June 13, 2014

Monet Vela
Office of Environmental Health Hazard Assessment
via email: monet.vela@oehha.ca.gov; P65Public.Comments@oehha.ca.gov
(Subject line: P65 Warning Regulation)

Re: Comments on pre-regulatory proposal on Proposition 65 warnings

Dear Ms. Vela,

The American Herbal Products Association (AHPA) hereby submits comments on the pre-regulatory proposal issued by the California Office of Environmental Health Hazard Assessment (OEHHA) on March 7, 2104 on Potential Amendments to the Title 27, California Code of Regulations (CCR), Article 6 – Clear and Reasonable Warnings (the OEHHA Pre-Regulatory Proposal). The OEHHA Pre-Regulatory Proposal addresses warnings required in relation to exposures of certain chemicals under the State’s Proposition 65.

AHPA is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs. Many AHPA members do business in California and thus are subject to Proposition 65.

AHPA’s comments to the OEHHA Pre-Regulatory Proposal are in the form of a separate document attached to this email with today’s date and marked with a header throughout as “AHPA Comments: P65 Warning Regulation.”

AHPA greatly appreciates the opportunity to comment on this important pre-regulatory proposal. Please feel free to contact me if any clarification is needed on any of the issues raised in these comments.

Sincerely,

Michael McGuffin
President, AHPA
mmcguffin@ahpa.org
P65 WARNING REGULATION

BEFORE

THE STATE OF CALIFORNIA

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY (Cal/EPA)

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT (OEHHA)

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

OEHHA’s MARCH 7, 2014 PRE-REGULATORY PROPOSAL TO AMEND

TITLE 27, CALIFORNIA CODE OF REGULATIONS,

§ 25601 ET SEQ. – CLEAR AND REASONABLE WARNINGS

June 13, 2014
Table of Contents

Summary of AHPA’s comments..........................................................................................................................1

I. Comments on Proposed 27 CCR § 25601 et seq. ...........................................................................................3
   I. 1. Comments regarding § 25602(d)........................................................................................................3
   I. 2. Comments regarding § 25602 - definition of “food”.......................................................................3
   I. 3. Comments regarding § 25603............................................................................................................4
   I. 4. Comments regarding § 25604............................................................................................................5
   I. 5. Comments regarding § 25605............................................................................................................7
   I. 6. Comments regarding § 25606(b) and § 25602(d)..........................................................................8
   I. 7. Comments regarding § 25607............................................................................................................10
   I. 8. Comments primarily regarding § 25607.1 and § 25607.3...............................................................10
   I. 9. Comments regarding § 25607.4.......................................................................................................14

II. Additional Comments on Proposition 65 Warning Regulations ..............................................................23
   II. 1. Comments regarding unequal application of disclosure requirements...........................................23
   II. 2. Comments regarding small business............................................................................................24
   II. 3. Comments regarding exemptions for contamination caused by others......................................25

III. AHPA joins and supports the comments of the California Chamber of Commerce Coalition.............26
Summary of AHPA’s comments

On March 7, 2014 the California Office of Environmental Health Hazard Assessment (OEHHA) issued a pre-regulatory proposal on Potential Amendments to Title 27, California Code of Regulations (CCR), Article 6 – Clear and Reasonable Warnings (the OEHHA Pre-Regulatory Proposal). The OEHHA Pre-Regulatory Proposal addresses warnings required in relation to exposures of certain chemicals under the State’s Safe Drinking Water and Toxic Enforcement Act of 1986, or Proposition 65.

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs. Many AHPA members do business in California and thus are subject to Proposition 65.

AHPA therefore submits the comments herein to identify specific concerns in regard to the OEHHA Pre-Regulatory Proposal and to make specific suggestions and requests for changes to this Proposal should this regulatory process proceed.

In preparing these comments, AHPA notes that in its “Initial statement of reasons” (ISOR)\(^1\) that accompanied this Pre-Regulatory Proposal, OEHHA cites California Governor Brown’s press release of March 7, 2013 in which he called for reforms to Proposition 65. OEHHA notes that the Governor had stated that the needed reforms would “revamp Proposition 65 by ending frivolous ‘shake-down’ lawsuits, improving how the public is warned about dangerous chemicals and strengthening the scientific basis for warning levels” and would “require more useful information to the public on what they are being exposed to and how they can protect themselves” (emphasis added by OEHHA).

OEHHA’s ISOR also describes the intention of the Pre-Regulatory Proposal as “to implement the Administration’s vision concerning improving the quality of the warnings being given and providing certainty for businesses subject to the Act,” and asserts that

\(^1\) Initial Statement of Reasons, Title 27, California Code of Regulations, Potential Amendments To Article 6, Clear and Reasonable Warnings. March 7, 2014.
OEHHA “is attempting to address the issues that have arisen since the original [Proposition 65] regulations were adopted, by making needed changes to the requirements for a ‘clear and reasonable’ warning and integrating new technology, in order to provide more useful information to Californians about their exposures to listed chemicals, more certainty for affected businesses and thereby further the purposes of the statute.”

AHPA believes that the OEHHA Pre-Regulatory Proposal as issued would not implement the described vision of the Brown Administration to improve the quality of Proposition 65 warnings and provide certainty for businesses, nor would the proposed regulatory changes provide more useful information to Californians about chemical exposures or increase certainty for affected businesses.

Adoption of the OEHHA Pre-Regulatory Proposal or any amendment to current warning regulations that is at all similar to this proposal would, in AHPA’s view, instead harm affected businesses without commensurate benefit for consumers, and would in fact be contrary to the purposes of the statute.

