



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
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This document has been electronically
approved and signed.

DATE: February 12, 2014

BALLOT VOTE SHEET

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Elliot F. Kaye, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
David M. DiMatteo, Attorney, OGC

SUBJECT: Federal Register Notice: Notice of Meeting for CPSC Workshop on Potential Ways to Reduce Third Party Testing Costs Through Determinations Consistent with Assuring Compliance

Ballot Vote Due: February 19, 2014

The Office of the General Counsel is providing for Commission consideration the attached draft notice for publication in the *Federal Register* of a workshop on potential ways to reduce third party testing costs through determinations consistent with assuring compliance.

Please indicate your vote on the following options:

- I. Approve publication of the attached document in the *Federal Register*, as drafted.

(Signature)

(Date)

II. Approve publication of the attached document in the *Federal Register*, with changes. (Please specify.)

(Signature)

(Date)

III. Do not approve publication of the attached document in the *Federal Register*.

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: CPSC Workshop on Potential Ways to Reduce Third Party Testing Costs through Determinations Consistent With Assuring Compliance

DRAFT 2-12-14

[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. CPSC-2011-0081]

CPSC Workshop on Potential Ways to Reduce Third Party Testing Costs through Determinations Consistent with Assuring Compliance

AGENCY: Consumer Product Safety Commission.

ACTION: Announcement of meeting and request for comments.

SUMMARY: The Consumer Product Safety Commission (CPSC, Commission, or we) staff is holding a workshop on potential ways to reduce third party testing costs through determinations consistent with assuring compliance. We invite interested parties to participate in or attend the workshop and to submit written comments.

DATES: The workshop will be held from 9 a.m. to 4 p.m. on April 3, 2014. Individuals interested in serving on panels or presenting information at the workshop should register by March 13, 2014; all other individuals who wish to attend the workshop should register by March 27, 2014. The workshop will also be available through a webcast, but viewers will not be able to interact with the panels and presenters. Written comments must be received by April 17, 2014.

ADDRESSES: The workshop will be held at the CPSC's National Product Testing and Evaluation Center, 5 Research Place, Rockville, MD 20850. There is no charge to attend the workshop. Persons interested in serving on a panel, presenting information, or attending the workshop should register online at:

<http://www.cpsc.gov/meetingsignup.html>, and click on the link titled, "Potential Ways to Reduce Third Party Testing Costs through Determinations Consistent with Assuring

DRAFT 2-12-14

Compliance Workshop.” More information about the workshop will be posted at:

[INSERT WEB ADDRESS HERE].

You may submit comments, identified by Docket No. CPSC-2011-0081, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except through: <http://www.regulations.gov>. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier, preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

DRAFT 2-12-14

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the Docket No. CPSC-2011-0081, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT:

Ms. Jacqueline Campbell, Directorate for Engineering Sciences, 5 Research Place, Rockville, MD 20850; telephone 301-987-2024; e-mail: jcampbell@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. What Does the Law Require?

The Consumer Product Safety Improvement Act of 2008 (CPSIA) established limits for the maximum lead content in substrate for accessible component parts of children’s products and for the maximum content limit of six phthalates for children’s toys and child care articles. Currently, the maximum lead content limit for accessible component parts of children’s products is 100 parts per million (ppm), and the maximum phthalate content limit is 0.1 percent (1000 ppm). Additionally, the CPSIA made ASTM F963-07, *Standard Consumer Safety Specification for Toy Safety*, or any successor version of the standard that the Commission does not reject, a mandatory consumer product safety standard. Currently, ASTM F963-11 (Toy Standard) is the mandatory version of the standard. Table 1 of section 4.3.5 of ASTM F963-11 lists the limits for the soluble amounts of eight elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium) allowable in toy substrates.

The CPSIA generally requires that children's products that are subject to a CPSC children's product safety rule must be tested by a third party CPSC-accepted laboratory for compliance with applicable CPSC rules. 15 U.S.C. 2063(a)(2)¹. Public Law No. 112-28 (August 12, 2011) (Pub. L. No. 112-28) directed the CPSC to seek comment on "opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation."

B. What Actions Has the Commission Taken?

In response to Pub. L. No. 112-28, the Commission published in the *Federal Register* a Request for Comment (RFC) titled, *Application of Third Party Testing Requirements; Reducing Third Party Testing Burdens*.² As directed by the Commission, staff submitted a briefing package³ to the Commission that described opportunities that the Commission could pursue to potentially reduce the third party testing costs consistent with assuring compliance.

