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## WARNINGS ABOUT HAZARDOUS SUBSTANCES

Chemical products that contain hazardous substances require a warning statement. Scientific and legal requirements shape this complex process and determine when a warning is required and the appropriate content of the warning statement. For hazardous substances, the law typically respects the science, much of which has been codified through state, federal, and international regulations. Although the law reflects a policy decision, certain aspects of these regulations give direction to and even provide a reliable methodology for warning about hazardous substances.

This paper suggests a framework for warning about hazardous substances that places science first but is also congruous with applicable law and regulations. This paper does not attempt to evaluate specific risk assessments or their methodology. Those distinctions are the province of toxicologists, industrial hygienists, chemists, and chemical engineering.

The content of a warning statement is only as reliable as the manufacturer's infrastructure supporting the product. This means that the content of the warning is derived, in part, from the manufacturer's institutional knowledge about the product, its design, its raw material components, its testing, its risk assessment, and information from other medical and scientific sources that bear upon the product's individual components and their impact on human health.

Outside applicable regulations, though, agreement about the science is rare. Scientists typically rely on risk assessments to characterize the risk present in a chemical product. In the risk assessment, a chemical product is evaluated to identify hazards, first. Those hazards are evaluated to understand their dose and exposure, second. A risk characterization is prepared, third, from which the risks in the chemical product are managed.

Hazard identification is typically a concrete determination that may be fixed at a point in time based upon current medical and scientific literature. Dose-response and exposure assessments are not as definitive because these assessments evaluate probabilities based upon predictive values, such as exposure scenarios, testing, and modeling. Also, these assessments are often subject to disagreement because



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approaches to the assessment vary depending on the methodology applied and depending on the professional judgment exercised by the individual scientist.

However, not all parts of a risk assessment are essential to the warnings analysis. Instead of its wholesale adoption, the manufacturer must carefully select the components of the risk assessment that are integral to the warnings analysis. These selected components must be supported by a sound, scientific basis and must be integrated into an overall framework that yields a reliable methodology to capture all hazardous substances in a chemical product and deliver essential information about those hazards to a product user in a warnings statement.

### ***The Difficulties Encountered When Creating Warnings About Hazardous Substances.***

Risks from hazards in chemical substances are difficult to predict. The inherent problem in communicating about hazardous substances lies in the uncertainties of the risk assessment process necessary to identify the dose-response relationship that predicts human exposure to a substance and characterizes the risk to human health. Exposure assessments are an integral part of the overall risk assessment. The question is whether an exposure assessment is integral to the warning statement.

Risk Assessment. Generally, risk assessment is the comparison of the hazard existing in a substance to one's exposure to that substance. The hazard itself is a specific, definable harm to human health. The risk of the hazard affecting human health is predicted by examining dose and exposure to the dose. Technically, the risk assessment equation is expressed as:  $RISK = HAZARD \times EXPOSURE$ .

The risk assessment itself is essential but problematic. Whether a hazard genuinely presents little or no risk is only known through a risk assessment, but the assessment itself is problematic because it is based on predictive values of dose-response and exposure assessments. These particular assessments are based on assumptions and general principles, some of which are unreliable depending on the individual scenario, circumstances, model, or values adopted for comparative determination. Even so, the risk assessment is essential because it evaluates what level of risk may exist.

Hazards. Hazards are known entities. Identifying the hazard existing in chemical substances is usually not difficult because carcinogens, toxic agents, highly toxic agents, irritants, mutagens, corrosives, and sensitizers are known through medical and scientific literature, ongoing examination, and empirical experience. This is accomplished through hazard identification. Hazard identification determines whether human health is adversely affected by exposure to a substance or an agent embedded in a substance. It does not evaluate exposure, and it does not evaluate dose. Instead, hazard identification seeks merely to determine whether a substance or an agent may adversely affect human health. Ultimately, warning statements must communicate hazards known or knowable to a manufacturer at the time the product was manufactured or distributed.

Hazard and risk must be understood separately. Generally, a hazard is a potential source of harm; a risk is the probability of injury, disease, or death from a hazard. Likewise, hazard identification is the finding of the source of the harm, and risk assessment is determining the probability of injury, disease, or death from the hazard. Toxicologists typically execute four steps in performing a risk assessment: (1) hazard identification; (2) dose-response assessment; (3) exposure assessment; and (4) risk characterization. See National Research Council (1983) *Risk Assessment in the Federal Government: Managing the Process*, National Academy Press, Washington, D.C. In this risk equation, "exposure" is comprised of a



dose-response and an exposure assessment. Dose-response assessment evaluates the human health effect of a given quantitative dose. An exposure assessment evaluates the intensity, frequency, and duration of the exposure.

Exposure. Exposures can only be predicted. Exposure assessments seek to estimate and predict risk. Although credible, an exposure assessment relies on modeling, literature, in vivo testing, in vitro testing, and exposure scenarios to bridge a knowledge gap based on a prediction. Compounding this problem, no common understanding or harmonization exists among toxicologists, regulatory agencies, or countries about an agreed exposure assessment approach. Thus, the exposure assessment is always subject to debate, disagreement, dissent, and claims to a better approach. The character of an exposure assessment is its uncertainty. It is rarely based on actual knowledge because it seeks to predict future use of the substance under certain exposure scenarios. It is typically subject to criticism because the approaches to assess exposure will vary. Conjunctively, it becomes fodder for claims and lawsuits alleging defective warnings.