AHPA appreciates the opportunity to provide input on the OEHHA Pre-Regulatory Proposal. These comments may provide OEHHA with thoughts and perspectives that may not have been considered to date in this regulatory process, and AHPA requests that these be taken into account should this process continue.

These comments are presented in three parts, beginning with comments on numerous of the specific regulatory sections proposed by OEHHA (i.e., proposed 27 CCR § 25601 et seq.), including as appropriate suggestions and requests for revisions to the proposed regulations. This is followed by several general comments on how Proposition 65 warning regulations may affect businesses in California, and these comments close with a statement of AHPA’s support for comments submitted on this date by the California Chamber of Commerce on behalf of a coalition of organizations, including AHPA.
I. Comments on Proposed 27 CCR § 25601 *et seq.*

I. 1. Comments regarding § 25602(d)

Proposed 27 CCR § 25602(d)\(^2\) provides, “‘Label’ or ‘Labeling’ means any written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.”

As discussed in comment # I.6 below regarding proposed § 25606(b), AHPA believes the definition of “label” should be maintained as a separate definition from “labeling.”

I. 2. Comments regarding § 25602 - definition of “food”

Proposed § 25607 differentiates between “food” and “consumer products other than food.” AHPA believes it is essential for businesses selling goods in California to be clearly informed of the category into which their products fit, in order to enable them to implement the appropriate requirements under the regulations. AHPA believes that in the absence of clarification, marketers of products such as gum, condiments, food ingredients, or dietary supplements may be uncertain whether their products are a “food” or a “consumer product other than food.”

This is particularly true for dietary supplements, since under California law dietary supplements “may be a food or a drug, or both a food and a drug, as these terms are defined in Health and Safety Code §§ 109935 and 109925.”\(^3\) Under Federal law dietary supplements are identified as foods,\(^4\) though under Federal law, if a product marketed as a dietary supplement makes any drug claim then it is no longer a dietary supplement but rather an illegal drug product. While it may be assumed that the California law is similarly intended to classify dietary supplements as drugs only when a drug claim is

\(^2\) AHPA notes that the OEHHA Pre-Regulatory Proposal renumbers numerous sections of Title 27 CCR Article 6, and also proposes numerous amendments therein. Unless otherwise indicated, AHPA intends for the proposals presented in these comments to apply to any renumbered or amended language in Title 27 CCR Section 6, and therefore further requests that the ideas presented be applied to whatever renumbered and amended form of Title 27 CCR Article 6 results from the OEHHA Pre-Regulatory Proposal.

\(^3\) 17 CCR § 10200.

made for a product marketed under the trade dress of a dietary supplement, that differentiation is not clear under California law.

This issue has been litigated in the California judiciary system insofar as it affects the status of dietary supplements under 17 CCR § 25501, the provision related to exposure to a naturally occurring chemical in food. In this case the Superior Court of California, County of San Francisco determined that the “representative products” presented to the court “are foods for purposes of Section 25501” of Title 27 of the California Code of Regulations.5 The representative products in this case were a variety of products marketed as dietary supplements.

AHPA therefore recommends that a definition be added to § 25602 for the term “food,” as follows:6

(d) ‘Food’ means any of the following:
   (1) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.
   (2) Any article used or intended for use as a component of any article designated in subdivision (1) or (3).
   (3) A dietary supplement.7

I. 3. Comments regarding § 25603

Proposed § 25603(a) provides, “Parties to court-approved settlements prescribing warning content and methods entered prior to January 1, 2015 are not subject to this Article.”

AHPA supports this provision as far as it goes, but believes it will create a multitude of problems unless the settlement language is extended to cover the same type of product


6 Throughout the comments, proposed deletions to regulatory language are marked in strikethrough font and proposed additions in underline font.

7 AHPA suggests this definition be inserted as (d) so as to maintain alphabetical order, and that subsequent definitions be redesignated correspondingly.
when marketed by companies who were not party to the settlement. Otherwise, retailers and others will be required to provide two different warnings for the same products (one for the settlement products and another, different, warning for similar products not covered by a settlement). This will place some products at a market disadvantage to others, and will be confusing to consumers.

AHPA supports an alternate approach which has also been advocated by others, which is for OEHHA to adopt all warnings that are currently being provided pursuant to informal opinions provided by the Attorney General’s office or OEHHA, and all current warnings in compliance with existing regulations, including those approved in court settlements. This will provide uniformity and an equal playing field, avoid confusing the public, minimize the costs incurred by businesses that already provide these warnings, and provide a wide range of businesses with certainty regarding the steps necessary for compliance. AHPA acknowledges OEHHA’s concern that this would “essentially result in little change in the content and methods of delivery for the warnings for many, many years, since the proposed regulations would only affect situations in which a warning is not currently being provided,” but does not agree that this concern outweighs the benefits that would accrue to broad adoption of existing warnings.

I. 4. Comments regarding § 25604

Proposed § 25604 proposes that OEHHA will establish a website “to collect and provide information to the public concerning exposures to listed chemicals for which warnings are being provided” and sets forth certain new requirements for persons who provide such warnings in the course of doing business in California.

AHPA joins the California Chamber of Commerce, which is submitting on this date comments to OEHHA on behalf of a broad Coalition of California-based and national organizations and businesses (hereinafter the “Coalition”), in finding the proposed OEHHA website to be highly problematic. Moreover, it is not clear to AHPA that OEHHA has the legal authority to mandate submission of such a broad range of information, nor whether it has the legal authority to publish said information. AHPA notes that much of this information is often confidential and/or trade secret commercial information.

