



AMERICAN WOOD COUNCIL

April 8, 2015

Via email to P65Public.Comments@oehha.ca.gov

Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P. O. Box 4010
Sacramento, California 95812-4010

Re: Proposed Repeal of Article 6 and Adoption of New Article 6 Proposition 65 Clear and Reasonable Warning Regulations

Dear Ms. Vela:

American Wood Council (AWC) is pleased to provide comments on the proposed adoption of a new version of Article 6 of Title 27 of the California Code of Regulations.

AWC represents over 75 percent of the North American traditional and engineered wood products industry. Among other things, AWC advocates on behalf of its members for environmental policies that promote and facilitate the use of this renewable resource.

AWC's members manufacture products such as dimensional lumber, plywood and other flat panels, molding, and other wood products that, when sawed, milled, drilled or sanded can generate wood dust. Some AWC members manufacture, distribute or sell wood products in California. It is unclear whether, by the mere act of selling or distributing wood products (but not wood dust) in California, AWC members fall within the class of persons required to provide a warning under California Health and Safety Code section 25249.6. Nevertheless, some or all of AWC's members have chosen to provide a warning with their products that is consistent with Health & Safety Code sections 25249.6 and 25249.11(f) and Title 27 Article 6 of the California Code of Regulations. Thus, AWC has a particular interest in the proposed revisions to the Article 6 regulations.

Adoption of Expanded "Safe Harbor" Warning Regulations

AWC supports, as a general matter, the Office of Environmental Health Hazard Assessment's (OEHHA's) goal of providing more-specific guidance to regulated entities and the public about the substance and methods of delivery for warnings that may be required under California Health & Safety Code Section 25249.6. Current Article 6 regulations are unclear or incomplete in a number of ways, and it is especially hard to predict what form of warning the State of California would consider adequate under section 25249.6 for something like wood dust, where products that may contain the listed substance are sold in a variety of forms and settings. In fact, AWC previously requested guidance about application of the Proposition 65 listing of wood dust to wood products in a September 3, 2010 letter to Susan Fiering, Esq. of the Office of the Attorney General of California (in that regard, AWC supports inclusion of provisions in the Article 6 regulations so that "businesses could request that OEHHA adopt a product or exposure-specific warning in Section 25608. This would enable OEHHA to consider the specific

circumstances that might make a particular warning's compliance with Section 25602 to be difficult, and to provide regulatory guidance as appropriate for a clear and reasonable warning.").

However, AWC has a number of specific concerns about the language of the proposed new Article 6 regulations, as set forth below. One overall comment is that the final rulemaking needs to be very clear that the examples of warnings and forms of delivery of those warnings set forth in the regulations are "safe harbors"—indications of actions that OEHHA has concluded will satisfy the obligation to provide "clear and reasonable" warning under Health & Safety Code Section 25249.6, rather than mandatory provisions. The regulations do not preclude the use of other warning language and graphics, or other methods of delivering the warning, that satisfy the dictates of Section 25249.6. The proposed Article 6 regulations themselves do state that (see, proposed section 25601(b)). AWC suggests, however, that the wording of section 25601(b) be modified, so that it is stated in the affirmative, for improved clarity, thusly: "(b) A person may provide a warning using content or methods other than those specified in this Article if that warning nevertheless complies with Section 25249.6 of the Act." In addition, OEHHA should remove any language in the remainder of Article 6 that, especially when read independently of section 25601(b), might appear to undercut that clear limitation on the effect of the Article 6 safe harbor guidance (see, e.g., proposed section 25608(a) ("Where such warning methods or content are included in this section, a person *must use* the warnings specified in this section in order *to satisfy the requirements* of this Article" (emphasis added)); proposed section 25608.10(a) ("A warning for exposures to wood dust by drilling, sawing, sanding or machining wood products *meets the requirements* of this Article if..." (emphasis added))).

