strategy and Evaluation Services (CSES) addressed a broader array of REACH regulations and revealed more nuanced conclusions about the relationship between regulation and innovation. According to the CSES website (http://www.cses.co.uk/new/50/), the study analyzed the results of an EU-wide survey of firms and interviews with experts and national authorities. It assessed the impact of various aspects of the European REACH Regulation on innovative activity and the innovative capacity of firms in the chemicals' sector (manufacturers of chemicals and chemical mixtures and their downstream users).

According to the CSES, some of the main findings of the study were:

- The regulatory burden placed on firms by the REACH Regulation tends to draw staff and funds away from more innovative work. As a result, 43% of companies think the regulation has had a negative impact on innovation while only 13% reported a positive impact so far.
- However, these appear to be mainly short-term effects that are expected to be offset in the longer term as companies reorient their R&D and innovation programs.
- The information creation, capture and dissemination mechanisms created by REACH (e.g. Registration Dossiers, Safety Data Sheets, Substance Information Exchange Fora) have acted as stimuli to product conception or innovation to varying degrees. 72% of companies thought they have led to an increase in access and scrutiny of information about chemical substances and 24% indicated that they had been able

benefit from this through increased knowledge of substances and properties. However, this has come at a significant handling cost to industry.

- The entry of a substance in the candidate list for authorization (use-specific licensing under the REACH program) usually tends to have a positive effect to innovative activity and forces companies to consider substitutes. The community rolling action plan is also creating a similar pressure.
- The authorization and restriction processes have had less impact so far as they have affected only very few firms. Indeed, no authorization applications have been filed to date under the REACH program.

In conclusion, the CSES study suggests that a future assessment would be required to determine whether the current negative impacts of REACH regulation on innovation will be offset in the longer term. The CSES study also suggests that REACH's information requirements and mechanisms have posed significant costs to industry. The CSES study's findings of short term negative effects on innovation are therefore at odds with the CIEL report's broad claims about the positive relationship between regulation and innovation. The CSES study suggests at a minimum that the CIEL report's claims about the impact of REACH regulations on innovation, in particular, are premature.

19. Please discuss your companies' experiences under REACH with respect to its requirements for minimum data sets for new chemicals,

a. What's been the impact of this requirement on innovation in new chemistries in the EU?

Response: Europe's REACH (Registration, Evaluation and Authorization of Chemicals) program requires a minimum data set to be submitted with each registration dossier. The system does not distinguish between new and existing chemicals. Although a final review has not yet been completed, the preliminary evidence suggests that new chemical applications in Europe are down sharply compared to other regions. In a recent assessment of REACH commissioned by the European Commission, the negative impact of REACH on innovation in an emerging technology like nanomaterials was a particular concern.[1] In that study, half of all manufacturers and importers considered that the uncertainties related to the REACH regulation were a challenge to bringing new nanomaterials to market, and that REACH had a negative or very negative effect on the time to market of their nanotechnology products. By contrast, under TSCA section 5 EPA has a track record that demonstrates it can successfully assess the health and environmental impacts of the vast majority of new chemicals very efficiently.

[1] See Final Report, Study on REACH Contribution to the Development of Emerging Technologies, GAIA, October 12, 2012, available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/emerg-techn-final-report_en.pdf.

b. How does that compare to the innovation in the U.S. under TSCA's new chemicals program?

Response: Some allege that the lack of required test data for all new chemicals in the PMN process means EPA approves new chemicals without any data on potential health or environmental effects or potential exposures. These critics call for a "minimum data set" requirement, similar to what's required for FDA approval of pharmaceuticals or EPA approval of pesticides, to assure EPA's decisions are protective.