In the event, however, that OEHHA goes forward with implementing § 25604, AHPA provides the following additional comments.
(a) Regarding the requirement in proposed § 25604(a)(2) to provide the “name and contact information for the manufacturer of any product the warning is intended to cover,” AHPA notes that the manufacturer of the product may not be known to the party submitting information to OEHHA due to the length and complexity of many supply chains. AHPA therefore recommends that, to the extent this or any similar provision survives in the next draft of the regulation, “manufacturer” should be replaced with “manufacturer, producer, packager, or distributor.”

(b) Regarding the requirement in proposed § 25604(a)(9) to provide “Reasonably available information concerning the anticipated level of human exposure to the listed chemical, if known,” AHPA notes that in many consumer products, especially those such as food, dietary supplements, and health and beauty aids made from natural sources, the level of the listed chemical may vary from batch to batch. Therefore, to the extent this or any similar provision survives in the next draft of the regulation, the system should enable submission of a range of levels where appropriate.

(c) Regarding the requirement in proposed § 25604(a)(10) to provide “Information concerning actions a person can take to minimize or eliminate exposure to the listed chemical, if any,” AHPA believes this will merely become the pretext for additional litigation and therefore opposes this provision. However, AHPA recommends that, to the extent this or any similar provision survives in the next draft of the regulation, it be changed to read, “Information concerning actions a person can take during use of the product to minimize or eliminate exposure to the listed chemical, if any.” This will clarify that product marketers are not expected to provide a blanket instruction that the public should not use the product being marketed.

(d) Regarding proposed § 25604(b) which provides, “A person doing business that provides in the warning all the required information in subsections 1 through 10 is not required to provide the information listed in subsections 1 through 11 to the Lead Agency, but is encouraged to do so,” AHPA believes that to the extent § 25604(a) or any similar provision survives in the next draft of the regulation OEHHA must provide an equal exemption for companies that provide this information on the company’s own website in addition to providing on the product labels or labeling the URL or a QR code linked to the URL that contains the additional information. AHPA notes that going to a
company website is no more burdensome to the consumer than going to the OEHHA website would be.

With respect to OEHHA’s expressed interest that the information on the website be accurate, AHPA believes that no one will be more motivated to ensure the accuracy of information concerning its product than the marketer of the product will be. There is already nothing to prevent an unscrupulous product marketer from providing inaccurate information in its submission to OEHHA, other than the threat of a Proposition 65 lawsuit; and such deterrent would apply equally to information provided on a private website and on OEHHA’s website. To the extent that transcription errors or other errors cause inaccuracies in the information on the website, the product manufacturer is far more likely to catch those errors and correct them promptly than OEHHA will be.

(AHPA here notes as an aside that, if any mandatory or voluntary provision to submit information to OEHHA survives in the next draft of the regulation, OEHHA should establish in the regulation a system by which product manufacturers can quickly get any inaccurate information on the OEHHA website corrected, and furthermore should establish provisions for redress in the event that the inaccuracies are the fault of OEHHA.)

With respect to OEHHA’s concern that the warning information should not include information that negates or reduces the effectiveness of the warnings, AHPA notes that OEHHA does not have the legal authority to prohibit disclosure of truthful and not misleading information to the consumer.8

I. 5. Comments regarding § 25605

Proposed § 25605(a) would require that the name of the chemical, substance, or mixture shall be specified in the Proposition 65 warning for certain listed substances. In the Initial Statement of Reasons (ISOR) for the proposed rule, OEHHA states that it “does not anticipate that warnings will contain more than one or two of the listed chemicals.” AHPA disagrees that this will be the case. AHPA furthermore disagrees that marketers should be required to disclose the name of any Proposition 65-listed chemical(s), as discussed in the Coalition’s letter; rather, marketers should be permitted

8 See comment # I.6 regarding proposed § 25607.1(c) and § 25607.3(c) below.
to utilize any warning language that meets the requirements of the law. AHPA however does not disagree that marketers could be permitted to disclose the name of the Proposition-65 listed chemical voluntarily; see comment # I.9.2.2 for detailed suggestions.

Furthermore, to the extent that the proposed requirement to list multiple chemicals survives in the next draft of the regulation, AHPA believes that OEHHA should, at a minimum, establish that no more than two listed chemicals are required to be disclosed on any one product label.

I. 6. Comments regarding § 25606(b) and § 25602(d)

(a) Proposed § 25606(b) provides in part, “Except in the case where a retail seller is selling a product under its own in-house label, any consequences for failure to comply with this article shall be the primary responsibility of the manufacturer, producer, distributor or packager of the consumer product, provided that the retail seller makes reasonable efforts to post, maintain, or periodically replace the warnings provided.” AHPA believes this sentence is unclear, as it does not seem to contemplate that the retail seller might be responsible to provide the warning in a context other than a sign (e.g., by providing the warning on documents accompanying a shipment to the consumer, or by posting a shelf talker). AHPA believes there are circumstances in which the retail seller is responsible to provide the notice through labeling (as distinct from signage), and that the regulation should reflect this.

AHPA furthermore believes the phrase “the warnings provided” is meant to indicate that the manufacturer, producer, packager, or distributor is responsible to determine the appropriate language for the warning and inform the retail seller of that language. However, AHPA is concerned the phrase could be read to mean the manufacturer, producer, packager, or distributor is required to provide the retail seller with the physical signs or printed literature necessary to disseminate the warning. AHPA believes it would be inappropriate to require this by regulation, and that the retail seller and its supplier should decide which party will furnish physical signs and printed literature.

AHPA therefore recommends proposed § 25606(b) be changed to read, “... provided that the retail seller makes reasonable efforts to post, provide, maintain, or periodically
replace the warnings indicated by the manufacturer, producer, packager, or distributor.”

