



August 5, 2010

Via U.S. Mail (Certified), Hand-Delivery and Electronic Mail

Dr. Joan Denton, Director
Office of Environmental Health Hazard Assessment
Post Office Box 4010, MS-19B
Sacramento, CA 95812-4010

Re: Petition to Rescind Authoritative Body Designation

Dear Dr. Denton:

Please find attached a petition from the Polycarbonate/BPA Global Group of the American Chemistry Council requesting that the designation of the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction as an authoritative body for the identification of chemicals causing reproductive toxicity under Proposition 65 be rescinded. Since action on this petition can only be taken by the Developmental and Reproductive Toxicant Identification Committee (DART IC), we further request that the petition be forwarded to the DART IC and placed on the agenda for their next public meeting.

The Polycarbonate/BPA Global Group consists of the leading global manufacturers of bisphenol A (BPA) and polycarbonate plastic. Although the petition is not limited to BPA, we have a significant interest in the outcome of this petition because OEHHA is currently considering a proposal to list BPA under the authoritative body mechanism. As indicated by the signatures on the attachment, the comments were prepared jointly with Stanley W. Landfair and Christian Volz (McKenna Long & Aldridge), Dr. F. Jay Murray (Murray & Associates), and Dr. Arthur Lawyer (Technology Sciences Group Inc.).

Please do not hesitate to contact me if I can be of further assistance to clarify any of the information provided or if additional information is needed. I can be reached at (703) 741-5588 or by e-mail at steve_hentges@americanchemistry.com.

Regards,

A handwritten signature in black ink, appearing to read "S. Hentges", with a long horizontal flourish extending to the right.

Steven G. Hentges, Ph.D.
Polycarbonate/BPA Global Group



AMERICAN CHEMISTRY COUNCIL
POLYCARBONATE / BPA GLOBAL GROUP

PETITION TO RESCIND DESIGNATION OF
NTP-CERHR
AS AN AUTHORITATIVE BODY
FOR PURPOSES OF PROPOSITION 65

F. Jay Murray, Ph.D., D.A.B.T.
MURRAY & ASSOCIATES

Arthur L. Lawyer, Ph.D.
TECHNOLOGY SCIENCES GROUP INC.

Christian Volz
Stanley W. Landfair
MCKENNA LONG & ALDRIDGE LLP

Steven G. Hentges, Ph.D.
POLYCARBONATE / BPA GLOBAL GROUP
AMERICAN CHEMISTRY COUNCIL

AUGUST 5, 2010

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I. INTRODUCTION

This Petition requests that the designation of the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (“NTP-CERHR”) as an authoritative body for the identification of chemicals as causing reproductive toxicity for purposes of Proposition 65¹ be rescinded. The Petition is submitted by the Polycarbonate/BPA Global Group of the American Chemistry Council (“Petitioner”),² which is composed of manufacturers that do business in California, and whose products are sold in California, so as to make them subject to Proposition 65. The members of this group, and of the American Chemistry Council more broadly, have a significant interest in the outcome of this Petition and in the outcome of any proposal to list chemicals, including but not limited to bisphenol A (“BPA”), as causing reproductive toxicity for purposes of Proposition 65 on the basis of reports published by NTP-CERHR.

Petitioner requests that the actions enumerated below be undertaken by the Office of Environmental Health Hazard Assessment (“OEHHA”), by the Executive Secretary of the Developmental and Reproductive Toxicant Identification Committee (“DART-IC”), and by the DART-IC itself. The Petition must be directed to the DART-IC under Section 25302(e) of the Regulations, and resolution of the matters raised in the petition is within the exclusive authority of the DART-IC pursuant to Section 25306(b). Petitioner asserts its rights and requests relief pursuant to Proposition 65, the Proposition 65 implementing regulations,³ the Administrative Procedure Act,⁴ and the California Code of Civil Procedure.⁵

Petitioner requests that OEHHA act promptly to confirm that the question raised by this Petition — whether to rescind the designation of the NTP-CERHR as an authoritative body — will be placed on the agenda of the next public meeting of the DART-IC, currently scheduled for October 20-21, 2010. Petitioner further requests that no chemicals, including BPA, be considered for listing or listed under the Authoritative Bodies Listing Mechanism on the basis of reports published by NTP-CERHR until the Petition has been resolved. Further consideration of any chemical for listing, including the issuance of any notice of intent to list, on the basis of such reports will cause Petitioner irreparable harm.

