PRE-REGULATORY DRAFT
INITIAL STATEMENT OF REASONS

TITLE 27, CALIFORNIA CODE OF REGULATIONS
PROPOSED AMENDMENTS TO ARTICLE 6
SAFE HARBOR CLEAR AND REASONABLE WARNINGS

PURPOSE

Food is different from other retail products. Consumers expect foods to be safe, and are more likely to be concerned about warnings for foods than other consumer items. The retail food industry is complex because most retail grocers carry hundreds or thousands of items purchased from multiple manufacturers, distributors or suppliers, so the logistics of providing Proposition 65[1] warnings can be difficult. In preparing these proposed regulatory amendments, the Office of Environmental Health Hazard Assessment (OEHHA) is mindful that food manufacturers do not always know where their products might eventually be sold. On the other hand, food retailers may not know which of the food products they sell may require a Proposition 65 warning. These proposed regulatory amendments would create a new web-based program to facilitate the interaction of all participants in the supply chain of food products in order to provide consumers with clear and reasonable warnings for food products sold at retail facilities.

Proposition 65 and Title 27, Cal. Code of Regulations, section 25601, require that businesses give clear and reasonable warnings to individuals before knowingly and intentionally exposing them to chemicals known to cause cancer or reproductive toxicity. OEHHA is the lead agency that implements Proposition 65 and has the authority to promulgate and amend regulations to further the purposes of the Act[2]. Regulations adopted by OEHHA[3] establish general criteria for providing "clear and reasonable" warnings. These regulations also provide general message content and approved warning methods for providing certain consumer product, occupational and environmental exposure warnings. Persons using these "safe harbor" messages and methods are assured that such warnings comply with the Act. The existing regulations allow the use of any warning method or content that provides a clear and reasonable warning.

Throughout the years, aspects of Section 25601 have been litigated and discussed or clarified in settlements. Court cases such as *Ingredient Communication Council (ICC) v. Lungren* (1992) 2 Cal. App. 4th 1480; 4 Cal Rptr.

[1] The Safe Drinking Water and Toxic Enforcement act of 1986, codified at Health and Safety Code section 25249.5 et seq. hereafter referred to as Proposition 65 or the Act.
[2] Health and Safety Code section 25249.12 (a)
[3] Title 27, Cal. Code of Regulations, Section 25601. All further references are to sections of Title 27 unless otherwise indicated.

2d 216, have defined acceptable methods for providing "clear and reasonable" warnings. In the ICC case, the court examined a method for providing warnings that consisted of a general in-store sign and newspaper ads notifying customers of a toll-free number where information could be found on products that might require a Proposition 65 warning. The court found that such a system was not clear and reasonable, saying that "*an invitation to inquire about possible warnings on products is not equivalent to providing the consumer a warning about a specific product*" (emphasis added). The court discussed the difficulties of calling a toll-free number for every product the consumer plans to buy at the grocery store. It also quoted experts who stated that two-thirds of products are purchased on impulse while the consumer is at the store, which makes it difficult for a consumer to access a warning before purchase. Finally, the court explained that "[An] effective 800 number system requires, as a first step, a *more complete in-store notification system which provides product-specific warnings*." *Id*. at 1497. (Emphasis added)

In *Environmental Law Foundation v. Wykle Research, Inc.* (2005) 134 Cal App 4th 60, 35 Cal Rptr. 3d 788 the court found that the various safe harbor provisions established in Section 25601 were not intended to be hierarchical. In other words, no warning method is necessarily better than another is. Any warning that fell into the established safe harbor provisions was adequate.

Since Section 25601 was adopted in 1988, there have been many requests for amendments. Manufacturer and retailer groups, along with consumer representatives, enforcement and environmental groups, have asked OEHHA to adopt regulatory amendments that provide more guidance concerning acceptable methods for providing warnings to consumers, and acceptable warning content. OEHHA was also asked to clarify the relative responsibilities of product manufacturers versus retailers in light of the statutory provision requiring "regulations implementing [the Act] shall to the extent practicable place the obligation to provide warning materials…on the producer or packager."[4].

