Evaluating Ingredient Portfolios for the New Endocrine Disruption Hazards Under the European Union (EU) Classification, Labelling and Packaging (CLP) Regulation

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Presenter biography

Ms. Ari Lewis is a principal at Gradient with over 20 years of consulting experience, with an emphasis on toxicological evaluation and human health risk assessment. Her expertise in toxicology and risk assessment allows her to lead and contribute to a variety of projects, including product safety evaluations, regulatory comment, and green chemistry assessments. Ms. Lewis has led several risk ranking and hazard evaluation projects, including many that have involved building databases, to support chemical management and product stewardship objectives.

Presentation abstract

Under the European Union (EU)'s chemical sustainability strategy, several new hazard categories were adopted in 2023, including those related to endocrine disruption (ED). Evaluating substances and mixtures for these new ED hazard categories, as described in existing and proposed regulatory frameworks is complex, resource intensive, and involves in-depth assessments of large amounts of information related to ED activity and potential adversity. While information on both ED activity and adversity can be gathered from in vivo tests, such studies are lacking for many substances.

This presentation describes a strategy for evaluating chemical portfolios for ED disruption, informed by existing regulatory frameworks and the draft classification, labeling, and packaging (CLP) guidance. The presentation will emphasize how to use existing information on adversity in conjunction with publicly available data on ED activity to make informed decisions about the ED potential of substances. The presentation will provide an introduction to data sources and approaches for screening large portfolios to identify data gaps and prioritize chemicals for further review. It will also address key evaluation criteria that will impact classification decisions.