The call for a "minimum data set" reveals a lack of understanding of the scientifically robust nature of EPA's review of new chemicals. It also ignores the major difference between TSCA and programs regulating pharmaceuticals and pesticides and the negative impacts that a minimum data set requirement would have on the development of new chemicals in the U.S. TSCA chemicals are not designed to be biologically active and they often have many more uses than do pharmaceuticals or pesticides. If every new TSCA chemical were required to provide a minimum set of data about the chemical's potential exposures from their potentially broad anticipated uses, the time required for companies to develop that information and for EPA to review it would be excessive. As a result, companies would go outside the U.S. to introduce new chemicals into the market and the U.S. would be competitively disadvantaged.

Under TSCA today, three times more new chemicals are brought for review in the United States than in any other country or region.

20. Heather White's submitted testimony, on behalf of EWG, cited two EWG studies that "detected nearly 300 industrial chemicals in the umbilical cord blood of newborn babies". Based on these studies, she raised alarms about "pre-polluted" infants.

a. Can you please explain to the Committee the ACC's position on biomonitoring information?

Response: The Centers for Disease Control and Prevention (CDC) regularly measures more than 300 chemicals in Americans' blood and urine. ACC supports the development of exposure information about chemicals and supports the CDC's development of biomonitoring information.

Importantly, biomonitoring information is just one type of exposure information and it has certain limitations: without more information you don't know the source or the magnitude or the duration of the exposure that caused the chemical to be detected in blood or urine. You also don't know what the information means in a risk context. It's ACC's position that biomonitoring information must be interpreted in a risk context if it is to be useful in the regulation of chemicals.

TSCA protects human health from unreasonable risks that may be posed from exposure to chemicals. ACC's position on biomonitoring is consistent with the Centers for Disease Control (CDC)'s interpretation of the information: just because a chemical can be detected in

our bodies does not mean that it causes harm. As a technical matter, the ability to detect the presence of chemicals has outpaced the scientific ability to interpret it in a risk context.

b. What does ACC think of the EWG's suggestion that cord blood testing be required as part of any chemical assessment process?

Response: Because biomonitoring information has the limitations discussed above (about source, magnitude and duration of exposure) and because biomonitoring information, by itself, cannot be interpreted in a risk context, ACC does not believe the EWG suggestion is either practicable or that it would provide value to the chemical assessment process. The suggestion assumes that mothers and the developing fetus will be exposed to all chemicals, which is clearly not the case. Further, this may be a particularly impractical suggestion since cord blood testing is probably more invasive with respect to privacy concerns than just about any other type of biomonitoring. It is not clear to ACC if EWG is suggesting that chemical manufacturers or the government should conduct such testing. If the suggestion is that manufacturers should conduct it, ACC contends that since the basic chemical manufacturers may not be the source of those exposures, it would not be fair to require manufacturers to conduct cord blood testing as a standard requirement of the chemical assessment process. If the EWG suggestion is for government to collect this information on a regular basis, it would be very costly and of questionable value for the government to do so, compared to the blood and urine biomonitoring the CDC currently conducts.

c. Please discuss the CDC's National Exposure Reports on measurement of chemicals in the blood and urine of Americans and the CDC's interpretation of that information?

Response: The CDC measures more than 300 chemicals in the blood and urine of Americans on a regular basis through its National Health and Nutrition Examination Survey. The CDC has been biomonitoring Americans for these chemicals since 2000. While CDC regards this information as valuable for understanding trends in chemical exposures, the CDC is also very careful in each of its National Exposure Reports to make clear that just because a chemical is present in blood or urine does not mean it is causing harm. The CDC reported presence of chemicals in blood or urine suggests only that an exposure has occurred – it does not supply sufficient information on the dose, or the effects of the exposure. Experts agree that more studies are needed to understand what biomonitoring information means in a risk context.

21. **During the hearing, there was quite a bit of discussion on the product Firemaster 550 and what the company or EPA did as part of its development and review process. I know your company does not make this product. In your capacity as Chairman of the American Chemistry Council's Executive Committee, could you please obtain the following information for the Committee from the manufacturer of Firemaster 550? Please include, at a minimum, the following:**

    a. The history of Firemaster 550, including interactions between the manufacturer and EPA

Response: The following information on Firemaster® 550 was provided by the manufacturer, Great Lakes Chemical Corporation, now a subsidiary of Chemtura Corporation.

