



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

This document has been electronically
approved and signed.

BALLOT VOTE SHEET

DATE: September 14, 2011

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Kenneth R. Hinson, Executive Director
Cheryl A. Falvey, General Counsel
Philip L. Chao, Assistant General Counsel

FROM: Jan S. Carlson, General Attorney

SUBJECT: Accreditation of Laboratory as "Firewalled" Third Party Conformity
Assessment Body

Ballot Vote Due: September 20, 2011

This vote sheet pertains to staff's memorandum recommending that the Commission accredit a conformity assessment body (laboratory) as a firewalled third party laboratory.

Please indicate your vote on the following options:

- I. Staff recommends that YKK Corporation Analysis Office, Analysis Technology Center, Machinery and Engineering Group, be accredited to perform tests under 16 CFR part 1303, "*Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint*"; Test Method CPSC-CH-E1002-08, "Standard Operating Procedure for Determining Lead (Pb) in Non-Metal Children's Products"; and Test Method CPSC-CH-E1001-08, "Standard Operating Procedure for Determining Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry)." Please indicate whether you approve or disapprove of this accreditation and the attached draft order.

_____ Approve accreditation and order (staff recommendation).

_____ Approve accreditation and order, with changes, as set forth below:

_____ Do not approve accreditation and order.

(Signature)

(Date)

- II. Staff also requests that the Commission authorize staff to decide any future requests by this laboratory for changes in the requirements and test methods that the laboratory is approved to evaluate as a third party laboratory. Please indicate your vote on this request. (If the Commission does not grant this authority to staff, the paragraph in the draft order granting such authority will be deleted.)
- A. Authorize staff to decide any future requests by this laboratory for changes in the requirements and test methods that the laboratory is approved to evaluate as a third party laboratory.

(Signature)

(Date)

- B. Do not authorize staff to decide any future requests by this laboratory for changes in the requirements and test methods that the laboratory is approved to evaluate as a third party laboratory.

(Signature)

(Date)

- III. Take other action. (This could include a direction to staff to answer additional questions regarding the laboratory; to obtain additional information related to one or more of the alternatives given above; to prepare materials concerning an adjudicatory proceeding to address any of the issues addressed above; or to take other action desired by the Commission. Please specify.)

(Signature)

(Date)

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. _____
	)	
YKK Corporation Analysis Office,	)	
Analysis Technology Center,	)	
Machinery and Engineering Group	)	
200 Yoshida	)	
Kurobe	)	
Toyama	)	
Japan	)	
938-8601	)	

ORDER

Having considered the application of YKK Corporation Analysis Office, Analysis Technology Center, Machinery and Engineering Group (“the applicant”) to be accredited by the U.S. Consumer Product Safety Commission (“Commission”) as a third party conformity assessment body, as that term is defined in 15 U.S.C. § 2063(f)(2), and having considered the analysis and recommendation of Commission 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.
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 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 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 with respect to 16 CFR part 1303, "*Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint*;" Test Method CPSC-CH-E1002-08, "Standard Operating Procedure for Determining Lead (Pb) in Non-Metal Children's Products," and Test Method CPSC-CH-E1001-08, "Standard Operating Procedure for Determining Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry)"; and it is

FURTHER ORDERED that the applicant will be placed on the list on the Commission's Internet website of entities that have been accredited to assess conformity with children's product safety rules in accordance with the requirements published by the Commission under 15 U.S.C. § 2063(a); and it is

FURTHER ORDERED that the authority to grant or deny subsequent applications by this applicant to be accredited for additional requirements or test methods is delegated to Commission staff.

Order issued on the ____ day of _____, 2011.

BY ORDER OF THE COMMISSION:

Todd A. Stevenson, Secretary
U.S. Consumer Product Safety Commission



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

This document has been electronically
approved and signed.

Date: 9/14/11

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH : Cheryl A. Falvey, 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

Scott R. Heh
Project Manager

SUBJECT: Consideration of YKK Corporation Analysis Office, Analysis
Technology Center, Machinery and Engineering Group
Application for Commission Acceptance as an Accredited
Firewalled Conformity Assessment Body

I. Introduction

Through this memorandum, U.S. Consumer Product Safety Commission (CPSC) staff recommends that the Commission accredit a conformity assessment body (also referred to as a testing laboratory) that has applied for accreditation as a "firewalled laboratory" (defined below) to perform specified product testing required by the Consumer Product Safety Act (hereafter referred to as the "CPSA" or the "Act"). The Commission has previously published the firewalled laboratory application and acceptance procedures in Federal Register (FR) notices. [1, 2, 3, 4,

