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Revised 14 October 2016

California Proposition 65 and Spices

Summary

A small number of substances listed under California Proposition 65 (“Prop 65”) are relevant to the spice industry. Although there have been very few enforcement actions involving spices in the thirty years that Prop 65 has been in force, information and awareness of the requirements of Prop 65 and the application of exemptions from its warning requirements are helpful in successfully addressing Prop 65 concerns of the spice industry and its customers.

Introduction

The Safe Drinking Water and Toxic Enforcement Act of 1986, also known as California Proposition 65 (“Prop 65”), was adopted through California’s public referendum procedure and calls for “clear and reasonable” warnings to be provided by business entities that may expose consumers to substances in consumer products or in the workplace that are determined by the state to be carcinogens or reproductive toxins. The California Office of Environmental Health Hazard Assessment (OEHHA) is the state agency responsible for the administration of Proposition 65. Much information is available on the [OEHHA website](#). The [Prop 65 statute](#) and implementing [regulations](#) are available.

Substances Listed Under Prop 65 of Interest to the Spice Industry

Substances are added to the Prop 65 list through two primary mechanisms:

1. The “authoritative bodies” mechanism in which substances can be added to the list if one or more specified authorities (e.g. the Environmental Protection Agency, National Toxicology Program, Food and Drug Administration, International Agency for Research on Cancer, etc.) conclude that the substance is a carcinogen or reproductive toxin. This is the most common mechanism for listing substances.
2. A full review of the available scientific information by an OEHHA-designated group of experts.

There are few substances listed as carcinogens or reproductive toxins under Prop 65 that are of interest to the spice industry and that are likely to lead to enforcement actions – the Prop 65 list is available at [OEHHA Prop65 List](#). Substances of interest that have been identified in spices include substances that are naturally occurring as constituents of spices, and some heavy metals and other substances that are present in spices as contaminants occurring as the result of human activity such as automobile exhaust, power generation, agriculture and subsequent processing. It is important to note the substances that have been identified in spices are also likely to have been identified in many other foods.

Natural constituents of spices that are listed under Prop 65 and some of the spices in which they have been identified include:

- Acetaldehyde – Garlic, onion, and parsley

- Estragole – Anise, basil, bay leaves, tarragon
- Methyl eugenol – Basil, cinnamon, clove, nutmeg, and rosemary
- *B*-Myrcene – Celery and dill
- Pulegone – Basil, mint spp., and rosemary
- Safrole – Cinnamon, coriander and nutmeg
- Styrene – Capsicums, cassia, and parsley

Contaminants that may occur in spices include lead and other heavy metals, and various agricultural chemicals and their residues such as ethylene oxide and various herbicides and pesticides. In addition, there are a variety of Prop 65 listed substances that may be present in spice and seasoning blends due to their presence in non-spice materials such as carriers, solvents and other adjuvants used to formulate these blends. It is prudent to review the specific composition of such blends for the presence of Prop 65 listed substances.

Prop 65 Compliance Issues

It is unlikely that spices and consumer products containing them will need to bear a Prop 65 warning due to the presence of spices that contain Prop 65-listed substances. “Natural constituents” of spices and other foods such as *B*-myrcene and methyl eugenol have not been the subject of enforcement actions under Prop 65.

The identification by OEHHA of substances as “natural constituents” of foods is important because “natural constituents” are more broadly protected from the Prop 65 warning requirements while “natural contaminants,” such as environmental lead, are more narrowly protected and must be reduced in products to the lowest level currently feasible. Therefore, [the “naturally occurring” exemption](#) from the Prop 65 warning requirement is likely to provide significant protection from the Prop 65 warning requirements. Additional protection may also be available in certain instances from a “no significant risk level” (NSRL).

The Prop 65 Warning Requirement

Prop 65 requires that “clear and reasonable” warnings be provided for any exposure to a listed carcinogen or reproductive toxin, unless the party responsible for the exposure can demonstrate that it is “not significant” under Prop 65. Prop 65 covers exposures to listed substances from foods and consumer products and also exposures in the workplace. Exposures that are “not significant” and that do not result in the requirement to provide warnings include exposures that are the result of the natural occurrence of the substance in food and exposures that are below a no significant risk level (NSRL).

