



Ballot Vote Sheet

TO: The Commission
Alberta E. Mills, Secretary

DATE: July 19, 2023

THROUGH: Austin C. Schlick, General Counsel
Jason Levine, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel, Regulatory Affairs
David M. DiMatteo, Attorney, Regulatory Affairs

SUBJECT: Accreditation of Four Conformity Assessment Bodies as a
"Firewalled" Third Party Laboratory

BALLOT VOTE DUE: Tuesday, July 25, 2023

CPSC staff is forwarding a memorandum to the Commission with accompanying draft Commission orders recommending that the Commission accredit the following four conformity assessment bodies as CPSC-accepted firewalled third party laboratories.

I. Laboratory of Firstunion Animation Technology Vietnam Co., Ltd.

A. Please indicate your vote on accreditation below:

1. _____ Approve the accreditation order.

(Signature)

(Date)

2. _____ Approve the accreditation order, with the specified changes:

(Signature)

(Date)

3. _____ Do not approve accreditation and order.

(Signature)

(Date)

4. _____ Take other action specified below.

(Signature)

(Date)

B. Staff also requests that the Commission authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director, to grant or deny subsequent accreditation applications by Laboratory of Firstunion Animation Technology Vietnam Co., Ltd. (e.g., to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance). If the Commission does not grant this authority to the Deputy Executive Director for Safety Operations, Office of the Executive Director, OGC will delete the paragraph in the draft order granting such authority.

Please indicate your vote below:

1. _____ Authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director, to grant or deny subsequent accreditation applications by Laboratory of Firstunion Animation Technology Vietnam Co., Ltd.

(Signature)

(Date)

2. _____ Do not authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director to grant or deny subsequent applications by Laboratory of Firstunion Animation Technology Vietnam Co., Ltd.

(Signature)

(Date)

3. Take other action as specified.

(Signature)

(Date)

II. Laboratory of Billion Max Vietnam Manufacturing Company Limited

A. Please indicate your vote below:

1. _____ Approve the accreditation order.

(Signature)

(Date)

2. _____ Approve the accreditation order, with the specified changes:

(Signature)

(Date)

3. _____ Do not approve accreditation and order.

(Signature)

(Date)

4. _____ Take other action specified below.

(Signature)

(Date)

B. Staff also requests that the Commission authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director, to grant or deny subsequent applications by Laboratory of Billion Max Vietnam Manufacturing Company Limited (e.g., to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance). If the Commission does not grant this authority to the Deputy Executive Director for Safety Operations, Office of the Executive Director, OGC will delete the paragraph in the draft order granting such authority.

Please indicate your vote below:

1. _____ Authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director, to grant or deny subsequent applications by Laboratory of Billion Max Vietnam Manufacturing Company Limited.

(Signature)

(Date)

2. _____ Do not authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director to grant or deny subsequent applications by Laboratory of Billion Max Vietnam Manufacturing Company Limited.

(Signature)

(Date)

3. Take other action as specified.

(Signature)

(Date)

III. Test & Innovation Lab s.r.l.

A. Please indicate your vote below:

1. _____ Approve the accreditation order.

(Signature)

(Date)

2. _____ Approve the accreditation order, with the specified changes:

(Signature)

(Date)

3. _____ Do not approve accreditation and order.

(Signature)

(Date)

4. _____ Take other action specified below.

(Signature)

(Date)

B. Staff also requests that the Commission authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director, to grant or deny subsequent applications by Test & Innovation Lab s.r.l. (e.g., to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance). If the Commission does not grant this authority to the Deputy Executive Director for Safety Operations, Office of the Executive Director, OGC will delete the paragraph in the draft order granting such authority.

Please indicate your vote below:

1. _____ Authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director, to grant or deny subsequent applications by Test & Innovation Lab s.r.l.

(Signature)

(Date)

2. _____ Do not authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director to grant or deny subsequent applications by Test & Innovation Lab s.r.l.

(Signature)

(Date)

3. Take other action as specified.

(Signature)

(Date)

IV. **Laboratorio Analisi Chimico Tessili SRL (ELLE.A.CI.TI)**

A. Please indicate your vote below:

1. _____ Approve the accreditation order.

(Signature)

(Date)

2. _____ Approve the accreditation order, with the specified changes:

(Signature)

(Date)

3. _____ Do not approve accreditation and order.

(Signature)

(Date)

4. _____ Take other action specified below.

(Signature)

(Date)

B. Staff also requests that the Commission authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director, to grant or deny subsequent applications by Laboratorio Analisi Chimico Tessili SRL (ELLE.A.CI.TI) (e.g., to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance). If the Commission does not grant this authority to the Deputy Executive Director for Safety Operations, Office of the Executive Director, OGC will delete the paragraph in the draft order granting such authority.

Please indicate your vote below:

1. _____ Authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director, to grant or deny subsequent applications by Laboratorio Analisi Chimico Tessili SRL (ELLE.A.CI.TI).

