



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814**

This document has been electronically approved and signed.

BALLOT VOTE SHEET

April 3, 2013

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Kenneth R. Hinson, Executive Director
Stephanie Tsacoumis, General Counsel

FROM: David M. DiMatteo, Attorney, OGC

SUBJECT: Draft Federal Register Notice: *Request for Information Regarding Third Party Testing for Lead Content, Phthalate Content, and the Solubility of the Eight Elements Listed in ASTM F963-11*

Ballot Vote Due - April 9, 2013

The Office of the General Counsel is providing for Commission consideration the attached draft *Federal Register* notice for a request for information on whether there are materials that can be determined not to include a prohibited element (lead or certain other elements) or chemical (six prohibited phthalates), such that third party testing is not required.

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 for *Request for Information Regarding Third Party Testing for Lead Content, Phthalate Content, and the Solubility of the Eight Elements Listed in ASTM F963-11*

DRAFT: APRIL 3, 2013

BILLING CODE 6355-01-P

U.S. CONSUMER PRODUCT SAFETY COMMISSION

Request for Information Regarding Third Party Testing for Lead Content, Phthalate Content, and the Solubility of the Eight Elements Listed in ASTM F963-11

[Docket No. CPSC-[INSERT]]

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice

SUMMARY: The Consumer Product Safety Commission (CPSC, or Commission) is issuing a notice seeking information on whether there are materials that can be determined not to include a prohibited element (lead or certain other elements) or chemical (six prohibited phthalates), such that third party testing is not required. The Commission also seeks information on materials that do not, and will not, contain the prohibited elements or chemicals in concentrations above their applicable maximum limit.

DATES: Written comments must be submitted by [insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. [INSERT DOCKET NUMBER] 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. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through

<http://www.regulations.gov>.

Written Submissions: Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions) preferably in five copies, to: Office of the Secretary, U.S. 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 to <http://www.regulations.gov>, including any personal information provided. Do not submit confidential business information, trade secret information, or other sensitive or protected information (such as a Social Security Number) electronically; if furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Randy Butturini, Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; 301-504-7562; e-mail: RButturini@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Consumer Product Safety Act (CPSA) generally requires that children's products be tested by a third party CPSC-accepted laboratory for compliance with the applicable children's product safety rules. The Commission notes, regardless of any third party testing obligation, compliance with the children's products requirements discussed in this Request for Information (RFI) is always required.

This RFI seeks information on whether there are materials, used in the manufacture of consumer products, that can be determined not to include a prohibited element (lead or certain

other elements) or chemical (the six prohibited phthalates that are listed in section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)), such that third party testing is not required. This RFI also seeks information on materials that do not, and will not, contain the prohibited elements or chemicals in concentrations above the legally allowable limit. Information provided by the public concerning the characteristics of such materials will be used to develop recommended courses of action for the Commission.

This RFI consists of four parts, seeking data and information concerning the following children's products and materials used to manufacture those products:

- Toys subject to ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*, and the presence, if any, or at what levels, of the eight elements designated in section 4.3.5 of the standard. The solubility of each element is limited to no more than the levels listed in Tables 1 and 2 of the standard. Additionally, for accessible component parts of toys primarily intended for children 12 years old and younger, the lead content must be no greater than 100 parts per million (ppm), and the lead content of paints or surface coatings must be no greater than 90 ppm, in accordance with section 101 of the CPSIA;
- Toys and certain child care articles, and the presence, if any, or at what levels, of the six prohibited phthalates listed in section 108 of the CPSIA. These products are subject to a maximum concentration of 1000 ppm (or 0.1 percent) for each of the six prohibited phthalates;

- Manufactured woods and the presence, if any, or at what levels, of lead.

Accessible manufactured wood in children's products is subject to the maximum allowable lead content requirement of 100 ppm;

- Synthetic food dyes and the presence, if any, or at what levels, of lead.

Accessible synthetic food dyes in children's products are subject to the maximum allowable lead content requirement of 100 ppm.

