Johnson & Johnson Guidelines: Responsible Use of Nanotechnology

March 2013

Background

Nanotechnology is the field of science and technology applied to the control of matter on the atomic scale, usually between 1 and 100 nanometers. Nanotechnologies encompass an extremely broad range of technologies, from well understood micronized materials used in consumer sunscreen applications, to micronized coating that change the behavior of substrates, to buckyballs/nano tubes, and to nanomilled pharmaceuticals.

The objective of these Guidelines for Responsible Use of Nanotechnology is to set standards for responsible behaviors across the Corporation and to provide a general framework to influence the wider global community in developing nanotechnology in a responsible manner. Johnson &Johnson Operating Companies should not rely on these Guidelines in isolation and adoption and/or use of these does not constitute compliance with relevant law. The following principles are only relevant insofar as they do not conflict with relevant international, national or other law.

Each Operating Company shall comply with the following guidelines insofar as the principles do not conflict with the specific commercial obligations relevant to the individual operating company.

Defining Nanomaterial

There is no universally accepted definition of nanotechnology or nanomaterials, although there have been some efforts to produce one.

The U.S. Food and Drug Administration (FDA) has announced that it is compiling an inventory of materials up to 1,000 nm. Materials that are between 100 and 1,000 nm that exhibit

nanoscale phenomena are considered to be nanomaterials by the FDA. Within Europe, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has adopted definitions for various forms of nanomaterials (nanoparticles, nanotubes, films, etc.) for regulatory use.

The U.S. National Nanotechnology Initiative, International Standards Organization, and the Organisation for Economic Cooperation and Development (OECD) Working Party on Nanomaterials have slightly different definitions. In addition, Health Canada has proposed a working definition based on similar considerations.

The Johnson & Johnson Definition of Nanomaterial

Johnson & Johnson will use the following definition that is consistent with, but not identical to, the above definitions:

Nanomaterials are defined as intentionally manufactured, solid, insoluble particulate substances either in powder form or as dispersions or as aerosols on the order of 1 to 100 nm

(i) which contain, when measured by standardized and recognized methods, at least 10 wt.-% of nano-objects, or

(ii) which have, when measured by appropriate methods, a volume specific surface area larger than 6 x 1/100 nm (60 m2/cm3).

The term "nanoscale phenomena" means properties of the product, material, substance, ingredient, device, system or structure which are attributable to its size, distinguishable and not extrapolations from the chemical or physical properties of individual atoms, individual molecules and bulk material.

Johnson & Johnson's Approach to Product Stewardship

The Johnson & Johnson Family of Companies has robust product stewardship programs, and a rigorous, data-based approach is taken to the risk assessment and selection of ingredients and materials for its products. All ingredients and their individual safety data (i.e. environmental effects, human health, physical and chemical properties), as well as data from external scientific

authorities, are reviewed by experts, such as medical doctors, toxicologists or biologists, prior to use in a product. Processes used to discover/research and manufacture a product also undergo technical review by industrial hygiene and process safety experts.

All Johnson & Johnson Operating Companies report to a sector management group (i.e., Consumer Products, Medical Devices & Diagnostics, or Pharmaceutical Products). Senior management of each sector recommends its Operating Companies adopt the following guidelines.

Johnson & Johnson Guidelines for Responsible Use of Nanotechnology

1. Each Operating Company should ensure that the responsibility for guiding and managing its involvement with nanotechnologies resides with an appropriate governing body.

2. Each Operating Company should seek input from key stakeholders and evaluate these inputs in development or use of products using nanotechnologies.

3. Each Operating Company should identify and minimize sources of risk for workers handling products using nanotechnologies, at all stages in the discovery/research and production processes or in industrial use, to ensure high standards of occupational and environmental health and safety.

4. Each Operating Company should carry out thorough risk assessments and minimize any potential human health, safety and environmental risks relating to its products using nanotechnologies.

5. Each Operating Company should consider and respond to any social and ethical implications and impacts in the development or sale of products using nanotechnologies.

6. Each Operating Company should adopt responsible practice in the sales and marketing of products using nanotechnologies.

7. Each Operating Company should consider the sustainability of nanomaterials.

8. Each Operating Company should engage with suppliers and/or business partners to assure there are no conflicts with these guidelines.

References

Auffan, M. et al. 2009. 'Towards a definition of inorganic nanoparticles from an environmental, health and safety perspective,' Nature Nanotechnology 4: 634-641.

Bergeson, L.L. 2008. Nano Opportunities & Risks. Environmental Claims J. 20: 144-159.

Berube, D.M. 2008. Rhetorical gamesmanship in the nano debates. J. Nanoparticle Research.

BIAC Nanotechnology Committee, 'Responsible Development of Nanotechnology: Turning Vision into Reality,' February 2013.

Commission of the European Communities, 'Commission recommendation on a code of conduct for responsible nanosciences and nanotechnologies research,' 2008.

Commission of the European Communities, 'Commission recommendations on the definition of a nanomaterial,' 2011.

Commonwealth of Australia Consolidated Acts, 'Industrial Chemicals (Notification and Assessment) Act,' 1989.

Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Office of Pharmaceutical Science (OPS) Manual of Policies and Procedures (MAPP), Reporting Format for Nanotechnology-Related Information in CMC Review, 2010.

Food and Drug Administration (FDA), 'Considering Whether and FDA-Regulated Product Involves the Application of Nanotechnology,' Draft Guidance 2011.

Health Canada, Policy Statement on Health Canada's Working Definition for Nanomaterials, October 2011.

OECD WPMN Publication Number 25: 'Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision' (ENV/JM/MONO(2009)20/REV, 2nd June, 2010)

United States, Memorandum for the Heads of Executive Departments and Agencies, 'Principles for Regulation and Oversight of Emerging Technologies,' 2011.

United States, Memorandum for the Heads of Executive Departments and Agencies, 'Policy Principles for the U.S. Decision-Making Concerning the Regulation and Oversight of Applications of nanotechnology and Nanomaterials,' 2011.

"VCI position on the definition of the term 'nanomaterial' for use in regulations laying down provisions on substances;" German Chemical Industries Association (Verband der Chemischen Industrie) (February 2010).