United States
Consumer Product Safety Commission

Memorandum

TO: The Commission
Alberta E. Mills, Secretary

March 8, 2023

THROUGH: Austin C. Schlick, General Counsel
Jason K. Levine, Executive Director
DeWane Ray, Deputy Executive Director for Safety Operations

FROM: Duane E. Boniface, Assistant Executive Director,
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SUBJECT: Report on CPSC Approval Process for Firewalled Testing Laboratories

I. Introduction

The FY 2023 CPSC Operating Plan directs staff to submit a briefing package reviewing the CPSC firewalled laboratory system and the laboratory accreditation practices. In addition to the directed review, this briefing package includes staff plans for changes to the current practices for review of firewalled laboratory applicants.

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The following sections of the report include:

- Background information on requirements for firewalled testing laboratories under section 14 of the Consumer Product Safety Act (CPSA) and the CPSC rule 16 CFR Part 1112;
- A summary of the current staff review process of firewalled laboratory applicants;
- Information on the firewalled laboratories currently approved by CSPC;
- Information regarding past violations of children's products regulations by firms with CPSC approved firewalled laboratories[1]; and
- Plans for additional staff actions when evaluating firewalled laboratory applications and submitting applications to the Commission for its consideration.

II. Background

CPSA: General Third Party Laboratory Requirements and Additional Requirements Applicable to Firewalled Laboratories

Section 14(a)(2) of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires manufacturers and importers of products subject to children's product safety rules to use third party conformity assessment bodies (third party testing laboratories), that have been accredited consistent with CPSC requirements, to test those children's products for compliance. Manufacturers and importers must use test results from a CPSC-accepted, third party testing laboratory to certify compliance with any applicable "children's product safety rule." 15 U.S.C. § 2063(a)(2). A "children's product safety rule" is defined as a "consumer product safety rule under [the CPSA] or similar rule, regulation, standard, or ban under any other Act enforced by the Commission, including a rule declaring a consumer product to be a banned hazardous product or substance." 15 U.S.C. § 2063(f)(1). Section 14 of the CPSA also requires the Commission to establish requirements for the accreditation of third party testing laboratories. 15 U.S.C. § 2063(a)(3).

The CPSA defines a "third party conformity assessment body" as a testing laboratory that is not owned, managed, or controlled by the manufacturer or private labeler of a product assessed by such testing laboratory, except that, under specified conditions, the Commission may accredit a laboratory that is owned, managed, or controlled by such a manufacturer or private labeler. 15 U.S.C. § 2063(f)(2)(A). Testing laboratories that comply with these specified conditions are considered to be "firewalled" against the possibility of undue influence.

[1] Where there are product violations involving firms with CPSC approved firewalled laboratories, it cannot be confirmed that the products were manufactured and/or tested at the facilities that have a CPSC approved firewalled laboratory.

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The Commission may accredit a laboratory as firewalled if the Commission finds, by order, that:

A) accreditation of the laboratory would provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party conformity assessment body; and

B) the laboratory has established procedures to ensure that–

i) its test results are protected from undue influence by the manufacturer, private labeler, or other interested party;

ii) the Commission is notified immediately of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over test results; and

iii) allegations of undue influence may be reported confidentially to the Commission.

15 U.S.C. § 2063(f)(2)(D).

The Commission has issued regulations implementing the statutory provisions concerning CPSC's accreditation of third party conformity assessment bodies. 16 CFR part 1112 (effective June 10, 2013). These regulations include baseline requirements for independent laboratories and establish the process required for firewalled laboratory applications and acceptances. The application and acceptance procedures for independent and firewalled third party testing laboratories are found at 16 CFR §§ 1112.13 and 1112.17.

Under 16 CFR part 1112, one of the requirements for CPSC acceptance of a testing laboratory is that the laboratory must be accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA) to ISO/IEC Standard 17025: "General requirements for the competence of testing and calibration laboratories" (ISO/IEC 17025). 16 CFR § 1112.13(a)(2)(i).

ILAC was formed in 1977 to promote international acceptance of test results performed by accredited laboratories. A series of standards developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) provides specifications for organizations that conduct conformity assessment activities. Technical committees comprised of experts from across the globe (including the United States) collaborate to develop conformity assessment standards to facilitate acceptance of testing results among countries. These standards were developed expressly to be used by accreditation bodies that have entered mutual recognition arrangements (MRAs) with equivalent bodies in other countries.

