The Honorable John Shimkus

1. The following two (2) questions relate to testimony provided to the Committee by Heather White, on behalf of EWG.

a. Ms. White 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?

In Procter & Gamble's experience, at the time of our Pre-Manufacture Notice (PMN) submission to EPA in support of a new chemical, we have already invested millions of dollars in research and development work to identify and scale-up production of the novel technology for use in consumer product applications. Our market launch timings are contingent upon the successful EPA review of the PMN under the New Chemicals Program. P&G makes extensive use of consultation meetings with EPA prior to submitting a PMN to help us scope and anticipate the necessary data and information EPA will need during their review in order to successfully complete the 90-day review period. This pre-submission consultation opportunity has greatly benefitted our PMN filing experiences and speed to market.

P&G conducts the necessary research on a new chemical to understand the potential hazards and exposures from intended uses. This research will often include assessment of existing data from structurally similar analogs, application of predictive models (including those that EPA makes publicly available on their website), and may include generation of new safety data through toxicological testing. Because we understand the way in which consumers and the environment will be exposed to the new chemical from our consumer product manufacturing, distribution, use, and disposal, we can generally anticipate the type of data and information EPA will need during the PMN review period, and further refine our understanding and tailoring of our PMN submission based on learnings from EPA during the pre-submission consultation meetings.

EPA's approach to New Chemical Review under TSCA Section 5 is scientifically rigorous, efficient, and workable within the marketplace. EPA obtains data and information through several methods to make science based decisions about new chemicals that protect against unreasonable risks. The Agency uses "read across" information from analog chemicals; structure activity relationship analysis; and other sophisticated models for predicting a chemical's properties, potential effects and exposures.

Under TSCA Section 5(e), EPA has the authority to take regulatory action for any new chemical substance where the existing information is insufficient to permit a "reasoned evaluation" of the substance's health or environmental safety of a material. EPA has used this authority to require testing for many PMN substances prior to market entry. Thus, it benefits a manufacturer to anticipate EPA's data and information needs and supply that which may be needed in the PMN submission to ensure speed to market with the new technology in a competitive marketplace. Ms. White's positioning in her testimony that EPA cannot request additional data unless the Agency has safety concerns is incorrect.

b. Ms. White 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.
i. Can you please explain to the Committee P&G's position on biomonitoring information?

P&G agrees with the caution expressed by the U.S. Centers for Disease Control and Prevention (CDC) to avoid over-interpretation of biomonitoring data. The mere presence of a particular chemical in human tissue is not an accurate measure of whether or not it will cause harm. People are exposed to thousands of naturally occurring and manmade substances in the foods we eat, water we drink, and air we breathe. As a consequence, many chemicals may be measurable in our bodies, yet have no adverse consequences.

ii. What does P&G think of the EWG's suggestion that cord blood testing be required as part of any chemical assessment process?

Today, scientists are able to accurately measure the presence of selected chemicals in nearly any kind of environmental or biological sample down to parts-per-trillion levels, or lower. Results from such biomonitoring studies have clearly demonstrated that both naturally occurring and manmade chemicals can be found in human blood and urine at measurable quantities. However, the significance of these findings for human health has not been established. The CDC encourages the public to avoid over-interpretation of the results:

> *The presence of an environmental chemical in people's blood or urine does not mean it will cause effects or disease…For most of the environmental chemicals included in the Fourth Report, more research is needed to determine whether exposure at the levels reported is a cause for health concern. (CDC, 2009)*

The presence of trace levels of materials as measured by the CDC indicates that these persons have had contact with these materials – not that they are causing harm. Similarly, cord blood testing would only provide one isolated piece of information (i.e., that the pregnant mother and her unborn child were exposed to a specific chemical), but will not provide the missing pieces of information needed to understand the exposure in context. The toxicity of a chemical is related to its dose or concentration, in addition to a person's individual susceptibility. Small amounts may be of no consequence, whereas larger amounts may cause adverse health effects. Further study is needed for biomonitored chemicals to determine the levels of the chemical that may cause health effects, the levels at which the body produces an adaptive response to maintain homeostasis, and the levels that are not a significant health concern. Furthermore, biomonitoring data provide no information that identifies the source (or sources) of exposure. At best, biomonitoring results provide evidence of exposure, which is information EPA can use to prioritize a chemical for further safety assessment and safety determination. P&G fully agrees with the caution expressed by the CDC to avoid over-interpretation of biomonitoring data and does not agree with the suggestion that biomonitoring following all infant births is a necessary requirement for a modernized US chemical management program.

iii. 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?

