NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

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By Federal Express, Facsimile, and Electronic Mail

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Re: **Petition for Listing of 18 Chemicals for Reproductive Toxicity Under the Safe Drinking Water and Toxic Enforcement Act of 1986**

Dear Ms. Cummings:

On August 22, you wrote to request additional information on the Natural Resources Defense Council's (NRDC's) July 6, 2006 petition to add eighteen chemicals to the list of chemicals "known to the state to cause . . . reproductive toxicity" under the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Act"). Cal. Health & Safety Code § 25249.8(a). We appreciate this opportunity to provide further information in support of NRDC's petition.

I. Hexafluoroacetone, Nitrous Oxide and Vinyl Cyclohexene Dioxide Must Be Listed by Law Because They Are Identified As Reproductive Toxins In the Hazard Communications Standard

Three of the chemicals for which NRDC has petitioned for listing – hexafluoroacetone, nitrous oxide and vinyl cyclohexene – should already have been listed as reproductive toxins by operation of law. These chemicals are identified as reproductive toxins through the United States Department of Labor's Hazard Communications Standard. The Governor has no discretion not to list these chemicals.

Section 25249.8(a) of the Act requires the Governor to publish and maintain, as of March 1, 1987, "a list of those chemicals known to the state to cause . . . reproductive toxicity." Cal. Health & Safety Code § 25249.8(a). That list "shall include *at a minimum*" "those substances identified additionally by reference in

Labor Code Section 6382(d)." *Id*. (emphasis added). Labor Code Section 6382(d) provides in relevant part that "any substance within the scope of the federal Hazard Communication Standard (29 C.F.R. Sec. 1910.1200) is a hazardous substance subject to this chapter." Cal Labor Code § 6382(d). As such, all "known carcinogens and reproductive toxins listed" "under [the Hazard Communication Standard]" should also be listed under Section 25249.8(a). *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425, 438 (Cal. Ct. App. 1989).

The Hazard Communication Standard, or HCS, designates two sources, one of which is "the latest edition of the American Conference of Government Industrial Hygienists (ACGIH's) Threshold Limit Values (TLVs)," "as establishing that the chemicals listed in them are hazardous." 29 C.F.R. § 1910.1200(d)(3). As such, the list of chemicals "known to the state . . . to cause reproductive toxicity" must incorporate all chemicals identified for reproductive toxicity in the most current, or 2006, ACGIH TLV publication. These chemicals are "within the scope of the federal Hazard Communication Standard," Cal. Labor Code § 6382(d), and "known . . . reproductive toxins" under that standard. *AFL-CIO*, 212 Cal. App. 3d at 438.

ACGIH's 2006 TLV publication indicates that hexafluoroacetone, nitrous oxide, and vinyl cyclohexene dioxide were assigned TLVs on basis of ACGIH's findings of male and female reproductive effects including testicular, embryonic and fetal damage. *See* App. A, "TLV Basis" entries. ACGIH's official documentation for these TLVs cites numerous animal (and, for nitrous oxide, human) studies identifying these chemicals are reproductive toxins. *See* App. B.

Because Section 25249.8(a) expressly incorporates the 2006 TLVs, and ACGIH has "already determined" in those TLVs that hexafluoroacetone, nitrous oxide and vinyl cyclohexene dioxide "cause . . . reproductive toxicity in humans or animals," the chemicals are presumptively "known to the state . . . to cause reproductive toxicity" and the Governor has "no discretion to exclude" them from the list. *Deukmejian*, 212 Cal. App. 3d at 440-41. The additional requirements for "authoritative body" listing under your Office's regulations, *see* 22 Cal. Code Reg. 12306(d), are therefore inapplicable. We request that these three chemicals now be listed pursuant to operation of law.

II. All Eighteen Chemicals Should Be Listed For Reproductive Toxicity Under Section 25249.8(b) Because NIOSH Has Formally Identified Them as Reproductive Toxins

Section 25249.8(b) of the Act provides that a chemical is known to the State to cause reproductive toxicity if an "authoritative body" has "formally identified" the chemical as causing reproductive toxicity. The implementing regulations for that section outline three requirements for determining that an authoritative body has made a "formal[] identif[ication]." First, the chemical must either have been "included on a list" of such chemicals issued by the authoritative body, or be the "subject of a report" by the authoritative body that "concludes that the chemical causes . . . reproductive toxicity," or be "otherwise . . . identified" as causing reproductive toxicity in a "document that indicates that such identification is a final action." 22 Cal. Code Reg. § 12306(d)(1). Second, the identifying document must "specifically and accurately identif[y] the chemical." 22 Cal. Code Reg. § 12306(d)(2). Third, the identifying document must meet one of six criteria that establish its "formal[ity]." Under these criteria, formal identifications include those that are: "published by" the body "in a publication," for an authoritative body that, like NIOSH, "is a federal agency"; "signed, when required, by the chief administrative officer of the authoritative body or a designee"; or "set forth in an official document utilized by the authoritative body for regulatory purposes." 22 Cal. Code Reg. §§ 22306(d)(2)(C), (D), & (F).