These accreditation bodies are accepted into the ILAC MRA only after they undergo an intensive peer evaluation from other accreditation bodies to determine compliance with

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ISO/IEC 17011 – "General requirements for bodies providing assessment and accreditation of conformity assessment bodies" (ISO/IEC 17011). The peer evaluation includes observing the performance of ISO/IEC 17025 technical assessors (of the accreditation body under evaluation) during actual laboratory assessments to ensure conformance with ISO and ILAC requirements. Every accreditation body undergoes a peer evaluation on a recurring periodic schedule.

Throughout the world, many public and industry stakeholders rely on laboratory accreditation to independently evaluate laboratory competence. Laboratory accreditation is based upon criteria and procedures from ISO/IEC 17025 to determine the technical and management competence of laboratories. The accreditation body employs expert technical assessors that are screened and trained according to procedures and criteria to conduct ISO/IEC 17025 assessments for the testing disciplines specific to the laboratory's operations. The assessment is a thorough evaluation of all factors of facility operations, including on-site inspection, in accordance with ISO/IEC 17025 impartiality requirements, technical competence requirements, and management process requirements. To ensure continued compliance, accredited laboratories are reassessed on a recurring regular cycle by their accreditation bodies to verify that they maintain their standards of independence and technical expertise.

ISO/IEC 17025 enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world.[2]

Technical assessors evaluate any laboratory seeking or renewing accreditation to all the requirements of ISO/IEC 17025, including the requirements in Section 4.1 - Impartiality:

> The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial, or other pressures to compromise impartiality.
>
> The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.
>
> NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.
>
> If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

[2] ISO Information Document on ISO/IEC 17025: https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100424.pdf

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ISO/IEC 17025 accreditation by an accreditation body that is a signatory to the ILAC-MRA is a baseline requirement for approval under the CPSA firewalled provisions. 16 CFR § 1112.13(a)(2) and (b).

During the rulemaking proceedings promulgating 16 CFR part 1112, the Commission noted in the preamble[3] in the NPR regarding proposed § 1112.13(b) (providing the requirements for firewalled laboratories):

> If the Commission determines that the firewalled-specific documents indicate that the laboratory has sufficient safeguards against and procedures concerning undue influence in place, and the laboratory satisfies the baseline criteria, including ISO/IEC 17025:2005[4] accreditation by an ILAC–MRA signatory body, then the Commission will consider that the applicant laboratory would provide equal consumer safety protection than the manufacturer's or private labeler's use of an independent laboratory.

Proposed § 1112.13(b) was unchanged in the final rule issued by the Commission.

16 CFR part 1112 also requires firewalled laboratory applicants to submit additional documentation demonstrating to the Commission that the laboratory complies with criteria establishing safeguards against undue influence as required in the statute and regulation.

Staff Review Process for Firewalled Laboratory Applications

The following is a summary of the firewalled laboratory application process and CPSC staff's review process.

1. The laboratory applies for firewalled acceptance via the CPSC online registration form. The applicant submits training materials and other information to show conformity with the criteria for acceptance of firewalled laboratories.

2. The Firewalled Laboratory Review Committee (Review Committee), comprised of the Deputy Assistant Executive Director for Hazard Identification and Reduction, the Associate Executive Director for Laboratory Sciences, and the Program Manager for Laboratory Accreditation, Laboratory Sciences and an OGC observer, reviews the application. The Review Committee members individually examine the application materials according to the criteria for firewalled laboratories set forth in 16 CFR part 1112.

3. The Review Committee assesses whether to recommend to the Commission that the applicant satisfied the baseline requirements for CPSC acceptance, as well as the criteria for firewalled laboratories set forth in section 14 of the CPSA and

[3] 77 FR 31086, at 31112 (May 24, 2012) - http://www.gpo.gov/fdsys/pkg/FR-2012-05-24/pdf/2012-10923.pdf.

[4] The Commission required ISO/IEC 17025:2005 accreditation when it issued 16 CFR part 1112 on March 12, 2013. On April 30, 2021, the Commission revised 16 CFR part 1112 to require accreditation to ISO/IEC 17025:2017.