- The manufacturer submitted a pre-manufacture notification (PMN) to EPA in **April 1995** for the brominated component (tetrabromobenzoate or "TBB") of Firemaster® 550. A PMN was not required for the phosphorous component of the product since it was already on the TSCA inventory. The PMN included information regarding the manufacturing process, chemical identity of the known constituents, estimates of production quantities, and the number of user facilities. EPA was informed that TBB would replace pentabromodiphenyl ether (PentaBDE) in the product.
- EPA and the manufacturer signed a Consent Order in **October 1996** requiring tiered testing of TBB, various stewardship activities, and a limit on TBB production.
- Limited commercial production of TBB began in **May 1997.**
- **Between 1997 and 2003**, the manufacturer submitted all the testing information requested by EPA as part of the Consent Order.
- In **December 2003**, EPA's Design for the Environment (DfE) initiated a review of PentaBDE alternatives, including TBB and Firemaster® 550, under the Furniture Flame Retardancy Partnership.
- In **February 2005**, EPA and the manufacturer signed a second testing agreement to obtain more information about potential effects of TBB on reproduction and/or fetal development as well as the potential for exposure from contact with flexible polyurethane foam.
- In **September 2005**, EPA's DfE assessment concluded that TBB had low persistence and bioaccumulation potential.
- In **fall 2009**, after reviewing results of the additional tests, EPA removed the production limit for TBB. To date, there have been no further requests for additional studies on TBB, Firemaster® 550, or the phosphorous component.
- In **March 2013**, EPA's Office of Pollution Prevention and Toxics announced that it would conduct a risk assessment of 20 flame retardants, including TBB, as part of it Chemical Work Plan Program. EPA did not include the phosphorus component in this assessment. The manufacturer has submitted all of the available data on TBB to EPA in anticipation of the review.

The timeline of interaction between EPA and the manufacture is included in the attached fact sheet.

b. A history of testing on Firemaster 550 and its constituent parts.

- Review of available health, safety, and environmental data of TBB - conducted prior to submission of the PMN.
- Environmental fate, bioaccumulation, and environmental toxicity of TBB – studies conducted between 1996 and 2003.
- Reproductive and developmental toxicity of TBB – studied conducted between 2005 and 2009.

- Exposure assessment – conducted between 2005 and 2009.

c. Information on those studies provided to EPA.

All of the information collected by the manufacturer on TBB was provided to EPA under the Consent Order. The available information was also submitted to EPA's DfE program in late 2003. All the information collected as part of the Consent Order was resubmitted to the Agency in anticipation of the review of flame retardants announced in March 2013, along with information developed for other regulatory agencies.

The manufacturer sponsored an assessment of the phosphorus component of Firemaster® 550 under EPA's High Production Volume (HPV) Challenge chemical screening process. Robust summaries of the available studies were submitted to EPA and posted on the HPV Challenge website in December 2001. EPA was aware that the phosphorus substance was a component of Firemaster® 550, but did not ask for information beyond that submitted as part of the HPV challenge.

d. Whether Section 14 of TSCA prevented EPA from looking at any portion of the submitted data it was provided by the manufacturer.

The manufacturer is not aware that Section 14 inhibited EPA's review of TBB and Firemaster® 550 in any way. Though vital compositional information was claimed to be confidential, no information was withheld from EPA scientists. As required by the PMN process, compositional information, manufacturing processes, and information about the use of the product were fully disclosed to EPA. No health and safety data were withheld from EPA and the information made publicly available by EPA through the PMN was sufficient for any interested party to ascertain the key endpoints related to the PMN substance. The information which was redacted for CBI purposes was simply to prevent another company from obtaining the study in its entirety and using it to support its own new substance notification in another country.

