AMERICAN HERBAL PRODUCTS ASSOCIATION

January 25, 2016

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

Re: Comments on proposed repeal of 27 CCR Article 6 and adoption of new Article 6

Dear Ms. Vela,

The American Herbal Products Association (AHPA) hereby submits comments on the regulatory proposal issued by the California Office of Environmental Health Hazard Assessment (OEHHA) on November 27, 2015 (the November 2015 proposal) to repeal current Article 6 in Title 27 of the California Code of Regulations with regard to "clear and reasonable warnings" required for certain exposures to chemicals that are listed as "known to the State of California" to cause cancer or reproductive harm. AHPA notes this November 2015 proposal withdrew an earlier proposal in the same matter, issued by OEHHA on January 16, 2015 (the January 2015 proposal).

Incorporation by reference of other comments; Restatement of comments

AHPA is one of the over 200 organizations that are included in the Coalition identified by the California Chamber of Commerce in comments submitted on the Coalition's behalf today in this matter, and AHPA hereby incorporates by reference to the current comments the Coalition's comments dated today.

AHPA submitted comments on April 8, 2015 in response to the January 2015 proposal. To ensure that AHPA's comments to the January 2015 proposal are also part of the administrative record for the November 2015 proposal, AHPA hereby incorporates by reference to the current comments its comments dated April 8, 2015. Further, it appears that in issuing the November 2015 proposal OEHHA ignored or overlooked most of the points raised in AHPA's April 2015 comments. AHPA therefore restates each of the specific comments submitted in April 2015 except those few that OEHHA adopted in its revised November 2015 proposal. AHPA is providing below representative examples of these previously submitted comments, some of which have been updated to reference specific language in the November 2015 proposal. Absence of any one of the details of the prior comments in today's submission, however, does not indicate withdrawal of the prior April 2015 comments, or any detail therein, except to the degree

OEHHA has already accepted AHPA's suggestions, requests, or recommendations.

Comments regarding proposed § 25600(c): Requests for adoption of specific warning methods or content

As stated in the April 2015 comments to the January 2015 proposal, AHPA appreciates and supports the proposal to allow interested parties to request the lead agency adopt a warning method or content specific to a product. AHPA continues to be concerned, however, that this allowance would apparently be limited to one particular company or brand of product and believes this should be adjusted to allow requests for warning method or content a type or category of related products. This could be accomplished by inserting the word "type" after the word "product" in proposed § 25600(c).

Comments regarding proposed § 25600(d): Supplemental information

AHPA agrees with the comments submitted today by the California Chamber of Commerce that the phrase that would restrict any supplement information provided in addition to a warning from contradicting the warning should be eliminated from this paragraph. If OEHHA is compelled to place any restriction on such supplemental information it should limit that restriction only to requiring it to be truthful and not misleading.

Comments regarding proposed § 25600.1: Certain definitions

AHPA expressed concerns in its April 2015 comments to the January 2015 proposal with regard to the definitions provided therein for the terms "Product exposure" and "Sign." Although the term "Product exposure" is now proposed to be replaced with the term "Consumer product exposure," the issues previously raised by AHPA have not been addressed. AHPA therefore restates here the same comments to these definitions as previously articulated, and therefore requests these definitions be changed as follows:

> "Consumer product exposure" means an exposure that results from a person's acquisition, purchase, storage, consumption, or ~~any reasonably foreseeable~~ use of a product in accordance with recommendations made in the product's labels or labeling or with other actual and accepted uses of the product, including consumption of a food.
>
> "Sign" means a physical presentation of written, printed, graphic or electronically provided communication, including shelf signs, other than a

label or labeling, posted in a conspicuous manner that is associated with the exposure requiring a warning under the Act, is clearly visible under all lighting conditions normally encountered during business hours and under such conditions as to make it likely to be seen and read~~, seen and understood by an ordinary person~~.

Comments regarding proposed § 25602(b): Alternative warning language for reproductive toxicants

AHPA notes proposed § 25601, "Safe Harbor Clear and Reasonable Warnings – Methods and Content," specifies: "Nothing in this subarticle shall be construed to preclude a person from providing a warning using content or methods other than those specified in this article that nevertheless complies with Section 25249.6 of the Act."

AHPA has previously suggested, most recently in its April 8, 2015 comments in response to the January 2015 proposal, specific alternative warning language for chemicals listed under Proposition 65 as 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 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.

Specifically, AHPA proposes that the following language be provided as an alternate option (as appropriate to the circumstances) for products that require a Proposition 65 warning due to presence of listed reproductive toxins:

- For reproductive toxicity that is known to the state to be associated with reduced fertility in women or fetal harm during conception or pregnancy due to maternal factors ("female reproductive toxicity"), "Not for use by women who are pregnant or trying to conceive."; or
- For reproductive toxicity that is known to the state to be associated with harm to neonates, infants, or children, either through maternal exposure or direct exposure ("developmental toxicity"), "Not for use by nursing women or by children."; or
- For reproductive toxicity that is known to the state to be associated with reduced fertility in men or fetal harm during conception due to paternal

> factors ("male reproductive toxicity"), "Not for use by men who are trying to conceive."

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, Federal regulation 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."[1]

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."[2]

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 the warning content AHPA is proposing here is consistent with the intent of the Act.

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 optional warnings would in fact be more reasonable and therefore may lead to greater compliance by industry. They would also be more clear and understandable to consumers than the current warnings or than the warnings presented in the November 2015 proposal, as they are more appropriately tailored to the target populations. Acknowledgement in regulation that the optional warnings that AHPA has proposed for reproductive toxins are "clear and reasonable" would therefore serve to further the purposes of the law.

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[1] 21 CFR § 201.63.

[2] 47 FR 54754.

In addition, AHPA believes that certainty that the alternate language proposed above is the type of "content … other than those specified in this article that nevertheless complies with Section 25249.6 of the Act" would likely lead to increased rates of compliance by businesses with the warning requirements.

AHPA therefore recommends this specific alternative warning language for Proposition 65-listed reproductive toxicants be deemed by regulation to meet the clear and reasonable warning requirements of Proposition 65. Although proposed § 25601(b) would seem to allow use of this language as "content … other than those specified in this article that nevertheless complies with Section 25249.6 of the Act," businesses providing warnings for reproductive toxicants will be forced to either use the new safe harbor language or risk being subjected to litigation over whether the reasonable alternative warnings suggested by AHPA will be subject to enforcement by private plaintiffs who would use the expense businesses face in the litigation process as leverage to continue to extract settlements, even though these warnings are clear and reasonable means to provide required warnings.

AHPA greatly appreciates the opportunity to comment on this 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
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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 JANUARY 16, 2015 REGULATORY PROPOSAL TO REPEAL CALIFORNIA CODE OF REGULATIONS TITLE 27, ARTICLE 6 AND ADOPT NEW REGULATIONS IN ARTICLE 6

April 8, 2015

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1.0 General comments

California's Office of Health Hazard Assessment (OEHHA) on January 16, 2015 issued a notice of proposed rulemaking to repeal Article 6 of Title 27 of the California Code of Regulations (CCR) and adopt new regulations in Article 6. As described by OEHHA, the new regulation would further the "right-to-know" purposes of the statute and provide more specific guidance on the content of safe harbor warnings for a variety of exposure situations, and corresponding methods for providing those warnings, and would also add a specific section to the regulations addressing the relative responsibilities for providing warnings for businesses in the chain of commerce versus retail sellers of a given product.

In a pre-regulatory proposal issued on March 7, 2014 OEHHA had similarly proposed significant amendments to Article 6.

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 proposal to repeal 27 CCR, Article 6 and adopt new regulations in Article 6. These comments follow on AHPA's June 13, 2014 comments to the original pre-regulatory proposal. In addition, AHPA notes that the California Chamber of Commerce has submitted on this date comments on this matter and AHPA shares many of the concerns expressed therein, including those articulated on the economic analysis.

AHPA appreciates that OEHHA has significantly revised its proposal for a Proposition 65[1] related website. In particular:

[1] Ballot Proposition 65, Restrictions on Toxic Discharges into Drinking Water; Requirement of Notice of Persons' Exposure to Toxics. Initiative Statute, 1986, also known as "Prop 65" or "the Act."

(1) AHPA greatly appreciates that OEHHA has moved the proposed regulations pertaining to the lead agency website to a separate Article and has clarified that compliance with Article 2 is not subject to lawsuit by private party plaintiffs.

