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August 10, 2015

VIA EMAIL AND U.S. MAIL

Stephanie Tsacoumis
General Counsel
U.S. Consumer Product Safety Commission
4330 East West Highway, Bethesda, Maryland 20814-4408
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Dear Ms. Tsacoumis:

Thank you for the meeting of ExxonMobil Chemical Company ("EMCC") representatives with you and your staff on July 24, 2015, to discuss certain legal issues pertaining to the Commission's implementation of Section 108 of the Consumer Product Safety Improvement Act.

At the meeting, we provided a slide deck with a summary of our views on these legal issues. Attached to this letter is a document that discusses these legal issues in greater detail; the slides were derived from this document. Essentially the same document is being provided with EMCC's comments on the CPSC staff cumulative risk assessment reanalysis, as Appendix C to those comments. We thought you might also find it useful to have the legal issue discussion as this stand-alone document.

We appreciate your office's willingness to hear from us on these critical legal points. We would be happy to provide any additional information that might assist you and the Commissioners as you proceed in the rulemaking process.

If you have any questions, please do not hesitate to contact me at 832-624-6428.

Sincerely,

Donna Petrone

Donna Petrone

Before the

CONSUMER PRODUCT SAFETY COMMISSION

LEGAL ISSUES PERTAINING TO THE COMMISSION'S IMPLEMENTATION OF SECTION 108 OF THE CONSUMER PRODUCTS SAFETY IMPROVEMENT ACT

Docket Number CPSC-2014-0033

ExxonMobil Chemical Company

22777 Springwoods Village Parkway

Spring, TX 77389

July 24, 2015

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the Commission's Implementation of Section 108 of
the Consumer Products Safety Improvement Act

INTRODUCTION AND SUMMARY

ExxonMobil Chemical Company ("EMCC"), a division of Exxon Mobil Corporation, is submitting these legal issue comments to the Consumer Product Safety Commission ("CPSC" or "the Commission") to address its implementation of Section 108 of the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), 15 U.S.C. § 2057c. In separate comments being submitted by August 7, 2015, we discuss information in the CPSC Reanalysis Document,[1] and what it demonstrates regarding the potential risks of DINP. In this document we address certain legal issues pertaining to the Commission's Section 108 obligations in light of the reanalysis results; these legal issues will appear as Appendix C to the comments submitted by August 7. EMCC also had addressed some of these issues in our April comments on CPSC's original proposed rule.[2]

Section I provides a brief summary of the statute and activities under it that are pertinent to the issues discussed herein. Section II then addresses the degree to which the Commission must or must not adhere to the recommendations of the Chronic Hazard Advisory Panel in conducting its phthalate rulemaking, especially in light of the reanalysis results. The CHAP is an advisory committee of private individuals; if the statute did require CPSC to rigidly follow its recommendations, that would raise serious questions as to whether the statute is unconstitutional. Such questions can be avoided, however, because the statute makes clear that the CHAP is simply an advisory group. It was appointed under Section 28 of the Consumer Product Safety Act like any other CHAP. It can make recommendations, but the Commission retains the decisional authority.

That the CPSIA directs CPSC to conduct its rulemaking "based on" the CHAP report does not alter the relative roles of the two entities. Congress did not state the Commission should

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[1] K. Carlson, S. Garland (2015). Estimated Phthalate Exposure and Risk to Pregnant Women and Women of Reproductive Age as Assessed Using Four NHANES Biomonitoring Data Sets (2005/2006, 2007/2008, 2009/2010, 2011/2012). CPSC/EXHR/TR—15/XXX, Directorate for Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, Rockville, MD, http://www.cpsc.gov/Global/Regulations-Laws-and-Standards/CPSIA/CHAP/NHANES-Biomonitoring-analysis-for-Commission.pdf (accessible from http://www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act/Phthalates/Chronic-Hazard-Advisory-Panel-CHAP-on-Phthalates/) [hereinafter "Reanalysis Document"].

[2] ExxonMobil Chemical Company, Comments on the Proposed Rule: Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, Docket Number CPSC-2014-0033-0086, submitted to the Consumer Product Safety Commission (April 14, 2015) [hereinafter "EMCC April Comments"].

make its determination "solely" or "exclusively" based on the CHAP, and "based on" can encompass a wide range in how a source is used to inform a matter. Most importantly, the CPSIA explicitly states that the phthalate rulemaking is to be done pursuant to Section 553 of the Administrative Procedures Act ("APA"). Under a rich lineage of case law, this means the Commission is to critically review the CHAP report and evaluate all relevant evidence independently, including evidence presented during the rulemaking and never considered by the CHAP. The Commission has an obligation to disregard the CHAP's report to the extent it is incorrect, unreasonable, inconsistent with existing CPSC policy, practice, regulations or governing statutes, or is based on data that is outdated or of poor quality.

