UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dr. Steven G. Hentges
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American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22208

Dear Dr. Hentges:

This letter is the response to the American Chemistry Council (ACC) Request for Correction (RFC) #10007, which was received on August 2, 2010. In the RFC, the Panel challenged the "objectivity" and "utility" of thirteen statements found in the EPA Bisphenol A (BPA) Action Plan[1]. The Panel alleged these statements are not consistent with the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*[2]. The Panel also recommended thirteen specific corrective actions to address their information quality concerns.

After reviewing the Panel's RFC, EPA has determined that the underlying information and conclusions presented in the Plan are objective and of high quality, consistent with the EPA Information Quality Guidelines. Accordingly, the BPA Action Plan will not be edited and will remain on the EPA website. The Agency's response to each of the Panel's information quality concerns can be found in the enclosed document. In addition, your letter and this RFC response will be placed in the docket for the BPA Action Plan (Docket ID No. EPA-HQ-OPPT-2010-0348).

The Action Plan is intended to describe the courses of action the Agency plans to pursue in the near term to address its concerns. The Agency also includes contextual scientific information to accompany the Action Plan. In preparing the Action Plan, EPA followed the Agency's Information Quality Guidelines to ensure the utility, objectivity, and integrity of the information disseminated in the Action Plan. EPA has determined that the information provided in the Action Plan is accurate and reliable, providing specific references to the best available science and supporting studies, and is presented in an unbiased manner with applicable uncertainties and limitations discussed. The Action Plan is also formatted and designed with the intended audience in mind, and posted on the website in a secure manner to protect the Action Plan from deliberate or accidental alteration. In addition, like other planning tools used by the Agency, Action Plans are not risk assessments or major work products undergoing peer review. Rather, Action Plans are brief public summaries and explanations of

[1] Bisphenol A (BPA) Action Plan, U.S. EPA (March 2010).
http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/bpa_action_plan.pdf
[2] (EPA's Information Quality Guidelines) 67 Fed. Reg. 63657 (October 15, 2002).
http://www.epa.gov/quailty/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf

EPA's interest in a chemical and the actions the Agency intends to take concerning that chemical based on its preliminary review of available information. Moreover, Action Plans do not constitute the support documents for the actions they describe. EPA provides the underlying scientific and technical support for an action described in an Action Plan at the time we initiate the action. Action Plans are simply intended to make the Agency's planning process more accessible and transparent to the public at an early stage. Any regulatory or other substantive actions undertaken by the Agency subsequent to the publication of an Action Plan would include the Agency's specific identification and assessment of the data on which the Agency relied, which may differ from the information presented in the Action Plan.

Before disseminating an Action Plan, EPA ensures that the information in the Action Plan comports with the Agency's Information Quality Guidelines. However, the BPA Action Plan is not, as ACC alleges, "influential information" under the Agency's Information Quality Guidelines. Information is "influential" for the purposes of the Agency's Information Quality Guidelines if the Agency can reasonably determine its dissemination of the information will have or does have a clear and substantial impact on important public policies or private sector decisions. As per the EPA Information Quality Guidelines, EPA will generally consider the following classes of information to be influential, and, to the extent that they contain scientific, financial, or statistical information, that information should adhere to a rigorous standard of quality:

- Information disseminated in support of top Agency actions (i.e., rules, substantive notices, policy documents, studies, guidance) that demand the ongoing involvement of the Administrator's Office and extensive cross-Agency involvement; issues that have the potential to result in major cross-Agency or cross-media policies, are highly controversial, or provide a significant opportunity to advance the Administrator's priorities. Top Agency actions usually have potentially great or widespread impacts on the private sector, the public or state, local or tribal governments. This category may also include precedent-setting or controversial scientific or economic issues.

- Information disseminated in support of Economically Significant actions as defined in Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), Agency actions that are likely to have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, Tribal, or local governments or communities.

- Major work products undergoing peer review as called for under the Agency's Peer Review Policy. Described in the *Science Policy Council Peer Review Handbook,* the EPA Peer Review Policy regards major scientific and technical work products as those that have a major impact, involve precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review. These Major work products are typically subjected to external peer review. Some products that may not be considered "major" under the EPA Peer Review Policy may be subjected to external peer review but EPA does not consider such products influential for purposes of these Guidelines.