The National Institute for Occupational Safety and Health (NIOSH) is a designated "authoritative body" for the identification of chemicals as causing reproductive toxicity. *See* 22 Cal. Code. Reg. § 12306(*l*)(2). As we noted in our July 6th petition, NIOSH regularly publishes and transmits to federal regulatory agencies, including OSHA, recommendations for regulating exposure to various chemicals. *See* July 6th petition, App. B, at Introduction, pp. 1-2; App. C at 1. To formulate these recommendations, NIOSH evaluates all known and available medical, biological, engineering, chemical, trade, and other information relevant to chemical hazards. *Id*. Because NIOSH publications formally identify the eighteen chemicals at issue in NRDC's petition as chemicals causing reproductive toxicity, Section 25249.8(b) provides for these chemicals to be listed as "known to the state to cause . . . reproductive toxicity."

a. NIOSH's 1988 Written *Testimony* on OSHA's Air Contaminants Rule Formally Identifies Six of These Chemicals As Causing Reproductive Toxicity

On August 1, 1988, the Director of NIOSH gave written *Testimony on OSHA's Proposed Rule on Air Contaminants* (*Testimony*). The Director's written *Testimony* sets forth "NIOSH policy concerning the hazard in question," as explained in NIOSH's subsequent *Compendium*, described *infra*, at Section II.b. *See* App. C, *Introduction* at 2; *see also id.* at 1 and 4 (*Section A Introduction*) (identifying the *Testimony* as a "NIOSH document[] that contain[s] recommendations for safety and health standards in the workplace").

The *Testimony* "specifically and accurately" "list[s]" acetaldehyde, acrylamide, carbaryl, di-sec-octyl phthalate, formamide, and p-nitrochlorobenzene as teratogenic or otherwise reproductively toxic to animals and summarizes relevant scientific research. *See* App. E.[1] The *Testimony* also explicitly associates NIOSH's recommended exposure level for one chemical, carbaryl, with the risk of human reproductive effects. *See* App. E, Table N3A, "REL" column. These identifications are "published by" NIOSH "in a publication"; identified in a document "signed" by NIOSH's "chief administrative officer" (the *Testimony* is that of NIOSH's Director); and "set forth in an official document utilized by [NIOSH] for regulatory purposes" (here, NIOSH's formal role of informing OSHA's air contaminants rule). 22 Cal. Code Reg. §§ 22306(d)(2)(C), (D), & (F). Each of the regulatory requirements for listing pursuant to the "authoritative body" mechanism is therefore met.

b. The 1992 NIOSH *Compendium* Formally Identifies Thirteen of These Chemicals as Causing Reproductive Toxicity

In 1992, NIOSH collected all of its recommended exposure limits for various chemicals in a single reference volume, the *NIOSH Recommendations for Occupational Safety and Health: Compendium of Policy Documents and Statements*, Publ. No. 92-100 (1992) ("*Compendium*"), *available at* http://www.cdc.gov/niosh/92-100.html (visited June 29, 2006). *See* July 6th

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[1] The fact that these summaries sometimes focus on potential carcinogenicity reflects that the *Testimony* was prepared in the context of OSHA's efforts to regulate chemicals as "potential occupational carcinogens" pursuant to its obligations under 29 C.F.R. 1990. *See, e.g.*, App H., *Testimony* at 7, 19. For each chemical, however, the summary indicates reproductive toxicity as well.

petition. Section B of the *Compendium* lists these chemicals and identifies the primary adverse "health effects" associated with each. App. C, *Introduction* at 1.

