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Subcommittee on Environment and the Economy

Hearing on
“Regulation of New Chemicals, Protection of Confidential Business Information,
and Innovation”

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Introduction

Chairman Shimkus, Ranking Member Tonko, members of the Committee, thank you for inviting me to testify today to discuss The Procter & Gamble Company's (P&G) experience with compliance under the Toxic Substance Control Act (TSCA), particularly our experiences with the new chemicals and confidential business information sections when bringing new innovation to the US market.

My name is Len Sauers. I am the Vice President, Global Sustainability, Product Safety and Regulatory Affairs at Procter & Gamble where I am responsible for the company's sustainability program, as well as the product safety and regulatory affairs organization.

P&G serves more than 4.6 billion people around the world with our trusted household and personal care brands. We have on the ground operations in nearly 80 countries worldwide, and dedicated innovation facilities on five continents. Ninety-nine percent of American households contain at least one P&G product. Over 90% of the products we sell in North America are manufactured in the U.S, where we operate 33 manufacturing facilities in 22 states (including California, Delaware, Georgia, Illinois, Iowa, Kansas, Maryland, Massachusetts, Missouri, Nebraska, New Jersey, North Carolina, Ohio, Pennsylvania, Tennessee, Utah, Vermont and Wisconsin). Our trusted, quality, leadership brands, including Pampers, Tide, Pantene, Bounty, Crest, Oral-B, Duracell, Olay, Gillette and many others, touch and improve the lives of consumers in virtually every country.

Innovation is integral to everything we do to improve the value consumers get from putting their trust in P&G brands. Since our founding in 1837, we have been inspired and driven by our Purpose — to touch and improve the lives of our consumers, in small but meaningful ways each and every day. As a company, we have chosen to deliver on our Purpose through innovation. At P&G, we believe innovation is our lifeblood.

I want to thank you, Mr. Chairman and Ranking Member Tonko, for your interest in learning more about TSCA, the need for modernization of the statute, and how this will impact US innovation. P&G recognizes that our consumers are concerned about chemicals used in everyday products and we fully support efforts to enhance public confidence in the safety and management of chemicals through the modernization of TSCA.

P&G supports robust federal modernization of the Toxic Substance Control Act of 1976. Federal action is urgently needed to slow the emergence of new individual state regulations which would result in an unworkable patchwork of varying requirements across the nation that would significantly disrupt innovation and U.S. market distribution. Further, many countries are emulating the European Union's REACH chemical framework which presents a significant barrier to innovation, lacks a science-based chemical prioritization process, or any obligation to systematically affirm the safety of priority chemical substances. The U.S. needs to provide global leadership in the chemical management arena by providing an alternative to REACH that protects human health and the environment and promotes sustainable innovation. P&G remains

committed to help develop workable, scientifically sound legislation that strengthens protection of human health and environmental safety to ensure U.S. leadership of sustainable innovation in the global marketplace.

New Chemicals

P&G believes that new chemical review under a modernized TSCA needs to balance protection against unreasonable risks from exposures to a new chemical with the promotion of innovation in a competitive, global marketplace. Over the last 30+ years, P&G has either submitted or been the major contributor to over 175 Pre-Manufacture Notices (PMNs) that have spanned commodity chemical manufacturing as part of our global P&G Chemicals business, to use of new chemistries in the formulation of our household brands. From our experience, we believe that both the law and EPA's governance of the New Chemicals Program have provided for scientifically robust reviews of the potential hazards and exposures of new chemicals entering the US market to ensure appropriate health and environmental protection.

One of the greatest strengths of the TSCA New Chemicals Program is the ability to custom tailor the safety data and information in a PMN submission to the specific new chemical in question and its potential exposures, rather than require a minimum safety data set that may either provide too little data or information that is not relevant about the new chemical. We believe a minimum data set approach to new chemical review is a wasteful practice that is resource-intensive, time consuming, and needlessly sacrifices the lives of animals. EPA's administration of the New Chemicals Program has followed

a more enlightened approach which fully utilizes all available safety data and information, including reliance on sophisticated predictive models and the development of new safety data when necessary, to make decisions. When developing our PMNs over the years, we have found EPA receptive to pre-submission consultations that have helped us anticipate and plan for the necessary safety data and information that EPA would need during their review. EPA's willingness to dialogue early in the development of a PMN has resulted in our positive experience with the New Chemicals Program and has allowed us the speed to market needed for competitive advantage and ensured our ability to delight our consumers with new-to-the-world innovations.

EPA has administered the New Chemicals Program efficiently by conducting the majority of PMN reviews within a 90 day period, although the Agency can (and does) have the duration of the review extended when needed to obtain additional, targeted safety related data and information about the new chemical. EPA has a broad range of regulatory tools that the Agency will exercise to limit exposure to a new chemical when needed. The restrictions imposed by the Agency can be based on the intended use of the new substance described in a PMN or any other uses of the new substance that raise EPA's concern. EPA's application of a Significant New Use Rule (SNUR) to a new chemical, among other regulatory options, demonstrates the Agency's intent in understanding and managing the full risk potential of a new chemical entering the market, beyond the specific uses described in the PMN.