- Case-by-case: The Agency may make determinations of what constitutes "influential information" beyond those classes of information already identified on a case-by-case basis for other types of disseminated information that may have a clear and substantial impact on important public policies or private sector decisions.

The hazard, exposure, and other technical information contained in the BPA Action Plan has already been disseminated through scientific journals, government reports, and other public channels. The only new information in the Action Plans consists of certain preliminary aspects of the Agency's planning process, including information about which studies the Agency has considered to date, and an outline of the risks that the chemicals may present. The purpose of such a document is to be transparent about the Agency's plans related to future actions being considered.

If you are dissatisfied with this response, you may submit a Request for Reconsideration (RFR). The EPA requests that any such RFR be submitted within 90 days of the date of EPA's response. If you choose to submit a RFR, please send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Processing Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460); electronic mail (quality@epa.gov); or fax ([202] 565-2441). If you submit a RFR, please reference the request number assigned to the original Request for Correction (RFC #10007).
Additional information about how to submit an RFR is listed on the EPA Information Quality Guidelines website at http://epa.gov/quality/informationguidelines/index.html.

Sincerely,

Stephen A. Owens
Assistant Administrator

Enclosure

cc: Malcolm D. Jackson, Assistant Administrator and Chief Information Officer, Office of Environmental Information

Enclosure
EPA Response to Specific Statements from the American Chemistry Council (ACC)
(Request for Correction (RFC) #10007)

Below are EPA's responses to the thirteen statements the ACC would like to see corrected (see ACC's RFC for full description of the requested changes).

1. "EPA intends to consider initiating rulemaking under section 5(b)(4) of the Toxic Substances Control Act (TSCA) to identify BPA on the Concern List as a substance that may present an unreasonable risk of injury to the environment on the basis of its potential for long-term adverse effects on growth, reproduction and development in aquatic species at concentrations similar to those found in the environment. A notice of proposed rulemaking is intended to publish in autumn, 2010."

   EPA Response #1: This statement accurately reported EPA's intent to *consider initiating* a rulemaking under section 5(b)(4) of TSCA that included BPA and provided a brief statement describing why that was being considered. The requestor suggests that EPA cannot use the information provided in the Action Plan as the basis for considering to include BPA in a proposed rule under section 5(b)(4) of TSCA. Although the Action Plan includes contextual scientific information as part of its explanation for the identified courses of action, the Action Plans do not constitute the support documents for the actions that are being considered by EPA. Independent of the Action Plan, EPA will provide the underlying scientific and technical support specific to an action at the time that the action is actually taken. Action Plans are simply intended to make the Agency's planning process more accessible and transparent to the public at an early stage. Any regulatory or other substantive actions undertaken by the Agency subsequent to the publication of an Action Plan would include the Agency's specific identification and assessment of the data on which the Agency relied to develop the action being proposed, which may differ from the information presented in the Action Plan. EPA has determined that the information provided in the Action Plan is accurate and reliable, providing specific references to the best available science and supporting studies, and is presented in an unbiased manner with applicable uncertainties and limitations discussed. Whether the data presented and reviewed in a subsequent proposed rule adequately support EPA's inclusion of BPA in that proposed rule, would be an issue for comment in that specific rulemaking proceeding.

2. "Because BPA is a reproductive, developmental, and systemic toxicant in animal studies and is weakly estrogenic, there are questions about its potential impact particularly on children's health and the environment."

3. "There is general agreement that BPA is a reproductive and developmental toxicant at doses in animal studies of > 50 mg/kg-bw/day (delayed puberty in male and female rats and male mice); > 235 mg/kg-bw/day (reduced fetal or birth weight or growth early in life, effects on testis of male rats); and > 500 mg/kg-bw/day (possible decreased fertility in mice, altered estrous cycling in female rats, and reduced survival of fetuses)."

