



State Water Resources Control Board

October 17, 2019

Karl Palmer, Acting Deputy Director Safer Products and Workplaces Program Department of Toxic Substances Control 1001 | Street Sacramento, CA 95814

SUBJECT: REQUEST FOR EXTERNAL PEER REVIEW FOR THE PROPOSED ADPOTION OF NAIL PRODUCTS CONTAINING TOLUENE AS A PRIORITY PRODUCT

Dear Mr. Palmer:

This letter responds to the attached July 29, 2019 request for external scientific peer review for the subject noted above. The review process is described below. All steps were conducted in confidence. Reviewers' identities were not disclosed.

To begin the process for selecting reviewers, I contacted the University of California, Berkeley (University) and requested recommendations for candidates considered qualified to perform the assignment. The University was provided with the July 29, 2019 request letter to me and attachments. No additional material was asked for. This service by the University includes interviews of each promising candidate and is supported through an Interagency Agreement cosigned by CalEPA and the University.

Each candidate who was both qualified and available for the review period was asked to complete a Conflict of Interest (COI) Disclosure form and send it to me for review, with Curriculum Vitae. The cover letter for the COI form describes the context for COI concerns that must be taken into consideration when completing the form. "As noted, staff will use this information to evaluate whether a reasonable member of the public would have a serious concern about [the candidate's] ability to provide a neutral and objective review of the work product."

E. JOAQUIN ESQUIVEL, CHAIR | EILEEN SOBECK, EXECUTIVE DIRECTOR



Later, I sent approved reviewers letters to initiate the review. These letters provided access instructions to a secure FTP site where all material to be reviewed was placed. Attachment 2 to the July 29, 2019 request memorandum was highlighted as the focus for the review. Each initiating letter identified specific conclusions which that reviewer committed to address. This commitment is detailed in the paragraph following "Attachment 2", appearing on page 2 of the letter. Thirty days were provided for the review. I also asked reviewers to direct enquiring third-parties to me after they have submitted their reviews.

With the same letter, I provided the attached October 2018 Supplement to the CalEPA Peer Review Guidelines, which, in part, serves two purposes: a) it provides guidance to ensure confidentiality through the course of the external review, and b) it notes reviewers are underno objection to discuss their comments with third-parties after reviews have been submitted. **We recommend they do not.** All outside parties are provided opportunities to address a proposed regulatory action through a well-defined rulemaking process.

Reviewers' names, affiliations, curriculum vitae, and reviews are being sent to you now with this letter. All attachments can be electronically accessed through the bookmark icon at the left of the screen.

Approved reviewers are as follows:

- Clifford P. Weisel, Ph.D. Professor
 Environmental and Occupational Health Sciences Institute School of Public Health – Rutgers University 170 Frelinghuysen Road
 Piscataway, N.J. 08854
- Lupita D. Montoya, Ph.D. Research Associate University of Colorado, Boulder 4001 Discovery Drive 607 UCB – S286A Boulder, CO 80303
- Scott E. Bowen, Ph.D.
 Professor and Chair
 Department of Psychology
 Wayne State University
 5057 Woodward Avenue, Suite 7906.1
 Detroit, MI 48202

If you have any questions, or require clarification from the reviewers, please contact medirectly.

Regards,

Gerald W. Bowes

Gerald W. Bowes, Ph.D. Manager, Cal/EPA Scientific Peer Review Program Office of Research, Planning and Performance State Water Resources Control Board

1001 "I" Street, 13th Floor Sacramento, California 95814

Telephone: (916) 341-5567 Email: gerald.bowes@waterboards.ca.gov

Attachments:

- (1) July 29, 2019 request by Karl Palmer for Scientific Peer Review
- (2) Letters to Reviewers Initiating the Review
 - (a) Clifford P. Weisel, Ph.D.
 - (b) Lupita D. Montoya, Ph.D.
 - (c) Scott E. Bowen, Ph.D.
- (3) October 22, 2018 Supplement to Cal/EPA Peer Review Guidelines
- (4) Curriculum Vitae
 - (a) Clifford P. Weisel, Ph.D.
 - (b) Lupita D. Montoya, Ph.D.
 - (c) Scott E. Bowen, Ph.D.
- (5) Reviews
 - (a) Clifford P. Weisel, Ph.D.
 - (b) Lupita D. Montoya, Ph.D.
 - (c) Scott E. Bowen, Ph.D.