¹ Safe Drinking Water & Toxic Enforcement Act of 1986, Cal. Health & Safety Code, §§ 25249.5 et seq., commonly referred to as Proposition 65 and referred to herein as “Proposition 65” or “the Act.” All citations to Proposition 65 appear herein as “Section ___ of the Act.”

² The Group, consisting of the leading global manufacturers of bisphenol A and polycarbonate plastic, supports and conducts scientific research regarding bisphenol A.

³ Cal. Code Regs., *tit.* 27, §§ 25201-25903. All citations to the Proposition 65 implementing regulations appear herein as “Section ___” or “Section ___ of the Regulations.”

⁴ Cal. Govt. Code § 11340 et. seq.

⁵ Cal. Code Civ. Proc. § 1085.

II. PETITION

Petitioner respectfully requests that:

- (1) the Director or the Executive Secretary place the Petition on the agenda for the next public meeting of the DART-IC, providing notice and soliciting public comment as required under Section 25302(d)(1) of the Regulations and the Administrative Procedure Act (“APA”) so that interested persons may submit written comments on the Petition prior to its consideration at the next public meeting and be heard at the public meeting itself;
- (2) the DART-IC rescind the designation of NTP-CERHR as an authoritative body pursuant to Section 25249.8(b) of the Act and Section 25306(b) of the regulations; and
- (3) OEHHA not proceed with its consideration of listing, issue a notice of intent to list, or list any chemicals under the Authoritative Bodies Listing Mechanism on the basis of NTP-CERHR reports, including specifically the reports known as NTP-CERHR Monographs⁶ pending disposition of the Petition.

III. BACKGROUND

Proposition 65 required the publication of a “list” of chemicals that were “known to the State to cause cancer or reproductive toxicity” on March 1, 1987, and presently requires that the list be “revised and republished . . . at least once each year.”⁷ Section 25249.8(b) of the Act provides for the listing of chemicals by the Authoritative Bodies Listing Mechanism, where “a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity”

The reference to “such experts” above is to the State’s Qualified Experts, appointed by the Governor to “consult” with the Governor regarding his duties (and with those to whom the Governor delegated such duties) and to carry out other duties as prescribed under the implementing regulations. With respect to reproductive toxicity, the State’s Qualified Experts are the members of the DART-IC.⁸ Among the DART-IC’s duties is the responsibility to “[i]dentify bodies which are considered to be authoritative and which have formally identified chemicals as causing reproductive toxicity.”⁹ No other person or entity has this authority.

⁶ For purposes of this Petition, the term “NTP-CERHR Monographs” embraces the NTP Briefs and the Expert Panel Reports, both individually and collectively.

⁷ Section 25249.8(a) of the Act.

⁸ Section 25302(a) of the Regulations.

⁹ Section 25305(a)(2) of the Regulations.

NTP-CERHR is currently designated as an authoritative body for reproductive toxicity. This designation, however, followed considerable controversy regarding the suitability of the National Toxicology Program (“NTP”) and its reports for making determinations relevant to Proposition 65.¹⁰ As background, NTP was one of five entities originally designated as authoritative bodies in 1987, when the Act was in its infancy. The DART-IC rescinded that designation with respect to reproductive toxicity in July 1998. After NTP established its Center for the Evaluation of Risks to Human Reproduction (“CERHR”) in 1998, the DART-IC considered, and ultimately adopted, a proposal to designate the CERHR as an authoritative body for reproductive toxicity in December 2002.