   EPA Response #2 & 3: EPA relied heavily on the CERHR/NTP document that ACC also cites. The CERHR clearly determined in their weight-of-evidence analysis that BPA causes developmental and reproductive effects in laboratory animals (see Figure 2b on p. 8 in NTP-

CERHR. 2008. *NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A*. National Toxicology Program. Center for the Evaluation of Risks to Human Reproduction. US Dept. of Health and Human Services. September 2008. NIH Publication No. 08-5994. URL: *http://cerhr.niehs.nih.gov/evals/bisphenol/bisphenol.pdf*). In fact, the 235 and 500 mg/kg/day doses described in the Action Plan are taken from this Figure. The >50 mg/kg/day represents the generally recognized NOAEL for reproductive effects identified by both US FDA [2008] and Japan [2004]. The key point is that there is agreement among these multiple reviewers about the reproductive and developmental toxicity of BPA in animal studies at high dose levels. The requestor's comment also expressed concern that the effects seen were the result of maternal toxicity. EPA notes that the maternal toxicity questions raised were addressed in the CERHR/NTP document as part of the CERHR/NTP's assessment of the quality of the studies used and the appropriate interpretation of the effects observed in those studies; however, EPA notes that for the Action Plan, the Agency did not separately assess endpoints as this would be going beyond the preliminary nature of the review conducted for the Action Plan.

4. "Although there is disagreement about the interpretation of these low-dose studies, they do raise potential concerns for long-term effects at similar concentrations, and some authorities, including Canada and some U.S. state and county governments, have taken interim risk management action to protect certain sensitive populations, such as infants and toddlers."

   EPA Response #4: This statement is factually correct. Despite the scientific disagreement over the interpretation of the low-dose studies, Canada and some U.S. state governments have taken legislative or regulatory risk management actions to protect some human populations out of concern for potential low-dose effects. Irrespective of their basis, the actions themselves were taken, and the Action Plan duly reported them without making judgments on them. The Action Plan did not endorse those risk management actions or rely on them as support for any interpretation of the low dose studies.

5. "There was a recent report in which a cross-sectional study design was used to suggest an association between BPA levels in humans and a higher risk of diabetes, heart disease, and elevation of certain liver enzyme activities (Lang et al., 2008). The authors examined the human data from the 2003-4 NHANES population. However, this report prompted an immediate review by the European Food Safety Authority (EFSA) (EFSA, 2008b) in late 2008 which concluded that the study did not provide sufficient proof for the stated associations. EPA notes that the same investigative group recently published an online research article repeating their original findings for heart disease but not diabetes on a second NHANES population from 2005-6 (Melzer et al., 2010)."

   EPA Response #5: These statements are factually correct. In this section of the Action Plan, EPA noted and summarized the wide range of information on human health issues that has been publicly reported in connection with BPA exposure. EPA offered no interpretation of the Lang and Melzer studies and did not rely on them. EPA further noted the EFSA review of and critical conclusion on the Lang study. No detailed technical discussion or interpretation was presented in the Action Plan on these or any studies because an Action Plan is not a risk assessment, but instead summarizes available hazard, exposure, and use information on chemicals; outlines the risks that each chemical may present; and identifies the specific steps

the Agency is taking to address those concerns. Any rulemaking actions that may be undertaken by the Agency subsequent to the publication of the Action Plan would include the Agency's specific identification and assessment of the data on which the Agency relied, and whether those data support those actions would be an issue for comment in those specific rulemaking proceedings.

6. "Thirty-eight scientists (known as the "Chapel Hill Group"; vom Saal et al., 2007) concluded that: (1) there is relevance of in vitro data to in vivo effects; (2) ecological studies are consistent with lab animal studies; (3) the low doses in animal studies are relevant to BPA levels found in humans; and (4) life stage is important in pharmacokinetics, exposure, and effects in animals and humans."

   EPA Response #6: The statement is factually correct. In this section of the Action Plan, EPA summarized the conclusions of four different groups (a California Advisory Committee to CalEPA, the U.S.-government funded "Chapel Hill Group"; the industry-funded Harvard Panel; and the NTP CERHR [a diverse government-funded panel that included government, academic and industry scientists]) on human health issues that have been publicly reported in connection with BPA hazard and exposure. This information was noted in the Action Plan appropriately to illustrate the existing, highly public disputes published within the scientific community concerning BPA.

7. "In general, studies have shown that BPA can affect growth, reproduction and development in aquatic organisms. Among freshwater organisms, fish appear to be the most sensitive species. Evidence of endocrine-related effects in fish, aquatic invertebrates, amphibians and reptiles has been reported at environmentally relevant exposure levels lower than those required for acute toxicity. There is a widespread variation in reported values for endocrine-related effects, but many fall in the range of 1µg/L to 1 mg/L. (Canada, 2008)."