Department of Toxic Substances Control



Gavin Newsom Governor

Jared Blumenfeld Secretary for Environmental Protection Meredith Williams, Ph.D. Acting Director 1001 "I" Street P.O. Box 806 Sacramento, California 95812-0806

TO: Gerald Bowes, Ph.D., Manager CalEPA Scientific Peer Review Program Office of Research, Planning and Performance State Water Resources Control Board

Karl Palmer

- FROM: Karl Palmer Acting Deputy Director Safer Products and Workplaces Program Department of Toxic Substances Control
- DATE: July 29, 2019
- SUBJECT: REQUEST FOR EXTERNAL PEER REVIEW FOR THE PROPOSED ADOPTION OF NAIL PRODUCTS CONTAINING TOLUENE AS A PRIORITY PRODUCT

The subject of this review is a proposed regulation to adopt the following product-chemical combination as a Priority Product:

Nail Products Containing Toluene

The California Safer Consumer Products (SCP) regulations¹ require the Department of Toxic Substances Control (DTSC) to identify product-chemical combinations that pose risks to people or the environment and to adopt them as Priority Products² in regulation. In accordance with

¹ California Code of Regulations, Title 22, sections 69503 – 69503.7

² "Priority Products" are consumer products that a) contain chemicals included in DTSC's Candidate Chemicals List; b) may expose people or the environment to these chemical(s) through normal use; and c) have been adopted in regulation. Candidate Chemicals exhibit hazard traits or environmental or toxicological endpoints and are included on authoritative lists established by government agencies or scientific organizations (<u>www.dtsc.ca.gov/SCP</u>).

Health and Safety Code section 57004, DTSC requests external scientific peer review of the basis for proposing nail products containing toluene as a Priority Product. As required by regulation, DTSC reviewed reliable scientific literature and concluded that this product-chemical combination meets the required regulatory criteria³ for listing as a Priority Product based on the following conclusions:

- 1. Toluene has hazard traits that can potentially cause significant adverse impacts on human health including neurotoxicity, developmental, and respiratory toxicity. Among other effects, scientific evidence suggests that toluene can be linked to adverse impacts on kidneys, eyes, skin, and immune system.
- 2. There is a potential for consumers and workers (i.e., nail technicians, salon workers) to be exposed to toluene during the use of nail products, and these exposures in nail technicians and salon workers are exacerbated by the working conditions (e.g., ventilation, long shifts, lack of personal protective equipment).
- 3. Certain sensitive subpopulations including nail industry workers, pregnant women (and their fetuses), infants, children, and adolescents may be especially susceptible to the adverse impacts of toluene.
- 4. Nail products containing toluene have the potential to cause or contribute to significant or widespread adverse impacts in consumers and workers due to the hazard trait and exposure considerations described in the chemical-product profile.

For this review, DTSC recommends that reviewers have expertise in the following areas, in order of importance:

- Human toxicology. This expertise is needed for Conclusions 1 and 3, as defined in the attachment.
- Human exposure assessment or industrial hygiene, particularly with a focus on indoor air exposure. This expertise is needed for Conclusion 2, as defined in the attachment.

We estimate that three reviewers will be adequate to cover all needed areas of expertise.

DTSC intends to initiate the formal rulemaking process late-2019 or early 2020. The documents are ready for review at any time, and the preferred period of review is 30 days. The following attachments are enclosed:

³ Prior to proposing a product-chemical combination for adoption as a Priority Product, DTSC must ensure that the product-chemical combination meets both of the following criteria: 1) there must be potential public and/or environmental exposure to the chemical(s) in the product; and 2) there must be potential for one or more exposures to contribute to or cause significant or widespread adverse impacts (22CCR section 69503.2(a)).

- Attachment 1: Plain English summary of the proposal to list Nail Products Containing Toluene as a Priority Product
- Attachment 2: Scientific Conclusions to Be Addressed by Peer Reviewers
- Attachment 3: List of Participants
 - Section A: DTSC Participants
 - Section B: External Participants
- Attachment 4: References

Please direct inquiries regarding this request to Nancy Ostrom, of my staff, at <u>nancy.ostrom@dtsc.ca.gov</u> or 916-445-3077.

Attachment 1:

Plain English Summary of the Proposal to Nail Products containing Toluene as a Priority Product

A. Brief Statement of Conclusions⁴

Toluene has been recognized as a neurotoxicant by the Agency for Toxic Substances Disease Registry (ATSDR), the U.S. Environmental Protection Agency (EPA), the California Office of Environmental Health Hazard Assessment (OEHHA) Reference Exposure Level (REL) database, and the U.S. Centers for Disease Control and Prevention (CDC) Fourth National Report on Human Exposure to Environmental Chemicals. Human and animal exposure studies demonstrate that toluene may cause nervous system damage. In occupational settings, effects linked to toluene exposure include dizziness, fatigue, headache, and decreased manual dexterity. Further, toluene is identified as a developmental toxicant by OEHHA and a toxic air contaminant by the California Air Resources Board. Additional hazard traits associated with toluene include respiratory, kidney, and dermal toxicity.

Toluene is used as a solvent in nail coatings and nail polish thinners. Toluene is a liquid at room temperature and readily volatilizes into air. Use of nail products in salons and at home has the potential to expose nail technicians, other salon workers, patrons, and nail product consumers to toluene. The primary exposure route from nail products is vapor inhalation. Toluene has been detected in air in nail salons at levels above California regulatory standards, and nail technicians have an especially high potential for exposure. Nail industry workers' exposure to chemicals is an environmental justice issue. In California, most nail technicians are Vietnamese immigrants of low socioeconomic status and are often women of childbearing age. Pregnant women (and their fetuses), infants, children, and adolescents are also especially vulnerable to toluene exposure from nail products.

