



September 15, 2009

Via U.S. Mail and Email

Joan E. Denton, Ph.D., Director
OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT
1001 "T" Street
Post Office Box 4010
Sacramento, California 95812

RE: OPPOSITION TO PETITION TO LIST BISPHENOL A UNDER PROPOSITION 65

Dear Dr. Denton:

Please find attached written comments from the Polycarbonate/BPA Global Group of the American Chemistry Council on the petition submitted by the Natural Resources Defense Council to list bisphenol A as a reproductive toxicant under Proposition 65. The Polycarbonate/BPA Global Group consists of the leading global manufacturers of bisphenol A and polycarbonate plastic, which for many years have supported and conducted scientific research to understand whether bisphenol A has the potential to cause health or environmental effects and to support scientifically sound public policy.

As indicated by the signatures at the end of the attachment, the comments were prepared jointly with Stanley 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.
Executive Director
Polycarbonate/BPA Global Group



AMERICAN CHEMISTRY COUNCIL
POLYCARBONATE / BPA GLOBAL GROUP

OPPOSITION TO
“PETITION FOR LISTING BISPHENOL-A PURSUANT
TO AUTHORITATIVE BODIES MECHANISM”
UNDER PROPOSITION 65

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I N T R O D U C T I O N

On July 15, 2009 the Developmental and Reproductive Toxicant Identification Committee (“DART IC,” also referred to as “the Committee” or “the Panel”) met in a virtually unprecedented full-day session to consider whether bisphenol A (“BPA”) should be listed as a chemical “known to the state to cause . . . reproductive toxicity” pursuant to Proposition 65. Having considered a 297-page long Hazard Identification Document on BPA carefully prepared by the staff of the Office of Environmental Health Hazard Assessment (“OEHHA,” also referred to as the “Agency”), which included as an attachment the 321-page NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A (“NTP-CERHR Monograph”), as well as voluminous public comments, the Committee then heard scientific and lay testimony from opponents and proponents of listing.

After careful consideration of this information, the DART IC deliberated in open forum for nearly an hour, and voted as follows on the three questions below:

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

With that series of votes, the question whether BPA should be placed on the Proposition 65 “List of Chemicals Known to Cause Cancer or Reproductive Toxicity” was resolved. Nevertheless, immediately following the vote, the Natural Resources Defense Council (“NRDC”) hand-delivered to OEHHA a “Petition for Listing Bisphenol A Pursuant to Authoritative Bodies Mechanism of Safe Drinking Water and Toxic Enforcement Act of 1986” (“Petition”).¹ The Petition focuses on a short passage from the 55-page NTP Brief, which in turn summarizes the peer-reviewed CERHR Expert Panel Report that the DART IC considered in its entirety, and claims that NTP “formally identified” BPA in the Brief as a reproductive toxicant within the meaning of Proposition 65.

In fact, NTP did nothing of the sort. Rather, the NTP Brief recites that NTP *concluded* it has “*some concern*” for developmental toxicity from exposure to BPA,² reasoning that BPA “*possibly*” can “affect human development or reproduction.”³ As discussed further herein, the passage on which the Petition is based — noting that certain studies showed “clear evidence of adverse effects on development *in laboratory animals*”⁴ — merely characterizes some of the data that NTP reviewed in its weight-of-the-evidence analysis. In context and fairly read, the passage indicates that certain adverse effects were noted in some studies, then indicates in the

¹ A copy of the Petition appears as Attachment A to these comments.

² NTP Brief, Abstract at vii.

³ NTP Brief at 6.

⁴ NTP Brief at 7.

next sentence that the adverse effects were observed at the same doses that caused maternal toxicity in the test animals, and explains in the following sentence that these effects were observed only at levels beyond the realm of human experience in children, adults or adult workers. In the following two paragraphs, NTP further explains that NTP's only basis for "some concern" of adverse effects *in humans* was certain other studies (*i.e.*, certain "low dose studies") in animals that were too unreliable to serve as the basis for any more definitive conclusion and, indeed, provide only "limited evidence" of adverse effects in animals. Then, in a graph depicting the "weight of evidence that bisphenol A causes adverse developmental or reproductive effects in humans," NTP sums up by indicating that there is "insufficient evidence for a conclusion."⁵

The Petition asks OEHHA and its Director to review the NTP-CERHR Monograph, and to reach a conclusion different from the DART IC's unanimous conclusion. The implicit argument on which the Petition is based — that OEHHA should disregard the conclusions expressed in the NTP-CERHR Monograph and list the chemical solely on the basis of NTP's characterization of some of the data in the NTP Brief instead — was presented to the DART IC at the July 15 public meeting. The Committee considered this argument and, having reviewed the entire Monograph, rejected it. OEHHA should reject the argument, too, both because the DART IC rejected it and, on its merits, for the same reasons that the Committee did so.

Thus, if the Petition is considered on its merits, it would fail. There is no rational way that OEHHA could reach a conclusion different from the one reached by the DART IC, given the Committee's findings and the standards that the Agency is required to follow, unless the Agency, its Director and its staff simply substitute their judgment for that of the NTP, as well as the collective judgment of the statutorily appointed State's qualified experts.

S U M M A R Y O F R E A S O N S W H Y T H E P E T I T I O N S H O U L D N O T B E G R A N T E D

By these comments, the American Chemistry Council and its Polycarbonate/BPA Global Group (hereinafter referred to as "ACC"), as well as the undersigned counsel and consultants to ACC, present three compelling reasons why the Petition should not be granted, and thus why OEHHA should not initiate another regulatory proceeding to consider listing BPA under Proposition 65.

1. *The Authoritative Bodies Listing Mechanism Is Not a Means to Overrule or Supersede a Decision by the State's Qualified Experts.* Fundamentally, that is exactly what the Petition seeks to do, by relying on the same data and statements in the NTP-CERHR Monograph that the State's qualified experts — here, the DART IC —unanimously found were not sufficient evidence to serve as a basis for listing BPA under Proposition 65, and asserting that they support a different conclusion.

⁵ NTP Brief at 7.

Section 25306 of the Proposition 65 regulations,⁶ which implements the authoritative bodies listing mechanism, as well as the Statement of Reasons that explain its purpose and intent, make it abundantly clear that the authoritative bodies mechanism is not to supplant the State’s qualified experts, who serve as the “primary” source of listing expertise, but rather *to supplement* their resources. The authoritative bodies mechanism thus allows chemicals that are designated by authoritative bodies as carcinogens or reproductive toxicants to be listed without direct input from the State’s qualified experts, but only under conditions intended to ensure that *only those chemicals that meet the criteria of the State’s qualified experts will qualify for authoritative bodies listing*.

The authoritative bodies mechanism does not, and was not intended to, allow for chemicals to be listed on standards that are different or less stringent than the State’s experts apply, or on the basis of scientific evidence that would not satisfy them. Therefore, because the DART IC explicitly considered whether to list BPA at the July 15 hearing and reached unanimous conclusions that all of the scientific evidence on BPA (including the same “evidence” that is the basis of the Petition) does *not* satisfy the Proposition 65 listing standard, it is conclusively settled that these same scientific data can not support a conclusion that BPA does qualify for listing. Thus, any proposal to list BPA under Proposition 65 under the authoritative bodies mechanism on the same evidence that the State’s qualified experts already reviewed is contrary to law.

2. *The Petition Ignores the Requirements of Section 25306.* Second, underscoring the point that it is not appropriate to initiate the authoritative body listing process for a chemical following a decision by the State’s qualified experts that it does not meet the criteria for listing, the Petition ignores the procedural requirements of Section 25306 that carry out its intent. In effect, the Petition seeks to compel OEHHA to reverse the judgment that the DART IC already made — that the available scientific evidence on BPA does not satisfy Proposition 65’s stringent listing criteria. The procedures that OEHHA would have to follow pursuant to Section 25306 would preclude such an illogical outcome.

As a precondition to initiating the authoritative bodies process to list BPA, OEHHA would have to, among other things, determine that BPA had been “formally identified” by NTP within the meaning of Section 25306(d) “as causing reproductive toxicity” within the meaning of Section 25306(g). As demonstrated in Section 3 of these comments, NTP-CERHR did *not* “conclude” or otherwise “formally identify” BPA as a reproductive toxicant, so the requirements of Section 25306(d) cannot be met.

Section 25306(g) also would require OEHHA to conclude that NTP-CERHR’s (nonexistent) formal identification of BPA as a reproductive toxicant was supported by “sufficient data” from animal studies to satisfy the Proposition 65 standards. As discussed in Sections 1 and 2 of these comments below, the DART IC found unanimously and conclusively on July 15 that the animal data on BPA *do not* satisfy those criteria. Although the OEHHA staff, and not the DART IC, are charged with evaluating those animal data for purposes of a potential authoritative body listing, it seems inconceivable that staff would presume to reach a conclusion that directly contradicts the DART IC ruling on this subject.

⁶ Cal. Code Regs., *tit.* 27, § 25306.

If this were to occur, *i.e.*, if OEHHA were to determine that NTP-CERHR did formally identify BPA as a reproductive toxicant and that contrary to DART IC's decision, the available animal data are "sufficient" to satisfy the Proposition 65 listing criteria, Section 25306(i) would require OEHHA to publish a notice of intent to add BPA to the list, to serve that notice on the DART IC, and to allow the DART IC (and interested parties) to object on the basis that "there is no substantial evidence that the criteria of [Section 25306(g)] have been satisfied."

Presuming that the DART IC were to submit comments on that issue (the same issue on which they already ruled) the Director then would be required under Section 25306(i) to determine whether the "criteria identified in [Section 25306(g)] have been satisfied." This would raise the following question: Is Section 25306(g) being implemented properly if it would cause the Director to sit in judgment of the findings already rendered by the Committee in a unanimous vote on a matter within their exclusive province? The answer, of course, would be "No."

Yet, that would not be the end of it. If the Director were to agree with the DART IC that there were "no substantial evidence" that the Section 25306(g) criteria were satisfied, she would be required to "refer the chemical [back] to the [DART IC] to determine whether, in the [DART IC's] opinion, the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause . . . reproductive toxicity."

That is the question on which the DART IC just voted. Indeed, the DART IC already decided *both* of these issues. As detailed herein, the DART IC reviewed voluminous scientific evidence, including written comments and oral testimony presented at the July 15 public meeting. The transcript shows that the DART IC considered this evidence and testimony and that its decision turned on these very issues. As detailed above, the DART IC voted 7 – 0, three times, concluding that BPA had not been "clearly shown through scientifically valid testing according to generally accepted principles to cause" developmental toxicity, female reproductive toxicity, or male reproductive toxicity. In reaching this conclusion, the DART IC clearly concluded through its colloquies with the presenters and in its deliberations that BPA was not "formally identified" by NTP as a reproductive toxicant, and that there was not "sufficient evidence" to support such an identification.

Thus, the Petition is a circular and improper attempt to compel the Agency to pit itself against the State's qualified experts and compel the experts to defend their judgment against the Agency.

3. *The NTP-CERHR Monograph Does Not "Formally Identify" BPA "as Causing Reproductive Toxicity" Within the Meaning of Section 25306(d).* Third, the Petition should be denied because the NTP-CERHR Monograph does not satisfy the requirements of Section 25306(d)(1). Although the NTP-CERHR Monograph contains certain observations about the scientific data on BPA, including the observation quoted above that certain studies show "clear evidence of developmental effects at high doses," that is to be expected in a document that explains an agency's assessment of the "weight-of-the-evidence." Neither the NTP-CERHR Monograph nor the NTP Brief that is a part of the Monograph "formally identifies" BPA as a reproductive toxicant.

In order for a chemical to be "formally identified" as a reproductive toxicant within the meaning of Section 25306(d)(1), the chemical must: (1) be included in a "list" of such chemicals that is published by an authoritative body; (2) be the subject of a "report which is published by

the authoritative body and which concludes that the chemical causes . . . reproductive toxicity;” or (3) be “otherwise . . . identified as causing . . . reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action.”

The NTP-CERHR Monograph that is the basis of the Petition obviously is not such a “list.” And the document clearly does not “conclude” that BPA is a reproductive toxicant. To demonstrate this, we examine in depth below the actual conclusions that the NTP-CERHR Monograph in fact articulates. These conclusions are clearly marked and very carefully stated not to include a conclusion that BPA is a reproductive toxicant. Rather, they indicate only that the NTP has “some concern” that BPA may cause developmental effects. As OEHHA would agree, “some concern” falls among the lower levels of “concern” in the NTP ranking system and would not be a basis for listing BPA under Proposition 65.

Turning to the third possibility, BPA is not “otherwise . . . identified” as “causing reproductive toxicity” in the NTP-CERHR Monograph. As a procedural matter, it would be a misapplication of Section 25306(d)(1) to construe an isolated statement or passage from the Monograph as having “identified” BPA as a reproductive toxicant, when the very purpose of the entire document was to examine whether the chemical causes developmental or reproductive toxicity and the authors deliberately declined to conclude that it does. The provision of Section 25306(d)(1) that allows for listing on the basis of collateral documents that “identify” chemicals as carcinogens or reproductive toxicants in the course of promulgating regulatory decisions does not extend to the circumstances here.

If OEHHA were to issue a Notice of Intent to List BPA on this basis, the Director first would have to conclude that the chemical has been identified in the NTP-CERHR Monograph “as causing reproductive toxicity.” As discussed above, that issue has been decided already by the DART IC, which explored that issue expressly and extensively, at the urging of the Petitioner, on the record. For the Agency to reach a conclusion to the contrary would be to defy the findings of the State’s qualified experts in a way that is unimaginable, if not legally impossible.

Finally, and now reaching the merits of the Petition, it is clear from the face of the NTP-CERHR Monograph that statements referred to in the Petition as evidence that BPA is “otherwise . . . identified” as “causing reproductive toxicity” do not satisfy the requirements of Section 23506(g)(2). Specifically, there is not “sufficient evidence” to support such a finding, because the studies identified and relied upon for the asserted finding that there is “clear evidence of adverse effects” and the Monograph itself plainly indicate that the effects observed occurred only in the presence of significant maternal toxicity. This is clear from the NTP Brief, from the underlying Expert Panel Report, and also from the studies cited in the Brief as support for the finding that the Petition asserts.

REASONS WHY THE PETITION SHOULD NOT BE GRANTED

1. *The Authoritative Bodies Listing Mechanism Is Not a Means to Overrule or Supersede a Decision by the State's Qualified Experts*

The unstated premise of the Petition — that BPA can be listed on the basis of isolated statements in the NTP-CERHR Monograph, immediately after the DART IC's unanimous decision rejecting that very Monograph and all other available evidence as a basis to list BPA — is based on a fundamental misunderstanding of the purposes of the authoritative bodies listing mechanism and Section 25306. A proposal to list BPA based on the authoritative bodies mechanism under these circumstances necessarily presupposes that an authoritative body listing validly can be based on: (1) a subset of the data that the State's qualified experts considered, and (2) a scientific/legal standard less stringent than Proposition 65's "clearly shown" standard, as interpreted and applied by the State's experts. That presupposition is contradicted by the plain terms of Section 25306(e), (g) and (i), which require an authoritative body listing to be based on scientific evidence that satisfies the standards of the State's qualified experts, and which collectively provide a fail-safe procedure to prevent the listing of a chemical where an authoritative body has "formally identified it as causing cancer or reproductive harm" based on standards less stringent than Proposition 65 requires.

The regulatory history of Section 25306, which implements the authoritative bodies listing mechanism authorized by Section 25249.8(b) of the Act, makes it very clear that the mechanism is not intended to allow or result in the listing of chemicals that do not satisfy the Proposition 65 listing criteria as the State's qualified experts would apply them. The Statement of Reasons⁷ clearly shows that the State's qualified experts,⁸ who are the persons authorized by Section 25249.8(b) of the Act to designate – or *not* to designate – bodies as "authoritative" and hence empowered to formally identify chemicals as causing cancer or reproductive toxicity, were very concerned to ensure that any listings by such authoritative bodies would satisfy Proposition 65's stringent criteria, as the State's qualified experts interpret and apply them.

The Scientific Advisory Panel was concerned that the authoritative bodies mechanism could result in unjustified or "unrestrained" listing of chemicals that do *not* satisfy the Proposition 65 criteria, and was unwilling to designate any body as authoritative unless and until regulatory safeguards were implemented to prevent such unjustified listings. This concern was the genesis of the development of Section 25306 (then Section 12306), as explained in the passage from the Statement of Reasons below.

⁷ A copy of the "Final Statement of Reasons" dated March 29, 1990, accompanying the adoption of Section 12306, the precursor to Section 25306, appears as Attachment B to these comments.

⁸ At that time, the "Scientific Advisory Panel" ("Panel"), the precursor to the CIC and DART IC.

“PROCEDURAL BACKGROUND

“The concept of this regulation was conceived following the Panel’s meeting of October 1987. In that meeting, *the Panel expressed strong reservations about designating any body as authoritative due to its concern that the designation would result in the unrestrained listing of chemicals. Consequently, the Agency determined that it would be necessary to implement and make specific the provisions of the Act relating [to] authoritative bodies* to enable the Panel to take advantage of this listing mechanism. Subsequently, the Agency commenced drafting this regulatory proposal. Copies of early proposals were circulated to interested persons and the Panel.

“On April 14, 1989, following a command from the Sacramento Superior Court, the Panel considered the question whether the United States Environmental Protection Agency (EPA) is an “authoritative body” within the meaning of the Act and concluded that EPA is authoritative, but *conditioned the designation upon application of certain controls to the listing of chemicals pursuant to that designation, and asked the Agency to draft rules embodying these controls.* The terms of the condition were similar to the controls in the draft regulatory proposal. Subsequently, on July 17, 1989, the Agency proposed section 12306 [recently renumbered as Section 25306] for adoption.”

Statement of Reasons, 2 (emphasis added).

Section 25306 defines in its subsections the scientific criteria that authoritative body listings must satisfy. For both carcinogens and reproductive toxicants, the Statement of Reasons explains that authoritative body listings are to be based on scientific evidence that satisfies the Scientific Panel’s own criteria.

Section 25306(e) sets forth the criteria for carcinogens. The Statement of Reasons recites:

“SUBSECTION (E)

“Subsection (e) provides that, for purposes of section 12306, the phrase “as causing cancer” means that either of two scientific criteria have been satisfied. Generally, the authoritative body may rely on either studies in humans or studies in animals. *These criteria are consistent with the criteria the Panel presently uses in evaluating chemicals for listing.* The Panel utilizes the EPA’s Classification System for Categorizing Weight of Evidence for Carcinogens From Human and Animal Studies [51 Fed. Reg. 33999 (Sept. 24, 1986)]. The same, or substantially similar criteria have been adopted by many regulatory agencies and scientific organizations involved in hazard identification. *The use of these criteria will ensure that the standards applied by an authoritative body are the same as or substantially similar to those used by the Panel to evaluate chemicals.*”

Statement of Reasons, 15 (emphasis added).

Section 25306(g) defines the scientific criteria that an authoritative body listing must satisfy for a reproductive toxicant.⁹ As was the case with carcinogens, the Statement of Reasons explicitly indicated that any authoritative body listing of a reproductive toxicant must be based on scientific evidence that satisfies the Scientific Panel’s own criteria:

“SUBSECTION (G)

“Subsection (g) provides that, for purposes of section 12306, the phrase “as causing reproductive toxicity” means that either of two scientific criteria have been satisfied. Generally, the authoritative body may rely on either studies in humans or studies in animals.

“Paragraph (g)(1) describes the criteria for determining that a chemical causes reproductive toxicity where the authoritative body relied on studies in humans. As with carcinogens discussed above, the proposed regulation requires that sufficient evidence exist from such studies, in that studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity.

“Paragraph (g)(2) describes the criteria for determining that a chemical causes reproductive toxicity where the authoritative body relied on studies in animals for its identification of a chemical as a reproductive toxicant. *Again, the proposed regulation requires that sufficient evidence exist from such studies. “Sufficient evidence” is defined to mean that there is sufficient data, which take into account the adequacy of the experimental design and other specified parameters,* indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible. *This is consistent with the criteria utilized by the Panel when it evaluates reproductive hazards.”*

Statement of Reasons, 21 – 22 (emphasis added).

Finally, Section 25306(i) establishes the procedure that OEHHA must follow in proposing an authoritative body listing. The references in subsection (i) to the scientific criteria of subsections (e) and (g) clearly signify that any authoritative body listing must be based on scientific evidence that satisfies the stringent Proposition 65 listing criteria, as interpreted by the State’s qualified experts. The Statement of Reasons confirms that subsection (i) was intended as a fail-safe mechanism to ensure that in the (hopefully infrequent) instance in which an authoritative body might “formally identify” a chemical as a carcinogen or reproductive toxicant on the basis of evidence that does *not* satisfy the Proposition 65 criteria, the chemical will be referred to the State’s experts for review prior to listing *so that such unjustified listing will be prevented:*

“SUBSECTION (I)

“Subsection (i) sets forth a procedure to be followed by the lead agency prior to the listing of chemicals on the ground that they are formally identified by authoritative bodies as causing cancer or reproductive toxicity. At least 60 days

⁹ The language of subsection (g) that was adopted in 1990 (as Section 12306(g)) is exactly the same as the current language of Section 25306(g).

prior to causing the chemical to be added to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency must publish a notice identifying the authoritative body and the chemical, stating its intention to cause the chemical to be added to the list. *Interested parties will have 30 days within which to object to the proposed listing on the ground that there is no substantial evidence that the scientific criteria set forth in subsection (e) and (g) have been satisfied.* Such objections must be in writing and be accompanied by supporting documentation.

“One commenter recommended that the Agency invite public comment on all aspects of a decision to identify a substance which has been listed by another authoritative body, not just the satisfaction of the criteria for identification of a chemical “as causing cancer” or reproductive toxicity in subsections (e) and (g). (C-9, p. 3) *Subsection (i) arises out of concerns that chemicals formally identified by authoritative bodies might be listed even though the criteria utilized by the Panel had not been satisfied.* The Panel applies scientific, not procedural, criteria when recommending chemicals for listing. *The purpose of subsection (i) is to establish a procedure for determining which chemicals should be referred to the Panel for its scientific review.* It is for this reason that the regulation limits objections to scientific criteria.”

