

Hazard Identification: Strong Sensitizers  
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*Presenter biography*

Joanna M. Matheson, Ph.D., is a Toxicologist in the Directorate for Health Sciences at the U.S. Consumer Product Safety Commission, an independent federal agency charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products. Her primary focus is to perform risk assessments relating to toxic exposure from consumer products, particularly to susceptible populations. In addition to her work involving lead in children's products, she is the project manager for agency's FHSA definition of "strong sensitizer" and works on Immunotoxicity issues as well as projects involving other substances such as mercury, cadmium and chromium and products such as problem drywall. In addition, she serves as the agency liaison to the Federal Liaison Group on Asthma, Federal Interagency Lead Task Force, Federal Committee on Indoor Air Quality, Federal Interagency Committees on the OECD Test Guideline Program and the GHS, and is co-chair of ICCVAM's Skin Sensitization Working Group. Her research background focused on the role of immune and inflammatory mediators in occupationally-induced diseases.

*Presentation abstract*

"Strong sensitizer" is one of the seven categories of hazards defined under the Federal Hazardous Substance Act (FHSA). The authority to administer the FHSA resided with the U.S. Food and Drug Administration (FDA) until that authority was transferred to the U.S. Consumer Product Safety Commission (CPSC, Commission) in 1973, shortly after the creation of CPSC in 1972. In 1986, the Commission issued a rule clarifying the FHSA's "strong sensitizer" definition with a supplemental definition, as recommended by a Technical Advisory Panel on Allergic Sensitization. The 1986 strong sensitizer supplemental definition was intended to clarify how the statutory definition should be interpreted in view of the current scientific knowledge, and the definition listed the factors the Commission would consider in determining whether a substance is a strong sensitizer.

Recognizing that the science on sensitization had changed since the 1986 supplemental definition was published CPSC staff convened an international panel of scientific experts from academia, industry, and the federal government. CPSC convened the panel of experts to examine the available scientific and medical information concerning sensitizers, and if deemed appropriate, to propose revisions to the supplemental definition of "strong sensitizer." In 2006, based on the expert panel's input, CPSC staff developed and sought public comment on a draft technical report proposing revisions to the supplemental definition. The technical report underwent U.S. federal agency peer review as well as external peer review. Reviewers were tasked with evaluating CPSC staff's draft technical report and the report's appendices and assessing whether the report reflected the current state of the science with regard to determining when a substance is a strong sensitizer. CPSC staff revised and updated the draft technical report, taking into consideration the comments from the peer review. In addition, based upon the public and peer review comments, staff drafted a revision of the supplemental definition of the term "strong sensitizer." In February 2013, staff provided the Commission with a briefing package

recommending certain revisions to the supplemental definition. On March 12, 2013, the Commission published a notice of proposed rulemaking (NPR), proposing to revise the FHSA supplemental definition of “strong sensitizer,” as staff had recommended. Staff believed that the proposed revision eliminated redundancy; removed subjective factors; incorporated new and future technology that will be available within the next 5 years; ranked the criteria for classification of strong sensitizers in order of importance (*e.g.*, human over animal data); defined criteria for “severity of reaction” (which is undefined in the existing definition and is a critical consideration for declaration of a “strong sensitizer”); and indicated that a weight-of-evidence approach will be used in the determining whether a substance is a “strong sensitizer.” Staff also prepared a guidance document describing the factors staff considers when evaluating consumer products that could contain a strong sensitizing substance; this guidance document is posted on the CPSC’s website.