DTSC has concluded that human exposure to toluene-containing nail products has the potential to cause significant and widespread adverse impacts, especially to certain sensitive subpopulations.

B. Overview of the Safer Consumer Products Regulatory Program

The SCP program's primary goal is to ensure safer products and healthier lives by reducing and eliminating use of toxic chemicals in consumer products sold in California.

⁴ From "Product-Chemical Profile for Nail Products containing Toluene."

The SCP regulations, implemented on October 1, 2013, specify the process for identifying consumer products that contain hazardous chemicals, evaluating safer alternatives to those chemicals, and eliminating or reducing potential exposures to and adverse impacts from these products. The regulations intentionally use a narrative standard for identifying and prioritizing product-chemical combinations, rather than a traditional risk-assessment-driven decision-making standard. This approach provides DTSC with a flexible process that allows the SCP program to make decisions based on a reasonable amount of reliable information and the potential for exposure and adverse impacts. The SCP regulations also use the hazard traits, toxicological and environmental endpoints, and other relevant data contained in Chapter 54 of the California Code of Regulations, Title 22.

To adopt a Priority Product listing, DTSC must follow the procedure described in the SCP regulations and adopt the listings through a rulemaking procedure. These regulations use the following prioritization factors⁵ for listing Priority Products:

- There must be potential⁶ public and/or aquatic, avian, or terrestrial animal or plant organism exposure⁷ to the Candidate Chemical(s) in the product; and
- There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.⁸

Once DTSC adopts a Priority Product listing, DTSC requires product manufacturers to submit a Priority Product notification⁹ and conduct one of several types of Alternatives Analyses to determine if safer alternatives exist.¹⁰ Alternatively, product manufacturers may elect to: remove or replace the chemical of concern in the product with a safer alternative, or remove the product from the California marketplace. If the product manufacturers do not comply, DTSC is authorized to require importers, assemblers, or retailers to stop selling the product in California.

⁵ CCR §69503.2 *et seq*.

⁶ "Potential" is defined as reasonably foreseeable, based on reliable information (CCR §69503.1(a)(51)).

⁷ The potential for exposure is evaluated by considering one or more of the following factors: market presence of the product, the occurrence or potential occurrence of exposures to the Candidate Chemical in the product, the household and workplace presence of the product, potential exposure to the Candidate Chemical in the product during the product's lifecycle (CCR §69503.3(b)).

⁸ 22 CCR §69503.2 and §69503.3. The potential to contribute to or cause adverse impacts is evaluated by considering reasonably available information about one or more of the following factors: hazard traits, endpoints, aggregate effects, cumulative effects, physicochemical properties, environmental fate, affected populations or organisms, potential for the Candidate Chemical(s) to degrade, form reaction products, or metabolize into another chemical that exhibits hazard traits or endpoints. DTSC shall give special consideration to the potential for adverse impacts to sensitive subpopulations, environmentally sensitive habitat, endangered and threatened species, and impaired environments. DTSC may also evaluate and consider adverse impacts associated with structurally or mechanistically similar chemicals with known toxicity profiles.

⁹ CCR §69503.7.

¹⁰ CCR §69505.1 et seq.

C. Overview of the Proposal to List Nail Products containing Toluene as a Priority Product

The proposed regulation describes nail products including nail coatings and nail polish thinners. The term "nail coatings" refers to any clear or colored coating product marketed or sold for application to the fingernails or toenails. The nail coatings category encompasses subproducts including nail polish, lacquers, enamels, base coats, undercoats, top coats, gel nails, gel nail polish, and paint for airbrush nail art. The term "nail polish thinner" means any liquid product that is marketed or sold for the use of reducing viscosity of nail coatings. It may be marketed for the use of increasing the fluidity or restoring the consistency of nail coatings.

As required by regulation, DTSC considered factors including the hazard traits and toxicological endpoints for toluene, and the potential adverse impacts on sensitive subpopulations including nail industry workers, pregnant women (and their fetuses), infants, children, and adolescents.

After reviewing available reliable information, and obtaining stakeholder input via a public workshop and comment period, DTSC has determined that there is potential for significant and widespread exposure to toluene during the use of nail products containing toluene, and human exposures may lead to significant and widespread adverse impacts, especially to sensitive subpopulations including nail industry workers, pregnant women (and their fetuses), infants, children, and adolescents.

Available reliable information suggests that toluene may display one or more hazard traits including:

- Neurotoxicity,
- Developmental toxicity,
- Neurodevelopmental toxicity,
- Respiratory toxicity,
- Nephrotoxicity,
- Dermatotoxicity
- Immunotoxicity,
- Ocular toxicity, and
- Ototoxicity.