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accompanying regulations at 16 CFR part 1112. Specifically, the Review Committee examines if:

i) The applicant provided valid and current copies of ISO/IEC 17025 accreditation certificates and accreditation by an accreditation body that is a signatory to the ILAC-MRA, as well as a statement of scope that clearly identifies each CPSC rule and/or test method for which CPSC acceptance is being sought. These documents satisfy the baseline criteria required for all CPSC-accepted laboratories.
ii) The applicant submitted documents that explain how the laboratories will protect test results from undue influence by the manufacturer, private labeler, or other interested party.
iii) The applicant provided documentation evidencing laboratory operating procedures or quality manuals with clear policies stating that attempts to exert undue influence must be immediately reported to the CPSC and that allegations of undue influence may be reported confidentially to the CPSC. CPSC contact information is included in each of these documents.
iv) The applicant provided training documents that explain procedures for addressing undue influence and reporting allegations of undue influence to the CPSC. The records include training dates and a list of employees who received such training. The procedures include a requirement for annual training.
v) The applicant submitted organizational charts for the laboratory, and for the broader organization as well, showing the reporting relationship of the laboratory within the broader organization.
vi) The applicant reported if there are laboratory staff with reporting relationships outside of the laboratory.

III. Current CPSC Approved Firewalled Laboratories

As of February 2023, there are over 600 CPSC accepted testing laboratories. Of these, there are 40 CPSC accepted firewalled laboratories, which were approved between 2009 and 2021 by Commission vote. To date, the Commission has not denied a firewalled laboratory application. The locations of these firewalled laboratories are:

- China 28 laboratories
- U.S. 4 laboratories
- U.K. 1 laboratory
- Indonesia 1 laboratory
- India 1 laboratory
- Thailand 1 laboratory
- Mexico 1 laboratory
- El Salvador 1 laboratory
- Malaysia 1 laboratory
- Japan 1 laboratory

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EXHR staff reports no notifications over this period alleging acts of undue influence with any CPSC firewalled laboratory.

IV. Data Review to Assess Possible Correlation Between Laboratory Ownership and Regulatory Violations

EXIS Data Search (Tab A - FOUO)

The Office of Import Surveillance (EXIS) searched the data in the Risk Assessment Methodology System (RAM) for records that include names on a list of importers and manufacturers associated with firewalled labs that was provided by the Office of Hazard Identification and Reduction (EXHR). Specifically, EXHR identified the CPSC-accepted firewalled laboratories, and then identified associated manufacturers/firms affiliated with them. Staff then searched the RAM Exam Log for those manufacturers and/or importers.

The search of the available data going back 9 ¾ years since the inception of the RAM system (January 2013 - September 2022) showed no records of potential non-compliance with substantive children's product safety rules associated with firms that have testing laboratories that are CPSC approved firewalled testing laboratories. The search included RAM Exam Log records detailing products examined from firms, or associated firms, of companies that have a CPSC approved firewalled laboratory. This analysis is described in detail in Tab A (FOUO). It should be noted that the number of RAM examinations involving firms that own firewalled laboratories and that tested the products at their firewalled laboratory may be an overestimate. The firm could have tested the product at an independent laboratory (i.e., another entity other than their affiliated firewalled laboratory).

When firms were identified in the data, there were either no violations identified in product screening or laboratory testing, or there were minor administrative violations, such as certificate or tracking label violations, that resulted in instructions to the importer to correct future production. There were no violations related to physical or chemical testing to CPSC testing standards. All examined shipments from these firms, including those that were sampled, were ultimately released.

EXIS staff reports that as part of CPSC's eFiling Initiative, there will be a pilot program which includes the electronic provision of laboratory information that is not currently collected for imported products for screening purposes but is available to CPSC staff through other means when needed. This information may help better establish from which testing facility specific samples originated.

EXC Data Search (Tab B- FOUO)

The Office of Compliance and Field Operations (EXC) reviewed records from October 1, 2007, through September 30, 2022, of children's products found in the Integrated Field System (IFS) that had substantive violations, such as small parts and excess lead, and

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excluded any records that only showed exclusively administrative violations (e.g., certificate or tracking label violations).