In deliberations over the designation, serious concerns were raised among the DART-IC members, and even from the OEHHA staff who favored the designation, concerning the form and content of the anticipated NTP-CERHR Monographs.¹¹ Specifically, NTP-CERHR had not published a Monograph in final form at the time of the Committee’s deliberations. The DART-IC had only a single draft Monograph to review when it made its decision to designate CERHR as an authoritative body.¹² A number of Expert Reports were available, and were viewed as “excellent” summaries of the available toxicological data.¹³ Yet, there was concern that the end-point of the CERHR evaluations did not include a “yes-or-no” determination as to whether a chemical is or is not a reproductive toxicant, but rather expressed only a “level of concern.”¹⁴

In addition, it was noted that the only draft Monograph available at the time presented internally contradictory statements: in the case of the chemical di-n-hexyl phthalate (“DNHP”), the draft Monograph indicated that the data were “insufficient to characterize” the chemical as a developmental toxicant, but elsewhere indicated that DNHP “was a developmental toxicant at high doses [9.9 grams per kilogram per day, “almost ten times the limit dose”].¹⁵ This, noted a DART-IC member, “seem[ed] to be kind of contradictory.”¹⁶ This process and nomenclature would create problems for OEHHA, noted an OEHHA staff member, by putting staff “always in the position of having to interpret any conclusions they draw in the context of Proposition 65. Sometimes it’s very easy, and sometimes it’s more difficult.”¹⁷ In the end, the DART-IC voted to designate NTP-CERHR as an authoritative body, but narrowly limited the designation “solely as to final reports of the National Toxicology Program’s Center for Evaluation of Risks to Human Reproduction.”¹⁸

Recent events reprise the controversy concerning the designation of NTP-CERHR as an authoritative body. In September 2008, NTP-CERHR published its Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A (“Monograph on BPA”). The

¹⁰ Transcript of public meeting of DART-IC, held on December 4, 2002 (“Transcript”), at pp. 125-127.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Transcript at pp. 128-129.

¹⁸ Section 25306(1)(3) of the Regulations.

Monograph on BPA presents the same issues that were the subject of the DART-IC's concerns in December 2002.

Using the now-standard five-level scale of "concerns,"¹⁹ NTP-CERHR made the following report in the BPA Monograph with respect to reproductive toxicity: "NTP has some concern . . . for effects on the brain, behavior, and prostate gland in fetuses," and "negligible concern that exposure to pregnant women . . . will result in fetal or neonatal mortality, birth defects or reduced birth weight and growth in their offspring" or "will cause reproductive effects in non-occupationally exposed adults and minimal concern for workers exposed to higher levels."²⁰

Addressing the crucial question, "Can Bisphenol A affect Human Development or Reproduction," NTP-CERHR responded only "Possibly." As NTP-CERHR explained in later text, certain "high" dose studies showed "clear evidence of adverse effects in animals," but the effects were observed only at doses that produced maternal toxicity in the test animals and at levels several thousand times higher than calculated exposures in the relevant human population.²¹ Summarizing its determination graphically, NTP-CERHR presented a statement in Figure 2a of the Monograph that "the weight of evidence that bisphenol A causes adverse developmental or reproductive effects in humans" indicated that there was "insufficient evidence for a conclusion."²² In Figure 3, presenting a separate graphic summary of the "possibilities that human development or reproduction might be affected by exposure to BPA," NTP-CERHR reported "*negligible* concern for adverse effects" for reproductive toxicity in adult men and women, fetal or neonatal mortality, birth defects, or reduced birth weight or growth."²³

In July 2009, the DART-IC considered BPA for listing under the State's Qualified Expert Mechanism. Seven members of the DART-IC evaluated the NTP-CERHR Monograph on BPA and all of the underlying information and data, including the Expert Panel Report and the studies referred to in the relevant passages of the Monograph discussed above. After careful consideration of this information, the DART-IC deliberated in open forum for nearly an hour, and unanimously voted as follows:

QUESTIONS TO DART IC	NO	YES
Has BPA been clearly shown to cause developmental toxicity?	7	0
Has BPA been clearly shown to cause reproductive toxicity (female)?	7	0
Has BPA been clearly shown to cause reproductive toxicity (male)?	7	0

¹⁹ NTP-CERHR evaluations now articulate one of five levels of concern, ranging from the lowest ("negligible concern") to the highest ("serious concern"). In its first Monograph for DnHP, NTP-CERHR had not yet adopted this five-level scale.