In determining that exposure to toluene during the use of nail products, such as nail coatings and nail thinners, has the potential to adversely affect workers, consumers, and sensitive subpopulations, DTSC has met the regulatory requirements for adoption of this 'productchemical' combination as a Priority Product in regulation. Once the proposed regulation is adopted, DTSC will have the authority to require manufacturers to determine if there are safer alternatives to toluene for use in nail products.

Attachment 2:

Scientific Conclusions to Be Addressed by Peer Reviewers Regarding DTSC's Proposal to List Nail Products containing Toluene as a Priority Product

The statutory mandate for external scientific peer review (Health and Safety Code section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed regulation is based on sound scientific knowledge, methods, and practices.

DTSC requests that you make this determination for each of the following conclusion statements that constitute the scientific portion of the proposed regulation. An explanatory statement is provided for each conclusion to focus this review.

The subject of this review is a proposed regulation to list *Nail Products Containing Toluene* as a Priority Product under the Safer Consumer Product regulatory framework. This framework requires DTSC to ensure that all product-chemical combinations proposed as Priority Products meet the following criteria:

- There is potential for exposure to the Candidate Chemical(s) in the product, and
- Exposures may contribute to or cause significant or widespread adverse impacts to people or the environment.

Following a review of available scientific literature, DTSC concluded that the proposal to list *nail products containing toluene* as a Priority Product meets the required regulatory criteria and requests that this review focus on the following conclusions:

- Toluene has hazard traits that can potentially cause significant adverse impacts on human health including neurotoxicity, developmental, and respiratory toxicity. Among other effects, scientific evidence suggests that toluene can be linked to adverse impacts on kidneys, eyes, skin, and immune system.
- There is a potential for consumers and workers (i.e., nail technicians, salon workers) to be exposed to toluene during the use of nail products, and these exposures in nail technicians and salon workers are exacerbated by the working conditions (e.g., ventilation, long shifts, lack of personal protective equipment).
- 3. Certain sensitive subpopulations including nail industry workers, pregnant women (and their fetuses), infants, children, and adolescents may be especially susceptible to the adverse impacts of toluene.
- 4. Nail products containing toluene have the potential to cause or contribute to significant or widespread adverse impacts in consumers and workers due to the hazard trait and exposure considerations described in the chemical-product profile.

The results of DTSC's literature review are presented in the report, "Product-Chemical Profile for Nail Products Containing Toluene" completed in March of 2019 and updated in May of 2019 in response to public comments. This report, the references listed in this report, and the framework regulations for the SCP program will be provided to the reviewers for upload from an FTP site.

Conclusion 1

Toluene has hazard traits that can potentially cause significant adverse impacts on human health.

Toluene is a neurotoxicant. Published human toluene exposure studies demonstrate nervous system damage caused by toluene abuse or occupational exposure. Particularly, occupational exposure studies performed at high and low concentrations haven shown adverse outcomes to workers' health. Animal studies also demonstrate that toluene inhalation exposure affects behavior, memory, and motor coordination.

Toluene is also a developmental toxicant. In humans, expectant mothers who inhale toluene as a recreational drug have given birth to infants with mental deficiencies and abnormal head size. Animal studies have demonstrated impairment in fetal growth, decreased birth weight, and fetal mortality.

Research studies suggest that toluene exhibits other hazard traits including neurodevelopmental toxicity, respiratory toxicity, and kidney toxicity. Toluene has also been linked to immunotoxicity and vision and hearing impairment.

The sections of the product-chemical profile (noted above) that pertain to Conclusion #1 include:

- Summary of the Rationale for Product-Chemical Selection
- Section 1.1 Scope of Candidate Chemical
- Section 2.3 Hazard Traits and/or Environmental or Toxicological Endpoints
- Section 2.5 Populations That May Be Harmed by the Candidate Chemical

Conclusion 2

There is a potential for exposure to toluene during the use of nail products, and these exposures may contribute to or cause significant or widespread adverse impacts to humans. Toluene is used in nail products, including nail coatings and nail polish thinner, and has been detected at concentrations up to 17.7 percent. Use of nail products in salons and at home has the potential to expose nail technicians, other salon workers, patrons, and nail product consumers to toluene. The primary exposure route from nail products is vapor inhalation. Toluene has been detected in air in nail salons at levels above California regulatory standards, and nail technicians (also known as manicurists) have an especially high potential for exposure.

Nail products and professional manicure/pedicure services are popular in the United States. In California alone, there are over 9,000 nail salons and more than 130,000 licensed manicurists. Nail products, including ones containing toluene, are also widely used at home. Retail sales of nail products exceed \$1 billion per year in the U.S. In 2015-16, nail polish sales represented \$741 million of this amount.