II. Background

A. Requirements

The CPSIA made the ASTM International toy safety standard, ASTM F963-11, a mandatory children's product safety standard. ASTM F963-11 includes restrictions on the maximum solubility of eight elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium) in coatings and substrates of toys subject to that standard.

The CPSIA also limits the concentration of six prohibited phthalates in component parts of children's toys and child care articles.

The CPSIA limits the lead content of component parts of children's products to 100 ppm (currently) in each accessible component part. A children's product is a consumer product that is designed and intended primarily for children 12 years old and younger.

B. Third Party Testing

Section 14(a) of the CPSA, as amended by section 102 of the CPSIA, requires third party testing of: children's products for lead content; toys and child care articles for the prohibited phthalates; and toys subject to the ASTM F963-11 toy safety standard for eight elements. For children's products, toys, and child care articles subject to CPSIA requirements, and toys subject

to ASTM F963-11 that may contain these prohibited materials, third party testing is required for certification, material change, and periodic testing.

Section 14(a) of the CPSA, as amend by section 102 of the CPSIA, requires third party testing for lead content in certain products and materials. The Commission, however, has determined that certain products or materials inherently do not contain lead at levels that exceed the specified lead content limits, and therefore, no third party testing of these products and materials is required. *See* 16 CFR 1500.91 for a list of the materials.

In addition to making these determinations, the Commission published a rule containing procedures and requirements for future Commission determinations regarding certain materials or products that do not, and would not, exceed the lead limits. 16 CFR 1500.89. Interested parties may consult the determinations rule at 16 CFR 1500.91 and the determinations procedures rule at 16 CFR 1500.89 for additional information about these prior Commission actions.

Section 14 of the CPSA requires third party testing of children's toys and certain child care articles for compliance with the phthalates requirements. In August 2009, the Commission made available a statement of policy on testing with respect to the CPSIA section 108 restrictions for phthalates in component parts of children's toys and child care articles, which can be found at: <http://www.cpsc.gov/PageFiles/110003/componenttestingpolicy.pdf>. In August 2012, in the notice of requirements (NOR), *Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With the Limits on Phthalates in Children's Toys and Child Care Articles*, the Commission included a footnote regarding materials that are not expected inherently to contain

phthalates, and thus, do not require third party testing. The NOR can be found at:

<http://www.gpo.gov/fdsys/pkg/FR-2011-08-10/pdf/2011-19678.pdf>.

Public Law 112-28 (PL 112-28), enacted on August 11, 2011, amended section 14 of the CPSA and directed the CPSC to consider ways to reduce the third party testing burden consistent with assuring compliance of children's products to the applicable consumer product safety rules.

The resulting briefing package, dated August 29, 2012, is available at:

<http://www.cpsc.gov/PageFiles/129398/reduce3pt.pdf>. In response to the third party testing

burden reduction briefing package, on January 18, 2013, the Commission directed staff to

develop an RFI to solicit information on the four topics listed above. The fiscal year 2013

Operating Plan text directing the staff can be found on page 24 at:

<http://www.cpsc.gov/Global/Budget/2013OperatingPlan.pdf>.

III. General Information Requested

In preparing comments to submit to CPSC regarding one or more sections of the RFI, commenters should include information on the following:

- The chemicals and raw materials used in manufacturing a specific product or component part, and their typical or possible concentrations of lead, phthalates, or the elements specified in the ASTM F963-11 toy safety standard;
- The extent to which recycled materials or other materials (such as plastic color concentrates or other additives) with potentially variable concentrations of lead, phthalates, or the elements specified in the ASTM F963-11 toy safety standard are used in manufacturing a specific product or component part;

- The manufacturing processes and conditions (such as potential sources of contaminants) that could increase the concentration in the product or material of lead, phthalates, or the elements specified in the ASTM F963-11 toy safety standard;
- The possibility that variations among worldwide manufacturers in their use of raw materials and processes could impact manufacturers' ability to meet consistently the concentration limits for lead, phthalates, or the elements specified in the ASTM F963-11 toy safety standard; and
- Other relevant factors that could impact the concentration in products or materials of lead, phthalates, or the elements specified in the ASTM F963-11 toy safety standard.