²⁰ NTP-CERHR Monograph on BPA at vii.

²¹ *Id.* at p. 6-7.

²² *Id.* at 7.

²³ *Id.* at p. 8 (emphasis added).

Notwithstanding this unanimous decision by the DART-IC, on February 12 2010, OEHHA issued a “determination” that BPA appears to qualify for listing under the Authoritative Bodies Listing Mechanism on the basis of the NTP-CERHR Monograph: “BPA appears to meet the criteria for listing as known to the State to cause reproductive toxicity under Proposition 65, based on findings of the National Toxicology Program’s Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2008).” Continuing, the OEHHA notice recited that: “This report concludes that the chemical causes developmental toxicity at high levels of exposure, and appears to satisfy the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations OEHHA is relying on the NTP-CERHR’s conclusions in the report that BPA causes reproductive toxicity. The NTP-CERHR report concludes that there is clear evidence of adverse developmental effects in laboratory animals at “high” levels of exposure. Developmental effects include fetal death and reduced litter size in rats and mice exposed prenatally Based on the NTP-CERHR report and the references cited in the report, the evidence appears sufficient for listing by the authoritative bodies’ mechanism.”²⁴

In other words, OEHHA proposed listing BPA as a developmental toxicant under the Authoritative Bodies Listing Mechanism on the basis of the NTP-CERHR Monograph on BPA, just months after the DART-IC voted unanimously that the same Monograph and the scientific data discussed within it do not satisfy the statutory criteria for listing. These events have re-opened the question whether NTP-CERHR Monographs are an appropriate basis for listing chemicals under the Authoritative Bodies Listing Mechanism, and whether the CERHR, a small center at NTP whose designation as an authoritative body is limited to its issuance of these Monographs, should continue to be designated as an authoritative body for purposes of the Act.

IV. STATUTORY AND REGULATORY BASIS FOR PETITION

Proposition 65 and its implementing regulations empower the DART-IC both to designate an entity as an authoritative body and to rescind the designation. Section 25305(b)(2) of the Regulations grants to the DART-IC the exclusive power to “[i]dentify bodies which are considered to be authoritative and which have formally identified chemicals as causing reproductive toxicity.” As a corollary to this authority, the DART-IC also has authority to rescind. To quote the Final Statement of Reasons, “[i]mplicit in the authority to designate authoritative bodies is the power to revoke or rescind such a designation.”²⁵

Section 25306(b) elaborates that the “DART Identification Committee shall have the authority to revoke or rescind any determination that a body is authoritative on the grounds that the respective Committee no longer considers the body to have expertise in the identification of chemicals as causing . . . reproductive toxicity” There is no limitation on the grounds on which the DART-IC may be revoked or rescinded a designation. The final sentence of Section 25306(b)

²⁴ Office of Environmental Health Hazard Assessment, Request for Relevant Information on a Chemical Being Considered for Listing by the Authoritative Bodies Mechanism: Bisphenol-A, February 12, 2010.

²⁵ “Final Statement of Reasons” refers to the Final Statement of Reasons accompanying the Proposition 65 Regulations that implement the authoritative bodies listing mechanism, published by the California Health and Welfare Agency, the predecessor to OEHHA as the “lead agency” with responsibility to implement Proposition 65.

confirms that the DART-IC's power is exclusive and unrestricted when it states that “[n]othing in this section [of the regulations] shall be construed to limit or otherwise interfere with such authority,” referring to the authority to revoke or rescind.²⁶

V. REASONS WHY THE DESIGNATION OF NTP-CERHR AS AN AUTHORITATIVE BODY SHOULD BE RESCINDED

Some eight years after NTP-CERHR was designated as an authoritative body, experience demonstrates that its evaluations of chemicals for risks to human reproduction are not suited to serve as the formal identification of chemicals as reproductive or developmental toxicants under the Authoritative Bodies Listing Mechanism. To the contrary, experience shows that the “concerns” expressed in the NTP-CERHR Monographs are derived from criteria and expressed in terminology that are inherently inconsistent with the definitional criteria for “formally identifying” chemicals “as causing reproductive toxicity” for purposes of Proposition 65.²⁷ Accordingly, the designation of NTP-CERHR as an authoritative body does not meet the statutory requirements.