Section III explains that the direction to consider cumulative effects is in the CPSIA charge to the CHAP (not the charge to the CPSC), and it does not mandate a quantitative cumulative risk assessment. To the extent the CPSC uses a quantitative cumulative risk in this decision making, the question for it under the CPSIA is whether the results of that risk assessment indicate that it is necessary to continue the prohibition on diisononyl phthalate ("DINP") to ensure a reasonable certainty of no harm to infants, pregnant women, or other susceptible populations. A reasonable certainty does not mean perfect certainty or reducing risk to zero, and it does not mean banning a substance that contributes only a negligible portion of the risk. Current data and the scientific evidence strongly demonstrate that there is a reasonable certainty of no harm even if the prohibition on DINP is lifted.

Finally, Section IV addresses the issue of evaluating foreseeable abuse or misuse of phthalate-containing products. The CHAP was directed to examine the likely levels of exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of children's products. This has been accomplished by use of the NHANES biomonitoring data, which is representative of the population as a whole and thus includes high exposures due to abuse/misuse. Use of the NHANES data, and particularly the more recent NHANES data utilized by the Reanalysis Document, therefore provides the "reasonable estimation" envisioned by Congress.

I. PERTINENT BACKGROUND

CPSIA Section 108 addresses use of phthalates in children's toys and childcare products ("children's products"). It permanently prohibited three phthalates in children's products,[3] and placed an interim prohibition on DINP and two other phthalates.[4] It required the Commission to establish a CHAP pursuant to Section 28 of the CPSA (15 U.S.C. § 2077). The CHAP was charged with examining all phthalates and phthalate alternatives and then preparing a report with the results of its examination and with recommendations to CPSC on whether any phthalate (or alternative) should be declared a banned hazardous substance. CPSIA § 108(b)(2), 15 U.S.C. § 2057c(b)(2). Section 108 then directs the Commission to promulgate a "final rule" pursuant to

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[3] These three phthalates are di-(2-ethylhexyl) phthalate ("DEHP"), dibutyl phthalate ("DBP") and butyl benzyl phthalate ("BBP"). Most specifically, they are permanently prohibited at concentrations of more than 0.1 percent in children's products. CPSIA § 108(a), 15 U.S.C. § 2057c(a).

[4] The other two phthalates are diisodecyl phthalate ("DIDP") and di-n-octyl phthalate ("DnOP"). The interim prohibition extends only to childcare articles and children's toys that can be placed in the mouth, at concentrations greater than 0.1 percent. CPSIA § 108(b)(1), 15 U.S.C. § 2057c(b)(1).

Section 553 of the APA (5 U.S.C. § 553). In such final rule, the Commission is to: (a) determine whether to continue in effect the interim prohibition on the three phthalates, and (b) declare any other phthalate or alternative a "banned hazardous product" if "necessary to protect the health of children." CPSIA § 108(b)(3), 15 U.S.C. § 2057c(b)(3).

This Section 108 CHAP held its first meeting in April 2010 and issued its final report in July 2014.[5] CPSC then published a Notice of Proposed Rulemaking ("NPR") on December 30, 2014[6] that, if finalized, would make the interim prohibition on DINP permanent.[7] EMCC timely submitted comments on the NPR, presenting evidence and legal arguments against a permanent DINP prohibition. On June 19, 2015, CPSC posted the Reanalysis Document, which applied the cumulative risk assessment methodology of this CHAP to more recent biomonitoring data.[8] CPSC is accepting comment until August 7, 2015.[9]

II. THE CPSIA IMPOSES NO MANDATE FOR CPSC TO FOLLOW OR OTHERWISE GIVE DEFERENCE TO THE SECTION 108 CHAP

We understand that some at CPSC may believe that Section 108 may mandate the Commission to rigidly adhere to the CHAP's recommendations or otherwise give significant deference to them, even given the results of the Reanalysis Document, which show cumulative risks to be below levels of concern. Apparently, this notion stems from Section 108(b)(3)'s instruction that CPSC shall promulgate a "final rule" "based on" the CHAP's report. This instruction, however, compels no such result.

Section 108 does not direct the Commission to promulgate a final rule "exclusively" or "solely" based on the CHAP's report, but instead to do so pursuant to the long-established rulemaking procedures under APA Section 553. The "based on" phrase, therefore, must be read in the full statutory context. Such context makes clear, as discussed below, that the CHAP's report is advisory in nature and that CPSC must examine the report critically, integrate it with all other relevant evidence and then make a reasoned, independent decision, as required in any rulemaking by the Commission pursuant to the CPSA and APA Section 553.

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5 Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternative (July 2012), http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf [hereinafter "CHAP Report"].

6 Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates. 79 Fed. Reg. 78324 (Dec. 30, 2014); Extension of Comment Period, 80 Fed. Reg. 14879 (Mar. 20, 2015) .

7 CPSC appropriately does not propose to extend the prohibition on DnOP or DIDP. CPSC proposes to ban four very small-volume phthalates not named in the CPSIA, which is inappropriate for many of the same reasons as is the proposal to permanently prohibit DINP. The focus of this memorandum, however, is on DINP.