(b) Proposed § 25606(b) also provides in part, “The placement and maintenance of warnings other than warnings provided on product labels shall be the primary responsibility of the retail seller.”

AHPA believes this provision is intended to exempt the retail seller from responsibility for the placement and maintenance of warnings contained in labels affixed to the retail product itself, while maintaining the retail seller’s responsibility for the placement and maintenance of warnings provided in other types of labeling such as notices affixed to the shelf with the product or accompanying shipments of the product. AHPA agrees that the party responsible for packaging of the retail product should be primarily responsible for warnings provided on labels, since it is generally the packager (or the company that contracts with a packager) and not the retail seller who controls the content of those labels; and furthermore that the retail seller should be primarily responsible for warnings that occur in other labeling, since it is the retail seller who controls placement of such labeling, unless such labeling has been provided by the party responsible for packaging of the retail product.

AHPA notes that OEHHA has proposed in § 25602(d) to merge the definitions of “label” and “labeling.” If this is done, then the meaning of proposed § 25606(b) will be confused and even undermined, because it could then be read in a manner that exempts the retail seller from primary responsibility for warnings that occur in labeling other than labels affixed to the product.

AHPA furthermore notes that merging these definitions would render the distinction between proposed § 25604(a) vs. § 25604(b) less clear, and would be inconsistent both with federal regulations and with normal usage of these words by the regulated industry.

AHPA therefore recommends that separate definitions be maintained for “labels” and “labeling.”

9 AHPA recognizes that this provision also makes the retail seller primarily responsible for signage, as distinct from labeling.
I. 7. Comments regarding § 25607

Proposed § 25607 provides that retail sellers with fewer than 25 employees should have a limited opportunity to cure a minor violation of the regulations under certain conditions.

AHPA shares the concerns expressed in the Coalition’s letter regarding the ambiguity and excessively narrow focus of this provision.

Furthermore, AHPA believes there is no reason to limit this provision to retail sellers with fewer than 25 employees. Every retail seller and every business, large and small, may occasionally have software problems, or a sign that gets damaged or obscured, or similar problems. There is no justification to allow an expensive and punitive lawsuit to proceed against any business that is making a good-faith effort to comply with the regulations; doing so will not improve the consistency or effectiveness with which Proposition 65 warnings are provided to consumers.

Therefore, AHPA strongly recommends that proposed § 25607(a) be revised to read, “A retail seller with fewer than 25 employees shall have a limited opportunity to cure....” Moreover, AHPA recommends the remainder of this section be modified in accordance with the concerns raised by the Coalition.

I. 8. Comments primarily regarding § 25607.1 and § 25607.3

Proposed § 25607.1 provides the methods by which Proposition 65 warnings must be transmitted for consumer products other than foods, prescription drugs, medical devices, and dental care; proposed § 25607.3 provides the methods by which Proposition 65 warnings must be transmitted for foods.

(a) Proposed § 25607.1 (a) and § 25607.3 (a) provide that Proposition 65 warnings “shall be provided using one or more of the following methods singly or in combination.” AHPA is concerned that the regulation does not specify who has the authority to determine which or how many of these methods must be used, and fears the ambiguity will be exploited by plaintiffs who will attempt to claim that a violation has occurred because a consumer product marketer did not use multiple methods of warning or used a method other than the one the plaintiff would prefer. AHPA therefore suggests § 25607.3 (a) should be modified to state, “...shall be provided using at least one or more
of the following methods singly or in combination at the sole discretion of the manufacturer, producer, packager, distributor, or retail seller."

(b) Proposed § 25607.3(a) as written fails to distinguish between food intended to be consumed by the person exposed to it, and food or food ingredients used in industrial or commercial processing which will not be consumed by the person exposed to it. These are very different circumstances entailing very different exposures. The former are properly addressed under § 25607.3 and § 25607.4, while the latter are properly addressed under § 25607.12 and § 25607.13.

To avoid confusion and redundancy (i.e., to avoid an interpretation where foods and food ingredients used in industrial or commercial processing that are not consumed are nevertheless required to comply both with § 25607.3 and § 25607.4 and with § 25607.12 and § 25607.13), AHPA recommends § 25607.3(a) be adjusted as follows: “For food products sold at retail, the warning message shall include...” or alternately, “For food products other than in an occupational setting, the warning message shall include....” Similar adjustments should be made to § 25607.4(a).

(c) AHPA notes that § 25607.1(a)(1) refers to the warning content specified in § 25607.2(b) requiring use of a pictogram while § 25607.3(a)(1) refers to the content warning specified in § 25607.4(b) which does not require use of a pictogram. Later sections of the proposed rule establish that Proposition 65 warnings for prescription drugs, prescription medical devices, dental care circumstances, and alcoholic beverages are also not required to include a pictogram.

AHPA does not believe that the pictogram is a good idea, as discussed in the Coalition comments.

However, should the pictogram requirement be maintained in the next draft of the rule, AHPA believes it would be highly inappropriate to require it for all consumer products other than food, prescription drugs and medical devices, and dental care, as this would have the effect of grouping innocuous items such as shampoo or ibuprofen with frankly hazardous chemicals such as pesticides.

AHPA believes a pictogram should not be required for any product intended for personal or medical care, including not only those which are currently exempted from a
pictogram requirement but also nonprescription (i.e., over-the-counter or “OTC”) drugs, OTC medical devices, and health and beauty aids (e.g., toiletries, cosmetics, etc.). AHPA believes that the only thing the pictogram is likely to succeed in communicating will be an ambiguous sense of emphasis, i.e., consumers will believe that products labeled with “WARNING” plus a pictogram are significantly more hazardous than products labeled only with “WARNING.” (AHPA notes that this would not, in fact, be an accurate assumption for consumers to make, but believes it is a likely outcome.)