Based on all the available information, DTSC has concluded that there is a significant potential for human exposure to toluene during the use of nail products, and these exposures have the potential to cause widespread or significant adverse human health impacts, especially for nail industry workers, pregnant women (and their fetuses), infants, children, and adolescents.

The sections of the product-chemical profile (noted above) that pertain to Conclusion #2 include:

- Summary of the Rationale for Product-Chemical Selection Section 2.5 Populations That May Be Harmed by the Candidate Chemical
- Section 3 Factors Related to Potential Exposure to the Candidate Chemical in the Priority Product

Conclusion 3

Nail industry workers, pregnant women (and their fetuses), infants, children, and adolescents may be especially susceptible to the adverse impacts of toluene.

Nail industry workers may be impacted by exposure to toluene due to its frequent use in the workplace and some nail technicians work while pregnant; thus, their fetuses are also at risk of toluene exposure. Nail salon workers may have daily exposure to toluene. They often have longer workdays and workweeks compared to employees in other sectors. California's nail industry work force is composed of approximately 130,000 licensed nail technicians. Reportedly, 97 percent of U.S. nail technicians are female, and many are of childbearing age. Pregnant women and their fetuses may be at greater risk of adverse impacts from toluene exposure.

Studies indicate that nail salon workers may suffer from a higher incidence of certain health problems than the general population. In addition to a higher incidence of specific health problems, a recent study suggests that nail care technicians experience a faster deterioration of their overall health compared to controls as a result of chronic exposure to low levels of VOCs.

Infants and children are especially vulnerable to toluene exposure from nail products if they accompany their parents to work at a nail salon or are nail salon customers. They are a sensitive subpopulation because of their increased ingestion and inhalation rates per unit of body weight, rapid development, immature physiological ability to detoxify environmental contaminants, and behavioral characteristics that predispose them to increased exposures to environmental contaminants. Even if they are not directly exposed to toluene-containing nail

products, nursing infants and children may be exposed to toluene as indicated by toluene detected in human milk.

The sections of the product-chemical profile (noted above) that pertain to Conclusion #3 include:

- Summary of the Rationale for Product-Chemical Selection Section 2.3 Hazard Traits and Environmental or Toxicological Endpoints
- Section 2.5 Populations That May Be Harmed by the Candidate Chemical

Conclusion 4

Nail products containing toluene have the potential to cause or contribute to significant or widespread adverse impacts in consumers and workers due to the hazard trait and exposure considerations described in the chemical-product profile.

Exposure to toluene through normal use of nail products may cause significant adverse impacts to Californians, including workers, pregnant women and their fetuses, infants, children and adolescents. This determination is based on toluene's volatility and the characteristics of the enclosed environment in nail salons and homes, as based on measured toluene levels in air samples, in addition to the hazard traits associated with toluene.

The sections of the product-chemical profile (noted above) that pertain to Conclusion #4 include:

- Section 2.3 Hazard Traits and/or Environmental or Toxicological Endpoints
- Section 3 Factors Related to Potential Exposure to the Candidate Chemical in the Priority Product
- Section 6 Discussion of Potential for Significant or Widespread Adverse Impacts

References included in these sections are listed in Attachment 4 and will be provided to the reviewers as part of this request.

The Big Picture

Reviewers are not limited to addressing only the specific issues presented above and are asked to contemplate the following questions.

- (a) In reading the product-chemical profile report and proposed implementation language, are there any additional scientific issues that are part of the scientific basis of the proposed regulation not described above? If so, please comment.
- (b) Taken as a whole, is the scientific portion of the proposed regulation based upon sound scientific knowledge, methods, and practices?

Reviewers should also note that some proposed regulatory actions might rely significantly on professional judgment where available scientific data are not as extensive as desired to support the statutory requirement for absolute scientific rigor. In these situations, the proposed course of action is favored over no action.

Reviewers should recognize that DTSC has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed regulation. Because of this obligation, reviewers are encouraged to focus feedback on the scientific issues that are relevant to the central regulatory elements being proposed.

Attachment 3: List of Participants

Section A. California Department of Toxic Substances Control Personnel
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Name	Title	Program	Location
Christine	Senior	Safer Products and Workplaces	Chatsworth, CA
Papagni	Environmental Scientist	Program	
Eric Sciullo	Staff Toxicologist	Human and Ecological Risk Office	Sacramento, CA
Diana Phelps	Hazardous Substances Engineer	Safer Products and Workplaces Program	Sacramento, CA
Andrew King*	Research Program Specialist II	Safer Products and Workplaces Program	Sacramento, CA
Kyle Harris	Research Program Specialist II	Safer Products and Workplaces Program	Sacramento, CA
Thomas Booze	Senior Toxicologist	Human and Ecological Risk Office	Sacramento, CA
Coby Graham	Senior Industrial Hygienist	Safer Products and Workplaces Program	Berkeley, CA
Vivek Mithrani	Staff Toxicologist	Human and Ecological Risk Office	Berkeley, CA
Dennis Guo	Research Scientist III	Safer Products and Workplaces Program	Sacramento, CA
Anne Cooper Doherty	Senior Environmental Scientist	Safer Products and Workplaces Program	Sacramento, CA
Daphne Molin	Senior Environmental Scientist	Safer Products and Workplaces Program	Sacramento, CA
Efrem Neuwirth	Staff Toxicologist	Human and Ecological Risk Office	Cypress, CA
Patrick Kerzic*	Staff Toxicologist	Human and Ecological Risk Office	Chatsworth, CA
Christopher Leonetti	Environmental Scientist	Safer Products and Workplaces Program	Sacramento, CA
Dicle Yardimci	Senior Hazardous	Safer Products and Workplaces	Sacramento, CA