8 Reanalysis Document, *supra* note 1.

9 *See* Notice of Availability: Estimated Phthalate Exposure and Risk to Pregnant Women and Women of Reproductive Age as Assessed Using Four NHANES Biomonitoring Data Sets (2005/2006, 2007/2008, 2009/2010, 2011/2012), 80 Fed. Reg. 35938 (June 23, 2015).

Inclusion of the phrase "based on" does not alter these principles. Under plain English,[10] the term "based on" has a wide range of meaning.[11] If the Commission considers the CHAP report, or uses some of its elements as a starting point for further development, or utilizes the CHAP's summaries of toxicology information in its own analysis, those would all fit the definition of making its determination "based on" the CHAP report. In fact, even if the Commission reviewed the CHAP report, double-checked all its citations and calculations, and refuted each conclusion of the report, before arriving at its determination, that would be basing its rulemaking on the CHAP's report. The CPSIA appropriately vests the rulemaking authority in the CPSC, and the Commission has a duty to ground its rule in reason, science and pertinent data. It cannot abdicate this duty to the CHAP by simply rubber-stamping its recommendations.

A. Any Such Mandate Would Raise Serious Questions as to Whether the CPSIA Is Unconstitutional

Let's assume for the sake of argument that it is correct that CPSC must make the prohibition on DINP permanent because that was the recommendation of the CHAP report. That would raise a serious question as to whether Section 108 is unconstitutional.

The Section 108 CHAP would seem, for constitutional purposes, to qualify as an advisory committee of private individuals – *i.e.*, individuals who are not officers or employees of the Federal Government – and not as an arm of the Federal Government.[12] If so, then if Section 108 mandates CPSC to follow the CHAP's recommendation or otherwise defer to it without regard to countervailing information, Section 108 clearly would ***not*** pass constitutional muster. That is because vesting the coercive power of government in a private entity violates various provisions of the U.S. Constitution, including, but not limited to, the nondelegation doctrine.[13]

In particular, it is long established that federal lawmakers cannot delegate regulatory authority to a private entity. To do so would be "legislative delegation in its most obnoxious form." *Carter v. Carter Coal Co.*, 298 U.S. 238, 311, 56 S. Ct. 855, 80 L. Ed. 1160 (1936). "This constitutional prohibition is the lesser-known cousin of the doctrine that Congress cannot delegate its legislative function to an agency of the Executive Branch. *See* U.S. Const. art. I, § 1 ('All legislative Powers herein granted shall be vested in a Congress of the United States . . . .');

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[10] "In the absence of an indication to the contrary, words in a statute are assumed to bear their 'ordinary, contemporary, common meaning.'" *Walters v. Metro. Educ. Enters., Inc.*, 519 U.S. 202, 207 (1997) (Scalia, J.) (quoting *Pioneer Inv. Servs. Co. v. Brunswick Assocs. Ltd. P'ship*, 507 U.S. 380, 388 (1993) (White, J.)).

[11] *See, e.g.*, the U.S. English entry for "base" at Oxford Dictionaries.com, Oxford University Press (2015), which includes: "verb [with object] 1 Have as the foundation for (something); use as a point from which (something) can develop; 'the film is based on a novel by Pat Conroy'."

[12] *See* CPSA § 28(b); 15 U.S.C. § 2077(b) ("Each Panel shall consist of 7 members … who are not officers or employees of the United States [with certain limited exceptions] …").

[13] A grant of governmental power to a private entity also likely violates the Constitution's Fifth Amendment Due Process Clause. *See Ass'n of Am. R.R. v. United States DOT*, 721 F.3d 666, 670 (D.C. Cir. 2013), reversed on other grounds by *Department of Transportation v. Association of American Railroads*, _ U.S. _ (2015).

see A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 529, 55 S. Ct. 837, 79 L. Ed. 1570 (1935)." *Ass'n of Am. R.R. v. United States DOT*, 721 F.3d 666, 670 (D.C. Cir. 2013), reversed on other grounds by *Department of Transportation v. Association of American Railroads*, _ U.S. _ (2015).

Private entities may "help a government agency make its regulatory decisions, for '[t]he Constitution has never been regarded as denying to the Congress the necessary resources of flexibility and practicality' that such schemes facilitate." *Id.* at 671 (quoting *Pan. Ref. Co. v. Ryan*, 293 U.S. 388, 421 (1935)). However, a private entity's "advisory role [will] trespass[ ] into an unconstitutional delegation" if it intrudes into the "administrative process." *Id*. Mandating that the CHAP's recommendation be followed unquestioningly would essentially grant the CHAP regulatory authority, which would be impermissible under the Constitution. *Id.*

Moreover, even if the Section 108 CHAP did somehow qualify as an arm of the Federal Government, then that would raise other serious constitutionality questions. As just one example, a Section 108 CHAP, if vested with Federal Government powers, would fail to satisfy the principle of accountability established in the Constitutional provisions that require an oath or affirmation and a commission. *See* U.S. Const. Art. VI, cl. 3 ("[A]ll executive and judicial Officers . . . shall be bound by Oath or Affirmation, to support this Constitution"); Art. II, §3, cl. 6 (The President "shall Commission all the Officers of the United States"); *see also Department of Transportation v. Association of American Railroads*, _ U.S. _ (2015) (holding that Amtrak is a part of the Federal Government and remanding for lower court to address questions implicating the Constitution's structural separation of powers and the Appointments Clause).

