

PUBLIC SUBMISSION

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Docket: CPSC-2010-0038
Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0030
Comment from The Zurich Silk Association

Submitter Information

Name: Thomas Schweizer
Address:
Zurich, Switzerland,
Submitter's Representative: Thomas Schweizer
Organization: The Zurich Silk Association

General Comment

See Attached

Attachments

CPSC-2010-0038-0030.1: Comment from The Zurich Silk Association

ZÜRCHERISCHE SEIDENINDUSTRIE-GESELLSCHAFT

ASSOCIATION ZURICHOISE DE L'INDUSTRIE DE LA SOIE

THE ZURICH SILK ASSOCIATION

Mr. Todd A. Stevenson
Secretary of the Consumer Product Safety Commission
4330 East Highway
Bethesda, Maryland 208 14-4408
United States

Zurich, 21st July, 2010
TS/ET 2.57.04

Dear Mr. Stevenson

Our association represents all the companies in Switzerland interested in silk from the merchants to the fashion designers. We have two important Silk weavers, who are both exporting to your country.

The rule proposed in the „Testing and Labelling pertaining to product certification“ allows for commentaries. We would like to take this opportunity.

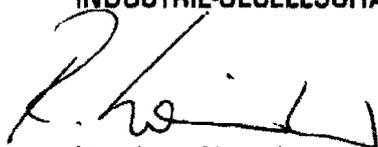
The Swiss manufactures of Silk fabrics exporting to the USA are concerned to the extent that the flammability testing requirements specified by 16CFR 1610 remain in force for their fabrics. We request urgently to include silk in the list of fibres that are exempted, like: acrylic, nylon, wool etc.

The obligation for testing is a big burden for us, because this testing is very expensive and delays our deliveries considerably.

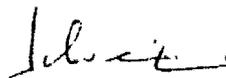
Silk reacts to fire in a similar way as wool, which is like silk also a protein fibre, and we see no reason for a different treatment of our fibre in the flame retardance issue.

Please consider our request, which is so very important for our members. We are at your disposal for any further information. Please call Ronald Weisbrod at 0041 79 412 33 58.

Best regards
**ZÜRCHERISCHE SEIDEN-
INDUSTRIE-GESELLSCHAFT**



Member of board
Ronald Weisbrod
Weisbrod-Zuerrer AG
CH 8915 Hausen am Albis



Thomas Schweizer
Secretary
The Zurich Silk Association
CH 8002 Zurich

PUBLIC SUBMISSION

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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0031
Comment from Tai Nam Industrial Company Limited

Submitter Information

Name: Chris Yip
Address: Hong Kong,
Submitter's Representative: Chris Yip
Organization: Tai Nam Industrial Company Limited

General Comment

See Attached

Attachments

CPSC-2010-0038-0031.1: Comment from Tai Nam Industrial Company Limited



大南玩具實業有限公司
TAI NAM INDUSTRIAL COMPANY LIMITED

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Fiat A, 1/F Block 4, Golden Dragon Ind. Centre, 182-190 Tai Li Road, Kwai Chung, N.T. H.K.

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Office of the Secretary
FOI

21st July, 2010

Office of the Secretary
U.S. Consumer Product Safety Commission
Room 502, 4330 East West Highway
Bethesda, MD20814
USA

Re: Docket No. CPSC-2010-0038

Comments on Proposed 16 CFR Part 1107 Subpart C – Certification of Children's Product

Dear Sir

We are writing to express our concerns and recommendations regarding the proposed 16 CFR Part 1107 Subpart C – Certification of children's product. The proposed 16 CFR Part 1107 Subpart C – Certification of children's products is designed to provide a high level of assurance that children's product comply with defined safety standards. The proposed rule depends heavily upon testing by 3rd party conformity assessment body. This heavy dependence upon testing by 3rd party conformity assessment body imposes high cost burden to the children's products industry and under-recognizes/under-utilizes the quality assurance professionalism and testing capabilities of many manufacturers and overseas factories of the children product industry. Our specific concerns and recommendations regarding the proposed 16 CFR Part 1107 Subpart C – Certification of children's products are as follows:

- 1107.20 Children Product Certification. Manufacturers must submit a sufficient number of samples of a children's product, or samples that are identical in all material respects to the children's product, to a third party conformity assessment body for testing to support certification.