Under the existing regulations, a warning is "clear" if it clearly communicates the chemical in question is known to the State to cause cancer, birth defects or other reproductive harm. It is "reasonable" if the method employed to transmit the message is reasonably calculated to make the warning message available to the individual prior to exposure.

The regulatory amendments OEHHA is proposing would create a web-based program that facilitates the transmission of a warning from the food manufacturer to the consumer. The program is only for food products sold at retail facilities. These proposed amendments would establish a database of food products that can be searched by food retailers and the public that will contain information on exposures to listed chemicals in food products.

[4] Health and Safety Code section 25249.11(f)

BACKGROUND

On March 14, 2008, OEHHA held a public workshop where the concept of the possible amendment of Section 25601 was introduced and stakeholder suggestions were invited. Five parties submitted written comments. One suggestion from the workshop was that OEHHA create a workgroup composed of representatives from different interest groups to work with OEHHA to develop possible regulatory amendments related to food warnings. A workgroup was created, and information about the meetings of the group was posted on the OEHHA web site, including comments received. The workgroup has 16 members, and their names and affiliations are posted on the OEHHA web site. Some of the groups represented are the Grocery Manufacturer's Association, California Retailers Association, California Grocers Association, Environmental Law Foundation, California League for Environmental Enforcement Now, and the California Attorney General's Office. The workgroup held four meetings between June and September 2008.

After receiving input from the workgroup, OEHHA developed a draft framework for a possible regulation that was discussed at a second public workshop on December 3, 2008. On February 18, 2009, OEHHA held an open teleconference to discuss the comments received on this draft framework.

In April 2009, a group consisting of the California Grocers Association, the California Retailers Association, the California League of Food Processors, the American Beverage Association and the Grocery Manufacturers Association submitted a proposal including draft regulatory amendments. These suggestions were posted on the OEHHA website.

On September 25, 2009, OEHHA again held a public workshop to introduce a draft regulation that incorporated suggested language from the materials presented to OEHHA by the above groups. After the September 2009 workshop, written comments were received from four interest groups. All comments were again posted on the OEHHA publicly available website. On December 9, 2009, another meeting of the workgroup was convened where OEHHA presented a list of issues highlighted from the written comments and OEHHA's responses to the comments. Since then, OEHHA has worked to refine the proposed regulatory amendments while consulting with members of the workgroup.

The amendments being proposed by OEHHA will bring more consistency throughout the food industry to how Proposition 65 warnings are provided and create a commonly understood program whereby the public can find product-specific warnings and other relevant information concerning the foods they are considering purchasing. The existing warning process is literally handled on a case-by-case basis, often as the result of enforcement actions. Methods and

content for warnings for exposures to Proposition listed chemicals food products have been included in judgments and settlements that only apply to the parties involved in those cases. For example, in the case *People v. Frito Lay et al.*, Los Angeles Superior Court, case number BC338956 (2008) the following warning language was agreed upon:

> "WARNING – Cooked potatoes that have been browned, such as potato crisps and/or potato chips contain acrylamide, a substance identified as causing cancer under California's Proposition 65. Acrylamide is not added to these foods but is created when these and certain other foods are browned. The FDA has not advised people to stop eating potato crisps and/or potato chips or any foods containing acrylamide as a result of cooking. For more information, see www.fda.gov".

While others may choose to use this warning language, they are not required to and may not even know it exists.

OEHHA's regulatory proposal would assure that warnings provided to consumers are consistent, clear and reasonable. Warnings for exposures to listed chemicals in foods will be provided to the customer at the retail location, prior to exposure. Finally, the program will establish a database where information on Proposition 65 listed chemicals in food products can be found.

Proposed Amendments

Section 25602: The proposed amendments add the following terms to the existing definitions: "food provider", "food retailer", "general information sign", "Retail Food Warning Program", and "Small Food Retailer". These terms would clarify terms used in new Section 25603.4.