The claims around the confidentiality of the chemical identity of TBB at the time of the PMN submission were necessary to protect trade secrets from foreign competition and conformed to EPA's requirements for claiming CBI. At the time Firemaster® 550 was introduced, foreign competitors were anxious to know what the alternative was so that they could copy it. Disclosure in the U.S. would compromise the manufacturer's ability to protect its investment and our U.S.-based manufacturing jobs.

In accordance with U.S. requirements and globally recognized practices for hazard communications, the hazard information for each of the relevant components of the manufacturer's formulations based on TBB was included at the time it started distributing the products to its customers and amended when needed to include any new hazard information that came to light through the testing it conducted.

e. Information about actions taken by the manufacturer, pursuant to, or EPA, in carrying out, TSCA section 5 as it relates to Firemaster 550 or its constituent substances.

The manufacturer:

- conducted toxicity, environmental fate, and exposure testing;
- developed shipping procedures and best practices for Firemaster® 550 to minimize environmental releases; and
- completed all studies and reported results to EPA within the deadlines established by the consent order.

EPA:

- conducted preliminary assessment of potential health and environmental effects using predictive models and professional judgment during initial PMN review;
- developed the Consent Order establishing testing requirements and product stewardship/ risk management practices;
- reviewed and approved all test protocols for research performed under the Consent Order and conducted compliance audits covering the PMN;
- reviewed persistence, bioaccumulation and environmental toxicity data for TBB submitted by the manufacturer between 1997 and 2003;
- reviewed reproductive and developmental toxicity data for TBB submitted by the manufacturer between 2005 and 2009;
- reviewed exposure data for Firemaster® 550 between 2005 and 2009; and
- removed production limits on TBB in 2009.

f. Other relevant information to inform the Committee on this matter

In its review of the PMN for TBB, EPA took a cautious and measured approach. It identified areas of uncertainty and required the manufacturer to address those uncertainties with data. Throughout the entire process, EPA maintained the authority to limit, and potentially stop, TBB production.

Under Section 4 of TSCA, EPA is authorized to require testing of chemical substances and mixtures. Suggestions that the Agency could not have required testing of the formulated product Firemaster® 550 are inaccurate.

A recent pilot study conducted by academic researchers suggesting health effects in offspring of rats exposed to Firemaster® 550, referenced in the written testimony of Ms. Heather White, conflicts with the results of larger, Good Laboratory Practice (GLP) compliant studies of TBB conducted by accredited laboratories following protocols prescribed and reviewed by EPA.

The Honorable Henry A. Waxman

At the July 11, 2013, hearing, you testified that current disclosures, including structurally descriptive, generic chemical names are sufficient for consumers. Generally, consumers would want to use chemical names to determine whether a product on the shelf has as an ingredient a chemical substance that they wish to avoid.

1. **Please provide an example of a generic chemical name used for a specific chemical in the products of your company that is sufficient to allow consumers to determine which products on the shelf include that specific chemical and which do not.**

Response: I am not able to provide a generic name that Momentive has used in a TSCA filing. Whenever Momentive claims chemical identity as confidential, we also claim confidential our company identity. Consequently, if I were to disclose a generic name that my company has used in this public response to your question, I would be revealing my company's connection to that substance, which would impair Momentive's ability to protect that CBI going forward.

Almost all of Momentive's chemistries are used for industrial purposes, and would be converted, transformed, or derivatized in any consumer-facing product or application. Any Momentive chemistry that is in consumer products is under the regulation of the Consumer Product Safety Commission or the Federal Drug Administration and is not subject to TSCA.