The Initial Statement of Reasons published to support the proposed regulations also indicates that the regulations provide "non-mandatory guidance" about acceptable warnings and "retain the safe harbor concept by giving a business the opportunity to use warning methods and content that OEHHA has deemed 'clear and reasonable', or a business may use any other warning method or content that is clear and reasonable under the Act." *Id.* at pp. 1, 13, 23. Other portions of the Initial Statement of Reasons, however, contain text that could be read to indicate that the statements in proposed Article 6 Subarticle 2 must be followed to comply with Proposition 65 warning obligations. For example:

Section 25604 sets out the *requirements* for providing a warning for an exposure to a listed chemical from a product, other than products that are covered in Section 25608 of the regulations. A business that is subject to the requirements of Section 25249.6 of the Act *must include* all the mandatory elements set out in Section 25604 or the relevant provisions of Section 25608, in order *for the warning to be considered clear and reasonable* under this Article. Initial Statement of Reasons p. 25 (emphasis added).

Similarly, "[S]ection 25608 *requires a person to provide a warning in a specific way and with specific content* where a warning covering that exposure has been adopted by OEHHA." *Id.* at 29 (emphasis added). "The regulation *requires* the following process for providing a warning for exposures to listed chemicals from furniture...." *Id.* at p. 35 (emphasis added). AWC urges OEHHA to review the Final Statement of Reasons and other statements that will be issued in

conjunction with promulgation of the revised Article 6 regulations to make sure that such potentially confusing language is eliminated.

In addition, AWC supports inclusion in the Article 6 regulations of provisions so that “businesses could request that OEHHA adopt a product or exposure-specific warning in Section 25608. This would enable OEHHA to consider the specific circumstances that might make a particular warning’s compliance with Section 25602 to be difficult, and to provide regulatory guidance as appropriate for a clear and reasonable warning” (Initial Statement of Reasons p. 23). The proposed regulatory language that this description of intent apparently refers to, however, proposed section 25600(c), does not clearly accomplish that purpose, since it would appear only to apply if OEHHA has not previously “adopted a warning method or content specific to a product, area, or chemical in Section 25608.”

Transition Period

AWC supports the approach proposed for new Article 6 regulations allowing affected businesses up to two years to conform their warnings to the safe harbor guidance in the new Article 6 regulations (see, Initial Statement of Reasons p. 5). Businesses required to provide warnings under Proposition 65 already have created warning labels or other forms of warning and developed methods and arrangements with other companies to make sure that the warnings reach the final purchaser. The proposed revisions to Article 6 will, in many cases, require changes to those warnings and arrangements, if the business wants to take advantage of the safe harbor provided by Article 6 Subarticle 2 regulations. The proposed regulatory language, however, is not clear as to the intended effect of the regulations as is the Initial Statement of Reasons. The latter states that the two-year delay in the effective date “will allow businesses to use either the old safe harbor warnings or the newly adopted safe harbor warnings for two years following adoption of the regulations” (*Id.* at 35). Proposed section 25600(b), however, states, “This Article will become effective 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.”

AWC suggests that OEHHA’s intent would be more apparent if the second sentence of proposed section 25600(b) is revised to read: “Prior to this two-year effective date, the lead agency has determined that a warning that complies either with Article 6 as previously written or with the version of Article 6 that will become effective after two years meets the requirement for a “clear and reasonable” warning under Section 25249.6 of the Act.”

Allocation of Responsibility To Provide Warnings

AWC supports OEHHA’s goal of clarifying how the responsibility for providing a warning to the purchaser of a product is allocated among the manufacturer, producer, packager, importer or distributor, and the retailer. It is very important, however, that the final regulations retain the provision in proposed section 25600.2(f), which allows a written agreement among some or all of those entities and the retailer to supersede OEHHA’s safe harbor description of their relative responsibilities with respect to providing the warning. This is important, to recognize the variety of circumstances in which products affected by Proposition 65 may be distributed and sold, and in order not to upset contractual arrangements that already exist.

Product Exposure Warnings Symbol

AWC opposes the proposed requirement in Section 25604 of the warning label pictogram of the black exclamation point in a yellow equilateral triangle with a bold black outline. This symbol is greatly similar in design to the "Warning" pictogram used in the 2012 Occupational Safety Hazard Administration (OSHA) Hazard Communication program revision. There would exist a significant contradiction between the uses of the exclamation mark symbol on a product label, given the differences between the use stipulated in Article 6 and 29 CFR 1910.1200. OSHA uses a different symbol ("Health Hazard") to indicate a material is a carcinogen, and uses the exclamation mark in a diamond symbol to indicate a material that is an irritant, skin sensitizer or is acutely toxic. The pictogram is, at best, meaningless and most likely, confusing and misleading. Moreover, it is redundant on a label or sign that begins with the bolded word "WARNING."