Proposed Section 25603.4 establishes a voluntary pilot food warning program that will provide safe-harbor protection for both food manufacturers and food retailers. It includes specific warning methods for exposures to Proposition 65 listed chemicals in food sold in retail facilities. It specifically includes by reference all the existing regulatory provisions. This section would create a new warning program that will be monitored by the lead agency. The program is intended to create a safe harbor for participating food manufacturers, producers, distributors, and retailers, who are already required by law to provide warnings for exposures to listed chemicals in food sold in retail facilities. Each proposed subsection of the amended regulation is discussed below.

25603.4(a) – Explains that this is a voluntary pilot program that incorporates all the existing warning methods and content authorized under Section 25603.3. It explains that Section 25603.4 establishes a web-based process for the exchange of information between product manufacturers, distributors, food retailers and

consumers to ensure that clear and reasonable warnings for exposures to listed chemicals in food are provided.

25603.4(b) – Provides that proposed amendments will only become effective when the lead agency publishes a notice in the *California Regulatory Notice Register* and on its website that the database and all other necessary components of the program are operative and publicly available. This is necessary to ensure that the database, which is an essential component of the food warning program, is in place before any of the safe harbor provisions in the new section become available to food manufacturers and retailers. In the event that the database is not developed, or there is insufficient participation by the food manufacturers to adequately populate the database, the regulation will not become effective.

25603.4(c) – Is a sunset provision. It states that Section 25603.4 will become inoperative on January 1, 2014 unless it is readopted or amended by the lead agency before that date. This provision ensures that if the food warning program is ultimately unsuccessful in reaching its goal of providing consumers with clear and reasonable warnings for exposures to listed chemicals in foods, it will not remain available. In the alternative, the lead agency may readopt or, if needed, amend the regulations to ensure the program does achieve this purpose.

25603.4(d) – This subsection describes how a food provider, as defined, can satisfy its warning obligations under the Act. The food provider must complete all the steps described below in order to claim the safe-harbor provided under the program.

- Register to participate in the Retail Food Warning Program. The lead agency or its designee will establish and monitor a publicly available website where food providers and food retailers can register. Food providers are required to upload information identifying the Proposition 65 listed chemicals in their food products and proposed warning content for those products. Participating food retailers can then download this information and provide it to the consumer via a variety of warning methods. The public will also be able to access the database to obtain information on listed chemicals, products that require a warning, and product-specific warning messages.

- Food Providers must upload the name and address of the food provider; name, brand and Universal Product Code (UPC) for the food product; the names and Chemical Abstracts Service (CAS) numbers, if available, for listed chemicals known to be present in the food and any other information requested. By requiring the food provider to supply information on known listed chemicals in food products, OEHHA does not intend to require new or additional

food product testing. However, if a food manufacturer believes in good faith that a warning is or may be required for and exposure to a listed chemical a food product; the food provider must provide the name(s) of the chemical(s) it believes require a warning message.

If the product contains more than three known listed chemicals that may require a warning, the food provider may list all the chemicals in the product that it believes in good faith require a warning, or list the three chemicals with the lowest daily intake levels (i.e. those with the highest potential health risk). Selection of the three chemicals to be identified is based on the daily intake levels established for those chemicals in Sections 25705, 25709, 25711, and 25805. When regulatory levels have been established for fewer than three of the chemicals for which a warning is required, the food provider must identify those chemicals that have regulatory levels, plus those chemicals with the highest concentrations in the food products. These selection criteria are intended to focus the consumer's attention on those chemicals that are presumed to be of greatest concern.

Proposition 65 states that warnings are required only where there is a "knowing and intentional exposure"[5] to a chemical known to the state to cause cancer or reproductive toxicity, unless an exemption applies[6]. The mere presence or potential presence of a listed chemical in a food product does not automatically require a warning. Food providers participating in this new program are not required to test all their products in search of potential chemicals that are present at levels that may require a warning. If the food provider, in good faith, does not know that their food product contains a listed chemical at a level that may require a warning, the provider is not required under this proposed regulation to test for chemicals beyond what federal and state laws already require.

- Food provider information must be updated at least annually so that the database remains current.

