Response to Comments Pertaining to the Notice of Intent to List Pentachlorophenol and By-Products of Its Synthesis (Complex Mixture) as Causing Cancer under Proposition 65

Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
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The Office of Environmental Health Hazard Assessment (OEHHA) has determined that pentachlorophenol and by-products of its synthesis (complex mixture) meets the criteria for listing under Proposition 65 via the authoritative bodies mechanism. This determination is based on conclusions by the National Toxicology Program (NTP) that the complex mixture pentachlorophenol and by-products of its synthesis causes cancer, and on the scientific evidence relied on by NTP. NTP is designated as an authoritative body for purposes of listing chemicals as causing cancer pursuant to Title 27, Cal. Code of Regulations, section 25306. Pentachlorophenol and by-products of its synthesis (complex mixture) will therefore be added to the Proposition 65 list as a chemical known to cause cancer.

OEHHA made this determination after reviewing public comments on the proposed listing of pentachlorophenol and by-products of its synthesis (complex mixture). On October 30, 2015, OEHHA issued a Notice of Intent to List (NOIL) “pentachlorophenol and by-products of its synthesis (complex mixture)” under Proposition 65 as a chemical known to the state to cause cancer. The action was based on Proposition 65 statutory requirements and on the authoritative bodies provision of the Proposition 65 implementing regulations, Section 25306. This document responds to public comments received on the Notice of Intent to List pentachlorophenol and by-products of its synthesis (complex mixture) under Proposition 65.

Under Section 25306, a chemical has been “formally identified” as causing cancer by an authoritative body if: (1) the chemical has been included in a list of chemicals causing cancer.

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1 The Safe Drinking Water and Toxic Enforcement Act of 1986 (codified at Health and Safety Code section 25249.5 et seq.) hereinafter referred to as Proposition 65 or the Act.
3 All further references are to sections of Title 27 of the California Code of Regulations, unless otherwise indicated.
5 Health and Safety Code section 25249.8(b)
cancer published by the authoritative body; is the subject of a report which is published by the authoritative body and which concludes that the chemical causes cancer; or has been “otherwise identified” as causing cancer by the authoritative body in a document that indicates that the identification is a final action; and (2) if the list, report, or document meets specified criteria in Section 25306(d)(2).

OEHHA has reviewed the conclusions and statements in the 2014 NTP Report on Carcinogens, Thirteenth Edition. OEHHA has determined that these conclusions and statements satisfy the Section 25306(d)(1) requirements. Specifically, pentachlorophenol and by-products of its synthesis has been included in a list of chemicals causing cancer published by the authoritative body; and it is the subject of a report published by the authoritative body that concludes that the complex mixture pentachlorophenol and by-products of its synthesis causes cancer; and the NTP Report on Carcinogens, Thirteenth Edition indicates this identification is a final action. Further, OEHHA has determined that the report meets the Section 25306(d)(2) requirements. Thus the NTP Report on Carcinogens satisfies the formal identification criteria in the Proposition 65 regulations for pentachlorophenol and by-products of its synthesis (complex mixture). In the 2014 Report on Carcinogens, NTP concludes that “the complex mixture pentachlorophenol and by-products of its synthesis is reasonably anticipated to be a human carcinogen based on limited evidence of carcinogenicity from studies in humans and sufficient evidence of carcinogenicity from studies in experimental animals”.

OEHHA is relying on NTP’s discussion of data and conclusions in the report that the complex mixture pentachlorophenol and by-products of its synthesis causes cancer. Evidence described in the report includes studies showing that pentachlorophenol and by-products of its synthesis increased the incidences of malignant liver tumors in male mice, combined malignant and benign liver tumors and combined malignant and benign adrenal-gland tumors in male and female mice, malignant tumors of the blood vessels of the spleen and/or liver in female mice, malignant tumors in the tunica vaginalis of the testes in male rats, and malignant tumors of the nose to an unusual degree with respect to tumor type in male rats.

The evidence cited by NTP in support of these conclusions was reviewed by OEHHA with regard to the sufficiency of evidence criteria in Section 25306(e)(2). Based on NTP’s conclusions and the data relied on by NTP in reaching those conclusions,

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7 Ibid.
OEHHA has determined that pentachlorophenol and by-products of its synthesis (complex mixture) meets the sufficiency of evidence criteria in Section 25306.