B. Such Constitutional Questions Must Be Avoided Because the CPSIA's Plain Language as well as the Context Provided by Other CPSC-Administered Statutes Incorporated into the CPSIA Establish the Limited – and Purely Advisory – Role of This CHAP

The doctrine of constitutional avoidance is long-established. In the words of the current Chief Justice to the U.S. Supreme Court,

> [I]t is well established that if a statute has two possible meanings, one of which violates the Constitution, courts should adopt the meaning that does not do so. Justice Story said that 180 years ago: 'No court ought, unless the terms of an act rendered it unavoidable, to give a construction to it which should involve a violation, however unintentional, of the constitution.' *Parsons v. Bedford*, 28 U.S. 433, 3 Pet. 433, 448-449 (1830). Justice Holmes made the same point a century later: '[T]he rule is settled that as between two possible interpretations of a statute, by one of which it would be unconstitutional and by the other valid, our plain duty is to adopt that which will save the Act.' *Blodgett v. Holden*, 275 U.S. 142, 148 (1927) (concurring opinion).

Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2593 (2012) (Roberts, C.J.). The doctrine of constitutional avoidance unquestionably applies here because CPSIA Section 108's plain

language as well as the context provided by other CPSC-administered statutes incorporated therein establish the limited – and purely advisory – role of this CHAP.

1. CPSIA Section 108(b)(2)(A) Explicitly States that This CHAP Is "A Chronic Hazard Advisory Panel" "Appointed" by CPSC Pursuant to the "Procedures of Section 28 of the Consumer Product Safety Act"

Section 108(b)(2)(A) provides as follows:

> Not earlier than 180 days after the date of enactment of this Act, the Commission shall begin the process of appointing a Chronic Hazard Advisory Panel pursuant to the procedures of section 28 of the Consumer Product Safety Act (15 U.S.C. 2077) to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles.

This statutory language is unambiguous in two key respects: It requires CPSC (1) to appoint a CHAP to study phthalates, and (2) to do so pursuant to the existing CPSA Section 28 procedure. Nothing in this language even hints that the Section 108 CHAP would have special authority or control over CPSC decision-making. To the contrary, it indicates that the Section 108 CHAP is "***a*** Chronic Hazard Advisory Panel" appointed just like any other CHAP pursuant to Section 28.

2. Both CPSA Section 28 and Its Other CHAP-related Provision, Section 31, Make Clear that a CHAP Operates Through the Commission and that a CHAP's Report Is Advisory in Nature, with the Commission Retaining Decisional Authority

In 1974, Congress recognized the valuable role advisory panels could play in supporting federal agencies, but also the potential for overuse and abuse of such panels; to establish a uniform rule of law across federal agencies, Congress enacted the Federal Advisory Committee Act (FACA), Pub. L. 92-463, 5 U.S.C. App. I (1974). FACA generally applies to advisory panels with non-government employees unless a statute specifies otherwise. CPSA is one of those statutes, as it exempts a Section 28-appointed CHAP from FACA. *See* CPSA § 31(b)(2)(D), 15 U.S.C. § 2077 ("The Federal Advisory Committee Act shall not apply with respect to any [Chronic Hazard Advisory] Panel established under this section.").

The FACA exemption for a Section 28-appointed CHAP means that a CHAP will not be subject to the open meetings, public involvement and reporting requirements that apply to many other federal agency advisory committees. It does not mean, however, that a CHAP operates an independent entity with control over CPSC decision-making or that CPSC otherwise owes a CHAP special deference. To the contrary, the CPSA makes clear that a CHAP operates through the Commission and that a CHAP's report is advisory in nature, with the Commission retaining decisional authority.

In particular, Section 28 coins the term "Chronic Hazard Advisory Panel" – a term that includes the word "advisory" with the plain dictionary meaning in this context[14] of "having or consisting in the power to make recommendations, but not to take action enforcing them."[15] Section 28 sets forth the duties and responsibilities of the CHAP consistent with this plain meaning. The Commission not only appoints the CHAP, but any CHAP "shall request information and disclose information to the public . . . ***only through the Commission***." CPSA § 28(g); 15 U.S.C. § 2077(g) (emphasis added). Moreover, a CHAP may share or obtain information from other "agencies and departments of the Federal Government" or "from States, industry and other private sources" only "***through the Commission***." CPSA § 28(h)(1); 15 U.S.C. § 2077(h)(1) (emphasis added).