AHPA believes it will be erroneous and misleading to create a communication system that implies OTC drugs, OTC medical devices, or health and beauty aids are more dangerous than foods, prescription drugs and medical devices, or professional dental care products; or that they are equally as dangerous as frankly hazardous chemicals such as many pesticides. It would be unwise and undesirable to discourage the public from using OTC drugs, OTC medical devices, or health and beauty aids.

AHPA therefore suggests that, if pictograms are to be required on any consumer products, the proposed rule should be revised so that OTC drugs, OTC medical devices, and health and beauty aids are categorized in a manner that does not require use of pictograms.

(d) Proposed § 25607.1(a)(2) and § 25607.3(a)(2) require that Proposition 65 warnings for internet purchases be “provided on the internet prior to the time the consumer completes its purchase of the product.”

AHPA believes this to be an extremely burdensome, impractical, and unjustified requirement. As a practical matter, this could require the retail seller either to obtain the consumer’s state or zip code of residence early in the browsing process, so that the required warning is displayed whenever the consumer views a product associated with a warning, or to use the consumer’s ship-to information and cart contents at the point of checkout to determine whether any Proposition 65 warnings were required, or to maintain a separate website for consumers located in California. Either way, expensive custom programming and/or expensive and duplicative website maintenance will be required.

AHPA notes that under existing regulations it has only been required to provide the warning prior to exposure, not prior to purchase. AHPA questions how changing from a
requirement to warn prior to exposure to a requirement to warn prior to purchase will improve public health goals. AHPA does not believe there is any public health justification to make this change.

Furthermore, AHPA notes that the text of Proposition 65 requires the warning to be provided prior to exposure, not prior to purchase. AHPA does not believe OEHHA has the authority to change this provision of the law.

(e) Proposed § 25607.1(a)(3) and § 25607.3(a)(3) require that Proposition 65 warnings for catalog purchases be “provided in the catalog in a manner that clearly associates it with the item being purchased.” AHPA believes this to be an onerous and unjustified requirement. Catalogs are expensive to print and ship; in order to reduce costs marketers must maximize the benefit they gain from every square inch, and must minimize the weight and thickness of the publication. Thus, a requirement to use valuable catalog space on Proposition 65 warnings, or to add inserts to the catalog (which causes increased printing, labor, and shipping costs), will be quite expensive.

Furthermore, as discussed above in (d), AHPA can see no public health justification to change from a requirement to warn prior to exposure to a requirement to warn prior to purchase; and believes OEHHA lacks the authority to impose this requirement.

(f) Proposed § 25607.1(a)(5) and § 25607.3(a)(5) captures other electronic means of providing a warning that provides the warning while the consumer is making a purchase, without requiring the consumer to seek out the warning.

As discussed above in (d), AHPA does not believe OEHHA has any public health justification to shift from a requirement to warn prior to exposure to a requirement to warn prior to purchase; and believes OEHHA lacks the authority to impose this requirement.

(g) Proposed § 25607.1(c) and § 25607.3(c) provide that additional information concerning the exposure may be provided, but must not be substituted for the warning methods required in the section, and shall not “dilute or negate” the Proposition 65 warning.
AHPA notes that a variety of truthful and not misleading information might conceivably be provided to the consumer which OEHHA might consider to “dilute or negate” the required warning. Such information might include, for example, information comparing the level of exposure associated with a product to other exposures the consumer is likely to encounter in day-to-day life (e.g., through drinking water), or information about the science on the basis of which it was decided to add a substance to the Proposition 65 list. AHPA does not believe that OEHHA can legally prohibit the dissemination of truthful, accurate, and not misleading information.

AHPA therefore recommends that § 25607.1(c) and § 25607.3(c) be changed to read, “Supplemental information such as a pamphlet or other method for the consumer to obtain additional information concerning the exposure may be provided, but shall not be substituted for the warning methods described in this section. In no case shall such additional information dilute or negate the warning provided pursuant to Health and Safety Code section 25249.6.

I. 9. Comments regarding § 25607.4

In this section, AHPA will discuss general concerns regarding warning statements and propose warning language that OEHHA should formally recognize as appropriate for foods that contain Proposition-65 listed reproductive toxicants.

I. 9.1 General comments regarding warning language

AHPA believes that the Proposition 65 warning language, at least for foods and personal care items, should be informative and as emotionally neutral as possible, rather than inflammatory and alarming.

(a) AHPA’s members¹⁰ and others¹¹ have found that the word “chemical” in and of itself is unusually alarming to consumers. The word “chemical” leads the consumer to believe

¹⁰ One company has communicated to AHPA that it has conducted market research on this issue and other members have communicated anecdotal experience.

the material in question is unnatural, artificial, synthetic, highly processed, and
dangerous, none of which is what a consumer wants in the things he will eat and none
of which is an accurate description of most consumable items (except perhaps drugs).

AHPA therefore suggests “chemical” should be replaced wherever it occurs in
consumer-oriented Proposition 65 communications with “substance,” which AHPA
believes to be free of the negative connotations that “chemical” suffers.

(b) The words “cancer,” “birth defects,” and “reproductive harm” are inherently
alarming to consumers. Studies have found that consumers do not understand the
importance of chemical dose and exposure; generally view chemicals as either
categorically safe or categorically dangerous; and equate even small exposures to toxic
or carcinogenic chemicals with almost certain harm.\textsuperscript{12} Less than a quarter of US
consumers understand that exposure to a carcinogenic chemical does not make one
likely to get cancer later in life.\textsuperscript{13}

Hence, any statement that a product will expose the consumer to a “chemical” that is
“known” to cause “cancer,” “birth defects,” or “reproductive harm” is inherently both
highly disturbing and highly misleading to the consumer. While it may be true that
consumers desire to have this information, they are not as a rule equipped with the
requisite knowledge to interpret the information accurately. It is therefore incumbent
upon OEHHA to implement strategies for informing consumers without confusing or
misleading them, and without exacerbating their existing tendency to vastly
overestimate risks.

