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The "Nano" Label – Developments and Potential Human Factors Issues

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Abstract

Over the past several years, increasing attention has been paid to particles on the nanometer scale with respect to their safe use. While the public, in general, seems to perceive these particles in a positive light, there is growing concern about potential health effects arising from their use. This concern has led the European Union to require the word "Nano" on packaging of cosmetics that contain nano materials with the intent that this would help consumers make informed choices. This is also one of the reasons for the development of an ISO standard that will likely have labeling guidelines. Research on the potential adverse health effects associated with the properties of nanoscale materials is ongoing; findings are currently inconclusive. This paper discusses a recommended process for developing labeling information for products containing nanoscale materials.

Introduction

Nanomaterials are physical structures, components, or systems whose size is in the range of 1nanometer (nm) to 100 nm. The European Union (EU) defines "nanomaterial" as "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm" (EU Regulation No. 1223/2009). In recent years, there has been an increased inclination to produce new structures and components on a nanoscale level because of their unique properties that promise scientific advancements in many sectors such as consumer products, medicine, manufacturing, etc. However, there has been some concern about the risks associated with the exposure to such nanomaterials. The National Institute for Occupational Safety and Health (NIOSH), for example, has expressed concerns that these particles may pose a toxicity hazard. NIOSH has expressed concerns that "low solubility nanomaterials are more toxic than larger particles on a mass for mass basis" (http://www.cdc.gov/niosh/topics/nanotech/) and that "there are also indications that nanoparticles can penetrate through the skin or move from the respiratory system to other organs" (http://www.cdc.gov/niosh/topics/nanotech/). However, research is ongoing and the specific health effects due to the properties of nanomaterials are still inconclusive.

The EU accepts that "At present, there is inadequate information on the risks associated with nanomaterials" (EU Regulation No. 1223/2009). Despite the lack of availability of risk-related information, the EU council mandated the use of the word "nano" on cosmetic labels. Germany issued a statement in response to the 2009 EU regulation that "the general mention on labels of nano scale

materials in cosmetic products using the term "nano" might be misunderstood by consumers as a warning" (Chemistry World, 2009).

In general, and especially in the United States, the public has favorable perceptions regarding nanotechnology (Simons et al., 2009; Cobb and Macoubrie 2004; Bainbridge 2002; Burri and Bellucci 2008; Priest 2006). The general public anticipates that the benefits of nanotechnology will outweigh the associated risks (Priest 2006; Bainbridge 2002). Based on current public perception of nanotechnology, the inclusion of the word "nano" on a product label in the absence of additional information could be interpreted as a positive feature of the product rather than as a warning that the product contains nanoscale particles.

However, the public does not have a good understanding of nanotechnology. For example, Batt, Waldron, and Broadwater found that most people could not scale sufficiently to understand nanotechnology (2008). New information released to the public related to nanotechnology has the potential to influence the public's perceptions (Cobb 2005, p. 223). The public's perception of nanotechnology may change as a result of varying media coverage associated with nanotechnology (Simons et al., 2009; Priest 2006). In such a situation, it becomes less likely that inclusion of the word "nano" on a product label in the absence of additional information would be interpreted as a positive feature of the product. Rather, it would likely be viewed as a warning that the product contains nanoscale particles. Thus, public risk perception would likely play a large part in determining how nanotechnology and the term "nano" on consumer product labels are interpreted.

In November 2009, the Council of the European Union approved a regulation that required cosmetic product manufacturers to list all nanomaterial ingredients in their products by placing the word 'nano' in brackets after the ingredient that is in the form of nanoscale particles on the packaging (EU Regulation No. 1223/2009). Currently, the International Standards Organization (ISO) is working towards a standard on labeling of nanomaterials entitled "Guidance on the labeling of manufactured nano-objects and products containing manufactured nano-objects" (ISO/DTS 13830). A draft version of this technical specification was circulated to the members of the Society of Chemical Hazard Communication (SCHC) requesting their comments. One of the purposes of this document is to recommend the use of the prefix "nano" in the labeling of manufactured nano-objects (MNO) or products containing MNOs.

This paper discusses a recommended process for developing labeling information for products containing nanoscale materials.

