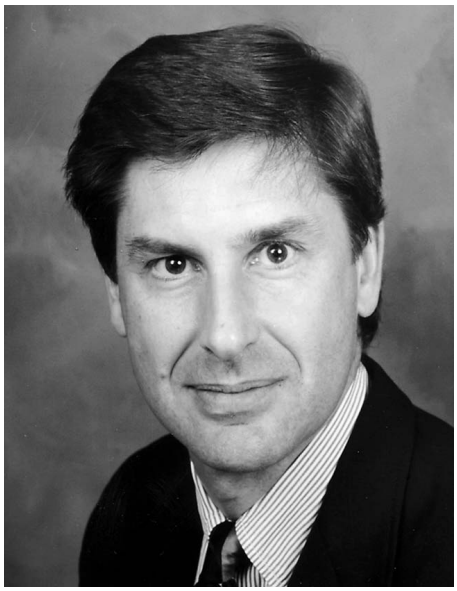
Consumer Labeling of Nanomaterials in the European Union and the United States

by John Pendergrass, with Linda Breggin, Robert Falkner, Nico Jaspers, and Read Porter



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Nanotechnologies have opened the way to a wide range of innovative products in food, cosmetics, healthcare, computing, energy storage, and other areas. The result of the deliberate manipulation of matter at the molecular level (typically at a scale of approximately 100 nanometers or less, a nanometer being one-billionth of a meter), nanomaterials have been used in a growing number of products that are available to consumers worldwide. Understanding of how nanomaterials interact with the environment and the human body, however, has not kept pace with the development of nanotechnologies. Early results of research suggest that the safety of all nanomaterials cannot be taken for granted. Furthermore, the ongoing expansion of nanotechnologies may produce novel nanostructures that cause currently unknown forms of hazard. While researchers and regulatory agencies are seeking to fill existing scientific knowledge gaps, the commercialization of nano-enabled products continues, primarily in Asia, Europe, and North America.

Consumer labeling of nanomaterials is set to become an important and potentially controversial issue on the transatlantic regulatory agenda. Until recently, neither the United States nor the European Union (EU) had enacted a general labeling requirement for nanomaterials. In November 2009, however, the EU enacted a regulation requiring the labeling of cosmetic products that contain nanoscale materials. The regulation consolidates and updates several prior regulations on cosmetics and requires ingredient listings to include the word "nano" for any nanoscale ingredients.

In light of this recent divergence between U.S. and EU approaches to consumer labeling of nanomaterials, it is time for governments to consider the implications of recent developments for international trade and potential means of promoting the development of common approaches. As a result of the growing trade in nanomaterials and nano-enabled consumer products, differences in risk management approaches will have important trade repercussions. Emerging differences in consumer labeling regimes, in particular, pose a challenge to regulatory cooperation between the EU and the United States.

The EU's recent action comes amidst a growing number of calls from consumer organizations, trade unions, and environmental groups for the introduction of comprehensive labeling of nanomaterials in consumer products. In contrast, U.S. regulators have indicated little interest in mandatory labeling. For example, in its 2007 Nanotechnology Task Force report, the U.S. Food and Drug Administration concluded that current science could not support a finding that classes of products with nanoscale materials presented greater safety concerns than classes of products without nanoscale materials and, therefore, label disclosure requirements should be handled on a case-by-case basis.

** This Column is based on a report by Robert Falkner, Linda Breggin, Nico Jaspers, John Pendergrass, and Read Porter,* Consumer Labeling of Nanomaterials in the EU and U.S: Convergence or Divergence?*, EERG Briefing Paper 2009/03 (Chatham House 2009). It reflects the findings of a research project conducted in 2008-2009 by a research team from the London School of Economics, ELI, Chatham House, and the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars. The project was funded by a European Commission grant and involved a comparative analysis of U.S. and EU nanomaterials regulation in the areas of chemicals, food, and cosmetics. More information on the research project and team can be found at http://www.lse.ac.uk/nanoregulation.*

This discrepancy in regulatory approaches mirrors the deep divide among stakeholder groups about whether and how to label nanomaterials. A recent study that interviewed and surveyed over 100 stakeholders found both strong proponents of comprehensive labeling as well as those who raised fundamental questions about its appropriateness and necessity.[1] For example, some stakeholders warned that labeling would be a costly way to inform the public about the presence of materials that will most likely be of little consequence to human health or the environment. Both U.S. and EU industry interviewees, in particular, questioned the usefulness and legitimacy of a general labeling requirement for all products that contain nanomaterials. Some compared this to the labeling of genetically modified (GM) food in the EU, which informs the consumer of the use of a certain technology, but not of specific risks involved in the consumption of GM food. Others noted the danger of information overload and were concerned that labels might confuse consumers more than inform them.