In order to be responsive to your interest in examples of generic names, however, please see the response to question 2 below concerning aryl hydrazide. In addition, I have identified here several generic names used in TSCA filings that were previously associated with confidential chemical identities that were declassified in 2009:

- alkyl salicylaldehyde
- disubstituted quinolone
- alkylpridinium

Much of what is known about chemical risk under the existing TSCA scheme is submitted to EPA and published online in the form of TSCA §8(e) notices. Several examples of such notices are attached. These examples, from the most recent batch posted for the public by EPA, have been redacted to protect information claimed by the submitter as confidential business information (CBI). The redactions include information that a consumer might use to identify the chemical implicated.

Almost the only thing left unredacted is the description of the harms found through chemical testing -"erosions and ulcerations in the forestomach," "severely dysfunctional pathological changes," and "spontaneous death." Clearly, these are chemicals that consumers could reasonably choose to avoid.

One of these notices also provides an example of what a manufacturer views as substantiation of a CBI claim. The manufacturer writes, "Disclosure of this information would harm [REDACTED]'s efforts to commercialize this compound." Given the serious risks identified in the notice, including atrophy of reproductive

organs, it seems quite likely that disclosure of this risk information could harm efforts to commercialize this compound.

2. **In your view, do these redacted notices provide enough information for consumers to make informed choices and avoid these chemicals if they so desire?**

Response: The purpose of TSCA section 8(e) notices is to ensure that the chemical industry provides EPA with timely notice when it obtains information (not otherwise known to EPA) about potentially substantial risks associated with a chemical substance or a mixture so that EPA can design appropriate regulations or other risk management responses. Typically, the source of what is reported to EPA under Section 8(e) is toxicological animal study reports, epidemiological studies, or information about environmental contamination and effects. What is reported under Section 8(e) is chemical substance/mixture specific. (It is generally not information about a chemical's potential risk from use in consumer products -- information that is subject to other federal regulations, such as the Federal Hazardous Substances Act). If consumers are to make informed choices based upon information in toxicological studies reported under TSCA 8(e), they require a certain level of scientific expertise and skills necessary to understand and interpret what the study may or may not mean, and whether the results of any particular study actually translates to an actual risk to human health or the environment. Structurally descriptive generic information about a chemical may provide more relevant information to consumers on the potential health or environmental effects of a substance.

Your question perhaps indicates an interest in highlighting the absence of a generic name in two of the three 8(e) submissions attached to your questions. EPA's TSCA section 8(e) guidance (http://www.epa.gov/oppt/tsca8e/pubs/confidentialbusinessinformation.html) does not require or request that companies claiming confidential chemical identity provide a generic name in a Section 8(e) submission. Therefore, the two submissions that do not contain generic names appear to comply with EPA's requirements for 8(e) submissions from a technical standpoint. ACC and Momentive support the use of structurally-descriptive generic names in all health and safety studies when a chemical identity is claimed CBI.

One of the TSCA section 8(e) notices attached to your questions, dated April 3, 2013, provides a generic name "aryl hydrazide," in lieu of the confidential chemical identity. Entering "aryl hydrazide" into the Toxnet Data Network yields 80 different health and safety studies on aryl hydrazides. In ACC's view, these studies would very likely provide useful information on the potential health and environmental effects to interested persons, as well as to persons who are trained to understand and interpret the information appropriately.

3. **Do you support requirements for up front substantiation of CBI claims?**

Response: The American Chemistry Council and its members support up-front substantiation of CBI claims.

4. **In your view is this example substantiation sufficient?**

Response: Each of the three 8(e) submissions attached to your questions (including the example quoted in the question) states that the substantiation of the CBI claims is contained in a letter attached to the 8(e) submission. EPA does not make substantiations public. As a result, we are not in a position to answer whether the specific substantiations made by the claimants in these examples were sufficient. However, we would note that searches conducted on the generic descriptions of chemical substances generally return significantly more information related to health or environmental effects than a search of a specific commercial product.