Statement of Reasons, 24 (emphasis added).

These provisions of Section 25306, as explained by the foregoing excerpts from the Statement of Reasons, conclusively establish that authoritative body listings legally may *not* be based on scientific evidence less stringent than the evidence that the State’s qualified experts – here, the DART IC – apply in their own review of chemicals for potential listing. On the contrary, the authoritative bodies mechanism was implemented with considerable safeguards and requirements to ensure that authoritative body listings would satisfy the same stringent criteria. That is the reason that the procedures include a provision to ensure that the State’s experts would have an opportunity to object to and ultimately override any proposed authoritative body listings that did not satisfy those criteria.

We acknowledge that the three listing mechanisms provided in Section 25249.8 of the Act are separate, and that the authoritative bodies mechanism in particular contemplates that OEHHA, not the DART IC, has the authority and responsibility to assess whether such authoritative body determinations are based on “sufficient data” as defined in Section 25306(g). It is hypothetically possible that regulations implementing the authoritative body listing mechanism could have allowed for such listings to be based on scientific evidence less stringent than required by the State’s qualified experts. As demonstrated above, however, that did not happen: Section 25306, and especially subsections (e), (g), and (i), clearly were intended to, and do, require that authoritative body listings meet the *same* stringent criteria.¹⁰

¹⁰ There is no authority to support a contrary conclusion. In particular, the July 20, 1998 memorandum authored by a former Chief Counsel to the Agency (hereinafter, “Counsel’s Memo”) and posted on the OEHHA website, is not authority and does not support a contrary view.

The Counsel’s Memo addresses, among other questions, “What effect, if any, does a determination by the CIC or DART Committee to not identify a chemical for listing under Proposition 65 have on the authority of the
(footnote continued

In the case of BPA, the DART IC has reviewed all the available scientific evidence, including not only the studies reviewed by NTP-CERHR but also the conclusions and observations expressed in the NTP-CERHR Monograph itself, and has reached the unanimous conclusion that BPA has *not* been “clearly shown through scientifically valid testing according

(footnote continued from previous page)

lead agency to list a chemical as causing cancer or reproductive toxicity on the basis of an authoritative body formal identification?” The author concludes that “each of the three listing mechanisms is independent of the other methods and has its own authority. Accordingly, a determination by the CIC or DART Committee to not identify a chemical for listing under the ‘State’s qualified expert’ mechanism is no bar or limitation on the authority of authoritative body to formally identify a chemical as causing cancer or reproductive toxicity. Again, the Statute (Section 25249.8(b)) is framed in the disjunctive – ‘or.’ If a chemical meets one of the three listing methods, it may be added to the list.”

In response, we note that the Counsel’s Memo is not a statute, regulation, rule or other authority, but only an opinion of the former Chief Counsel, by which the Agency is not bound, and which can and should be corrected as a misstatement of the law, if it would be mistaken as authority to allow the Petition to be granted. First, the author cites no authority other than her observation that the three listing mechanisms identified in Section 25249.8(a) of the statute are “independent,” because they are connected by the word “or.” Second, while it is obviously true that the various “mechanisms” are independent, that is no reason to conclude that the mechanisms are intended to support different results, or that the separate clauses of Section 25249.8(b) that establish separate listing “mechanisms” should be read to establish different listing *criteria*. Third, the Statement of Reasons, which includes the Agency’s official interpretation of the Act and implementing regulations, provides expressly to the contrary. As noted above and in the Statement of Reasons, Section 25249.8(b) of the statute vests in the State’s qualified experts the exclusive authority to determine what bodies are “considered to be authoritative” and thus, implicitly, to establish criteria for their designation as “authoritative.” Given that the clause in Section 25249.8(b) that provides for authoritative bodies – which reads in its entirety as follows: “or if a body considered to be authoritative by such experts has formally identified [a chemical] as causing cancer or reproductive toxicity” – includes *no* listing criteria, the Agency at the Scientific Advisory Panel’s request promulgated Section 25306, which does include listing criteria, for the express purpose of ensuring that the any bodies that the Panel deemed to be authoritative would be bodies that applied criteria that are “*consistent with the criteria used by the Panel.*”

Fourth, putting the above legal premises aside, the ultimate conclusion expressed in the Counsel’s Memo – that a ruling by the CIC or DART IC that a chemical does not qualify for listing under Proposition 65 is “no bar or limitation on the authoritative body to formally identify a chemical as causing cancer or reproductive toxicity” – does not address the situation here. We are not faced with the question whether the decision of a Scientific Advisory Panel (here, the DART IC) has any effect on the authoritative body to go about its business, as the Counsel’s Memo addresses. Indeed, we would agree with the conclusion that an authoritative body has every right to consider a chemical for whatever purposes its statutory mission may require, and to accept or reject the findings of the DART IC. The different question that we must answer here is whether the Agency may ignore the conclusion of a Scientific Advisory Panel (again, the DART IC) that a report issued by an authoritative body (here, the NTP-CERHR) does not establish that a chemical meets the Section 25306(g)(2) criteria for listing under Proposition 65. For the reasons discussed in the text of these comments above, the Agency may not ignore that opinion. The Counsel’s Memo does not say otherwise.

Finally, and related to the fourth point above, the most that can be drawn from the Counsel’s Memo is guidance with which to address hypothetically a question that has not occurred here, but might conceivably occur in the future: if NTP-CERHR or another authoritative body does evaluate BPA in the future, then OEHHA may review that authoritative body’s report (or other document) to determine whether the authoritative body “concludes that the chemical causes . . . reproductive toxicity” (or whether the document “otherwise identifies” BPA as “causing reproductive toxicity”), taking into account the “sufficient evidence” standard set forth in Section 25306(g). Unless and until that event occurs, however, the Counsel’s Memo simply does not apply to the decision whether BPA should be listed, and certainly has no bearing on whether the Petition should be granted.

to generally accepted principles to cause . . . reproductive toxicity.” Moreover, and as detailed in the next section of these comments, the DART IC was quite clear in explaining why the evidence on BPA fails to satisfy the Section 25306(g) criteria. Under these circumstances, the DART IC’s decision is conclusive. Any attempt to list BPA based on isolated statements in the NTP-CERHR Monograph alone, on the assertion that they constitute a “finding” by the NTP that BPA is a reproductive toxicant, would necessarily be an attempt to list the chemical based on scientific evidence that does not satisfy the Proposition 65 criteria, which would be unlawful

2. *The Petition Ignores the Requirements of Section 25306(g)*

Wholly aside from the crucial point discussed above — that the DART IC’s July 15, 2009 decision not to list BPA is final and precludes an “authoritative body” listing as a matter of law — the Petition should be denied. The questions to be addressed by Section 25306, as well as the requirements for the Agency and the DART IC to refer inquiries back and forth to each other for determinations (1) whether the NTP-CERHR Monograph “formally identified” BPA as “causing reproductive toxicity,” (2) if so, whether that conclusion is supported by “sufficient evidence,” and (3) if not, whether BPA has been “clearly shown to cause reproductive toxicity,” already have been addressed by the DART IC’s deliberations and unanimous votes. It is obvious from the many questions that Section 25306(g) requires to be addressed and the fact that they already have been addressed by the DART IC that the regulations do not contemplate, and should not tolerate, granting the Petition to address the same questions again.

As discussed in Section 3 of these comments, the NTP-CERHR Monograph does *not* “formally identify” BPA as required in Section 25306(d). Thus, OEHHA cannot determine that NTP-CERHR identified BPA “as causing reproductive toxicity” based on scientific data that satisfy the criteria of Section 25306(g), because the DART IC clearly and definitively determined on the record at the July 15 public meeting that the scientific evidence does *not* satisfy those criteria. The scientific evidence in the HID, reviewed by the DART IC at and prior to the public meeting, included all the scientific evidence reviewed by NTP-CERHR, and in addition, included NTP-CERHR’s own discussion of the evidence.

Given that the DART IC explicitly considered the document that the Petition invokes to demand that BPA be listed, the following point bears repeating: at the end of the July 15 hearing, the DART IC was asked three times to vote on whether to list BPA and addressed the following questions:

“Has Bisphenol [A] been clearly shown, through scientifically valid testing, according to generally accepted principles, to cause developmental toxicity?”

“Has Bisphenol [A] been clearly shown, through scientifically valid testing, according to generally accepted principles, to cause female reproductive toxicity?”

“Has Bisphenol [A] been clearly shown, through scientifically valid testing, according to generally accepted principles, to cause male reproductive toxicity?”

Three times, the DART IC voted unanimously that BPA does not meet the listing criteria. “So the Committee . . . voted not to list Bisphenol A.” Tr. at 254-255.

Those unanimous votes by the DART IC are a clear and conclusive judgment that any “formal identification” of BPA in the NTP-CERHR Monograph as a reproductive toxicant was not supported by “sufficient evidence” within the meaning of Section 25306(g). In fact, the record shows that the DART IC reached its decision not to list BPA based on two general conclusions regarding the scientific evidence on BPA:

- (1) that the well-conducted studies described in the NTP-CERHR Monograph as showing “clear evidence of developmental effects at high doses” showed maternal toxicity at the same and lower doses, making the evidence of developmental effects unpersuasive; and
- (2) that the very large number of “unconventional” studies purporting to show effects at low doses did not qualify as “scientifically valid testing according to generally accepted principles.”

These DART IC conclusions expressly address the very factors that are required to be considered under Section 25306(g) in determining whether an authoritative body has “formally identified” a chemical “as causing reproductive toxicity,” as the Petition asserts. *See* Section 25306(d).

Section 25306(g) provides as follows:

“(g) for purposes of this section, “as causing reproductive toxicity” means that either of the following criteria have been satisfied:

“(1) studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity, or

“(2) studies in experimental animals indicate that there are *sufficient data, taking into account the adequacy of the experimental design and other parameters* such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels *and consideration of maternal toxicity*, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.”¹¹

The transcript of the July 15 public hearing demonstrates that the DART IC considered these factors in reaching its unanimous opinion not to list BPA, and also addressed the question whether the passage cited in the NTP-CERHR Monograph satisfies Section 25306(g).

Specifically, the significance of maternal toxicity in the well-conducted multi-generation animal studies performed by Tyl, *et al.* was addressed explicitly by ACC in its written comments on the HID, and by Dr. Solomon (for NRDC) and Dr. Tyl and Dr. Murray (for ACC) in oral presentations at the July 15 hearing, and by the DART IC members themselves in their discussion of the scientific evidence prior to their unanimous votes not to list BPA. The issue was introduced by Dr. Solomon, who argued that the principal studies cited in the NTP-CERHR Monograph showed “clear evidence of adverse effects with high doses . . .” Tr. at 51.

¹¹ Cal. Code Regs., *tit.* 22, § 25306(g) (emphasis added).

Dr. Solomon:

“[T]he conclusion was that they’re not simply secondary to maternal toxicity . . . [M]ost of the ones we’re talking about are the Research Triangle Institute studies by Tyl, et al., the study abstracts when you just read those and the conclusions seem to indicate that the developmental effects are only in the setting of maternal toxicity, might not represent true developmental toxicity.

“And then when you actually go through and you look at the data in the reports, it’s actually quite clear that there are effects in the setting of minimal, if any, maternal toxicity in most of those studies. *And that’s what the CERHR panel based their conclusion of clear evidence of adverse effects on.*” Tr. at 52 (emphasis added).

There is no basis in the NTP-CERHR Monograph to support the assertion that the CERHR panel reached such a conclusion about the role of maternal toxicity in the studies in question. Indeed, DART IC member Roberts immediately pointed out that the peer-reviewed Expert Panel Report concluded that there are “sufficient data” to conclude that BPA does not: “cause malformations or birth defects in fetuses, exposed during gestation at levels up to 640 milligrams per kilogram per day [in rats] than the 1,000 milligrams per kilogram per day [in mice;” (2) “alter male or female fertility in rats after gestational exposure;” (3) “change the age of puberty in male or female rats;” (4) or “permanently affect prostrate weight in adult rats or mice;” and (5) “there are sufficient data [only] *to suggest* that developmental exposures to [BPA] causes neural and behavioral alterations related to sexual dimorphism in rats and mice.” Tr. at 54 (emphasis added).

Dr. Tyl, the principal author of several of the crucial studies, later described those studies in detail. Tr. at 112 – 129. Among other points, Dr. Tyl directly addressed and rebutted assertions that the developmental effects in certain studies at high dose levels were “not simply secondary to maternal toxicity” and that they occurred “in the setting of minimal, if any, maternal toxicity.” Following a detailed description of the design and results of a multi-generation rat study, Dr. Tyl summarized its results as follows:

Dr. Tyl:

“[W]e only saw . . . reproductive and developmental effects of BPA at a dose that was clearly systemically toxic and at a dose that was lower than that and still toxic, we still didn’t see anything.

“We concluded that BPA was not considered a selective reproductive or developmental toxicant in rats. Okay, because *you didn’t see the reproductive or developmental effects, unless you also saw maternal toxicity.* And even at lower maternal toxicity, you didn’t see the effects.” Tr. at 118 (emphasis added).

Dr. Tyl went on to explain that because there was some (unfounded) criticism that the rat strain used in the foregoing study was “insensitive” to estrogenic effects, her laboratory was commissioned to perform a comparable study on mice. Tr. at 119. Dr. Tyl described in detail the performance of a “range-finding” study with estradiol, a known estrogen, to set dose levels for the subsequent two-generation mouse study. Tr. at 119 – 121. Dr. Tyl then described in detail the design, and the results, of the two-generation mouse study itself. Tr. 122 – 124.

Dr. Tyl:

“We got adult systemic toxicity at the top two doses, sound vaguely familiar. Hepatic histopathology at 50. And at 600 milligrams per kilogram per day, we got reduced body weights. We got increased liver and kidney weights. And we saw the same kind of histopathological problems in the liver and the kidneys.

*“The developmental effects at 600 milligrams per kilogram per day, included delayed testis descent, which you normally see in the last week of lactation. It ultimately happened, but it happened slightly later. Transient hypoplastic testes, because we looked at weanling animals histopathologically, and slightly delayed acquisition of puberty in offspring males okay, considered not driven by estrogenic activity, but **likely secondary to systemic tox.***

*“We saw no effects on adult reproductive functions, including andrology or structures, included testes, epididymides, prostate, ovaries, mammary glands, uterus/cervix. And we looked at those in the weanlings and the adults for the F0 adults, the F1 weanlings, the F1 adults and then the F2 weanlings. There were no low dose effects again at .5 to .003 milligrams per kilogram per day. No evidence for non-monotonic dose response curves for any parameter at any dose in any generation. Responses to the E2 positive control, confirmed the sensitivity of the CD-1 mouse to estrogens and confirmed the findings that we had presented for the one-gen and the two-gen[] study, because **we only saw effects in the presence of systemic tox, and only at the highest dose. And the second to highest dose also has systemic tox and no reproductive or developmental effects.** We considered BPA was not a selective reproductive or developmental toxicant in mice either. Tr. at 124 – 125 (emphasis added).*

* * * * *

*“[S]o BPA is not a selective developmental reproductive toxicant in rats or mice. **The reproductive and developmental effects seen at high BPA-dietary doses are only observed in the presence of systemic tox. So they are considered secondary to the systemic toxicity observed.***

“[T]here was no evidence of effects at low BPA doses and no non-monotonic dose response curves in any parameter in either species in rats or in mice at any dose level.

“[T]he interesting thing is the insensitive rat and the sensitive mouse have exactly the same systemic and reproductive NOELs, which I think is fascinating.

“[T]he final comment is the BPA reproductive and developmental effects observed at these high doses are not consistent with estrogenic activity. We know what the normal estrogenic activity should be, because we did the one- and two-generation E2 studies to make sure we could document those. And the effects we saw at high doses are not those associated with an estrogen.” Tr. at 126 – 127 (emphasis added).

Dr. Murray followed Dr. Tyl. Dr. Murray’s oral comments contradicted Dr. Solomon’s claims about CERHR’s “conclusions,” Tr. at 131 – 132, and concurred with Dr. Tyl’s

conclusions. Dr. Murray also addressed the large number of “unconventional” studies listed in the HID. He noted that CERHR had described many of these studies as “inadequate or of limited utility,” Tr. at 133, and went on to draw attention to a long list of shortcomings in terms of study design, route of administration, inadequate numbers of test animals, etc. Tr. at 133 – 136. Dr. Murray concluded that the weight of the scientific evidence clearly did not support listing BPA. Tr. at 138 – 139.

Ultimately, of course, the DART IC’s conclusions on the evidence and arguments presented to it are what matter. The record is quite clear that the DART IC concluded that adverse developmental effects observed in the high dose studies occurred only in the presence of significant maternal toxicity, and that the numerous unconventional studies listed in the HID were too inconsistent and of insufficient quality to satisfy Proposition 65’s “clearly shown” standard:

Committee Member Roberts, addressing developmental toxicity:

“We referred to high dose studies. *The high dose studies have clear evidence of developmental toxicity. They do occur in the presence of maternal toxicity. And the issue isn’t whether or not developmental toxicity occurs. It’s whether or not there is sufficient maternal toxicity to potentially be causing the other.*

“And when you have situations where the animals are either losing weight or gaining very little weight or they’re described as emaciated, that to me can be a cause of something like an increase in resorptions prenatally. Surprisingly, *even when there were some fairly strong forms of maternal toxicity, it did not cause malformations. So it doesn’t seem that that particular endpoint out of the four is of concern.*

“When there is maternal toxicity, it does have a decrease in fetal body weight. It has an increase in prenatal loss. Those are both endpoints that are more commonly associated with severe maternal toxicity than others.

“And a decrease in ossification does not – as long as it is a decrease in ossification, and not a structural change, it tends to go along with decrease in fetal body weight.” Tr. at 236 – 237 (emphasis added).

Committee Member Keen, following Dr. Roberts:

“My reading of the binders was remarkably similar to what you read. As is usually the case, I’d like to really compliment OEHHA for bringing a lot of these together, because I think the materials that we got were – I’ll use the word “overwhelming”, but in a positive sense of the word. It gave a pretty good comprehensive view of what the state of the literature is. I just want to iterate some of the points so it’s clear that we’re pretty much on the same page.

“As I look at the literature, *I see very little evidence that there is an increased risk, absence of maternal toxicity [sic.; what Dr. Keen said was “absent maternal toxicity” or “in the absence of maternal toxicity”]*, of fetal or neonatal mortality. I don’t see any clear trends for malformations or specific birth effects. No clear evidence of reduced birth weight or growth.

“In the occasional paper, and there’s over 70, which I went back and read each of the individual papers, you’ll find a sporadic report of something. But where I get a little concerned or actually quite concerned is the lack of consistency as you go across the reports.” Tr. at 238 – 239 (emphasis added).

As to the balance of the data, including the so-called “‘low’ dose studies,” the following comments illustrate the panel’s conclusions:

Committee Member Keen:

“[A]s I read the literature now, it’s confusing, and it doesn’t, by any criteria, meet my definition of clear. So I’ll stop at that point.” Tr. at 243.

Chairperson Burk, following Dr. Keen:

“But again, *most of the studies are not our generally accepted sort of things, due to the numbers, as you mentioned, and the, you know, single dose and all those kind of things.*” Tr. at 243 (emphasis added).

Committee Member Keen:

“But I think it’s also worth noting those as when they did signal some out as being, what they thought I guess were, the more robust studies, I see females no effect, males no effect.” Tr. at 248 (emphasis added).

Committee Member Roberts, following Dr. Keen:

“I’m looking at the NTP brief on page 20. And on the left-hand column, it says, *“Overall the current literature cannot yet be fully interpreted for biological or experimental consistency or for relevance to human health”*, which implies that they think that something may come of this in the future, but they are not there yet.” *Id.* (emphasis added).

Thus, the record is clear. The question of whether the “clear evidence of developmental effects at high doses” in certain studies was, or was not, secondary to maternal toxicity was presented squarely to the DART IC for its decision, and the Committee decided clearly that it was. It is also clear that the DART IC – like NTP-CERHR and other expert agencies that have reviewed them – considered the numerous “unconventional” studies to fall well short of Proposition 65’s standard of “clearly shown” and “generally accepted principles.”

We recognize that under ordinary circumstances, where there has not been a recent and conclusive DART IC review of the scientific evidence on a particular chemical, OEHHA staff would perform only a limited review of the evidence that an authoritative body such as NTP-CERHR relied upon in reaching a “conclusion” that is the basis for a potential authoritative body listing. We also recognize that in such a limited review, OEHHA staff would not necessarily discern that NTP’s observation of “clear evidence of developmental effects” failed to note that such effects were secondary to maternal toxicity, and similarly, that OEHHA staff would not necessarily conclude on their own initiative that the numerous “unconventional” studies on BPA do not satisfy Proposition 65 standards. But this is not an “ordinary circumstance” and OEHHA staff cannot ignore the facts of DART IC’s clear findings and conclusions. To do so would be an abuse of discretion and a conscious, willful disregard of plainly relevant information.

