

in focus

Navigating ingredient disclosure

Understanding the complexity
of developing a harmonized
compliance plan



In the US, requirements for ingredient disclosure vary from state to state and retailer to retailer, making it particularly challenging for chemical companies distributing products nationwide to have a harmonized compliance plan. TSG Consulting's Dr Jamie Shetzline sheds light on some of the disparities and highlights a couple of ingredient disclosure programs that are either currently in effect or are expected shortly.



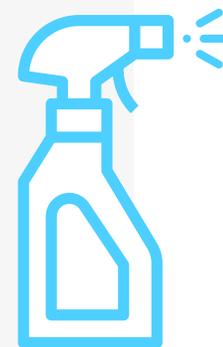
Today's consumers are savvy. They want to know what chemicals they are bringing into their homes and understand what their family, children and pets are being exposed to, in order to make informed decisions about the products they buy. Today's consumer has a renewed voice in the form of non-government organizations (NGOs). Further, state governments and the big retailers, like Walmart, Home Depot and Target, are also listening to what consumers want. This public movement towards ingredient disclosure has changed the face of how chemical companies communicate information about and position their products. In an already heavily-regulated industry, it has resulted in another layer of complexity.

However, the issue is not as simple as disclosing the ingredients that are in a product. The complexity is driven by what information must be disclosed and where. Each state and retailer that has adopted an ingredient disclosure requirement has done so in a different way with varying principles, definitions and deadlines.

The majority of chemical producers in the US are distributing nationwide and therefore need a harmonized way to fulfill ingredient disclosure requirements in all states and sales venues. This is complex though as manufacturers will need to monitor multiple lists in order to remain compliant in all the states they distribute their products in.

To highlight the disparity, let's look at a couple of the ingredient disclosure programs that are either currently in effect or are expected shortly.

Ingredient disclosure varies by state and retailer, making it particularly challenging for chemical companies distributing products nationwide to develop a harmonized compliance plan.



California

California's SB 258 passed in September 2017. SB 258 (Cleaning Products Right to Know Act) will require disclosure of ingredients via product labeling and online disclosures, allowing consumers and workers to make more informed decisions regarding cleaning products. Manufacturers will be required to provide information on intentionally added ingredients which appear on 'designated lists'.

In total, 23 lists must be checked. The lists are derived from international, federal and state regulations and programs including California's Proposition 65 (Prop 65), the European Union's Substances of Very High Concern (SVHC), the US Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) for neurotoxicity, carcinogenicity, etc., the European Chemical Agency (ECHA) SVHC, and the International Agency for Research on Cancer (IARC), among others.

The functional purpose of each intentionally added ingredient will also have to be disclosed online with hyperlinks to the Safety Data Sheets for each product and any government information websites associated with the chemicals. While the Act authorizes manufacturers to protect certain chemicals from disclosure by using a generic name if the chemical is considered confidential business information, the bar for qualification is high and the designated nomenclature is complex. Understandably the disclosure of this confidential information is causing angst among some

companies in industry. The manufacturer will be required to maintain justification for the Confidential Business Information (CBI) claim and provide information in the event of an audit from the Auditor General pursuant to the Uniform Trade Secrets Act.

California's SB 258's online requirements will go into effect January 1, 2020, with label compliance requirements required by January 1, 2021 (Prop 65 label requirements effective January 1, 2023). This will not affect products produced prior to the effective date (California has permitted unlimited sell-through for products produced prior to January 1, 2020). Air care products, automotive products, general cleaning products, and polish or floor maintenance products manufactured on or after the deadline are subject to the requirements.¹



New York

New York's ingredient disclosure regulation has existed since the 1970s, but no guidance was ever put into place on how to disclose the information to the public. The regulation gave the New York State Department of Environmental Conservation (DEC) the authority to have manufacturers disclose ingredients of their products including health or safety studies.



In 2008, environmental groups requested information from companies who sold cleaning products in New York on chemicals used in cleaning products and any harmful health or environmental effects from the products. When the companies did not comply with the request, these environmental groups sued specific companies for not disclosing the ingredient information. The suit was quickly dismissed due to guidance never being established. Subsequently New York set out to define and establish guidance on how ingredient information should be disclosed, and after nine years, the guidance was finalized by the Department of Environmental Conservation. Disclosure is required for all cleaning products distributed, sold, or offered for sale in New York. The disclosures for New York are online only and are required for all intentionally added ingredients, fragrances, contaminants, and allergens (unless claiming CBI).

As of October 1, 2019, companies must identify intentionally added ingredients and non-functional ingredients above trace quantities on NY's designated list. Additionally, companies will be required to have completed a NY certification form, certifying that the information provided is 'true, accurate, and complete', to the best of the company's knowledge. The remaining requirements will trickle in starting January 2020 through January 2023. Products included in this disclosure requirement include, in part, soaps and detergents containing a surfactant as a wetting or dirt emulsifying agent and used primarily for domestic or commercial cleaning purposes. This includes, but is not limited to, the cleansing of fabrics, dishes, food utensils and household and commercial premises. New York's guidance also addresses other products that may be covered under the regulation as well as a whole host of exclusions, none of which are particularly easy to navigate.²

2. NY Household Cleansing Product Information Disclosure Policy does NOT include foods, drugs and cosmetics (including personal care items), cleansing products used in industrial manufacturing, production and assembling processes (such as oil and gas, steel production, heavy industry manufacturing, industrial water treatment, industrial textile maintenance and processing other industrial laundering, food and beverage processing and packaging, other industrial manufacturing processes), pesticides as defined in Article 33 of the Environmental Conservation Law.

Retailers

Due to increasing demand by consumers to understand what chemicals are in the products they use, big box stores like Walmart and Target have developed programs that require their suppliers to disclose the ingredient information for products sold in their stores.