Proposition 65 and the implementing regulations also make clear that State's Qualified Experts Mechanism is the “primary approach to listing.”²⁸ The purpose of the Authoritative Bodies Listing Mechanism and the delegation of ministerial duties under that mechanism to the OEHHA staff is merely to conserve the resources of the State's Qualified Experts to focus their attention on chemicals “which have not previously been evaluated,” rather than to establish an alternative basis for listing chemicals.²⁹ The Authoritative Bodies Listing Mechanism was not intended to allow or result in the listing of chemicals that do not satisfy the criteria of Proposition 65 used by the State's Qualified Experts themselves in evaluating chemicals for listing.³⁰

Briefly, there are four separate but related reasons why NTP-CERHR Monographs are ill-suited for listing chemicals under the Authoritative Bodies Mechanism, and why the designation of NTP-CERHR as an “authoritative body” under should be rescinded:

1. NTP-CERHR Monographs that focus on quantification of risk rather than identification of hazard are not suited to identifying chemicals as reproductive toxicants for purposes of Proposition 65.

Proposition 65 requires the identification of chemicals that are “*known*” to cause reproductive toxicity. The purpose of the NTP-CERHR is to provide “evaluations of the *potential* for adverse effects on reproduction or development resulting from human exposures to substances in

²⁶ See also Final Statement of Reasons at 7 (“Subsection (b) further provides that [Section 25306(b)] shall not be construed to limit or otherwise interfere with the authority to revoke or rescind an authoritative body designation.”).

²⁷ Section 25249.8(b) of the Act.

²⁸ Final Statement of Reasons at 8. See also *Exxon Mobil v. OEHHA*, 169 Cal.App.4th at 1282 (referring to State's Qualified Expert Mechanism as “primary approach” to listing).

²⁹ *Id.*

³⁰ *Id.* at 10.

the environment.”³¹ These standards are materially different. As discussed above, it is clear from the NTP-CERHR Monographs that the analyses performed by the NTP Expert Panels and the NTP staff do not consider (or do not consider fully) all of the factors that must be taken into account for purposes of Proposition 65 and, conversely, do take into account factors that are not relevant for purposes of Proposition 65. The NTP-CERHR focus on risk as opposed to hazard identification, especially in cases where risk is low or not apparent, results in less scrutiny of factors and criteria that are critical to making a hazard identification for purposes of Proposition 65.

2. *The terms that NTP-CERHR uses to express its concerns about the possibility or probability of risk are inconsistent with the unequivocal conclusions required for listing decisions under Proposition 65.*

Designation of a chemical as a reproductive toxicant under Proposition 65 requires a hazard identification finding that the chemical is “known to the State” to cause reproductive toxicity. Furthermore, the use of the Authoritative Bodies Listing Mechanism requires that the authoritative body “has formally identified it [the chemical] as causing . . . reproductive toxicity.”³²

The NTP-CERHR evaluations do not result in clear conclusions of hazard identification to support such findings. For example, the Monograph on BPA concludes, with respect to hazard identification, only that the chemical “possibly” can affect human development or reproduction.³³ The Monograph goes on to explain that, while there is “insufficient evidence for a conclusion,” based on certain studies that “the possibility that bisphenol A may alter human development cannot be dismissed.”³⁴ As the DART-IC stated in 2002, that determination of “possibility” is neither a “yes” nor a “no” and certainly is not a finding that the scientific evidence “clearly shows” that BPA causes adverse developmental effects.