Finally, in the almost unconceivable event that OEHHA were to determine that in *its* opinion (putting aside whatever DART IC thinks . . .) the scientific data satisfy the criteria of Section 25306(g), OEHHA would be required to propose its intention to list BPA pursuant to Section 25306(i). For reference, the full text of Section 123206(i) is quoted below:

“(i) At least 60 days prior to adding a chemical determined to have been formally identified by an authoritative body as causing . . . reproductive toxicity to the list of chemicals known to the state to cause . . . reproductive toxicity, the lead agency shall cause to be published in the California Regulatory Notice Register a notice identifying the authoritative body and the chemical, and stating the lead agency’s intention to cause the chemical to be added to the list. *Copies of the notice shall be provided to . . . the DART Identification Committee . . . to permit the . . . Committee at least 30 days to review and comment on the proposed action.*

“*Within 30 days following the publication of the notice, interested parties, including any member of the appropriate Committee, shall submit to the lead agency their written objections to the addition of the chemical to the list of chemical known to the state to cause . . . reproductive toxicity, along with any supporting documentation. Objections shall be made on the basis that there is no substantial evidence that the criteria identified in subsection . . . (g) have been satisfied.*

“The lead agency shall review such objections. If the lead agency finds that there is no substantial evidence that the criteria identified in subsection . . . (g) have been satisfied, *the lead agency shall refer the chemical to the . . . Committee to determine whether, in the Committee’s opinion, the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause . . . reproductive toxicity.*”¹²

We have demonstrated above that the DART IC already has rendered opinions as to whether the data that are the subject of the passage in the NTP-CERHR Monograph on which the Petition relies satisfy the requirements of Section 25306(g). To repeat, however, the many comments of the DART IC on the public record, as well as the Committee’s unanimous votes, demonstrate unequivocal conclusions on the part of all seven DART IC members that the isolated statements in the NTP-CERHR Monograph do not satisfy those requirements.

Thus, in order to grant the Petition, OEHHA, in the name of the Director, would have to serve on the seven Panel members written notice that she disagrees with and desires to supersede their conclusion. Presuming that the Panel members (all of whom are fully employed in positions of considerable responsibility and who serve as Committee members without pay, assistants, or clerical staff) take the time to object to the proposed listing and to repeat their publicly recorded statements and votes, the Director then would have to overrule those objections again. Or, if the Director *agreed* with those objections, she would be called upon to refer BPA to the DART IC yet again, this time to “determine” whether BPA “has been clearly shown to cause . . . reproductive toxicity.”

¹² Cal. Code Regs., *tit.* 22, § 25306(g) (emphasis added; reformatted for clarity).

It should be obvious from reading Section 23506(i) that the authoritative body listing mechanism was not contemplated to create such a circular process. Given that the DART IC already has rendered its opinions in a lengthy public hearing, following the submission of written materials, oral testimony from experts, extensive deliberations, and unanimous votes on both of the scientific and legal conclusions that Section 23056(i) would require, it is clear that Section 23056(i) does not contemplate repeating that process to address the same questions again, and OEHHA should not compel them to do so by granting the Petition.

Rather, OEHHA should acknowledge and respect the conclusions of the DART IC as the State's qualified experts, and recognize that as a matter of both fact and law, the Committee has already decided that "there is no substantial evidence that the criteria of [Section 25306(g)] have been satisfied." On this basis alone, OEHHA should deny the Petition, without reaching the merits of its underlying argument.

3. *NTP Has Not "Formally Identified" BPA as "Causing Reproductive Toxicity"*

In order for BPA to be listed as a reproductive toxicant under the "authoritative bodies" mechanism, the chemical must be "formally identified" by an "authoritative body" as causing as "causing reproductive toxicity." There is no dispute that the NTP is an "authoritative body" for this purpose.¹³ It is equally clear, however, that NTP has not "formally identified" BPA as a "causing reproductive toxicity."

Section 25306(d)(1), quoted below, establishes three ways in which a chemical may be "formally identified:"

"For purposes of this section, a chemical is '*formally identified*' by an authoritative body when [OEHHA] determines that . . . the chemical . . .

"has been included on a list of chemicals causing . . . reproductive toxicity; or

"is the subject of a report which is published by the authoritative body and *which concludes that the chemical causes . . . reproductive toxicity*; or

"has otherwise been identified as causing . . . reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action"^{14,15}

Obviously, BPA has not been "included on a list," so there is no claim that BPA has been "formally identified" in that manner. Rather, the Petition *appears* to claim that BPA has been "formally identified" in *both* the second and third manner, asserting that BPA "is the subject of a final report [*i.e.*, the NTP-CERHR Monograph] which concludes that the chemical causes

¹³ See Cal. Code Regs., *tit.* 22, § 25306(1)(3).

¹⁴ Cal. Code Regs., *tit.* 22, § 25306(D)(1) (emphasis added).

¹⁵ The same regulation goes on, at subsection (2), to establish various alternative criteria by which a "list, report, or document" referred to in subsection (1) may be published or adopted for purposes of the regulation. See Cal. Code Regs., *tit.* 22, § 25306(D)(2). Publication or adoption is not at issue here.

reproductive toxicity,” and that “the report identifies [BPA] as causing reproductive toxicity in a document that indicates that such identification is a final action following peer review and public comment.”

Therefore, it is appropriate to examine the differences between a “*report*” that “concludes that the chemical causes . . . reproductive toxicity” and another “*document*” in which a chemical “has otherwise been identified as causing . . . reproductive toxicity,” and to analyze what the regulation contemplates in designating these two distinctly different types of publications as separate bases for listing. The Statement of Reasons illustrates the difference, and indicates that an authoritative body *report* that is commissioned for the express purpose of examining a chemical for its potential to cause adverse reproductive effects and does not conclude that the chemical “causes reproductive toxicity” is not intended to serve as a *document* that “otherwise” “identifies” the same chemical as “causing . . . reproductive toxicity.”

“SUBSECTION (D)

“Subsection (d) defines the circumstances under which a chemical is ‘formally identified’ within the meaning of section 25249.8 [of the Act]. . . . Subsection (d) goes on to describe these requirements in paragraphs (1) and (2).

“*Paragraph (d)(1) requires some kind of written identification.* Specifically, the chemical must

“(1) *be included on a list* of chemicals causing . . . reproductive toxicity, or

“(2) *be the subject of a report* which is published by the authoritative body *concluding that the chemical causes . . . reproductive toxicity*, or

“(3) *be otherwise identified as causing . . . reproductive toxicity* by the authoritative body *in a document which indicates that such identification is a final action.*

“Lists and reports are methods of identification commonly used by governmental and non-governmental entities alike to identify chemical hazards.

“However, *in order to permit the designation of authoritative bodies which use other methods to identify chemical hazards, the paragraph permits identification of such hazards in other documents dealing with the chemical which include some indication that the identification of the chemical . . . as a reproductive toxicant is a final action.*

“*The Agency recognizes that many organizations which may be considered authoritative do not treat the identification of chemical hazards as a regulatory endpoint.* For them, the regulatory endpoint is the adoption of an exposure or discharge limit for a chemical, once it has been determined that the chemical poses a hazard. Hazard identification is simply one step toward the ultimate determination of a regulatory exposure limit, tolerance, level, etc. *Documents explaining or noticing the progression of an exposure or discharge limit, tolerance or other standard through the regulatory process will likely identify a chemical as a . . . reproductive hazard with finality* long before the standard is finally adopted.

“It is the intention of the Agency that such an identification will be sufficient indication of a ‘final action’ on the issue of hazard identification to conclude that the chemical has been ‘formally identified.’”

Statement of Reasons, 11 (emphasis added; reformatted for clarity).

The Statement of Reasons and the regulations effectively treat both authoritative body “lists of chemicals causing . . . reproductive toxicity” and “reports concluding that [a] chemical causes reproductive toxicity” as self-identifying. Thus, they explain in detail only what is meant by a “document” in which a chemical may be “otherwise identified as causing . . . reproductive toxicity.” In describing such documents, the Statement of Reasons ascribes them to agencies that “do not treat the identification of chemical hazards as a regulatory endpoint,” yet “identify a chemical as a . . . reproductive hazard with finality” as part of the progression toward establishing a regulatory “standard,” (e.g., a “regulatory exposure limit, tolerance, level, etc.).”

With this background in mind, it is clear that the NTP-CERHR Monograph is not a “report . . . which concludes that the chemical causes . . . reproductive toxicity,” *and* that BPA is not “otherwise identified” in the Monograph as “causing . . . reproductive toxicity.” Both of these issues are addressed separately below.

A. *The NTP-CERHR Monograph NTP Does Not “Conclude” that Bisphenol A “Causes Reproductive Toxicity”*

The Petition argues that the NTP-CERHR Monograph “concluded that bisphenol A can affect human development or reproduction” In support of that argument, the Petition cites an isolated passage from the NTP Brief indicating that “studies with laboratory rodents show that exposure to high dose levels of bisphenol A during pregnancy and/or lactation can reduce survival, birth weight and growth of offspring early in life, and delay the onset of puberty in males and females” and quotes another sentence fragment indicating that these effects are “not considered scientifically controversial and provide clear evidence of adverse effects” Petition at 2, citing the NTP Brief at 6-8.

As we pointed out in the introduction to these comments, this characterization of these statements from the NTP-CERHR Monograph is incomplete and misleading. The truncated quotations omit important portions of the sentences attributing the studies and effects only to “laboratory animals,” and ignore two vitally important qualifications to both statements, which read: (1) “These effects were seen at the same dose levels that also produced some weight loss in pregnant animals (‘dams’)” and (2) “However, the estimated dose levels associated with delayed puberty (≥ 50 mg/kg bw/day), growth reductions (≥ 300 mg/kg bw/day), or survival (≥ 500 mg/kg bw/day) are far in excess of the highest estimated daily intake of bisphenol A in children.” NTP Brief at 7. Moreover, the entire discussion comes under a heading, rhetorically styled as a question, in which the NTP asks: **“CAN BISPHENOL A AFFECT HUMAN DEVELOPMENT OR REPRODUCTION?,”** to which NTP responds only *“Possibly.”* NTP Brief at 6 (emphasis in original). Thus, the passage from which the Petition quotes and cites as its very basis does not support a fair argument that the NTP-CERHR Monograph “concludes” that BPA causes reproductive toxicity.

The manipulation and truncation of selective quotes from the NTP Brief, so easily rebutted and explained, would not be important except for this larger point: in deciding whether to grant the Petition, OEHHA must read the NTP-CERHR Monograph as a whole.¹⁶ All of the statements in the NTP Brief should be read in context and in light of the accompanying Expert Panel Report, so that their meaning is not distorted. It is particularly important to discuss the *conclusions* articulated in these documents, because they were written very deliberately and clearly *not* to conclude that BPA is a reproductive toxicant.

For your convenience, we have reproduced the pertinent portions of the NTP Brief below. The most appropriate place to begin is the section entitled “Abstract,” which states the purpose of the NTP evaluation of bisphenol A – to evaluate the potential for adverse effects in humans – and the conclusions that NTP reached. The conclusions are quoted in full below, and are stated with such clarity as to speak for themselves.

“ABSTRACT

“NTP-CERHR MONOGRAPH ON THE POTENTIAL HUMAN REPRODUCTIVE AND DEVELOPMENTAL EFFECTS OF BISPHENOL A

“The National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) conducted an evaluation of the potential for bisphenol A to cause adverse effects on reproduction and development *in humans*. The CERHR Expert Panel on Bisphenol A completed its evaluation in August 2007. [Emphasis added].

“CERHR selected bisphenol A for evaluation because of the

- Widespread human exposure
- Public concern for possible health effects from human exposures
- High production volume
- Evidence of reproductive and developmental toxicity *in laboratory animals* [Emphasis added.]

[Remainder of paragraph omitted.]

“The results of this bisphenol A evaluation are published in an NTP-CERHR Monograph that includes the (1) NTP Brief and (2) Expert Panel Report on the Reproductive and Developmental Toxicity of Bisphenol A. [Remainder of paragraph omitted.]

“The NTP reached the following *conclusions* on the *possible* effects of exposure to bisphenol A on human development and reproduction. Note that the possible levels of concern, from lowest to highest, are negligible concern, minimal concern, some concern, concern, and serious concern. [Emphasis added.]

¹⁶ See *Exxon Mobil Corporation v. OEHHA*, 169 Cal. App. 4th 1264, 1285 (2009) (NTP-CERHR Monograph and NTP Brief must be considered together in determining whether NTP considered factors prescribed by Section 25306(g)).

“The NTP has *some concern* for effects on the brain, behavior and prostate gland in fetuses, infants, and children at current human exposure to bisphenol A.

“The NTP has *minimal concern* for effects on the mammary gland and earlier age for puberty for females in fetuses, infants, and children at current human exposures to bisphenol A.

“The NTP has *negligible concern* that exposure to pregnant women to bisphenol A will result in fetal or neonatal mortality, birth defects or reduced birth weight and growth in their offspring.

“The NTP has *negligible concern* that exposure to bisphenol A will cause reproductive effects in non-occupationally exposed adults and minimal concern for workers exposed to higher levels in occupational settings.

[Final paragraph omitted.]”¹⁷

These conclusions, even drawn from the abbreviated “Abstract” of the NTP-CERHR Monograph, establish premises that are critical in determining whether to grant the Petition. First, as a general matter, they establish that the NTP Brief and the Expert Panel Report on the Reproductive and Developmental Toxicity of Bisphenol A are both parts of the NTP-CERHR Monograph.¹⁸ In this regard, the NTP Brief largely summarizes the voluminous and technically drafted Expert Panel Report in lay terminology, adopting the findings of the Expert Panel except where indicating otherwise. Thus, it is clear that the NTP Brief and Expert Panel Report are two complementary documents to be read as a whole, one supplementing the other, and that discrete statements from within either document should not be read in isolation, and certainly should not be read to contradict the NTP *conclusions*.

Second, as to the substance of the Monograph, it is clear from the “Abstract” that NTP conducted its evaluation for the purpose of analyzing the potential for exposure to bisphenol A to cause reproductive toxicity *in humans*, that based its evaluation in part on test data from studies conducted *on laboratory animals*, and that NTP’s highest level of concern for any reproductive toxicity endpoint in humans, using NTP’s nomenclature, was only “some concern.”

The obvious conclusions that OEHHA should draw from these statements in evaluating the Petition are two. The first is stated explicitly: NTP did not *conclude* that bisphenol A is a reproductive toxicant *in humans*. The second, though stated implicitly, is no less clear: The animal data on which NTP relied, although they showed “evidence of reproductive and developmental toxicity *in laboratory animals* (emphasis added),” did not cause NTP to conclude that bisphenol A is a reproductive toxicant *in humans*.

These conclusions are manifest throughout the body of the NTP Brief, discussed below. The thrust of the NTP Brief addresses the key, indeed dispositive, question that OEHHA should address in evaluating the Petition: whether BPA is a reproductive toxicant *in humans*. That portion of the NTP Brief begins on page 6 and is reproduced in pertinent part below.

¹⁷ NTP Brief at vii-viii (emphasis in original, except as indicated).

¹⁸ See *Exxon Mobil Corporation v. OEHHA*, cited at n. 12, *supra*.

“CAN BISPHENOL A AFFECT HUMAN DEVELOPMENT OR REPRODUCTION?”

“Possibly. [Emphasis in original].

“Although there is no direct evidence that bisphenol A adversely affects reproduction or development, *studies with laboratory rodents show that exposure to high dose levels of bisphenol A during pregnancy and/or lactation can reduce survival, birth weight, and growth of offspring early in life, and delay onset of puberty in males and females.* [Emphasis added.]

“These effects were seen at the same dose levels that also produced some weight loss in pregnant animals (“dams”).

“These “high” dose effects of bisphenol A are not considered scientifically controversial and provide clear evidence of adverse effect on development *in laboratory animals.*

“However, *the administered dose levels associated with delayed puberty* (≥ 50 mg/kg bw/day), *growth reductions* (≥ 300 mg/kg bw/day), *or survival* (≥ 500 mg/kg bw/day) *are far in excess of the highest estimated daily intake of bisphenol A in children* (< 0.0147 mg/kg bw/day), *adults* (< 0.0015 mg/kg bw/day), or *workers* (0.100 mg/kg bw/day).”¹⁹ [Emphasis added.]

The key word in this passage is **“Possibly.”**²⁰ In addressing the direct question whether bisphenol A can affect human development or reproduction, NTP’s informed response, based on the painstaking review of hundreds of studies evaluated and summarized in the Expert Panel Report, was only **“possibly.”** This word speaks volumes when one is acquainted with the NTP’s scale of responses to this question. NTP did not answer “Yes,” which would indicate a conclusion that BPA is a reproductive toxicant, or “Probably,” which would indicate that BPA is probably a reproductive toxicant. Rather, NTP indicated only that BPA may “possibly” affect human development or reproduction.

The remainder of the passage, following the answer **“Possibly,”** is equally important. In a single paragraph, NTP captures the essence of the scientific controversy between the proponents of listing BPA (represented by the Petitioner) and the mainstream scientific community (represented by every regulatory body, including the DART IC, that has evaluated bisphenol A). As NTP summarizes, there is a body of data that do indeed show “adverse effects on development in laboratory animals.” These effects occurred in the presence of maternal toxicity: “These effects were seen at the same dose levels that also produced some weight loss in pregnant animals (‘dams’).” Because these data come from studies that were well-conducted, according to generally accepted scientific principles, they are “not considered scientifically controversial.” *However*, the adverse developmental effects seen in these studies were produced only when the test animals were subjected to bisphenol A at extremely high doses, thus giving rise to the term the “‘high’ dose effects.”

¹⁹ NTP Brief at 6-7 (reformatted for clarity).

²⁰ “Answers to this and subsequent questions [posed in the NTP Brief] may be: Yes, Probably, Possibly, Probably Not, No or Unknown.” NTP Brief at 1, note 4.

The NTP Brief then takes care to explain that these high dose effects are virtually irrelevant to the NTP’s analysis, because the dose levels administered were so “far in excess of the highest amount” to which humans are known to be exposed. Indeed, those dose levels were *orders of magnitude* higher than the “highest estimated daily intake of bisphenol A in children . . . , adults . . . or workers”

The NTP went on to examine the so-called “‘low’ dose findings,” from a body of studies about which there *is* “scientific controversy.”²¹

“In addition to effects on survival and growth seen at high dose level of bisphenol A, *a variety of effects* related to neural and behavior alterations, potentially precancerous lesions in the prostate and mammary glands, altered prostate gland and urinary tract development, and early onset of puberty in females *have been reported in laboratory rodents exposed during development to much lower doses of bisphenol A (≥0.0024 mg/kg bw/day) that are more similar to human exposure.* In contrast to the “high” dose developmental effects of bisphenol A, there is scientific controversy over the interpretation of the “low” dose findings. When considered together, *the results of the “low” dose studies of bisphenol A provide limited evidence for adverse effects on development in laboratory animals (see Figures 2a & 2b).* [Emphasis added.]

“Recognizing the lack of data on the effects of bisphenol A in humans and *despite the limitations in the evidence for “low” dose effects of laboratory animals discussed in more detail below, the possibility that bisphenol A may alter human development cannot be dismissed (see Figure 3).*” [Emphasis added.]²²

NTP thus concluded that the “low dose findings” (due to their scientific inadequacies), provided only “limited evidence” of adverse effects on development in laboratory animals and, therefore, there was “some concern” that exposure to bisphenol A “possibly” may result in developmental effects in humans. They further show that NTP did not “conclude” that BPA is a reproductive or developmental toxicant in humans.

The next section of the NTP Brief, entitled “Are Current Exposures to Bisphenol A High Enough to Cause Concern?” further makes this clear.

“ARE CURRENT EXPOSURES TO BISPHENOL A HIGH ENOUGH TO CAUSE CONCERN?”

“*Possibly.* [Emphasis in original.]

The “high” dose effects of bisphenol A in laboratory animals that provide clear evidence for adverse effects on development, i.e., reduced survival, birth weight, and growth of offspring early in life, and delayed puberty in female rats and

²¹ Because OEHHA is familiar with the many scientific inadequacies of the “low dose” data, we will not elaborate here. Those inadequacies are described in detail, however, pages 9-15 of the NTP Brief.

²² NTP Brief at 7 (emphasis added).

male rats and mice, *are observed at levels of exposure that far exceed those encountered by humans.*

“However, estimated exposure in pregnant women and fetuses, infants, and children are similar to levels of bisphenol A associated with several “low” dose laboratory animal findings of effects on the brain and behavior, prostate and mammary gland development, and early onset of puberty in females. When considered together, these laboratory animal findings provide limited evidence that bisphenol A has adverse effects on development (Figure 2b).

“Exposure in humans and laboratory animals can be compared using approaches based on either estimated daily intake (based on aggregating biomonitoring data) or measured blood concentrations of free bisphenol A. Each approach has a unique set of assumptions and limitations.

“The conclusion of *similarities between exposures of certain human populations and laboratory animals treated with “low” doses* of bisphenol A is supported by multiple approaches. *For this reason, the possibility that human development may be altered by bisphenol A at current exposure levels cannot be dismissed.*”²³

In other words, NTP concluded that the “high dose findings” occurred at doses that so far exceeded exposures to humans as to be outside the realm of human experience, thus rendering the results of questionable relevance in predicting effects in humans. Rather it was the “low dose findings” that gave the NTP “some concern.” *Yet, these data supported only a finding of “Limited evidence of adverse effects,”²⁴ clearly not a conclusion that BPA was “formally identified” for purposes of Section 25306(d)(1).*

The final section of the NTP Brief, entitled “NTP Conclusions,” summarizes the NTP’s thinking concisely. The NTP Conclusions demonstrate clearly that it was the “low dose findings” that were the source of “some concern,” and is supported by only “limited evidence.”

“NTP CONCLUSIONS

“The NTP reached the following conclusions on the possible effects of exposure to Bisphenol A on human development and reproduction. Note that the possible levels of concern, from lowest to highest, are negligible concern, minimal concern, some concern, concern, and serious concern.”

“The NTP has some concern for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A. [Emphasis in original.]

“The NTP concurs with the conclusion for the CERHR Expert Panel on Bisphenol A that the scientific evidence supports a conclusion of *some concern* [emphasis in original] for exposures in fetus, infants and children *based on a*

²³ NTP Brief at 34 (reformatted for clarity; emphasis added, except as indicated).

²⁴ NTP Brief at 8, Figure 2b.

number of laboratory animal studies reporting that “low” level exposure to bisphenol A during development can cause changes in the brain and behavior.