Label Development

It should be noted that the authors make a distinction between a label and a warning for the purposes of this discussion. A label is written, printed or graphic information provided on the product, its container or packaging (ISO/DTS 13830). A warning is information designed to increase the overall safe use of a product. A typical warning may include a statement of the hazard, information about potential consequences, and information regarding a means to avoid the hazard (ANSI Z535.4-2007).

When evaluating the need for warning information, a risk-based approach should be utilized. This should include considerations of incident severity, likelihood, potential hazards, and human factors issues associated with the user population, the environment, tools and technologies, the organization, and the activity. The decisions about what to warn about should be based on an evaluation of relative risk, together with the costs associated with each kind of incident (McCarthy et al., 1995). Under this view, only those hazards associated with the highest risk would be warned about (McCarthy et al., 1982).

One must consider a host of possible accident scenarios that might result from the use of a particular piece of equipment or product when deciding what warnings are most important to be provided to a user. Given the wide variety of consumer products that may utilize nanotechnologies or nanomaterials, and given the inconclusive scientific information on risks associated with nanomaterials, accurate conclusions about the likelihood or severity of any potential health risks cannot be made. A warnings development approach that relies on speculation about the hazards, likelihood of those hazards, and severity of those hazards is not based on sound science.

The opposite of a risk-based methodology for determining what to warn about is the "precautionary principle". This principle, at the most basic level, states that the lack of scientific certainty should not be a justification for a failure to take action. However, misapplication of the principle is creating a belief that providing information is sufficient without regard for the intended purpose or how the information will be interpreted by the receiver.

Presently, there is inadequate scientific information on the risks associated with nanomaterials. Therefore, a risk-based approach to warnings may result in no information about potential hazards associated with nanoscale materials being included on a product. In contrast, use of the precautionary principle, as referenced in the draft ISO technical specification, suggests that consumers should be informed about all of the properties associated with nanomaterials for them to make informed choices.

At this time, based on the inconclusive scientific evidence with regard to potential adverse health effects related to nanomaterials, we think it is inappropriate to warn about unspecified or unknown hazards. Such information will not improve the overall safe use of a product, which should be the goal of warning label design. If a product manufacturer chooses to provide information related to nanomaterials, we believe that can be accomplished using properly designed labeling.

Human Factors Considerations for Label Development

While it is simple to provide technical information about nanomaterials contained within a product, how that information is presented must be driven by consideration of the user, the environment, the task, the organization, and the tools and technology, similar to the framework developed in the Balance Theory (Smith and Carayon-Sainfort 1989).

Person. Consideration should be given to capabilities and limitations of the user population, such as their education, training, knowledge, skills, and experience.

Organization. This would include the policies and procedures put forth by an employer, regulatory entities, or other organizations that may affect the receiver's understanding or interpretation of the label and their interaction with the product. This would also include social relationships and supervision.

Technologies and Tools. This refers to any equipment or resources associated with the receiver's interaction with the nanomaterial-containing product. Examples would include personal protective equipment, ventilation systems, industrial equipment, or safety data sheets.

Tasks. Activities that users are involved in during their interaction with the nanomaterial-containing product.

Environment. This refers to the physical characteristics of the location where the product is being utilized.

Failure to evaluate the applicable factors in the label design process may result in information that is either incomplete or diverts from the primary purpose of assisting in making informed choices. Given that the goal of a label is to provide information to a user, the litmus test for a label is whether the receiver of the label gets the necessary information from the label (Ayres et al., 1989). Considering the wide application and properties of nanomaterials, it is clear that no single label will fit all future products.

Conclusion

With the exponential growth in the development and application of manufactured nano objects in consumer and industrial products, various organizations are calling for the development of guidelines for on-product labeling. Currently it appears that the intent of providing labels on products containing manufactured nano objects is to assist the individual or organization in making informed decisions about the use or avoidance of products containing nanoscale materials.

Current efforts do not include adequate consideration of the important human factors that play a part in designing labeling. This paper proposes a new way to conceptualize labeling design based on the Balance Theory. This theory advocates the evaluation of the entire system surrounding a potential user in order to develop the most appropriate label for a particular application.

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