(2) AHPA greatly appreciates that OEHHA has explicitly included "dietary supplements" as a category of "food," where they rightfully belong based both on Federal law and on the nature of the ingredients they contain, and has included by reference the definitions of "food" found in Health and Safety Code Section 109935 and in Title 17 of the California Code of Regulations, section 10200.

(3) AHPA appreciates that OEHHA has maintained separate definitions for "labels" and "labeling," for clarity and to maintain consistency with Federal regulations and industry usage of the terms.

(4) AHPA supports changing the proposed required warning content from "will expose" to "can expose" (or "may expose").

2.0 Comments regarding proposed § 25600

2.1 Proposed § 25600(b)

AHPA believes the proposed effective date of two years from adoption is far too short, at least for product warnings. Stock turnover for commercial products ranges from a few months up to several years; therefore, even if a company changes its labels to comply with the new regulation,[2] after two years there will often be significant quantities of older product packaged under previous versions of the label remaining in the marketplace. Firms should not be forced to recall and repackage such product, nor to make other onerous and complicated arrangements to ensure such product complies

[2] AHPA is aware that the regulations theoretically provide an option for businesses to use warning content that differs from the language included in the regulation. In practice, however, any business using anything other than the warning language specified in current regulations runs an increased risk of being sued by a private plaintiff. As a result, the "option" to use alternate language is not truly practicable.

with the new regulations. Such exercises would impose significant costs on industry with little commensurate public benefit.

Therefore, AHPA requests that § 25600(b) be revised as follows:

> This Article will become effective two years after the date of adoption, except that with respect to product warnings provided on labels, this Article will become effective only with respect to newly-packaged product beginning two years after the date of adoption. A person may provide a warning that complies with this Article prior to its two-year effective date.

2.2 Proposed § 25600(c)

AHPA appreciates and supports the proposal to allow interested parties to request the lead agency adopt a warning method or content specific to a product. However, AHPA is concerned that this provision should be adjusted to clarify that the warning method or content would be specific to a type or category of product, not to a specific company or brand of product. This would be consistent with those product types for which OEHHA is currently proposing warning methods and content under proposed § 25608, such as foods, alcoholic beverages, prescription drugs, etc.

AHPA therefore requests that proposed § 25600(c) be revised as follows for completeness:

> If the lead agency has not adopted a warning method or content specific to a product type, area, or chemical in Section 25608, an interested party may request that the lead agency adopt one pursuant to Government Code Section 11340.6 et seq. (Petition for Rulemaking), or may request guidance from the lead agency pursuant to Article 2, section 25203 (Interpretive Guideline Request) or Article 2, section 25204 (Safe Use Determination).

2.3 Proposed § 25600(d)

AHPA notes that OEHHA does not have the legal authority to prohibit disclosure of truthful and not misleading information to the consumer, even if the information "contradicts, dilutes, or diminishes" the warning.

As discussed in greater detail in comment 8.1 below, Prop 65 warnings are inherently confusing and misleading to consumers. Companies have the constitutional right to provide supplementary explanations, perspective, and context so as to mitigate the erroneous impression created by warnings themselves, so long as the information thus provided is truthful and not misleading. Such information will, in many cases, necessarily serve to counteract the inherently confusing and misleading content of the mandated warning language and will thereby "contradict, dilute, or diminish" the warning.

AHPA therefore requests that proposed § 25600(d) be revised as follows:

> A person may provide information to the exposed individual that is supplemental to the warning required by Section 25249.6 of the Act, such as further information about the form or nature of the exposure and ways to avoid exposure. In order to comply with this Article, supplemental information ~~may not contradict, dilute, or diminish the warning~~ must be truthful and not misleading. Supplemental information may not be substituted for the warning required by Section 25249.6 of the Act.

2.4 Proposed § 25600(e)

AHPA appreciates and supports the explicit statement that it is not necessary to provide a separate warning to each exposed individual. While not strictly speaking necessary since it is also stated in the Act itself,[3] it is helpful to reiterate this provision in the regulation.

[3] In Section 25249.11 of the Act, the definition of "Warning" provides that warnings "need not be provided separately to each exposed individual."

However, AHPA notes that not only does the Act explicitly rule out a responsibility to warn each exposed individual, the Act implicitly rules out a responsibility to provide repetitive warnings to the same exposed individual. The Act provides that warnings may be provided by general methods such as "inclusion of notices in mailings to water customers" and "placing notices in public news media," which are methods that would not suffice to ensure that each exposed individual is warned prior to each and every exposure that occurs from the same source. Furthermore, it is reasonable to expect that having once been warned about an exposure caused by a particular source, the exposed individual will remember that information for some time into the future.

AHPA therefore requests that § 25600(e) be revised as follows:

> A person is not required to provide separate warnings to each exposed individual, nor is a person required to provide the same warning to the same exposed individual for the same exposure more than once per year.

3.0 Comments regarding proposed § 25600.1

3.1 Proposed § 25600.1(h)

AHPA is extremely concerned with the proposal that businesses are required to anticipate "any reasonably foreseeable use of a product." This phrase is an open invitation to excessively broad interpretation by private plaintiffs. Inclusion of such a vague criterion directly contravenes the intended purpose of Governor Brown's reforms of Prop 65, which includes in relevant part the ending of "frivolous 'shake-down' lawsuits."

Rather than a vague criterion that leaves the door open to willful misinterpretation, the regulation should define "product exposure" with as much clarity and precision as possible. AHPA therefore requests §25600.1(h) be revised as follows:

> "Product exposure" means an exposure that results from a person's acquisition, purchase, storage, consumption, or ~~any reasonably foreseeable~~ use of a product in accordance with recommendations made in the product's labels or labeling or

> with other actual and accepted uses of the product, including consumption of a food or dietary supplement.

3.2 Proposed § 25600.1(j)

AHPA is concerned that the proposed requirement for signs to be "understood by an ordinary person" is impractically vague, and implies that firms who rely on signs to provide Prop 65 warnings must conduct consumer research to ensure the signs will be understood. This may not be what OEHHA intends to imply, but AHPA believes the proposed requirement would allow motivated private plaintiffs to challenge firms to prove that their signage is "understood." Furthermore, AHPA does not believe it necessary to specify that signs must be "understood" because to "read" inherently connotes a basic level of understanding; for example, it would be peculiar and unreasonable to expect a person who does not know Spanish to "read" a sign written in Spanish.

AHPA therefore requests §25600.1(j) be revised as follows:

> "Sign" means a physical presentation of written, printed, graphic or electronically provided communication, other than a label or labeling, posted in a conspicuous manner that is associated with the exposure and under such conditions as to make it likely to be seen and read~~, seen and understood by an ordinary person~~.

4.0 Comments regarding proposed § 25600.2(b)

4.1 Inclusion of importers

AHPA is extremely concerned by the inclusion of "importers" in proposed § 25600.2(b) and elsewhere throughout the proposed regulations, as it erroneously implies that all products imported through California ports – even if only for transshipment to other destinations – are subject to Prop 65. AHPA does not believe that OEHHA intends, or has the authority, to impose Prop 65 requirements so broadly, and AHPA believes that any

such attempt would create a significant disincentive to use of California ports, thus contravening the conclusions of the economic impact analysis presented in OEHHA's Notice of Proposed Regulation.[4] Furthermore, AHPA does not believe inclusion of "importer" adds anything useful to the regulation, as any importer that sells or otherwise circulates product within California will be covered by one of the other terms (i.e., manufacturer, producer, packager, or distributor).

Moreover, it is not clear what entities would be covered by the term "importer." The term has a number of different definitions in use by agencies such as Customs and Border Protection (CBP) and the Food and Drug Administration (FDA); according to their usage, it may even refer to a foreign firm.

AHPA therefore strongly recommends that "importer" be removed from § 25600.2(b) as well as elsewhere in the regulation.

> The manufacturer, producer, packager, ~~importer~~ or distributor of a product may comply with this section either by affixing a label to the product bearing a warning that satisfies Section 25249.6 of the Act, or by providing a written notice directly to the authorized agent for a retailer who is subject to Section 25249.6 of the Act, which…

If OEHHA retains "importer" here or elsewhere in the regulation, AHPA requests OEHHA to provide a definition of the term and to provide language that appropriately circumscribes the applicability of the regulation to importers.