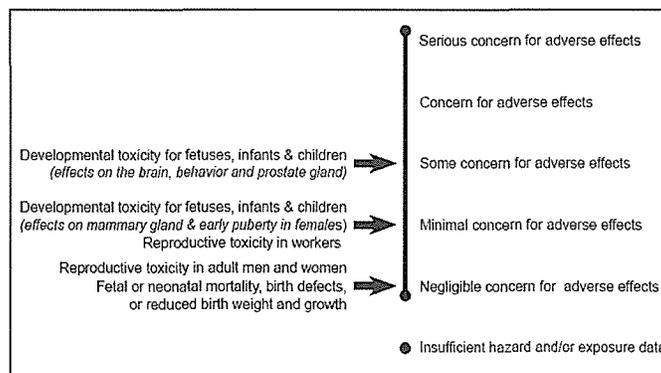
*“In addition, the NTP has some concern for exposures to these populations based on effects on the prostate gland observed in [a low dose study in] laboratory animals. This level of concern for effects on the prostate gland is higher than that expressed by the Expert Panel and is based primarily on new supportive data related to (1) the interpretation of studies that use a non-oral route of administration in neonatal rodents, and (2) an additional publication reporting subtle cellular changes in the prostate gland. These reports were not published when the Expert Panel completed its deliberations. **These studies in laboratory animals provide only limited evidence for adverse effects on development and more research is needed to better understand their implications for human health.***

“However, because these effects in animals occur at bisphenol A exposure levels similar to those experienced by humans, the possibility that bisphenol A may alter human development cannot be dismissed.”²⁵

Thus, in summary, the NTP concluded that exposure to bisphenol A causes only “*some concern*” for adverse developmental effects in humans, and qualified that conclusion further by noting that it was supported only by “limited evidence.” By contrast, the “high dose findings,” which are the subject of the Petition, supported only a “*negligible concern*” for “fetal or neonatal mortality, birth defects or reduced birth weight and growth in . . . offspring” arising from exposure to pregnant women, or for “reproductive effects in non-occupationally exposed adults” and “*minimal concern* for workers exposed to higher levels in occupational settings.” None of these findings support a conclusion that the NTP-CERHR Monograph “concluded” that BPA is a reproductive toxicant for purposes of Section 25306(d)(1).

Figure 3, reproduced below, summarizes the conclusions graphically.

Figure 3. NTP conclusions regarding the possibilities that human development or reproduction might be effected by exposure to bisphenol A



Significantly, the effects for which NTP has “some concern” are not sufficient to warrant listing under Proposition 65.

²⁵ NTP Brief at 38 (emphasis added, except as indicated). The remainder of the NTP Conclusions, in which NTP expressed even lower levels of concern for other potential effects, need not be considered here, except to reinforce even further the fact that NTP did not conclude that BPA is a reproductive toxicant.

B. *BPA Is Not “Otherwise Identified” in the NTP-CERHR Monograph as “Causing . . . Reproductive Toxicity”*

Given the conclusions from the NTP Brief summarized and analyzed above — wherein NTP so carefully avoided any conclusion that bisphenol A is a reproductive toxicant — it would be counterintuitive and illogical to conclude that the very same NTP Brief “otherwise identified” BPA as causing reproductive toxicity. Yet that is exactly what the Petition requests OEHHA to do. We demonstrate below that this illogical result can be reached only by misreading the Proposition 65 regulations.

As summarized above, the Statement of Reasons indicates that the purpose of the clause in Section 25306(d)(1) that allows a chemical to be considered for listing where it “has otherwise been identified as causing . . . reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action” is to address the situation where an agency considered to be “authoritative” (such as the federal Environmental Protection Agency) may evaluate the carcinogenic or reproductive potential of a chemical in the course of reaching a regulatory decision, but may not issue a formal report on that issue, either because that is not the primary purpose of the regulatory decision for which the document is generated or because that determination was reached at an earlier point in the progression toward that regulatory decision. In such a circumstance, *i.e.*, where the agency’s document does not “conclude that the chemical causes . . . reproductive toxicity,” but nevertheless “otherwise . . . identif[es the chemical] as causing reproductive toxicity,” the chemical may be considered for listing, provided that the authoritative body’s document is one that “indicates that such identification is a final action.”²⁶

The NTP-CERHR Monograph does not fit this description. According to the NTP Brief itself, the NTP’s express purpose was to conduct “an evaluation of the potential for bisphenol A to cause adverse effects on reproduction and development in humans.” In response to that mandate, NTP concluded only that there was “*some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A.” The report thus did not “conclude[] that the chemical causes . . . reproductive toxicity,” and therefore can not serve as a basis for listing BPA under Proposition 65. Given this conclusion, it is impossible to read a single statement (or any collection of statements) from the report to “identify” BPA as “causing . . . reproductive toxicity,” when portions of the report that are labeled as *the “Conclusions,” and the document as whole, do not “conclude” that BPA “causes . . . reproductive toxicity.”*

In effect, the Petition thus requests OEHHA to “substitute its judgment for that of the authoritative body,” which OEHHA is not allowed to do.²⁷ Section 25306(d)(1) was not intended, and should not be invoked now, as a reason to reach behind the conclusions expressed so clearly in the NTP Brief by citing the NTP’s characterization of some of the data it examined when it reached its conclusion that bisphenol A presents no more than “*some concern.*”

²⁶ Statement of Reasons, at 11, explaining the purpose of Section 25306(d)(1), also quoted in full above.

²⁷ Statement of Reasons at 18.

C. *The NTP-CERHR Monograph Does Not Identify Bisphenol A “as Causing Reproductive Toxicity” Within the Meaning of Section 25306(g)*

If, notwithstanding the objections above, OEHHA now were to issue a Notice of Intent to List BPA, the ultimate question would be this: Does the NTP’s characterization of the “‘high’ dose effects” referred to at page seven of the NTP Brief identify BPA “as causing reproductive toxicity” within the meaning of Section 25306(g)(2)? For the reasons below, the Petition fails to satisfy this standard, as well.

Section 25306(g)(2) assigns a special meaning to this term:

“(g) for purposes of this section, “*as causing reproductive toxicity*” means that either of the following criteria have been satisfied:

“(1) studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity, or

“(2) studies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.”²⁸

As discussed in Sections 1 and 2 of these comments, the determination whether BPA can be identified “as causing reproductive toxicity” already has been made. The transcript of the July 15 public meeting demonstrates that the State’s qualified experts reviewed the entire NTP-CERHR Monograph, including the cited passage of the NTP Brief. Indeed, the Petitioner’s Dr. Solomon expressly brought this passage to the attention of the DART IC in her oral presentation.

First, Dr. Solomon argued that the DART IC could or should list BPA on the basis of the asserted finding in the NTP Brief, as well as in their own right.

Dr. Solomon:

“ . . . [*W*]hat I just wanted to do at the beginning was point our one key sort of *backstop that I feel like there is in this decision*. And that is the [NTP Brief]. That report was finalized actually after this panel had already decided to prioritize BPA and bring it here. Their final report came out nearly a year ago Tr. at 50 (emphasis added).

In support of her argument, Dr. Solomon focused on the NTP’s characterization of the “weight of the evidence” that BPA causes adverse developmental effects in laboratory animals, quoting from Figure 2b, at page seven of the NTP Brief, enumerating the alleged adverse effects.

²⁸ Cal. Code Regs., tit. 22, § 25306(g) (emphasis added).

Dr. Solomon:

“CERHR found that there’s “Clear evidence of adverse effects” with high doses of BPA in guideline studies in looking at five developmental outcomes: Fetal death in rats, decreased litter size in rats, decreased number of live pups per litter in rats and mice, reduced growth in rats and mice, and delayed puberty in male and female rats and in male mice. Tr. at 51 (emphasis added).

Dr. Solomon referred to “eight studies” as supporting her conclusion:

Dr. Solomon:

“The NTP cited eight studies showing these effects. And there was quite a bit of consistency in the findings. And you heard many of these studies again today and additional studies as well.” Tr. at 51.

Then, Dr. Solomon argued her interpretation of the data, contending that the maternal toxicity was “minimal, if any”:

Dr. Solomon:

“The effects were found at fairly high dose levels, but CERHR and also reviewed by OEHHA staff, the conclusion was that they’re not simply secondary to maternal toxicity. . . . [M]ost of the ones we’re talking about are the Research Triangle Institute studies by Tyl, *et al.*, the study abstracts when you just read those and the conclusions seem to indicate that the developmental effects are only in the setting of maternal toxicity, might not represent true developmental toxicity.

“And then when you actually go through and you look at the data in the reports, it’s actually quite clear that there are effects in the setting of minimal, if any maternal toxicity in most of those studies. And that’s what the CERHR panel based their conclusion of clear evidence of adverse effects on. Tr. at 52.

Summarizing, Dr. Solomon then argued that the NTP’s characterization of the “high dose findings” support an authoritative body listing.

Dr. Solomon:

“So my basic conclusion here is CERHR looked at those high-dose studies, concluded that there’s clear evidence of adverse effects. The language that they use clearly parallels the Prop 65 language, so their criteria were similar to ours. And this panel did recognize CERHR as an authoritative body. So in making your decision, it’s just, you know, something that I encourage you to think about. And I very much encourage you to list BPA as a developmental toxicant in its own right, based on the data that’s before you and consideration of panels that have come before.” Tr. at 53 (emphasis added).

On behalf of the DART IC, Committee Member Roberts then referred to other passages from the Report, reciting the many conclusions that there was “sufficient evidence” to conclude the BPA does *not* cause reproductive toxicity. Giving the “‘high’ dose findings” greater context, the Expert Panel Report refuted Dr. Solomon’s interpretation of the passage from the NTP Brief:

Committee Member Roberts:

“If I can ask, I’m looking at their publication. And in their publication Birth Defects Research Part B, Page 329, what we have under Summary and Conclusion of Developmental Hazards, *‘There are sufficient data to conclude that Bisphenol A does not cause malformations or birth defects in fetuses, exposed during gestation at levels up to 640 milligrams per kilogram per day than the 1,000 milligrams per kilogram per day [in] mice.* This is consistent with the lack of malformation seen in offspring of multi-gen. *There are sufficient data to conclude that Bisphenol A dose not alter male or female fertility in rats after gestational exposure.’*”

“The next paragraph goes, *‘There are sufficient data to conclude that Bisphenol A does not change the age of puberty in male or female rats.’*”

“Next paragraph, *‘there are sufficient data to conclude that Bisphenol A exposure during development does not permanently affect prostrate weight in adult rats or mice.’* And then the final paragraph, *‘there are sufficient data to suggest that developmental exposures to Bisphenol A causes neural and behavioral alterations related to sexual dimorphism in rats and mice.’*” Tr. at 54 - 55 (emphasis added).

Dr. Solomon then sought to distinguish the NTP Brief, which is the basis for the Petition, from the underlying Expert Report. Committee Member Roberts, by contrast, referred to the Expert Report.

Dr. Solomon: “Are you -- I’m reading from the final report. Tr. at 55.

Committee Member Roberts: “I’m looking at the peer-reviewed publication.” *Id.*

Dr. Solomon: “Because, yeah, it’s the final -- I was reading from the final report where on page -- I assume that’s also in the binder, but --” Tr. at 55.

Chairman Burk: “Yes.” Tr. at 55.

Committee Member Roberts: “Okay, all right.” Tr. at 55.

Dr. Solomon:

“And it says on page seven, “The NTP finds that there’s clear evidence of adverse developmental effects at quote ‘high doses’ of Bisphenol A in the form of fetal death, decreased litter size, or decreased number of live pups per litter in rats greater than or equal to 500 milligrams per kilogram body weight per day, and mice greater than 875 milligrams per kilogram body weight per day . . .,” et cetera. And there’s a paragraph that continues with each endpoint, *so that’s page seven of the final.* Tr. at 55 (emphasis added).

“There are other -- you know, there's a lot of conclusions as you saw in the CERHR reports on you know, lots of different endpoints. So I was just focusing on the one where they actually found clear evidence. There were a lot of others where they find either some evidence or no evidence.” *Id.*

Finally, Committee Member Roberts made clear that the source of this information in the NTP Brief was understood:

Committee Member Roberts: “Okay, that explains it. Thank you.” Tr. at 56.

Thus, the DART IC examined the information that is the basis of the Petition now. Other passages from the transcript, most notably the comments from Committee Members Roberts and Keen quoted above, demonstrate that the panel considered that information, and concluded in the end that any reproductive or developmental effects observed in these studies occurred in the presence of maternal toxicity. Because the comments by Committee Members Roberts and Keen address precisely the question that must be addressed under Section 25306(g), they bear repeating here:

Committee Member Roberts, addressing developmental toxicity:

“We referred to high dose studies. *The high dose studies have clear evidence of developmental toxicity. They do occur in the presence of maternal toxicity. And the issue isn’t whether or not developmental toxicity occurs. It’s whether or not there is sufficient maternal toxicity to potentially be causing the other.*”

“And when you have situations where the animals are either losing weight or gaining very little weight or they’re described as emaciated, that to me can be a cause of something like an increase in resorptions prenatally. Surprisingly, even when there were some fairly strong forms of maternal toxicity, it did not cause malformations. So it doesn’t seem that that particular endpoint out of the four is of concern.”

“When there is maternal toxicity, it does have a decrease in fetal body weight. It has an increase in prenatal loss. Those are both endpoints that are more commonly associated with severe maternal toxicity than others.”

“And a decrease in ossification does not – as long as it is a decrease in ossification, and not a structural change, it tends to go along with decrease in fetal body weight.” Tr. at 236 – 237 (emphasis added).

Committee Member Keen, following Dr. Roberts:

“My reading of the binders was remarkably similar to what you read. As is usually the case, I’d like to really compliment OEHHA for bringing a lot of these together, because I think the materials that we got were – I’ll use the word “overwhelming”, but in a positive sense of the word. It gave a pretty good comprehensive view of what the state of the literature is. I just want to iterate some of the points so it’s clear that we’re pretty much on the same page.”

“As I look at the literature, *I see very little evidence that there is an increased risk, absence of maternal toxicity [sic.; what Dr. Keen said was “absent maternal toxicity” or “in the absence of maternal toxicity”]*, of fetal or neonatal mortality. I don’t see any clear trends for malformations or specific birth effects. No clear evidence of reduced birth weight or growth.”

“In the occasional paper, and there’s over 70, which I went back and read each of the individual papers, you’ll find a sporadic report of something. But where I

get a little concerned or actually quite concerned is the lack of consistency as you go across the reports.” Tr. at 238 – 239 (emphasis added).

Not to belabor the point, but the DART IC, after considering the very argument that is now reprised in the Petition, then voted unanimously not to list BPA. It could not be more clear, therefore, that the State’s qualified experts already have addressed the ultimate issue that the Petition would have OEHHA address again now. For that reason alone, the Director should conclude that the NTP-CERHR Monograph would not satisfy the requirements of Section 25306(g).

For the reasons below, moreover, even if the Agency were determined to contradict and overrule the DART IC on its determination, the NTP’s characterization of the “high dose findings” in the NTP Brief would not constitute a conclusion that would satisfy Section 12306(g). For the sake of clarity, and to demonstrate why the asserted findings in the NTP CERHR Monograph do not satisfy the “sufficient evidence” test, we present the complete analysis below.

If the Agency were to issue a Notice of Intent to List the chemical, it would be required first to determine, in the words of Section 25306(g), that:

“(1) *studies in humans* indicate that there is a causal relationship between the chemical and reproductive toxicity, or

“(2) *studies in experimental animals* indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.”²⁹

Studies in Humans. The NTP Brief itself states clearly that the human data do not support a finding that bisphenol A causes reproductive toxicity, for any relevant toxicological endpoint.

“The NTP concurs with finding of the recent evaluations [notes omitted] that while these studies may suggest directions for future research, there is currently insufficient evidence to determine if bisphenol A causes or does not cause reproductive toxicity in exposed adults. There is also insufficient evidence from studies in humans to determine if bisphenol A does or does not cause developmental toxicity when exposure occurs prenatally or during infancy and childhood.”³⁰

Thus, there is no issue here to address.

²⁹ Cal. Code Regs., *tit.* 22, § 25306(g) (emphasis added).

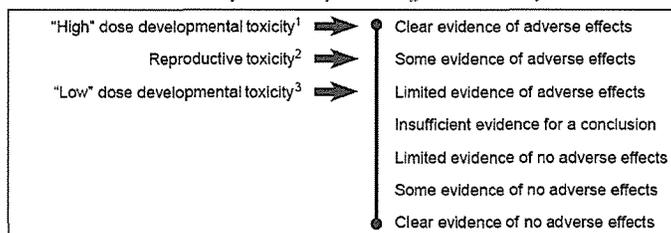
³⁰ NTP Brief at 15.

Studies in experimental animals. For all of the reasons that Committee Members Roberts and Keen discussed at the July 15 meeting, and for those reasons discussed in ACC’s written and oral submissions to the DART IC, the characterization of the “high dose findings” as “clear evidence of adverse effects of developmental effects in laboratory animals” in the NTP Brief does not identify BPA as a reproductive toxicant for purposes of Proposition 65. In short, none of these effects were observed to occur in the absence of maternal toxicity. Thus, the data to which this statement refers are not “sufficient evidence” within the meaning of Section 23506(g)(2), taking into account “considerations of maternal toxicity.”

That point is made clear in the NTP-CERHR Monograph itself. First, as noted above, the very passage at page seven of the NTP Brief acknowledges that the “adverse effects” referred to “were seen at the same dose levels that produced some weight loss in pregnant animals (“dams”). Second, the point is also made at page eight, in Figure 2b, on which Dr. Solomon relied on the testimony quoted above.

Figure 2b, in our observation, frequently appears in NTP-CERHR Monographs as a graphic summary of the NTP’s findings. It is important to note that NTP characterized the “weight of evidence” for developmental toxicity or reproductive toxicity in animals twice: once separately for both the “high dose” and “low dose” data. In our experience, this is unique, the only occasion of which we are aware when NTP has issued such “split” findings. In this context, it is important that the findings of “clear evidence of adverse effects” in Figure 2b are restricted to the “high dose” data. By contrast, NTP’s evaluation of the weight of the “low dose” data indicates that these studies present only “Limited evidence of adverse effects.”

Figure 2b. The weight of evidence that bisphenol A causes adverse developmental or reproductive effects in laboratory animals



¹Based on reduced survival in fetuses or newborns (≥ 500 mg/kg bw/day) (36–40), reduced fetal or birth weight or growth of offspring early in life (≥ 300 mg/kg bw/day) (36, 37, 41), and delayed puberty in female rats (≥ 50 mg/kg bw/day) and male rats and mice (≥ 50 mg/kg bw/day) (37, 41–43).

²Based on possible decreased fertility in mice (≥ 875 mg/kg bw/day) (40); altered estrous cycling in female rats (≥ 600 mg/kg bw/day) (110), and cellular effects on the testis of male rats (235 mg/kg bw/day) (111).

³Based a variety of effects related to neural and behavior alterations (≥ 10 μ g/kg bw/day) (44–50), lesions in the prostate (10 μ g/kg bw/day) (51) and mammary glands (0.0025–1 mg/kg bw/day) (52, 53); altered prostate gland and urinary tract development (10 μ g/kg bw/day) (54), and early onset of puberty (2.4 and 200 μ g/kg bw/day) (48, 55).

Further illustrating the same point, Footnote 1 to Figure 2b specifies the adverse effects for which there was “clear evidence,” the dose levels at which they were observed, and the studies to which the effects were attributed. According to Footnote 1, “reduced survival in fetuses or newborns” was observed at doses ≥ 500 milligrams per kilogram body weight per day (“mg/kg bw/day”); reduced fetal weight or birth weight or growth of offspring early in life was observed at doses of ≥ 300 mg/kg bw/day; and delayed puberty in female rats and in male rats and mice was observed at doses of ≥ 50 mg/kg bw/day.

Significantly, the “eight studies” to which Dr. Solomon refers in the testimony quoted above are the studies that NTP identifies in Footnote 1 as “References” 36 – 43 from the bibliography to the NTP Brief. A brief analysis of those studies further emphasizes the point

that the “adverse effects” referred to in the NTP Brief were observed only in the presence of maternal or systemic toxicity. Of these eight studies, we summarized five in ACC’s written submission to the Panel, demonstrating in each case that exposure to BPA caused no adverse developmental or reproductive toxicity except in the presence of systemic or maternal toxicity. For your convenience, we have summarized all eight studies here.³¹

³¹ Reference 36, *Kim, et al. (2001) Evaluation of developmental toxicity in rats exposed to the environmental estrogen bisphenol A during pregnancy*, showed no evidence of teratogenicity in the offspring of dams administered BPA by gavage on GD 1-20, and reported fetotoxicity (increased resorptions and decreased fetal body weight) and “severe maternal toxicity: at the high dose (1000 mg/kg bw/day). Fetotoxicity was not observed in the absence of maternal toxicity.

Reference 37, *Tyl, et. al (2002) Three Generation Reproductive Study of Dietary Bisphenol A in CD Sprague-Dawley Rats*, one of the most comprehensive studies conducted for BPA or any chemical, exposed rats to BPA in the diet at concentrations of 0, 0.015, 0.3, 4.5, 75, 750 and 750 ppm, the approximate equivalent to doses of 0, 0.001, 0.02, 0.3, 5, 50, and 500 mg/kg bw/day. A decrease in litter size at birth was observed in all three generations, but only at the high dose (500 mg/kg bw/day), which exceeded the maximum tolerated dose in the parental rats. Doses of 50 mg/kg bw/day or greater were associated with significant systemic toxicity, including decreased body weight, weight gain and organ weight changes. The LOAELs for developmental and systemic toxicity were 500 and 50 mg/kg bw/day, respectively. The study concluded: “Based on the absence of reproductive and developmental effects in offspring in this study, at doses where there was no significant maternal systemic toxicity, BPA should not be considered a selective reproductive or developmental toxicant.”

Reference 38, *Morrissey, et al. (1987) Fundamental Applied Toxicology, The Developmental Toxicity of bisphenol A in Rats and Mice*, conducted by the NTP, reported fetotoxicity in mice, but not in rats, at a maternally toxic dose during organogenesis. Fetotoxicity (increased resorptions and decreased fetal body weight) was observed only at the high dose (1250 mg/kg bw/day), which was associated with severe maternal toxicity, including maternal death (18%). Administration of lower doses to mice produced maternal toxicity, but not fetotoxicity. Signs of maternal toxicity in the rat were reported at all doses up to 640 mg/kg bw/day (the high dose), but no evidence of developmental toxicity was observed at any dose.