The October 30, 2015 notice initiated a 30-day public comment period. Three sets of comments were submitted by the following organizations and private citizens:

- Chuck Idol
- Creative Pultrusions, Inc.
- Pentachlorophenol Task Force

OEHHA reviewed all of the comments and accompanying materials submitted in the context of the regulatory criteria for listing chemicals under the authoritative bodies mechanism in Section 25306.

Comments relevant to the NOIL from individuals and groups listed above are summarized, grouped, and numbered by topic, and responses follow below.

1. **In support of listing**

   **Comment:**
   Chuck Idol supports the listing. Mr. Idol also provides information on cancer and non-cancer toxicity reported for pentachlorophenol and related mixtures, in the form of brief summaries of published studies other toxicity information, and links to several web pages.

   **Response:**
   OEHHA acknowledges the additional toxicity and related information provided, and the commenter’s support for the listing.

2. **Alternative to pentachlorophenol-treated wooden utility poles**

   **Comment:**
   Chuck Idol notes that there are available alternatives, such as steel and fiber reinforced polymer to the use of pentachlorophenol-treated wood for use as utility poles.

   Creative Pultrusions, Inc. proposes their product line of fiberglass reinforced polymer poles as an alternative to pentachlorophenol-treated wooden utility poles. The commenter also notes that “pentachlorophenol and its by products should be prohibited for use in and near waterways and replaced with a synthetic, engineered pole that meets the ecology standards for non-cancer causing chemicals near drinking water”.
Response:
OEHHA acknowledges these comments regarding the availability of alternatives to pentachlorophenol-treated wooden utility poles. However, consideration and availability of alternatives are not part of the criteria for listing a chemical under Proposition 65.

OEHHA notes that the listing of a chemical under Proposition 65 does not ban or restrict the use of a product. A listing can trigger two separate provisions of law. First, under Health and Safety Code section 25249.5, a person is prohibited from releasing a significant amount of the listed chemical into sources of drinking water. This requirement becomes effective automatically 20 months after the chemical is listed. The second provision of law that is triggered by a listing is Health and Safety Code section 25249.6, which requires businesses that expose people to a significant amount of the chemical to first provide a clear and reasonable warning. This requirement becomes effective automatically 12 months after the listing.

3. Listing is duplicative

Comment:
The Pentachlorophenol Task Force states:

“…pentachlorophenol and by-products of its synthesis (complex mixture) is nothing more than the form of pentachlorophenol (technical grade) that is registered with the U.S. EPA as a wood preservative and is the form of pentachlorophenol to which persons in the State of California would potentially be exposed. There is no other article of commerce that contains pentachlorophenol.”

“…all of the components (microcontaminants) of “Pentachlorophenol and by-products of its synthesis (complex mixture)” that are associated with carcinogenicity, principally Polychlorinated dibenzo-p-dioxins, Polychlorinated dibenzofurans, and Hexachlorobenzene, are already listed as carcinogens under Proposition 65.”

“…a separate listing for Pentachlorophenol and by-products of its synthesis (complex mixture) would be duplicative of existing listings and would be unnecessary.”
Response:
OEHHA disagrees that the proposed listing of “pentachlorophenol and by-products of its synthesis (complex mixture)” is duplicative of existing listings under Proposition 65. The proposed listing is of a complex mixture of chemicals that co-occur with pentachlorophenol as a result of their formation during pentachlorophenol synthesis. Further, OEHHA notes that while some of the commonly found by-products of pentachlorophenol synthesis are listed individually under Proposition 65, others are not (e.g., five trichlorophenol isomers, three tetrachlorophenol isomers).

Under California law, chemicals are required to be listed via the authoritative bodies listing mechanism as known to cause cancer if they meet certain criteria specified in Section 25306. That regulation provides that a chemical is known to the state to cause cancer if a body considered to be authoritative has “formally identified” the chemical as causing cancer and if certain scientific criteria are met. As discussed on pages 2 and 3 above, OEHHA has determined that an authoritative body, NTP, has identified pentachlorophenol and by-products of its synthesis (complex mixture) as causing cancer in the 2014 NTP Report on Carcinogens, Thirteenth Edition\(^8\), and that the formal identification and scientific sufficiency criteria in Section 25306 have been met.

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