The ultimate safety assurance responsibility of children's product lies with the manufacturer and the overseas factory (where applicable). To fulfill this responsibility, many manufacturers and overseas factories hire qualified engineers and quality assurance professions, and set up qualified testing facility that conforms to ISO 17025:2005 – General requirements for the competence of testing and calibration laboratories.

To minimize testing cost, to utilize the qualified testing facility of manufacturers and overseas factories, and to encourage manufacturers and overseas factories to set up systems and qualified testing facility to undertake their safety assurance responsibility, we would like to recommend that if the manufacturer and or the overseas factory has testing facility that conforms to ISO 17025:2005 – General requirements for the competence of testing and calibration laboratories, the number of samples requires to submit to 3rd party conformity assessment body for testing to support certification can be reduced to half provided that the manufacturer and or the overseas factory's testing facility perform certification testing with minimum the same sample size as the 3rd party conformity assessment body.

- 1107.21 Periodic Testing. All periodic testing must be conducted by a third party conformity assessment body.

Our comment and recommendation is same as for 1107.20 Children Product Certification

- 1107.23 Random Samples. Each manufacturer must select samples for periodic testing by using a process that assigns each sample in the production an equal probability of being selected. A manufacturer may use a procedure that randomly selects items from a list to determine which samples are the random samples used for periodic testing before production begins.

The Random Samples rule imposes extreme high risk and heavy financial burden to manufacturers. The current business model of most manufacturers is to ship products that have been checked, inspected and or tested for compliance by their own team or their appointed representative. Under the Random Samples rule, if the manufacturers wish to continue with this current business model, the numbers of periodic test and the associated

testing costs by 3rd party conformity assessment body are likely to be so high that most manufacturers are not able to afford. If the manufacturers change their business model to random sampling and testing as products are distributed in commerce, the business risk and potential financial burden are a big issue. Incidental failure may happen in mass production and the famous Murphy's Law tells us that failure may then be found during random sample testing. While the manufacturers can ultimately prove "incidentalness" using lots of data and test samples, the time loss and the loss of confidence by retailers and consumers may kill the product anyway. We strongly suggest removing the Random Samples rule. The periodic testing is used for certifying for the next production and shipping period.

On another note the current proposed Random Samples rule has some deficiencies. One technical problem is that the "population" is a forecast by the manufacturer and may change frequently and drastically. There may be time that the forecast is completed but then there are several additional orders later within the periodic testing period. There may be other time that the production order for the children's product is halted immediately such that the manufacturer will not be able to complete the original random samples plan for drawing random samples. The current proposed Random Samples rule does not cater for these situations. The proposed Random Samples rule also does not contain procedure that the manufacturer must follow if one or more samples fail during the periodic testing for manufacturer who produces children's products that continue to be distributed in commerce, and the manufacturer uses a procedure that randomly selects items from a list to determine which samples are the random samples used for periodic testing before production begins, and tests the selected samples as they are manufactured.

- 1107.23 Material Changes. If a children's product undergoes a material change in product design or manufacturing process, including the sourcing of component parts, the manufacturer must submit a sufficient number of samples of the materially changed product for testing by a third party conformity assessment body. Such testing must occur before a manufacturer can certify the children's product.

Manufacturer and overseas factory make frequent product improvement during production to enhance safety margin. The requirement to submit a sufficient number of samples of the materially changed product for testing by a 3rd party conformity assessment body period to certifying the change is costly and very time consuming. This will definitely deter the manufacturer and overseas factory's good intention to make continuous improvement effect to enhance the safety margin of children's product. We are extremely worried that this will result in lower safety assurance of children's product. We would

like to recommend that if the manufacturer and or the overseas factory have testing facility that conforms to ISO 17025:2005 – General requirements for the competence of testing and calibration laboratories, the manufacturer and or the overseas factory testing facility are allowed to conduct the certification of material change themselves.

Yours faithfully

For and on behalf of

Tai Nam Industrial Company Limited

A handwritten signature in black ink, appearing to be 'Chris Yip', written over a vertical dotted line.