Firemaster® 550 Flame Retardant

Firemaster® 550 is a flame retardant that protects lives and property by significantly reducing the risk of fire. By decreasing the probability of ignition from hazards such as lighters, matches, candles, and smoldering cigarettes, it makes products made with polyurethane foam safer. It is a blend of a brominated flame retardant and a phosphorus flame retardant. Firemaster® 550's high efficiency as a flame retardant is a result of the synergy of these components.

Firemaster® 550 does not contain polybrominated diphenylethers (PBDEs). The commercial introduction of Firemaster® 550 provided an alternative to furniture foam manufacturers that allowed them to rapidly eliminate the use of pentaBDE from the U.S. market. The brominated component of Firemaster® 550, which is comprised of tetrabromobenzoate (TBB), the main ingredient, and tetrabromophthalate (TBPH), provides equivalent fire safety and performance with an improved environmental profile.

About Brominated Flame Retardants

By interacting with fire in the gas phase, bromine works to prevent ignition or slow the spread of a fire. Brominated flame retardants also can be added to materials like plastic with minimal impact on their properties. As a result, flame retardants can be used to reduce the flammability of a variety of flammable materials, including textiles, electronics, building materials, plastics, and foams.

Laboratory tests show that it takes more time for flammable materials to catch fire after they have been treated with Firemaster® 550. This gives people more time to evacuate and call for help.

Products Containing Firemaster® 550 Flame Retardant

Firemaster® 550 reduces the flammability of materials, such as flexible polyurethane foam, which is used as cushioning for a wide variety of consumer and commercial products, including furniture, carpet, transportation, bedding, sound insulation, and packaging.

EPA Extensive Review & Approval Process

The Toxic Substance Control Act (TSCA) is one of more than a dozen federal laws and regulations that ensure chemicals used in commerce are safe for their intended uses.

As required by EPA for any new chemical, the manufacturer filed a Premanufacture Notice for TBB in 1995 and following a nearly two–year review, began limited commercial production in 1997. After that filing, 15 studies were submitted to EPA during the agency's 13-year assessment of TBB. Another 17 studies were conducted on TBB for regulatory authorities in other countries and were submitted to EPA in 2012 as part of its Work Plan Chemicals program. These included studies designed to assess the potential exposure of consumers to the substance, as well as persistence and potential for bioaccumulation. All of this research was conducted at independent laboratories following standardized methods prescribed by organizations such as the Organization for Economic Cooperation and Development (OECD).

Based on these studies, EPA determined that TBB has low potential for persistence and bioaccumulation.

Consumer Exposure is Extremely Low

EPA evaluates the risks of new chemicals before they are manufactured to ensure they do not pose an unreasonable risk. A series of studies was conducted to assess the environmental fate and toxicity of TBB at the direction of EPA. The results indicated the level of exposure that could cause an unfavorable effect in humans is much higher than what a person encounters in the real world.

Regulatory Agencies that have Ruled on the Safety of TBB

- U.S. Environmental Protection Agency
- Australian Department of the Environment and Heritage
- Environment Canada

Flame Retardants Work

In a 2012 study, researchers at the Fire Technology Research Laboratory at Southwest Research Institute conducted a series of 79 full-scale fire tests using upholstered furniture mockups made from foam, fabrics, and other materials. The study showed that flame retardants used in upholstered furniture were effective in slowing the spread of fire and providing valuable escape time.

