



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

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BALLOT VOTE SHEET

Date: April 17, 2013

TO : The Commission
Todd A. Stevenson, Secretary

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

FROM : Patricia M. Pollitzer, Assistant General Counsel
Hyun S. Kim, Attorney

SUBJECT : Petition Requesting Exception from Lead Content Limits: BIC USA Inc.

BALLOT VOTE Due: April 23, 2013

Attached is a draft *Federal Register* notice regarding a petition requesting exception from the lead content limits under section 101(b) of the Consumer Product Safety Improvement Act, as amended by Public Law 112-28. The petition was submitted by BIC USA Inc. for the BIC Children's Pen.

A. Please indicate your vote on the following options:

I. Approve publication of the draft notice in the *Federal Register*.

(Signature)

(Date)

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

(Signature)

(Date)

III. Do not approve publication of the draft notice in the *Federal Register*.

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* notice: Petition Requesting Exception from Lead Content Limits: BIC USA Inc.

CONSUMER PRODUCT SAFETY COMMISSION

Petition Requesting Exception from Lead Content Limits: BIC USA Inc.

[CPSC Docket Number: CPSC-2013-]

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Commission (Commission or CPSC) has received a petition requesting an exception from the 100 ppm lead content limit under section 101(b) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), as amended by Public Law 112-28 from BIC USA Inc. (BIC). We invite written comments concerning the petition.

DATE: Submit comments by **[insert date that is 30 days after publication]**.

ADDRESSES:

You may submit comments, identified by Docket No. CPSC-2013-____, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except through 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 (for paper, disk, or CD-ROM submissions), 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 that you do not want to be available to the public. 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>, and insert the docket number, CPSC-2013-, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, Consumer Product Safety Commission, 5 Research Pl, Rockville, MD 20850; e-mail: khatilelid@cpsc.gov; telephone: 301-987-2558.

SUPPLEMENTARY INFORMATION:

Under section 101(a) of the CPSIA, consumer products designed or intended primarily for children 12 years old and younger that contain lead content in excess of 100 ppm are considered to be banned hazardous substances under the Federal Hazardous Substances Act (FHSA).

Section 101(b)(1) of the CPSIA provides for a functional purpose exception from lead content limits under certain circumstances. The exception allows the CPSC, on the Commission’s own initiative, or upon petition by an interested party,

to exclude a specific product, class of product, material, or component part from the lead limits established for children's products under the CPSIA if, after notice and a hearing, the Commission determines that: (i) the product, class of product, material, or component part requires the inclusion of lead because it is not practicable or not technologically feasible to manufacture such product, class of product, material, or component part, as the case may be, in accordance with section 101(a) of the CPSIA by removing the excessive lead or by making the lead inaccessible; (ii) the product, class of product, material, or component part is not likely to be placed in the mouth or ingested, taking into account normal and reasonably foreseeable use and abuse of such product, class of product, material, or component part by a child; and (iii) an exception for the product, class of product, material, or component part will have no measurable adverse effect on public health or safety, taking into account normal and reasonably foreseeable use and abuse.

Under section 101(b)(1)(B) of the CPSIA, there is no measurable adverse effect on public health or safety if the exception will result in no measurable increase in blood lead levels of a child. In November 2012, CPSC staff issued a report, which found that, for the purposes of evaluating children's products for an exception from the CPSIA lead limit, a product will have no measurable adverse effect on public health or safety if a potential exposure to lead from the product is estimated to result in an increase in a child's blood lead level of less than 0.8 µg/dL. The level of exposure that would be associated with such an increase is approximately 2.2 µg per day. That report may be viewed at:

<http://www.cpsc.gov/PageFiles/133902/lead101.pdf>.

Given the highly technical nature of the information required for an exception, including data on the lead content of the product and test methods used to obtain those data, the Commission finds that notice of the petition and solicitation for written comments would provide the most efficient process for providing an adequate opportunity for all interested parties to participate in the proceeding. However, the Commission may hold a public hearing or public meeting if the Commission deems a public hearing or public meeting appropriate and necessary to determine whether the petition for a functional purpose exception should be granted.

On March 25, 2013, BIC submitted a petition requesting an exception from the lead content limit of 100 ppm under section 101(b) of the CPSIA for a new line of writing instrument products aimed at children age 5 and up (BIC Children's Pen) to address the needs of young children who are in the early stages of learning to write. BIC specifically requests the functional purpose exemption for the point component of the BIC Children's Pen. The accessible portion of the nickel silver points assembly that BIC proposes to use in its BIC Children's Pen contains total lead of approximately 8720 ppm (point and point support subassembly). According to BIC, all of the other accessible components of the BIC Children's Pen contain total lead below 100 ppm.

BIC contends that removing or making excess lead inaccessible in manufacturing the BIC Children's Pen is neither practicable nor technologically feasible. BIC states that if BIC were to change the metal alloy to reduce the lead content to below 100 ppm, millions of dollars in high-speed manufacturing

equipment would require retooling and use of cutting oil to produce the points, requiring significant resources and capital. In addition, BIC asserts that adjusting manufacturing processes in this way would result in lower point manufacturing productivity and a reduction in machine speeds and machine cycling.

BIC further states that the only metal alloy available for pen points that contain lead below 100 ppm is stainless steel. However, BIC does not produce stainless steel points in any of its factories. According to BIC, stainless steel points are more commonly used with water-based inks typically found in roller ball pens and gel ink pens. The BIC Children's Pen will not contain a water-based ink; rather, the pen will contain a solvent-based ink that is used in BIC's ballpoint pens.

BIC also contends that the BIC Children's Pen point is not likely to be placed in the mouth or ingested. According to BIC, the BIC Children's Pen is designed without a cap, clip, or pen body that can be opened. In addition, the point is securely adhered to the ink cartridge, and therefore, the point is not easily detachable, and the point is retractable. BIC states that the frequency of mouthing of objects by children who are intended to use the BIC Children's Pen is relatively low for the user age group (ages 5–12), and because the pen point is sharp, children will not mouth the pen point end of the product.

Finally, BIC asserts that granting an exception will have no measurable adverse effect on public health or safety, taking into account normal and foreseeable use and abuse because the potential exposure to the pen point would have no measurable increase in blood lead levels of a child. According to BIC, a child's fingers would not likely be in contact with the pen point during normal use

conditions, and the point would be extremely difficult to grip. In addition, BIC states that a wipe test of the pen point shows that even in a worst case analysis (assuming purposeful dermal contact), the potential exposure to lead would be 0.31 µg/day, which is far less than the CPSC staff recommendation that 2.2 µg/day can be used in a determination of a “measurable increase” in blood lead levels of a child.

Through this notice, we invite written comments on the petition. Interested parties may view a copy of the petition under supporting and related materials identified by Docket No. CPSC-2013- ____, through <http://www.regulations.gov>. Interested parties also may obtain a copy of the petition by writing or calling the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Room 820, Bethesda, MD 20184; e-mail: cpsc-os@cpsc.gov, telephone 301-504-7923.

Dated: _____

Todd A. Stevenson, Secretary
Consumer Product Safety Commission