The U.S. Centers for Disease Control and Prevention (CDC) released its *Fourth National Report on Human Exposure to Environmental Chemicals* (Fourth Report) in 2009, which reported the results of CDC's ongoing biomonitoring assessment of the U.S. population's exposure to environmental chemicals by measuring chemicals in people's blood and urine. The *Fourth Report* presents exposure data from the National Health and Nutrition Examination Survey for the civilian U.S. population over a two-year survey period of 2003–2004. In addition to presenting data from 2003–2004, the *Fourth Report* also included the data from 1999–2000 and 2001–2002 as reported in the *Second* and *Third National Report on Human Exposure to Environmental Chemicals* issued in 2003 and 2005, respectively. The CDC website is a one-stop source for the CDC's latest biomonitoring publications and information, including a list of chemicals included in the CDC's biomonitoring program.

Among the substances the CDC has been tracking are heavy metals such as lead and mercury, pesticides, a marker for tobacco smoke, and phthalate metabolic breakdown products.

The CDC expressed caution to the general public with the publication of the *Fourth Report* to avoid the over-interpretation of biomonitoring data:

> *The presence of an environmental chemical in people's blood or urine does not mean it will cause effects or disease…For most of the environmental chemicals included in the Fourth Report, more research is needed to determine whether exposure at the levels reported is a cause for health concern. (CDC, 2009)*

2. 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?

Europe's REACH (Registration, Evaluation and Authorization of Chemicals) program requires a minimum data set to be submitted with each registration dossier for existing and new chemicals that exceed certain manufacturing or import volume thresholds. Although a complete review has not yet been completed, the preliminary evidence suggests that new chemical applications in Europe are down sharply compared to other regions. 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.

EPA thoroughly reviews each PMN under the TSCA New Chemicals Program to determine whether the new chemical presents an unreasonable risk to human health or the environment. EPA's approach to new chemical review tailors the predictive modeling and data/ information requirements to the individual new chemical in question, with careful consideration of the anticipated use and exposure patterns in US commerce. This approach ensures that the expenditure of resources to generate and review data/ information for a new chemical is directly correlated to EPA questions about the new chemical. The minimum data set approach of REACH inevitably wastes resources and can lead to unnecessary animal testing by generating and submitting data/ information that are not relevant to an individual

chemical or does not provide the right type of data/information to answer specific questions about a chemical.

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

Under TSCA, EPA applies a much more tailored approach in requiring only that data and information needed to evaluate each new chemical that enters the US market.

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

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

EPA requires submission of a Notice of Commencement (NOC) upon the first commercial production or import of the new chemical in the US market. Customer demand will drive a chemical manufacturer's decision whether to commence manufacture of a new chemical. While a chemical manufacturer may submit multiple PMNs for new technologies that show promise in the research and development (R&D) stage, the manufacturer will only invest resources into the commercial production or import of a new technology for which a customer market exists and from which there is opportunity to recoup initial investment and probability for profit. Customer demand may simply change after a manufacturer submits a PMN, which is a key influencer to a manufacturer's decision of which PMNs to commence.

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

This is really a case-by-case situation. The investment by the manufacturer in a new chemical really determines the impact of stopping or curtailing production. Some companies file a PMN for a new chemical and begin production of small quantities until customer demand increases and a market for the chemical becomes established. At that point, the chemical manufacturer will make a greater investment in the chemical and ramp up production. Stopping or curtailing production will be easier in the very early stages when the manufacturer has not made a significant investment in production quantities or has built dedicated manufacturing lines or new plants. For innovative product formulators like P&G, we have a very clear understanding of the intended use of a new chemical after having completed extensive R&D research in specific product applications. When P&G files a PMN, we are committed to the new technology and schedule product launch timings following the EPA review period. For our PMN chemicals, a large production volume of the substance will be needed to support consumer product manufacture, and widespread exposure will occur due to household consumer use of the product containing the new chemical ingredient. This knowledge directs our safety testing and allows us to specifically customize and tailor the testing to answer specific questions we may have about the chemical, or in anticipation of what EPA may need to complete the new chemical review.

