



April 26, 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 Warnings Regulation)

Re: Comments on proposed repeal of 27 CCR Article 6 (Sections 25601 through 25605.2) 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 March 25, 2016 (the March 2016 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 March 2016 replaced earlier proposals in the same matter, issued by OEHHA on January 16, 2015 (the January 2015 proposal) and on November 27, 2015 (the November 2015 proposal) proposal.

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 dated today. The comments submitted herein and separately by AHPA are therefore in addition to the Coalition’s comments.

Comments regarding proposed § 25600.1(e)

AHPA is 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 enforcers. Inclusion of such a vague criterion directly contravenes the intended purpose of Governor Brown’s reforms of Proposition 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(e) be revised 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.

Comments regarding proposed § 25600.1(m)

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 Proposition 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 enforcers 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 “understand” 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, 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, ~~and understood by an ordinary person.~~

Comments regarding proposed § 25600.2(f)

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 an allegation of the presence of a Proposition 65 chemical. 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 – 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.

AHPA therefore believes the proposed timeframe of five 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 Proposition 65 listed chemicals at the extremely low thresholds that trigger the required Proposition 65 warning are effects which develop, if at all, 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 Proposition 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 Proposition 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 Proposition 65, to be warned as soon as possible when a product may cause exposure to a listed chemical. 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(f) be revised as follows:

For purposes of paragraph (e)(5) of this section, “actual knowledge” means specific knowledge of the consumer product exposure received by the retail seller 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 retail seller shall not be deemed to have actual knowledge of any consumer product exposure that is alleged in the notice until ~~five~~ **thirty** business days after the retail seller receives a notice that provides a description of the product with sufficient specificity for the retail seller to readily identify the product in accordance with Article 9, section 25903(b)(2)(D), **and that also provides 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; 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.”**

Comments regarding proposed § 25601(b)

AHPA notes proposed § 25601, “Safe Harbor Clear and Reasonable Warnings – Methods and Content,” specifies in paragraph (b): “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 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

¹ 21 CFR § 201.63.

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 March 2016 proposal, as they are more appropriately tailored to the target populations. Acknowledgement in revised regulation itself 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.

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 by adding this alternative language as optional warnings in proposed §§ 25603 and 25607.2.

² 47 FR 54754.

Comments regarding proposed § 25601(f)

AHPA agrees with the Coalition's comments submitted today that the stated restriction in this proposed section on any information provided supplemental to a warning would violate the First Amendment and Due Process. AHPA strongly encourages OEHHA to address this matter, either by the means proposed in the Coalition's comments, or by revising this section as follows:

The warning may contain information that is supplemental to the warning content required by this article only to the extent that it ~~explains the source of the exposure or provides information on how to avoid or reduce exposure to the identified chemical or chemicals~~ **is truthful and not misleading**. Such supplemental information may not be substituted for the warning required by this article.

Comments regarding proposed § 25602(c)

AHPA is concerned that the regulation establishes no clear definition of "catalog" and that without a clear definition private enforcers may attempt to define any sales literature as a "catalog" that is required to bear warnings. AHPA strongly objects to any possible interpretation that all forms of sales literature are required to bear Proposition 65 warnings and 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.

Comments regarding proposed § 25602(d)

AHPA is concerned that proposed § 25602(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:

If any label, labeling or sign that provides consumer information 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 that label, labeling or sign, **or by other electronic, written or verbal means.**

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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