Disconnect Between Proposed Safe Harbor Warning Language and Future Content of the Referenced OEHHA Website

Both the generic guidance on product exposure warnings in proposed section 25604(a) and the guidance specific to "raw wood product" in proposed section 25608.11 describes a warning label that includes the statement: "For more information go to www.P65Warnings.ca.gov/product." For example, for "raw wood products," the warning would direct readers to www.P65Warnings.ca.gov/wood. The referenced website does not yet exist, however, and OEHHA to date has only proposed general descriptions of what that website will contain. It is impossible for AWC and other members of the public to comment on the reasonableness of the proposed safe harbor warnings without knowing what will be incorporated into the warning through the proposed reference to that OEHHA website. Similarly, AWC will not be able to judge whether the final Article 6 regulations are reasonable and consistent with the statutory language until it can see the content of the website to which the Article 6 safe harbor warnings will refer.

OEHHA should make the proposed content of the www.P65Warnings.ca.gov/product websites available for comment as soon as possible, and before the revised Article 6 regulations are promulgated. The Article 6 regulations also should state that regulated entities, as well as members of the public, will have an opportunity to review and comment on proposed content before it is incorporated into the website.

In fact, the entire concept of incorporating into Article 6 safe harbor warnings a reference to an OEHHA-maintained website is fraught with potential problems. In the first place, this approach effectively forces product manufacturers (if they wish to benefit from the safe harbor created by the regulations) to issue a warning whose content or "message" the manufacturer does not control. Even worse, it appears that OEHHA would be able unilaterally to change the content of the www.P65Warnings.ca.gov/product website, which would mean that a manufacturer would be providing a warning without knowing what that warning will convey once the product reaches the purchaser or potential purchaser. And since all products falling within one of the product categories listed in proposed section 25608 would have a safe harbor warning that refers to the same OEHHA website for that product category, and OEHHA would not even know what all those products are, at best the website could only provide very generic information, and at worst it could be inaccurate or misleading in many cases.

These concepts and problems are not addressed at all in the statute, nor are they explored adequately in the Initial Statement of Reasons for the proposed regulations. AWC suggests that OEHHA pursue its approach of providing additional information about chemical exposure to the public through an agency website, if at all, without requiring a direct reference to such a website in the safe harbor product warning regulations. At the very least, if OEHHA retains that language in the safe harbor warnings, it would be essential for the OEHHA website to reference and rely on the most accurate and up-to-date scientific information. Later in these comments AWC offers some input in that regard, concerning wood dust.

General Comments on Revisions to Safe Harbor Warnings

AWC appreciates OEHHA's statements that reinforce the fact that Proposition 65 only requires a warning when the product manufacturer knows that it will expose individuals to a listed chemical:

The statute clearly states that warnings are required for *knowing and intentional exposures* to listed chemicals. Warnings are not required where a product simply "contains" a listed chemical but may not actually have the potential to cause an exposure. Using the word "contains" in the warning is confusing for both businesses and the individuals receiving the warning. For example, under the existing regulation it is unclear to many businesses if a warning is required for a chemical that is contained in a product in such a way that it cannot foreseeably cause an exposure (e.g. where the chemical is bound in a matrix such as titanium dioxide in paper, or sealed inside the product like a battery that contains lead, but is inaccessible to the average user of the product). Initial Statement of Reasons, p. 26 (emphasis in original).

OEHHA's proposal to change the safe harbor warning language from a statement that the product "contains" a chemical to a statement that the product "can expose you to" a chemical is an insufficient way of addressing this issue.

One fundamental problem is that, despite the statement quoted above, in many instances OEHHA, the California Attorney General's Office, private litigants, and the courts have treated the fact that a product contains a chemical as essentially the same as saying that the product exposes individuals to that chemical (In fact, the proposed safe harbor warning for raw wood products in section 25608.11(a)(3) is a good example of this, as although most drilling in wood creates little or no airborne wood dust, the proposed warning reflects an implicit assumption that drilling causes an inhalation exposure to wood dust). Since product manufacturers are, as a practical matter, assumed to be causing meaningful exposure to a chemical merely because their product contains that chemical, and overcoming that presumption is difficult if not virtually impossible, product manufacturers often have had no reasonable alternative to providing a warning whenever they know that the product merely contains a listed chemical.