4. When P&G does testing on their chemicals prior to submitting a Pre-Manufacturing Notice:

a. Are there use and exposure patterns that drive chemical testing?

Yes. For example, if a new chemical will be used as an ingredient in an aerosol spray air freshener product, the anticipated consumer use pattern of this product indicates that inhalation will be the major exposure scenario. We will assess the inhalation toxicity of the

new chemical to understand the risk potential of the ingredient in the aerosol spray application and make decisions about overall safety.

b. Do volumetric changes in a chemical change the focus of testing?

The production volume of a chemical is an indicator of exposure, meaning higher production volumes are likely to equate to increased exposure potential. However, it is important to understand the actual exposure of the chemical during intended or reasonably foreseeable use. Actual exposure is determined by multiple factors, including concentration of the chemical, duration of exposure, frequency of exposure and route of exposure, and can target the focus and design of the exposure testing.

5. What is the major criticism of the Pre-Manufacturing Notice program under TSCA?

Lack of Minimum Test Data (i.e., PMNs with "no data"). Some critics 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.

EPA's approach to New Chemical Review under TSCA Section 5 is scientifically rigorous, efficient, and workable within the marketplace. EPA obtains data and information through several methods to make science based decisions about new chemicals that protect against unreasonable risks to human health or the environment. The Agency uses "read across" information from analog chemicals; structure activity relationship analysis; and other sophisticated models for predicting a chemical's properties, potential effects, and exposures.

EPA's approach to New Chemical Review tailors the predictive modeling and data/ information requirements to the individual new chemical in question, with careful consideration of the anticipated use and exposure patterns in US commerce. This approach ensures that the expenditure of resources to generate and review data/ information for a new chemical is directly correlated to EPA questions about the new chemical. The minimum data set approach inevitably wastes resources and can lead to unnecessary animal testing by generating and submitting data/ information that are not relevant to an individual chemical or does not provide the right type of data/information to answer specific questions about a chemical.

Finally, EPA has the authority to take regulatory action for any new chemical substance where the existing information is insufficient to permit a "reasoned evaluation" of the substance's health or environmental safety of a material. EPA has used this authority to require testing for many PMN substances prior to market entry.

6. Can EPA obtain enough data (without a minimum data set requirement) on which to make a science based decision on whether a new chemical should be introduced into commerce?

Yes. Under TSCA today, EPA obtains data and information through several methods to make science-based decisions about new chemicals that protect against unreasonable risks to

human health and the environment. The Agency uses "read across" information from analog chemicals; structure activity relationship analysis; and 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.

7. Does EPA approve new chemicals quickly enough to meet marketplace needs? When does it work well and when does it not work as well?

For the most part, EPA's review of new chemicals is very timely from a marketplace perspective. The vast majority of reviews are completed within 90 days. The willingness of the PMN submitter to consult with the Agency prior to PMN submission and to remain engaged throughout the 90 day review period contributes to EPA's timely review of new chemicals.

8. What is a trade secret and what does TSCA section 14 protect?

Section 14 provides broad protection for trade secret or confidential commercial information. Without this protection, EPA would have broad discretion to release all information provided to the Agency under TSCA, even if sensitive commercial information were involved. This would be problematic from the perspective that sensitive commercial information would be made available to competitors.

9. Can health and safety information be claimed CBI and kept from the public under TSCA?

No, health and safety information cannot be claimed CBI under TSCA. However, confidential information and data that may be contained within the study, such as the confidential chemical name or a company name, can and should be protected while disclosing the potential health and environmental impacts.