In FY 2013, subsequent to fulfilling Pub. L. No. 112-28's requirement that the Commission solicit and review comments regarding potential opportunities to reduce the cost of third party testing requirements consistent with assuring compliance, the Commission chose to direct staff to develop a Request for Information (RFI) on four such potential opportunities, asking for information on the following issues:

¹ See also 16 CFR part 1107.

² <http://www.cpsc.gov/PageFiles/103251/3ptreduce.pdf>.

³ <http://www.cpsc.gov/PageFiles/129398/Reduce3pt.pdf>.

DRAFT 2-12-14

- Are there materials that qualify for a determination, under the Commission's existing determinations process, that do not, and will not, contain higher-than-allowed soluble concentrations of any of the eight elements specified in section 4.3.5 of ASTM F963-II?
- Are there materials that qualify for a determination, under the Commission's existing determinations process, that do not, and will not, contain any prohibited phthalates above their allowed content limit of 0.1 percent, and thus, would not be subject to third party testing?
- Are there any adhesives used in manufactured woods that can be determined not to contain lead in amounts above 100 ppm, and thus, would not be subject to third party testing?
- Can the process by which materials are determined not to contain lead in amounts above 100 ppm be expanded to include synthetic food additives?

The RFI was published in the *Federal Register* on April 16, 2013.⁴ The comment period for the RFI closed on June 17, 2013. The Commission received eight comments. The Commission's FY 14 Operating Plan directed staff to “. . . undertake additional necessary research and/or necessary testing with priority given to those materials most likely to provide the widest scope of relief.” To obtain information and evidence to further explore the possibilities for reducing the costs of third party testing through rulemaking, CPSC staff is conducting a workshop focusing on determinations.

II. What Are We Trying to Accomplish With the Workshop?

⁴ <http://www.gpo.gov/fdsys/pkg/FR-2013-04-16/pdf/2013-08858.pdf>.

DRAFT 2-12-14

The goal of the workshop is to provide CPSC staff with information and evidence concerning possible determinations that certain materials, irrespective of their manufacturing origin or manufacturing process, comply with the applicable content or solubility limits of applicable children's product safety rules with a high degree of assurance,⁵ without requiring third party testing.⁶ Staff seeks information concerning the factors relevant to demonstrating a high degree of assurance of compliance to the applicable children's product safety rules, including consideration of raw material sourcing, the manufacturing processes used, whether recycled materials are or may be included, and the potential for contamination.

III. What Topics Will the Workshop Address?

We plan to discuss the three areas in which determinations may be made: lead content, phthalate content, and the solubility of the eight elements listed in the Toy Standard.

In each case, staff is interested in obtaining information regarding worldwide production of materials used in children's products, including current and past approaches, rather than attestations that a particular manufacturer or brand does not include the chemical of interest. Because determinations encompass all production of a material (which may include future production by new entrants), an attestation by a current manufacturer is likely to be of limited utility in supporting a staff recommendation of a determination that must apply to all current and future manufacturers.

⁵ *High degree of assurance* means an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture. 16 CFR 1107.2.

⁶ Regardless of any third party testing relief provided, compliance with the applicable children's product safety rules, including those for lead and phthalates content, is always required.

CPSC staff is interested in obtaining information on the following topics:

A. Phthalates Content

Should staff consider a determination recommendation regarding the six prohibited phthalates, such a determination would identify materials that do not, and will not, contain the prohibited phthalates in concentrations above 0.1 percent (1000 ppm).

Phthalates, unlike naturally occurring elements, are man-made chemicals, and are used intentionally in specific applications. Additionally, certain materials or processing conditions (such as extremely high temperatures) inherently may preclude or eliminate the presence of phthalates. These factors might be used as part of a method to identify materials that do not, and will not, contain the banned phthalates, regardless of the manufacturer or manufacturing process used. Additional information is sought on this issue.

A determination that a material does not, and will not, contain the prohibited phthalates above 0.1 percent could be similar to the lead determinations in 16 CFR 1500.91. Such a determination would identify materials that intrinsically do not contain the prohibited phthalates or are subject to some factor in their manufacture, such as high temperatures or a deleterious effect on the performance of the material that precludes the presence of the prohibited phthalates above 0.1 percent. To consider this possibility, staff is interested in learning:

- What specific data should staff consider when deciding whether to recommend that the Commission make a determination?