In terms of exposures from food and consumer products, it is important to note that the exposure is generally determined on a per product basis. That is, an “exposure” for Prop 65 enforcement purposes is determined on a per product per person per day basis. An exposure for Prop 65 enforcement purposes is not determined to be a person’s cumulative exposure to a listed substance from all

brands of products. For example, a person may consume a variety of products that may contain methyl eugenol through its presence in basil such as Brands A and B basil, Brands C and D tomato sauce, Brand E seasoning blend, and Brand F pesto sauce. The warning requirement generally applies to each individual branded product and not to a consumer's overall exposure to methyl eugenol from all foods or consumer products. This point is important in understanding the application of NSRLs (see below).

In 2016, OEHHA revised its Prop 65 regulations on warnings through revisions to Article 6 of Title 27 of the Code of California Regulations on Clear and Reasonable Warnings. Much information is available on the OEHHA website (www.oehha.ca.gov). A "[side-by-side](#)" comparison of the original regulations and the revisions has been provided by OEHHA and is a useful way to review the changes. Many of the changes may not be directly relevant to spices and are more relevant to retail consumer products. The revised regulations now require that the name of the listed substance be provided in the warning and that a contact person be designated to respond to inquiries. The definition of "consumer product" at Title 27, Section 25600.1(d) has also been expanded to explicitly include components of such products. A new website has also been created by OEHHA specific to issues associated with Prop 65 warnings which will include a searchable database of listed substances and warnings.

Because of current Prop 65 compliance practices employed in the spice industry, changes in the warning requirement regulations may not necessitate changes in current practices regarding the need for Prop 65 warnings and spices.

The Naturally Occurring Exemption

The naturally occurring exemption as currently interpreted exempts from the Prop 65 warning requirement exposures to substances naturally occurring in food such as methyl eugenol, pulegone, *B*-myrcene and other "natural constituents" of spices. Key points relevant to the naturally occurring exemption include:

1. Acetaldehyde, estragole, methyl eugenol, *B*-myrcene, pulegone, safrole, and styrene are considered "natural constituents" of spices and other foods placing these substances clearly within the current interpretation of the naturally occurring exemption.
2. Of importance to the current interpretation of the naturally occurring exemption is the 2002 opinion rendered by [OEHHA on methyl eugenol](#).
 - The opinion letter clearly states that methyl eugenol both as a constituent of the botanical food source and its derivatives, and as a discrete substance isolated from its botanical food source are covered by the naturally occurring exemption.

- The opinion letter also makes it clear that the naturally occurring exemption applies to exposures from food and from consumer products that are not food.
- There have been no enforcement actions on methyl eugenol or other natural constituents of spices since they were listed under Prop 65.

3. In terms of evaluating whether a food or consumer product that contains a listed substance must bear a Prop 65 warning label one should first determine the source of the substance in the product.

- If the substance is present in the product as a natural constituent of a spice, essential oil, extract or other food product then the naturally occurring exemption applies and no warning label is required.
- If listed substances are added as individual substances to foods or consumer products, and the substances are derived from foods such as a spice in which they are naturally occurring then the naturally occurring exemption applies and no warning is required.
- If listed substances are added as individual substances to foods or consumer products and they are produced synthetically then the naturally occurring exemption does not apply and a warning may be required if the exposure exceeds a NSRL.

No Significant Risk Levels and Safe Harbor Levels

No significant risk levels (NSRLs), also known as safe harbor levels when established by OEHHA, provide a way in which Prop 65 warnings are not required for exposures to listed substances when the exposures are below a certain level. Safe harbor levels for carcinogens as established by OEHHA are referred to as “NSRLs” and as “MADLs” (maximum allowable dose levels) for reproductive toxins. Such levels may be established and employed in two ways:

1. OEHHA may determine a NSRL or MADL and promulgate it as a [regulatory “safe harbor” level](#) with the resulting public awareness of exposures that do not require warnings (link to PDF).
2. Private parties may determine NSRLs using scientifically accepted methods and maintain these NSRLs without publishing them for use by the private party in defense of a Prop 65 enforcement action.