A specific, confidential chemical name is not needed to conduct a study, interpret the study results, and communicate the study's observed health effects and conclusions. The external laboratories that P&G contracts to conduct safety studies do all of this without ever knowing the specific chemical name of the test substance. EPA provides guidance on generic names that can be used to replace the chemical identity and ensure public access to appropriate health and safety information. A generic chemical name can also assist with the linkage of a confidential chemical to scientific and toxicological literature on similarly structured substances.

10. What happens when a company submits a health and safety study to EPA under TSCA and the company claims confidential chemical identity?

A company will submit two versions of the study to the Agency. One is the full study complete with the actual chemical identity; the other version of the study redacts the actual chemical name and inserts a structurally descriptive generic name in its place. The Agency and the company may negotiate the actual generic name that is chosen for insertion into the study that will be subject to public disclosure.

11. How critical to your business is protection of CBI?

It's absolutely business critical. Protection of confidential chemical identities and other pieces of sensitive business information preserves our competitive advantage and allows us to bring new innovations to the US market and delight our consumers. Without sufficient CBI protection, our competitors will capitalize on our significant investment in R&D, quickly replicate our innovations, and benefit from the safety assurance of the extensive health and safety data we've developed in support of the new technology.

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

Customer lists, marketing and sales information, information identifying the customers of a manufacturer, processor, or distributor, precise information about the use, function, or application of a substance or a mixture are all examples of CBI other than the trade secret chemical identity.

13. Is confidential information always disclosed to EPA?

Yes, EPA staff always knows the actual chemical identity and all the confidential commercial information that is not disclosed to the public.

14. What is the purpose of the generic name?

Structurally-descriptive generic names can provide the public with detailed information about the structure of the chemical, which allows the linkage to scientific and toxicological literature on similarly structured substances.

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

The most important changes that must be made are the following:

- Add clarity about what information can be protected, including chemical identity.
- Allow protection of qualifying information for as long as the need can be substantiated.
- Require up-front justification of claims.
- EPA should review and evaluate CBI claims, proportionate to Agency resource capability.
- Require structurally-descriptive generic names when chemical identity is claimed confidential.
- Allow for the sharing of CBI with US states in appropriate circumstances when the states can provide equivalent CBI protection as US EPA.

16. Hasn't there been disagreement among some stakeholders, as well as EPA, about whether chemical identity can be claimed CBI?

a. Don't they maintain that section 14 requires disclosure of chemical identity in health and safety studies except in two limited circumstances?

The disagreement on the interpretation of section 14 and its application to confidential chemical identity only arose very recently – in 2010. Prior to 2010, more than 35 years of EPA practice permitted chemical identity to be claimed CBI, even in a health and safety

study. For more than 35 years, TSCA has not been encumbered by EPA's recent administration of this new interpretation of TSCA Section 14.

b. If so, what are those?

EPA's recent change in practice reflects a new interpretation that chemical identity ***is*** health and safety data (and therefore, subject to public disclosure). P&G and our industry partners disagree with this interpretation. As discussed in our response to question #9, a specific chemical identity is not information that reveals the relevant health effects from a study. A specific, confidential chemical name is not needed to conduct a study, interpret the study results, and communicate the study's observed health effects and conclusions.

17. What accounts for this disagreement in interpretation?

Unfortunately, section 14 is not entirely clear as written. This lack of clarity has resulted in the differences in interpretation. As part of TSCA modernization, Section 14 should make clear that chemical identity can always be claimed confidential, subject to an up-front justification of the claim and the use of an acceptable generic name.

18. Do Canada and Europe provide CBI protections under their chemical management programs?

Canada and the European Union provide protections for confidential business information under the Chemical Management Plan and REACH (respectively). Canada allows a manufacturer to make a claim of confidential business information subject to substantiation upon request by the Canadian government (generally, in response to a Freedom of Information Act request). The Canadian government will ask the CBI owner for substantiation before releasing any information claimed as confidential. Articles 118 and 119 of REACH provide a broad allowance for substantiated claims of confidential business information, though the European Chemicals Agency has recently pulled back on protecting CBI claims for some pieces of information originally eligible for protection (e.g., company name).