Reference 39, *Tyl, et al. (2002) Abbreviated one-generation study of dietary bisphenol A (Bisphenol A) in CD-1 (Swiss) mice*, was conducted in preparation for a two-generation study in mice (discussed below). Male and female mice were administered diets containing BPA at concentrations of 0, 5000 or 10,000 ppm for two weeks prior to and during mating, and the females were exposed throughout gestation. Dams and litters were necropsied on PND 0. Maternal toxicity was observed at both 5000 and 10,000 ppm. Fetotoxicity was observed “only at 10,000 ppm, expressed as slightly (statistically significant) reduced total and live pups/litter, with no significant effects on pre- or postimplantation *in utero* loss or on pup body weights per litter (sexes separately or combined).” At 10,000 ppm, BPA produced significant maternal toxicity, including decreased body weight, decreased body weight gain, decreased food consumption, increased relative liver and kidney weights, and altered histopathology of the liver and kidneys. The results of the one-generation reproductive toxicity study are consistent with those of the two-generation study discussed below. Both studies showed that BPA is not a selective developmental toxicant in mice.

Reference 40, *NTP (1985) Continuous breeding study of bisphenol A in CD-1 mice*, fed mice diets containing 0, 0.25, 0.5 or 1.0 percent BPA (0, 437.5, 875 or 1750 mg/kg bw/day, respectively). Postpartum F0 dam weights were reduced at the high dose. Relative liver and kidney weights were significantly increased among adult F0 males and females; at the mid- and low-dose levels, organs were not weighed. General systemic toxicity, including increased relative liver and kidney weights, was observed at all doses in the F1 generation. Evidence of developmental toxicity was limited to decreased number of live pups per litter at the mid- and high-dose levels (5 and 9% decrease, respectively). Pup weight adjusted for litter size was unchanged. The results of this study, which are consistent with the those of Tyl et al. (2002) in mice, do not demonstrate that BPA is a selective developmental toxicant.

(footnote continued)

Importantly, this information appears within the four corners of the NTP-CERHR Monograph. Thus, we are not asking OEHHA to examine information that was not before the NTP, or to substitute its judgment for that of the authoritative body. To the contrary, ***this was the judgment of the authoritative body***, and these studies were the basis for its judgment, as demonstrated in the NTP-CERHR Monograph, both in the text of the Expert Panel Report and in Figure 2b of the NTP Brief, reproduced above. It is incumbent upon OEHHA to review the entire Monograph to determine whether the asserted identification of BPA as “causing reproductive toxicity” is supported by “sufficient evidence.”³²

These data are summarized under the heading that clearly identifies them as the conclusions of the Expert Panel, and continue on for nearly a page, addressing all developmental and reproductive endpoints of concern, in considerable detail.

“Summary and Conclusions of Developmental Hazards

“There are ***sufficient data*** to ***conclude*** that bisphenol A does not cause malformations or birth defects in fetuses exposed during gestation at levels up to 640 mg/kg day (rats) and 1000 mg/kg/day (mice) (Morrissey *et al*, 1987). This

(footnote continued from previous page)

Reference 41, *Tyl, et al. (2008) Two-generation reproductive toxicity study of dietary bisphenol A (Bisphenol A) in CD-1 (R) (Swiss) mice*, exposed mice to BPA in the diet at concentrations of 0, 0.018, 0.18, 1.8, 30, 300 and 3500 ppm, approximately equivalent to doses of 0, 0.003, 0.03, 0.3, 5, 50 and 600 mg/kg bw/day. Adult systemic toxicity, including decreased body weight, increased organ weights (liver, kidney), centrilobular hepatocyte hypertrophy, and renal nephropathy in males was observed at the high dose (600 mg/kg bw/day). Centrilobular hepatocyte hypertrophy was observed at 50 mg/kg bw/day. There was no evidence of developmental toxicity at birth at any dose level in either generation. Pup survival on PND 0 was not significantly affected.^{31, 31} The study reported no effects in the F1/F2 generations on the number of implantation sites per litter; total number of live litters on PND 0; live birth index; and the number of total, live, and dead pups and sex ratio (% males) per litter on PND 0. Postimplantation loss per litter and still birth index were statistically equivalent across all groups. Pup weight at birth was not significantly affected. Other changes were reported among pups, but none of these were observed at or near the time of birth; these findings are discussed later in the sections on reproductive toxicity. The study concluded: “BPA is not considered a selective reproductive or developmental toxicant in mice.”

Reference 42, *Tan et al. (2003) Assessment of pubertal development in juvenile male rats after sub-acute exposure to bisphenol A and nonylphenol*, exposed male rats postnatally during puberty (PND 23-53) to a single high dose (100 mg/kg bw/day) of BPA by gavage, either alone or in combination with nonylphenol. Fewer BPA-exposed rats achieved preputial separation by PND 53 than the control males (67% vs. 100%). Systemic toxicity among the BPA-exposed males included significant increases in absolute and relative kidney and thyroid weights, decreased absolute and relative liver weights, and histological changes in the kidneys. The results of this study do not indicate that BPA is a selective reproductive toxicant. (Of note, this study exposed the rats to BPA postnatally, not prenatally, and Proposition 65 limits developmental toxicity to effects that occur as a result of prenatal exposure.)

Reference 43, *Tinwell et al. (2002) Normal sexual development of two strains of rat exposed in utero to low doses of bisphenol A*, exposed two strains of pregnant rats to 0, 0.02, 0.1, or 50 mg/kg bw/day of BPA on GD 6-21. In both strains, BPA exposure had no effect on litter size, sex ratio, birth weight, anogenital distance, first day of estrus, or age at preputial separation at any dose. The only effect in female offspring was a delay in vaginal opening in one strain of rats at the high dose only. In males, decreased sperm counts were observed at the high dose in one strain of rats, but not the other. CERHR stated: “Modest effects were noted in male and female offspring in the 50 mg/kg [high dose] group.” The study authors concluded that this study failed to confirm low-dose endocrine effects.

³² See *Exxon Mobil v. OEHHA*, cited at notes 12, 14, *supra*.

is consistent with the lack of malformations seen in offspring in multigenerational studies (Tyl *et al.*, 2002b, 2006).

“There are **sufficient data to conclude** that bisphenol A does not alter male or female fertility in rats or mice after gestational exposure up to doses of 450 mg/kg/day (Cagen *et al.*, 199b; Tyl *et al.*, 200a, 2002b; Ema *et al.*, 2001).

“There are **sufficient data to conclude** that bisphenol A does not change the age of puberty in male or female rats [NOAELs of 0.2 mg/kg day (Ema *et al.*, 2001) and 1823 mg/kg/day (Tyl *et al.*, 2002b)]. While **limited data suggest** an effect on the onset of female puberty in mice [LOEAEL 0.2 mg/kg/day (Ryan and Vandenberg, 2006), 0.002 mg/kg/day, (Howedeshell *et al.*, 1999)], the **data are insufficient to conclude** that bisphenol A accelerates puberty in female mice. The **limited data available, suggest, but are insufficient to conclude**, that bisphenol A slightly delays the age of puberty in male mice at a LOAEL of ca. 550-800 mg/kg/day (Tyl *et al.*, 2006).

“There are sufficient data to **conclude** that bisphenol A exposure during development does not permanently affect prostate weight in adult rats or mice [NOAELs of: 1823 mg/kg/day (Tyl *et al.*, 2002b), 600 mg/kg/day (Tyl *et al.*, 2006), 4 mg/kg/day (Cagen *et al.*, 1999b), 0.2 mg/kg/day (Ema *et al.*, 2001), 50 mg/kg/day (Tinwell *et al.*, 2002), and 320 mg/kg/day (Kwon *et al.*, 2000) There are sufficient data to **conclude** that bisphenol A does not cause prostate cancer in rats or mice after adult exposure [calculated dose ranges of 25-4500 mg/kg/day for rats, 600-3000 mg/kg/day, mice (NTP, 1982)]. **There are slight suggestions, but insufficient data to conclude**, that bisphenol A might predispose toward prostate cancer in rats in later life following developmental exposure [at 10 µg/kg (Ho *et al.*, 2006a)]. There are **slight suggestions, but insufficient evidence to conclude**, that fetal exposure to bisphenol A can contribute to urinary tract deformations in mice [10 µg/kg (Timms *et al.*, 2005)].

“There are sufficient data **to suggest** that developmental exposure to bisphenol A causes neural and behavioral alterations related to sexual dimorphism in rats and mice (ca 2.5 mg/kg/day, gestation and lactation in rats, (Funabashi *et al.*, 2004(a); LOEL 0.00002 mg/kg/day, fetal mice, (Nishizawa *et al.*, 2005a); 0.0002 mg/kg/day, fetal mice (Nishizawa *et al.*, 2003), 0104 mg/kg/day, weaning to puberty, rats (Ceccarelli *et al.*, 2007); 0.1 mg/kg/day, GD 3-PND 20, rats, (Negishi *et al.*, 2004a); 0.2 mg/kg/day, GD-3PND 20, mice (Ryan and Vandenberg, 2006); 0.01 mg/kg/day, GD 11-18, mice, (Laviola *et al.*, 2005), although other studies report no change in a related measure, the size of the sexually dimorphic nucleus of the pre-optic area (SDN-POA)_[300 µg/kg/day, rats (Nagao *et al.*, 1999); NOEL of 320 mg/kg/day, rats (Kwon *et al.*, 2000)].”³³

Significantly, these are the same Conclusions (with the supporting data) that Committee Member Roberts recited in her colloquy with Dr. Solomon, quoted above, in response to Dr. Solomon’s assertion that the NTP Brief formally identified BPA as a reproductive toxicant. For

³³ Expert Report at 329-30 (emphasis added).

the same reasons that they were persuasive to Dr. Roberts, they should be persuasive to OEHHA here.³⁴ Indeed, the many conclusions recited by the NTP above, indicating that there are “sufficient data” from which to *conclude* that BPA does not cause adverse developmental effects (or reproductive effects), should dispel the notion that the isolated characterization of the “high dose findings” cited by NRDC was intended to *identify* BPA as a selective developmental toxicant, in the absence of maternal toxicity.

C O N C L U S I O N

For all of the reasons above, OEHHA should not grant the Petition, and thus should not initiate the “authoritative bodies” process to list BPA as a reproductive toxicant under Proposition 65. Rather than repeat or summarize those reasons here, we would like to emphasize sound policy concerns that supplement them.

The Agency should recognize, as the statute implies and the Statement of Reasons expressly indicates, that the State’s Qualified Expert Mechanism is the “primary mechanism for listing,” and the authoritative bodies mechanism was intended only to “streamline[the] process for the Panel.” Thus, the latter process, while separate once established, was not intended to override or circumvent determinations by the Panel, or to establish a less stringent listing standard.

Accordingly, the authoritative body mechanism should not be viewed as a “re-opener,” encouraging disappointed advocates of listing to re-visit the Panel’s listing decisions within minutes of a Panel vote, without any new evidence, or on the mistaken notion that the authoritative body mechanism employs a lower standard. Aside from showing disrespect for the Committee, whose members are designated by virtue of their appointment by the Governor as the State’s experts, this does not encourage respect for Proposition 65 or for the Agency’s listing decisions.

It also is useful to note that all Proposition 65 listing decisions, regardless of the listing mechanism by which they are made, are directed toward the same statutory warning

³⁴ For reasons stated in Sections 1 and 2 of these comments, we believe it would be inconsistent with Section 25306(e), (g) and (i), as well as arbitrary, capricious and therefore unlawful, for OEHHA to disregard the findings of the State’s qualified experts by even considering making a finding that the NTP Brief “formally identified” BPA as a reproductive toxicant on the basis of “sufficient evidence,” notwithstanding the absence of adverse effects in the absence of maternal toxicity. Even if OEHHA disagrees, however, the conclusion of the DART IC should, at the very least, inform OEHHA’s judgment. The authoritative bodies mechanism may indeed be “separate” from the qualified experts mechanism, as the Agency has indicated many times. That does not mean, however, that the two mechanisms contemplate different results or the application of different standards, especially where the State’s qualified experts already have rendered their unanimous opinion, on the basis of the very same evidence, that BPA does not meet the statutory standard for listing. As discussed above, the Statement of Reasons, which stands as OEHHA’s official and binding interpretation of the Proposition 65 implementing regulations, indicates that the purpose of Section 25306(e) (and therefore Section 25306(g) as well) is to “ensure that the standards applied by an authoritative body are the same as or substantially similar to those used by the Panel to evaluate chemicals.” A finding by the Director or the OEHHA staff that BPA causes reproductive toxicity and should be listed would not be “the same or substantially similar” to the decision by the Panel; rather it would be significantly different, indicating that the standards that the Agency applied were significantly different as well.

requirement. If OEHHA were to countenance *seriatim* considerations of the same chemical under different listing mechanisms, by purportedly different standards, it would raise the following question: Should the “safe harbor” warnings be changed to allow for different warnings as “clear and reasonable,” depending on the process by which the chemicals were listed? This question is rhetorical, of course, but its absurdity is only a reflection of the notion that the State’s qualified experts may vote unanimously on one day that a chemical does not meet the statutory standard for listing, and the Director might be petitioned to reach a different conclusion on the basis of the very same evidence that the experts just considered.

Respectfully submitted,

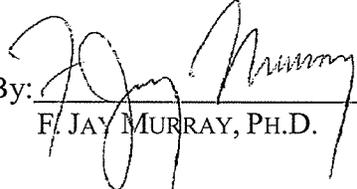
AMERICAN CHEMISTRY COUNCIL

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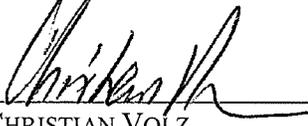
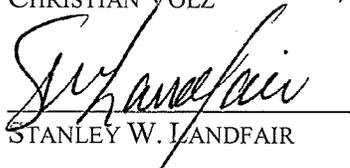


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ATTACHMENT

A

July 15, 2009

Delivered by Hand and Via E-mail

Joan E. Denton, Ph.D., Director
Office of Environmental Health Hazard Assessment
1001 "I" Street
PO Box 4010
Sacramento, CA 95812
jdenton@oehha.ca.gov

Re: Petition for Listing of Bisphenol A Pursuant to Authoritative Bodies Mechanism of Safe Drinking Water and Toxic Enforcement Act of 1986

Dear Dr. Denton:

We write on behalf of the Natural Resources Defense Council – an environmental and public health organization which has 1.2 million members and activists, 250,000 of whom are Californians – to ask that OEHHA move forward immediately to list bisphenol A [CAS # 80-05-7] under Proposition 65 as a chemical that is “known to the state to cause reproductive toxicity” because it has been identified as a reproductive toxicant by an authoritative body. California Health and Safety Code § 25249.8(b); 27 Cal. Code Regs. § 25306.

Under section 25249.8(b) of the Act, and 27 Cal. Code Reg. § 25306, a chemical is known to the State to cause reproductive toxicity if OEHHA determines that an authoritative body has formally identified the chemical as causing reproductive toxicity. OEHHA’s implementing regulations, set out at 27 Cal. Code Reg. § 25306 (attached as Appendix A), provide criteria for such a determination. These criteria are met for bisphenol A. Specifically:

- The National Toxicology Program, as to final reports of the National Toxicology Program’s Center for Evaluation of Risks to Human Reproduction (“NTP-CERHR”), is an authoritative body for purposes of the identification of chemicals as causing reproductive toxicity. 27 Cal. Code Regs. § 25306(1)(3).
- Bisphenol A is the subject of a final report which concludes that the chemical causes reproductive toxicity; the report identifies bisphenol A as causing reproductive toxicity in a document that indicates that such identification is a final action following peer review and public comment. 27 Cal. Code Regs. § 25306(d)(1); Center for the Evaluation of Risks to Human Reproduction, National Toxicology Program, U.S. Department of Health and Human Services, *NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A*, NIH Publication No. 08-5994 (September 2008) (“NTP Monograph”).¹ BPA is used in the manufacture of polycarbonate and polyvinyl chloride plastics and epoxy resins and found in the urine of more than 90% of

¹ The NTP Monograph is available at <http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf>, and a copy of relevant portions of the report is enclosed as Appendix B.

Americans. NTP Monograph, NTP Brief on Bisphenol A, at 1, 4. The NTP Monograph concluded that humans are exposed to bisphenol A and that the primary route of exposure is contaminated food. *Id.* at 1. They also concluded that bisphenol A can affect human development or reproduction, stating that “studies with laboratory rodents show that exposure to high dose levels of bisphenol A during pregnancy and/or lactation can reduce survival, birth weight, and growth of offspring early in life, and delay the onset of puberty in males and females” and that these effects are “not considered scientifically controversial and provide clear evidence of adverse effects” for developmental toxicity. *Id.* at 6-8. OEHHA regulations recognize chemicals as causing reproductive toxicity if required labeling or identification for the chemical uses words or phrases intended to communicate a risk of reproductive harm to men and women, or a risk of birth defects or other developmental harm. 27 Cal. Code Regs. § 25902.

- The NTP Monograph “specifically and accurately” identifies bisphenol A. NTP Monograph, NTP Brief on Bisphenol A, at *i*, 1; 27 Cal. Code Regs. § 25306(d)(2). The NTP Monograph was reviewed by a scientific advisory committee, the NTP Board of Scientific Advisors, in a public meeting and was made subject to multiple rounds of public review and comment prior to its issuance. NTP Monograph, Preface, at v; see the Peer Review Report and Public Comment History at <http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.html> (last updated Sept. 3, 2008); 27 Cal. Code Regs. § 25306(d)(2)(A)-(B). The NTP Monograph was also published in a publication – not only in NIH Publication No. 08-5994, but also in *Birth Defects Research Part B: Developmental and Reproductive Toxicology*. Chapin, R. E., J. Adams, et al., *NTP-CERHR expert panel report on the reproductive and developmental toxicity of bisphenol A*, *Birth Defects Res B Dev Reprod Toxicol* 83(3): 157-395 (2008); 27 Cal. Code Regs. § 25306(d)(2)(C).

For these reasons, bisphenol A should be listed as a reproductive toxin pursuant to Proposition 65.

Please do not hesitate to contact us should you have any questions. We look forward to prompt action on this petition.

Sincerely,



Gina M. Solomon, MD, MPH
Senior Scientist



Avinash Kar
Staff Attorney

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

ATTACHMENT

B

FACE SHEET

(See Instructions on Reverse)

ENCLOSED FILED
IN THE OFFICE OF

90 MAR 29 PM 4:14

MARCH FONG EU
SECRETARY OF STATE
OF CALIFORNIA

FOR FILING ADMINISTRATIVE REGULATIONS
WITH THE OFFICE OF ADMINISTRATIVE LAW
CERTIFICATION: I hereby certify that the attached are true and correct copies of regulations adopted, amended or repealed by this agency and that the information specified on this Face Sheet is true and correct.

CERT

ENDORSED
APPROVED FOR FILING
MAR 29 1990

HEALTH AND WELFARE AGENCY

(AGENCY)

Thomas S. Warrin
AGENCY OFFICER WITH RULEMAKING AUTHORITY

Date: 2-27-90

For use of Office of Adm Law

For use by Secretary of State only

1. AGENCY CONTACT PERSON FOR THIS FILING (See instructions) TITLE TELEPHONE
Steven A. Book, Ph.D., Science Advisor to the Secretary (916) 445-6900

2. Type of filing, (check one) 30-day Review Emergency Certificate of Compliance (Complete Part 4 below)
 Regulatory changes resulting from Govt. Code 11349.7 review (Complete Part 6 below)
 Nonsubstantive changes with nonregulatory effect Printing Error Correction

3. a. Specify California Administrative Code title and sections as follows:

Title 22
and 26

SECTIONS ADOPTED:
~~12306~~ 12306
SECTIONS AMENDED:
SECTIONS REPEALED:

The following sections listed in 3a contain modifications to the text originally made available to the public: ~~12306~~ 12306

4. CERTIFICATE OF COMPLIANCE (Government Code Section 11346.1(e): The above-named agency officer certifies that this agency complied with the provisions of Government Code Sections 11346.4-11346.8. (Check one)
 prior to the emergency adoption
 within 120 days of the effective date of the emergency adoption of the above-referenced regulations.

5. Is this filing a resubmittal of a previously disapproved or withdrawn regulation?
 No Yes, if yes, give date(s) of prior submittal(s) to OAL: _____

6. Is the filing submitted to carry out amendments or repeals identified in the statement of review completion submitted as a result of the agency's review of regulations administered by it as of June 30, 1980?
 No Yes, if yes, give date statement was submitted to OAL _____

7. If these regulations required prior review and approval or concurrence by any of the following agencies, check appropriate box(es)
 Fair Political Practices Commission (Include FPPC approval stamp) Building Standards Commission (Attach approval)
 State Fire Marshall (Attach approval) Department of Finance (Attach properly signed Std. 399)
 Other _____ (SPECIFY AGENCY)

8. a. PUBLICATION DATE OF NOTICE IN CALIFORNIA ADMINISTRATIVE NOTICE REGISTER 7/21/89
b. DATE OF FINAL AGENCY ACTION 2/27/90
c. DATES OF AVAILABILITY OF MODIFIED REGULATION(S) (GOVT. CODE SEC. 11346.8(c)) 10/13/89-10/30/89 and 12/13/89-12/29/89

9. Effective date of regulatory changes: (See Government Code Section 11346.2 and instructions on reverse)
a. Effective 30th day after filing with the Secretary of State.
b. Effective upon filing with the Secretary of State.
 Effective on _____ as required or allowed by the following statute(s): _____
 Effective on _____ (Designate effective date earlier than 30 days after filing with the Secretary of State pursuant to Govt. Code Sect. 11346.2(d).)
Attach request demonstrating good cause for early effective date. Request subject to OAL approval.
e. Effective on _____ (Designate effective date later than the normal effective date for the type of order filed.)