Section 31 reinforces this plain meaning. It requires CPSC to appoint a required CHAP prior to any advance notice of proposed rulemaking for a chronic hazard-related consumer product safety rule. CPSA § 31(b); 15 U.S.C. § 2080(b). Yet, it makes clear that the purpose of this requirement is purely advisory: A CHAP "reports its determination to the Commission" and "shall [then] terminate . . . unless the Commission extends the existence of the Panel." CPSA § 31(b)(2)(C); 15 U.S.C. § 2080(b)(2)(C). A CHAP, therefore, is not an ongoing authoritative body, but an advisory one, limited as to both purpose and existence. Moreover, Section 31 mandates that once a CHAP has delivered its report and terminated, "[t]he Commission shall consider the report of the Panel and incorporate such report into the advance notice of proposed rulemaking and final rule." CPSA § 31(c); 15 U.S.C. § 2080(c). This language, when read in context, commands CPSC to "consider" a CHAP's report, but not to be controlled by it or defer to it.

3. CPSIA Section 108 is Consistent with CPSA Sections 28 and 31 in Establishing the Advisory Role of a CHAP for Phthalates

a. Section 108 Mandates Appointment of a CHAP for Phthalates Limited in Both Time of Existence and Scope of Responsibility

Section 108 requires CPSC to appoint a CHAP for phthalates pursuant to CPSA Section 28 and requires this CHAP to conduct and complete within 18 months thereafter an "examination" of specified potential hazards for "the full range of phthalates that are used in products for children." CPSIA § 108(b)(2)(B), 15 U.S.C. § 2057c(b)(2)(B). "Not later than 180 days after completing its examination," this CHAP must deliver its report on this examination to the Commission. CPSIA § 108(b)(2)(C), 15 U.S.C. § 2057c(b)(2)(C). Once such report has been delivered, Section 108 neither provides expressly for a continuing role for this CHAP nor implies that it would have one. Instead, Section 108's express incorporation of CPSA Section 28, which in turn refers to CPSA Section 31, coupled with Section 108's mandate for CPSA to promulgate a "final rule" after receiving the report, indicates that this CHAP, as required by Section 31,

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[14] *See supra*, note 10.

[15] See the U.S. English entry for "advisory" at Oxford Dictionaries.com, Oxford University Press (2015), which includes: "adjective 1 Having or consisting in the power to make recommendations but not to take action enforcing them: 'an independent advisory committee'; 'the Commission acts in an advisory capacity to the government'; 1.1 Recommended but not compulsory: 'universities may treat the recommendations as advisory'."

"shall [then] terminate . . . unless the Commission extends [its] . . . existence." CPSA § 31(b)(2)(C); 15 U.S.C. § 2080(b)(2)(C).

This statutory structure plainly indicates the Section 108 CHAP for phthalates is a one-time deal. This CHAP has no continuing obligation or role once its report has been delivered to CPSA. This CHAP – the same as all other Section 28-appointed CHAPs – has been constituted as an advisory body within the plain dictionary meaning of the word in this context of "having or consisting in the power to make recommendations, but not to take action enforcing them."[16]

b. Section 108 Mandates CPSC Decision-Making Once the CHAP for Phthalates Has Terminated Pursuant to APA Section 553, and Therefore Does Not Permit CPSC to Consider Only This CHAP's Report or to Defer To It, but Instead Requires CPSC to Provide Adequate Public Notice, to Consider All Evidence and Arguments Submitted in Response to Such Public Notice and to Justify Its Final Rule Based on the Rulemaking Record as a Whole

The final – and utterly irrefutable – indication that Congress intended the CHAP for phthalates to have the same advisory role as all other Section 28-appointed CHAPs lies in the following Section 108(b)(3) mandate:

> (3) PERMANENT PROHIBITION BY RULE.—Not later than 180 days after receiving the report of the panel under paragraph (2)(C), the Commission shall, pursuant to section 553 of title 5, United States Code, promulgate a final rule to—
>
> (A) determine, based on such report, whether to continue in effect the prohibition under paragraph (1), in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety; and
>
> (B) evaluate the findings and recommendations of the Chronic Hazard Advisory Panel and declare any children's product containing any phthalates to be a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057), as the Commission determines necessary to protect the health of children.

The mandate here is unambiguous: CPSC must engage in a rulemaking on phthalates pursuant to CPSA Sections 8, 9, 28 and 31[17] as well as – last but not least – Section 553 of the Administrative Procedures Act (APA). This language clearly indicates that this rulemaking must take into account this CHAP's report the same as CPSC must do in any other rulemaking.

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[16] *See supra,* note 15.

[17] Section 108(b)(3) refers only to CPSA Section 8, but Section 8 requires the Commission to follow the procedures set forth in CPSA Section 9, and Section 31 prohibits the issuance of an "advance notice or proposed rulemaking" under Section 9 "relating to a risk of cancer, birth defects, or gene mutations from a consumer product" without first convening a CHAP pursuant to CPSA Section 28.