In addition to identifying the materials that could be determined to be compliant with an applicable chemical limit without requiring third party testing, commenters should explain in detail why such a conclusion could be made. Commenters should explain their reasons and provide evidence to support their claim that present and future production will continue to comply with the applicable children's product safety rules.

IV. Additional Information Requested

A. Children's Toys and the Eight Elements in ASTM F963-11

Section 4.3.5 of ASTM F963-11 establishes limits on the maximum soluble content of the eight elements in paints, surface coatings, and substrates of toys subject to the standard. (Of these elements, the standard—and the CPSIA—limit the total lead content in paints and surface coatings to 90 ppm and the total lead content of accessible substrates to 100 ppm.) Some of the ways compliance with the soluble limit could be demonstrated are through:

- component part testing showing that all of the component parts of the toy have a solubility of one or more of the eight elements of no more than their maximum allowable values; or
- showing that the component parts' content limit for an element is at or below the maximum solubility limit allowed, which also indicates compliance with that limit. (This alternate route to show compliance is provided for by section 8.3.1 of the ASTM F963-11 standard).

The commenter should explain, in addition to the requested general information, how consistent compliance to the soluble limit of element(s) in a material or component part, can be assured without third party testing.

B. Phthalate Concentrations in Plasticized Component Parts

Section 108 of the CPSIA permanently prohibits the sale of any “children’s toy or child care article” containing concentrations of more than 0.1 percent of the following chemicals:

- dibutyl phthalate (DBP);
- butyl benzyl phthalate (BBP); or
- di(2-ethylhexyl) phthalate (DEHP).

Section 108 prohibits on an interim basis the sale of “any children’s toy that can be placed in a child’s mouth” or “child care article” containing concentrations of more than 0.1 percent of:

- di-n-octyl phthalate (DnOP);
- diisononyl phthalate (DINP); or
- diisodecyl phthalate (DIDP),

pending review by a Chronic Hazard Advisory Panel (CHAP).

Section 108 of the CPSIA defines the terms “children’s toy,” “children’s toy that can be placed in a child’s mouth,” and “child care article.” Additional information is available at:

<http://www.cpsc.gov/Regulations-Laws--Standards/CPSIA/Phthalates/Phthalates-Information>.

Phthalates commonly are used as plasticizers (softeners) in plastics. Phthalates also are used in other products, including, but not limited to, paints, inks, adhesives, sealants, air fresheners, and scented products. In August 2009, the Commission issued a statement of policy listing materials that:

- may contain phthalates, and therefore, should always be tested; and
- normally do not contain phthalates, and therefore, may not require testing.

In the August 2012 NOR, a footnote indicated that the following materials are not expected inherently to contain phthalates, and thus, do not require third party testing::

- untreated/unfinished wood;
- metal;
- natural fibers;
- natural latex; and
- mineral products.

Staff is interested in information relating to materials that do not contain the prohibited phthalates in amounts greater than 1000 ppm. In addition to the requested general information, the commenter should explain how consistent compliance to the phthalates limits in a material or component part can be assured without third party testing.

C. Lead Content in Manufactured Wood Products

For the purposes of this RFI, “manufactured wood” refers to composite wood products that are wood-based materials, such as particle board, medium density fiber board, and plywood, consisting largely of natural, untreated wood and glues, adhesives, waxes, resins, and similar materials. Only these constituents are the subject of the RFI.

The Commission previously determined that natural wood (untreated, unadulterated, and uncoated) does not, and will not, contain lead in concentrations in excess of 100 ppm, as detailed in 16 CFR 1500.91. The Commission has not made a similar determination for the adhesives or other possible constituents of a manufactured wood product.

Manufactured wood products are complex, nonhomogeneous products. Therefore, some of the ways compliance with the lead content limit could be demonstrated are:

- by testing a sample of a finished product, which must contain no more than 100 ppm lead;
- through component part testing of all the constituents of the manufactured wood, with test results showing that all of the constituents used to make the finished product contain no more than 100 ppm lead; or
- by demonstrating that a finished product will never exceed 100 ppm lead content, even if one or more constituents of the manufactured wood product contains lead in excess of 100 ppm.