AHPA appreciates that OEHHA has proposed to remove “birth defects” from the
required warnings, at least for consumer products, although it would still be required
under other circumstances (e.g., for restaurants) and is presumably intended to appear
on OEHHA’s envisioned consumer-oriented Proposition 65 website. AHPA strongly
encourages OEHHA to eliminate “birth defects” in all contexts except where there is a

\textsuperscript{12} \textit{ibid}.

risk to human reproductive health that is proven beyond doubt to be caused by the actual product that presents an exposure (e.g., alcoholic beverages).

Needless to say, AHPA agrees with the concerns expressed in the Coalition’s letter regarding the proposed “short form” hazard language. AHPA furthermore believes that wherever possible, language should be crafted that will protect the health of the consumer without requiring use of any of the words “chemical,” “cancer,” or “reproductive harm.”

I. 9.2 Comments regarding warning language for reproductive toxicants

In this section AHPA proposes specific warning language for reproductive hazards. AHPA believes that where this warning language is used, it should be deemed to meet the requirements of Proposition 65.

I. 9.2.1 Background to this section of comments

In the ISOR for the OEHHA Pre-Regulatory Proposal, OEHHA states that it is proposing regulatory amendments to Title 27 CCR Article 6 for a number of reasons, including among others to “provide consistent, understandable information concerning exposures to listed chemicals” and to “provide more useful information to Californians about their exposures to listed chemicals.”

AHPA agrees that the above cited reasons to amend the Proposition 65 warning regulations are sound, and in fact asserts that the current regulations implementing the clear and reasonable warning provision of Proposition 65 are in need of amendment to ensure dissemination of more accurate information in warnings required under Proposition 65.

OEHHA also states in the ISOR document that it “intends to adopt specific warning methods and content for common types of exposures that frequently occur in California,” and expressly requests stakeholders “to submit tailored warnings for possible inclusion in the initial version of the regulation.”

AHPA also agrees that specific warning content for certain common types of exposures would be both appropriate and more informative for consumers, and proposes such language below.
I. 9.2.2 Comments regarding the warning language for Proposition 65-listed reproductive toxicants

AHPA believes that warnings for exposures to Proposition 65-listed reproductive toxicants would be much more informative if they consisted of instructions that the product should not be used by those populations who could be negatively affected by exposure, rather than, as is established under current the regulations, requiring declaration of the presence of a chemical that is “known to the State of California to cause birth defects or other reproductive harm.” A warning that the product should not be used by specific consumers who might be harmed by it would be much more clear, understandable, and useful for consumers.

In order to establish an optional alternative to the language currently required and proposed to be required for products containing Proposition 65-listed reproductive toxicants, at least in food products, and to thereby provide warnings that would be more clear, more reasonable, more useful, and more effective, AHPA therefore proposes the following amendments to proposed § 25607.4: 14,15

14 AHPA notes that the OEHHA Pre-Regulatory Proposal would amend current § 25601 and AHPA has no comments at this time to the proposed amendment to that section, other than those contained in the Coalition’s letter. If, however, OEHHA retains § 25601 as currently written, AHPA requests that § 25601 be amended as follows:

Whenever a clear and reasonable warning is required under Section 25249.6 of the Act, the method employed to transmit the warning must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure. The message must clearly communicate either that the chemical substance in question is known to the state to cause cancer, birth defects or other reproductive harm, or must provide clear instructions that the product must not be used by those specific types of consumers who are subject to possible harm. Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in this article that satisfy the requirements of this article, or to require that warnings be provided separately to each exposed individual.

15 AHPA strongly requests OEHHA to consider the proposals made here for alternate food warning language, whether or not any other amendments are made to 27 CCR Article 6 through the process initiated by the OEHHA Pre-Regulatory Proposal.
(a) The warning message for food products shall be provided via one or more of the methods specified in 25607.3 and, except where warnings are provided directly on the product’s labeling, may include the name of the chemical or chemicals and shall include, at a minimum, all the following elements:

(1) The word “WARNING” in all capital letters and bold print.

(2) For products that cause exposures to a listed carcinogen, the words “Consuming this product will expose you to a This product contains a chemical substance known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.”

(3) For exposures to listed reproductive toxicants, either:

(A) The words “Consuming this product will expose you to This product contains a chemical substance known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.”; or

(B) If the reproductive toxicity is known by the state to be associated with reduced fertility in women or fetal harm during conception or pregnancy due to maternal factors (“female reproductive toxicity”), the words “Not for use by women who are pregnant or may become pregnant.”; or

(C) If the reproductive toxicity is known by the state to be associated with harm to neonates, infants, or children, either through maternal exposure or direct exposure (“developmental toxicity”), the words “Not for use by nursing women or by children.”; or

---

16 AHPA joins the Coalition’s comments regarding the extreme inadvisability of requiring warnings to state “will expose you to” instead of “contains.”