(Signature)

(Date)

2. _____ Do not authorize the Deputy Executive Director for Safety Operations, Office of the Executive Director to grant or deny subsequent applications by Laboratorio Analisi Chimico Tessili SRL (ELLE.A.CI.TI).

(Signature)

(Date)

3. Take other action as specified.

(Signature)

(Date)

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

<p>In the Matter of the Application for Accreditation as a Firewalled Third Party Conformity Assessment Body</p> <p style="text-align: center;">of</p> <p>Laboratory of Firstunion Animation Technology Vietnam Co., Ltd. Lot CCN1, Thuy Son Industrial Zone, Thuy Son Commune Thai Binh Thai Thuy District Vietnam 410000</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>CPSC Docket No. _____</p>
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ORDER

Having considered the application of the Laboratory of Firstunion Animation Technology Vietnam Co., Ltd. (the applicant) to be accredited by the U.S. Consumer Product Safety Commission as a “third party conformity assessment body,” as that term is defined in 15 U.S.C. § 2063(f)(2)(A) and (D), and having considered the analysis and recommendation of CPSC staff, the Commission, by order, finds that:

1. The applicant is owned, managed, or controlled by the manufacturer or private labeler of products that would be assessed by the applicant, if the applicant is accredited as a third party conformity assessment body by the Commission;
2. The applicant is accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement;
3. The applicant has established procedures to ensure that:
 - a. its test results are protected from undue influence by the manufacturer, private labeler, or other interested party;

b. the Consumer Product Safety 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

c. allegations of undue influence may be reported confidentially to the Consumer Product Safety Commission;

and

4. In view of the findings numbered 2 and 3 above, the accreditation of the applicant will provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party conformity assessment body for the requirements and test method(s) for which accreditation is ordered.

Accordingly, it is

ORDERED that the applicant is accredited as a third party conformity assessment body for testing children's products for:

- 16 CFR Part 1501, Small Parts Regulation;
- Section 4.6, *Small Objects* (ASTM F963-17);
- Section 4.7, *Accessible Edges* (ASTM F963-17);
- Section 4.8, *Projections* (except bath toy projections) (ASTM F963-17);
- Section 4.9, *Accessible Points* (ASTM F963-17);
- Section 4.10, *Wires or Rods* (ASTM F963-17);
- Section 4.11, *Nails and Fasteners* (ASTM F963-17);
- Section 4.12, *Plastic Film* (ASTM F963-17);
- Section 4.13, *Folding Mechanisms and Hinges* (exclude 4.13.1 Folding Mechanisms) (ASTM F963-17);
- Section 4.14, *Cords, Straps, and Elastics* (exclude 4.14.4 Strings and Lines for Flying Devices and 4.14.5 Cords on Toy Bags Intended for Children Up to 18 Months) (ASTM F963-17);
- Section 4.17, *Wheels, Tires, and Axles* (ASTM F963-17);
- Section 4.18, *Holes, Clearances, and Accessibility of Mechanisms* (exclude 4.18.3 Chains and Belts and 4.18.6 Coil Springs) (ASTM F963-17);
- Section 4.21, *Projectile Toys* (Exclude 4.21.4 Rotors) (ASTM F963-17);
- Section 4.32, *Certain Toys with Nearly Spherical Ends* (ASTM F963-17);
- and
- Section 4.36, *Hemispheric-Shaped Object* (ASTM F963-17); and it is

FURTHER ORDERED that the applicant will be placed on the list of entities on the CPSC's Internet website that have been accredited to assess conformity with children's product safety rules in accordance with the requirements in 16 CFR part 1112; and it is

FURTHER ORDERED that if the applicant does not continue to meet the requirements of 16 CFR part 1112, the applicant would be subject to suspension or withdrawal in accordance with the procedures provided in 16 CFR part 1112; and it is

FURTHER ORDERED that the authority to grant or deny subsequent applications by this applicant (*e.g.*, to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance) is delegated to the Deputy Executive Director for Safety Operations, Office of the Executive Director.

Order issued on the ____ day of _____, 2023.

BY ORDER OF THE COMMISSION:

Alberta E. Mills, Secretary
U.S. Consumer Product Safety Commission

CPSC Docket No. _____

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

c. allegations of undue influence may be reported confidentially to the Consumer Product Safety Commission;

and

4. In view of the findings numbered 2 and 3 above, the accreditation of the applicant will provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party conformity assessment body for the requirements and test method(s) for which accreditation is ordered.