Specifically, exposure assessments are performed to bridge a knowledge gap because actual knowledge is not available. See A.Falk-Filipsson, A.Hanberg, K.Victorin, M.Warholm, M.Walle, *Assessment Factors—Applications in Health Risk Assessment of Chemicals*, Environmental Research 104 (2007) at 108-127. Modeling, toxicological profiles, exposure scenarios, and benchmarks help determine an exposure assessment and, in fact, bring toxicologists closer to understanding minimum risk levels for a hazardous substance. C.Chou, M.Williams, D.Jones, C.De Rosa, *Evaluating Toxicologic End Points to Derive Minimum Risk Levels for Hazardous Substances*, International Journal of Hygiene and Industrial Health, 205(1-2) (2002) at 71-75. Reliance on these very methods, however, reflects the absence of actual knowledge. Also, individual professional judgment is necessary to perform a risk assessment, which does not allow a consistent or systematic approach to the assessment and which further exacerbates the common approach problem. See also M.Bogdanffy, G.Datson, E.Faustman, C.Kimmel, G.Kimmel, J.Seed, V.Vu, *Harmonization of Cancer and Noncancer Risk Assessment: Proceedings of a Consensus-Building Workshop*, Toxicological Sciences, 61 (2001) at 18-19.

### ***A Solution to Creating Warnings About Hazardous Substances.***

At its most basic level, warnings about hazardous substances requires the chemical manufacturer to identify the hazard present in the substance, exempt a substance that does not present a hazard, and provide a warning about the hazardous substance. The framework should be supported by statutory and regulatory authority for the manufacturer to fulfill its duty to warn.

Content in the Warning Statement. Warning statements should focus on the hazard. The focus of the warning must be the hazard and not the hazard classification. Also, warning should first seek to inform of the hazard, and not unduly focus on managing risk. Some communication about hazardous substances is made more difficult because the exposure assessment ultimately seeks to manage risk, instead of identify hazards. Specific medical and scientific disciplines, as well as the manufacturer's own reliable scientific assessments, must be included in the risk assessment because it benefits directly from multi-disciplinary inputs.

Warning statements should instruct about product use. The overall risk assessment leads to a risk characterization, which becomes one factor in making a risk management decision about a hazardous



substance. When used properly, this information may instruct a product user about proper use and about proper misuse of the product.

Legal Requirements in a Warning. Certainly, warnings must meet legal requirements to be adequate under applicable law. Under common law, a manufacturer's warning about its product must communicate the hazards identified in the product and the likely consequences a user may encounter from those hazards. For example, chemical manufacturers must create hazard determination reports to comply with OSHA requirements. See 29 CFR 1910.1200(d). OSHA sets standards for identifying and assessing hazardous substances used in the workplace and requires preparation of a hazard determination report. Hazard determination reports may be a source for identifying hazards in a product that require warnings and product instructions.

For chemical products, the hazards arise in component substances and the consequences of the hazard affect human health, including death. In most states, manufacturers are strictly liable for defective warnings, which range from the failure to give a warning or identify a specific hazard to its placement, format, and ability to alert and instruct. Importantly, the warning statement must include foreseeable hazards associated with use of the product, based upon the best medical and scientific knowledge available at the time when the product was manufactured or distributed. Warning statements that communicate reliable information about product dangers and safe use, including foreseeable hazards, will be regarded as adequate in most states.

Regulatory Agencies and Industry Groups. Chemical manufacturers should rely on certain criteria from regulatory agencies and working organizations to identify hazardous substances. To be of practical use, the framework for creating warnings must employ a reliable, objective test or methodology for delineating between those substances that require warnings and those that may be exempted from the warnings statement. Certain state, national, and international regulations not only establish a credible methodology for selecting and listing hazardous substances that must be controlled, but provide a list of hazardous substances already selected by the respective agency via its selection methodology.

This body of work already exists. For example, California Proposition 65, the International Agency for Research on Cancer, and the European Union's REACH legislation are credible authorities that provide reliable methodologies to identify hazardous substances and list or will list hazardous substances that must be controlled. Other examples exist. See National Toxicology Program, National Institute for Occupation Safety and Health, the U.S. Environmental Protection Agency (contaminants and pollutants), and the U.N. Global Harmonization System. Other countries also provide a list of hazardous substances and regulate their control. However, their individual methodology for selecting substances needs to be closely evaluated. These authorities are supported by diverse academic, scientific, and medical disciplines in their work with hazardous substances and a few draw upon substantial legislative history as further support for their credibility. Other international regulations, such as the EU, China, and California directives on Restriction of Hazardous Substances (RoHS) are also credible authorities that identify a limited number of hazardous substances under regulatory control but do not provide methodologies for selecting such substances.

Chemical manufacturers should rely upon reliable scientific assessments specifically designated to exempt hazardous substances from warnings. Risk assessments must be identified to assure that the warning does not over-assess or under-assess the identified hazard. These assessments are not new or specially created. Instead, these are existing assessments that are reliable and credible and because



they give a scientific basis for exempting a hazardous substance from a warning. Existing assessments may accomplish this purpose where the assessment meets the two-fold test of a credible methodology and a reliable scientific basis for exempting the hazardous substance from the warning, which meets or exceeds a Daubert analysis. See *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993); *General Electric Co. v. Joiner*, 522 U.S. 136 (1997); and *Kumho Tire v. Carmichael*, 526 U.S. 137 (1999).

Overall, these criteria comprise a central framework for warning about hazardous substances. The framework itself must be based on credible, reliable sources as its authority—both legal and scientific. Further, the framework must execute a manufacturer's policy objectives to create adequate product warnings and instructions and must integrate the manufacturer's existing work to identify and exempt hazardous substances based on reliable, scientific risk assessments.

A framework that meets these objectives yields several advantages. It builds upon a manufacturer's existing business process and relies on existing external sources, such as regulations, to identify and exempt hazardous substances from a warnings analysis. In this way, the framework is dynamic. Further, it captures all hazardous substances that require warning statements and positions the manufacturer strategically to defend and win against claims alleging defective warnings.

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