Changing "contains" to "can expose you to" in the safe harbor warnings will do little or nothing to change that reality. Moreover, the language OEHHA has proposed for safe harbor warnings seems likely to convey to many individuals an inaccurate impression that they definitely will be exposed to the listed chemical, and in significant amounts. The word "can" generally connotes "is capable of," rather than simply "has the potential in some cases to." At the very least, using

"may" or "might" instead of "can" would better convey the actual situation. Moreover, AWC suggests that, among other things, OEHHA consider regulatory language that will provide some of the helpful explanation of the warning requirement that OEHHA included in the statement quoted above and other related discussions in the Initial Statement of Reasons.

AWC also wishes to point out two lesser, technical issues with the proposed language for Article 6. First, because the definition of "label" in proposed section 25600.1(e) includes something printed on the product itself, as well as something printed on the product's immediate container or wrapper, proposed section 25603(a)(3) can and should just refer to a warning provided by a label, not by "a label on the product." The language in the proposed rule creates potential confusion about whether the safe harbor warning can be transmitted through something printed on packaging rather than on the product itself.

Second, AWC supports what it understands to be the intent of proposed section 25608(a), which is that, for a product or type of exposure addressed in section 25608 (such as "raw wood product"), a business that conforms the content and method of transmission of its warning to the specifications of section 25608 has met its obligation to provide a clear and reasonable warning under section 25249.6 of the Act, regardless of whether any other provision of Article 6 might otherwise apply to the warning. That intent could be clearer in the regulations, however.

Proposed Safe Harbor Warning for "Raw Wood Product"

As an initial matter, the proposed regulations do not define "raw wood product." Since the safe harbor of proposed sections 25608.10-25608.11 only extends to raw wood products, it is important that there be a clear understanding of what this category encompasses. AWC suggests that OEHHA include a definition of "raw wood product," in proposed section 25600.1, as "logs, sawn lumber, plywood and composite wood panels, engineered structural wood products, and similar wood products that are for the most part uncoated and have not been processed into other useful products and have the strong likelihood to be sawed, sanded, or drilled so as to generate wood dust."

Although as explained above, AWC does have concerns with the wording "can expose you to" that OEHHA has proposed for all warning labels, and it is arguable whether a supplier of any wood *product* has an obligation to provide a warning for wood *dust*, AWC, otherwise does not object to the warning language proposed in section 25608.11 as a safe harbor warning for raw wood products. AWC believes the industry is currently providing either the same or very similar language in warnings with certain wood products.

Scientific Perspectives on Cancer Risk Associated with Exposure to Wood Dust

As explained above, it is crucial that any regulation about safe harbor warnings for wood dust exposure, as well as any statements in the www.P65Warnings.ca.gov/wood website OEHHA is planning, reflect the most current and best available science on the listed substance.

Rarity of the tumor type associated in the literature with wood dust

Wood dust has been associated with adenocarcinoma of the ethmoid sinus, a rare tumor type.¹ In addition to exposures from wood dust, leather dust from boot and shoe manufacture is also a known factor, and other cases have unidentifiable causes.² To place this rare lesion within the context of occurrences in California, we have extracted data from the National Cancer Institute's

Surveillance, Epidemiology and End Results (SEER) Registry, which currently provides data through 2011. The database includes the San Francisco-Oakland SMSA Registry which covers five counties – Alameda, Contra Costa, Marin, San Francisco and San Mateo. Based on 2011 data, the population of these counties accounted for approximately 12 percent of the state's total population.

The SEER registry first included all of the above counties in 2000. For this specific disease, the average incidence rate over the period 2000-2011 was 0.009 per 100,000 based on a total of 5 cases. (For all U.S. SEER registries the incidence rate for the same period was 0.011 per 100,000). By way of comparison, the average all-cancer incidence rate for all five counties based on SEER was 449 per 100,000 for the same time period. Thus, for adenocarcinomas of the ethmoid sinus, the 2000-2011 average incidence rate of 0.009 equates to 0.002 percent of the all-cancer incidence rate. These data serve to highlight the rarity of the disease. These facts should be noted in the informational website, along with other relevant information including that which follows.