New chemical review is a key element of TSCA. It is P&G's opinion, and one that is shared broadly by chemical manufacturers and innovative formulators across the industry, that the new chemical provisions of TSCA function efficiently and effectively. We encourage the subcommittee to protect this positive element of TSCA when considering any effort to modernize the statute.

Confidential Business Information

Procter & Gamble invests \$2 billion annually in research & development (R&D), which is about 60% more than our next closest competitor and more than most of our competitors combined. We have a significant interest in protecting our new-to-the-world chemistries, our formulation designs and process technology, and other confidential business information from public disclosure to our competitors in order to succeed in the marketplace by delighting our consumers with innovation. P&G holds 55,000 active patents globally, but patents alone are not enough to protect the continual improvements we make to our product designs. We rely heavily on the protection of confidential business information afforded by Section 14 of TSCA to remain competitive in the US and global marketplace. The challenge of a competitive marketplace and of earning the right to win with consumers incentivizes us to continually search for more sustainable innovations that meaningfully improve the lives of our consumers and deliver real environmental benefits.

We recognize that EPA has to carefully balance the protection of confidential business information under TSCA with providing public access to health and safety information

on chemicals in U.S. commerce. P&G fully supports transparency with health and safety information in EPA's administration of TSCA Section 14. However, we believe the broad language of TSCA Section 14 has led to misinterpretations of what constitutes health and safety information. Our particular concern is with EPA's recent decision to reverse 35+ years of practice by requiring in all instances the public disclosure of the confidential chemical identities for which health and safety studies are provided. A specific, confidential chemical identity is not needed to conduct a health and safety study, interpret its results, or communicate the study's observed health effects and conclusions. The external, 3rd party laboratories that P&G contracts to conduct safety studies and interpret the results, complete these tasks without ever knowing the specific, confidential chemical name of the test substance. Structurally descriptive, generic chemical names are sufficient to provide the public with information about the structure of the chemical and its hazard profile, which in turn provides a linkage and access to publicly available, scientific and toxicological literature on similarly structured substances.

P&G's concern with EPA's new practice culminated in late 2011 when EPA sent to the Office of Management and Budget (OMB) for its review a draft proposed rule to amend the PMN regulations. This proposed rule, if ever finalized, could delete the longstanding opportunity of PMN submitters to protect from disclosure the confidentiality of new chemical identities in health and safety studies.

In our industry, confidential chemical identities are often the most valuable type of intellectual property. Disclosure of a specific, confidential chemical identity in a PMN submission that contains supporting health and safety data provides information to competitors about the company's go-to-market plans. P&G files hundreds of patents each year to protect a range of technological options for our potential use, but a PMN is rarer, and when followed by submission of a Notice of Commencement (NOC) to EPA, provides a clear signal to competitors that we are invested in and intend to use the new-to-the-world technology described in the PMN. Disclosure of a specific, confidential chemical identity in a PMN submission can provide competitors with the necessary information to unravel our formulary science, replicate our product formulations, and importantly, benefit from the health and safety assurance of our toxicological studies in the PMN submission – all without investing the same significant time, resources, and billions of dollars in research and development as P&G.

P&G's development and market introduction of Tide Coldwater provides an example of the impact on innovation that EPA's changing interpretations of TSCA Section 14 have created. P&G's formulary scientists discovered a new-to-the-world-surfactant needed for laundry detergents to deliver world-class cleaning performance and stain removal in cold wash water. This innovation led to P&G's introduction of Tide Coldwater in the US market. This technological breakthrough enabled consumers to obtain the same strong performance benefits from washing in cold water that they knew to expect from washing with standard detergents in warm or hot wash temperatures. Tide Coldwater represented a sustainable innovation that delighted consumers by helping them save

money on their energy bills and providing a way in which to meaningfully benefit the environment by reducing CO₂ emissions from the energy-intensive process of heating water for the laundry wash cycle. For instance, if every household in the United States used cold water for laundry, the energy savings would be 33 billion kilowatt hours per year which is the equivalent use of electric consumption in 4.4 million households.

P&G submitted two PMNs to EPA to create Tide Coldwater. Both PMNs claimed the chemical identity as confidential to prevent competitors from piecing together the required chain lengths, isomeric structures, and salt derivatives of the sulfated alcohols needed for optimal surfactancy in cold water wash. P&G's development costs of the two PMNs totaled about \$150 million. The submitted PMN documents weighed 150 lbs., mostly due to the extensive safety studies provided by P&G. EPA's new interpretation of TSCA Section 14(b) would have meant disclosing to competitors those confidential chemical identities because of the submitted safety studies and thereby risking P&G's ability to succeed in the US marketplace with an innovation that delivered meaningful and measurable environmental benefits.

A modernized TSCA must not create a disincentive for companies to invest in the development of new chemicals and to support the safe use of those chemicals by generating appropriate health and safety studies. A modernized TSCA must continue to strike the right balance of protection of confidential business information with public access to health and safety information about chemicals in US commerce.

Conclusion

Mr. Chairman, Ranking Member Tonko, thank you again for the invitation to testify this morning. P&G values our partnership with you and this Subcommittee and we remain committed to working with you to develop a practical, scientifically sound chemical management program that strengthens protection of human health and the environment and ensures U.S. leadership of sustainable innovation in the global marketplace.