DRAFT 2-12-14

- How can staff be assured that a material, regardless of its origin, manufacturing process, potential for contamination or any other factor, would continue to comply with the phthalates limit indefinitely into the future as the material continues to be produced?
- What kind of follow-up activities should be required to assure continued compliance of a material?
- What other technical, practical, or implementation issues should CPSC staff consider before possibly making recommendations to the Commission regarding phthalates determinations?
- What materials would provide the greatest cost savings if the Commission made a determination that the material did not contain the prohibited phthalates above 0.1 percent? Why?

The 2009 Statement of Policy⁷ listed examples of materials that may contain phthalates. Those materials are:

- Polyvinyl chloride (PVC) and related polymers, such as polyvinylidene chloride (PVDC), and polyvinyl acetate (PVA);
- Soft or flexible plastics, except polyolefins;
- Soft or flexible rubber, except silicone rubber and natural latex;
- Foam rubber or foam plastic, such as polyurethane (PU);
- Surface coatings, non-slip coatings, finishes, decals, and printed designs;
- Elastic materials on apparel, such as sleepwear;
- Adhesives and sealants; and

⁷ <http://www.cpsc.gov/PageFiles/126588/componenttestingpolicy.pdf>.

DRAFT 2-12-14

- Electrical insulation.

Other materials, such as other plastics, inks, air fresheners, and scented products, may contain phthalates.

To identify materials that could contain phthalates, and thus, cannot meet the requirements for a determination, staff is interested in learning:

- What materials should always require third party testing because of potential phthalate content above 0.1 percent? Why?
- What specific data or other information should be sufficient to characterize a material as potentially containing one or more of the prohibited phthalates, and thus, always require third party testing for compliance to the phthalates limit?

Phthalates are added to plastics to make the resulting material more flexible. We are seeking information and evidence regarding whether phthalates are uniformly excluded from specific plastics such that the plastic has no application involving the addition of phthalates at levels approaching 0.1 percent, even considering any potential recycled or reclaimed materials. Staff seeks information and evidence relating to a potential recommendation that specific plastics that potentially meet these requirements do not, and will not, contain the prohibited phthalates above 0.1 percent. Staff is interested in learning:

- What raw materials are used, could be used, or may be used to create plastics that meet these requirements, as well as information about the possibility of those materials containing or being exposed to any prohibited phthalate?

DRAFT 2-12-14

- Information about the potential use of recycled content in these plastics, and the possibility that phthalates may be included at noncompliant levels?
- Information about the possibility or likelihood of contamination of the component part or finished product with a prohibited phthalate?
- How or why continued manufacture, regardless of origin, would continue to be compliant with the phthalates limit?
- How the Commission might effectively address new applications or methods of production of plastics that may include the addition of phthalates or otherwise result in unacceptable levels of phthalates?
- What other technical, practical, or implementation issues should CPSC staff consider before possibly making recommendations to the Commission regarding a phthalates determination for a plastic?
- What would be the potential cost savings if such a determination were recommended and adopted, especially considering that compliance with the underlying standard(s) would still be required?

B. Lead Content

Third party testing requirements impose a burden on certifiers of children's products to assure that certifiers' products comply with the applicable children's product safety rules. However, testing might not be required if the Commission has evidence that establishes with a high degree of assurance that the material does not, and will not, contain lead in substrate in amounts above 100 ppm. The lead determinations in 16 CFR 1500.91 list materials that the Commission has determined do not exceed 100 ppm lead

DRAFT 2-12-14

content, and thus, are not subject to third party testing. The procedures and requirements for determinations regarding lead content of materials are listed in 16 CFR 1500.89.

If the Commission could identify additional materials that do not, and will not, contain lead in amounts above 100 ppm, the Commission could add these materials to the list in 16 CFR 1500.91. Staff is interested in learning:

- What specific information and data should staff assess in considering a recommendation that a determination be made that a material intrinsically does not, and will not, contain lead above 100 ppm? Is this information obtainable?
- For manufactured materials, what specific information and data should staff assess in considering a recommendation that the material's production does not, and will not, result in a lead content above 100 ppm?
- How lead in the recycling stream can be kept from rendering a material noncompliant?
- How the potential for contamination is addressed by all manufacturers of a material?
- What specific information and data staff should obtain to be assured that continued production of a material, regardless of its origin, will continue to be compliant with the lead content limit without requiring third party testing?
- What other information the staff should consider before potentially making recommendations to the Commission regarding a determination for lead content?

DRAFT 2-12-14

- What changes would you recommend to improve the procedures of 16 CFR 1500.89 in furtherance of the Commission's specific determinations-related direction to staff?
- What additional lead determinations would provide the greatest cost savings, assuming that the determinations have a satisfactory legal and evidentiary basis and are adopted by the Commission?