Name	Title	Program	Location
	Substances Engineer	Program	
Lynn Goldman	Attorney	Office of Legal Affairs	Sacramento, CA
Nancy Ostrom	Senior	Safer Products and Workplaces	Sacramento, CA
	Environmental	Program	
	Scientist		
André Algazi	Senior	Safer Products and Workplaces	Sacramento, CA
	Environmental	Program	
	Scientist		
Karl Palmer	Environmental	Safer Products and Workplaces	Sacramento, CA
	Program Manager I	Program	
Meredith	Acting Director	DTSC	Sacramento, CA
Williams			

* No longer works for DTSC

Name	Title	Department / Program	Location
Sara Hoover	Research Scientist III	Scientific Affairs Division, Office of Environmental Health Hazard Assessment	Sacramento, CA
Gail Krowech	Staff Toxicologist	Scientific Affairs Division, Office of Environmental Health Hazard Assessment	Sacramento, CA

Section B. External Participants

Attachment 4:

Reference Titles

Regulatory:

California Code of Regulations, Title 22, sections 69401 – 69407.2 California Code of Regulations, Title 22, sections 69503 – 69503.7 Product-Chemical Profile for Nail Products Containing Toluene California Code of Regulations, Title 22, proposed sections 69511(b)(6) and 69511.6

Literature Relied Upon:

- 40 C.F.R. §63 (2006) Code of Federal Regulations. Title 40: Protection of Environment. Chapter I: Environmental Protection Agency. Part 63- National Emission Standards for Hazardous Air Pollutants for Source Categories. Appendix Table 2 to Subpart F of Part 63, Organic Hazardous Air Pollutants. In: Regulations CoF (ed). vol Title 40, Ch. I, §63,
- 40 C.F.R. § 716.120 (1994) Code of Federal Regulations. Title 40: Protection of Environment. Chapter I: Environmental Protection Agency. Part 716.120 - Substances and listed mixtures to which this subpart applies. In: Regulations CoF (ed). vol Title 40, Ch. I, §716.120,
- 42 U.S.C. § 7412 (1999) 42 U.S. Code § 7412 Hazardous air pollutants. In: Code US (ed) 42 US Code Title 42: The Public Health and Welfare Chapter 85: Air Pollution Prevention and Control § 7412 - Hazardous air pollutants. vol Title 42, Ch. 85, Sub Chapter I, Part A, § 7412,
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State Water Resources Control Board

September 3, 2019

Clifford P. Weisel, Ph.D. Professor Environmental and Occupational Health Sciences Institute School of Public Health – Rutgers University 170 Frelinghuysen Road Piscataway, N.J. 08854

SUBJECT: INITIATION OF EXTERNAL PEER REVIEW OF THE DEPARTMENT OF TOXIC SUBSTANCES CONTROL FOR THE PROPOSED ADOPTION OF NAIL PRODUCTS CONTAINING TOLUENE AS A PRIORITY PRODUCT

Dear Professor Weisel,

The purpose of this letter is to initiate the external review.

The Department of Toxic Substances Control (DTSC) will receive reviewers' comments and curriculum vitae from me after the review has concluded, and not be a party to the process.

Documents for review are being provided through a secure FTP site. Sections I and II below give instructions for accessing the FTP site and list the documents on the site.

You can access this site through the one month period of review. The URL, username and password are as follows:

I. <u>https://ftp.waterboards.ca.gov/WebInterface/login.html</u>

Username: gbowes-ftp13 Password: 8kQFvn

- II. List of Documents at FTP site:
 - A. July 29, 2019, Memorandum signed by Karl Palmer, "Request for an External Peer Review for the Proposed Adoption of Nail Products Containing Toluene as a Priority Product."
 - **Attachment 1:** Plain English Summary of the Proposal to Nail Products Containing Toluene as a Priority Product.

E. JOAQUIN ESQUIVEL, CHAIR | EILEEN SOBECK, EXECUTIVE DIRECTOR

^{1001 |} Street, Sacramento, CA 95814 | Mailing Address: P.O. Box 100, Sacramento, CA 95812-0100 | www.waterboards.ca.gov



Attachment 2: Description of Scientific Assumptions, Findings, and Conclusions for Peer Review.