- Food providers must update the information on the program website within 30 days of becoming aware of the presence of a listed chemical at a level that requires a warning in a food product. A food provider may become aware in different ways that an exposure to a listed chemical in a food product may require a warning. This includes product testing, new scientific evidence that is widely available, information from a private party advising that a listed chemical is present in the product, or notice from OEHHA or

[5] Health and Safety Code section 25249.6
[6] Health and Safety Code section 25249.10

the Attorney General's Office that a listed chemical may be present in a particular food. This provision ensures that where the food provider becomes aware that a warning may be required for a given product, the food provider will timely update the information on the publicly available website to reflect this knowledge.

- Upload a proposed product-specific warning message for each product that requires a warning. These messages must prominently and clearly state that the food contains a listed chemical and be consistent with all other statutory and regulatory requirements. The proposed warning may contain explanatory information provided by the U.S. Food and Drug Administration or other appropriate state or federal regulatory agencies. Other content may also be included but must first be approved by the lead agency. The lead agency may disapprove any proposed warning message by providing written notice to the food provider explaining the reasons for the disapproval.

  Receipt of a disapproval notice from the lead agency may not be used as evidence of non-compliance against the provider if the provider corrects the insufficiencies identified in the notice and resubmits it to the lead agency within 30 days. This provision ensures that businesses that are attempting to use the food warning program will not be at risk of litigation simply based on their communications with the lead agency.

- Notify in writing each food retailer to which it directly sells a food product that a warning is required for that food along with a product-specific warning or a link to the Food Warning Program website. The food provider certifies when signing up for the Food Warning Program that it agrees to provide such notice. This provision will help ensure that eventually all food retailers and distributors will be aware that warnings are required for products they sell and will assist them in locating the necessary warnings.

- To participate in this program, the food provider must pay the necessary fees established by the lead agency for this purpose. OEHHA anticipates requiring an initial sign-up fee as well as on-going maintenance fees in order to offset the cost of establishing and maintaining the database and related activities supporting the program. OEHHA cannot cover these costs with existing resources.

A distributor or other business in the chain of distribution that alters the food product previously in compliance by cooking or repackaging the product may not automatically take advantage of the safe harbor provision. If the product

is no longer in compliance, the distributor or other business that caused the alteration requiring a warning becomes responsible for providing a warning for that product.

25603.4(e) – This subsection sets out the steps a food retailer must take to receive the benefit of a safe harbor under the Retail Food Warning Program. Although the food manufacturer is in the best position to know what chemicals are in a food and therefore whether a warning is required for particular food items, the food retailer is also responsible under the Act for the exposure and is the party in direct contact with the consumer. Unless the full warning message is printed directly on a product by the food manufacturer, all other methods of warning provided in these proposed amendments are within the retailer's control. OEHHA has provided a variety of options for the food retailer so that it can choose the option(s) that work best for its business. No option is deemed superior to any other. To receive the safe harbor under the program, a food retailer must follow all of the following steps.

- Register to participate in the Retail Food Warning Program through the OEHHA website.

- Check the website at least once every three months to see if any new food items sold by them require a warning or if any new food-specific warnings have become available.

- Update the in-store information within 30 days after discovering the need for a warning on any food product sold by the retailer.

- Conspicuously post a General Information Sign at one or more locations in the store where it is reasonably expected to be seen by customers before they purchase food products that require a warning. The sign must be no smaller than 8 ½ by 11 inches and the print must be 28 point type or larger. The content of this sign will be provided by the lead agency and can be obtained from the Program's publicly available website. The content must also be consistent with the product-specific warning method(s) used by the retailer. For example, if the store chooses to provide warnings by using shelf tags, the General Information Sign would state that certain products require a Proposition 65 warning and these can be identified by looking at the shelf tags. The sign must also provide the link to the Program website for further information.