17 See comment # I.9.1 regarding this change.

18 See comment # I.4 regarding this deletion.
(D) If the reproductive toxicity is known by the state to be associated with reduced fertility in men or fetal harm during conception due to paternal factors (“male reproductive toxicity”), the words “Not for use by men who are planning pregnancy.”; or

(E) If the reproductive toxicity is known by the state to be associated with more than one of female reproductive toxicity, developmental toxicity, and male reproductive toxicity, words that include the relevant words in paragraphs (3)(B), (3)(C) and (3)(D) of this section. For example, a chemical known by the state to be associated female reproductive toxicity and developmental toxicity and male reproductive toxicity must include either the words in (3)(A) of this section or the words “Not for use by women who are pregnant or nursing or may become pregnant, or by men who are planning pregnancy, or by children.”

(4) For exposures to chemicals listed as carcinogens and reproductive toxicants, the words that combine the appropriate words set forth in paragraphs (2) and (3) of this section. “Consuming this product will expose you to a chemical [or chemicals] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.”

(5) The name of the chemical or chemicals if listed in section 25605.

(b) Except where prohibited by federal law on-product food label warnings may be provided as specified below. The text of the message shall be enclosed in a box and shall may include the name of the chemical or chemicals listed in section 25605 where a warning is required for such exposure.

(1) For products that cause exposures to a listed carcinogen:
(A) The word “WARNING” in all capital letters, in bold print no smaller than 10 point type. 19

(B) The words “Cancer Hazard” in no smaller than 8 point type.

(C) The phrase words “Will expose you to This product contains [chemical name]” where such chemical name is required to be listed under section 25605 or the words “This product contains a substance known to the State of California to cause cancer.”

(D) The Uniform Resource Locator: www.P65Warnings.ca.gov.

(2) For products that cause exposures to a listed reproductive toxicant:

(A) The word “WARNING” in all capital letters, in bold print no smaller than 10 point type.

(B) The words “Reproductive Hazard” in no smaller than 8 point type. Either:

(i) The phrase words “Will expose you to This product contains [chemical name]” where such chemical name is required to be listed under section 25605; or

(ii) The appropriate words as stated in paragraphs (a)(3)(A) through (E) of this section relevant to the specific type of reproductive toxicity associated with the reproductive toxicant.

(D) The Uniform Resource Locator: www.P65Warnings.ca.gov.

19 AHPA believes 10 point type will be impossibly large to fit on many labels and labeling.
(3) For products that cause exposures to both a listed carcinogen and a reproductive toxicant:

(A) The word “WARNING” in all capital letters, in bold print no smaller than 10 point type.

(B) The words “Cancer and Reproductive Hazard” in no smaller than 8 point type.

(C) The phrase words “Will expose you to This product contains [chemical name],” where such chemical name is required to be listed under section 25605 or the words “This product contains a substance known to the State of California to cause cancer and reproductive harm,” or the words “This product contains a substance known to the State of California to cause cancer” and the appropriate words as stated in paragraphs (a)(3)(A) through (E) of this section relevant to the specific type of reproductive toxicity associated with the reproductive toxicant.

(D) The Uniform Resource Locator: www.P65Warnings.ca.gov.

(c) Supplemental information may be provided in the warning or on a website identified in the warning in addition to the basic elements required in subsection (a), including, but not limited to the following:

(1) The manner in which the chemical is formed, occurs in, or is added or not added to the food.

(2) Information concerning other sources of exposure to the listed chemical.

(3) Any specific population of concern, such as children or pregnant women.
(4) References to governmental information such as advice from the federal Food and Drug Administration.

(5) Information about the quantitative relationship of the level of the chemical in the food to the level established as acceptable levels by domestic or international health or regulatory agencies or scientific bodies, or to the levels used by the State of California to determine that the chemical is known to the State to cause cancer or reproductive harm.

(6) In no case shall such additional information dilute or negate the warning provided pursuant to Health and Safety Code section 25249.6.

(d) Where the Lead Agency has adopted a chemical, product or location-specific warning as provided in Section 25607 that addresses the exposure in question, the business may use that warning.

The language proposed above is not original, and the same or similar language is used in other contexts where the intent of a warning is to prevent exposure to a substance that presents a risk of reproductive harm.

For example, it is well established in the Federal regulation that requires certain OTC drugs intended for systematic absorption to bear a “pregnancy/breast-feeding warning,” as follows:

“Warning: If pregnant or breast-feeding, ask a health professional before use.”

In promulgating the regulation for the OTC pregnancy/breast-feeding warning, the U.S. Food and Drug Administration (FDA) expressed its view that the general pregnancy/breast-feeding warning would be unlikely to be ignored:
“This pregnancy-nursing warning requirement is intended to provide women an opportunity to use OTC drugs safely and effectively in appropriate situations. The agency believes that it is reasonable to expect that most pregnant and nursing women will heed the warning out of concern for themselves and their children.”

AHPA agrees with FDA’s view that pregnant and nursing women “will heed the warning” against use of products labeled to prevent use, and therefore believes that the proposed warning content is consistent with the intent of Proposition 65.

Hence, the instructive warnings proposed here by AHPA would fully conform to and satisfy the intent of Proposition 65 as regards reproductive toxins to ensure that consumers receive “clear and reasonable warning” relevant to exposures to these substances. These proposed warnings would in fact be more reasonable and more clear and understandable to consumers than the current warnings or than the warnings proposed in new § 25607.4, as they are more appropriately tailored to the target populations. OEHHA’s acceptance of the warnings that AHPA has proposed for reproductive toxins would therefore serve to further the purposes of the law.

II. Additional Comments on Proposition 65 Warning Regulations

II. 1. Comments regarding unequal application of disclosure requirements

AHPA notes that most consumer products sold in retail stores, catalogs, or websites are required to provide a Proposition 65 warning that is clearly associated with each individual product that is subject to the warning requirement, while other consumer products (e.g., restaurant food, alcoholic beverages served in a restaurant, products used in dental offices) are allowed to provide a general warning and invite the public to request further information.
AHPA is aware that, due to the court decision in *Ingredient Communication Council (ICC) v. Lungren*, OEHHA may not be able to provide the same reasonable warning option for consumer products sold in retail stores, catalogs, and websites as it does for consumer products used or sold in retail service establishments. However, AHPA notes for the record that it is fundamentally illogical and unfair for consumer products to be treated differently in one retail circumstance vs. another.

