Representative Brooks Q1: Are microbeads having different impacts on different parts of the country or are microbeads having a blanket impact on all U.S. waterways? Are there certain states where this is more problematic than others?

A: While comprehensive data do not exist today to determine if microbeads are occurring in all U.S. waterways, it is likely that the potential presence of microbeads is different across the country and coming from a variety of sources. This may be due to several possible causes:

- Waterways that have facilities that manufacture microbeads alongside them will likely have higher concentrations of microbeads (at least prior to waste water treatment facility removal).
- Different water treatment facilities across the country have different removal capabilities, and thus could result in different levels of microbeads in the environment.
- It's unclear what contribution various sources of microbeads have in the aquatic environment. However, if any microbeads are coming from rinse off consumer products, waterways near high population areas would be expected to have higher levels of microbeads going into waste water treatment facilities.

Representative Butterfield Q1: What is involved in the process of reformulation and what is the cost to companies to reformulate?

A: When product reformulation is necessary, it is very complex, time-consuming and expensive. It is not a matter of simply switching out one ingredient for a different ingredient. A lot of questions need to be answered by many experts before an updated product can go to market. The process typically involves:

- Research & development to identify, test and qualify a replacement ingredient
- Efficacy/effectiveness consumer testing and qualification of the reformulated product containing the new ingredient
- Meeting safety and regulatory requirements for the new ingredient and product
- Scale-up and qualification of new manufacturing process, distribution, etc. (i.e. supply chain issues)

The following infographic helps to explain the complicated process of product reformulation.

THE ROAD TO REFORMULATING PERSONAL CARE PRODUCTS

COSMETICS INFO .ORG

Why does it take so long to reformulate a personal care product? A lot of questions need to be answered by a lot of experts before an updated product can go to market.

Start

Raw Material Research & Development

12-18 MONTHS

- Is there an alternative ingredient?
- Is the alternative ingredient safe for use by people?
- Does the new ingredient cause stinging, burning, itching?
- Is the new ingredient going to provide the same benefits?
- Has anyone already patented the ingredient such that it cannot be used?
- Is the new ingredient compatible with the other ingredients already in the product?
- Does it cause the formula to change color?
- Can a supplier provide the ingredient in the quantities and at the quality required?

BIOCHEMISTS
CHEMISTS
TOXICOLOGISTS
PRODUCT DEVELOPERS
PATENT & TRADEMARK ATTORNEYS

Product Testing and Qualification

6-12 MONTHS

- Is the reformulated product stable to temperature, light, etc. during storage, transportation, and use?
- Can the product be preserved?
- Is a new package required to keep the product stable?
- Does the product feel, smell, and have the same thickness, color or consistency as the original?
- Can the new formula be made in the same factory on the same equipment under Good Manufacturing Practices?
- Do employees need to be trained on handling the new raw material?
- Is there sufficient safety data available on the new ingredient?

PRODUCT DEVELOPERS
CHEMICAL ENGINEERS
PACKAGE ENGINEERS
CONSUMER SCIENTISTS
CLINICAL SCIENTISTS
ENVIRONMENTAL SCIENTISTS
ANALYTICAL SCIENTISTS
QUALITY ASSURANCE
MICROBIOLOGISTS
PROCESS ENGINEERS

Safety & Regulatory Requirements

6-12 MONTHS

- Has safety and claims been adequately demonstrated on the reformulated finished product?
- Are special studies (analyses?) required by a dermatologist, pediatrician, or ophthalmologist?
- Are additional consumer studies needed?
- Is any specific safety/regulatory labeling needed on the product?

TOXICOLOGISTS
CONSUMER SCIENTISTS
CLINICAL SCIENTISTS
REGULATORY EXPERT
STATISTICIANS

Manufacturing & Marketing

6-12 MONTHS

- Are new graphics required for the label?
- When can the printer deliver new product labels?
- How will current products on the shelf be phased out?
- How soon can the reformulated product be manufactured and distributed?
- How much product inventory is required at retailers?

GRAPHICS DESIGN
LOGISTICS
SUPPLY CHAIN
TRANSPORTATION
IMPORT/EXPORT
MARKETING & SALES

Post-Market Surveillance

CONTINUAL EVALUATION

- Are any specific consumer/retailer communications required about the product update?
- How will we monitor the safety and effectiveness of the new formulation with consumers?

MEDICAL AFFAIRS EXPERT
CUSTOMER RELATIONS

COSMETICS INFO .ORG

Representative Butterfield Q2: What amount of time does the industry need to phase out the use of microbeads?

A: Illinois was the first state to ban the use of synthetic plastic microbeads in personal care products. The effective dates ban the manufacture of products effective December 31, 2017 and ban the sale of products containing microbeads effective December 31, 2018. An additional year is provided for over-the-counter drugs, as these products follow a different FDA regulatory scheme.

This timeframe ensures manufacturers of all sizes have adequate time to reformulate with alternative ingredients that are safe for consumers, the environment and meet all requirements of the Federal Food, Drug and Cosmetic Act.

Representative Butterfield Q3: What steps have some in your industry already taken to address the inclusion of microbeads in products?

A: Plastic microbeads are used in cosmetic and personal care products because of their safe and effective exfoliating properties. However, despite the absence of any peer-reviewed science on the contribution from personal care products of plastic microbeads in the aquatic environment, and out of an abundance of caution, many personal care products companies have voluntarily committed to discontinue formulating with plastic microbeads in cleansing products in favor of other viable alternatives.

Representative Butterfield Q4: Is the industry united in asking for a federal solution?

A: The nation's personal care products companies are pleased to support efforts that demonstrate our longstanding commitment to the global stewardship of their products. We urge policy makers to work with all sectors of the business community as they seek to eliminate plastic waste in our waterways and to identify effective and realistic solutions that consider the existing and emerging science as it becomes available.

Our industry, NGOs and various other stakeholders worked collaboratively in 2014 to pass landmark legislation in Illinois banning microbeads from cleansing and rinse-off personal care products. Shortly thereafter, the Council of State Governments approved model legislation – based on the success in Illinois – banning microbeads in personal care products, and accepted it as "Suggested State Legislation" in order to help officials in other states shape public policy on this issue. Our preference is to advocate for similar legislation to be enacted throughout the United States (i.e., a federal approach). This would avoid a patchwork of potentially different regulations across the states.