Accordingly, it is

ORDERED that the applicant is accredited as a third party conformity assessment body for testing children's products for:

- 16 CFR Part 1501, Small Parts Regulation;
- 16 CFR Part 1510, Rattles;
- Section 4.5, *Sound Producing Toys* (ASTM F963-17);
- Section 4.6, *Small Objects* (except 4.6.2 mouth-actuated toys) (ASTM F963-17);
- Section 4.7, *Accessible Edges* (ASTM F963-17);
- Section 4.8, *Projections* (ASTM F963-17);
- Section 4.9, *Accessible Points* (ASTM F963-17);
- Section 4.10, *Wires or Rods* (ASTM F963-17);
- Section 4.11, *Nails and Fasteners* (ASTM F963-17);
- Section 4.12, *Plastic Film* (excluding a minimum of 1% of the vent area of plastic film) (ASTM F963-17);
- Section 4.13, *Folding Mechanisms and Hinges* (only 4.13.2 Hinge-Line Clearance) (ASTM F963-17);
- Section 4.14, *Cords, Straps, and Elastics* (except for 4.14.4 Strings and Lines for Flying Devices) (ASTM F963-17);
- Section 4.16, *Confined Spaces* (except for 4.16.2 Closures) (ASTM F963-17);
- Section 4.17, *Wheels, Tires, and Axles* (ASTM F963-17);
- Section 4.18, *Holes, Clearances, and Accessibility of Mechanisms* (except 4.18.3 Chains and Belts, 4.18.6 Coil Springs) (ASTM F963-17);
- Section 4.19, *Simulated Protective Devices* (ASTM F963-17);
- Section 4.21, *Projectile Toys* (ASTM F963-17);
- Section 4.22, *Teethers and Teething Toys* (ASTM F963-17);
- Section 4.23.1, *Rattles with nearly spherical, hemispherical, or circular flared ends* (ASTM F963-17);
- Section 4.24, *Squeeze Toys* (ASTM F963-17);
- Section 4.27, *Stuffed and Beanbag-Type Toys* (ASTM F963-17);
- Section 4.30, *Toy Gun Marking* (ASTM F963-17);

- Section 4.32, *Certain Toys with Nearly Spherical Ends* (ASTM F963-17);
- Section 4.35, *Pompoms* (ASTM F963-17);
- Section 4.36, *Hemispheric-Shaped Object* (ASTM F963-17);
- Section 4.39, *Jaw Entrapment in Handles and Steering Wheels* (ASTM F963-17); and
- Section 4.41, *Toy Chests* (except 4.41.1 Lid Support) (ASTM F963-17); and it is

FURTHER ORDERED that the applicant will be placed on the list of entities on the CPSC's Internet website that have been accredited to assess conformity with children's product safety rules in accordance with the requirements in 16 CFR part 1112; and it is

FURTHER ORDERED that if the applicant does not continue to meet the requirements of 16 CFR part 1112, the applicant would be subject to suspension or withdrawal in accordance with the procedures provided in 16 CFR part 1112; and it is

FURTHER ORDERED that the authority to grant or deny subsequent applications by this applicant (*e.g.*, to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance) is delegated to the Deputy Executive Director for Safety Operations, Office of the Executive Director.

Order issued on the ____ day of _____, 2023.

BY ORDER OF THE COMMISSION:

Alberta E. Mills, Secretary
U.S. Consumer Product Safety Commission

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

<p>In the Matter of the Application for Accreditation as a Firewalled Third Party Conformity Assessment Body</p> <p style="text-align: center;">of</p> <p>Test & Innovation Lab s.r.l. Viale Montegrappa 318/324 Prato 59100 Italy</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>CPSC Docket No. _____</p>
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ORDER

Having considered the application of the Test & Innovation Lab s.r.l. (the applicant) to be accredited by the U.S. Consumer Product Safety Commission as a “third party conformity assessment body,” as that term is defined in 15 U.S.C. § 2063(f)(2)(A) and (D), and having considered the analysis and recommendation of CPSC staff, the Commission, by order, finds that:

1. The applicant is owned, managed, or controlled by the manufacturer or private labeler of products that would be assessed by the applicant, if the applicant is accredited as a third party conformity assessment body by the Commission;
2. The applicant is accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement;
3. The applicant has established procedures to ensure that:
 - a. its test results are protected from undue influence by the manufacturer, private labeler, or other interested party;
 - b. the Consumer Product Safety 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

c. allegations of undue influence may be reported confidentially to the Consumer Product Safety Commission;

and

4. In view of the findings numbered 2 and 3 above, the accreditation of the applicant will provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party conformity assessment body for the requirements and test method(s) for which accreditation is ordered.