In that *Compendium* section, NIOSH "specifically and accurately" "list[s]," 22 Cal. Code Reg. § 12306(d)(1), thirteen of the chemicals subject to NRDC's petition – acetaldehyde, acrylamide, carbaryl, diethyl phthalate, diphenylamine, formamide, hexafluoracetone, methoxyflurane, monocrotophos, nitrous oxide, p-nitrochlorobenzene, styrene, and trimethyl phosphate – as toxic to the reproductive system or individual reproductive organs. *See* App. D (Section B excerpts, "Health Effects" entries). In addition, these NIOSH listings are "published by" NIOSH "in a publication" and "set forth in an official document utilized by [NIOSH] for regulatory purposes." 22 Cal. Code Reg. §§ 22306(d)(2)(C) & (F). [2]

c. The 2005 NIOSH *Pocket Guide* Formally Identifies All Eighteen Chemicals as Causing Reproductive Toxicity

Since publishing its *Compendium* in 1992, NIOSH has maintained a *Pocket Guide to Chemical Hazards* (Pub. No. 2005-151) ("*NIOSH Pocket Guide*"), *available at* http://www.cdc.gov/niosh/npg/ (visited June 29, 2006), relevant excerpts of which were included in Appendix B to NRDC's July 6th petition. The *Pocket Guide*, like the *Compendium*, is designed to collect and make more conveniently available the technical information found in NIOSH's exposure recommendations to OSHA and other bodies. *See* July 6th petition, App. B, at Introduction, pp. 1. It is periodically updated to incorporate new toxicity data for various chemicals. *Id*. As NRDC's petition noted, the current *Pocket Guide* formally identifies all eighteen of the chemicals NRDC has petitioned to list as toxic to the reproductive system or individual reproductive organs. *See* App. F (fact sheets, "Target Organs" and "Symptoms" fields).

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[2] The *Compendium* also cites a number of "criteria" documents on individual chemicals or chemical classes "developed to provide the basis for the comprehensive occupational safety and health standards sought by Congress." App. C, *Introduction* at 2. Some of these documents also cite research identifying several of the above-cited chemicals as animal reproductive toxins. *See* Apps. G (acrylamide), H (di-sec-octyl phalate). Each of these documents also independently satisfies the regulatory requirements for formal identification by NIOSH.

d. The 1988 *Testimony*, 1992 *Compendium*, and 2005 *Pocket Guide* All Reflect "Formal Identifications" By NIOSH

As illustrated above and in the attachments to this and our July 6 petition, the Director's 1988 written *Testimony*, the 1992 NIOSH *Compendium*, and the 2005 NIOSH *Pocket Guide* each satisfy the definition of documents through which an authoritative body may "formally identify" a chemical as causing reproductive toxicity. Among other things, they are all "publications" of NIOSH that incorporate "specific[] and accurate" identifying information for chemicals associated health hazards, and they are all used "for regulatory purposes." 22 Cal. Code Reg. § 12306(d)(2). Because these formal publications collectively, and to some extent repetitively, identify all eighteen of the chemicals in NRDC's petition as causing reproductive toxicity, all eighteen chemicals must be listed as "known to the state as causing . . . reproductive toxicity" under Section 25249.8(b) of the Act.

Your August 22, 2006 letter questioned whether the *Pocket Guide*'s reproductive effects entries "reflect a NIOSH identification" of any of the eighteen chemicals at issue here as causing reproductive toxicity, as opposed to compilation of determinations in other NIOSH reports, documents and information available from other sources." Our research suggests that the current *Pocket Guide* does indeed largely "compil[e]" the conclusions of other documents and research formally identifying these eighteen chemicals as, *inter alia*, reproductively toxic. However, we fail to see why this would move it outside the ambit of those documents in which NIOSH has formally identified chemicals as causing reproductive toxicity. The "identifying document" regulations at California Code Section 12306(d) do not exclude compilations.

Your letter also questioned whether NIOSH's use of terms such as "target organs" in the *Guide* was intended to mirror OSHA's regulatory definitions of those or similar terms. We have not been able to confirm whether NIOSH's use of "target organs" in the *Guide*, specifically, is in all circumstances precisely the same as OSHA's regulatory definition of "target organ effects" in the HCS, 29 C.F.R. 1910. It seems natural to presume that NIOSH would employ definitions similar if not identical to OSHA's, since NIOSH's core mandate includes making recommendations on chemical hazards to OSHA. Again, however, we do not see how NIOSH's precise definition of this term is relevant. The normal and obvious meaning of "target organs" is plainly broad enough to encompass reproductive toxicity when the target organ is a reproductive organ.

III. Conclusion

For these reasons, we reiterate our request that your office list the eighteen chemicals identified in NRDC's July 6, 2006 petition as known to the State to cause reproductive toxicity. Should you have any further questions about NRDC's petition, please do not hesitate to contact us. We look forward to your prompt action.

Sincerely,

Michael E. Wall
Selena Kyle
Attorneys

cc: Cynthia Oshita (by email to coshita@oehha.ca.gov) (without enclosure)