Indeed, Section 108(b)(3) states that the Commission must "determine, based on such report" whether to continue the interim ban; it does not say based "*solely*" or "*exclusively*" on such report. *See Sierra Club v. E.P.A.*, 325 F.3d 374, 377 (D.C. Cir. 2003) (holding that a Clean Air Act provision requiring EPA to promulgate a rule "based on" a study does not require EPA to do anything more than consider the study because, among other reasons, the statute does not say "that the rule must be based exclusively on the study" and mandates the agency to consider criteria independent from such study).

c. APA Section 553 Requires the Commission to Evaluate the CHAP's Report Critically and in Light of Comments and Other Evidence and to Engage in Independent, Reasoned Decision-making

The fact that CPSIA requires APA Section 553 rulemaking belies any notion that Congress intended the Commission to give this CHAP's report controlling or greater weight than any other CHAP report. APA Section 553 establishes the requirements for "informal rulemaking," and a related provision, APA Section 706, sets forth the standards for judicial review of any informal rulemaking.[18] Nearly sixty years of case law has well established that an agency must satisfy the following minimum requirements in any informal rulemaking:

- ***Adequate Notice.*** Notice that is "sufficiently descriptive of the subjects and issues involved so that interested parties may offer informed criticism and comments."[19]

- ***Sufficient Opportunity For Public To Comment.*** An opportunity for interested persons to comment, including "an opportunity to develop evidence in the record to support their objections to a rule . . . [in order to] enhance[] the quality of judicial review."[20]

- ***Final Rule Not "Arbitrary and Capricious."*** Issuance of a final rule that is not "arbitrary and capricious," which means a final rule that:

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[18] 5 U.S.C. § 706 ("To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall— (1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be— (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.").

[19] *Ethyl Corp. v. EPA*, 541 F.2d. 1, 48 (D.C. Cir. 1976) (internal citations omitted).

[20] *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983) (internal citation omitted).

- is a "***logical outgrowth***" of the proposed rule;[21]
- demonstrates each agency official has an "***open mind***" "on matters critical to the disposition of the proceeding";[22]
- includes a "concise ***statement of the basis and purpose*** of the rule[] ultimately adopted";[23]
- includes "the agency's ***response to public comments*** . . . and [explains] why the agency reacted to them as it did";[24] and
- otherwise reflects decision-making which is ***not "arbitrary and capricious"*** – meaning that the agency's decision-making must ***not***:
    - "rely on factors which Congress has not intended it to consider;[25]
    - "fail[] to consider an important aspect of the program"; [26]
    - fail to "examine[] relevant data";[27]
    - "fail[] to respond meaningfully to the evidence,"[28] including evidence presented by public commenters;
    - "offer[] an explanation for its decision that runs counter to the evidence before the agency,"[29] including evidence presented by public commenters;

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[21] *See, e.g., Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1108 (D.C. Cir. 2014) ("[A]gencies may not 'pull a surprise switcheroo on regulated entities.'").

[22] *United Steelworkers of Am., AFL-CIO-CLC v. Marshall*, 647 F.2d 1189, 1209 (D.C. Cir. 1980) ("[A]n agency official must be disqualified from rulemaking 'only when there has been a clear and convincing showing that [she] has an unalterably closed mind on matters critical to the disposition of the proceeding.'") (quoting *Ass'n of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d. 1151, 1195 (D.C. Cir. 1979)).

[23] *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 (D.C. Cir. 1977) (internal citations omitted).

[24] *Pub. Citizen v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993).

[25] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (internal citations omitted).

[26] *Id.*

[27] *Id.*

[28] *Mistick PBT v. Chao*, 440 F.3d 503, 512 (D.C. Cir. 2006) ("An agency's failure to respond meaningfully to the evidence renders its decisions arbitrary and capricious. Unless an agency answers objections that on their face appear legitimate, its decisions can hardly be said to be reasoned.") (internal citations and quotations omitted).

[29] *Id.*

- be "so implausible that it could not be ascribed to difference in view or the product of agency expertise";[30] or

- fail to "articulate a 'rational connection between the facts found and the choice made.'"[31]

It would be impossible – literally so – for the Commission to adhere to APA Section 553 if it solely considers the Section 108 CHAP report or defers to it. To the contrary, the Commission must evaluate all relevant evidence independently, including evidence presented during the rulemaking and never considered by the CHAP. **That means the Commission has an obligation to disregard the CHAP's report to the extent it is incorrect, unreasonable, inconsistent with existing CPSC policy, practice, regulations or governing statutes or is based on data that is outdated or of poor quality.** To the extent the results of the reanalysis compel a different conclusion from that of the CHAP, the Commission must make a determination contrary to the CHAP's recommendation.

III. THE CPSIA DOES NOT MANDATE A CUMULATIVE RISK ASSESSMENT FOR PHTHALATES NOR A BAN FOR NEGLIGIBLE CONTRIBUTIONS TO THEORETICAL CUMULATIVE RISK

It is our understanding that CPSC may believe that the CPSIA requires it to ban any phthalate that contributes in any amount to a cumulative risk assessment ("CRA"), if the hazard index for the CRA is greater than 1. Review of the statute, however, demonstrates that this is not the case and the science demonstrates that DINP should not be banned on the basis of the CHAP's CRA.