5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17]. This memorandum describes the process used by CPSC staff to evaluate the application.¹

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 certain Commission product safety rules, to use third party conformity assessment bodies (third party testing laboratories) that have been accredited under CPSC requirements to test children's products for compliance with those product safety rules. Such testing is to be used by the manufacturer or importer as the basis for a manufacturer's or importer's certification of compliance with a "children's product safety rule," which is defined as a "consumer product safety rule under the CPSA or similar rule, regulation, standard or ban under any other Act [than the CPSA] enforced by the Commission, including a rule declaring a consumer product to be a banned hazardous product or substance." See CPSA § 14(f)(1). The Act further requires that the Commission establish requirements for accreditation of third party testing laboratories.

The CPSIA defines a "third party testing laboratory" as one 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 conformity assessment body. Laboratories that comply with these specified conditions are said to be "firewalled" against the possibility of undue influence.

The Commission may accredit a laboratory under the Act's firewalled provision if the Commission finds, by order, that:

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

B) the laboratory has established procedures to ensure that –

¹ The application and related supporting materials are not attached to this memorandum but are available for review by any Commissioner.

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.

The CPSC laboratory accreditation requirements, including baseline requirements for third party laboratories and the process for firewalled laboratory application and acceptance procedures, were approved by the Commission and published in the *Federal Register* notices referenced above. Below is a summary of the procedures that apply to third party laboratories and firewalled laboratories:

All third party laboratories must be accredited to the International Organization for Standardization ("ISO") Standard ISO/IEC 17025:2005--General Requirements for the Competence of Testing and Calibration Laboratories. The accreditation must be by an accreditation body that is a full signatory to the International Laboratory Accreditation Cooperation--Mutual Recognition Arrangement ("ILAC-MRA"), and the scope of the accreditation must include the specific CPSC regulation and/or test methodology for which the laboratory seeks CPSC acceptance. These criteria are referred to as the "baseline accreditation requirements."

A true copy in English of the accreditation and scope documents demonstrating compliance with these requirements must be registered with the Commission electronically.

In addition to the baseline accreditation requirements applicable to all third party laboratories, firewalled laboratories seeking accredited status must submit to the Commission copies in English of their training documents showing how employees are trained to notify the Commission immediately and confidentially of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over the laboratory's test results. This additional requirement applies if there is an

ownership interest in the applicant laboratory of 10 percent or more by a manufacturer or private labeler of children's products to be tested by the laboratory for compliance with requirements for which the laboratory is applying.

The Commission has established an electronic accreditation acceptance and registration system accessed via the Commission's Internet site at <http://www.cpsc.gov/cgibin/labregentry/>. The applicant provides, in English, basic identifying information concerning its location, the type of accreditation it is seeking, electronic copies of its accreditation certificate, a scope of accreditation document, and firewalled laboratory training document(s), if relevant. Commission staff reviews that submission for accuracy and completeness.

In the case of a laboratory seeking accredited firewalled status, when the review is complete, the staff transmits its recommendation on accreditation to the Commission for consideration. If the Commission decides to accredit a firewalled laboratory, the Commission will issue an order to that effect, making the statutory findings, and that laboratory will be added to the CPSC's list of accredited laboratories.

III. Discussion

As discussed in the previous staff memoranda to the Commission on accreditation requirements for third party conformity assessment bodies (testing laboratories), the ISO/IEC 17025 standard has technical requirements for testing laboratories and management requirements on topics such as organization, management systems, document control, audits, and management reviews. Several of these management requirements address impartiality and safeguard against conflicts of interest. If the laboratory is part of an organization that performs activities other than testing, the responsibilities of key personnel in the organization that have an involvement with or influence on the testing and/or calibration activities of the laboratory must be defined in order to identify potential conflicts of interest. The laboratory must have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial, or other pressures and influences that may affect adversely the quality of their work. Further, the laboratory must have policies and procedures to avoid involvement in any

activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.

To ensure continued compliance, accredited laboratories are reexamined regularly to make certain that they maintain their standards of independence and technical expertise.

Under the ISO 17025 accreditation, not only commercial laboratories, but also manufacturers' laboratories and government laboratories must have arrangements to ensure that their management and personnel are free from any undue internal and external commercial, financial, or other pressures and influences that may affect adversely the quality of their work.