4.2 Comments regarding proposed § 25600.2(b) and new suggested § 25600.2(b)

AHPA is concerned that the plain language of proposed § 25600.2(b) does not actually require any of the named entities (the manufacturer, producer, packager, importer, or distributor) to provide a Prop 65 warning when exposure of California citizens to a listed

[4] Notice of Proposed Rulemaking and Announcement of Public Hearing, Title 27, California Code of Regulations, Proposed Adoption of Section 25205 Proposition 65 Lead Agency Website, January 16, 2015.

chemical occurs. It explicitly states that the named entities *may* comply, thus indicating that compliance is optional. AHPA doubts this is what OEHHA intends to say as it would be inconsistent with the Act. Rather, AHPA believes that OEHHA intends to state that compliance is required, but that compliance may be achieved by any of the named entities in any of the enumerated manners.

Furthermore, AHPA notes that while proposed § 25600.2(b) takes care to avoid requiring duplicative Prop 65 warnings by both the retailer and another party, it provides no such clarity with respect to others in the supply chain. Since there is no benefit but only a burden associated with having multiple parties in the supply chain provide a required Prop 65 warning to the individual who may be exposed, the regulation should clearly acknowledge it sufficient for any one of the parties to provide the warning so long as the warning is provided prior to the point of actual exposure. To facilitate this clear division of responsibilities, the parties should be permitted to allocate legal responsibility for providing the warning via contractual agreements.

Finally, AHPA notes that OEHHA incorrectly assumes in its Notice of Proposed Rulemaking that "the proposed regulatory action will not impose any mandatory requirements on small businesses" because "Proposition 65 expressly exempts businesses with less than 10 employees." In practice, small manufacturers, producers, and packagers cannot access the marketplace unless they contractually agree to indemnify wholesalers and retailers for all Prop 65 risks associated with their products.[5] Plaintiffs' attorneys have therefore found they can circumvent the intended small business exemption by naming the wholesaler and retailer (who often have more than 10 employees and are therefore not exempt) as parties to the suit in addition to the manufacturer, producer, or packager. Thus, the latter party is dragged into and forced to bear the primary burden for the lawsuit even if it is a small business with fewer than 10 employees. Similar to the circumstances with small retailers that OEHHA describes in

[5] In the Statement of Reasons (page 9), OEHHA expresses concern that small retail facilities suffer under Prop 65. OEHHA needs to recognize that small manufacturers, producers, and packagers suffer equally, because they lack the economic clout to stand up to large distribution companies and retail chains; they have no choice but to accept the commercial terms that the distributors and retailers offer.

the Statement of Reasons,[6] small manufacturers, producers, and packagers are usually forced to quickly settle with the plaintiff – even where no Prop 65 warning is legitimately required - since they lack the financial resources for a court battle.

AHPA is unsure whether proposed § 25600.2(d)(5)(A) is intended to address this problem. In the Statement of Reasons,[7] OEHHA mentions that a retailer will be responsible to provide the required warning if the manufacturer, producer, packager, or distributor has fewer than 10 employees. AHPA believes this provision provides a degree of clarity in the limited circumstance where it is known and accepted that a warning is required and where all parties in the supply chain other than the retailer are small businesses with fewer than 10 employees. However, this does not describe most circumstances that actually occur. For example, it does not address cases where, for example, the distributor has 10 or more employees although the manufacturer, producer, and packager do not. It also does not prevent frivolous lawsuits against products that legitimately do not require a warning and therefore will have no warning provided by anyone in the supply chain. In either of these cases, the manufacturer, producer, or packager will often be contractually obligated to bear the burden of defending the distributor and retailer against the suit. In such cases it is routine, especially for small manufacturers, producers, and packagers, to bear the painful cost of settling the suit rather than bear the much greater cost of going to court.

AHPA strongly believes OEHHA should, in order to accomplish the goal of protecting small businesses stated in the Prop 65 Ballot Proposition and the goal of reducing frivolous lawsuits stated by Governor Brown, definitively close this loophole.

Therefore, AHPA suggests that OEHHA insert a new § 25600.2(b) as follows, and redesignate the subsequent subsections correspondingly:

> <u>When clear and reasonable warning of a product exposure is required under Section 25249.6 of the Act, such warning must be provided either by the manufacturer, producer, packager, distributor, or retailer; except that no</u>

[6] Page 9.

[7] Page 11.

warning is required for any product manufactured, produced, or packaged by a business employing fewer than 10 employees. Except as established in paragraph (e) of this subdivision [formerly proposed paragraph (d) concerning retailer responsibility], legal responsibility for providing required Prop 65 warnings may be established through contractual agreements between the manufacturer, producer, packager, and/or distributor, and such agreements shall be binding for purposes of enforcement of the Act.

4.3 Lack of authorized agents and direct relationships

AHPA calls OEHHA's attention to the fact that in many cases, it is not possible to identify the authorized agent for a retailer. Particularly in these days of the internet, it is not uncommon for product to be sold into California by individuals and companies that either do not know or do not care to establish an authorized agent, and that are several intermediaries removed from the original manufacturer, producer, packager, or distributor of the product and are thus beyond that firm's control. Anyone can sell anything on sites such as EBay or Amazon, and they routinely do sell everything from foods and personal care products to baby products, clothing, paint, toys, and weed killer. Such individuals and companies may not know or not care that a Prop 65 warning is required for the product when sold in California, and may, even if a Prop 65 warning is provided by the original manufacturer, producer, packager, and distributor, take steps to omit or remove the warning.

AHPA is aware of companies who have been trapped in the impossible situation of being required to provide the Prop 65 warning to an individual or firm that is selling the company's products into California without the authorization of the company and even in direct contravention of the company's wishes, instructions, and contractual agreements, yet despite their best efforts the company is unable to contact the individual or firm or to identify any authorized agent. These companies report that they have suffered financial penalties under Prop 65 as a result of this inability to achieve the impossible.

(It might be argued that such companies could meet their responsibility to warn by including the Prop 65 warning on the product label. In actual fact, this is frequently infeasible due either to constraints on label size or to the impossibility of maintaining specially-labeled inventory for distribution only into California. Furthermore, even if the warning were to be printed on labels there is nothing to prevent unscrupulous retailers from covering, removing, or effacing it.)

AHPA believes the Prop 65 regulations must provide a clear, practical, and feasible means for manufacturers, producers, packagers, and distributors to discharge their responsibility to warn. The regulations must not impose a burden that is impossible for firms to meet and then penalize them for their failure to meet it.

Therefore, AHPA requests that the introductory sentence of proposed § 25600.2(b) be revised as follows:

> The manufacturer, producer, packager, ~~importer~~[8] or distributor of a product may comply with this section either (i) by affixing a label to the product bearing a warning that satisfies Section 25249.6 of the Act, or (ii) by entering into contractual agreements with each of its commercial customers binding the customer to provide the warning when the product is sold in California and requiring the customer to enter into similar binding contractual agreements with its own commercial customers, or (iii) by providing a written notice directly to the authorized agent for a retailer who is subject to Section 25249.6 of the Act, or if the authorized agent for the retailer does not exist or cannot be located then by providing the written notice to any warehouse, website, or other commercial entity involved in the sale of the product, which…

For similar reasons, AHPA objects to the proposed requirements in paragraphs (4) and (5). Since there is frequently no direct connection – or ANY connection - between the manufacturer, producer, packager, or distributor of the product and the retailer, it will frequently be impossible to obtain a written acknowledgement from the retailer even once, much less every 180 days. AHPA notes that unless the retailer is a direct customer

[8] See comment 4.1 above.

of the manufacturer, producer, packager, or distributor of the product, the manufacturer, producer, packager, or distributor will neither have any way to compel the retailer to provide a written acknowledgement, nor any way to prevent the retailer from obtaining the product from intermediaries over which the manufacturer, producer, packager, or distributor has no control.

Furthermore, a requirement for the retailer to renew the acknowledgement (or for the manufacturer, producer, packager, or distributor to renew the notice) in writing every 180 days is needlessly onerous. AHPA acknowledges and appreciates that proposed § 25600.2(f) would permit the parties to avoid this requirement through contractual agreement; but this presupposes that a direct commercial relationship exists between the parties. As discussed above, it is common for multiple intermediaries – the identity of which may be unknown – to exist in between the manufacturer, producer, packager, or distributor and the retailer, and it is commonly not even possible for the party at one end of the supply chain to discover the identity or contact information for the party at the other end of the supply chain. Given that manufacturers, producers, packagers, and distributors often have hundreds or thousands of customers, and that retailers often buy product coming from hundreds or thousands of sources, any requirement to periodically re-address the provision of Prop 65 warnings represents a significant burden, especially if required at frequencies more often than once every few years.

Therefore, AHPA requests that proposed § 25600.2(b)(4) and (5) be revised as follows:

(4) Has been received and acknowledged in writing by the retailer, if there exists a direct commercial relationship between the manufacturer, producer, packager, or distributor and the retailer; or if not, then proof of mailing is maintained to document that the required written notice has been sent to the retailer or its authorized agent, or if the retailer or its authorized agent cannot be contacted, then to any other person involved in the sale of the product into California such as a website or warehouse.~~; and~~

~~(5) Has been renewed and acknowledged in writing by the retailer at least every 180 days during the period in which the product is sold in California by the retailer~~.

5.0 Comments regarding proposed § 25600.2(d)

5.1 Placement of "or"

AHPA notes that proposed § 25600.2(d)(3) ends with "or," but the list of circumstances continues beyond option (4). AHPA is unsure why the list of five circumstances is divided into two parts, the first four of which are presented as logical alternatives through use of "or," and the fifth of which is not logically linked to the others using either "and" or "or."

AHPA believes for clarity it would be preferable to move "or" from the end of (3) to the end of (4), so that (5) is included as a logical alternative to the previous four options:

> (3) The retailer has covered, obscured or altered a warning label that has been affixed to the product pursuant to subdivision (b); ~~or~~
> (4) The retailer has received warning information and materials (or an offer to provide warning materials) for the exposure pursuant to subdivision (b) and the retailer has sold the product without conspicuously posting those warning materials~~.~~; or

5.2 Comments regarding proposed § 25600.2(d)(5)(B)

AHPA notes that proposed § 25600.2(d)(5)(B) assumes that any foreign person having an agent for service of process in the US can readily be compelled to comply with Section 25249.6 of the Act. AHPA does not believe this to be accurate. AHPA believes that even if an agent for service of process exists, it will often be difficult or impossible for OEHHA, private plaintiffs, or others to force foreign entities to comply with Prop 65.

AHPA believes there is no reason for the applicability of § 25600.2(d)(5)(B) to be limited only to circumstances where a foreign person has no agent for service of process. This limitation does not further the purposes of the Act and needlessly places domestic manufacturers, producers, packagers, and distributors at a disadvantage compared to

foreign persons, because it provides an incentive for retailers to buy from foreign companies that have an agent for service of process as opposed to domestic companies (i.e., by buying from the former, retailers may find ways to avoid responsibility for required warnings that cannot be avoided by buying from domestic companies).

AHPA therefore requests the language to be modified as follows for clarity and equity:

> The manufacturer, producer, packager, ~~importer~~[9] or distributor of the product who ~~have~~ has[10] the duty to provide warnings for the exposure cannot readily be compelled to comply with Section 25249.6 of the Act because they are foreign persons ~~with no agent for service of process in the United States~~.

5.3 Comments regarding proposed § 25600.2(d)(5)(C)

AHPA does not believe that a retailer should be deemed to have "actual knowledge" that a warning is required unless the notice served pursuant to Section 25249.7 (d)(1) of the Act includes not simply an allegation but also detailed information to support the allegation. At a minimum, the notice should include the number of samples tested; the dates, times, and locations from which the samples were obtained; identifying information such as lot or batch numbers or expiration dates, if present; the test results of each sample; the test method used; the identity and contact information for the laboratory that performed the testing; and the dates on which the testing was performed.

Even with this information provided, the regulations cannot simply assume that the data forming the basis of the allegation is necessarily accurate. Data from any source can be, and often is, inaccurate due to use of analytical methods that are not valid for the matrix in question; laboratory error; unrepresentative sampling; and other problems. Often, a commercial entity associated with the product – rather than an outside party –

[9] See comment 4.1.

[10] AHPA suggests this change for grammatical correctness and also to avoid any implication that all (as opposed to only one) of the named entities have the duty to warn, as discussed in comment 4.2 above.

is the person with the most accurate and complete data concerning a product and who is in the best position to choose appropriate analytical methods and compile comprehensive data to determine whether a warning is required.[11]

AHPA therefore believes the proposed timeframe of two business days after receiving a notice served pursuant to Section 25249.7 (d)(1) of the Act is too short a timeframe to deem a retailer to possess "actual knowledge." After receiving any such notice, the retailer should be provided an opportunity to make appropriate investigations to determine the accuracy and validity of the allegations in the notice. For example, a retailer should have sufficient time to contact the product manufacturer for further information, or to send samples for testing to confirm the allegations. The retailer should not be deemed to possess "actual knowledge" until the accuracy and validity of the allegations has been confirmed to the retailer's satisfaction, which may require several weeks (e.g., for test results to be obtained).

AHPA notes that the purported health effects of Prop 65 listed chemicals at the extremely low thresholds that trigger the required Prop 65 warning are effects which develop, if at all, then only over extended periods of exposure. (Any product causing an exposure sufficiently high to result in acute (i.e. immediate or short-term) health effects would be subject to immediate removal from the marketplace, rather than a Prop 65 warning.) Therefore, there is no scientific justification to require retailers to react prematurely to a Section 25249.7 (d)(1) notice. If it turns out that a Prop 65 warning is legitimately required for the product, a delay of a few weeks or even months will have no discernible effect on public health.

AHPA imagines that some might object that consumers have the right, under Prop 65, to be warned as soon as possible when a product may cause exposure to a listed chemical.

[11] A notable recent example demonstrating this fact can be seen in the controversy caused by the New York Attorney General's use of invalid DNA testing, which led the Attorney General (AG) erroneously to allege that herbal products marketed by GNC Holdings Inc. (GNC) failed to contain the ingredients listed on the label; a position from which the AG was subsequently forced to retreat after GNC was vindicated through use of appropriate analytical methods. (See the March 27, 2015 agreement between the AG and GNC, available at http://www.ag.ny.gov/pdfs/NYAG-GNC%20AGREEMENT.%20FINAL%20AGREEMENT.%203.28.2015..pdf.) While this instance had nothing to do with Prop 65 listed chemicals, it exemplifies the errors that may occur through an inadequate understanding of product matrices and the inappropriate choice of analytical technologies and laboratories.

However, businesses have the countervailing right, under the US Constitution, not to be forced to cease distribution of a lawful product or to disseminate government-mandated information that is incorrect, inaccurate, or misleading, as would be the case if a business were forced to provide warnings for or cease distribution of a product in response to a Section 25249.7 (d)(1) notice that turned out to be invalid.

Therefore, AHPA requests that proposed § 25600.2(d)(5)(C) be revised as follows:

> For purposes of subdivision (5), "actual knowledge" means specific knowledge of the product exposure that the retailer receives from any reliable source. If the source of this knowledge is a notice served pursuant to Section 25249.7 (d)(1) of the Act, the retailer shall not be deemed to have actual knowledge of any product exposure that is alleged in the notice unless the notice includes data to support the allegation, including the number of samples tested; the dates, times, and locations from which the samples were obtained; identifying information such as lot or batch numbers or expiration dates, if present; the test results of each sample; the test method used; the identity and contact information for the laboratory that performed the testing; and the dates on which the testing was performed, and furthermore the retailer shall not be deemed to have actual knowledge until ~~two~~ thirty business days after the retailer receives the notice; provided that if the retailer has or obtains scientifically valid data that cast doubt on the accuracy or validity of the allegations contained in the notice served pursuant to Section 25249.7 (d)(1) of the Act, then the retailer shall not be considered to possess "actual knowledge."

5.4 Additional comments regarding proposed § 25600.2(d)

Proposed § 25603(d) addresses the provision of required warnings in multiple languages. AHPA believes these requirements must, as a practical matter, impose a related burden on retailers that requires enumeration in § 25600.2(d).

As discussed in comment 7.6 below, AHPA is concerned that proposed § 25603(d) implies that the manufacturer, producer, packager, or distributor is required to have

advance knowledge about all of the languages in which retailers selling its products may choose to provide labeling or signage about the product. Such a requirement would be infeasible both because there is no way for the manufacturer, producer, packager, or distributor who provides required warnings to anticipate all of the languages that may be used by retailers, especially if there are one or more intermediary companies between the entity providing warnings and the retailer; and because, where warnings are provided on product labels, the inherent space limitations of the label make it impossible to include the warning in more than one or two languages.

AHPA believes that where a manufacturer, producer, packager, or distributor provides a required warning in labels, labeling, or signs, and a retailer chooses to provide labeling or signage about a product in languages other than those in which the warning is provided by the manufacturer, producer, packager, or distributor, it must be the responsibility of the retailer to provide the warning translated into those other languages.

AHPA therefore requests that a new paragraph be added to § 25600.2(d) as follows:

> <u>The manufacturer, producer, packager, or distributor has provided the required warning in labels, labeling, or signs, and the retailer chooses to provide labeling or signs in languages other than those the manufacturer, producer, packager, or distributor has used to provide the warning.</u>

5.5 Comments regarding proposed § 25600.2(e)

AHPA supports inclusion of the flexibility provided by "to the extent that this information is reasonably available to the retailer."

However, AHPA does not believe it necessary to provide the identity of every party in the product's supply chain. Access to this information will only serve to facilitate lawsuits by the plaintiff against every one of the named parties. This would in many cases run contrary to the plain language of proposed § 25600.2, which sets forth various clear delineations of responsibility for providing the required warning. Furthermore,

AHPA notes it is the stated intention of the California State government, including both the Governor's office and the legislature (e.g., in 2013), to reduce frivolous lawsuits under Prop 65. There is no public benefit to be gained by permitting private plaintiffs to file lawsuits against every entity in a product's supply chain. Rather, legal responsibility to provide the warning should be established as per § 26500.2 (including the new § 26500.2(b) suggested in AHPA's comment 4.2 above); only the party bearing that legal responsibility should be subject to enforcement action, and only that party's identity and contact information should be subject to disclosure under § 25600.2(e).

Furthermore, AHPA notes that the identity of various parties in the product supply chain may be confidential business information. For example, the distributor of a private label product may consider the identity of its manufacturer or packager to be confidential; the distributor of an imported product may consider the identity of the importer to be confidential; or the importer may consider the identity of the product manufacturer to be confidential. There is no reason for OEHHA to require so much confidential business information to be publicly disclosed, especially when (as discussed in comment 4.2 above) a specific party in the supply chain has been contractually obligated to take responsibility for the provision of required warnings.

Finally, AHPA notes that the name and contact information of the product importer is not relevant to Prop 65 enforcement unless the importer is the manufacturer, producer, packager, or is a distributor that distributes the product within California. In many cases, a company such as a licensed Customs broker serves as the importer of record to facilitate entrance of the goods into the United States; such firms are paid a nominal sum to handle many types of goods for many different companies, and they cannot be expected to know or understand the technical nuances of the thousands of different products that pass through their hands.

AHPA therefore requests the following changes to proposed § 25600.2(e):

> The retailer of a product that can cause a product exposure shall provide the name and contact information for the manufacturer, producer, packager, ~~importer~~ and distributor of the product to the following persons on written request, to the extent that this information is reasonably available to the

> retailer; provided that where a manufacturer, producer, packager, or distributor is contractually obligated to take responsibility to provide required warnings as provided in § 25600.2(b) [newly proposed by AHPA in comment 4.2 above], only the name of that person shall be provided.

5.6 Comments regarding proposed § 25600.2(f)

AHPA supports the provisions of proposed § 25600.2(f), and believes they should broadened to encompass agreements made between manufacturers, producers, packagers, and distributors to allocate responsibility for providing required warnings as described in comment 4.2 above.

In addition, AHPA believes agreements between manufacturers, producers, packagers, or distributors and retailers may supersede not only subparagraphs (b) and (d) but also (c).

AHPA therefore requests the following changes to proposed § 25600.2(f):

> The manufacturer, producer, packager, importer or distributor of a product that may cause a product exposure may enter into a written agreement with each other or with the retailer of the product to allocate legal responsibility among themselves for providing a warning for the product, which shall bind the parties to that agreement, including for purposes of enforcement; ~~and which~~ in the case of agreements that include the retailer, the provisions of any such agreement shall supersede the requirements of subparagraphs (b), (c), and (d) to the extent that the warning provided to the purchaser of the product meets the requirements of Section 25249.6 of the Act.

6.0 Comments regarding proposed § 25602

AHPA strongly objects to the phrase “reasonably calculated to occur” to describe the level of listed chemical that requires a warning. This phrase introduces ambiguity which

private plaintiffs will use to their advantage. In order to avoid frivolous lawsuits, it is necessary that the regulations be stated with as much clarity and precision as possible.

Furthermore, the purpose of including "to the extent that an exposure to that chemical is reasonably calculated to occur at a level that requires a warning" in this subdivision is unclear. If OEHHA wishes to clarify the circumstances under which a warning is required, that clarification should be generally applicable to all warnings, rather than being limited to circumstances where the warning content described in § 25602(a) is used.

In addition, in the Statement of Reasons[12], OEHHA "anticipates that most warnings will not contain more than one or two of the chemicals included in this section." AHPA disagrees that this will be the case. AHPA furthermore disagrees with OEHHA's proposal[13] that businesses whose product contains multiple chemicals listed in this section should either use the "short form" warning or request OEHHA to adopt a product or exposure-specific warning. As discussed in our comments to Article 2, AHPA opposes the inclusion of product-specific or brand-specific information in the proposed web portal. Furthermore, AHPA doubts it will be practical for OEHHA to develop and adopt warning regulations that are specific to a particular product or brand of product.

AHPA believes marketers should be permitted to utilize any warning language that meets the requirements of the law. OEHHA appears to agree with this, insofar as the Statement of Reasons states "a business may use its own warning language as long as such a warning is 'clear and reasonable' for purposes of the Act." However, proposed § 25602(a) inherently makes listing of the chemical names mandatory in order to qualify for safe harbor, meaning any firm that deviates from the stated language is left open to lawsuit; this is reinforced by consideration of proposed § 25604(c), which states that a person using warnings pursuant to § 25604(b) "is not required" to comply with § 26502, thus clearly implying that persons using warnings other than those in § 25604(b) *ARE* required to comply with § 25602. As a result, the purported option for a business to "use its own warning language" does not, as a practical matter, exist.

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[12] Page 23.

[13] Ibid.

AHPA does not disagree that marketers could be permitted to disclose the name of the Proposition-65 listed chemical, but believes it should be voluntarily.[14] AHPA therefore requests that the introductory sentence of § 25602(a) be revised as follows:

> ~~Except as provided in Section 25604(c), a~~ A warning ~~meets the requirements of this Article if~~ may include the name or names of the chemicals listed in this section ~~are included~~ in the text of the warning, to the extent that an exposure to that chemical ~~is reasonably calculated to~~ occurs ~~at a level that requires a warning~~.

However, if the listing of chemicals is maintained as a de facto requirement of the safe harbor language, AHPA requests that the introductory sentence of § 25602(a) be revised as follows for practicality:

> Except as provided in Section 25604(c), a warning meets the requirements of this Article if the name or names of the chemicals listed in this section are included in the text of the warning, to the extent that an exposure to that chemical ~~is reasonably calculated to~~ occurs ~~at a level that requires a warning~~; provided, however, that if exposure to more than two chemicals occurs, the names of only the two chemicals causing the highest average exposures are required in the warning.

7.0 Comments regarding proposed § 25603

As a general matter, 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.

[14] See also comments 8.4 and 11.2 below regarding warning content.

AHPA is aware that, due to the court decision in *Ingredient Communication Council (ICC) v. Lungren*,[15] 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 would like to note for the record that it is fundamentally illogical and unfair for consumer products to be treated differently in one retail circumstance vs. another. It is also inherently misleading, because placement of warnings in direct association with particular products inevitably implies that those products pose a greater risk of exposure than products for which the warning occurs only via general, non-product-specific signage.

7.1 Comments regarding the introductory sentence of proposed § 25603(a)

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 § 25603(a) should be modified to state, "...and is provided using <u>at least</u> one ~~or more~~ of the following methods <u>at the sole discretion of the manufacturer, producer, packager, distributor, or retailer</u>."

7.2 Comments regarding proposed § 25603(a)(1)

AHPA believes the type size requirement in proposed § 25603(a)(1) is unreasonable and impractical. It is common for shelf signs and shelf tags to include text in an exaggeratedly large font size in order to draw attention to a product (e.g. "Sale!" or "10% off" or "Weekly special"). It is neither feasible nor necessary for Prop 65 warnings

[15] 2 Cal. App. 4th 1480 (1992).

to be presented in the same large type size as is used to initially attract the consumer's attention.

Furthermore, AHPA notes that the proposed requirements of § 25603(a)(1) are, as a practical matter, incompatible with the requirements of proposed § 25600.2(b)(3), which envisions that shelf signs and tags bearing the required warning will be provided by the manufacturer, producer, packager, or distributor. There is no way for such an entity, when it prints the shelf signs or tags bearing the warning, to know in advance the type sizes that will be used by various retailers for their own promotional signs or tags; nor is it reasonable to expect the manufacturer, producer, packager, or distributor to maintain an inventory of different shelf signs or tags printed in different type sizes for use by different retailers.

AHPA therefore requests that proposed § 25603(a)(1) be revised as follows:

> A product-specific warning provided on a shelf tag or on a shelf sign for the product at each point of display of the product. The entire warning message must be in a type size not less than 2 mm[16] in height [alternately, AHPA proposes "large enough to be noticed and read by the consumer," but fears this ambiguity would open the door to lawsuits]. ~~font no smaller than the largest type size used for other information on the shelf tag or shelf signs for the same or similar products~~.

If OEHHA determines to maintain the requirement for the type size to be no smaller than the largest type size used for other information, AHPA requests that, at a minimum, proposed § 25603(a)(1) be revised as follows:

> A product-specific warning provided on a shelf tag or on a shelf sign for the product at each point of display of the product. The entire warning message must be in a font no smaller than the largest type size used for other information

[16] AHPA believes 2 mm to be sufficiently large for the warning to be noticed and read by the customer. AHPA notes that for alcoholic beverages, 2 mm is a text size used by the Alcohol and Tobacco Tax and Trade Bureau for the required pregnancy warning (see 27 CFR § 16.22).

on the shelf tag or shelf signs for the same or similar products, excluding any prominent promotional text designed to attract the consumer's attention.

7.3 Comments regarding proposed § 25603(a)(2) and (b)

Proposed § 25603(a)(2) would require that electronic warnings be provided "prior to or during the purchase of the product" and proposed § 25603(b) would require that warnings be provided "before the purchaser completes his or her 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 zipcode of residence[17] early in the browsing process, so that the required warning was displayed whenever the consumer viewed 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. In the Statement of Reasons, OEHHA itself acknowledges that a warning meets the requirements of the Act if it is "available to the individual prior to exposure."[18] 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.

[17] AHPA notes that the consumer's state of residence may be different from the location indicated by the consumer's IP address or browser.

[18] Page 1.

Furthermore, AHPA notes that the Act 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.

Finally, AHPA notes that the combined effect of proposed § 25603(a) and (b) will be to necessitate duplicative warnings in cases where products sold over the internet include the warning on product labels or elsewhere. AHPA does not believe such duplicative warnings would serve to further the purposes of the Act, but would only create needless burdens and expenses for business.

AHPA notes that proposed § 25603(a)(2) is optional, insofar as the warning may be provided in any one of the listed manners. AHPA therefore does not object to proposed § 25603(a)(2) as written so long as the list of optional methods of transmission is expanded as described in comment 7.4 below.

AHPA does request that proposed § 25603(b) be revised as follows to maintain consistency with the Act, remain within the scope of OEHHA's authority, avoid imposing a requirement for duplicative warnings, and ease the burden on businesses by clarifying that it is optional, not mandatory, to provide warnings during internet purchases:

> Where warnings are provided during ~~For~~ internet purchases, the warning message must be provided by a clearly marked hyperlink on the product display page, or otherwise prominently displayed to the purchaser before the purchaser completes his or her purchase of the product. For purposes of this Article, a warning is not prominently displayed if the purchaser must search for it in the general content of the website.

7.4 Additional comments regarding proposed § 25603(a)

AHPA notes that proposed § 25603(c) mandates that warnings be provided in catalogs, but proposed § 25603(a) fails to acknowledge that such a warning will meet the requirements of Article 6. In addition, AHPA notes there are other means by which a warning may be delivered prior to exposure occurring, and asks that these be similarly

included in the § 25603(a) list of methods stipulated to meet the requirements. This will serve to ease the burden on businesses by allowing each firm to choose the most efficient method of warning delivery for each circumstance, while still meeting the requirement of the Act by ensuring the warning is delivered prior to exposure. It will also serve to take advantage of new means of communication that have developed in recent decades.

AHPA therefore requests that the following be added to § 25603(a):

(4) A product-specific warning provided in the catalog from which the product is ordered.

(5) A product-specific warning provided in labeling or other literature accompanying the sale of the product.[19]

(6) A product-specific warning provided verbally to the customer (e.g., during ordering of the product by telephone, or at the time of retail sale), provided that an audio recording is retained as proof of delivery of the warning or written confirmation of receipt of the warning is obtained from the customer.[20]

(7) An email sent to the customer (e.g., after receipt of an order received by fax or email), provided that the text of the email and proof of delivery of the email are retained.

AHPA reiterates in the strongest possible terms that the above is intended as a list of optional *alternative* methods by which warnings may be delivered; that these methods should be explicitly acknowledged in the regulation as adequate to meet the

[19] AHPA notes that this method of transmission is analogous to "inclusion of notices in mailings to water customers" which is provided for in the Act.

[20] AHPA notes that this option may be particularly important in cases where, for example, a retailer chooses to provide signage pertaining to a particular product in a language other than the language in which the product manufacturer has provided a required warning, and the warning therefore needs to be provided in additional languages.

requirements of the Act; and that under no circumstances should delivery of warnings by multiple routes of transmission be required.

7.5 Comments regarding proposed § 25603(c)

AHPA reiterates its objection to requiring delivery of the warning prior to purchase, rather than prior to exposure (see comment 7.3 above).

In addition, AHPA notes that the combined effect of proposed § 25603(a) and (c) will be to necessitate duplicative warnings in cases where products sold via catalog include warnings provided on the product label or by other means. AHPA does not believe such duplicative warnings would serve to further the purposes of the Act, but would only create needless burdens and expenses for business. Furthermore, AHPA believes a requirement to place warnings in catalogs to be onerous and unjustified. 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.

AHPA therefore requests that proposed § 25603(c) be revised as follows to maintain consistency with the Act, remain within the scope of OEHHA's authority, avoid imposing a requirement for duplicative warnings, and ease the burden on businesses by clarifying that it is optional, not mandatory, to provide warnings in catalogs:

> Where warning messages are provided in catalogs ~~For catalog purchases~~, the warning message must be provided in the catalog in a manner that clearly associates it with the item being purchased.

Furthermore, to the extent that a requirement to provide warnings in catalogs is maintained in subsequent drafts of the regulation, AHPA is concerned that the regulation establishes no clear definition of "catalog." AHPA believes that without a clear definition, private plaintiffs are likely to attempt to define any sales literature as a

"catalog" that is required to bear any necessary warning. AHPA strongly objects to any possible interpretation that all forms of sales literature are required to bear Prop 65 warnings.

AHPA therefore requests that the following definition of "catalog" be added to § 25600.1:

> "Catalog" means a printed pamphlet, booklet, or similar document identifying products offered for sale along with pricing and ordering information.

7.6 Comments regarding proposed § 25603(d)

AHPA is concerned that proposed § 25603(d) implies that the manufacturer, producer, packager, or distributor is required to have advance knowledge about all of the languages in which retailers selling its products may choose to provide labeling or signage about the product. Such a requirement would be infeasible both because there is no way for the manufacturer, producer, packager, or distributor who provides required warnings to anticipate all of the languages that may be used by retailers, especially if there are one or more intermediary companies between the entity providing warning and the retailer; and because, where warnings are provided on product labels, the inherent space limitations of the label make it impossible to include the warning in more than one or two languages.

Furthermore, the existing proposed language implies that all warnings for the product must be provided in precisely the same printed material, which AHPA does not believe is necessary. For example, if a product label with the warning is printed in English but the product is sold in a store that uses signage in, say, Spanish or Filipino or Korean, this should not mean the label must be printed to include the warning in both English and Spanish or Filipino or Korean (much less all of these); rather, the requirements of the Act will be adequately fulfilled if the warning is delivered via labeling or signs printed in the necessary additional language(s), or by any other means such as electronic or verbal communication in the additional language(s).

AHPA therefore requests the following changes to proposed § 25603(d) for clarity and practicality:[21]

> If any label, labeling or sign about a product is provided in a language or languages other than or in addition to English, then a warning for that product meets the requirements of this Article only if the warning is also provided in the same language or languages either on the label~~,~~ or in labeling or a sign, or by other electronic, written, or verbal means.

8.0 Comments regarding proposed § 25604(a)

8.1 General comments regarding proposed § 25604(a)

AHPA continues to believe that the proposed content of product exposure warnings is excessively alarming and inflammatory.

All the evidence available to AHPA, including market research conducted by its members; anecdotal reports from its members; and peer-reviewed studies published in the scientific literature, indicate that Prop 65 warnings are inherently confusing and misleading to consumers. For example, AHPA's members and others[22] have found that the word "chemical" in and of itself is unusually alarming to consumers. The word "chemical" leads the consumer to believe the material in question is unnatural, artificial, synthetic, and quite dangerous, none of which is what most consumers want in a product (especially foods and personal care items) and none of which is an accurate description of many naturally-derived products. In addition, the words "cancer," "birth defects," and "reproductive harm" are inherently alarming to consumers. Studies have found that consumers do not understand the importance of dose and exposure;

[21] See also comment 5.4 regarding the need for retailers to bear responsibility for providing the warning in additional languages when the manufacturer, producer, packager, or distributor has already provided the warning.

[22] Studies have repeatedly found the public has strong negative attitudes toward "chemicals" and the risks they pose. (For example, "Intuitive Toxicology: Expert and Lay Judgments of Chemical Risks," N. Neil et al, *Toxicol Pathol* 1994 22: 198 Nancy Neil, Torbjörn Malmfors and Paul Slovic; also "Intuitive Toxicology. II. Expert and Lay Judgments of Chemical Risks in Canada," Paul Slovic et al, Risk Analysis, Volume 15, Issue 6, pages 661–675, December 1995.)

generally view chemicals as either categorically safe or dangerous; and equate even small exposures to toxic or carcinogenic chemicals with almost certain harm.[23] 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.[24]

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 often not 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 believes the warning content proposed in § 25604 will exacerbate, rather than reduce, the confusing and misleading nature of Prop 65 warnings. The proposed pictogram symbol along with the bolded all-capitals "**WARNING**" will make the warnings even more alarming than they currently are.

In the Statement of Reasons, OEHHA states, "Including this word in bold and capital letters ensures that consumers will immediately know the information being provided is important and not just informational in nature."[25] AHPA disagrees with this characterization; as has been stated numerous times,[26] Prop 65 is a "right to know" law that requires information to be provided to exposed individuals, not a public safety law designed to protect the public health. The law requires that exposed individuals be warned, not that they be frightened. Moreover, there is no scientific consensus that

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[23] "Intuitive Toxicology: Expert and Lay Judgments of Chemical Risks," N. Neil et al, *Toxicol Pathol* 1994 22: 198 Nancy Neil, Torbjörn Malmfors and Paul Slovic; also "Intuitive Toxicology. II. Expert and Lay Judgments of Chemical Risks in Canada," Paul Slovic et al, Risk Analysis, Volume 15, Issue 6, pages 661–675, December 1995.

[24] "Intuitive Toxicology: Expert and Lay Judgments of Chemical Risks," N. Neil et al, *Toxicol Pathol* 1994 22: 198 Nancy Neil, Torbjörn Malmfors and Paul Slovic.

[25] Page 26.

[26] For example, in the Statement of Reasons at pp. 2, 26, 27, and 41.

many listed chemicals in fact cause negative health effects at the very low levels that trigger a required warning, making unnecessary alarmism even less justified.

AHPA believes that the Prop 65 warning language, at least for foods, personal care items, and other products that are not frank toxins, and/or in products where the listed chemical occurs at levels below those at which there is scientific consensus of harm, should be informative and as emotionally neutral as possible, rather than needlessly inflammatory and alarming.

AHPA therefore objects to the proposed blanket requirement to include the pictogram symbol and the bolded all-capitals "**WARNING**" text in all product exposure warnings except as established in § 25608. AHPA also reiterates its suggestion in earlier comments that "chemical" should be replaced wherever it occurs with "substance," which AHPA believes to be free of the negative connotations that "chemical" suffers.

8.2 Comments regarding proposed §§ 25604(a)(2)(A) through (D)

AHPA appreciates that no type size requirements are proposed in §§ 25604(a)(2)(A) through (D).

With respect to §§ 25604(a)(2)(B), (C), and (D), AHPA objects to the requirement to list both "birth defects" and "reproductive harm," especially in cases where the listed chemical that is the subject of the warning is known to cause only one or the other. AHPA requests that OEHHA return to previously-proposed warning language[27] that would mention only "reproductive toxicity" (or better yet, "reproductive harm") instead of "birth defects," as the former includes the latter. If OEHHA mandates use of both terms ("birth defects" and "reproductive "harm") in reproductive toxicity warnings, then persons providing a warning should be required to include only that term which appropriately fits the circumstances, and should be required to include both terms only for chemicals that may cause both types of harm. For OEHHA to require both terms to

[27] Title 27, California Code of Regulations Article 6 Clear and Reasonable Warnings, Draft Regulation for Discussion Purposes Only, September 23, 2014.

be used in all reproductive toxicity warnings will reduce the factual accuracy of the warnings.

With respect to proposed § 25604(a)(2)(D), AHPA objects to the requirement to list both the name of the chemical or chemicals and the words "chemicals" or "chemicals." Where the warning includes the specific name of the chemical, there is no need to also state that this is a "chemical," especially since the word "chemical" carries excessively negative connotations for many consumers. AHPA believes that omission of the word "chemical(s)" will make businesses significantly less hesitant to provide the warning, and will thereby improve compliance.

AHPA also objects to the proposed requirements in § 25604(a)(2)(A) through (D) to include a link to OEHHA's website. AHPA does not object to OEHHA creating such a website so long as AHPA's separately-submitted comments to proposed Article 2 are incorporated; but AHPA objects to a requirement to include the link in all warnings, especially for small package sizes. There exist product labels so small they will have difficulty including any additional text, much less several lines of text. As with Federal labeling regulations,[28] provisions should be made for small packages to include less information – without penalizing the product by necessitating a warning that is even more cryptic and frightening than the usual Prop 65 warning (i.e., the alternate warnings described in § 25604(b)).

8.3 Alternate 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. AHPA believes that the alternate language proposed in this section will lead to increased rates of compliance by businesses with the warning requirements.

[28] See for example 21 CFR §§ 101.9 and 101.36.

8.3.1 Background to this section of comments

In the Statement of Reasons,[29] OEHHA stated that it is proposing regulatory amendments to Title 27 CCR Article 6 for a number of reasons, including among others to "provide consistent, understandable warnings for 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 Prop 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 the Act.

OEHHA also states in the Statement of Reasons that the revised regulations are intended to "provide specific guidance on methods and content for safe harbor warnings that will provide more detailed information for the public,"[30] and that OEHHA wishes to "encourage businesses to continue to work with OEHHA" to develop "tailored" warning methods or messages.[31]

AHPA agrees that tailored warning content for certain common types of exposures would be both appropriate and more informative for consumers, and proposes such language below.

8.3.2 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 and proposed regulations,

[29] Page 3.

[30] Page 2.

[31] Page 5.

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.

Specifically, AHPA proposes that the following language be provided as an alternate option (as appropriate to the circumstances) for products that require a Prop 65 warning:[32]

> For reproductive toxicity that 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"), "Not for use by women who are pregnant or trying to conceive."; or
>
> For reproductive toxicity that is known by the state to be associated with harm to neonates, infants, or children, either through maternal exposure or direct exposure ("developmental toxicity"), "Not for use by nursing women or by children."; or
>
> For reproductive toxicity that 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"), "Not for use by men who are trying to conceive."

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, Federal regulation requires certain OTC drugs intended for systematic absorption to bear a "pregnancy/breast-feeding warning," as follows:

[32] In previous comments submitted to OEHHA, AHPA proposed this language in connection with warnings for food products. Upon further consideration, AHPA believes the language also to be appropriate for products other than food.

> "Warning: If pregnant or breast-feeding, ask a health professional before use."[33]

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."[34]

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 the Act.
Hence, the instructive warnings proposed here by AHPA would fully conform to and satisfy the intent of Prop 65 as regards reproductive toxins to ensure that consumers receive "clear and reasonable warning" relevant to exposures to these substances. These proposed optional warnings would in fact be more reasonable and therefore may lead to greater compliance by industry. They would also be more clear and understandable to consumers than the current warnings or than the warnings proposed in new §§ 25604(a) and 25608.2(a), as they are more appropriately tailored to the target populations. OEHHA's acceptance of the optional warnings that AHPA has proposed for reproductive toxins would therefore serve to further the purposes of the law.