As provided in 16 CFR 1500.91, a natural wood component part does not require testing.

The commenter should explain, in addition to the requested general information, how consistent compliance to the lead concentration limit of the finished manufactured wood or the constituents can be assured without third party testing.

D. Synthetic Food Additives

As detailed in 16 CFR 1500.91, the Commission previously determined that natural materials, such as natural fibers and other plant-derived and animal-derived materials, do not contain lead in concentrations above 100 ppm. These natural materials could include substances that may be used as food additives. However, certain synthetic materials that may be used as food additives are not included in the Commission determinations. Therefore, if a synthetic food additive is used in manufacturing a children's product, the resulting finished product or component part is subject to the CPSC requirements for lead content for children's products, including the third party testing requirements.

Substances used as food additives are subject to the requirements of the U.S. Food and Drug Administration (FDA), including 21 CFR part 172. Because 21 CFR part 172 does not require third party testing, compliance with FDA requirements is not sufficient to indicate compliance with section 101 of the CPSIA. To the extent that any synthetic food additive can be shown consistently not to contain lead at levels that exceed the specified lead content limits, recommendations could be made for future Commission action.

The commenter should explain, in addition to the requested general information, how consistent compliance to the lead content limit of the synthetic food additive(s) can be assured without third party testing.

Dated: _____

Todd A. Stevenson, Secretary
Consumer Product Safety Commission



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically
approved and signed.

Memorandum

Date: April 2, 2013

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM: J. DeWane Ray
Assistant Executive Director
Office of Hazard Identification and Reduction

Randy Butturini, Project Manager
Office of Hazard Identification and Reduction

SUBJECT: Request for Information Regarding Third Party Testing for Lead Content,
Phthalate Content, and the Solubility of the Eight Elements Listed in ASTM
F963-11

1. Introduction

The Consumer Product Safety Act (CPSA) generally requires that children's products be tested by a third party, CPSC-accepted laboratory for compliance with the applicable federal children's product safety requirements. This memorandum contains information addressing potential actions to relieve the burden of the mandatory third party testing requirements for children's products. This information would form the basis for a U.S. Consumer Product Safety Commission (CPSC) *Federal Register* notice requesting information about certain products and materials that can be determined not to include prohibited substances.

If approved by the Commission, staff will publish in the *Federal Register* a Request for Information (RFI) seeking information on whether there are materials, used in the manufacture of consumer products, that can be determined not to include a prohibited element (lead or certain other elements) or chemical (the six prohibited phthalates that is listed in section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)), such that third party testing is not required. The RFI will also seek information on materials that do not, and will not, contain the prohibited elements or chemicals in concentrations above the legally allowable limit. Information provided by the public concerning the characteristics of such materials will be used to develop recommended courses of action for the Commission.

*These comments are those of the CPSC staff, have not been reviewed or approved by,
and may not necessarily reflect the views of, the Commission.*

The RFI will consist of four parts, seeking data and information concerning the following children's products and materials used to manufacture those products:

1. Toys subject to ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*,¹ and the presence, if any, or at what levels, of the eight elements designated in section 4.3.5 of the standard. The solubility of each element is limited to no more than the levels listed in Tables 1 and 2 of the standard. Additionally, for accessible component parts of toys primarily intended for children 12 years old and younger, the lead content must be no greater than 100 parts per million (ppm), and the lead content of paints or surface coatings must be no greater than 90 ppm, in accordance with section 101 of the CPSIA;
2. Toys and certain child care articles, and the presence, if any, or at what levels, of the six prohibited phthalates listed in section 108 of the CPSIA. These products are subject to a maximum concentration of 1000 ppm (or 0.1 percent) for each of the six prohibited phthalates;
3. Manufactured woods and the presence, if any, or at what levels, of lead. Accessible manufactured wood in children's products is subject to the maximum allowable lead content requirement of 100 ppm;
4. Synthetic food dyes and the presence, if any, or at what levels, of lead. Accessible synthetic food dyes in children's products are subject to the maximum allowable lead content requirement of 100 ppm.