ISO 17025 accreditation of a laboratory includes an assessment to confirm the technical competence of the laboratory for a given scope, as well as an assessment of a laboratory's management and organization to ensure that there are safeguards against undue influence. Given these aspects of ISO 17025 accreditation, staff recommended that the Commission recognize ISO 17025 accreditation by an ILAC-MRA signatory accreditation body as a significant requirement that must be met for firewalled laboratories to be considered for approval under the firewalled provisions.

In addition, as recommended by staff and published in the cited FR notices, for a laboratory to be considered under the firewalled provision, the laboratory must submit additional documentation that is satisfactory to the Commission to demonstrate compliance with criteria on protections from undue influence.

Staff Review of Firewalled Laboratory Application

CPSC staff completed a review of the YKK Corporation Analysis Office, Analysis Technology Center, Machinery and Engineering Group's application for Commission acceptance of accreditation as a firewalled laboratory. Staff's review process was as follows:

- a. The laboratory applied for firewalled acceptance via the CPSC online registration form. The applicant submitted training materials and other information to show conformance with the criteria for acceptance for firewalled laboratories.

- b. The Firewalled Laboratory Review Committee (Review Committee), comprised of four senior CPSC staff members, reviewed the application. The Review Committee members individually examined the application materials according to the criteria for firewalled laboratories, as described in the CPSIA and in the Commission-published requirements for laboratory accreditation. After individual members conducted their assessments, the Review Committee met as a group to discuss each person's reasoning with regard to the laboratory's conformity with the firewalled laboratory criteria. The team reviewed documentation that included: the elements of the applicant's training program and records of training attendance; policies stated in its laboratory operating manual related to prohibition on acts of undue influence; organizational charts; and the certification and scope documents associated with ISO 17025 accreditation.
- c. The Review Committee agreed that the documentation supplied by the applicant supported the statutory requirements for acceptance as a firewalled laboratory.

IV. Firewalled Laboratory Review Committee Conclusions

The Review Committee recommended that the Commission approve the following laboratory applicant as a firewalled laboratory:

YKK Corporation Analysis Office, Analysis Technology Center, Machinery
and Engineering Group
200 Yoshida
Kurobe
Toyama
Japan
938-8601

The Review Committee approved the laboratory for:

- Lead in Children's Metal Products, CPSC-CH-E1001-08 and/or CPSC-CH-E1001-08.1;
- Lead in Non-Metal Children's Products, CPSC-CH-E1002-08 and/or CPSC-CH-E1002-08.1; and
- Lead Paint Regulation at 16 CFR part 1303 (CPSC-CH-E1003-09 or CPSC-CH-E1003-09.1).

V. Recommendations

Staff recommends that the Commission accept the accreditation of the laboratory listed in Section IV in accordance with the firewalled procedures as described in the FR notices for CPSC accreditation requirements for third party conformity assessment bodies. These recommendations are based on the assessments of the CPSC Firewalled Laboratory Review Committee that examined the application materials and agreed that the documentation supplied by the applicant supported the conditions for acceptance as a firewalled laboratory.

If the Commission approves the firewalled accreditation of this laboratory, staff recommends that the Commission authorize staff to approve any future applications by the laboratory to be approved by the CPSC to conduct testing for additional CPSC children's product safety requirements, provided the applications comply with the baseline requirements for third party laboratories.² The expansion of approved scope would not normally affect the additional factors to be considered in the approval of a firewalled laboratory. (The Commission granted staff this authority for the laboratories the Commission previously accredited as firewalled laboratories.)

VI. Commission Options

(1) The Commission can vote to approve YKK Corporation Analysis Office, Analysis Technology Center, Machinery and Engineering Group for recognition as a firewalled laboratory for the specified testing scope. In this event, the Commission is required to issue an order finding that the additional requirements for firewalled laboratories exist for the laboratory.

(2) The Commission can vote not to approve YKK Corporation Analysis Office, Analysis Technology Center, Machinery and Engineering Group for recognition as a firewalled laboratory for the specified testing scope if the Commission decides that the documentation submitted by the applicant is not sufficient to support a Commission finding to accept the accreditation of the applicant laboratory under the firewalled provisions. Under this option, the Commission also could decide to direct staff to obtain additional information relevant to whether the Commission should accredit the laboratory.

² To maintain CPSC acceptance of accreditation, the laboratory must maintain the baseline requirements of ISO 17025 accreditation by an accreditation body that is a signatory to the ILAC-MRA. In addition, all laboratories will be subject to any auditing requirements required by CPSA § 14(d)(1) that the Commission approves in the future.