19. Does the TSCA new chemicals program contribute to technological and sustainable innovation?

Yes, the TSCA New Chemicals Program has been a driver for technological and sustainable innovation in the US. One measure of this is the number of U.S. patents related to chemistry: 17% of all US patents are chemistry or chemistry related. The US leads the world in chemistry patents, and review under TSCA section 5 provides a regulatory framework to enable those patents to be commercialized. The chemical industry has designed new chemistries in recent years to make meaningful improvements in safety or environmental protection and have introduced those new chemistries to the US market through the TSCA New Chemical Program.

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.**

P&G filed a confidential Pre-Manufacture Notice (PMN) for a new polymer in 2004 in which we provided the structurally descriptive chemical name of "substituted acrylic acid maleic anhydride copolymer." The generic chemical name clearly indicated that the PMN material was a polyacrylate polymer and allowed the general public to understand that the results of the health and safety studies that P&G included in the PMN package were attributed to a modified type of polyacrylate polymer. The PMN indicated that this new polyacrylate polymer would be used in granular automatic dishwashing detergents. A review of P&G's corporate product safety website (www.pgproductsafety.com) reveals that "modified polyacrylate" is an intentionally added ingredient to our US marketed granular automatic dishwashing brand (i.e., Cascade ®).

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.

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?

The majority of TSCA 8(e) Notices of Substantial Risk reveal harmful effects observed during testing of Research & Development (R&D) chemicals. The chemical dose in such testing can be greatly exaggerated above anticipated and reasonable exposure levels to specifically elicit a response. Since R&D chemicals are not in US commerce, consumers are not exposed to these chemicals and do not require detailed confidential information about these prototype technologies in order to "reasonably choose to avoid" such chemicals.

We support the use of structurally-descriptive generic names in all TSCA filings that protect confidential chemical identities as CBI. Such generic names can provide the public with detailed information about the structure of the chemical, which allows the linkage to scientific and toxicological literature on similarly structured substances and provides information needed for

consumers to "reasonably choose to avoid" the class of chemical substances that could potentially produce an effect of concern at elevated exposure levels.

Additionally, EPA staff always knows the actual chemical identity and all the confidential commercial information that is not disclosed to the public for a subject chemical of a TSCA 8(e) Notice of Substantial Risk. The Agency can use that information to take necessary regulatory action under TSCA to protect public health and the environment.

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.

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

Yes. P&G fully supports a requirement for upfront substantiation of CBI claims as part of a modernized TSCA.

4. In your view is this example substantiation sufficient?

As detailed on EPA's TSCA 8(e) Notice webpage, all submitters of TSCA 8(e) Notices of Substantial Risk must substantiate any CBI claims by answering 14 substantiation questions. EPA's thorough list of CBI substantiation questions under the TSCA 8(e) program provides a model that could be re-applied to substantiation of all CBI claims under all reporting provisions of a modernized TSCA.

Responsible submitters of TSCA 8(e) Notices of Substantial Risk address the following substantiation questions in order to claim CBI:

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.
2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.
3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.
4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.
5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).
6. Does the information claimed as confidential appear or is it referred to in any of the following:
    a. Advertising or promotional material for the chemical substance or the resulting and product;
    b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer

or sale);
c. Professional or trade publications; or
d. Any other media or publications available to the public or to your competitors.

If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.
8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors access to your customers. Address each piece of information claimed CBI separately.
9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?
10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market?
    a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?
    b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate bow soon a market will be established.
    c. What is the substance used for and what type of product(s) does it appear in.
11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?
12. Do you assert that disclosure of this information you are claiming CBI would reveal:
    a. confidential processes used in manufacturing the substance;
    b. if a mixture, the actual portions of the substance in the mixture; or
    c. information unrelated to the effects of the substance on human health or the environment?

    If your answer to any of the above questions is yes, explain how such information would be revealed.
13. Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.
14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.

Please see EPA's TSCA 8(e) Notice Webpage for more information about claiming confidentiality in Notices of Substantial Risk:

http://www.epa.gov/oppt/tsca8e/pubs/confidentialbusinessinformation.html