2. Background

2.1. Requirements

The CPSIA made the ASTM International toy safety standard, F963-11, a mandatory children's product safety standard. This standard includes restrictions on the maximum solubility of eight elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium) in coatings and substrates of toys subject to that standard.

The CPSIA also limits the concentration of six prohibited phthalates in children's toys and child care articles.

The CPSIA limits the lead content of children's products to 100 ppm (currently) in each accessible component part. A children's product is a consumer product that is designed and intended primarily for children 12 years old and younger.

2.2. Third Party Testing

¹ www.ASTM.org.

Section 14(a) of the CPSA, as amended by section 102 of the CPSIA, requires third party testing of: children's products for lead content, toys and child care articles for the prohibited phthalates, and toys subject to the ASTM F963-11 toy safety standard for the solubility of eight elements. For children's products, toys and child care articles subject to CPSIA requirements, and toys subject to ASTM F963-11 that may contain these prohibited materials, third party testing is required for certification, material change, and periodic testing.

Section 14 of the CPSA requires third party testing for lead content in certain products and materials. The Commission, however, has determined that certain products or materials inherently do not contain lead at levels that exceed the specified lead content limits, and therefore, no third party testing of these products and materials is required. *See* 16 CFR § 1500.91 for a list of the materials and products.

In addition to making these determinations, the Commission published a rule containing procedures and requirements for future Commission determinations regarding certain materials or products that do not, and would not, exceed the lead limits. 16 CFR § 1500.89. Interested parties may consult the determinations rule at 16 CFR § 1500.91 and the determinations procedures rule at 16 CFR § 1500.89 for additional information about these prior Commission actions.

Section 14 of the CPSA requires third party testing of children's toys and certain child care articles for compliance with the phthalates requirements. In August 2009, the Commission made available a statement of policy on testing with respect to the CPSIA section 108 restrictions for phthalates in component parts of children's toys and child care articles, which can be found at: <http://www.cpsc.gov/PageFiles/110003/componenttestingpolicy.pdf>. In August 2012, in the notice of requirements (NOR), *Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With the Limits on Phthalates in Children's Toys and Child Care Articles*, the Commission included a footnote regarding materials that are not expected inherently to contain phthalates, and thus, do not require third party testing. The NOR can be found at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-10/pdf/2011-19678.pdf>.

Public Law 112-28 (PL 112-28), enacted on August 11, 2011, amended section 14 of the CPSA and directed the CPSC to consider ways to reduce the third party testing burden consistent with assuring compliance of children's products to the applicable consumer product safety rules. The resulting briefing package, dated August 29, 2012, is available at: <http://www.cpsc.gov/PageFiles/129398/reduce3pt.pdf>.

In response to the third party testing burden reduction briefing package, on January 18, 2013, the Commission directed staff to develop an RFI to solicit information on the four topics listed above in Section 1 (See Appendix A for the text of the Commission direction to the staff.).

3. General Information Requested

In preparing comments to submit to CPSC regarding one or more sections of RFI, commenters should include information on the following:

- The chemicals and raw materials used in manufacturing a specific product or component part, and their typical or possible concentrations of lead, phthalates, or the elements specified in the ASTM F963-11 toy safety standard;
- The extent to which recycled materials or other materials (such as plastic color concentrates or other additives) with potentially variable concentrations of lead, phthalates, or the elements specified in the ASTM F963-11 toy safety standard are used in manufacturing a specific product or component part;
- The manufacturing processes and conditions (such as potential sources of contaminants) that could increase the concentration in the product or material of lead, phthalates, or the elements specified in the ASTM F963-11 toy safety standard;
- The possibility that variations among worldwide manufacturers in their use of raw materials and processes could impact manufacturers' ability to meet consistently the concentration limits for lead, phthalates, or the elements specified in the ASTM F963-11 toy safety standard; and
- Other relevant factors that could impact the concentration in products or materials of lead, phthalates, or the elements specified in the ASTM F963-11 toy safety standard.