These are the focus for the review. Earlier, you indicated you would be able to address Conclusion 1 with confidence. Please do so, and preface your comments with that perspective, and address other conclusions with any qualification you wish to make. DTSC also would like reviewers to address the two subjects in the Big Picture section.

Attachment 3: List of participants, Section A: DTSC Participants, and Section B: External Participants.

Attachment 4: Reference Titles.

- B. Regulatory References: Product-Chemical Profile for Toluene in Nail Products.
 - California Code of Regulations, Title 22, sections 69401-69407.2.
 - California Code of Regulations, Title 22, sections 69501-69511.
 - California Code of Regulations, Title 22, proposed sections 69511(b) (7)-69511.7.
- C. Copies of Literature Relied Upon.
- D. October 18, 2018 Supplement to the CalEPA Peer Review Guidelines.

Please send your reviews to me on October 1, 2019 to ensure I receive all on the same day.

Questions about the review should be for clarification, in writing – email is fine, and addressed to me. My responses will be in writing also. All this information will be posted at the DTSC program web site for this proposal. Your acceptance of this review assignment is most appreciated.

Sincerely,

Gerald M. Borges

Gerald W. Bowes, Ph.D. Manager, Cal/EPA Scientific Peer Review Program Office of Research, Planning and Performance State Water Resources Control Board 1001 "I" Street, MS-16B Sacramento, California 95814

Telephone: (916) 341-5567 Email: <u>Gerald.Bowes@waterboards.ca.gov</u>





State Water Resources Control Board

September 3, 2019

Lupita D. Montoya, Ph.D. Research Associate University of Colorado, Boulder 4001 Discovery Drive 607 UCB – S286A Boulder, CO 80303

SUBJECT: INITIATION OF EXTERNAL PEER REVIEW OF THE DEPARTMENT OF TOXIC SUBSTANCES CONTROL FOR THE PROPOSED ADOPTION OF NAIL PRODUCTS CONTAINING TOLUENE AS A PRIORITY PRODUCT

Dear Dr. Montoya,

The purpose of this letter is to initiate the external review.

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Telephone: (916) 341-5567 Email: <u>Gerald.Bowes@waterboards.ca.gov</u>





State Water Resources Control Board

September 3, 2019

Scott E. Bowen, Ph.D. Professor and Chair Department of Psychology Wayne State University 5057 Woodward Avenue, Suite 7906.1 Detroit, MI 48202

SUBJECT: INITIATION OF EXTERNAL PEER REVIEW OF THE DEPARTMENT OF TOXIC SUBSTANCES CONTROL FOR THE PROPOSED ADOPTION OF NAIL PRODUCTS CONTAINING TOLUENE AS A PRIORITY PRODUCT

Dear Professor Bowen,

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Supplement to Cal/EPA External Scientific Peer Review Guidelines – "Exhibit F" in Cal/EPA Interagency Agreement with University of California Gerald W. Bowes, Ph.D.

1. **REVISIONS**. If changes are made in the final, signed request for review, and before the review has begun, a revised request must be discussed with, and submitted to the review manager. Normally, this is the CalEPA program manager for scientific peer review. The accepted revision must clearly describe changes, and at the time of review initiation, be sent to the reviewers by the program manager as the basis for the review. The original final request had been sent earlier to candidate reviewers and discussed with them during an interview. Candidates that were eventually approved as reviewers, must clearly understand parts of the request have been changed, and where.

A revised cover letter must a) indicate in red text at the top right corner, "**Revised**" and date of revision; and b) be re-signed by the requesting party.

The cover letter also must describe in red text the nature of the changes and where they occur, e.g. in Attachment 2. "**Revised**" and date of revision must be typed in red text at the top right corner on each page where a change has been made. Revised text also must be highlighted in red, and presented in strikeout/underline format.

- DOCUMENTS REQUIRING REVIEW. All scientific underpinnings of a proposed sciencebased rule must be submitted for external peer review. The underpinnings include all publications, conference proceedings, reports, model descriptions, and raw data upon which the proposal is based. Data from proprietary models cannot be used to support a proposal.
- 3. DOCUMENTS NOT REQUIRING PEER REVIEW. The Cal/EPA External Peer Review Guidelines note that there are circumstances where external peer review of supporting scientific documents is not required. An example would be "A particular work product that has been peer reviewed with a known record by a recognized expert or expert body." This allowance should be treated with caution. The context of the work product must be taken into account, and considered with respect to relevance to the proposal to be reviewed. The reviewers' independence and objectivity for the prior review must be considered. A safe approach would be to provide such a document to the reviewers, and let them decide if their review is needed, or at least for parts of the work product.
- 4. REVIEW OF IMPLEMENTATION STRATEGY. Publications which have a solid peer review record, such as a US EPA Criteria document, do not always include an implementation strategy. The Cal/EPA Guidelines require that the implementation of the scientific components of a proposal, or other initiative, must be submitted for external review.