Moreover, the NTP-CERHR’s equivocal determination on hazard identification is not confined to the case of BPA. A review of all NTP-CERHR Monographs shows that NTP-CERHR consistently uses inconclusive language to describe the potential that a reviewed chemical “might” or “possibly” or “potentially” have adverse effects.³⁵ These determinations, indicating that chemicals “might,” “possibly” or “potentially” cause adverse effects do not provide the level of certainty to constitute the “formal identification” required by Proposition 65.

3. *NTP-CERHR’s evaluation of adverse effects attributable to post-natal exposure makes it unsuitable as an authoritative body.*

NTP-CERHR considers reproductive toxicity in infants to include developmental toxicity, and developmental toxicity to include effects that are attributable to either (or both) pre- and post-

³¹ NTP-CERHR Monograph on BPA, Preface at v (emphasis added).

³² Section 25249.8(b) of the Act.

³³ NTP-CERHR Monograph on BPA at 6.

³⁴ *Id.* at 7.

³⁵ The NTP-CERHR Monographs are available on the NTP website at <http://cerhr.niehs.nih.gov/evaluations/index.html>

natal exposure.³⁶ By contrast, developmental toxicity under Proposition 65 is confined to effects that are attributable solely to pre-natal exposure.³⁷ The data that lead NTP-CERHR to a determination that the weight of the evidence would support a determination with respect to adverse developmental effects are different from the data that would support such a conclusion for purposes of Proposition 65. Similarly, NTP-CERHR's determination that a chemical might "possibly" cause adverse developmental effects does not "identify" the chemical as a "reproductive toxicant" for purposes of Proposition 65.

4. Use of NTP-CERHR evaluations as the basis of authoritative bodies listings distorts the standard for sufficiency of data to support a finding under Proposition 65.

Finally, Section 25306(g) of the Regulations and the Final Statement of Reasons supporting that regulation clearly demonstrate that the Authoritative Bodies Listing Mechanism is intended merely as an administrative convenience, and should result in listing only the chemicals that the State's Qualified Experts would decide to list themselves, based on the scientific criteria for listing under Proposition 65. Returning to the example of BPA, OEHHA's current consideration of the chemical for listing based on the NTP-CERHR Monograph, after the DART-IC unanimously concluded that BPA does not satisfy the listing criteria, will result in scientifically unjustified and inconsistent bases for listing under Proposition 65.

The conflict between the standard of NTP-CERHR and Proposition 65 is manifested in the consideration of factors such as dose-response curves and maternal toxicity, which NTP-CERHR may or may not take into account in evaluating risk, but which Section 23506(g) requires to be taken into account in reaching a conclusion regarding hazard. The Monograph on BPA, evaluating the data discussed above, stopped short of analyzing the relationship between maternal toxicity and adverse developmental effects in test animals, apparently because such analysis was not necessary to a determination regarding risk, given the extremely high levels of exposure in the test animals relative to exposure in humans. In contrast, the DART-IC criteria require that effects due to maternal toxicity not be considered as causing reproductive toxicity.³⁸ Therefore, when called under Proposition 65 to evaluate the data and to consider maternal toxicity, the DART-IC found that any adverse developmental effects were secondary to maternal toxicity. With such fundamentally different approaches, NTP-CERHR's observations concerning studies involving maternal toxicity cannot be relied on as a "conclusion" regarding BPA for purposes of Proposition 65. Indeed, the DART-IC's conclusion that BPA is not a reproductive toxicant after examining the same studies makes that patently clear.

The conflict further ignores the well-known principle of toxicology that virtually all chemicals are capable of causing adverse effects in test animals if administered at sufficiently high doses during gestation, and the fact that modern testing protocols (such as Good Laboratory Practices imposed under most regulatory testing regimes) require the administration of the test agent at levels

³⁶ See generally NTP-CERHR Monographs.

³⁷ Section 25306(g)(2) of the Regulations.