Accordingly, it is

ORDERED that the applicant is accredited as a third party conformity assessment body for testing children's products for:

- 16 CFR Part 1303 (CPSC-CH-E1003-09 or CPSC-CH-E1003-09.1), Lead Paint Regulation;
- 16 CFR Part 1610, Standard for the Flammability of Clothing Textiles;
- Section 4.3.5.1(2), *Surface Coating Materials - Soluble Test for Metals* (ASTM F963-17);
- Section 4.3.5.2, *Toy Substrate Materials* (ASTM F963-17);
- Lead in Non-Metal Children's Products (test method CPSC-CH-E1002-08 and/or CPSC-CH-E1002-08.1 and/or CPSC-CH-E1002-08.2 and/or CPSC-CH-E1002-08.3);
- Lead in Children's Metal Products (test method CPSC-CH-E1001-08 and/or CPSC-CH-E1001-08.1 and/or CPSC-CH-E1001-08.2 and/or CPSC-CH-E1001-08.3); and
- Lead in Children's Metal Jewelry (test method CPSC-CH-E1001-08 and/or CPSC-CH-E1001-08.1 and/or CPSC-CH-E1001-08.2 and/or CPSC-CH-E1001-08.3); and
- Determination of Phthalates (Test Method CPSC-CH-C1001-09.4; and it is

FURTHER ORDERED that the applicant will be placed on the list of entities on the CPSC's Internet website that have been accredited to assess conformity with children's product safety rules in accordance with the requirements in 16 CFR part 1112; and it is

FURTHER ORDERED that if the applicant does not continue to meet the requirements of 16 CFR part 1112, the applicant would be subject to suspension or withdrawal in accordance with the procedures provided in 16 CFR part 1112; and it is

FURTHER ORDERED that the authority to grant or deny subsequent applications by this applicant (e.g., to be accredited for additional requirements or test methods or to

renew their accreditation information and CPSC acceptance) is delegated to the Deputy Executive Director for Safety Operations, Office of the Executive Director.

Order issued on the ____ day of _____, 2023.

BY ORDER OF THE COMMISSION:

Alberta E. Mills, Secretary
U.S. Consumer Product Safety Commission

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

)	
In the Matter of the Application for)	
Accreditation as a Firewalled Third)	
Party Conformity Assessment Body)	
)	
of)	CPSC Docket No. _____
)	
Laboratorio Analisi Chimico Tessili SRL)	
(ELLE.A.CI.TI))	
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Italy)	
)	

ORDER

Having considered the application of the Laboratorio Analisi Chimico Tessili SRL (ELLE.A.CI.TI) (the applicant) to be accredited by the U.S. Consumer Product Safety Commission as a “third party conformity assessment body,” as that term is defined in 15 U.S.C. § 2063(f)(2)(A) and (D), and having considered the analysis and recommendation of CPSC staff, the Commission, by order, finds that:

1. The applicant is owned, managed, or controlled by the manufacturer or private labeler of products that would be assessed by the applicant, if the applicant is accredited as a third party conformity assessment body by the Commission;
2. The applicant is accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement;
3. The applicant has established procedures to ensure that:
 - a. its test results are protected from undue influence by the manufacturer, private labeler, or other interested party;
 - b. the Consumer Product Safety 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

c. allegations of undue influence may be reported confidentially to the Consumer Product Safety Commission;

and

4. In view of the findings numbered 2 and 3 above, the accreditation of the applicant will provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party conformity assessment body for the requirements and test method(s) for which accreditation is ordered.

Accordingly, it is

ORDERED that the applicant is accredited as a third party conformity assessment body for testing children's products for:

- 16 CFR Part 1610, Standard for the Flammability of Clothing Textiles; and it is

FURTHER ORDERED that the applicant will be placed on the list of entities on the CPSC's Internet website that have been accredited to assess conformity with children's product safety rules in accordance with the requirements in 16 CFR part 1112; and it is

FURTHER ORDERED that if the applicant does not continue to meet the requirements of 16 CFR part 1112, the applicant would be subject to suspension or withdrawal in accordance with the procedures provided in 16 CFR part 1112; and it is

FURTHER ORDERED that the authority to grant or deny subsequent applications by this applicant (*e.g.*, to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance) is delegated to the Deputy Executive Director for Safety Operations, Office of the Executive Director.

Order issued on the ____ day of _____, 2023.

BY ORDER OF THE COMMISSION:

Alberta E. Mills, Secretary
U.S. Consumer Product Safety Commission



Memorandum

TO: The Commission
Alberta E. Mills, Secretary

DATE: July 19, 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,
Office of Hazard Identification and Reduction

Scott Heh
Program Manager
Third Party Laboratory Accreditation
Directorate for Laboratory Sciences

SUBJECT: Applications for Commission Consideration as a Firewalled
Conformity Assessment Body

I. Introduction

CPSC staff recommends that the Commission accredit four laboratories: 1. Test & Innovation Lab (TIL) – Italy. 2. Laboratory of Billion Max Vietnam Manufacturing Company Limited, 3. Laboratory of Firstunion Animation Technology Vietnam Co., Ltd., and 4. Laboratorio Analisi Chimico Tessili SRL (ELLE.A.CI.TI) – Italy, as firewalled conformity assessment bodies (firewalled testing laboratories) authorized to perform specified children's product testing required by the Consumer Product Safety Act (CPSA)¹. CPSC's regulation at 16 C.F.R. part 1112 sets forth the firewalled laboratory application and acceptance procedures. This memorandum describes the process CPSC staff used to evaluate the four applications.

