

**U.S. Consumer Product Safety Commission
LOG OF MEETING**

SUBJECT: Legal issues and concerns related to the NPR "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates."

DATE OF MEETING: July 24, 2015

LOG ENTRY SOURCE: David M. DiMatteo

DATE OF LOG ENTRY: July 27, 2015

LOCATION: Room 737A, CPSC Headquarters

CPSC ATTENDEE(S): Stephanie Tsacoumis, General Counsel, CPSC OGC; Mary Boyle, Deputy General Counsel, CPSC OGC; Patrica Pollitzer, Assistant General Counsel, Regulatory Affairs Division, CPSC OGC; and David DiMatteo, Attorney, Regulatory Affairs Division, CPSC OGC.

NON-CPSC ATTENDEE(S): Donna Petrone, Counsel, ExxonMobil; Chris W, Wallace, ExxonMobil; and Ann Claassen, Latham & Watkins, LLP.

SUMMARY OF MEETING: ExxonMobil discussed various legal issues and concerns regarding the NPR "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates" with CPSC OGC staff. ExxonMobil provided a handout at the meeting which is attached to this meeting log.

LATHAM & WATKINS

Legal Issues Pertaining to CPSC Implementation of CPSIA Section 108(b)(3)

Ann Claassen
Latham & Watkins LLP
July 24, 2015

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Section 108(b)(3)

(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.

CPSIA Does Not Bind CPSC to Follow the CHAP Recommendations

- Section 108(b)(3)(A) must be read in the full statutory context
- Constitutional, statutory and administrative law principles require CPSC to critically review the CHAP's report and its conclusions and then promulgate its rulemaking
- CPSC has a duty to independently make its determination in light of public comment and current data, even if contrary to the CHAP's recommendations

“Based on” Does Not Mean “Rigidly Adhere To”

- “Based on” in plain English encompasses many approaches, e.g.
 - foundation
 - starting point
 - consideration of
 - See US English entry for “base” at OxfordDictionaries.com, Oxford University Press (2015)
- For example, the Reanalysis is based on the CHAP report
 - staff recreated the CHAP’s cumulative risk model
 - plugged current data into that model

Requiring Rigid Adherence to the CHAP Report Raises Serious Constitutional Issues

- CHAP is an advisory committee of private individuals (not officers or employees of the Federal Government)
- Vesting the “coercive power of government” in a private entity would violate Constitution provisions, including the nondelegation doctrine
 - *Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936)
 - *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)
- Such Constitutional concern must be and is avoided because the statute clearly establishes that the CHAP’s role is limited and advisory
 - *Nat’l Fed’s of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2593 (2012) (Roberts, C.J.).

CPSIA Plain Language Establishes the Limited and Purely Advisory Role of the Phthalate CHAP

- “A” CHAP appointed under CPSA 28
- CHAP operates through the Commission
- CHAP is advisory – makes recommendations but does not implement or enforce them
- The CHAP makes a recommendation; the Commission makes a determination
- CPSIA does not state CPSC must base its determination “solely” or “exclusively” on the CHAP report

Sierra Club v. EPA 325 F.3d 374, 377 (D.C. Cir. 2003)

Under APA 553, CPSC Must Disregard CHAP Report if It Is Based on Incorrect or Outdated Data

- CPSC Must Provide Sufficient Opportunity for Public Comment
 - *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983)
 - If CHAP recommendation must be followed, there is no actual opportunity for public comment
- CPSC Determination Must Not Be Arbitrary and Capricious
 - CPSC cannot fail to examine relevant data
 - *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)
 - CPSC cannot fail to respond meaningfully to the evidence
 - *Mistick PBT v. Chao*, 440 F.3d 503, 512 (D.C. Cir. 2006)

CPSIA Did Not Mandate that the CHAP Conduct a Cumulative Risk Assessment

- As part of its 108(b)(2)(B) examination, CHAP was to “consider the cumulative effect of total exposure to phthalates.”
- “Consider” does not equate to “conduct a quantitative cumulative risk assessment”
- CHAP was charged to make recommendations on phthalates which should be considered “banned hazardous substances” – FHSA defined term
- FHSA allows ban of mixtures of substances, but not of a single substance based on cumulative effect of the mixture
 - CHAP did not recommend ban of the mixture but of an individual phthalate

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

- Reference to “cumulative effect” is in the charge to CHAP, not the charge to the CPSC
- If CPSC relies on a cumulative risk assessment, the issue for CPSC is whether the results indicate a ban is necessary to ensure a reasonable certainty of no harm

Reasonable Certainty of No Harm Does Not Mean Zero Risk or 100% Certainty

- If negligible contribution to a cumulative risk were sufficient to maintain ban, the CHAP examination and CPSC determination would be superfluous
 - *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.)).
- The scientific evidence so strongly indicates DINP does not significantly contribute to CRA that continuing the ban would be arbitrary and capricious

Foreseeable Misuse/Abuse is Accounted for by Use of the NHANES Biomonitoring Data

- NHANES samples carefully designed to be representative of the US population
- Thus they encompass both those who normally use and those who misuse/abuse the products
- By using NHANES data, Commission has considered foreseeable misuse/abuse

Questions?

Thank you