



De Minimis & Unintentionally Added White Paper

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GCA has consistently advocated that the “safer alternatives” regulations should only apply to intentionally added ingredients that serve a functional purpose at or above 0.1%, consistent with many other state, federal and international systems by which manufacturers are currently regulated. The focus on intentionally added is furthered in California through the concept of intentional introduction that has been successfully incorporated in the California's Toxics in Packaging Act. Current California law has language for "intentional introduction" and "incidental presence" incorporated into H&S Code Section 25214.12(d)-(e). If these regulations are to form the basis of a feasible safer alternatives program, then “unintentional constituents” must not be included. Requiring manufacturers to evaluate and find alternatives to chemicals that may have an incidental presence in the consumer products will not result in the significant improvements that are anticipated by the Act. As opposed distractions that will result in excessive testing and wasted resources, the successful program must be designed to focus on important safety concerns.

The European Classification, Labeling and Packaging (CLP) directive applies to both chemicals and product mixtures. One refinement is that for some chemicals on a case-by-case basis, a lower or higher concentration is identified by authorities based on a risk assessment, not unlike the approach to develop Proposition 65 chemical specific exposure thresholds in “no significant risk levels” (NSRL). The GCA has supported this type of refinement on a case-by-case basis.

There are existing resources in other regulatory systems that California could use as guidance in developing a system of trigger levels for products that are protective of public health and could address the need for certain chemicals to have lower limits based on hazard and use profiles:

- Endpoint-specific cutoff values articulated in the Global GHS guidance materials (which explicitly discuss adjusting thresholds) or those used by other countries in their GHS-based classification and labeling programs. Under the EU's GHS Classification and Labeling program the *de minimis* trigger level is 0.1% in a product (1000 ppm) unless a different level is identified based on a health risk assessment <http://ecb.jrc.ec.europa.eu/classification-labelling/> For the over 3000 chemicals addressed in this regulation, 15% have thresholds adjusted to lower or higher levels, and 85% operate at 0.1%.
- The EU Cosmetic Directive addresses over 1300 hazardous chemicals with a default *de minimis* of 0.1% in product, but also contains specific threshold levels for over 300 chemicals that range between 0.001% and 25% (w/w) http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/index_en.htm
- In Proposition 65, California has developed chemical specific exposure limits. Regardless of the presence or total content of a substance in a consumer product, no significant risk levels (NSRL) require consideration of how exposure to the environment and to users may occur.

- In the European Union's REACH regulation, hazardous chemicals contained in articles are limited to 0.1% in product. There is no *de minimis* adjustment mechanism.

The reason why there are so few adjustments in the referenced systems, even in the case of CMRs, is simply that "intentionally-added" ingredients typically are added at much higher levels than 1000 ppm. These concentrations contribute significantly more to potential exposure than substances at levels below 1000 ppm.

Aggregation

The overarching goal of the Green Chemistry Initiative is to reduce significant adverse impact to public health and the environment. In this vein, the process should focus on key contributors to exposure that are of "real concern" to human health or the environment.

In terms of aggregation, there are two factors that must be considered together: mode of action + ADME toxicokinetic profile. Depending on the route of exposure, the chemical structure, and the breakdown products and consequently the relevant active metabolite, the effective dose of the active metabolite may differ depending on the parent compounds' characteristics. A simple linear aggregation for the same chemical across products would not be an accurate representation of the situation. The error would be further compounded were the aggregation attempted with multiple chemicals.

***For additional information, please contact GCA's co-chairs
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