A. The CPSIA Did Not Mandate that the CHAP Conduct a Cumulative Risk Assessment nor Base Its Recommendations on One

The CPSIA does not mandate that a cumulative risk assessment be undertaken at all. As part of its examination, the CHAP was directed to "consider the cumulative effect of total exposure to phthalates." CPSIA § 108(b)(2)(B)(iv); 15 U.S.C. § 2057c(b)(2)(B)(iv). "Consider the cumulative effect" does not equate to "conduct a quantitative cumulative risk assessment." The CHAP's consideration could have included consideration of the current rudimentary state of cumulative risk assessment science, and thus the infirmness of a quantitative CRA for making bright-line recommendations about risk management. It could have considered the fact that additivity may be an inappropriate assumption at the very low doses to which humans are exposed. It could have made a qualitative judgment that cumulative effects might be possible for antiandrogenic effects and recommended that be taken into consideration for substances showing a small margin of safety in isolation.

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[30] *Advocates for Highway and Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1144-45 (D.C. Cir. 2005) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

[31] *Nat'l Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1145 (D.C. Cir. 2013) (citations omitted).

Congress's charge to the CHAP to provide recommendations to the Commission did not mandate that it base its recommendations on the result of a cumulative risk assessment – quantitative or qualitative. The CPSIA directs that the CHAP:

> shall report to the Commission the results of the examination conducted under this section and shall make recommendations to the Commission regarding any phthalates (or combinations of phthalates) in addition to those identified in subsection (a) or phthalate alternatives that the panel determines should be declared banned hazardous substances.

CPSIA § 108(b)(2)(C); 15 U.S.C. § 2057c(b)(2)(C). The CHAP's examination was to consider a multitude of factors, of which consideration of the cumulative effects of total exposure to phthalates was only one. *See* CPSIA § 108(b)(2)(B)(i-viii); 15 U.S.C. § 2057c(b)(2)(B)(i-viii). Congress's direction to the CHAP does not state that its recommendations were to be based on the results of a cumulative risk assessment, nor that a determination of whether a phthalate or alternative should be declared a banned hazardous substance is to be based on whether a given substance can contribute in any amount to a cumulative risk.

In fact, by directing that CHAP to make recommendations regarding phthalates or combinations of phthalates that the CHAP determines should be declared "banned hazardous substances," it appears Congress withheld authority to recommend a ban on an individual phthalate based only on a cumulative risk assessment. The term "banned hazardous substance" is defined by the Federal Hazardous Substances Act ("FHSA"). FHSA § 2(q)(1); 15 U.S.C. § 1261(q)(1). Under the FHSA, the CPSC can ban products containing a mixture if that mixture meets the toxicity criteria, FHSA § 3(a)(1); 15 U.S.C. § 1262(a)(1), but the FHSA does not have a provision allowing an individual chemical to be banned on the basis that it contributes to an overall cumulative risk. Congress appears to have contemplated this approach when it directed that the CHAP make recommendations "regarding any phthalates (or combinations of phthalates)." Thus, the CHAP potentially could have recommended that products containing a *mixture* of the five CRA phthalates be banned hazardous substances, if that mixture poses a high risk, but not that products containing just DINP itself should be declared banned hazardous substances.[32]

B. The CPSIA Does Not Mandate that CPSC Base Its Determination on a Cumulative Risk Assessment

As discussed in the previous section, the reference to cumulative risk is in Congress's charge to the CHAP. CPSIA § 108(b)(2)(B)(iv); 15 U.S.C. § 2057c(b)(2)(B)(iv). Congress's charge to the CPSC is in a separate subsection. CPSIA § 108(b)(3); 15 U.S.C. § 2057c(b)(3). While the Commission is to use the CHAP's report in making its determination, Congress in no manner specifically directed the CPSC to base its determination on a cumulative risk assessment, nor to assure that any phthalate contributing to a cumulative risk be banned no matter how negligible its contribution.

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[32] This issue is discussed in greater detail in the Attachment to Part 1 of EMCC's April 14, 2015 comments.

What Congress did state was that CPSC should "determine, based on [the CHAP] report, whether to continue in effect the prohibition [on DINP, DIDP or DnOP], in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety." CPSIA § 108(b)(3)(A); 15 U.S.C. § 2057c(b)(3)(A). To the extent the Commission bases it determination on a cumulative risk assessment, the issue is whether the results of that risk assessment indicate that it is necessary to continue the prohibition on DINP, DIDP and/or DnOP "in order to ensure a reasonable certainty of no harm." And, in accordance with the Commission's obligations under APA Section 553, as discussed above, Section II(b)(3)(c), that inquiry must be made using current data.

C. The CPSIA Does Not Mandate that CPSC Ban a Phthalate that Has a Negligible Contribution to Purely Theoretical Risk

The "reasonable certainty of no harm" standard just quoted in the previous subsection does not mean that there should be absolutely no risk. On its face, the term "reasonable certainty" shows that Congress did not intend that CPSC determine there is 100 percent certainty of no harm. Had it done so, this would establish an unsurmountable barrier to ever lifting the interim prohibition, as it is impossible to prove the negative—*i.e.*, that there is absolutely zero risk of harm from the substance. With such an unsurmountable barrier, there would be no point in having the CHAP conduct its examination or having the CPSC determine whether to continue the interim ban. "It is a 'cardinal principle of statutory construction' that 'a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.'"[33] Thus, the Commission cannot interpret the CPSIA to mean that any phthalate that contributes to a theoretical cumulative risk, no matter how small such contribution, must be prohibited.