Following this analysis, EXHR provided EXC with a spreadsheet that contained firm names, associated foreign manufacturers, and other pertinent information about associated firewalled laboratories. Working with EXHR, EXC staff cross-referenced the spreadsheet with the data collected from IFS to determine if any of the laboratories on the spreadsheet were associated with a manufacturer that was identified in the list of violative samples. In this 15-year period, EXC and EXHR identified 16 children's product samples with one or more substantive violations that may be connected to firms that were associated with CPSC approved firewalled laboratories.

EXHR examination of the 16 records showed they were from firms that may be connected to manufacturers that own firewalled laboratories. However, the importer product brand names and the address of manufacture do not match the names and location of CPSC approved firewalled laboratories, and it is possible that these may have been tested at an independent third-party laboratory. The results are shown in Tab B (FOUO).

Key Takeaways from Historical Data

Analysis of sample collection data by EXC and EXIS shows no indication of particular concerns with non-compliant children's products associated with firms that have CPSC approved firewalled laboratories.

Based on IFS data, the percentage of substantive violations involving children's products that may be associated with firms that own a CPSC approved firewalled laboratory is less than 0.15 percent of the total number of substantive violations involving children's products over the same period of time. This low number is particularly noteworthy given that the manufacturers associated with firewalled laboratories tend to be larger producers with above-average US sales.

EXHR has received no complaints related to attempts to exert undue influence at any CPSC approved firewalled laboratory.

V. Staff Plans for Changes to the Staff Review Process for CPSC Firewalled Laboratory Applicants

A review of years of compliance and import surveillance data does not suggest evidence of significant numbers of non-compliant children's products associated with firms that have CPSC approved firewalled laboratories. Over an almost 15-year period, a total of 16 records were found involving such products. However, in the interest of continued improvement staff has identified ways to strengthen the CPSC firewalled laboratory review process to better evaluate protections from undue influence for laboratories applying to be CPSC approved firewalled laboratories.

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Staff reviewed existing legal authorities and ISO/IEC 17025 general requirements for impartiality to identify additional information that would be useful for the Commission to consider as part of the CPSC firewalled laboratory approval process. Further, while laboratory applicants already provide in Form 223 (the CPSC on-line application) a general attestation that the applicant has read, understands, and agrees to the regulations in Part 1112, it would also be useful to request a specific signed attestation from a senior official for a CPSC firewalled laboratory applicant in support of their application. Additionally, staff recognizes the Commission would benefit from staff providing the results of a staff review of data related to any prior issues of non-compliance with CPSC rules from firms applying to be CPSC approved firewalled laboratories as part of the staff briefing packages that would be sent for future applications.

As a result, staff plans on collecting the following additional data and documents from CPSC firewalled laboratory applicants for Commission consideration:

- A For Official Use Only (FOUO) review by EXC staff of data related to any prior issues of non-compliance with CPSC regulations for products associated with the applicant firm.
- The applicant firm's response to a CPSC staff request for the laboratory to submit all documents that support the laboratory's accreditation specific to ISO/IEC 17025: Section 4.1 - Requirements for Impartiality.
- The firm's response to a CPSC staff request for a signed attestation from a senior official that clearly communicates the laboratory's commitment to conducting testing impartially and commitment to their procedures for reporting actions of undue influence to the CPSC (See Attachment for Example).

The requests for this additional information are within the existing authority of the CPSC rule for Requirements Pertaining To Third Party Conformity Assessment Bodies under 16 CFR §1112.13(g).

The staff will also provide, for future firewalled laboratory approval packages submitted for Commission consideration, all supporting documentation and CPSC review committee findings in a restricted Tab For Official Use Only. In the past, these documents were provided only if requested by Commissioners.

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Attachment

Example of Attestation Request from Firewalled Laboratory Senior Official

Attestation of Impartiality and Policy to Reject Undue Influence

Laboratory name management and personnel shall be free from pressures and undue influences from *Parent Company Name* and undue influences (internal or external to the company) that may adversely affect the quality of *Laboratory name's* work. *Laboratory name* shall avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.

As part of this commitment, the laboratory has issued an operating procedure (*name of procedure and document control number*) that communicates to all staff that any attempts of undue influence related to testing to United States consumer product safety standards must be immediately reported to the U.S. Consumer Product Safety Commission (CPSC) and may be done so confidentially. All staff shall be trained on this procedure at least annually.

Signature of Authorized Senior Official _____

Date _____

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TAB A

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TAB B

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