In addition to identifying the material(s) that could be determined to be compliant with an applicable chemical limit without requiring third party testing, commenters should explain in detail why such a conclusion could be made. Commenters should explain their reasons and provide evidence to support their claim that present and future production will continue to comply with the applicable children's product safety rules.

4. Additional Information Requested

4.1. Children's Toys and the Eight Elements in ASTM F963-11

Section 4.3.5 of ASTM F963-11 establishes limits on the maximum soluble content of the eight elements in paints, surface coatings, and substrates of toys subject to the standard. (Of these elements, the standard—and the CPSIA—limit the total lead content in paints and surface coatings to 90 ppm and the total lead content of accessible substrates to 100 ppm.) Some of the ways compliance with the soluble limit could be demonstrated are through:

- component part testing showing that all of the component parts of the toy have a solubility of one or more of the eight elements of no more than their maximum allowable values; or
- showing that the component parts' content limit for an element is at or below the maximum solubility limit allowed, which also indicates compliance with that limit. (This alternate route to show compliance is provided for by section 8.3.1 of the ASTM F963-11 standard).

For purposes of this section, the commenter should explain, in addition to the requested general information, how consistent compliance to the soluble limit of element(s) in a material or component part, can be assured without third party testing.

4.2. Phthalate Concentrations in Plasticized Component Parts

Section 108 of the CPSIA permanently prohibits the sale of any “children’s toy or child care article” containing concentrations of more than 0.1 percent of the following chemicals:

- dibutyl phthalate (DBP);
- butyl benzyl phthalate (BBP); or
- di(2-ethylhexyl) phthalate (DEHP).

Section 108 prohibits on an interim basis the sale of “any children’s toy that can be placed in a child’s mouth” or “child care article” containing concentrations of more than 0.1 percent of:

- di-n-octyl phthalate (DnOP);
- diisononyl phthalate (DINP); or
- diisodecyl phthalate (DIDP),

pending review by a Chronic Hazard Advisory Panel (CHAP).

The terms “children’s toy,” “children’s toy that can be placed in a child’s mouth,” and “child care article” are defined in section 108 of the CPSIA. Additional information is available at:

<http://www.epsc.gov/Regulations-Laws--Standards/CPSIA/Phthalates/Phthalates-Information>.

Phthalates commonly are used as plasticizers (softeners) in plastics. Phthalates also are used in other products, including, but not limited to, paints, inks, adhesives, sealants, air fresheners, and scented products. In August 2009, the Commission issued a statement of policy listing materials that:

- may contain phthalates, and therefore, should always be tested; and
- normally do not contain phthalates, and therefore, may not require testing.

In August 2012, in the NOR, the footnote regarding materials that are not expected inherently to contain phthalates, and thus, do not require third party testing were listed as:

- untreated/unfinished wood;
- metal;
- natural fibers;

- natural latex; and
- mineral products.

Staff is interested in information relating to materials that do not contain the prohibited phthalates in amounts greater than 1000 ppm. For purposes of this section, in addition to the requested general information, the commenter should explain how consistent compliance to the phthalates limits in a material or component part can be assured without third party testing.

4.3. Lead Content in Manufactured Wood Products

For the purposes of the RFI, “manufactured wood” refers to composite wood products that are wood-based materials, such as particle board, medium density fiber board, and plywood, consisting largely of natural, untreated wood and glues, adhesives, waxes, resins, and similar materials. Only these constituents are the subject of the RFI.

The Commission previously determined that natural wood (untreated, unadulterated, and uncoated) does not, and will not, contain lead in concentrations in excess of 100 ppm, as detailed in 16 CFR § 1500.91. The Commission has not made a similar determination for the adhesives or other possible constituents of a manufactured wood product.

Manufactured wood products are complex, nonhomogeneous products. Therefore, some of the ways compliance with the lead content limit could be demonstrated are:

- by testing a sample of a finished product, which must contain no more than 100 ppm lead;
- through component part testing of all the constituents of the manufactured wood, with test results showing that all of the constituents used to make the finished product contain no more than 100 ppm lead; or
- by demonstrating that a finished product will never exceed 100 ppm lead content, even if one or more constituents of the manufactured wood product contains lead in excess of 100 ppm.