(3) If the applicant is approved for recognition as a firewalled laboratory for the specified testing scope, the Commission could accept or reject the staff recommendation that the Commission delegate to staff the power to approve subsequent applications by the same firewalled laboratory to conduct testing for additional CPSC requirements.

(4) Consider other options, as directed by the Commission.

The Office of the General Counsel has prepared a ballot vote presenting these options and provided a draft order for the Commission's consideration if the laboratory is approved.

References

References 1 through 17 are available on the CPSC website at:

<http://www.cpsc.gov/about/cpsia/labaccred.html>.

[1] Federal Register: September 22, 2008 (Volume 73, Number 184)]

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1303 of Title 16, Code of Federal Regulations.

[2] Federal Register: October 22, 2008 (Volume 73, Number 205)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1508, Part 1509, and/or Part 1511 of Title 16, Code of Federal Regulations.

[3] Federal Register: November 17, 2008 (Volume 73, Number 222)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1501 of Title 16, Code of Federal Regulations.

[4] Federal Register: December 22, 2008 (Volume 73, Number 246)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of requirements for accreditation of third party conformity assessment bodies to assess conformity with the 600 parts per million (“ppm”) and 300 ppm lead content limits in metal and metal alloy parts of children’s metal jewelry established by the Consumer Product Safety Improvement Act of 2008.

[5] Federal Register: September 2, 2009 (Volume 74, Number 169)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Parts 1203, 1510, 1512, and/or 1513 and §1500.86(a)(7) and/or (a)(8) of Title 16, Code of Federal Regulations

[6] Federal Register: October 29, 2009 (Volume 74, Number 208)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: 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 Total Lead in Children's Products

[7] Federal Register: April 30, 2010 (Volume 75, Number 83)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1505 and/or § 1500.86(a)(5) of Title 16, Code of Federal Regulations

[8] Federal Register: June 4, 2010 (Volume 75, Number 107)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements - Third Party Testing for Certain Children's Products; Infant Bath Seats: Requirements for Accreditation of Third Party Conformity

[9] Federal Register: June 21, 2010 (Volume 75, Number 118)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Safety Standard for Infant Walkers; Revocation of Regulations Banning Certain Baby Walkers; Third Party Testing for Certain Children's

Products; Infant Walkers: Requirements for Accreditation of Third Party Conformity Assessment Bodies and Agency Information Collection Activities; Proposed Collection; Comment Request; Final Rules and Notice.

[10] Federal Register: July 21, 2010 (Volume 75, Number 139)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements - Third Party Testing for Certain Children's Products; Vinyl Plastic Film: Requirements for Accreditation of Third Party Conformity Assessment Bodies

[11] Federal Register: July 21, 2010 (Volume 75, Number 139)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements - Third Party Testing for Certain Children's Products; Carpets and Rugs: Requirements for Accreditation of Third Party Conformity Assessment Bodies

[12] Federal Register: August 18, 2010 (Volume 75, Number 159)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements - Third Party Testing for Certain Children's Products; Clothing Textiles: Requirements for Accreditation of Third Party Conformity Assessment Bodies

[13] Federal Register: August 18, 2010 (Volume 75, Number 159)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements - Third Party Testing for Certain Children's Products; Mattresses, Mattress Pads, and/or Mattress Sets: Requirements for Accreditation of Third Party Conformity Assessment Bodies

[14] Federal Register: August 27, 2010 (Volume 75, Number 166)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements - Third Party Testing for Certain Children's Products; Youth All-Terrain Vehicles: Requirements for Accreditation of Third Party Conformity Assessment Bodies

[15] Federal Register: November 19, 2010 (Volume 75, Number 223)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements - Third Party Testing for Certain Children's Products; Children's Sleepwear, Sizes 0 Through 6X and 7 Through 14: Requirements for Accreditation of Third Party Conformity Assessment Bodies

[16] Federal Register: December 28, 2010 (Volume 75, Number 248)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements - 16 CFR parts 1219 and 1220. Third Party Testing for Certain Children's Products; Full-Size Baby Cribs and Non-Full-Size Baby Cribs: Requirements for Accreditation of Third Party Conformity Assessment Bodies

[17] Federal Register: April 20, 2011 (Volume 76, Number 76)

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice of Requirements - Third Party Testing for Certain Children's Products; Toddler Beds: Requirements for Accreditation of Third Party Conformity Assessment Bodies