22 CALIFORNIA CODE OF REGULATIONS DIVISION 2
STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
CHAPTER 3. SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

ARTICLE 3. SCIENTIFIC ADVISORY PANEL

12306. Chemicals Formally Identified by Authoritative Bodies

(a) Pursuant to Health and Safety Code section 25249.8(b), a chemical is known to the state to cause cancer or reproductive toxicity if a body is considered to be authoritative by the state's qualified experts and the lead agency has determined that the body has formally identified the chemical as causing cancer or reproductive toxicity, as described in this section.

(b) A "body considered to be authoritative" is an agency or formally organized program or group which utilizes one of the methods set forth in subsection (d)(1) for the identification of chemicals, and which the Panel has identified as having expertise in the identification of chemicals as causing cancer or reproductive toxicity. For purposes of this section, "authoritative body" means a body considered to be authoritative" by the Panel. The Panel shall have the authority to revoke or rescind any determination by it that a body is authoritative on the grounds that the Panel no longer considers the body to demonstrate sufficient expertise in the identification of chemicals as causing cancer or reproductive toxicity, in which

case chemicals listed pursuant to this section
prior to the effective date of the revocation shall remain
on the list. Nothing in this section shall be construed to limit
or otherwise interfere with such authority.

(c) The lead agency shall determine which chemicals have been
formally identified by an authoritative body as causing cancer or
reproductive toxicity.

(d) For purposes of this section a chemical is "formally
identified" by an authoritative body when the lead agency
determines that:

(1) the chemical has been included on a list of chemicals
causing cancer or reproductive toxicity issued by the
authoritative body; or is the subject of a report which is
published by the authoritative body and which concludes that
the chemical causes cancer or reproductive toxicity; or has
otherwise been identified as causing cancer or reproductive
toxicity by the authoritative body in a document that
indicates that such identification is a final action; and

(2) the list, report, or document specifically and
accurately identifies the chemical, and has been:

A. Reviewed by an advisory committee in a public
meeting, if a public meeting is required, or

B. Made subject to public review and comment prior to its issuance, or

C. Published by the authoritative body in a publication, such as, but not limited to, the federal register for an authoritative body which is a federal agency, or

D. Signed, where required, by the chief administrative officer of the authoritative body or a designee, or

E. Adopted as a final rule by the authoritative body, or

F. Otherwise set forth in an official document utilized by the authoritative body for regulatory purposes.

(e) For purposes of this section, "as causing cancer" means that either of the following criteria has been satisfied:

(1) Sufficient evidence of carcinogenicity exists from studies in humans. For purposes of this paragraph, "sufficient evidence" means studies in humans indicate that there is a causal relationship between the chemical and cancer.

(2) Sufficient evidence of carcinogenicity exists from studies in experimental animals. For purposes of this paragraph, "sufficient evidence" means studies in experimental animals indicate that there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains, in multiple experiments (e.g., with different routes of administration or using different dose levels), or, to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset.

(f) The lead agency shall find that a chemical does not satisfy the definition of "as causing cancer" if scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria of subsection (e)(1) or (e)(2).

(g) For purposes of this section, "as causing reproductive toxicity" means that either of the following criteria have been satisfied:

(1) Studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity, or

(2) Studies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.

(h) The lead agency shall find that a chemical does not satisfy the definition of "as causing reproductive toxicity" if scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria of subsection (g)(1) or (g)(2).

(i) At least 60 days prior to adding a chemical determined to have been formally identified by an authoritative body as causing cancer or reproductive toxicity to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency shall cause to be published in the California Regulatory Notice Register a notice identifying the authoritative body and the chemical, and stating the lead agency's intention to cause the chemical to be added to the list. Copies of the notice shall be provided to the Panel to permit the Panel at least 30 days to review and comment on the proposed action. Within 30 days following the publication of the notice, interested parties, including any member of the Panel, shall submit to the lead agency their written objections to the addition of the chemical to the list of chemicals known to the state to cause cancer or reproductive toxicity, along with any supporting documentation. Objections shall be made on the basis that there is no substantial evidence that the criteria identified in subsection (e) or in subsection (g) have been satisfied. The lead agency shall review such objections. If the lead agency finds that there is no substantial evidence that the criteria identified in subsection (e) or in subsection (g) have been satisfied, the lead agency shall refer the chemical to the Panel to determine whether, in the Panel's opinion, the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity.

(j) Subsequent to the addition of a chemical determined to have

been formally identified by an authoritative body as causing cancer or reproductive toxicity to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency shall reconsider its determination that the chemical has been formally identified as causing cancer or reproductive toxicity if the lead agency finds:

(1) there is no substantial evidence that the criteria identified in subsection (e) or subsection (g) have been satisfied, or

(2) the chemical is no longer identified as causing cancer or reproductive toxicity by the authoritative body.

Reconsideration may be initiated by the lead agency on its own motion, or on a request from an interested party, including any member of the Panel. The lead agency shall refer chemicals under reconsideration pursuant to this subsection to the Panel for a recommendation concerning whether the chemical should continue to be included on the list of chemicals known to the state to cause cancer or reproductive toxicity. Pending such reconsideration, the chemical shall remain on the list.

(k) The Panel may condition any determination that a body is considered to be authoritative upon the subsequent application of the controls set forth in this section to the determination of

which chemicals have been formally identified by the body as causing cancer or reproductive toxicity. In the event that this section or any portion thereof is found to be invalid by any court of competent jurisdiction, the Panel may determine that such invalidation constitutes a failure of the condition. Upon finding such failure of condition, the determination that the body is authoritative shall be deemed to be revoked. Chemicals which the lead agency has determined have been formally identified by the body as causing cancer or reproductive toxicity pursuant to the controls set forth in this section and which have been placed upon the list of chemicals known to the state to cause cancer or reproductive toxicity prior to such revocation shall remain on the list.

(1) The Panel has identified the following as an authoritative body, for purposes of this section.

- (1) U. S. Environmental Protection Agency
- (2) International Agency for Research on Cancer
- (3) National Toxicology Program

AUTHORITY: Section 25249.12, Health and Safety Code.
REFERENCE: Sections 25249.8 and 25249.12,
Health and Safety Code

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UPDATED
INFORMATIVE DIGEST
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12306 - Chemicals Formally Identified by Authoritative Bodies

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Act) prohibits certain discharges of chemicals known to the state to cause cancer or reproductive toxicity, and prohibits certain exposures to chemicals known to the state to cause cancer or reproductive toxicity which are not preceded by a clear and reasonable warning. Chemicals are known to the state to cause cancer or reproductive toxicity if they satisfy certain criteria set forth in Health and Safety Code section 25249.8(b). One criteria for a chemical to be known to the state to cause cancer or reproductive toxicity is a determination that a body is considered to be authoritative by the state's qualified experts and that the authoritative body has formally identified the chemical as causing cancer or reproductive toxicity.

This regulation defines the terms "body considered to be authoritative," "formally identified," "as causing cancer," and "as . . . causing reproductive toxicity," and establishes procedures which the Health and Welfare Agency will utilize to determine whether a chemical has been formally identified as causing cancer or reproductive toxicity by a body considered to be authoritative. This regulation also refers to the bodies which the state's qualified experts have designated as authoritative.

FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12306 - Chemicals Formally identified by Authoritative Bodies

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Health & Saf. Code, sec. 25249.5, et seq.) (hereinafter the "Act") was adopted as an initiative statute at a general election on November 4, 1986. The Act prohibits any person in the course of doing business from knowingly discharging or releasing a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into a source of drinking water. (Health & Saf. Code, sec. 25249.5.) It further prohibits such persons from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning. (Health & Saf. Code, sec. 25249.6.)

Under the Act, a chemical is known to the state to cause cancer or reproductive toxicity (1) if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, (2) if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or (3) if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity. (Health & Saf. Code, sec. 25249.8(b).)

The Act requires the Governor to cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity, and to cause this list to be revised and republished in light of additional knowledge at least once per year. (Health & Saf. Code, sec. 25249.8(a).) The Act also requires the Governor to identify and consult with the state's qualified experts as necessary to carry out his duty regarding the list. (Health & Saf. Code, sec. 25249.8(d).) The Act further requires that the Governor designate a lead agency, and such other agencies as may be required, to implement the provisions of the Act. These agencies are authorized to adopt and modify regulations, standards, and permits as necessary to conform with and implement the provisions of the Act and further the purposes of the Act. (Health & Saf. Code, sec. 25249.12.)

By Executive Order D-61-87, the Governor designated the Health and Welfare Agency (Agency) as the lead agency for the implementation of the Act. The Agency subsequently adopted section 12302 of Title 22 of the California Code of Regulations, which created in the Agency the Scientific Advisory Panel (Panel) as the "state's qualified experts" to advise and assist the

Governor in the implementation of Health and Safety Code section 25249.8. As an advisory body to the Governor and the lead agency, the Panel was authorized (1) to determine whether specific chemicals are "known to the state to cause cancer or reproductive toxicity" pursuant to Health and Safety Code section 25249.8(b), and (2) to identify bodies which are considered to be authoritative and which have formally identified carcinogens or reproductive toxicants. (22 C.C.R., sec. 12305, subd. (a) and (b).)

One year after the date a chemical is added to the list of chemicals known to the state to cause cancer or reproductive toxicity, the warning requirement of Health and Safety Code section 25249.6 becomes applicable to the chemical. Twenty months after the date of listing, the discharge prohibition applies to the chemical. Violations of the Act may be enjoined and made subject to a civil penalty not to exceed \$2500 per day for each such violation, in addition to any other penalty established by law.

The purpose of this proposed regulation is to implement and make specific the provision of Health and Safety Code section 25249.8 which provides that a chemical is known to the state to cause cancer or reproductive toxicity "if a body considered to be authoritative by [the Panel] has formally identified it as causing cancer or reproductive toxicity."

Procedural Background

The concept of this regulation was conceived following the Panel's meeting of October, 1987. In that meeting, the Panel expressed strong reservations about designating any body as authoritative due to its concern that the designation would result in the unrestrained listing of chemicals. Consequently, the Agency determined that it would be necessary to implement and make specific the provisions of the Act relating authoritative bodies to enable the Panel to take advantage of this listing mechanism. Subsequently, the Agency commenced drafting this regulatory proposal. Copies of early proposals were circulated to interested persons and the Panel.

On April 14, 1989, following a command from the Sacramento Superior Court, the Panel considered the question whether the United States Environmental Protection Agency (EPA) is an "authoritative body" within the meaning of the Act and concluded that EPA is authoritative, but conditioned the designation upon application of certain controls to the listing of chemicals pursuant to that designation, and asked the Agency to draft rules embodying these controls. The terms of the condition were similar to the controls in the draft regulatory proposal. Subsequently, on July 17, 1989, the Agency proposed section 12306 for adoption.

Public hearing on the proposed regulation was held on September 13, 1989. Fourteen written comments were submitted. The Agency reviewed these comments and the regulation, and on October 13, 1989, noticed proposed changes to the regulation. One post-hearing comment was received. In response to that comment, and based upon the Agency's own continuing review, further proposed changes were noticed on December 13, 1989. The commentor on the October 13 notice orally resubmitted its comment in response to the December 13 notice, and one additional comment was received.

Necessity for the Regulation

The regulation is necessary because the language of section 25249.8 contains several terms which are subject to differing constructions. The Panel has expressed serious concerns about what would constitute an "authoritative body," about what constitutes "formal identification," and about which chemicals would be identified as "causing cancer or reproductive toxicity." Persons subject to the Act, and persons enforcing the Act, need to know specifically which chemicals are subject to the Act.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final language adopted by the Agency section 12306, and responds to the objections and recommendations submitted regarding that section as originally proposed in the July 17 proposal and modified by the October 13 and December 13 proposals. Government Code section 11346.7, subsection (b)(3) requires that the final statement of reasons submitted with an amended or adopted regulation contain a summary of each objection or recommendation made regarding the adoption or amendment, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. It specifically provides that this requirement applies only to objections or recommendations specifically directed at the Agency's proposed action, or to the procedures followed by the Agency in proposing or adopting the action.

Some parties included in their written or oral comments remarks or observations about these regulations or other regulations which do not constitute an objection or recommendation directed at the proposed action or the procedures followed. Also, some parties offered their interpretation of the intent or meaning of the proposed regulations or other regulations, sometimes in connection with their support of or decision not to object to the July 17, the October 13, or December 13 proposals. Again, this does not constitute an objection or recommendation directed at the proposed action or the procedures followed. Accordingly, the Agency is not obligated under Government Code section 11346.7 to respond to such remarks in this final statement of reasons. Since the Agency is constrained by limitations upon its time and resources, and is not obligated by law to respond to such

remarks, the Agency has not responded to these remarks in this final statement of reasons. The absence of response in this final statement of reasons to such remarks should not be construed to mean that the lead agency agrees with them.

Specific Findings

Throughout the adoption process of this regulation, the Agency has considered the alternatives available to determine which would be more effective in carrying out the purpose for which the regulations were proposed, or would be as effective and less burdensome to affected private persons than the proposed regulations. The Agency has determined that no alternative considered would be more effective than, or as effective and less burdensome to affected persons than, the adopted regulation.

The Agency has determined that the regulation imposes no mandate on local agencies or school districts.

Rulemaking File

The rulemaking file submitted with the final regulation and this final statement of reasons is the complete rulemaking file for section 12306. However, because regulations other than section 12306 were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to section 12306. This final statement of reasons cites only the relevant material. Comments regarding the regulations other than section 12306 in comments submitted concurrently have been or will be discussed in separate final statements of reason.

SECTION 12306

Subsection (a)

Subsection (a) of the proposed regulation restates the relevant portions of Health and Safety Code section 25249.8, and provides that the designation of authoritative bodies and of chemicals formally identified as causing cancer or reproductive toxicity shall be conducted as described in section 12306. This makes clear that the definitions and procedures described in the regulation will govern the listing of chemicals pursuant to the designation of a body which the Panel considers to be authoritative.

One commentator recommended that the Agency add at the end of subsection (a) ", and it has been clearly shown through scientifically valid testing to cause cancer or reproductive toxicity." (C-13, p. 5.) In effect, the adoption of this recommendation would require that each chemical which has been formally identified by a designated authoritative body meets the same criteria which the Panel would apply if the Panel were considering the chemical individually. In other words, there

would need to be some scientific review prior to the listing of the chemical, presumably conducted by the Panel. As discussed below, one purpose of the authoritative bodies provision is to avoid duplicative scientific review in order to streamline the listing process and free the Panel to consider chemicals the hazards of which have not been thoroughly evaluated. The adoption of this recommendation would defeat this purpose. Accordingly, this recommendation was not adopted.

Subsection (b)

Subsection (b) makes specific the phrase "body considered to be authoritative" found in Health and Safety Code section 25249.8(b). Under subsection (b), a body considered to be authoritative "is an agency or formally organized program or group which utilizes one of the methods set forth in subsection (c)(1) for the identification of chemicals, and which the Panel has identified as having expertise in the identification of chemicals as causing cancer or reproductive toxicity."

There are many organizations which potentially may be identified by the Panel as "authoritative." The organizations may be governmental or non-governmental. The reference to "an agency or formally organized program or group" was chosen to include both types of organizations. It was also chosen to make certain that the term "body considered to be authoritative" does not include individuals. The body must consist of a group of individuals in a formal organization, such as a program or agency.

One commentator recommended that the regulation make clear that an authoritative body can be a public agency only, not a private program or group, since private programs and groups do not allow public access to their processes. (C-9, p. 2.) The fact that a program or group may limit public access to its process is simply one factor which may be considered when deciding whether the program or group is "authoritative." The Panel may have a difficult time determining that a body which completely excludes outside input and review is "authoritative." However, the Agency cannot conclude that the ability of a private program or group to limit public input precludes them from consideration as authoritative bodies. Accordingly, this recommendation was not adopted.

The purpose of designating a "body considered to be authoritative" is to place chemicals on the list of chemicals known to the state to cause cancer or reproductive toxicity. In order for a chemical to be listed as the result of the Panel's designation of a body considered by to authoritative, Health and Safety Code section 25249.8(b) requires that the chemical must be "formally identified" by the body as causing cancer or reproductive toxicity. The term "formally identified" is defined in subsection (d) of the regulation, and includes certain limitations. It would be a useless act for the Panel to spend

the time and resources necessary to designate a body considered to be authoritative if the body does not utilize at least one of the mechanisms of formal identification set forth in subsection (c)(1). Accordingly, "body considered to be authoritative" is further defined with the limitation that the agency or formally organized program or group must utilize at least one of the mechanisms for the identification of chemicals set forth in subsection (c)(1).

One commentator recommended that the words "or more" be inserted after "one." (C-13, Exhibit "A", p. 1.) This amendment does not appear to be necessary. The purpose of this section is to make certain that a body under consideration utilizes at least one of the methods for the identification of chemicals, so that the authoritative body designation will have some practical effect. Obviously, if the body utilizes more than one of the methods, that will be sufficient. Therefore, this recommendation was not adopted.

As originally proposed, subsection (b) made reference only to subsection (c), not subsection (c)(1). However, some of the criteria in subsection (c) require a review of the identification of each individual chemical. The Panel would not be in a position to apply these criteria, since the task of determining which chemicals are "formally identified" belongs to the lead agency. Accordingly, the limitation in subsection (b) was limited in the December 12 proposal. The Panel need only consider whether the agency, program or group issues a list, publishes a report, or otherwise documents their conclusions that certain chemicals cause cancer or reproductive toxicity.

Under subsection (b), a "body considered to be authoritative" must, in the Panel's opinion, have "expertise in the identification of carcinogens or reproductive toxicants." In arriving at such a determination, it is assumed that the Panel will consider the reputation of the body in identifying carcinogens or reproductive toxicants on which the Panel can rely. As originally proposed, subsection (b) provided that the Panel must identify "a body considered by it to have an established and recognized expertise in the identification of chemicals." This language proved to be awkward. The December 12 proposal adopted the present language to simplify the expression of the Agency's intent.

The phrase "body considered to be authoritative" in section 25249.8(b) is too cumbersome to use throughout the regulation. Thus, subsection (b) provides that "authoritative body" shall be a shorthand form having the same meaning as "body considered to be authoritative."

Implicit in the power to designate authoritative bodies is the power to revoke or rescind such a designation. Subsection (b) makes this power explicit by specifying that the Panel shall have

the authority to revoke or rescind any designation on the grounds that the Panel no longer considers the body to demonstrate sufficient expertise in the identification of chemicals.

As originally proposed, subsection (b) simply provided that the Panel had the authority to revoke or rescind its determination that a body is authoritative. One commentor recommended that the regulation specify the bases for the revocation of an authoritative body, i.e. either it no longer utilizes one of the methods set forth in subsection (c) or it no longer has established and recognized expertise. (C-11, p. 3.) The October 13 proposal amended subsection (b) to further provide the grounds on which the revocation may be made. If the Panel no longer considers the body to have expertise in the identification of chemicals as causing cancer or reproductive toxicity, the Panel may revoke its determination that the body is authoritative. It was decided that requiring the Panel to find that the body no longer has an "established and recognized" expertise would be unworkable, since a body which has ceased to produce work of acceptable quality may still have an "established and recognized expertise." Accordingly, the words "established and recognized" were not included.

It was further determined that the failure of an authoritative body to continue using one of the methods set forth in subsection (c), now subsection (d)(1), should not provide a basis for revocation. The requirement that the body use one of the methods in subsection (d)(1) was designed to prevent the Panel from undertaking the useless act of finding a body authoritative when no listing of chemicals could result. Once a body is considered authoritative, further action on the part of the Panel is unnecessary. If the body stops using any of the methods set forth in subsection (d)(1), no Panel action would be required. Thus, the Panel would not be in the position of performing a useless act. In addition, if the body ceases to use any of the methods described in subsection (d)(1), it could just as easily begin again. Therefore, the fact that a body ceases to use one of the methods set forth in subsection (d)(1) was not made a basis for revocation.

Subsection (b) further provides that section 12306 shall not be construed to limit or otherwise interfere with the authority to revoke or rescind an authoritative body designation.

Subsection (c)

Subsection (c) provides that the lead agency designated pursuant to Health and Safety Code section 25249.12 shall determine which chemicals are "formally identified as causing cancer or reproductive toxicity" within the meaning of the Act. The Act provides that the state's qualified experts may consider a body to be authoritative, but does not specify the mechanism for determining which chemicals have been "formally identified as

causing cancer or reproductive toxicity" after a body has been found to be authoritative. The fact that the task of determining which specific chemicals to list by this process was not delegated to the state's experts suggests that the voters intended a different approach.

Under the primary approach to listing, the Panel must determine whether a chemical has been clearly shown, based upon scientifically valid testing according to generally accepted principles, to cause cancer or reproductive toxicity. This can be a time-consuming process. The apparent purpose of the authoritative bodies provision is to establish a streamlined process for the Panel. Rather than review each chemical already subjected to review by another organization, the Panel needs only to determine the organization's competence. The chemicals which the organization has formally identified as causing cancer or reproductive toxicity can then be listed. This permits the Panel to focus its attention on chemicals which have not previously been evaluated.

To determine which chemicals have been "formally identified as causing cancer or reproductive toxicity," it will be necessary to review those identifications which the body has made, both for their formality and scientific basis. Requiring that the Panel make this determination could consume substantial amounts of the time which the authoritative bodies provision was intended to save, distracting the Panel from its other responsibilities.

Determining which chemicals are formally identified as causing cancer or reproductive toxicity is essentially ministerial. If there is sufficient documentation of an identification based upon valid epidemiologic or animal bioassay data, the chemical is listed. This simply involves a review of the literature, and does not require a panel of experts to conduct. Since the task of making such determinations is essentially ministerial, it is more suited to full-time staff than to part-time experts.

Accordingly, the original version of the regulation assigned to the Agency the task of determining which chemicals an authoritative body has formally identified as causing cancer or reproductive toxicity. This approach takes full advantage of the resources available through the Agency, and conserves the energies of the Panel as the Act apparently intended.