OEHHA’s methods for determining safe harbor levels are well-established and often are significantly more conservative (i.e. yielding a relative low level that would not constitute an “exposure” under Prop 65) than alternative methods that may be employed by private parties. Key points relevant to NSRLs include:

1. NSRLs allow for a quantitative assessment whether a specific exposure will be subject to a warning requirement. If the exposure is above the established level, either an OEHHA-promulgated safe harbor level or a privately determined NSRL,

then a warning is required unless the listed substance falls within the naturally occurring exemption.

2. In determining whether an exposure is below an OEHHA-established safe harbor level or a privately determined NSRL, it is important to note that only the amount of the listed substance that is not “naturally occurring” is counted toward the exposure.

- In other words, methyl eugenol present as a natural constituent of basil or added as such when derived from basil would not count toward the estimated exposure.
- For example, for a tomato sauce flavored with basil, methyl eugenol derived from basil, and methyl eugenol synthesized from petroleum feed-stocks, only the synthesized methyl eugenol would count toward the exposure for the purposes of compliance with the safe harbor level or NSRL.

There are currently no safe harbor levels or NSRLs for the Prop 65-listed substances that are natural constituents of spices because food manufacturers and marketers have been able to rely on the naturally occurring exemption and it has been concluded that so far there is no need to pursue the establishment of such levels.

Prop 65 Enforcement

The enforcement of Prop 65 is through civil lawsuits that may be brought by the state Attorney General, district attorneys, certain city attorneys, and private parties acting in the public interest, commonly known as “bounty hunter” lawsuits. Bounty hunter lawsuits are a common method of enforcement.

In 2015, the California Attorney General’s office began an initiative to provide limitations on the settlement of Prop 65 enforcement actions commonly known as “bounty hunter actions.” This initiative resulted in the adoption of changes to Chapters 1 and 3 of Title 11 of the California Code of Regulations, Division 4 – Proposition 65 Private Enforcement. A description of the changes and the accompanying rationale is available in the Final Statement of [Reasons from the California Attorney General](#). The changes are effective on 1 October 2016. There are a number of specific changes but in general they are intended to assure that OEHHA receives the civil penalty funds resulting from settlements that are legally due to the agency, to increase transparency of settlements, and to assure that civil enforcement actions have a public health benefit.

Enforcement Actions Relevant to Spices

There have been very few enforcement actions (“bounty hunter” civil lawsuits) relevant to spices during the thirty years that Prop 65 has been in force. The few actions that have been initiated by “bounty hunters” involved the alleged presence of lead in ginger and the alleged presence of styrene in some spices packaged in plastic containers. There have been no enforcement actions initiated due to the presence of Prop 65-listed naturally occurring constituents of spices. It

will be very helpful to consult with expert Prop 65 legal counsel should you become involved in a Prop 65 enforcement action.

A significant source of enforcement actions (“bounty hunter” civil lawsuits) over the years has been the alleged presence of lead in a wide variety of consumer products including a few actions involving the spice, ginger. Lead has been a common target for private enforcement actions because of its ubiquity in the environment and therefore its presence in many products. Lead is listed under Prop 65 as both a carcinogen and a reproductive toxin. The OEHHA-established safe harbor levels are 15 $\mu\text{g}/\text{day}$ for oral exposures to lead as a carcinogen and a MADL of 0.5 $\mu\text{g}/\text{day}$ for all exposures to lead as a reproductive toxin – the MADL is the level that has been relevant in previous enforcement actions. Current OEHHA policy in lead enforcement actions has been to determine an “exposure” for Prop 65 purposes if the daily average exposure over a 14-day period exceeds the MADL of 0.5 $\mu\text{g}/\text{day}$. Because the concentrations of lead in spices is likely to be low and spices are typically consumed in very small amounts it is unlikely that the MADL for lead would be exceeded.

OEHHA is currently considering changes to its enforcement policy on lead related to the determination of an “exposure” and the MADL, and whether certain foods may be “unprocessed” and therefore not subject to the warning requirement. It will be very helpful to consult with expert Prop 65 legal counsel should you become involved in a Prop 65 enforcement action on exposure to lead.

For More Information

Please contact John Hallagan, ASTA General Counsel, with any questions or comments that you may have (202.331.2333; Hondobear@aol.com).