On March 8, 2023, the CPSC staff published a report on the CPSC firewalled laboratory review process that included staff plans to collect, review, and submit to the Commission additional elements and collection of additional information from CPSC firewalled laboratory applicants.² The staff's evaluation process described below includes the staff's consideration of those additional elements described in that report as well as the traditional requirements from part 1112. The additional elements are: 1. a For Official Use Only (FOUO) review of any prior issues of non-compliance with CPSC regulations for products associated with the applicant firm, 2. a signed attestation from a senior official of each applicant that clearly communicates the laboratory's commitment to conducting testing impartially and commitment to their procedures for

¹ FOUO Tab A discusses the results of data searches related to past non-compliance findings of children's products associated with these firms, ownership entities, and known associated firms.

² <https://www.cpsc.gov/s3fs-public/Report-on-CPSC-Approval-Process-for-Firewalled-Testing-Laboratories.pdf?VersionId=BoVH0k5mGrxQgxrl6MR5gGldpFIMvWt>



Memorandum

reporting actions of undue influence to the CPSC, and 3. the applicants' procedures/policies that support ISO/IEC 17025: Section 4.1 – Requirements for Impartiality.

This briefing package provides FOUO Tabs containing the additional information for Commission consideration. In FOUO Tab A, the Office of Compliance and Field Operations (EXC) reports the results of a data search of any prior issues of non-compliant children's products related to the affiliated manufacturing firms for each proposed firewalled laboratory. Each laboratory applicant's supporting materials in support of its application are provided in FOUO Tabs B, C, D, and E.

II. Background

CPSA: Third Party Laboratory Requirements and Conditions Applicable to Firewalled Laboratories

Section 14 of the CPSA, as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires manufacturers and importers of children's products subject to applicable children's product safety rules to use third party conformity assessment bodies (third party testing laboratories), that have been accredited in accordance with CPSC requirements. 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." 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 accreditation of third party testing laboratories.

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 a laboratory that is owned, managed, or controlled by the manufacturer or private labeler, under certain specified conditions, may be recognized as accredited by the Commission as a third party testing laboratory. 15 U.S.C. § 2063(f)(2). Testing laboratories that comply with these specified conditions are considered to be "firewalled" against the possibility of undue influence.

The Commission may accredit a firewalled laboratory 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;



Memorandum

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 C.F.R. part 1112 (effective June 10, 2013). These regulations include baseline requirements for independent laboratories and describe the process for firewalled laboratory application and acceptance procedures. The application and acceptance procedures for independent and firewalled third party testing laboratories are found at §§ 1112.13 and 1112.17. (Appendix A).

III. Discussion

Under 16 C.F.R. 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 C.F.R. § 1112.13(a)(2).

ILAC is an organization that 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. The ISO/IEC is a specialized system for worldwide standardization. Technical committees comprised of members from across the globe (including the United States) collaborate to develop these 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. Laboratory accreditation is based upon criteria and procedures from ISO/IEC 17025 to determine the technical and management competence of laboratories. Technical assessors conduct a thorough evaluation of all factors of facility operations that affect the production of technical data.

The technical assessors of laboratories are members of ILAC MRA accreditation bodies. Acceptance into the ILAC MRA requires an intensive peer evaluation from other accreditation bodies to determine compliance with ISO/IEC 17011 – "General requirements for bodies providing assessment and accreditation of conformity assessment bodies" (ISO/IEC 17011). The peer evaluators also witness the performance of assessors during actual laboratory assessments to determine if the laboratory is in compliance with ISO/IEC 17025. This evaluation is a recurring one, for accreditors to maintain their credentials.



Memorandum

ISO/IEC 17025 enables testing laboratories to demonstrate that they operate competently and generate valid test results, thereby promoting confidence in their work both nationally and around the world.³

Technical assessors evaluate a laboratory to all requirements in ISO/IEC 17025, including the impartiality criteria in Section 4.1 of the standard:

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.

All laboratories, including third party independent and first party (manufacturer owned) laboratories, must identify risks to impartiality and demonstrate how they eliminate or minimize those risks.

To ensure continued compliance, accredited laboratories are reassessed regularly by their accreditation bodies to verify that they maintain their standards of independence and technical expertise. Laboratories across the world have had their accreditations suspended or withdrawn by their accreditation bodies because the laboratories did not make corrective actions to nonconformities identified in a reassessment.

ISO/IEC 17025 accreditation includes an assessment to ensure the laboratory has the technical competence to conduct testing for its specified scope of test methods and standards, and to ensure that the laboratory's activities are structured and managed to safeguard impartiality. The Commission included, among other requirements, ISO/IEC 17025 accreditation by an accreditation body that is a signatory to the ILAC-MRA as a requirement for approval under the CPSA firewalled provisions. 16 C.F.R. § 1112.13(a)(2) and (b).