- 5. **CONFIDENTIALITY OF REVIEWER IDENTITIES, AND REVIEWS**. External reviewers must not know the identity of other reviewers. Their identities can only be known to the CalEPA program manager for peer review (who manages the reviews), or other person delegated to managing the review. After the reviews have been completed and submitted by the program manager to the organization which requested the review, the timing of release of the reviews and identities of reviewers and their curriculum vitae, is a decision to be made by the organization, including participating legal staff.
- 6. **REQUESTS FROM REVIEWERS FOR ADDITIONAL SPECIFIC SUPPORTING DOCUMENTS, OR CLARIFICATION.** This should be provided to the requesting reviewer, and to all other reviewers to ensure all reviewers have the same information.
- 7. **USE OF PANELS**. Formation of reviewer panels is not appropriate. Panels can take on the appearance of scientific advisory committees and the external reviewers identified through the Cal/EPA process are not to be used as scientific advisors.
- 8. USE OF EXTERNAL EXPERTS TO ASSIST IN PREPARATION OF RESPONSES TO EXTERNAL REVIEWERS. California Health and Safety Code Section 57004 directs external reviewers to critically analyze CalEPA staff-developed assumptions, findings, and conclusions as the basis for proposed science-based rules. These are derived from staff's review and interpretation of relevant scientific literature. They are described in the review request, Attachment 2.

Normally, staff prepares responses to reviewers' comments, which are reviewed by the respective executive offices. On rare occasions, staff may solicit outside expert assistance in preparing these responses. Staff must be careful that rules of confidentiality are followed by assisting experts to protect reviewers' identities and nature of the reviews. Each review sent to such experts must be marked, "Highly Confidential – Not to be Shared". Communications must be directly between the staff person designated as the contact for the assisting experts, and the experts.

Prior to this engagement, the CalEPA organization seeking outside assistance must ensure through a conflict of interest vetting process that the enlisted experts meet certain criteria. First, the experts must have no financial interest in the outcome of the review. Second, they have no working relationships with any private or public sector entity that would benefit by, or be restricted in some way by, the proposed regulation.

If the outside assistance takes the form of experts brought together as a panel (not recommended) with a designated chair, assuring confidentiality becomes more of a challenge. Further, a panel report implies the expert reviews represent a consensus of panel members on the stated conclusions. This would be misleading. The panel expertise is identified as a critical mass which collectively could cover the range of conclusions described as the basis for the proposed rule. It would mirror the critical mass expertise originally identified and approved as reviewers of the proposal itself. The reviewers agree to address one or a few of the conclusions, based on expertise. Similarly, staff is best served by receiving independent and objective comments from individual advising experts on the reviews, based on expertise. The path taken to solicit such assisting experts, and the path back for this assistance, must be described and approved before such steps are taken. This must include a description of measures designed to protect reviewers' identities and the substance of their reviews.

Guidance to Reviewers:

1. **Discussion of review.**

Reviewers are not allowed to discuss the proposal with individuals who participated in development of the proposal. These individuals are listed in Attachment 3 of the review request.

Discussions between staff and reviewers are not permitted.

Reviewers may request clarification of certain aspects of the review process or the documents sent to them. The requests and responses must be in writing These communications will become part of the administrative record.

The organization requesting independent review should be careful that organizationreviewer communications do not become collaboration, or are perceived by others to have become so. The reviewers are not technical advisors. As such, they would be considered participants in the development of the proposal, and would not be considered by the University of California as external reviewers for future revisions of this or related proposals. The statute requiring external review of science-based rules proposed by Cal/EPA organizations prohibits participants serving as peer reviewers.

2. Disclosure of reviewer Identity and release of review comments.

Confidentiality begins at the point a potential candidate is contacted by the University of California. Candidates who agree to complete the conflict of interest disclosure form should keep this matter confidential, and should not inform others about their possible role as reviewer.

Reviewer identities must be kept confidential until review comments are received by the organization that requested the review. After the comments are received, reviewer identity and comments must be made available to anyone requesting them, within a reasonable time period specified by legal staff.

Reviewers are under no obligation to disclose their identity to anyone enquiring. It is recommended reviewers keep their role confidential until after their reviews have been made public by requesting CalEPA organization.

3. Requests to reviewers by third parties to discuss comments.

After they have submitted their reviews, reviewers may be approached by third parties representing special interests, the press, or by colleagues. Reviewers are under no obligation to discuss their comments with them, <u>and we recommend that they do not</u>.

All outside parties are provided an opportunity to address a proposed regulatory action during the public comment period and at the Cal/EPA organization meeting where the proposal is considered for adoption. <u>Discussions outside these provided</u> <u>avenues for comment could seriously impede the orderly process for vetting the proposal under consideration</u>.

4. **Reviewer contact information.**

The reviewer's name, professional affiliation, and date should accompany each review. Home address and other personal contact information are considered confidential and should not be part of the comment submittal.