II. 2. Comments regarding small business

In the ISOR, OEHHA states that the “proposed regulatory action will not adversely impact very small businesses because Proposition 65 is limited by its terms to businesses with 10 or more employees.” Furthermore, the author of the recent bill amending Proposition 65 stated in press releases, “This bill won’t halt all Prop. 65 lawsuits, but will halt almost all unjust Prop. 65 lawsuits.”

Both of these statements are incorrect.

While it is true that Proposition 65 is intended to exempt small business from Proposition 65’s warning provisions (indeed the Ballot Proposition promised the public it would do so), in practice it is very common for small businesses to be swept into Proposition 65 settlements. This is because wholesalers and retailers commonly refuse to carry a given consumer product unless the manufacturer, producer, or packager contractually indemnifies them for all Proposition 65 risks. The plaintiffs’ attorneys have therefore found they can circumvent the intended small business exemption by naming the wholesaler or retailer (who usually has more than 10 employees and is therefore not exempt) as party to a Proposition 65 complaint in addition to the manufacturer, producer, or packager (who may have fewer than 10 employees and be therefore intended to be exempt from Proposition 65). Thus, the latter party is dragged into and forced to bear the burden for the lawsuit, because it is forced to respond to its customers’ contractual claim even if it is a small business with fewer than 10 employees. The Proposition 65 plaintiff thereby uses the small business’ customer as a collection agent, and this is precisely why they are targeted by the plaintiffs’ attorneys. These

---

small businesses may be forced to quickly settle with the plaintiff since they lack the financial resources for a court battle.\textsuperscript{23}

The legislature recently attempted to stop small businesses from being subject to “Prop. 65’s crushing $2,500 per-day retroactive fine, plus legal fees and the stress of battling unfair litigation,”\textsuperscript{24} but was only partially successful in that attempt. AHPA therefore strongly believes OEHHA should, in order to accomplish the goals promised in the Proposition 65 Ballot Proposition and intended by the 2013 California legislature, definitively close this loophole by including in the regulation a provision stating, “No Proposition 65 warning is required, nor may any Proposition 65 warning be required in the resolution of litigation for, any consumer product manufactured, produced, or packaged by a business employing fewer than 10 employees; nor may any other party be found liable under Proposition 65 for selling such a consumer product.”

II. 3. Comments regarding exemptions for contamination caused by others

AHPA notes that the regulations currently exclude a number of entities from Proposition 65 responsibility for contamination caused by others, such as public and private drinking water sources; food prepared using drinking water, to the extent the contamination results from the use of the drinking water; and “stormwater runoff from a place of doing business containing a listed chemical, the presence of which is not the direct and immediate result of the business activities conducted at the place from which the runoff flows.”

In view of these facts and in the interest of equitable treatment, AHPA strongly believes that the regulations should be revised to provide that in evaluating whether a consumer product requires a Proposition 65 warning, contaminants are excluded to the extent


that they occur in the product’s ingredients or components that are derived from natural sources and are not intentionally added to the product.

AHPA furthermore notes that this interpretation would be consistent with the trial court’s decision in People Brown v. Tri Union Seafoods LLC, which was upheld on appeal (although the appellate court declined to review this particular aspect of the trial court’s decision).

AHPA realizes it is longstanding OEHHA policy that “naturally occurring” contamination shall not include contamination caused by any activity of man, and that OEHHA has vigorously defended that position. However, AHPA believes there is no valid public health consideration which can justify treating manufacturers of consumer products any differently from other businesses subject to Proposition 65.

III. AHPA joins and supports the comments of the California Chamber of Commerce Coalition

AHPA is a signatory to comments submitted by the California Chamber of Commerce on behalf of a broad Coalition of organization on the matter of the OEHHA Pre-Regulatory Proposal, and AHPA joins and supports these comments.

In particular, AHPA supports the following assertions made in the above-cited comments of the Coalition:

- “OEHHA’s proposal would substantially exacerbate the already abusive Proposition 65 litigation climate, would further increase consumer alarm and confusion about Proposition 65 warnings, would significantly decrease business certainty, and would dramatically increase compliance costs and defense costs for businesses of all sizes, with absolutely no demonstrable public benefit.”
- “OEHHA’s proposal as written is unworkable and does nothing to achieve the Governor’s stated goals for meaningful Proposition 65 reform.”
- “OEHHA’s proposal, although supposedly intended to resolve and clarify uncertainties surrounding the applicability of existing Proposition 65 requirements, instead makes understanding the requirements more nebulous, leaving disputes about material facts to be adjudicated by the courts. OEHHA’s
proposal is based on a faulty assumption that businesses ‘know’ (or, alternative, should know) when a Proposition 65 warning is required.”

- “Although we appreciate OEHHA’s apparent intent to create certainty to businesses and reduce litigation, the current proposal will increase uncertainty and litigation, not decrease it.”

AHPA therefore joins the California Chamber of Commerce and the identified Coalition in expressing to OEHHA that AHPA would appreciate the opportunity to work with OEHHA moving forward to implement the recommendations proposed in the present AHPA comments and in the cited comments of the Coalition.

AHPA notes however that there are some differences in the details of the comments submitted here by AHPA and those submitted by the Coalition. In all such instances the comments submitted by AHPA take precedence in expressing AHPA’s views.