Walmart has chosen to mirror California's SB 258 ingredient disclosure regulations with the addition of Minnesota Substances of High Concern to their designated list. Target has opted for greater transparency and is committed to receiving

material disclosures concerning all intentionally added ingredients from suppliers. Target has also developed a plan to eliminate unwanted chemicals from certain product categories by 2020.



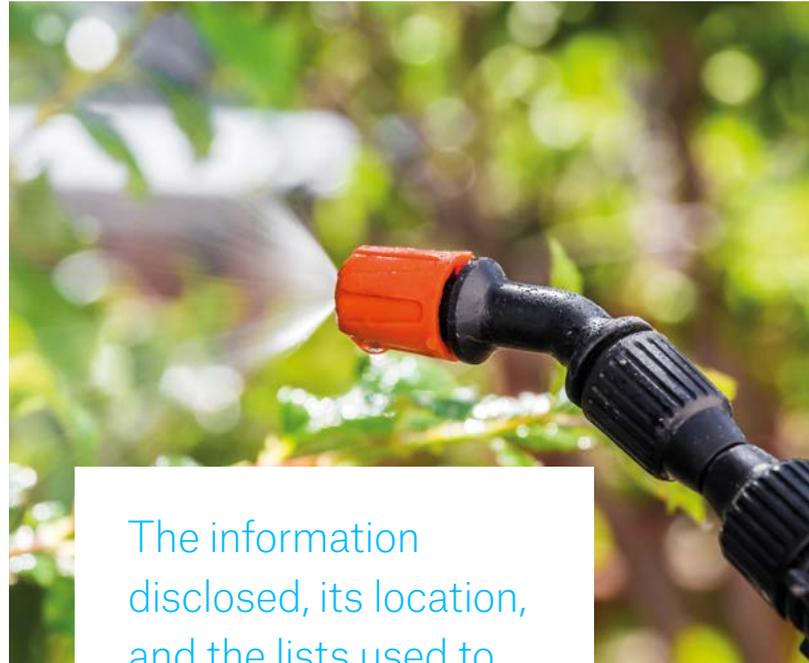
Disparities among ingredient disclosure programs

The difficulty for industry comes as one starts to look at the disparities between the different programs.

As an example, there is a conflict between CBI claims in California (CA) and New York (NY). For both CA and NY, CBI claims will determine how much information must be disclosed. All intentionally added ingredients, contaminants, fragrances, and allergens must be disclosed online unless claiming CBI.

For California, CBI claims must be approved by the EPA for the Toxic Substances Control Act (TSCA) Confidential Inventory and must provide the generic name as listed in the inventory. If the chemical is not on the TSCA inventory, a generic name must be developed following the framework outlined in the regulations. Companies will be required to maintain justification for the CBI claim and provide it to the CA Attorney General if audited. CBI claims will not be permitted for designated allergens or ingredients on the California Department of Toxic Substance Control chemical of concern candidate list.

For New York, CBI claims must meet the requirements set out in the NY code. Similarly, CBI ingredients will follow naming requirements set by the TSCA inventory. Chemical name information may be withheld even if a chemical of concern is present, but companies must indicate the presence of a chemical of concern. Chemical names that have been withheld as CBI should be labeled as the functional name.



The information disclosed, its location, and the lists used to determine disclosures are common disparities between ingredient disclosure programs.

A second example relates to states and retailers using different lists to determine what must be disclosed and what the appropriate chemical nomenclature is when a chemical is identified. Many of the lists cited as source documents in the various programs are not static. Manufacturers will need to monitor multiple lists for changes and be sure to incorporate them. Additionally, the programs are disparate with regards to implementation deadlines and the vehicles by which the information is to be provided.

One final example relates to pesticide products marketed directly to consumers. While CA and NY will allow pesticide ingredient disclosure via a company's website, the retail requirements stipulate on-pack disclosure. While it is true that the retail

requirements are not enforceable by law, it is equally true that many consumer products will not be profitable if sales are not allowed through these larger retail channels. Pesticide labels cannot be amended to include ingredient disclosure without prior US EPA and state approval. Currently, the US EPA will not allow partial disclosure of ingredients. There is a stipulation that if any non-active ingredient is disclosed on the product label then all ingredients must be disclosed; this is yet one more challenge in a series of conflicts among the regulations and policies at play in this arena.



Dealing with ingredient disclosure in the USA can be confusing and overwhelming, particularly for chemical companies distributing products nationwide. By applying due diligence and following a strategic and systematic approach to compliance planning, companies can minimize the risks of non-compliance.



How TSG can help

TSG Consulting has been closely following the ingredient disclosure regulations and has developed a master list to assist clients in identifying chemicals present on the both CA and NY designated lists. We understand the relevant federal and state regulations as well as the guidance companies must follow to sell their products in the big box retail venues. We understand how best to leverage CBI to protect proprietary components of formulations and can offer strategies so that products can be compliant for nationwide distribution and sale.

We have expertise in TSCA and Proposition 65 and can assist clients in the development of a compliance plan for ingredient disclosures.

Interested in learning more?

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About the author

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Jamie specializes in analytical chemistry and the regulatory compliance of industrial chemicals in the USA, assisting chemical companies comply with Proposition 65 and the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). She has experience with electrotechnical materials such as lithium batteries, fuel cells, films, and polymers, as well as food contact substances (FCS) and medical devices needing 510k submissions under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Jamie earned a BS degree in Chemistry from Delaware Valley University and a PhD in Chemistry from Clemson University.

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TSG Consulting provides companies with high-quality regulatory and scientific consulting services. We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry. This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance.

TSG Consulting has offices in the USA, Canada, France, Germany, Spain and UK. TSG is a Science Group (London listed) company.

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