Some commentators objected that the regulation would shift to the Agency the authority to determine which chemicals have been "formally identified." (C-14, p. 2.) Some supported the rule. (C-12, p. 1.) One alleged that (1) the Act gives this role to the Panel, (2) giving the responsibility for scientific determinations to the lead agency rather than the Panel undermines the credibility of the process, and (3) the efforts of the lead agency in determining what is "formally identified" will be duplicative of the Panel's designation of the body as

authoritative, since Panel will need to look at what has been formally identified to determine whether a body is authoritative. (C-8, p. 2-5.) However, as indicated above, the Act assigns the Panel the role of determining what bodies are authoritative, but does not assign the task of determining which chemicals are "formally identified as causing cancer or reproductive toxicity." Second, the task of determining which chemicals are "formally identified as causing cancer or reproductive toxicity" under this section are essentially ministerial. The limited time and resources of the state's experts should not be expended performing ministerial functions. Finally, subsection (b) describes what the Panel must find to designate a body as authoritative. The Panel does not need to reexamine every hazard identification issue considered by the body to conclude that the body has expertise in the identification of chemicals causing cancer or reproductive toxicity.

One commentator objected on the ground that authorizing the lead agency to make the determination is inconsistent with the recommendation of the Panel that the Panel make the determination. (C-13, p. 5.) On April 14, 1989, the Panel expressly charged the Agency with developing limitations on the listing of chemicals which would follow the designation of EPA as an authoritative body. Nothing in the Panel's charge suggested that the Panel intended to reserve unto itself the task of deciding which chemicals to list. Subsequently, the Panel designated IARC and NTP, as well as EPA, as authoritative bodies subject to the controls of this section.

One commentator recommended that the designation of an authoritative body form the basis for a list of candidate chemicals, which would then be considered by the Panel on a priority basis. (C-5, p. 3.) This interpretation, however, would write the authoritative bodies provision out of the Act. The Act provides that a chemical is "known to the state to cause cancer or reproductive toxicity" if it is formally identified by an authoritative body as causing cancer or reproductive toxicity, and must be listed under the Act. It does not provide that the Panel must subsequently find that it has been clearly shown through scientifically valid testing to present a cancer or reproductive hazard.

One commentator recommended that the NTP should not be designated as an authoritative body because NTP does not regard its reports as an authoritative statement of carcinogenicity, and most of the NTP listings are for chemicals which are merely "reasonably anticipated" carcinogens, not "known" carcinogens. (C-6, p. 1-2.) At the time this comment was made, the regulation did not reflect that the NTP was considered to be authoritative. Subsequently, the Panel concluded that NTP is authoritative, and the regulation was amended accordingly.

Under the Act, the Panel determines whether it considers a body

to be authoritative. The fact that a body under consideration may not consider itself to be authoritative for certain purposes is something for the Panel to weigh in its considerations. However, it does not appear to preclude the Panel from finding that the body is authoritative.

One commentator objected that the regulation is unconstitutional on the ground that, allegedly, it would effectively delegate to "authoritative bodies" the unfettered discretion to make determinations that would be binding as a matter of law. This commentator contends (1) that a regulation may not delegate to another jurisdiction unchecked authority to promulgate rules, regulations, or standards that will be binding as a matter of law, (2) that the regulation must provide procedural checks that will ensure that the body to which power has been delegated will exercise its authority in conformity with the fundamental policy decisions made in the statute, and (3) that this regulation would completely delegate an aspect of its rulemaking authority without a workable mechanism for meaningful state review. The commentator does not describe how the regulation grants unfettered discretion to authoritative bodies, but concludes that it does.
(C-13, p. 1-5.)

Even assuming that the commentator's exposition of the law regarding delegations of authority is correct, the regulation does not grant unfettered discretion to authoritative bodies. To the contrary, it limits which bodies may be designated as "authoritative," and it limits the listing of chemicals based upon such a designation to chemicals which the lead agency determines have satisfied certain procedural and scientific criteria. The Panel's concern that the designation of an authoritative body could lead to the unrestricted listing of chemicals provided the motivation for adoption of the regulation. Consequently, this commentator's fundamental premise appears to be flawed. The regulation does provide procedural checks to ensure that the consequences of designating a body as "authoritative" will conform with the policies expressed in the Act. Accordingly, the regulation does not make an unconstitutional delegation of authority.

As originally proposed, subsection (c) also contained the criteria which the lead agency would apply to determine that a chemical has been "formally identified" as causing cancer or reproductive toxicity. To simplify that subsection, the December 13 proposal separated this definition from the charge to the Agency, moving the criteria to a new subsection (d).

Subsection (d)

Subsection (d) defines the circumstances under which a chemical is "formally identified" within the meaning of section 25249.8. The lead agency must make a determination that specified requirements of identification and formality have been satisfied. Subsection (d) goes on to describe these requirements in paragraphs (1) and (2).

Paragraph (d)(1) requires some kind of written identification. Specifically, the chemical must (1) be included on a list of chemicals causing cancer or reproductive toxicity, or (2) be the subject of a report which is published by the authoritative body concluding that the chemical causes cancer or reproductive toxicity, or (3) be otherwise identified as causing cancer or reproductive toxicity by the authoritative body in a document which indicates that such identification is a final action. Lists and reports are methods of identification commonly used by governmental and non-governmental entities alike to identify chemical hazards. However, in order to permit the designation of authoritative bodies which use other methods to identify chemical hazards, this paragraph permits identification of such hazards in other documents dealing with the chemical which include some indication that the identification of the chemical as a carcinogen or reproductive toxicant is a final action.

The Agency recognizes that many organizations which may be considered authoritative do not treat the identification of chemical hazards as a regulatory endpoint. For them, the regulatory endpoint is the adoption of an exposure or discharge limit for a chemical, once it has been determined that the chemical poses a hazard. Hazard identification is simply one step toward the ultimate determination of a regulatory exposure limit, tolerance, level, etc. Documents explaining or noticing the progression of an exposure or discharge limit, tolerance or other standard through the regulatory process will likely identify a chemical as a cancer or reproductive hazard with finality long before the standard is finally adopted. It is the intention of the Agency that such an identification will be sufficient indication of a "final action" on the issue of hazard identification to conclude that the chemical has been "formally identified."

The words "indicates that such identification is a final action" are intended to prevent the listing of chemicals on the basis of preliminary discussions as to whether a chemical should be considered a cancer or a reproductive hazard, or draft documents dealing with the identification of a chemical hazard. The requirement is not intended to limit the formal identification of a chemical to documents which take final action on the regulatory endpoint. It is not intended to require specific language within the document stating that the identification of the chemical as a cancer or reproductive hazard is a final action.

Whether the identification of a chemical as a cancer or reproductive hazard is final should be determined from the circumstances surrounding the issuance of the document, not just from the document's language.

One commentator recommended that the word "formally" be inserted before the word "issued" with regard to lists issued by the authoritative body. (C-9, p. 2) The purpose of subsection (d)(1), however, is to specify what forms of identification the authoritative body must utilize. Subsection (d)(2) specifies what formality is required. Inserting the word "formally" in subsection (d)(1) would only raise further questions about the requisite formality, e.g. what is a formally issued list. Since this recommendation would add nothing to the regulation, the Agency did not adopt it.

Similarly, another commentator recommended that the regulation add the phrase "stating the authoritative body's formal conclusion" after the word "report." (C-13, p. 6.) Again, subsection (d)(1) specifies what forms of identification must be used, and subsection (d)(2) specifies what formality is required. Injecting into subsection (d)(1) formality criteria more suited to subsection (d)(2) would only serve to confuse. Accordingly, this recommendation was not adopted.

One post-hearing commentator recommended that the lists and reports relied upon for identification be "final" or "issued as a final action." (PH2-1, p. 1.) This recommendation, however, was not directed at any change to the regulation noticed for public availability. Under Government Code section 11346.7(b)(3) and 11346.8(c), the Agency is obligated to respond to objections and recommendations directed at the Agency's proposed actions. In the case of post-hearing changes, the proposed action is the change to the proposed regulation, not the unchanged language. Since this comment is not directed at any change to the proposed language, and is directed at unchanged language, the Agency is not obligated to respond to the recommendation.

Subsection (d)(2) specifies what formality is required. Paragraph (d)(2) requires that the list, report or document specifically and accurately identify the chemical. In addition, the list report or document must have been (A) reviewed by an advisory committee in a public meeting, if a public meeting is required, or (B) made subject to public review and comment prior to its issuance, or (C) published in a manner appropriate to the authoritative body, or (D) signed by the chief administrative officer of the body, or (E) adopted as a final rule or regulation by the body, or (F) otherwise set forth in an official document utilized by the authoritative body for regulatory purposes.

The requirements for formality are based on limitations suggested by the Panel at its April 14, 1989, meeting on its designation of the U.S. Environmental Protection Agency (EPA) as an

authoritative body. The limitations were:

"(a) EPA's designation is by means of a notice in the Federal Register signed by the Administrator;

"(b) EPA's designation addresses specifically and unambiguously the chemical formula, the valence state, the routes of exposure and the identity of members within a class of chemical for which designation as a carcinogen or reproductive toxicant is warranted by the scientific information available;

"(c) The designation and its rationale have been reviewed by the EPA's Science Advisory Board at a public hearing at which interested parties have had the opportunity to make comment;

"(d) The EPA's Science Advisory Board has concurred in a written report to the EPA Administrator that the designation is clearly warranted by the scientific information available."

Since the proposed regulation is intended to be generic in its application, some of the limitations proposed by the Panel for EPA may not be applicable to other potential authoritative bodies. Hence, the requirements for formality are presented in the disjunctive, rather than the conjunctive. An identification must satisfy at least one of the requirements set forth in subsection (d)(2). The Agency considered requiring that each requirement for formality be satisfied and rejected this alternative, since different bodies observe different formalities in identifying chemicals, and many bodies use one or more of the formalities specified, but few use them all.

One commentator objected that the procedural steps in subparagraphs (A) through (F) are listed in the disjunctive, and recommended that all steps should be required in the conjunctive. (C-3, p.4; C-9, p. 2; C-13, p. 6.) However, as indicated above, the Agency considered requiring that each requirement for formality be satisfied and rejected this alternative. Requiring each of the steps in the conjunctive would impose such stringent requirements of formality before a chemical could be listed that few, if any, would survive the process and be listed. As a consequence, the majority of chemicals considered by the authoritative body would need to be referred to the Panel for its consideration whether the chemicals have been clearly shown through scientifically valid testing to cause cancer or reproductive toxicity. In effect, the primary purpose of the authoritative bodies provision, which is to relieve the Panel of the burden of a chemical-by-chemical review for substances already well considered by reputable organizations so that the Panel can freely pursue other issues, would be defeated.

One commentator recommended that the regulation be amended to assure that listing is limited to chemicals which have been formally and finally adopted by authoritative bodies as causing cancer or reproductive toxicity, pointing out that during EPA review of pesticides, final determination is often not made because new information indicates that the chemical is not carcinogenic. (C-4, p. 1.) Subsection (d)(1) does make reference to finality, as discussed above. As for formality, the purpose of subsection (d)(2) is to prescribe what constitutes sufficient formality. Injecting references to finality will only serve to confuse. Prescribing that formality means that the chemical has been formally adopted by the authoritative body would be circular. Therefore, no modification was made.

The alternative provision in paragraph (d)(2)A. that the list, report or document have been reviewed by an advisory committee simply recognizes that peer review (within the authoritative body itself or by an advisory committee) is generally utilized by the scientific community to validate the results and/or conclusions of a study or a scientific document, a process similar to that utilized by the Panel to evaluate chemicals for listing under the Act. One commentator recommended that the phrase "and formally accepted or approved by" be added before the words "an advisory committee." (C-13, p. 6.) This, however, would use the word "formally" to define formality, and would raise issues as to when the advisory committee has accepted and approved the document, list or report. Whether a document, list or report has been reviewed by an advisory committee should be simple to determine, and the requirement that the document, list or report reflect that the chemical causes cancer or reproductive toxicity will often imply acceptance or approval. Accordingly, this recommendation was not adopted.

The provision that the list, report or document be made subject to public review and comment prior to its issuance takes into account that some potential authoritative bodies may be regulatory agencies which afford opportunities for comment by the public and the regulated community. One commentator recommended that formal public review, where required, should be required. (C-13, p. 6.) However, as currently drafted, the regulation encourages public review, even where it is not required. Other commentators have pointed out that public input is beneficial. Therefore, the Agency believes that the less restrictive approach is preferable.

The alternative that the list, report or document be published acknowledges that published reports generally are subjected to a thorough review prior to publication. By way of illustration, the regulation refers to the Federal Register as a manner of publication appropriate to a federal agency. This is not intended to suggest that publication in the Federal Register is the only means by which a list, report or document issued by a federal agency will satisfy this requirement for formal

identification. For example, EPA documents not published in the Federal Register may be sufficient.

The signature of the chief administrative officer of the body or a designee is also evidence of formality. It is unlikely that such an officer would sign such a document prior to completion of all necessary levels of internal review. The adoption of the list, report or document by the body as a final rule or regulation would also indicate a thorough internal review and consideration of public comment as well.

Similarly, the use of the list, report or document in an official document utilized by the body for regulatory purposes indicates completion of necessary internal review. One commentator recommended that the regulation be amended to delete the phrase "utilized by the authoritative body for regulatory purposes" and replace it with the phrase "that identifies chemicals that are regulated as carcinogens by said authoritative body." (C-13, p. 7.) This recommendation was not adopted because it would require that the chemical in fact be regulated before this standard of formality could be utilized, and did not otherwise improve upon the language proposed.

As proposed, this regulation did not require use of the list, report or document in an "official" document. This adjective was added in the December 13 proposal to clarify that the document utilized for regulatory purposes must be the official product of a government agency.

Subsection (e)

Subsection (e) provides that, for purposes of section 12306, the phrase "as causing cancer" means that either of two scientific criteria have been satisfied. Generally, the authoritative body may rely on either studies in humans or studies in animals. These criteria are consistent with the criteria the Panel presently uses in evaluating chemicals for listing. The Panel utilizes the EPA's Classification System for Categorizing Weight of Evidence for Carcinogens From Human and Animal Studies (51 Fed. Reg. 33999 (Sept. 24, 1986)). The same, or substantially similar criteria have been adopted by many regulatory agencies and scientific organizations involved in hazard identification. The use of these criteria will ensure that the standards applied by an authoritative body are the same as or substantially similar to those used by the Panel to evaluate chemicals.

As originally proposed, subsection (e) (then subsection (d)) provided:

"Except as provided in subdivisions (e), (h) or (i), the lead agency shall determine that a chemical is formally identified by an authoritative body as causing cancer

when either of the following criteria has been satisfied:"

One commentor recommended clarification that the criteria of subsection (c) and subsection (d) must be satisfied, urging that the phrase ", in addition to the requirements of subsection (c)," be added after the word "when." (C-3, p. 5.) This recommendation was accepted in the October 13 proposal of the regulation, but subsequent review revealed a potential for confusion, since both subsections proposed criteria for determining that a chemical has been "formally identified by an authoritative body as causing cancer or reproductive toxicity." To avoid this confusion, subsection (e) was amended in the December 13 proposal to resemble subsection (d), and simply provide, "For purposes of this section, 'as causing cancer' means that either of the following criteria has been satisfied:" This made clear that subsections (d) and (e) implement different terms. Subsection (d) implements the terms "formally identified," and subsection (e) implements the terms "as causing cancer."

One commentor recommended that the lead agency rely upon a "weight-of-the-evidence," rather than a "strength-of-the-evidence" approach when determining which chemicals have been identified "as causing cancer." Apparently, this commentor perceives "strength-of-the-evidence" to mean that hazard identifications are based upon studies showing carcinogenic activity, ignoring studies showing a lack of carcinogenic activity. Weight-of-the evidence would consider both negative and positive studies.

If an authoritative body uses the weight-of-the-evidence approach, the results will be reflected in the document, list or report which the body issues. In other words, chemicals which did not meet the body's weight-of-the-evidence test would not be formally identified as causing cancer. Therefore, the recommended approach would have practical effect only where the authoritative body uses the strength-of-the-evidence approach. It would place the Agency in the position of superimposing a weight-of-the-evidence test upon the authoritative body's conclusions.

One commentor recommended that subsection (e) provide that the same or substantially similar criteria be "determined by the authoritative body to be, or is in fact, satisfied:" (PH1-1) This would have the opposite effect of the previous recommendation. It could place the Agency in the position of deferring to the conclusions of the authoritative body, even where the criteria had not been satisfied.

As indicated below, it is not the intention of the Agency in adopting this regulation to substitute its scientific judgment for the judgment of the authoritative body where sufficient

evidence exists. Thus, if there are four animal studies on a particular chemical, two of them positive and two of them negative, and the authoritative body concludes on the basis of the positive tests that the chemical causes cancer, the Agency does not intend to revisit the issue. Thus, if an authoritative body properly applies a strength-of-the-evidence approach, the Agency will not substitute its judgment on the basis of negative data, unless new data not considered by the authoritative body clearly establishes that there is not sufficient evidence in either animals or humans.

On the other hand, where there is in fact an insufficient number of positive animal or human studies, but the authoritative body has concluded anyway that the chemical causes cancer, the Agency will be prevented by the regulation from bringing the chemical to the list. The Agency will not completely defer to the authoritative body, and will at least determine that the body relied upon the requisite human or animal studies.

This same commentor recommended that the Agency should consider the differences in listing substances as "possible," "probable," "known," "reasonably anticipated to be," or "suspect" carcinogens by various governmental and nongovernmental groups before automatically adopting such lists under the Act. (C-6, Attachment 1, p. 3.) Under the regulation, there is no automatic adoption of an authoritative body's list. The Agency will investigate to make certain that there are sufficient animal or human data. As indicated below, the terms "possible," "probable," "known," "reasonably anticipated to be," and "suspect" are often used to describe the certainty afforded by sufficient data in animals. Therefore, it appears that these differences have been adequately considered.

Paragraph (e)(1) describes the criteria for determining that a chemical causes cancer where the authoritative body relied on studies in humans. The regulation requires that sufficient evidence exist from studies in humans which indicate that there is a causal relationship between the chemical and cancer. This definition of "sufficient evidence" is well-established in the scientific community, and several references to this concept are offered by way of illustration in the bibliography to the regulation. Under these references, chemicals for which there is sufficient evidence based upon evidence in humans have been identified as chemicals "known to be carcinogens" (NTP, Fourth Annual Report on Carcinogens, Summary, 1985, p. 8), "Group I--carcinogenic to humans" (International Agency for Research on Cancer (IARC), IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42, Supplement 7, 1987, p. 30), and "Group A-- human carcinogens" (EPA, Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33999 (Sept. 24, 1986)).

The use of the term "sufficient evidence" is not offered to create or impose an additional legal standard or burden of proof. The term has its own special significance within the scientific community and is used in this context only for that purpose.

It is not the intention of the Agency to substitute its scientific judgment for that of the authoritative body. The Agency's inquiry will be limited to whether the authoritative body relied upon scientific data in an amount sufficient to conclude that the chemical causes cancer. The Agency does not intend by this section to go behind the studies relied upon by the authoritative body to determine their scientific validity. Because the body is considered authoritative, and the body utilizes the same or substantially the same criteria as set forth in subsection (e), it will be assumed that the data relied upon is scientifically valid. The Agency will look to determine whether the authoritative body relied upon animal or human data in an amount sufficient to satisfy the criteria. If so, the chemical will be proposed for listing.

Two commentators recommended that the words "scientifically valid" be inserted before "studies," and that the words "clearly show" be inserted after "humans." (C-13, p. 7; C-4, p. 1.) When the Panel evaluates individual chemicals to determine whether it has been clearly shown according to scientifically valid studies to cause cancer, it follows the criteria adopted by the EPA to evaluate carcinogenic hazards. The definition of "sufficient evidence" in the regulation is derived directly from the EPA criteria. This promotes reasonable consistency between the listing of chemicals by the Panel and the listing of chemicals following the Panel's designation of an authoritative body. Adopting this recommendation would not enhance that consistency, and may lead to confusion. Further, adopting this recommendation would be duplicative, since the EPA criteria already imply the use of scientifically valid data, and a clear showing of the causal relationship between the chemical and cancer. Accordingly, this recommendation was not adopted.

Paragraph (e)(2) describes the criteria for determining that a chemical causes cancer where the authoritative body relied on studies in animals. Again, the regulation requires that sufficient evidence exist from such studies, and defines "sufficient evidence" to mean that studies in experimental animals indicate that there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains, in multiple experiments (e.g., with different routes of administration or using different dose levels), or, to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset. This definition of "sufficient evidence" is also well-established in the scientific community, and several references to this concept are further offered by way of illustration in the bibliography. Under these references, chemicals having

sufficient evidence from animal studies have been identified as chemicals "reasonably anticipated to be carcinogens" (NTP), and "Group 2A-- probably carcinogenic to humans" or "Group 2B--possibly carcinogenic to humans" (IARC). Whether a chemical is given IARC's 2A or 2B classification depends generally on the presence or absence of limited human data and the presence or absence of sufficient animal data.

EPA identifies chemicals having sufficient evidence in animals as "Group B-- probable human carcinogens." EPA subdivides its Group B into B1 (with limited human evidence) and B2 (sufficient animal evidence and inadequate or absent human data).

Again, the use of the term "sufficient evidence" is not offered to create or impose an additional legal standard or burden of proof. The term has its own special significance within the scientific community and is used in this context only for that purpose.

It should be noted that the definition of "sufficient evidence" in this section does not include evidence of short-term in vitro testing. In vitro tests are not studies in animals, and the Panel has not included such testing in its own criteria for listing chemicals. The criteria utilized by IARC, NTP and EPA do utilize short-term testing. Consequently, the chemicals which are identified as causing cancer pursuant to this section will not necessarily include all the chemicals included in EPA's Group B. Similarly, not all of NTP's "reasonably anticipated" carcinogens or IARC's Group 2 carcinogens will necessarily be among the chemicals identified as causing cancer pursuant to this section.