Update on Cohort of Wood Workers the United Kingdom

The association between ethmoidal adenocarcinomas and wood dust was first reported among furniture workers in High Wycombe, United Kingdom in the mid-1960s.³ Researchers in the U.K. have recently reported an update of that cohort study.⁴ The study found a major decline in the incidence of nasal adenocarcinomas in woodworkers. They undertook a prospective case series of all cases of nasal adenocarcinoma presented in woodworkers in Wycombe General Hospital between 1965 and 2012. The study represents a follow-on study to the seminal studies performed in the High Wycombe region of Great Britain during the 1960s that reported the association between woodworking and nasal cancer, in particular adenocarcinomas of the ethmoid sinuses.

Specifically, this study reported on the analysis of data from 105 cases of adenocarcinoma of the ethmoid sinuses among wood workers diagnosed between 1965 and 2012. From the data, a number of relationships were examined, including:

- The size of the population working in the furniture industry, and the number of new cases of nasal cancer diagnosed. The analysis was completed incorporating a conservative 25-year latency period. These latter cases were all exposed prior to 1970.
- The number of new cases diagnosed and year of diagnosis.
- Age at diagnosis and year of diagnosis.

Linear regression analysis applied to worker population size and number of new cases showed a statistically significant reduction in the number of new cases associated with a declining workforce. However, when the latency period of 25 years was entered into the analysis, only 56 percent of the variance in number of new cases is associated with the number of workers in the industry. Thus, the declining workforce exclusively did not explain the drop in the number of new cases. The authors' explanation for the further case decline is due to the marked improvement in working conditions, likely occurring between the 1960s and 1980s when recognition of the disease became prominent. The initiation of improvements, such as local exhaust ventilation, preceded regulatory standards adopted in Great Britain in 1988, which established a 5 milligram per cubic meter (mg/m³) inhalable dust exposure limit. Analysis of the

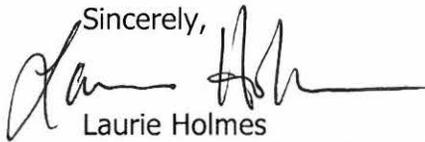
data on age at diagnosis and year of diagnosis shows a significant linear relationship, with the age at diagnosis increasingly higher over the years of the study period. The authors view this relationship as suggesting the "tail end" of an "epidemic" that resulted from the "intolerable" dust levels beginning in the 1930s following automation of the furniture-making process. They state further that based on their findings that "It is our contention that this disease is disappearing."

AWC believes this research provides a unique and useful perspective in describing the consequences of exposure levels and occurrence of disease. Given the long latency period of the disease and exposures prior to the 1970s, along with the observed considerable decline in disease occurrence, it is much more likely than not that the disease is related to the poor working conditions of the past that are no longer occurring due to industry work practices and current regulation.

Conclusion

AWC and its members appreciate the opportunity to comment on the proposed rulemaking. Please contact Laurie Holmes at 202-463-5174 or lholmes@awc.org if you have any questions or require further information about these comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Laurie Holmes', written over a horizontal line.

Laurie Holmes

Director, Chemicals & Product Stewardship

References

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- ¹ Adenocarcinoma of ethmoid sinus: an occupational disease. Acta Otorhinolaryngol Ital. 2004 Aug; 24(4):199-203. Bimbi G, Saraceno MS, Riccio S, Gatta G, Licitra L, Cantù G.
 - ² Intestinal type adenocarcinoma of the ethmoid sinus in wood and leather workers: a retrospective study of 153 cases. Cantu G, Solero CL, Mariani L, Lo Vullo S, Riccio S, Colombo S, Pompilio M, Perrone F, Formillo P, Quattrone P. Head Neck. 2011 Apr; 33(4):535-42.
 - ³ Nasal cancer in woodworkers in the furniture industry. Acheson ED, Cowdell RH, Hadfield E, Macbeth RG. Br Med J. 1968 Jun 8;2(5605):587-96.
 - ⁴ Decreasing incidence of nasal adenocarcinoma in Wycombe woodworkers. Rourke T, Grover S, Wager N, Capper J. Laryngoscope. 2014 May; 124(5):1078-82.