The CPSC staff reanalysis based on the CHAP's methodology and current biomonitoring data demonstrates that there in fact is no unacceptable cumulative risk from phthalates, and therefore there is a reasonable certainty of no harm even if the prohibition on DINP is lifted. Even under the prior CHAP analysis that used outdated biomonitoring data, the contribution of DINP to the calculated cumulative risk is negligible.[34] Further, that calculated risk is merely theoretical, given the many layers of conservatism built into the analysis and the strong evidence that the effects seen in laboratory rats are not relevant for human risk assessment. In fact, for the reasons detailed in EMCC's April 14 comments, **the science strongly demonstrates that the Commission can have a reasonable certainty of no harm if the ban on DINP is lifted. Indeed, the science is so strong that it would be unreasonable to conclude otherwise, making a continuing prohibition on DINP arbitrary and capricious.**

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[33] *TRW, Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (Ginsburg, J.) (*quoting Duncan v. Walker*, 533 U.S. 167, 173 (2001) (O'Connor, J.)).

[34] See Figure 1 on page I-27 of EMCC's April 14, 2015 comments.

IV. "FORESEEABLE ABUSE" OF PHTHALATE-CONTAINING PRODUCTS IS ACCOUNTED FOR BY USE OF BIOMONITORING DATA

We understand that there may be a concern that CPSC must consider abuse or misuse of products containing phthalates, and therefore must exercise extra caution in making its determination. This need not be a concern, because foreseeable abuse/misuse would be accounted for by the fact that the NHANES data is representative of the population – including those who may abuse phthalate-containing products.

Congress's charge to the CHAP[35] included a direction that it "examine the likely levels of children's, pregnant women's, and others' exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of such products." CPSIA § 108(b)(2)(B)(iii); 15 U.S.C. § 2057c(b)(2)(B)(iii). As this language plainly indicates, the CHAP must take into account (a) "normal and foreseeable use and abuse" only as it pertains to (b) "a reasonable estimation of likely levels of . . . exposure to phthalates." The phrase "normal and foreseeable" makes clear that neither the CHAP nor CPSC should be conjuring up theoretical or improbable use and abuse scenarios or otherwise exercising extra caution beyond the conservatism already built into the risk assessment methodology.[36] Moreover, the purpose of considering normal and foreseeable use and abuse is only to make a *reasonable* estimate of exposure.

Notably, any and all "normal and foreseeable use and abuse" would be accounted for in the NHANES data. The NHANES sampling protocol is carefully designed so that the data is representative of the entire U.S. population – including of individuals who may "abuse" or misuse phthalate-containing products. Use of the NHANES data, therefore, surely provides the "reasonable estimation" envisioned by Congress. And the more recent data in particular indicates what is foreseeable use and abuse/misuse.

In addition, the "normal and foreseeable use and abuse" language was contained in the original CPSIA of 2008. Subsequently, Congress amended the CPSIA to exclude from the phthalate prohibitions inaccessible component parts – that is, components "not accessible to a child through normal and reasonably foreseeable use and abuse of such product." CPSIA § 108(d); 15 U.S.C. § 2057c(d). The new section defined "reasonably foreseeable use and abuse" to include "swallowing, mouthing, breaking, or other children's activities, and the aging of the product." CPSIA § 108(d)(1); 15 U.S.C. § 2057c(d)(1). While Congress did not make this

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[35] As with cumulative effects, it was the CHAP, not the CPSC, that was instructed to estimate exposure from normal and foreseeable use and abuse of children's products.

[36] Such conservatism includes: basing the risk assessment on rat data and applying safety factors that assume humans are more sensitive than rats, when there is strong evidence humans are less sensitive or completely immune to phthalates causing the effects of interest; including DINP in the CRA although it does not show the same suite of effects as the other CRA phthalates; selecting a low "no observed effect" level for DINP when the data indicate a higher level would also produce no effect; and calculating the hazard index with biomonitoring data that integrates *all* exposures, not just those from children's products. EMCC supports use of conservatism in risk assessment and management, but it is important to understand the *very* wide margin of safety given by the CHAP's and CPSC's methodology.

definition applicable to all of Section 108, it does provide insight into the likely meaning of "foreseeable use and abuse" in the charge to the CHAP. Again, elevated exposure to phthalates from activities such as swallowing, mouthing, or breaking products would be captured in the biomonitoring exposure data. (In fact, the 95th percentile is used rather than the median or average so as to capture those with high exposures.)

One could dream up extreme scenarios that could cause particularly high exposure to phthalates; for example, a woman of reproductive age who eats a rubber duck made from phthalate-plasticized vinyl every day. But this would be highly implausible, not "foreseeable abuse." Exposures due to plausible abuse or misuse have been captured by using biomonitoring data that is representative of the US population.

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