C. The Eight Elements Listed in the Toy Standard

A possible determination could identify materials that do not, and will not, contain the eight elements listed in the Toy Standard, either with respect to chemical content or to solubility of the elements at levels that do not exceed the allowable limits. Because the Commission intends any additional determinations to reduce the testing costs consistent with assuring compliance, a candidate material for a determination must comply with the limits for all eight elements. The testing costs may not be reduced substantially if content or solubility testing is still required for one or more of the eight elements.

Regarding the eight elements listed in the Toy Standard, staff is interested in learning:

- Which materials, by their nature, do not, and will not contain any of the eight elements in content above their solubility limits?
- Which materials have a solubility of all seven elements other than lead that is low enough for a determination to possibly be recommended that the material will comply with ASTM F963-11, regardless of the elements' content levels (lead content must not exceed 100 ppm for substrates, and 90 ppm for surface coatings)?

DRAFT 2-12-14

- How can compliance with the solubility limits of the elements other than lead be inferred from content measurements, irrespective of the shape or other physical characteristics of the material as a component part of a toy?
- Which materials would present the greatest cost reduction if the Commission determined that third party testing is not required, especially considering that compliance with the underlying standard(s) would still be required?
- What other information staff should consider before potentially making recommendations to the Commission regarding a determination of compliance with the limitations on the eight elements listed in the Toy Standard?

IV. What Topics Will Not Be Discussed in the Workshop?

This staff workshop will focus exclusively on potential ways to reduce third party testing costs through determinations consistent with assuring compliance as described in this announcement. Other matters, such as certification issues, test methods, statutory content limits, or definitions will not be discussed at this workshop, nor are comments on these other topics appropriate in response to this announcement. Staff will not make recommendations for determinations at the workshop. The purpose of the workshop is to collect specific and potentially actionable information and evidence to be considered by staff for any potential future determinations.

V. Details Regarding the Workshop

A. When and Where Will the Workshop Be Held?

CPSC staff will hold the workshop from 9 a.m. to 4 p.m. on April 3, 2014, at the CPSC's National Product Testing and Evaluation Center, 5 Research Place, Rockville,

MD 20850. The workshop will also be available through a webcast, but viewers will not be able to interact with the panels and presenters.

B. How Do You Register for the Workshop?

If you would like to make a presentation at the workshop or be considered as a panel member for a specific topic or topics, you should register by March 13, 2014. (*See the **ADDRESSES** portion of this document for the website link and instructions on where to register.*) We also ask that you indicate whether you would like to serve on a panel or make a presentation, and indicate each topic for which you wish to be considered. We ask that you limit the number of topics to no more than three. We will select panelists and individuals who will make presentations at the workshop, based on considerations such as the individual's demonstrated familiarity or expertise with the topic to be discussed; the practical utility of the information to be presented (such as a discussion of specific methods), and the individual's viewpoint or ability to represent certain interests (such as large manufacturers, small manufacturers, consumer organizations). We would like the presentations to represent and address a wide variety of interests.

Although we will make an effort to accommodate all persons who wish to make a presentation, the time allotted for presentations will depend on the number of persons who wish to speak on a given topic and the agenda. We recommend that individuals and organizations with common interests consolidate or coordinate their presentations and request time for a joint presentation. If you wish to make a presentation and want to make copies of your presentation or other handouts available, you should bring copies to the workshop. We will notify those who are selected to make a presentation or

DRAFT 2-12-14

participate in a panel at least two weeks before the workshop. Please inform Ms. Jacqueline Campbell, jcampbell@cpsc.gov, 301-987-2024, if you need any special equipment to make a presentation.

If you would like to attend the workshop but do not wish to make a presentation or participate on a panel, we ask that you register by March 27, 2014. Please be aware that seating will be on a first-come, first-served basis.

If you need special accommodations because of disability, please contact Ms. Jacqueline Campbell, jcampbell@cpsc.gov, 301-987-2024, at least 10 days before the workshop.

In addition, we encourage written or electronic comments. Written or electronic comments will be accepted until April 17, 2014. Please note that all comments should be restricted to the topics covered by the workshop as described in this Announcement.

C. What Happens if Few People Register for the Workshop?

If fewer than 15 individuals register for the workshop, we may cancel the workshop. If we decide to cancel the workshop, we will post a cancellation notice by March 28, 2014, on the Web page for the workshop [**INSERT WEB ADDRESS HERE**] and send an e-mail to all registered participants who provide their e-mail address when they register.

Dated: _____

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission