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

VOTE SHEET

DATE: JUL 2 0 2009

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Jacqueline Elder, Acting Executive Director JC
Cheryl A. Falvey, General Counsel CAF
Philip L. Chao, Assistant General Counsel PLC

FROM: Harleigh Ewell, Attorney, OGC HE

SUBJECT: Accreditation of Seven Laboratories As "Firewalled" Third Party Conformity Assessment Bodies

Ballot Vote Due July 24, 2009

This vote sheet relates to the staff's memorandum recommending that the Commission accredit seven conformity assessment bodies (laboratories) as firewalled third party laboratories. Please indicate your vote on the following options:

I. The staff recommended that the following laboratories be accredited for the requirements and test methods indicated. Please indicate whether you approve or disapprove accreditation for each of the laboratories listed for the requirement(s) or test method(s) described. (A vote for approval also constitutes a vote for approval of the draft order for that laboratory, unless changes to the draft order are indicated in section IV of this vote sheet. The draft orders are attached to the legal memorandum from the Office of the General Counsel.)

A. Mattel - Fisher Price - Montoi Laboratory Product Integrity, Nuevo Leon, Mexico (for Lead Paint Regulation – 16 CFR Part 1303 and Small Parts Regulation – 16 CFR Part 1501).

_____ Approve accreditation and order. (staff recommendation)

_____ Disapprove.

(Signature) (Date)

B. Mattel Malaysia SDN BHD, Malaysia (for: Lead Paint Regulation – 16 CFR Part 1303).

_____ Approve accreditation and order. (staff recommendation)

_____ Disapprove.

(Signature) (Date)

C. Dongguan Radica Games Manufacturing Co. Ltd. – PI Laboratory, China (for: Lead Paint Regulation – 16 CFR Part 1303 and Small Parts Regulation – 16 CFR Part 1501) .

_____ Approve accreditation and order. (staff recommendation)

_____ Disapprove.

(Signature) (Date)

D. Mattel Toys Technical Consultancy (Shenzhen) Ltd. – Conformance Laboratory, China (for: Lead Paint Regulation – 16 CFR Part 1303).

_____ Approve accreditation and order. (staff recommendation)

_____ Disapprove.

_____ _____
(Signature) (Date)

E. Laboratorio de Mabamex S.A. de C.V., Tijuana, Baja California, Mexico (for: Lead Paint Regulation – 16 CFR Part 1303 and Small Parts Regulation – 16 CFR Part 1501).

_____ Approve accreditation and order. (staff recommendation)

_____ Disapprove.

_____ _____
(Signature) (Date)

F. Mattel El Segundo Product Integrity Laboratory, El Segundo, CA, United States (for: Lead Paint Regulation – 16 CFR Part 1303) .

_____ Approve accreditation and order. (staff recommendation)

_____ Disapprove.

(Signature) (Date)

G. PT Mattel Indonesia, Indonesia (for: Lead Paint Regulation – 16 CFR Part 1303 and Small Parts Regulation – 16 CFR Part 1501) .

_____ Approve accreditation and order. (staff recommendation)

_____ Disapprove.

(Signature) (Date)

II. The staff recommended against accrediting the following laboratories for the requirements and test methods indicated. Please indicate whether you approve or disapprove accreditation for each of the laboratories listed for the requirement(s) or test method(s) described. (If accreditation is disapproved for the requirement indicated, staff will notify the applicant of that action.)

A. Laboratorio de Mabamex S.A. de C.V., Tijuana, Baja California, Mexico (for: Lead Content in Children's Metal Jewelry – CPSC-CH-E1001-08).

_____ Approve.

_____ Disapprove. (staff recommendation)

_____ _____

(Signature) (Date)

B. Mattel El Segundo Product Integrity Laboratory, El Segundo, CA, United States (for: Small Parts Regulation – 16 CFR Part 1501).

_____ Approve.

_____ Disapprove. (staff recommendation)

_____ _____

(Signature) (Date)

III. The staff also requested that the Commission authorize the staff to decide any future requests by any of these laboratories that the Commission accredits as a firewalled 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 the staff, the paragraph in the draft orders granting such authority will be deleted.

A. Authorize the staff to decide any future requests by any of these laboratories that the Commission accredits as a firewalled 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 the staff to decide any future requests by any of these laboratories that the Commission accredits as a firewalled laboratory for changes in the requirements and test methods that the laboratory is approved to evaluate as a third party laboratory.

_____ _____

(Signature) (Date)

IV. Other. (This could include: a direction to the staff to obtain further information relating to one or more of the alternatives given above; a direction to the staff to prepare materials concerning an adjudicatory proceeding to address any of the issues addressed above; changes to the draft order for any laboratory to be accredited as a firewalled third party laboratory; or other action desired by the Commission. Please specify.)

_____

_____

_____

_____ _____

(Signature) (Date)

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Date: JUL 20 2009

TO: The Commission
Todd Stevenson, Secretary

THROUGH : Cheryl Falvey, General Counsel CAF
Jaqueline Elder, Acting Executive Director JE

FROM: Robert Howell RH
Assistant Executive Director
Office of Hazard Identification and Reduction

Scott Heh SH for RH
Project Manager

SUBJECT: Consideration of Certain Conformity Assessment Bodies that Applied for Commission Acceptance as Accredited Firewalled Conformity Assessment Bodies

I. Introduction

In this memorandum, U.S. Consumer Product Safety Commission (CPSC) staff recommends that the Commission accredit seven conformity assessment bodies (also referred to as testing laboratories) that applied for accreditation as "firewalled laboratories" (defined below) to perform specified product testing required by the Consumer Product Safety Improvement Act of 2008 (hereafter referred to as "CPSIA" or the "Act"). The firewalled laboratory application and acceptance procedures have been published previously by the Commission in Federal Register (FR) notices. [1, 2, 3, 4] In addition, this memorandum describes the process used by CPSC staff to evaluate the applications.[1]

[1] The applications and related supporting materials have not been attached to this memorandum but are available for review by any Commissioner.

II. Background

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

The CPSIA amended section 14 of the Consumer Product Safety Act (CPSA) to require that the Commission establish requirements for accreditation of third party conformity assessment bodies (third party testing laboratories). The Act further requires manufacturers and importers to use third party laboratories that have been recognized as accredited under CPSC requirements to test children's products for compliance with certain Commission 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 this Act 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 CPSIA § 102(f)(1).

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 laboratory that is so owned, managed, or controlled by the manufacturer or private labeler may under certain specified conditions be recognized as accredited by the Commission. 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'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.

CPSC laboratory accreditation requirements, including baseline requirements for third party laboratories and the process described 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 are ownership interests in the applicant laboratory of 10% or more by manufacturers or private labelers of children's products subject to the safety 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/genlabapp.aspx. The applicant provides, in English, basic identifying information concerning its location, the type of accreditation it is seeking, electronic copies of its ILAC-MRA accreditation certificate, a scope

statement and firewalled laboratory training document(s), if relevant. Commission staff reviews that submission for accuracy and completeness.

In the case of a firewalled laboratory seeking accredited 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 and that laboratory will be added to the CPSC 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),[2] 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 or influence on the testing and/or calibration activities of the laboratory shall 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 and other pressures and influences that may adversely affect 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 regularly re-examined, at least every two years, with either an on-site surveillance or a full reassessment, to ensure that they maintain their standards of independence and technical expertise.

Under the ISO 17025 accreditation, not only commercial laboratories, but manufacturer's laboratories and government laboratories must have arrangements to ensure that their management and personnel are free from any undue internal

[2] The latest staff memorandum to the Commission, "CPSC Staff Briefing Memorandum - Accreditation Requirements for Third Party Conformity Assessment Bodies to Test to the Requirements for Lead Content in Children's Metal Jewelry as Established by the Consumer Product Safety Improvement Act of 2008," December 2008, is available on the CPSC Web site at http://www.cpsc.gov/library/foia/foia09/brief/leadjewelry.pdf

and external commercial, financial, and/or other pressures and influences that may adversely affect 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 and also includes an assessment of a laboratory's management and organization to ensure safeguards against undue influence. Given these aspects of ISO 17025 accreditation, the staff recommended that the Commission recognize ISO 17025 accreditation by an ILAC-MRA Signatory as a significant component that must be met for firewalled laboratories to be considered for approval under the firewalled provisions.

In addition, as recommended by staff and as published in the 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 Laboratories' Applications

The staff completed a review of several firewalled laboratory applicants that seek Commission acceptance of accreditation as firewalled laboratories. The staff review process was as follows:

a. Laboratories applied for firewalled acceptance via the CPSC on-line registration form. Each applicant submitted training materials and other information to show conformance with the criteria for acceptance for firewalled laboratories.

b. A Firewalled Laboratory Review Committee comprised of four senior level CPSC staff members reviewed the applications. The committee members individually compared the applications for each laboratory with 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 committee met as a group to discuss each person's reasoning with regard to a laboratory's conformity or non-conformity with the firewalled laboratory criteria. The team reviewed documentation that included elements of training programs and records of training attendance, policies stated in laboratory quality manuals and operating manuals related to prohibition on acts of undue influence, organizational charts, and certification and scope documents associated with ISO 17025 accreditation.

c. The Review Committee concluded, by majority vote,[3] that the documentation supplied by the applicants supported requirements for acceptance as firewalled laboratories. The Review Committee recommended that a memorandum be prepared for Commission review with a recommendation to accept the applicants as firewalled laboratories and to list the laboratories on the CPSC Web site for the testing scopes approved by the Review Committee.