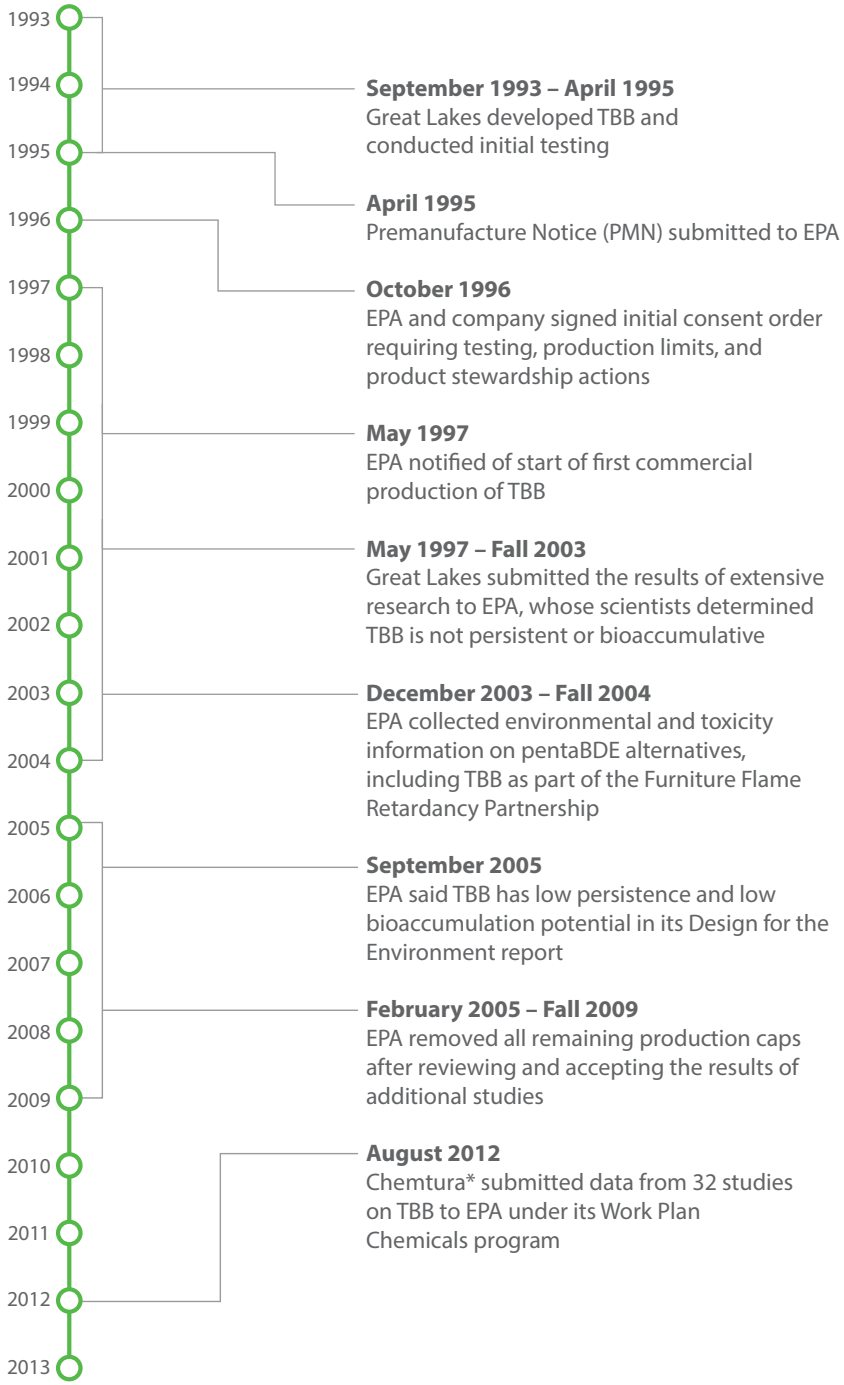
For More Information:

- Read about Firemaster® 550 flame retardant at www.chemturaflameretardants.com
- Visit the North American Flame Retardant Alliance to learn about the wide range of flame-retardant chemistries at flameretardants.americanchemistry.com.

1801 U.S. Highway 52 West | West Lafayette, Indiana 47906

Timeline of EPA's Scientific Assessment

These are some of the steps Chemtura took during the U.S. government's review of tetrabromobenzoate (TBB).



** In 2005, Great Lakes Chemical Corporation completed a merger with Crompton Corporation to form Chemtura Corporation.*

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