- Provide a product-specific warning to the customer prior to exposure. The product-specific warning must communicate to the customer that a particular food or foods require a Proposition 65 warning. The content of the product-specific warning be can either the existing safe harbor language in Section 25603.2 or language

that has been approved for the Program by the lead agency. To the extent feasible, OEHHA encourages food providers to work together to develop the necessary materials and software that will be needed to implement this program. Having each food provider developing their own materials would be inefficient and difficult for participating retailers to manage. Required warnings may be provided using one or more of the following approved methods:

- A warning message on the cash register receipt, which can be printed on the front or back of the receipt or on another slip of paper that prints out with the receipt, such as is currently used for coupons or advertisements. However, the retailer must identify each product that requires a warning, i.e. an asterisk may be placed next to each item on the receipt, with the text of the required warnings being printed on the back of the receipt. The receipt or related printout must also provide the link to the Program website so customers can find further information about the product. The type size of the warning must be no smaller than the largest type used in other portions of the receipt. Retailers are not required to repeat redundant warning content.

- A warning message on a shelf tag. The entire warning message must be printed on the shelf tag, using a type size no smaller than the largest type-size used for other information on the shelf tag so that the consumer can readily read the warning. The warning must include the link to the Program website.

- A pamphlet available at each point of sale. The pamphlet must clearly identify each of the food products sold in the store that require a warning. Products information may be provided in an appendix included in the pamphlet that lists all affected products alphabetically or grouped alphabetically by product category. In the alternative, the pamphlet may be used in conjunction with an on-product identifier or shelf-tag identifier (such as a symbol, icon or color-coding). In order to maintain consistency for the overall Proposition 65 program, the pamphlet's form, content, and any on-product or shelf-tag identifier must be approved in advance by the lead agency. The pamphlet must also contain the Program website address. The retailer must make the pamphlet readily available to the customer in a conspicuous location at each point of sale or checkout counter, but employees do not have to hand the pamphlet to each customer. Such a

practice would be expensive and potentially irritating to customers.

- A warning provided via any electronic device or process that automatically provides the warning to the customer while the customer is in the store, prior to purchase, and without requiring the customer to seek out the warning. This section allows for the eventual use of developing technology such as radio-frequency identification (RFID) tags, Global Standard 1 barcodes, or other automatic warning systems that satisfy the statutory requirements for providing a clear and reasonable warning. This method must be approved in advance by the lead agency. This method may be used in conjunction with an on-product or shelf-tag identifier. To maintain consistency, the on-product identifier or shelf-tag must be approved in advance by the lead agency.

- An in-store compendium. This is a book, binder, electronic database or other tool that a customer may use quickly and easily to find product-specific warning information. Product-specific information may be downloaded from the Program's publicly available website. However, because this method requires the customer to actively search for product-specific warning materials, it may only be used with an on-product identifier or a shelf-tag identifier that alerts the customer to those products that require a warning.[7] To ensure timely customer access to the information, more than one copy of the compendium must be provided in large stores or where there is substantial customer interest.

- Product-specific warnings and methods that are required by court order or by a settlement also satisfy this subsection. This provision will allow a defendant company or retailer to use product-specific warning methods or content that are required by a court and still receive the benefit of the "safe harbor" protection offered by this Program.

- Any other method of providing a product-specific, clear and reasonable warning that is approved in advance by the lead agency. OEHHA is including this "catch-all" provision to allow for the use of new technology or processes that are not now available or were not specifically considered during the development of this regulation.

[7] *Ingredient Communication Council (ICC) v. Lungren,* Ibid

- The participating retailer must timely pay any participation fees associated with the Program. OEHHA anticipates requiring an initial sign-up fee as well as on-going maintenance fees in order to offset the cost of establishing and maintaining the database so that it is a self-sustaining program.

OEHHA is proposing a limited opportunity to cure for the food retailer, who in good faith, is unaware that a shelf sign has been inadvertently removed or the electronic method of warning is temporarily malfunctioning. This limited opportunity to cure is intended for food retailers who, in all other times, have made a good faith effort to comply with this subsection to provide required warnings to consumers. If the minor deviation is corrected within a reasonable time, there is no violation. A reasonable time can vary depending on the situation. Where there is an immediate, simple solution to the problem, such as changing the paper reel on a cash register (for register receipt warnings) that should be done right away. If a software problem occurs, a fix may take somewhat longer, but may still be considered reasonable in a particular circumstance.