   EPA Response #7: The statements are a factually correct representation taken from Canada, 2008. In this section of the Action Plan, EPA noted and summarized the range of information on environmental hazard issues that has been publicly reported in connection with BPA exposure. No detailed technical discussion or interpretation was presented in the Action Plan on these or any studies because an Action Plan is not a risk assessment. The Action Plan summarizes available hazard, exposure, and use information on chemicals; outlines the risks that each chemical may present; and identifies the specific steps the Agency is taking to address those concerns. Any rulemaking actions that may be undertaken by the Agency subsequent to the publication of the Action Plan would include the Agency's specific identification and assessment of the data on which the Agency relied, and whether those data support those actions would be an issue for comment in those specific rulemaking proceedings.

8. "Canada concluded in its hazard characterization that "[c]onsidered together, the data provide strong evidence that bisphenol A is capable of eliciting adverse effects (1) following prolonged exposure at levels below those usually seen to elicit effects in standard toxicity tests (i.e., tests based on recognized methods which evaluate endpoints such as survival, reproduction and growth); (2) following brief low-dose exposure, particularly at sensitive developmental stages, with effects apparent later in the life cycle; (3) on filial generations following parental exposure; and (4) using more than one mode of action." (Canada, 2008)"

EPA Response #8: The statement is factually correct: it accurately quotes the Canadian document. In this section of the Action Plan, EPA noted and summarized the range of information on environmental hazard issues that has been publicly reported in connection with BPA exposure. As stated on page 2 of the action plan "This Action Plan is based on and encompasses EPA's initial review of readily available use, exposure, and hazard information on BPA." EPA is not endorsing any findings in the citations provided in the Action Plan, but is only noting that they have been identified as part of an initial review. Any rulemaking actions that may be undertaken by the Agency subsequent to the publication of the Action Plan would include the Agency's specific identification and assessment of the data on which the Agency relied, and whether those data support those actions would be an issue for comment in those specific rulemaking proceedings.

9. "Limited information is available for BPA concentrations in U.S. water and other environmental media (Table 4, providing values from all of the studies cited in this discussion)."

EPA Response #9: EPA believes that the sampling was limited in terms of temporal and spatial coverage, providing only isolated snapshots in time (see Action Plan at page 15). In its review of readily available information on BPA concentrations in U.S. surface waters and other environmental media, EPA determined that the number of studies citing monitoring data and the number of samples analyzed for the occurrence of BPA were limited in terms of spatial as well as temporal coverage. Although some information is available on BPA concentrations in certain U.S. waters and other environmental media, in the studies EPA reviewed the number of sites tested were not sufficient to define the nationwide distribution of BPA in surface waters. Different methodologies were used for measurements (some more robust than others), the sources of the measured BPA concentrations were unclear, and for some environmental media (e.g., landfill leachate), only one location was tested and that single location was likely not representative of the entire United States.

10. "E-FAST2 modeling of BPA releases in the 2007 TRI showed the most conservative estimates of the potential acute dose rate for ingestion of BPA in drinking water by children ages 1-2 ranged from 0.0000531 to 16.5 µg/kg/day, and the most conservative estimates of the surface water concentration ranged from 0.000574 to 232 µg/L. The EFAST2 model is intended to be used for screening level exposure characterization. EFAST2 is based on numerous assumptions that are designed to be conservative; for example, E-FAST2 does not account for the half life of a chemical in surface water. The inputs selected for the E-FAST2 modeling of BPA were also selected to be conservative; for example, the bioconcentration factor was selected to be at the high end of the range of values reported for BPA in the literature."

EPA Response #10: These statements are factually correct, reporting the results of E-FAST2 modeling and appropriately noting the conservatism of the inputs selected. EPA routinely uses modeling in preliminary reviews when exposure data are unavailable to obtain a picture of the range of potential values. EPA reported these results to provide a context for exposure estimates, but appropriately did not represent them either as being authoritative or as being the basis for decision-making. EPA would use the best available exposure data in any further assessment or rulemaking proceeding. If sufficient representative data are not

available, EPA would use conservative screening models such as E-FAST as needed to supplement reliable, representative monitoring data.

11. "Workers may be exposed to BPA by inhalation or skin contact during the manufacture of BPA and BPA-containing products. No data were available for dermal exposures, and limited data were available for inhalation exposures. Table 5 summarizes EPA's estimates for occupational exposures that may occur during manufacturing. These estimates were derived using models developed by EPA/OPPT for use in preparing screening-level exposure assessments of chemicals. These models do not take into account the effect of any personal protective equipment that may be used."