As noted above, 16 CFR § 1500.91 provides that a natural wood component part does not require testing.

For purposes of this section, the commenter should explain, in addition to the requested general information, how consistent compliance to the lead concentration limit of the finished manufactured wood or its constituents can be assured without third party testing.

4.4. Synthetic Food Additives

As detailed in 16 CFR § 1500.91, the Commission previously determined that natural materials, such as natural fibers and other plant-derived and animal-derived materials, do not contain lead in concentrations above 100 ppm. These natural materials could include substances that may be used as food additives. However, certain synthetic materials that may be used as food additives are not included in the Commission determinations. Therefore, if a synthetic food additive is used in manufacturing a children's product, the resulting finished product or component part is subject to the CPSC requirements for lead content for children's products, including the third party testing requirements.

Substances used as food additives are subject to the requirements of the U.S. Food and Drug Administration (FDA), including 21 CFR part 172. Because 21 CFR part 172 does not require third party testing, compliance with FDA requirements is not sufficient to indicate compliance with section 101 of the CPSIA. To the extent that any synthetic food additive can be shown consistently not to contain lead at levels that exceed the specified lead content limits, recommendations could be made for future Commission action to relieve the burden of third-party testing.

For purposes of this section, the commenter should explain, in addition to the requested general information, how consistent compliance to the lead content limit of the synthetic food additive(s) can be assured without third party testing.

5. Conclusion

With the RFI, the CPSC staff will seek input from interested parties that will be used by staff to develop recommended courses of action for the Commission to consider regarding third party testing requirements for children's product component parts and finished products. In response to the RFI, interested parties should provide information on materials that may be determined not to include a prohibited element (lead or certain other elements) or chemical (the six prohibited phthalates), such that third party testing to assure compliance to the applicable children's product safety rules is not required. Interested parties also may provide information on how to meet the burden of demonstrating that such a material does not, and will not, contain the restricted element or chemical in concentrations above its maximum limit, which could result in relief from the mandatory third party testing requirement for the material.

Regardless of any third party testing obligation, compliance to the children's products requirements discussed in this memorandum is always required.

Appendix A: Commission direction to staff regarding a request for information on burden reduction

1. **Determinations Regarding Heavy Metals:** Staff will draft a Request For Information (RFI) for publication in the *Federal Register* regarding whether there are materials that qualify for a determination, under the Commission's existing determinations process, that do not, and will not, contain higher-than-allowed concentrations of any of the eight heavy elements specified in Section 4.3.5 of ASTM F963-II (The elements are antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium.). The burden for demonstrating whether any material qualifies for a determination shall be on the submitter of the information requested in the RFI.
2. **Determinations Regarding Phthalates:** Staff will draft a Request For Information (RFI) for publication in the *Federal Register* regarding whether there are materials that qualify for a determination, under the Commission's existing determinations process, that do not, and will not, contain prohibited phthalates, and thus are not subject to third party testing. The burden for demonstrating whether any material qualifies for a determination shall be on the submitter of the information requested in the RFI.
3. **Determinations Regarding Adhesives in Manufactured Woods:** Staff will draft a Request for Information (RFI) for publication in the *Federal Register* regarding whether any adhesives used in manufactured woods can be determined not to contain lead in amounts above 100 ppm. The burden for demonstrating which, if any, adhesives should qualify for a determination shall be on the submitter of the information requested in the RFI.
4. **Determinations Regarding Synthetic Food Additives:** Staff will draft a Request For Information (RFI) for publication in the *Federal Register* regarding whether the process by which materials are determined not to contain lead in amounts above 100 ppm can be expanded to include synthetic food additives. The burden for demonstrating which, if any, synthetic food additives should qualify for a determination shall be on the submitter of the information requested in the RFI.

The fiscal year 2013 Operating Plan text directing the staff can be found on page 24 at: <http://www.cpsc.gov/Global/Budget/2013OperatingPlan.pdf>.