A food retailer must post any new or revised General Information Sign no later than 60 days after it becomes available on the Program publicly available website. While OEHHA is aware that a retailer will incur costs to update the warning information for products it sells, Proposition 65 requires that a clear and reasonable warning be provided for exposures to listed chemicals. On balance, requiring a retailer to update the in-store information every three months is necessary in order to ensure that consumers are receiving timely warnings for exposures to listed chemicals.

If a food retailer causes a listed chemical to be added to a food product by cooking, reprocessing, repackaging, or in some other manner altering the product such that a product-specific warning becomes inapplicable, inaccurate, or incomplete, the food retailer must provide an appropriate warning for the product in order to obtain the safe harbor provided by this Program. If the modifications made by the food retailer are according to instructions furnished by the food provider, for example water added to a soup base, and the product-specific warning furnished by the food provider is still applicable, the food retailer need add no further warning. If the modifications described in this paragraph are performed by a food distributor, instead of the food retailer, the same terms apply to the food distributor. This provision is intended to protect the original food provider from liability for exposures to listed chemicals that may occur because a food retailer or distributor modified their product in some way. In that case, according to the Act, the food retailer or distributor takes on the same responsibilities as the food provider and must provide an adequate warning for the product.[8]

[8] Health and Safety Code section 25249.11(f)

Participation in the food warning program does not release a food retailer from a duty to provide a warning if the retailer receives actual, written notice from a food provider that a warning is required for a product. It is important for consumers to receive timely information about the products they purchase. Therefore, if a food retailer is provided with actual, written notice from a food provider that a warning is required and within 60 days fails to provide such a warning, a knowing and intentional exposure to the listed chemical will occur so the food retailer has a duty to provide a clear and reasonable warning. As is discussed above, the food retailer may request reimbursement from the food provider for any costs incurred.

A small food retailer as defined in Section 25602(l) is not required to use any of the warning methods described above and may receive the benefit of the "safe harbor" provided by this program if it provides a General Information Sign designed specifically for this purpose. This sign will be available on the Program publicly available website. According to information provided to OEHHA by the California Retailers Association that was compiled by Information Resources, Inc., 99.3% of all households shop at one or more of California's top 15 retailers. Therefore, OEHHA is persuaded that there will be sufficient market saturation with product-specific warnings provided through mid-to-large size food retailers to accomplish the goal of Proposition 65 to provide warnings prior to exposure. It should be noted that the Act states that warnings need not be provided to every individual and may be provided through general methods.[9] Because of the expense and logistical difficulties for a small retailer to set up a full warning program for what likely would be a very small number of products, OEHHA has determined that it is appropriate to allow "small retailers" to benefit from the Program's safe harbor provision as long as they register with the program on the publicly available website and conspicuously post a General Information Sign that is designed for this purpose and will be made available on the Program website.

25603.4(f) – This subsection sets out the responsibilities of the lead agency in developing and maintain this new Program. The lead agency or its designee must develop and maintain the publicly available website to support the Retail Food Warning Program. This website must be accessible to the participating food providers so all the necessary information on the provider's products can be uploaded. The participating retailers must also have access to this website so they can download all the necessary and applicable warnings for the products they sell. The public must also have access to this website so they can easily access information on food products they are considering purchasing or have purchased.

This subsection also explains the lead agency's role in approving content and format for the product-specific warning described above. Since the lead agency has the responsibility for implementing the program, it must retain the ultimate authority to approve each of the components of this program. This provision is

[9] Health and Safety Code section 25249.11(f)

also necessary in order to provide clarity and consistency throughout the Program, assist affected businesses with compliance efforts and avoid consumer confusion.

All requests for approval must be submitted to the lead agency in writing and the lead agency must provide explanations for any response other than an unconditional approval. The requester will then be allowed 30 days to modify and resubmit this request. However, until the request has been approved by the lead agency, the safe harbor is not available under the food warning program for that product, method of warning, etc. Requests for approval and all correspondence related to them remain confidential unless the confidentiality is waived by the requesting party. The proposed regulations provide that these materials will not be admissible in any enforcement actions based on the failure to provide a required warning. This provision is needed to encourage businesses to participate in the program.