IV. Firewalled Laboratory Review Committee Conclusions

All of the laboratory applicants addressed in this memorandum are owned by Mattel. The Review Committee recommended for Commission approval the following laboratory applicants as firewalled laboratories:

1) Mattel - Fisher Price - Montoi Laboratory Product Integrity
Libramiento Noreste Km. 27
Escobedo
Nuevo Leon
Mexico
[Review Committee approved for scopes: Lead Paint Regulation – 16 CFR Part 1303 and Small Parts Regulation – 16 CFR Part 1501]

2) Mattel Malaysia SDN BHD
Plot 206, Prai Free Trade Zone
Prai Industrial Estate
Prai
Penang
Malaysia
[Review Committee approved for scope: Lead Paint Regulation – 16 CFR Part 1303]

[3] For all of the laboratories discussed in this memorandum, the vote was unanimous.

3) Dongguan Radica Games Manufacturing Co. Ltd. - PI Laboratory
1-2/F, A Building, Radica Games Manufacturing Co. Ltd.
Longyan Management District, Humen
Dongguan
Guangdong
China
[Review Committee approved for scopes: Lead Paint Regulation – 16 CFR Part 1303 and Small Parts Regulation – 16 CFR Part 1501]

4) Mattel Toys Technical Consultancy (Shenzhen) Ltd. - Conformance Laboratory
6/F, #6 Building, Heng Sheng Chong Industrial Center, 107 Fu Kang Road
Heng Gang Town, Long Gang District
Shenzhen City
Guang Dong Province
China
[Review Committee approved for scope: Lead Paint Regulation – 16 CFR Part 1303]

5) Laboratorio de Mabamex S.A. de C.V.
Boulevard El Refugio 25551 Fideicomiso El Florido
Tijuana
Baja California
Mexico
[Review Committee approved for scopes: Lead Paint Regulation – 16 CFR Part 1303 and Small Parts Regulation – 16 CFR Part 1501]
[Review Committee did not[4] approve for scope: Lead Content in Children's Metal Jewelry – CPSC-CH-E1001-08]

6) Mattel El Segundo Product Integrity Laboratory
2031 E. Mariposa Ave.
El Segundo
CA
United States
[Review Committee approved for scope: Lead Paint Regulation – 16 CFR Part 1303]

[4] In some cases the Review Committee voted that the laboratory met the special conditions for firewalled laboratories, but, the laboratory failed to meet one of the baseline conditions by not having a proper reference to the CPSC safety requirement or test method in the scope document issued by the accrediting body that accompanied the laboratory's accreditation certificate. If the accrediting body updates or clarifies the scope document in the future, the applicant can seek approval to that scope.

[Review Committee did not approve for scope: Small Parts Regulation – 16 CFR Part 1501]

7) PT Mattel Indonesia
Jl. Industri Utama Blok SS Kav 1-3
Kawasan Industri Cikarang Tahap 2
Bekasi
Jawa Barat
Indonesia
[Review Committee approved for scopes: Lead Paint Regulation – 16 CFR Part 1303 and Small Parts Regulation – 16 CFR Part 1501]

V. Recommendations

The staff recommends that the Commission accept the accreditation of the laboratories 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 applicants supported the conditions for acceptance as firewalled laboratories.

The staff also recommends that should the Commission approve the firewalled accreditation of these laboratories, any future applications by these same laboratories to conduct testing for additional CPSC children's product safety requirements (scopes) be approved at the staff level, provided the application complies with the baseline requirements for third party laboratories.[5] This is because the expansion of approved scopes would not normally affect the additional factors to be considered in the approval of a firewalled laboratory.

VI. Commission Options

1) The Commission can vote to approve one or more of the seven laboratories as recommended by the Review Committee for recognition as a firewalled laboratory for the specified testing scopes. In this event, the Commission is required to issue an order finding that the additional requirements for firewalled laboratories exist for the approved laboratories.

[5] To maintain CPSC acceptance of accreditation, the laboratory must maintain the baseline requirements of ISO 17025 accreditation by a full member ILAC-MRA Signatory accrediting body. In addition, all laboratories will be subject to any auditing requirements that the Commission approves in the future.

2) If the Commission decides that the documentation submitted by the applicants is not sufficient to support a Commission finding to accept the accreditation of the applicant laboratories under the firewalled provisions, the Commission can vote to not accept one or more of the applicant laboratories under the firewall provisions. Under this option, the Commission could also decide to direct the staff to obtain additional information relevant to whether the Commission should accredit the laboratories.

3) The Commission could accept or reject the staff recommendation that the Commission delegate to the staff the power to approve subsequent applications by these same firewalled laboratories to conduct testing for additional CPSC requirements.

4) Other options as directed by the Commission.

The Office of General Counsel has prepared a ballot vote presenting these options and has prepared draft orders for the Commission's consideration if one or more of the laboratories are approved.

References

References 1 through 4 are available on the CPSC Web site at http://www.cpsc.gov/about/cpsia/labaccred.html

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

AGENCY: 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: 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: 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: 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.