³ ISO Information Document on ISO/IEC 17025:
<https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100424.pdf>



Memorandum

During the rulemaking proceedings promulgating 16 C.F.R. part 1112, the Commission noted in the preamble⁴ of the notice of proposed rulemaking 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 17025:2005⁵ 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 C.F.R. part 1112 further requires laboratory applicants for firewalled status to submit documentation demonstrating to the Commission that the laboratory complies with the additional criteria establishing safeguards against undue influence.

Staff Review of Firewalled Laboratory Application

CPSC staff reviewed the four testing laboratory applications seeking Commission accreditation as firewalled laboratories. Staff summarizes the firewalled laboratory application and review process below:

1. The laboratories applied for firewalled acceptance via the CPSC online registration form. The applicants submitted training materials and other information to show conformity with the additional criteria for acceptance as firewalled laboratories.
2. The Firewalled Laboratory Review Committee (Review Committee), comprised of the Laboratory Accreditation Program Manager, the Deputy Assistant Executive Director for Hazard Identification and Reduction, the Associate Executive Director for Laboratory Sciences, and an OGC observer, reviewed the applications. The Review Committee members individually examined the application materials according to the criteria for firewalled laboratories set forth in 16 C.F.R. part 1112. After individual members conducted independent assessments, the Review Committee convened to discuss whether the laboratory met the baseline requirements for CPSC acceptance and satisfied the additional firewalled laboratory criteria.
3. After the Review Committee examined and discussed application documents from the laboratories, the committee members concluded that the applicants satisfy the baseline requirements for CPSC acceptance, as well as the additional criteria for firewalled laboratories set forth in section 14 of the CPSA and accompanying regulations at 16 C.F.R. part 1112. Specifically, the Review Committee determined:

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

⁵ The Commission required ISO/IEC 17025:2005 accreditation when it issued 16 C.F.R. part 1112 on March 12, 2013. On April 30, 2021, the Commission revised 16 C.F.R. part 1112 to require accreditation to ISO/IEC 17025:2017.



Memorandum

- i) The applicants provided current valid copies of ISO/IEC 17025 accreditation certificates and accreditation by an accreditation body that is a signatory to the ILAC-MRA. The applicants also submitted a statement of scope that clearly identified each CPSC rule and/or test method for which CPSC acceptance was being sought. These documents satisfy the baseline criteria required for all CPSC-accepted laboratories.
- ii) The applicants submitted documents that explained how the laboratories will protect test results from undue influence by the manufacturer, private labeler, or other interested party.
- iii) The applicants provided documentation describing 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 applicants provided training documents that explain the applicant's procedures for addressing undue influence and reporting allegations of undue influence to the CPSC. The training records included training dates with a list of employees who received such training. The applicants' procedures included a requirement for annual training regarding undue influence.
- v) The applicants submitted organizational charts for the laboratory, and for the broader organizations as well, showing the reporting relationship of the laboratory within the broader organization.
- vi) The applicants showed that there are no laboratory staff with reporting relationships outside of the laboratory.

In addition, the Review Committee confirmed that the applicants provided an 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. The applicant laboratories also submitted documents that support its commitment to impartiality requirements in ISO/IEC 17025.

The applicants' laboratories supporting materials are found in the following FOUO tabs:

FOUO Tab B - Test & Innovation Lab (TIL) s.r.l.

FOUO Tab C – Laboratory of Billion Max Vietnam Manufacturing Company Limited

FOUO Tab D– Laboratory of Firstunion Animation Technology Vietnam Co., Ltd.

FOUO Tab E - Laboratorio Analisi Chimico Tessili SRL (ELLE.A.CI.TI)

4. Based on the information supplied by the applicants as described above, the Review Committee concluded that the four applicants have established procedures to satisfy the statutory criteria for accreditation as a firewalled laboratory. The Review Committee further determined that it is reasonable to expect the applicants would provide equal or greater consumer protection than the use of an independent third party assessment body, and that the applicants had established procedures to ensure that its test results are protected from undue influence by the manufacturer, private labeler, or other interested party. Lastly, the Review Committee determined that the applicants have procedures in place to notify the Commission immediately of any attempt to exert undue influence over test results and that allegations of undue influence may be reported confidentially to the Commission.



Memorandum

IV. Firewalled Laboratory Review Committee Conclusions

Based on a review of whether the applicant laboratories' applications meet the criteria to be a CPSC accredited firewalled laboratory, the Review Committee recommended that the Commission accredit the following laboratory applicants as firewalled laboratories:

1. Test & Innovation Lab (TIL) s.r.l.

Viale Montegrappa 318/324
Prato
59100
Italy

The Review Committee recommended accreditation of this laboratory for the following scope:

4.3.5.1(2) (ASTM F963-17), Surface Coating Materials - Soluble Test for Metals
4.3.5.2 (ASTM F963-17), Toy Substrate Materials
16 C.F.R. Part 1303 (CPSC-CH-E1003-09.1), Lead Paint Regulation
Lead in Non-Metal Children's Products (test method CPSC-CH-E1002-08.3)
Lead in Children's Metal Products (test method CPSC-CH-E1001-08.3)
Lead in Children's Metal Jewelry (test method CPSC-CH-E1001-08.3)
Determination of Phthalates (Test Method CPSC-CH-C1001-09.4)
16 C.F.R. Part 1610, Standard for the Flammability of Clothing Textiles

2. Laboratory of Billion Max Vietnam Manufacturing Company Limited

Tay Cang Chan May Street, Loc Tien Commune
Phu Loc District
Thua Thien Hue Province
Vietnam

The Review Committee recommended accreditation of this laboratory for the following scope:

4.5 (ASTM F963-17), Sound Producing Toys
4.6 (ASTM F963-17), Small Objects (Except 4.6.2 mouth-actuated toys)
4.7 (ASTM F963-17), Accessible Edges
4.8 (ASTM F963-17), Projections
4.9 (ASTM F963-17), Accessible Points
4.10 (ASTM F963-17), Wires or Rods
4.11 (ASTM F963-17), Nails and Fasteners
4.12 (ASTM F963-17), Plastic Film (Excluding a minimum of 1% of the vent area of plastic film)
4.13 (ASTM F963-17), Folding Mechanisms and Hinges (Only 4.13.2 Hinge-Line Clearance)



Memorandum

4.14 (ASTM F963-17), Cords, Straps, and Elastics (Except for 4.14.4 Strings and Lines for Flying Devices)
4.16 (ASTM F963-17), Confined Spaces (Except for 4.16.2 Closures)
4.17 (ASTM F963-17), Wheels, Tires, and Axles
4.18 (ASTM F963-17), Holes, Clearances, and Accessibility of Mechanisms (Except 4.18.3 Chains and Belts, 4.18.6 Coil Springs)
4.19 (ASTM F963-17), Simulated Protective Devices
4.21 (ASTM F963-17), Projectile Toys
4.22 (ASTM F963-17), Teethers and Teething Toys
4.23.1 (ASTM F963-17), Rattles with nearly spherical, hemispherical, or circular flared ends
4.24 (ASTM F963-17), Squeeze Toys
4.27 (ASTM F963-17), Stuffed and Beanbag-Type Toys
4.30 (ASTM F963-17), Toy Gun Marking
4.32 (ASTM F963-17), Certain Toys with Nearly Spherical Ends
4.35 (ASTM F963-17), Pompoms
4.36 (ASTM F963-17), Hemispheric-Shaped Objects
4.39 (ASTM F963-17), Jaw Entrapment in Handles and Steering Wheels
4.41 (ASTM F963-17), Toy Chests (Except 4.41.1 Lid Support)
16 C.F.R. Part 1501, Small Parts Regulation
16 C.F.R. Part 1510, Rattles

3. Laboratory of Firstunion Animation Technology Vietnam Co., Ltd.

Lot CCN1, Thuy Son Industrial Zone, Thuy Son Commune
Thai Binh
Thai Thuy District
Vietnam
410000

The Review Committee recommended accreditation of this laboratory for the following scope:

16 CFR Part 1501, Small Parts Regulation
4.6 (ASTM F963-17), Small Objects
4.7 (ASTM F963-17), Accessible Edges
4.8 (ASTM F963-17), Projections
4.9 (ASTM F963-17), Accessible Points
4.10 (ASTM F963-17), Wires or Rods
4.11 (ASTM F963-17), Nails and Fasteners
4.12 (ASTM F963-17), Plastic Film
4.13 (ASTM F963-17), Folding Mechanisms and Hinges (Exclude 4.13.1 Folding Mechanisms)
4.14 (ASTM F963-17), Cords, Straps, and Elastics (Exclude 4.14.4 Strings and Lines for Flying Devices and 4.14.5 Cords on Toy Bags Intended for Children Up to 18 Months)
4.17 (ASTM F963-17), Wheels, Tires, and Axles



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4.18 (ASTM F963-17), Holes, Clearances, and Accessibility of Mechanisms (Exclude 4.18.3 Chains and Belts and 4.18.6 Coil Springs)
4.21 (ASTM F963-17), Projectile Toys (Exclude 4.21.4 Rotors)
4.32 (ASTM F963-17), Certain Toys with Nearly Spherical Ends
4.36 (ASTM F963-17), Hemispheric-Shaped Objects

4. Laboratorio Analisi Chimico Tessili SRL (ELLE.A.CI.TI)

via Leopardi 11/a
Lurate Caccivio
Italy

The Review Committee recommended accreditation of this laboratory for the following scope:

16 C.F.R. Part 1610, Standard for the Flammability of Clothing Textiles

V. Recommendation

Staff recommends that the Commission approve the four applications for accreditation, in accordance with the firewalled procedures described in 16 C.F.R. part 1112. This recommendation is based on the assessment conducted by the CPSC Firewalled Laboratory Review Committee, which examined the submitted application materials and agreed that the applicants' documentation met the conditions for accreditation as a firewalled laboratory.

Delegation Approval Requested

If the Commission accredits one or more the applicants as firewalled laboratories by order, staff requests that the Commission authorize the Deputy Executive Director for Operations, Office of the Executive Director, to approve any future applications by these laboratories.

Such applications would include, for example, applications to conduct testing for additional CPSC children's product safety requirements, or applications to renew the applicants' accreditation information and CPSC acceptance as a firewalled laboratory. Future applications typically would involve CPSC staff's review of technical scope competency and accreditation status by its ILAC-MRA accreditation body and would involve review of undue influence policies and staff training. Authorizing the Deputy Executive Director for Operations, Office of the Executive Director to approve future applications by these laboratories would be consistent with prior Commission practice regarding 38 out of 40 firewalled laboratories the Commission has previously accredited.

U.S. Consumer Product
Safety Commission
4330 East-West Highway
Bethesda, MD 20814

National Product Testing
and Evaluation Center
5 Research Place
Rockville, MD 20850



Memorandum

Appendix A – Excerpt from CPSC’s Regulations at 16 C.F.R. Part 1112

§1112.13⁶ How does a third party conformity assessment body apply for CPSC acceptance?

(a) Baseline Requirements. Each third party conformity assessment body seeking CPSC acceptance must:

(1) Submit a completed Consumer Product Conformity Assessment Body Registration Form (CPSC Form 223 or Application). In submitting a CPSC Form 223, the third party conformity assessment body must attest to facts and characteristics about its business that will determine whether the third party conformity assessment body is independent, firewalled, or governmental. The third party conformity assessment body also must attest that it has read, understood, and agrees to the regulations in this part. The third party conformity assessment body must update its CPSC Form 223 whenever any information previously supplied on the form changes.

(2) Submit the following documentation:

(i) Accreditation certificate.

(A) The third party conformity assessment body must be accredited to the ISO/IEC Standard 17025, “General requirements for the competence of testing and calibration laboratories.”

(B) The accreditation must be by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA).

(ii) Statement of scope. The third party conformity assessment body’s accreditation must include a statement of scope that clearly identifies each CPSC rule and/or test method for which CPSC acceptance is sought. Although a third party conformity assessment body may include more than one CPSC rule and/or test method in its scope in one application, it must submit a new application if the CPSC has already accepted the third party conformity assessment body for a particular scope, and the third party conformity assessment body wishes to expand its acceptance to include additional CPSC rules and/or test methods.

(b) Additional Requirements for Firewalled Third Party Conformity Assessment Bodies.

(1) A third party conformity assessment body may be accepted as a firewalled third party conformity assessment body if the Commission, by order, makes the findings described in §1112.17(b).

(2) For the Commission to evaluate whether an applicant firewalled third party conformity assessment body satisfies the criteria listed in §1112.17(b), and in addition to the baseline accreditation requirements in paragraph (a) of this section, a firewalled third party conformity assessment body applying for acceptance of its accreditation must submit copies of:

(i) The third party conformity assessment body’s established policies and procedures that explain:

⁶ The complete rule is linked at: www.ecfr.gov. Browse Title 16 - Commercial Practices. Go to part 1112, “REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES.”



Memorandum

(A) How the third party conformity assessment body will protect its test results from undue influence by the manufacturer, private labeler, or other interested party;

(B) That the CPSC will be notified immediately of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over the third party conformity assessment body's test results; and

(C) That allegations of undue influence may be reported confidentially to the CPSC;

(ii) Training documents, including a description of the training program content, showing how employees are trained annually on the policies and procedures described in paragraph (b)(2)(i) of this section;

(iii) Training records, including a list and corresponding signatures, of the staff members who received the training identified in paragraph (b)(2)(ii) of this section. The records must include training dates, location, and the name and title of the individual providing the training;

(iv) An organizational chart(s) of the third party conformity assessment body that includes the names of all third party conformity assessment body personnel, both temporary and permanent, and their reporting relationship within the third party conformity assessment body;

(v) An organizational chart(s) of the broader organization that identifies the reporting relationships of the third party conformity assessment body within the broader organization (using both position titles and staff names); and

(vi) A list of all third party conformity assessment body personnel with reporting relationships outside of the third party conformity assessment body. The list must identify the name and title of the relevant third party conformity assessment body employee(s) and the names, titles, and employer(s) of all individuals outside of the third party conformity assessment body to whom they report;

§1112.17 How will the CPSC respond to each application?

(a) CPSC staff will review each application and may contact the third party conformity assessment body with questions or to request submission of missing information.

(b) The application of a firewalled third party conformity assessment body will be accepted by order of the Commission, if the Commission finds that:

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

(2) The third party conformity assessment body 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 CPSC 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 CPSC.



Memorandum

(c) The CPSC will communicate its decision on each application in writing to the applicant, which may be by electronic mail.

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