When the evidence from experimental animals concerning the carcinogenicity of a chemical is not sufficient, the NTP list of carcinogens does not include it. IARC calls the chemical "Group 3--not classifiable" or "Group 4--probably not carcinogenic." When EPA's evaluation of studies in experimental animals indicates that the evidence of carcinogenicity is "limited" rather than "sufficient," EPA identifies the chemical as belonging to "Group C--possible human carcinogen." Depending on the evidence, the Panel has listed some EPA Group C chemicals and not others. Under this regulation, Group C carcinogens or their equivalents will continue to be evaluated on a chemical by chemical basis, and involve determinations by the Panel.

It is not the intention of the Agency to substitute its scientific judgment for that of the authoritative body. The Agency's inquiry will be limited to whether the authoritative body relied upon scientific data in an amount sufficient to conclude that the chemical causes cancer. The Agency does not intend by this section to go behind the studies relied upon by the authoritative body to determine their scientific validity. Because the body is considered authoritative, it will be assumed

that the data relied upon is scientifically valid. The Agency will look to determine whether the authoritative body relied upon animal or human data in an amount sufficient to satisfy the criteria. If so, the chemical will be proposed for listing.

Two commentators recommended that the words "scientifically valid" be inserted before "studies," and that the words "clearly show" be inserted after "animals." (C-13, p. 7; C-4, p. 1.) When the Panel evaluates individual chemicals to determine whether it has been clearly shown according to scientifically valid studies to cause cancer, it follows the criteria adopted by the EPA to evaluate carcinogenic hazards. The definition of "sufficient evidence" in the regulation is derived directly from the EPA criteria. This promotes reasonable consistency between the listing of chemicals by the Panel and the listing of chemicals following the Panel's designation of an authoritative body. Adopting this recommendation would not enhance that consistency and may lead to confusion. Further, adopting this recommendation would be duplicative, since the EPA criteria already imply the use of scientifically valid data, and a clear showing of the causal relationship between the chemical and cancer. Accordingly, this recommendation was not adopted.

Subsection (f)

Subsection (f) states that a chemical does not satisfy the definition of "as causing cancer" if scientifically valid data not considered by the authoritative body clearly establish that there is not sufficient evidence that the chemical causes cancer or reproductive toxicity. The science of hazard identification is not static. Studies relied upon today may, in the light of new data, be unreliable tomorrow. The identification of chemicals under the Act was intended by the voters to be based upon scientific testing. (Ballot pamphlet, Rebuttal to Argument Against Proposition 65 as presented to the voters (Nov. 4, 1986).) It would make little sense to have chemicals listed under the Act where the data relied upon by an authoritative body is outdated and clearly contradicted by newer data. Further, the lists, reports or documents of an authoritative body may not always be intended to have practical or regulatory effect. The authoritative body, therefore, may not have a legal duty or the need to expeditiously re-evaluate its conclusions in the light of new data, especially when its resources are limited. However, the regulatory implications of listing under the Act require a consideration of current data.

One commentator objected that the lead agency, rather than the Panel, will make the determination whether the criteria have been met. (C-13, p. 8.) As a practical matter, however, assigning responsibility for the initial determination could cause the Panel to be overwhelmed by petitions from interested parties demanding review of new data to prevent the Agency from listing the chemical. This could place a substantial burden on the

Panel's resources and its members. Nothing in the regulation prevents the Agency from seeking the advice of the Panel in the event the newer data clearly shows that the old data is insufficient. However, the Agency appears to be in the best position to make the initial determination.

As originally proposed, subsection (f) (then subsection (e)) provided:

"A chemical has not been formally identified by an authoritative body as causing cancer if the lead agency makes a determination, based upon scientifically valid data not considered by the authoritative body, that subsection (d) is not applicable."

One commentor recommended that the section be rewritten to read:

"A chemical shall not be added to the list of chemicals known to the State to cause cancer if the Panel or lead agency makes a determination, based upon scientifically valid data not considered by the authoritative body, that the criteria set forth in subsection (d) have not been satisfied." (C-13, p. 8.)

This comment brought to the Agency's attention the potential for confusion in the original version. It was unclear whether the newer data which provides the basis for the Agency's determination means that the chemical had not been formally identified, or whether the new data would mean that the chemical does not cause cancer. To make clear that the affected term is "as causing cancer," subsection (f) was amended by the December 13 proposal to provide that a chemical does not satisfy the definition of "as causing cancer" if there is sufficient new data.

Subsection (g)

Subsection (g) provides that, for purposes of section 12306, the phrase "as causing reproductive toxicity" means that either of two scientific criteria have been satisfied. Generally, the authoritative body may rely on either studies in humans or studies in animals.

Paragraph (g)(1) describes the criteria for determining that a chemical causes reproductive toxicity where the authoritative body relied on studies in humans. As with carcinogens discussed above, the proposed regulation requires that sufficient evidence exist from such studies, in that studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity.

Paragraph (g)(2) describes the criteria for determining that a chemical causes reproductive toxicity where the authoritative

body relied on studies in animals for its identification of a chemical as a reproductive toxicant. Again, the proposed regulation requires that sufficient evidence exist from such studies. "Sufficient evidence" is defined to mean that there is sufficient data, which take into account the adequacy of the experimental design and other specified parameters, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible. This is consistent with the criteria utilized by the Panel when it evaluates reproductive hazards.

It is not the intention of the Agency to substitute its scientific judgment for that of the authoritative body. The Agency's inquiry will be limited to whether the authoritative body relied upon scientific data in an amount sufficient to conclude that the chemical causes reproductive toxicity. The Agency does not intend by this section to go behind the studies relied upon by the authoritative body to determine their scientific validity. Because the body is considered authoritative, and the body utilizes the same or substantially the same criteria as set forth in subsection (g), it will be assumed that the data relied upon is scientifically valid. The Agency will look to determine whether the authoritative body relied upon animal or human data in an amount sufficient to satisfy the criteria. If so, the chemical will be proposed for listing.

One commentator objected that the standard requiring "studies that indicate a biologically plausible association" cannot be squared with a statutory standard which requires that causation be clearly shown through scientifically valid testing. (C-13, p. 8.) However, biological plausibility is the standard applied by the Panel when it determines on a chemical-by-chemical basis that a chemical has been clearly shown through scientifically valid testing according to generally accepted principles. It appears that, in the case of reproductive toxicity, a biologically plausible association based upon animal data can constitute a clear showing.

One post-hearing commentator recommended that the subsection (g)(2) require that studies in experimental animals "clearly" indicate that there is an association between the "chemical" and adverse reproductive effects. (PH2-1, pp. 1-2.) This recommendation, however, was not directed at any change to the regulation noticed for public availability. Under Government Code section 11346.7(b)(3) and 11346.8(c), the Agency is obligated to respond to objections and recommendations directed at the Agency's proposed actions. In the case of post-hearing changes, the proposed action is the change to the proposed regulation, not the unchanged language. Since this comment is not directed at any change to the proposed language, and is directed at unchanged language, the Agency is not obligated to respond to the recommendation.

Subsection (h)

Subsection (h) states that a chemical does not satisfy the definition of "as causing reproductive toxicity" if scientifically valid data not considered by the authoritative body clearly establish that there is not sufficient evidence that the chemical causes reproductive toxicity. Again, as with carcinogens, the science of hazard identification is not static. Studies relied upon today may, in the light of new data, be unreliable tomorrow. The identification of chemicals under the Act was intended by the voters to be based upon scientific testing. (Ballot pamphlet, Rebuttal to Argument Against Proposition 65 as presented to the voters (Nov. 4, 1986).) It would make little sense to have chemicals listed under the Act where the data relied upon by an authoritative body is outdated and clearly contradicted by newer data. Further, the lists, reports or documents of an authoritative body may not always be intended to have practical or regulatory effect. The authoritative body, therefore, may not have a legal duty or the need to expeditiously re-evaluate its conclusions in the light of new data, especially when its resources are limited. Thus, several years may lapse before an authoritative body amends its list of reproductive toxicants to reflect the newer data. The listing of a chemical under the Act, on the other hand, does have regulatory implications. This requires a more expeditious consideration of current data.

As originally proposed, subsection (h) (then subsection (g)) provided:

"A chemical has not been formally identified by an authoritative body as causing cancer if the lead agency makes a determination, based upon scientifically valid data not considered by the authoritative body, that subsection (f) is not applicable."

One commentor recommended that the section be rewritten to read:

"A chemical shall not be added to the list of chemicals known to the State to cause reproductive toxicity if the Panel or lead agency makes a determination, based upon scientifically valid data not considered by the authoritative body, that the criteria set forth in subsection (f) have not been satisfied." (C-13, p. 9.)

This comment brought to the Agency's attention the potential for confusion in the original version. It was unclear whether the newer data which provides the basis for the Agency's determination means that the chemical had not been formally identified, or whether the new data would mean that the chemical does not cause reproductive toxicity. To make clear that the affected term is "as causing reproductive toxicity," subsection

(f) was amended by the December 13 proposal to provide that a chemical does not satisfy the definition of "as causing reproductive toxicity" if there is sufficient new data.

Subsection (i)

Subsection (i) sets forth a procedure to be followed by the lead agency prior to the listing of chemicals on the ground that they are formally identified by authoritative bodies as causing cancer or reproductive toxicity. At least 60 days prior to causing the chemical to be added to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency must publish a notice identifying the authoritative body and the chemical, stating its intention to cause the chemical to be added to the list. Interested parties will have 30 days within which to object to the proposed listing on the ground that there is no substantial evidence that the scientific criteria set forth in subsection (e) and (g) have been satisfied. Such objections must be in writing and be accompanied by supporting documentation.

One commentor recommended that the Agency invite public comment on all aspects of a decision to identify a substance which has been listed by another authoritative body, not just the satisfaction of the criteria for identification of a chemical "as causing cancer" or reproductive toxicity in subsections (e) and (g). (C-9, p. 3.) Subsection (i) arises out of concerns that chemicals formally identified by authoritative bodies might be listed even though the criteria utilized by the Panel had not been satisfied. The Panel applies scientific, not procedural, criteria when recommending chemicals for listing. The purpose of subsection (i) is to establish a procedure for determining which chemicals should be referred to the Panel for its scientific review. It is for this reason that the regulation limits objections to scientific criteria.

If a scientific objection is valid, Panel review will be appropriate. The Panel's expertise is not necessary to determine whether the identification of a chemical as a carcinogen or reproductive toxicant has been properly documented. To permit objections on the basis of procedure would require that procedural issues be referred to the Panel. Thus, a portion of the Panel's limited time would be absorbed resolving essentially ministerial matters, which would contravene the purpose of the authoritative bodies provision. Accordingly, this recommendation was not accepted.

One commentor objected that, under the regulation, the Panel may not even review a chemical unless there is no substantial evidence. The commentor contends that this turns the statute on its head, since the Panel can prevent listing only if it can be shown that the chemical is not a carcinogen. The commentor recommended that the regulation be amended to read:

"If objections are made on the basis of substantial evidence that the criteria identified in subsection (d) or in subsection (f) have not been satisfied, then prior to listing, the Panel shall advise the Agency as to whether the criteria in subsection (d) or subsection (f) have been met." (C-13, p. 9.)

As indicated above, the Agency does not intend to substitute its scientific judgment for that of the authoritative body. It does not intend to reevaluate the science to determine whether the authoritative body should have reached a different result. In effect, there is a presumption that the authoritative body properly applied the criteria. Adopting this recommendation would require that the Agency reweigh the science. Requiring that objections show there is no substantial evidence preserves this presumptive effect, and limits chemicals referred to the Panel to those which do not satisfy the authoritative body's own standards, again preserving the Panel's limited and valuable time.

Subsection (j)

Subsection (j) requires the reconsideration by the lead agency of its determination that a chemical is identified by an authoritative body as causing cancer or reproductive toxicity after the chemical has been added to the list of chemicals known to the State to cause cancer or reproductive toxicity where (1) there is no substantial evidence that the criteria identified in subsections (e) or (g) have been satisfied, or (2) the authoritative body no longer identifies the chemical as causing cancer or reproductive toxicity. This will permit an ongoing review to ensure the accuracy of the list of chemicals. Since the issues involved are essentially scientific, chemicals under reconsideration will be referred to the Panel for its recommendation. However, until this review has been completed, this subsection provides that the chemical under review will continue to be listed.

One commentor recommended that the regulation be amended to make clear that the Panel can recommend removal of a chemical from the list if there is "substantial evidence" that the listing criteria have not been met. (C-13, p. 10.) Similar objections were made to subsection (i), which authorizes objections to be made at the time the Agency proposes to list a chemical as formally identified by an authoritative body as causing cancer or reproductive toxicity on the ground that there is no substantial evidence that scientific criteria have been satisfied. For the same reasons, this recommendation was not adopted.

One commentor objected that criteria for removing a chemical from the list are narrow, observing that the Agency lists on the basis of criteria, and this subsection would permit reconsideration only if it does not meet these criteria. This approach, the

commentor contends, would virtually eliminate review. (C-14, p. 3.) The purpose of this regulation is to permit reconsideration where the Agency has listed a chemical in error, and where the authoritative body itself has changed its conclusion. The Agency would err if it listed a chemical even though there is no substantial evidence to do so.

Limiting reconsideration in this manner may limit the review of chemicals by the Panel, but the purpose of this subsection is not to permit a review of each chemical by Panel. Permitting expanded reconsideration criteria might encourage interested persons to seek reconsideration where a chemical has been properly listed, which might place an undue burden on the Agency and the Panel.

Subsection (k)

As originally proposed, section 12306 contained no provision governing the designation of authoritative bodies and the listing of chemicals if the regulation is declared invalid. It became apparent that such a provision is necessary because authoritative bodies are designated by the Panel, the Panel has serious concerns that the listing of chemicals as the result of such a designation should be controlled, and competing interest groups differ strongly on the extent of the controls which should be applied.

One commentor recommended the addition of a new subsection (k), which would read:

"(k) in the event that any provision of this section 12306 shall be held by any court to be invalid for any reason, the entire section 12306 and each subsection hereof shall be deemed to be void and of no effect, and any determination made hereunder that any body is authoritative, or that any chemical has been formally identified by an authoritative body as a carcinogen or a reproductive toxicant, or that by virtue of any such identification any chemical has been added to the list of chemicals known to the state to cause cancer or reproductive toxicity, shall be similarly void and of no effect." (C-5, p. 3.)

This approach appeared too harsh, since it provided no way for the Panel to ratify the designation of authoritative bodies or the listing of chemicals following a successful challenge to the regulation. Consequently, the October 13 proposal provided:

"In the event that a court holds that this regulation or any portion thereof is invalid, any determination that a body is authoritative shall be deemed void and of no effect, unless subsequently ratified by the Panel."

One post-hearing commentator objected to this proposal, questioning its authority. (PH1-1, p. 4.) Upon further review, the Agency determined that this approach would serve as an invitation for industry groups to challenge the validity of the regulation. If a business or industry uses a chemical listed by the Agency under this section, and an enforcement action is brought against the business or industry for exposures to or discharges of the chemical, the business or industry could collaterally attack this regulation and, under this subsection, invalidate the designation of the authoritative body which caused the chemical to be listed. This appeared to be an undesirable result.

Consequently, the December 13 proposal substituted the following language:

"The Panel may condition any determination that a body is considered to be authoritative upon the subsequent application of the controls set forth in this section to the determination of which chemicals have been formally identified by the body as causing cancer or reproductive toxicity. In the event that this section or any portion thereof is found to be invalid by any court of competent jurisdiction, the Panel may determine that such invalidation constitutes a failure of the condition. Upon finding such failure of condition the determination that the body is authoritative shall be deemed to be revoked. Chemicals which the lead agency has determined have been formally identified by the body as causing cancer or reproductive toxicity pursuant to the controls set forth in this section and which have been placed upon the list of chemicals known to the state to cause cancer or reproductive toxicity prior to such revocation shall remain on the list."

If the Panel has discretion in designating authoritative bodies, it may condition its designation. One of the Panel's primary concerns is that the designation of authoritative bodies will result in the uncontrolled listing of chemicals. Therefore, to satisfy its own concerns, it makes sense for the Panel to condition its designation upon the application of suitable controls. This section simply affirms that this solution is available. The Panel may condition its designation of an authoritative body upon the subsequent application of controls. If those controls are found inapplicable, then the Panel may find a failure of condition, in which case the body is no longer considered authoritative, and the Agency may no longer list the chemicals which body formally identifies as causing cancer or reproductive toxicity. Thus, chemicals will be listed only in a controlled manner.

However, unless some provision is made regarding chemicals already listed pursuant to this section, conditioning the designation of an authoritative body upon the application of

controls in this section might continue to serve as an invitation for affected persons to challenge those controls. It could be argued that the failure of condition would have a retroactive effect, removing from the list chemicals added when the controls were in effect. Accordingly, the December 13 proposal further provided that chemicals listed subject to the controls would remain on the list.

Subsection (l)

At its meeting on April 14, 1989, the Panel made a provisional decision to designate the EPA as an "authoritative body" for purposes of the Act. Accordingly, the original version of this regulation provided that EPA had been designated as an authoritative body.

One commentor objected that this was inaccurate; that the Panel had identified EPA on a provisional basis on certain terms and conditions. The commentor recommended that the regulation be amended to add the phrase "on the express condition that all the procedures and safeguards set forth in this section 12306 be given full force and effect." (C-13, p. 10.) However, this too would be inaccurate, because at the time the Panel designated EPA as authoritative, section 12306 had not yet been proposed.

On October 20, 1989, the Panel reaffirmed this designation, and further designated IARC and NTP as authoritative bodies, subject to the controls in section 12306, which was adopted as an emergency regulation on that date. Accordingly, subsection (j) states that the Panel has identified the EPA, IARC and NTP as authoritative bodies "for purposes of this section." This subsection is intended to provide an easy reference to designated authoritative bodies, yet be consistent with the conditions established under the regulation. The subsection is structured so that additional authoritative bodies may be added upon designation by the Panel.

ADDENDUM
-FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12306 - Chemicals Formally identified by Authoritative Bodies

Insert at bottom of page 13:

"One commentor recommended the addition of language to subparagraphs (2)(A)-(F) which will make it clear that a condition will apply only where applicable. (C-13, p. 6.) The purpose of subparagraph (2) is to specify what formality is required to accompany an identification of a chemical. Formality can be evidenced in many ways, and a body's process need not be complete in order for the steps taken to indicate formality in the identification of a chemical. A body may require several steps in order to complete its own process, but each of these steps may evidence formality. The Agency considers each step set forth in subparagraph (2)(A)-(F) to be a sufficient indicium of formality for purposes of the Act. Under this commentor's recommendation, however, the authoritative body would likely need to have completed its process and have satisfied several steps in order for the chemical to be listed, even though any single step appears sufficient to demonstrate formality. This could severely limit the chemicals which the Agency could list and effectively defeat the purpose of the authoritative bodies provision to relieve the Panel of unnecessary chemical-by-chemical review. Accordingly, this recommendation was not adopted."

Insert after the first sentence in the third full paragraph on page 15:

"Two commentors objected to subparagraph (2)(F) on the ground that it is vague. (C-3, p. 4, fn. 4; C-13, p. 7.) One commentor observed that the original language could describe "everything from dictionaries to press releases," and recommended that the provision be amended to read:

'otherwise set forth in a document that formally identifies chemicals regulated as carcinogens or reproductive toxicants by said authoritative body.'

"As indicated above, to provide that formality is satisfied where a document "formally identifies" a chemical begs the question as to what is "formal." Therefore, this recommendation was not adopted. The vagueness objection, however, has been addressed by the insertion of the word 'official' before the word 'document.'"

Add new paragraph before subheading for subsection (i) on page 24:

"One commentor recommended that a comma be inserted between the words 'body' and 'clearly' in subsection (g), now subsection (h). (C-11, p. 3.) The comma had been inadvertently omitted from the original proposal. The December 13 proposal rewrote subsection (h) and eliminated the language containing this typographical error. No comma is necessary in the revised version."

Insert new paragraph after the last full paragraph on page 24:

"This does not mean that the Agency will refuse objections grounded in procedure. It has been the policy of the Agency to consider public input. If the Agency receives information that a chemical has not been 'formally identified' within the meaning of subsection (d), the Agency will consider the information. If the information comes as an objection to the Agency's notice of intent to list a chemical, it will likewise be considered. If the objection is valid, the Agency will react accordingly. The issue will not, and should not, be referred to the Panel for its consideration for the reasons stated above."

Insert new paragraph after the first paragraph under the "Subsection (j)" subheading on page 25:

"If a chemical is referred to the Panel under this subsection, the Agency believes that listing of the chemical by the authoritative bodies mechanism is no longer justifiable. If the Panel agrees, the Panel may recommend that the chemical be removed from the list, or recommend that the chemical continue to be listed because it has been clearly shown through scientifically valid testing to cause cancer or reproductive toxicity. If the Panel disagrees, it may recommend that the chemical continue to be listed under the authoritative bodies mechanism. In any case, the Agency intends to act on the Panel's recommendation."

Insert new paragraph after the last full paragraph on page 27:

"The term 'controls' was chosen to broadly describe the provisions of this regulation. It refers to any provision in section 12306, including subsection (k). This approach appeared to be preferable to an enumeration of the various provisions of section 12306 which contain the controls, since virtually every subsection contains elements arguably essential to the overall scheme.

"Discretion is vested in the Panel to determine whether the invalidation of any provision in section 12306 frustrates the Panel's intentions in imposing conditions in the first place. This discretion is afforded by providing that the Panel 'may'

find a failure of condition following invalidation. For example, the invalidation of subsection (b) may frustrate the Panel's intention that the designation of a body accurately reflect the Panel's ongoing confidence in the body. The invalidation of subsection (d) could contravene that Panel's desire for constraints on the listing of chemicals once an authoritative body is designated. In either case, the determination whether there is a failure is for the Panel."

Insert before "Accordingly" in the fourth line of the last paragraph on page 28:

"The Panel has apparently concluded that these bodies satisfy the criteria of subsection (b)."