8.4 Requested revisions to proposed § 25604(a)

In view of all the above, AHPA requests the following amendments to proposed § 25604(a):

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[33] 21 CFR § 201.63.

[34] 47 FR 54754.

(a) Unless otherwise specified in Section 25608, a warning meets the requirements of this Article if it is provided using one or more of the methods required in Section 25603 and includes ~~all~~ the following elements.

~~(1) A symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. Where other signage or labeling for the product is not provided in color, the symbol may be printed in black and white. The symbol shall be placed to the left of the text of the warning, in a size no smaller than the height of the word "WARNING".~~

~~(2) The word "**WARNING**" in all capital letters and bold print, and:~~

~~(A)~~ (1) For exposures to listed carcinogens, the words, "This product can expose you to a ~~chemical [or chemicals]~~ substance [or substances] known to the State of California to cause cancer. ~~For more information go to www.P65Warnings.ca.gov/product.~~"

(~~B)~~ (2) For exposures to listed reproductive toxicants, either:

(A) The words, "This product can expose you to a ~~chemical [or chemicals]~~ substance [or substances] known to the State of California to cause ~~birth defects or other~~ reproductive harm. ~~For more information go to www.P65Warnings.ca.gov/product.~~"; 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 trying to conceive."; 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

(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 trying to conceive."; 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 (2)(B), (2)(C) and (2)(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 (2)(A) of this section or the words "Not for use by women who are pregnant or nursing, by men or women who are trying to conceive, or by children."

~~(C)~~ (3) For exposures to listed carcinogens and reproductive toxicants, ~~the~~ words that combine the appropriate words set forth in paragraphs (1) and (2) of this section.~~, "This product can expose you to a chemical [or chemicals] substance [or substances] 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/product."~~

~~(D)~~ (4) Where the name or names of chemicals are ~~required to be~~ included in the warning pursuant to Section 25602, or the person providing the warning includes the name or names of other chemicals, and the warning is provided in the form specified in paragraphs (1) or (2)(A) of this section, the words, "This product can expose you to ~~a~~

~~chemical [or chemicals] such as~~[35] [name or names of chemicals], which ~~that~~ is [are] known to the State of California to cause cancer [or ~~birth defects or other~~ reproductive harm or cancer and ~~birth defects or other~~ reproductive harm]. ~~For more information go to www.P65Warnings.ca.gov/product.~~"

9.0 Comments regarding proposed § 25604(b)

As discussed in comment 8.1, AHPA believes that the proposed content of product exposure warnings is excessively alarming and inflammatory. AHPA believes that the proposed shortened warnings described in § 25604(b) are even worse; due to highly abbreviated form they provide even less context than the full warnings.

However, in view of the fact that the shortened warnings are optional rather than required, AHPA does not object to firms being given the opportunity to use these shortened forms voluntarily.

10.0 Comments on proposed § 25608.1

AHPA supports the explicit inclusion of dietary supplements in this text, in order to clarify that they are food for purposes of the Act as well as under Federal law.

AHPA has similar concerns with proposed § 25608.1(b) as with proposed § 25603(d). For similar reasons to those explained in comment 7.6 above, AHPA requests the following changes to proposed § 25608.1(b) for clarity and practicality:[36]

> If any label, labeling or sign about a food or dietary supplement is provided in a language or languages other than or in addition to English, then a warning for that product meets the requirements of this Article only if the warning is also

[35] AHPA believes that omission of the word "chemical(s)" will make businesses significantly less hesitant to provide the warning, and will thereby improve compliance.
[36] See also comment 5.4 regarding the need for retailers to bear responsibility for providing the warning in additional languages when the manufacturer, producer, packager, or distributor has already provided the warning.

provided in the same language or languages either on the label~~,~~ or in labeling or a sign, or by other electronic, written, or verbal means.

11.0 Comments on proposed § 25608.2

11.1 General comments on proposed § 25608.2(a)

AHPA appreciates that the pictogram symbol described in § 25604(a)(1) is not proposed as a requirement for safe harbor in § 25608.2.

AHPA reiterates its objection to the requirement for a bold, all-capitals "WARNING" text and to the use of the word "chemical," as discussed in comment 8.1 above.

AHPA notes that proposed § 25608.4(a)(1) through (5) include specific type size requirements, and that this differs from the proposed requirements of § 25604(a). AHPA sees no justification to impose specific type size requirements on food products in particular, when none are required for other products in general. Furthermore, AHPA believes the proposed type sizes to be impractically large, especially for small packages; AHPA notes that Federal labeling regulations permit font sizes as small as 6 point for conventional foods[37] and as small as 4.5 point for dietary supplements,[38] due to the large amount of information that is required on food labels and the frequently very small package sizes involved.

In addition, AHPA believes the alternate warning statements proposed in comments 8.3 and 8.4 above are appropriate for foods.

11.2 Requested changes to proposed § 25608.2(a)

As a result of all the above, AHPA requests the following changes to proposed § 25608.2(a)(1) through (5):

[37] 21 CFR 101.9(d)(1)(iii).

[38] 21 CFR 101.36(i)(2)(i) and (ii).

~~(1) The word "**WARNING**" in all capital letters and bold print no smaller than 10-point type.~~

~~(2)~~ (1) For exposure to a listed carcinogen, the words, "Consuming this product can expose you to a chemical [or chemicals] known to the State of California to cause cancer. ~~For more information go to www.P65Warnings.ca.gov/food," in no smaller than 8-point type~~.

~~(3)~~ (2) For exposure to a listed reproductive toxicant, either:

(A) ~~t~~The words, "Consuming this product can expose you to a chemical [or chemicals] known to the State of California to ~~cause birth defects or other~~ reproductive harm. ~~For more information go to www.P65Warnings.ca.gov/food," in no smaller than 8-point type.~~ ; 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 trying to conceive."; 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

(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 trying to conceive."; 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 (2)(B), (2)(C) and (2)(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 (2)(A) of this section or the words "Not for use by women who are pregnant or nursing, by men or women who are trying to conceive, or by children."

~~(4)~~(3) For exposures to chemicals listed as carcinogens and reproductive toxicants, ~~the~~ words that combine the appropriate words set forth in paragraphs (1) and (2) of this section~~, "Consuming this product can 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/food," in no smaller than 8-point type~~.

~~(5)~~ (4) Where the name or names of chemicals are ~~required to be~~ included in the warning pursuant to Section 25602, or the ~~noticing party~~ person providing the warning[39] includes the name or names of other chemicals, and the warning is provided in the form specified in paragraphs (1) or (2)(A) of this section, the words, "Consuming this product can expose you to ~~a chemical [or chemicals] such as~~[40] [name or names of chemicals], which ~~that~~ is [are] known to the State of California to cause cancer [or ~~birth defects or other~~ reproductive harm or cancer and ~~birth defects or other~~ reproductive harm]. ~~For more information go to www.P65Warnings.ca.gov/product.~~"

11.3 Comments regarding proposed § 25608.2(b)

AHPA opposes a requirement to provide the warning in text that is "set off from surrounding information and enclosed in a box." AHPA notes and appreciates that insofar as proposed § 25608.2(b) uses the word "may," such placement is optional.

[39] AHPA believes "person providing the warning" as used in proposed § 25604(a) is more clear and less confusing than "noticing party."

[40] AHPA believes that omission of the word "chemical(s)" will make businesses significantly less hesitant to provide the warning, and will thereby improve compliance.

AHPA is concerned that the proposed text of § 25608.2(b) seems to imply that a warning provided in this form should be applied as a "label on the product" that is separate from the normal label included on the product. AHPA doubts whether this is what OEHHA intends, as there would appear to be no particular advantage to using a separate label to provide the warning as opposed to printing the warning as part of the usual label.

Finally, AHPA does not believe that the alternate shortened warnings proposed in § 25604(b) are an appropriate option for foods.

In view of the above, AHPA proposes the following modifications to § 25608.2(b):

> The warning may be provided in the form of ~~a label~~ text on the product label that is set off from other surrounding information and enclosed in a box; however, this placement is not required in order to meet the requirements of this Article. ~~The label must include the elements and text size specified in Section 25604(b)(2).~~