    EPA Response #11: These statements are factually correct, reporting the results of OPPT modeling and providing the cautionary notation that the modeling did not take into account the effect of any personal protective equipment. EPA routinely uses modeling in preliminary reviews when exposure data are unavailable to obtain a picture of the range of potential values. EPA reported these results, but appropriately did not represent them either as being authoritative or as being the basis for decision-making. Although the EU risk assessment did include worker exposure information for Europe, those data may or may not be comparable to exposures in the U.S. If a further exposure assessment is conducted by EPA, the best available worker exposure information would be evaluated and considered. EPA would use screening models as needed if reliable, representative monitoring data were not available.

12. "Connecticut, Minnesota, Wisconsin, Washington, Chicago and Suffolk County, N.Y., have banned the sale of polycarbonate baby bottles, food containers and cups that contain BPA. The Connecticut ban also applies to infant formula cans and all reusable food and beverage containers. The Suffolk County ban (County of Suffolk, 2009) went into effect in July 2009. The Minnesota ban (Minnesota, 2009) went into effect on 1/1/2010, and the Chicago ban (Chicago, 2009) on 1/31/2010. The Wisconsin ban (Wisconsin 2010) will go into effect on 6/15/2010, and the Connecticut ban (Connecticut, 2009) will take effect on 10/1/2011. The Washington state ban (Washington, 2010) will take effect on 7/1/2010 concerning food and drink containers for children three years old and under, and will ban BPA in sports water bottles effective 7/1/2012. Similar bills banning BPA in children's food and drink containers passed both houses in Maryland (Maryland, 2010) in February 2010, and if they are signed into law by the governor, would take effect on 1/1/2012. California bill (California, 2009) to ban the use of BPA in baby bottles and cups and infant formula cans failed to pass in September 2009 and was moved to the inactive file. A similar bill failed to pass in Oregon (Oregon, 2010) in February 2010."

    EPA Response #12: These statements are factually correct. In this section of the Action Plan, EPA noted and summarized the range of regulatory reviews and risk management actions being taken by a variety of jurisdictions addressing BPA, reflecting the high degree of public interest in this chemical worldwide. Irrespective of their basis, the actions themselves were taken, and the Action Plan duly reported them without making judgments on them. The Action Plan did not endorse those actions or rely on them as support for any actions being considered by EPA.

13. "Although there is disagreement in interpreting the novel low-dose studies and some of the effects observed in the many aquatic toxicity studies performed thus far with BPA, a

comparison of the range of predicted no effect concentration (PNEC) values used in the three international regulatory risk assessments (0.175 to 1.6 µg/L, Table 3) with measured concentrations in U.S. waters and sediments, which included values as high as 12 µg/L (surface water), 2.55 µg/L (ground water), and 140 µg/kg sediment (freshwater sediment) (Table 4), raises concern about possible risk of injury to aquatic organisms. However, limited information is available for BPA concentrations in U.S. water, and most available environmental monitoring results show that the concentrations of BPA in water bodies are lower than 1 µg/L (median concentration of 0.14 µg/L, below any calculated PNEC). These environmental measurements represent only isolated snapshots in time and do not provide an indication of how many areas may exceed PNEC values or concentrations of concern, how often or how long such concentrations may be exceeded, or the pathways leading to BPA presence in the environment from manufacturing, processing, distribution in commerce, use, or disposal. Additional information would help to resolve these uncertainties."

EPA Response #13: These statements are factually correct, and were presented to provide a preliminary explanatory context for the comparison of the general range of hazard values for BPA with the general range of reported potential environmental exposures. An Action Plan is not a risk assessment, but instead summarizes available hazard, exposure, and use information on chemicals; outlines the risks that each chemical may present; and identifies the specific steps the Agency is taking to address those concerns. At this time EPA is not endorsing any findings, but instead identified all the international and other assessments as being information sources. EPA considered it appropriate to employ a conservative approach in conducting such a preliminary review. However, any rulemaking actions that may be undertaken by the Agency subsequent to the publication of the Action Plan would include the Agency's specific identification and assessment of the data on which the Agency relied, and whether those data support those actions would be an issue for comment in those specific rulemaking proceedings.