2019 CPSC Nanomaterial Statement

The U.S. Consumer Product Safety Commission (CPSC) is an independent regulatory agency with jurisdiction over 15,000 types of consumer products used in or around the home¹.

1. What are Nanomaterials?

- 1.1 Nanomaterials are materials/particles that range in size from 1 to 100 nanometers (nm) in length. Although certain nanomaterials may have the same name as other materials historically in use, because of their small size, these newer materials may demonstrate different physical and chemical properties. Some manufacturers use these new nanomaterials in their consumer products, with the stated purpose of improving the performance and durability of their products.
- 1.2 Products produced by nanotechnology continue to demonstrate significant growth potential, with an expected market value of more than \$100B in the next 5 years.
- 1.3 Nanomaterials represent a wide range of compounds that may vary significantly in their structure, physical and chemical properties, and potentially, in their behavior in the environment and human body.
- 1.4 There is wide variation in potential health effects regarding specific nanomaterials, in addition to a dearth of data on exposure and toxicity, particularly chronic toxicity. This is particularly true of nanomaterials in and released from nano-enabled consumer products.

2. Assessment of Potential Health and Safety Effects

The potential health and safety risks of nanomaterials are assessed under these CPSC statutes, regulations, and guidelines:

- 2.1 CPSC staff assesses products' potential health effects under the Federal Hazardous Substances Act (FHSA). Under the FHSA, a "hazardous substance" is toxic, or one of the other hazards enumerated in the statute; and, it has the potential to cause "substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use." Therefore, exposure and the subsequent risk must be considered, in addition to toxicity, when assessing potential hazards under the FHSA. The CPSC risk assessment approach includes reviewing available toxicity data, examining the chemical's form and characteristics, among other criteria, as described in the Chronic Hazard Guidelines.
- 2.2 Under the Consumer Product Safety Act (CPSA), staff evaluates a consumer product to determine whether the product contains a defect which creates a "substantial product hazard" or warrants recommending that the Commission set a consumer product safety standard by regulation to prevent or reduce an unreasonable risk of injury. In the absence of an express regulation, staff will look to see whether a defective product with nanomaterials

¹ Except certain items excluded by statute, for example, aircraft, food, drugs, cosmetics, medical devices, and pesticides.

- creates a substantial risk of injury because of, among other factors, the pattern of the defect, the number of defective products distributed in commerce, and the severity of the risk.
- 2.3 Manufacturers, retailers, and distributors of nano-enabled products, as with any consumer product under the CPSC's jurisdiction, must report to the CPSC immediately if they obtain information that reasonably supports the conclusion that their product fails to comply with an applicable consumer product safety rule; contains a defect which could create a substantial product hazard; or creates an unreasonable risk of serious injury or death. More detailed information for manufacturers, retailers, distributors, and importers can be found on the CPSC Business and Manufacturing webpage.

3. CPSC Nanotechnology Activities

- 3.1 To develop data on the exposure and toxicity of nanomaterials, CPSC entered into more than 60 interagency agreements with other federal agencies and contractors since 2007 to: (1) develop methods that identify, characterize, and quantify nanomaterials in consumer products; (2) develop tools to prioritize nanomaterial research and model potential consumer exposure; and (3) perform literature searches for available toxicology data to assess potential adverse health effects. Technical reports and links to publications produced from these agreements can be found on the CPSC's Chemical webpage.
- 3.2 CPSC staff is involved in a number of voluntary standard activities with standard development organizations, including ANSI, ASTM International, and the International Organization for Standardization. Activities include developing standards, guidance documents and technical reports for: terminology; informatics and nomenclature; measurement and characterization; test methods; modeling; environmental, health and safety; and nano-enabled consumer products. Information derived from the CPSC interagency agreements is being developed into ASTM and ISO voluntary standards to provide consistency, reliability, and transparency to methodologies characterizing and assessing the release of nanomaterials from consumer products. These standards provide a foundation for CPSC and the regulated community to meet statutory responsibilities for nanomaterials.

4. Other Resources

The <u>National Nanotechnology Initiative</u> coordinates U.S. federal work in nanotechnology research and development, including the support of responsible development of nanotechnology, fostering communication among federal agencies, and promoting data-sharing and best available practices for regulating nanomaterials. Other sources of information on nanomaterials include the U.S. federal agency websites of <u>OSHA</u>, <u>NIOSH</u>, <u>FDA</u>, and <u>EPA</u>.