On the other hand, some interviewees suggested that the labeling of nanomaterials in food and cosmetic products would be of particular importance in the future, not least as a means of building consumer trust through enhanced transparency. Some see this becoming increasingly important as more and more nanomaterials enter the market. Although most producer companies remain skeptical about a general labeling requirement, some retail firms, e.g., supermarkets, are likely to view nano-labeling more favorably as a way of assuring consumers that no risks, whether actual or potential, are hidden from them. Several civil society and consumer groups have called for better labeling provisions as part of a broader attempt to ensure consumers' right-to-know.

This argument for nanomaterials labeling is seen by proponents as a means of ensuring that consumers are free to express views not only on the safety of nanomaterials but also on ethical dimensions of the use of nanotechnologies, particularly in food and cosmetics. In this perspective, labeling becomes a tool for embedding nanomaterials regulation in a wider social and ethical context without sacrificing the scientific foundations of the core risk assessment process. Opponents have pointed out, however, that any comprehensive labeling of nanomaterials would be misleading, particularly if it failed to notify consumers either of specific health or environmental risks or of specific benefits of the nanomaterials. A question that is at the heart of such disagreements is whether ethical concerns that are unrelated to specific concerns about environmental and health risks are legitimate reasons for introducing a labeling regime.

Such differences in interpretation of labeling schemes are not unique to the debate on nanomaterials. Similar arguments have been used in the context of the use of GM organisms in food production and the creation of biotechnology-based labeling requirements in the EU. They have also characterized the debate on whether technology- or process-based labeling regimes violate the international trade rules of the World Trade Organization (WTO) system, and particularly the rules of the Technical Barriers to Trade Agreement and the Sanitary and Phytosanitary Measures Agreement. Rehearsing the arguments of this long-running debate is beyond the scope of this Column, but this does point to the possibility that differences in EU and U.S. labeling regimes for nanomaterials will also play into future transatlantic relations within a WTO context. Both sides should therefore consider the implications of different labeling requirements, whether already established or newly created, for the proper functioning of international trade.

If the United States and the EU were to explore the possibility of developing common approaches or standards for nanomaterials labeling, such an undertaking should involve a multi-stakeholder forum to engage relevant groups from industry and civil society in order to give full weight to the different commercial and ethical concerns. Current transatlantic dialogues, such as those within the Trans Atlantic Consumers Dialogue and the TransAtlantic Business Dialogue, could provide useful fora for taking this debate forward.

Some coordination is already underway at the international level, but with only limited success. The United States and the EU are in the process of implementing the Globally Harmonized System of Classification and Labeling of Chemicals, which will standardize the information on hazards and toxicity from internationally traded chemicals. In the food area, the Codex Alimentarius Commission has promoted international harmonization of rules on food safety labeling. While the Codex has made progress in a number of areas, an international agreement on standards for the labeling of biotech food products has so far proved elusive. International agreement on cosmetics labeling has similarly failed to materialize, underlining the complexity of reaching international agreement in the field of labeling.

Labeling of nanomaterials in consumer products is likely to be more widely used as more and more nano-enabled products enter the market. It is noteworthy that amid the controversy on legally binding consumer labeling requirements for nanomaterials, some companies have recently introduced the first voluntary labeling in positive (identifying nanomaterials) and negative (declaring to be free of nanomaterials) forms. The emergence of such private labeling schemes, although not inconsistent with WTO rules per se, nevertheless raises the spectre of the growth of an increasingly complex and inconsistent set of labeling rules that complicate the flow of nano-enabled goods across international borders. The time is ripe, therefore, for the EU and the United States to lead the way in creating internationally coordinated approaches for nanomaterials labeling.

Endnote

1. Linda Breggin et al., Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation (Chatham House 2009), *available at* http://www2.lse.ac.uk/internationalRelations/centresandunits/regulatingnanotechnologies/publications.aspx.