³⁸ Cal Code Regs. Tit 27, § 25306(g); DART-IC Criteria (November 1993) at 4.

sufficient to induce maternal toxicity.³⁹ When these principles are ignored, the evaluation of nearly any well-designed study results in a determination that nearly every chemical tested causes adverse developmental effects, because it ignores deliberately induced toxicity in the mother. The evaluation of test data by the DART-IC under the State's Qualified Expert Mechanism allows for these factors to be considered, as they should be; the elusive search for "conclusions" regarding hazard identification in an NTP-CERHR Monograph, which evaluates for risk rather than hazard, deliberately avoids consideration of these factors and leads to improper conclusions for purposes of Proposition 65.

VI. CONCLUSION

In the words of Section 25306(1)(3) of the Regulations, the designation of NTP as an authoritative body "for the identification of chemicals as causing reproductive toxicity" is strictly limited to the "final reports of the National Toxicology Program's Center for Evaluation of Risks to Human Reproduction," or NTP-CERHR. As demonstrated above and by the example of BPA, the NTP-CERHR Monographs (the "final reports" that NTP-CERHR issues) are ill-suited to the "identification" of such chemicals for purposes of Proposition 65. Indeed, the use of these reports as the basis for designating chemicals as reproductive toxicants under the Authoritative Bodies Listing Mechanism results in application of criteria less rigorous than those imposed under the Act. Accordingly, the designation of NTP-CERHR as an authoritative body should be rescinded.

Petitioner does not question the validity of the NTP-CERHR Monographs for the purpose intended by NTP, when they are properly considered. To the contrary, the Monographs usually provide exhaustive and authoritative summaries of data and opinions that are appropriate to NTP-CERHR's mandates. For purposes of Proposition 65, however, the Monographs are better suited to use by the DART-IC under the State's Qualified Expert Listing Mechanism, where the Proposition 65 Regulations require the Committee to determine from the scientific data whether a chemical has been "clearly shown, through scientifically valid testing according to generally accepted principles to cause reproductive toxicity."⁴⁰

Rescinding the designation of the NTP-CERHR would not detract from the efficient implementation of Proposition 65. In its twelve-year history, the NTP-CERHR has issued only twenty final Monographs.⁴¹ Such a small number of chemicals over more than a decade could be considered just as well by the State's Qualified Experts. Indeed, removing the controversy concerning the proper use of the Monographs by restricting their use to the State's Qualified Experts Mechanism would allow the Monographs to be used productively and consistently.

³⁹ See, e.g., US EPA Health Effects Test Guidelines, Office of Prevention, Pesticides and Toxic Substances, July 2000 at 4.

⁴⁰ Section 25305(b)(1) of the Regulations.

⁴¹ A list of the chemicals that NTP-CERHR has evaluated appears on the NTP website at <http://cerhr.niehs.nih.gov/evaluations/index.html>.

For the reasons stated above, the Petition must be placed on the agenda for the next public meeting of the DART-IC and an opportunity provided for public comment. For these and other reasons that Petitioners and others may explain during the comment period, the Petition should be GRANTED by the Committee.

Respectfully submitted,

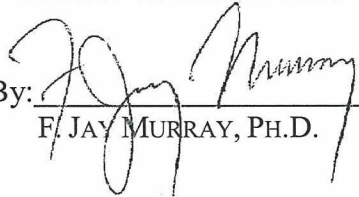
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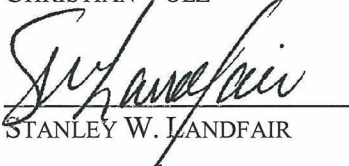


STEVEN G. HENTGES, PH.D.
POLYCARBONATE/BPA GLOBAL GROUP

MURRAY & ASSOCIATES

By: 
F. JAY MURRAY, PH.D.

MCKENNA LONG
& ALDRIDGE LLP

By: 
CHRISTIAN VOLZ

STANLEY W. LANDFAIR

TECHNOLOGY
SCIENCES GROUP INC.

By: 
ARTHUR L. LAWYER, PH.D.

cc: Dr. Joan Denton, Director, OEHHA
Carol Monahan-Cummings, Chief Counsel, OEHHA