The lead agency will have 90 days to respond to these requests, unless there is good cause to extend this period. Written notice of the extension must be sent to the requester. The lead agency is also responsible for developing the content, format and placement guidance for the General Information Signs for the same reasons noted above.

Fees will be established by the lead agency to defray the costs associated with the Program. It is not clear yet how much the Program will cost to start-up or maintain. Once such estimates are made, OEHHA will communicate these to the affected stakeholders and work to reach an agreement regarding reasonable fees. OEHHA is unable to establish or maintain the program using existing resources, so OEHHA has determined that the program will need to be self-supporting via the imposition of user fees. OEHHA will not charge fees for public access to the program website.

NECESSITY

In 2007, OEHHA initiated its ongoing effort to review and update its regulations dealing with Proposition 65. During the process of prioritizing potential regulatory actions for the project, comments were solicited and received from interested parties by way of written and oral comments at a public workshop held November 2, 2007. This workshop was attended by many interest groups from a wide range of areas such as manufacturers, retailers, agriculture, environmental non-profit organizations, and enforcement groups. At this workshop, suggestions were made for potential regulatory amendments or other changes that were needed. One common complaint was that the clear and reasonable warning regulations did not sufficiently describe acceptable content and methods for warnings on food products and that the regulations did not adequately define the

roles of food manufacturers and retailers in light of Health and Safety Code section 25249.11(f)[10]. See "Background" section on page 3 above.

OEHHA believes this regulatory proposal addresses the core issues raised by the interested parties throughout the process.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS.

As noted above, OEHHA reviewed public records from cases filed under Proposition 65 including:

- *Ingredient Communication Council (ICC) v. Lungren* (1992) 2 Cal. App. 4th 1480; 4 Cal Rptr. 2d 216,
- *Environmental Law Foundation v. Wykle Research, Inc.* (2005) 134 Cal App 4th 60, 35 Cal Rptr. 3d 788.

OEHHA also reviewed:

- Draft regulatory language submitted by the California Grocers Association, the California Retailers Association, the California League of Food Processors, the American Beverage Association and the Grocery Manufacturers Association.
- The Information Resources, Inc. Consumer Network chart submitted to OEHHA by the retailers association.
- Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 Ecology L.Q. 305, 322-325 (1996).
- Public oral and written comments from interested parties that were offered as part of pre-regulatory workshops and meetings of the stakeholder workgroup on food warnings.

No other technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of this regulation.

REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES.

An alternative proposal for amending the warning regulations was offered by the Grocery Manufacturers Association, the American Beverage Association, the

[10] This subsection of Proposition 65 provides as follows: "In order to minimize the burden on retail sellers of consumer products including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation of providing any warning materials such as labels on the producer or packager, rather than the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question."

California Grocers Association, and the California Retailers Association. This proposed language was taken into consideration and a considerable portion of it was incorporated into this regulatory proposal. OEHHA believes that the alternative language proposed by these groups was an adequate place to start drafting the regulation but did not go far enough into the details of the warning program envisioned by the agency. OEHHA's responsibility is to ensure that this regulatory effort remains consistent within the purpose of the statute and protects the interests of the public as well as other interested parties[11].

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESS.

The proposed regulatory action will not adversely impact small business. Proposition 65 is limited by its terms to businesses with 10 or more employees (Health and Safety Code §§ 25249.5, 25249.6, and 25249.11(b)). This regulatory proposal creates a voluntary program to provide safe harbor to businesses in the food retail sector. Additionally, the proposed regulation includes a component that allows small businesses to participate in the safe harbor program with a minimum of effort required.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON ANY BUSINESS.

The proposed regulatory action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed regulation does not impose any new requirements upon private persons or businesses; it instead offers a voluntary safe harbor for those food manufacturing, distributing and retail businesses that already must comply with Proposition 65.

EFFORTS TO AVOID UNNECESSARY DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS ADDRESSING THE SAME ISSUES.

Proposition 65 is a California law that has no federal counterpart. There are no federal regulations addressing the same issues and thus there is not duplication or conflict with federal regulations.

[11] Health and Safety Code section 25249.12(a)