Chris Yip

Director of Quality Assurance and Compliance

CC : Mr. David Chu – Chairman, Tai Nam Ind. Co. Ltd.

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Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0032
Comment from Dongguan Jauntway Toys Company

Submitter Information

Name: YK Wong
Address: China,
Submitter's Representative: YK Wong
Organization: Dongguan Jauntway Toys Company

General Comment

See Attached

Attachments

CPSC-2010-0038-0032.1: Comment from Dongguan Jauntway Toys Company

東莞鎮揚玩具有限公司
 DONGGUAN JAUNTIWAY TOYS COMPANY
 LIMITED

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中國廣東省
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 三中金龍工業區

23rd July, 2010

Office of the Secretary
 U.S. Consumer Product Safety Commission
 Room 502, 4330 East West Highway
 Bethesda, MD20814
 USA

Re: Docket No. CPSC-2010-0038

Comments on Proposed 16 CFR Part 1107 Subpart C - Certification of Children's Product

We are a toys manufacturing company operating in China with our major market of export to our customers in the United States of America. In reference to the above, we express our concerns and recommendations regarding the proposed 16 CFR Part 1107 Subpart C Certification of children's product. The proposed 16 CFR Part 1107 Subpart C Certification of children's products is designed to provide a high level of assurance that children's product comply with defined safety standards. The proposed rule depends heavily upon testing by 3rd party conformity assessment body. This heavy dependence upon testing by 3rd party conformity assessment body imposes high cost burden to the children's products industry and under-recognizes/under-utilizes the quality assurance professionalism and testing capabilities of many manufacturers and overseas factories of the children product industry. Our specific concerns and recommendations regarding the proposed 16 CFR Part 1107 Subpart C - Certification of children's products are as follows:

- 1107.20 Children Product Certification. Manufacturers must submit a sufficient number of samples of a children's product, or samples that are identical in all material

respects to the children's product, to a third party conformity assessment body for testing to support certification.

The ultimate safety assurance responsibility of children's product lies with the manufacturer and the overseas factory (where applicable). To fulfill this responsibility, many manufacturers and overseas factories hire qualified engineers and quality assurance professions, and set up qualified testing facility that conforms to ISO 17025:2005 - General requirements for the competence of testing and calibration laboratories.

To minimize testing cost, to utilize the qualified testing facility of manufacturers and overseas factories, and to encourage manufacturers and overseas factories to set up systems and qualified testing facility to undertake their safety assurance responsibility, we would like to recommend that if the manufacturer and or the overseas factory has testing facility that conforms to ISO 17025:2005 - General requirements for the competence of testing and calibration laboratories, the number of samples requires to submit to 3rd party conformity assessment body for testing to support certification can be reduced to half provided that the manufacturer and or the overseas factory's testing facility perform certification testing with minimum the same sample size as the 3rd party conformity assessment body.

- 1107.21 Periodic Testing. All periodic testing must be conducted by a third party conformity assessment body.

Our comment and recommendation is same as for 1107.20 Children Product Certification

- 1107.23 Random Samples. Each manufacturer must select samples for periodic testing by using a process that assigns each sample in the production an equal probability of being selected. A manufacturer may use a procedure that randomly selects items from a list to determine which samples are the random samples used for periodic testing before production begins.

The Random Samples rule imposes extreme high risk and heavy financial burden to manufacturers. The current business model of most manufacturers is to ship products that have been checked, inspected and or tested for compliance by their own team or their appointed representative. Under the Random Samples rule, if the manufacturers wish to continue with this current business model, the numbers of periodic test and the associated

testing costs by 3rd party conformity assessment body are likely to be so high that most manufacturers are not able to afford. If the manufacturers change their business model to random sampling and testing as products are distributed in commerce, the business risk and potential financial burden are a big issue. Incidental failure may happen in mass production and the famous Murphy's Law tells us that failure may then be found during random sample testing. While the manufacturers can ultimately prove "incidental" using lots of data and test samples, the time loss and the loss of confidence by retailers and consumers may kill the product anyway. We strongly suggest removing the Random Samples rule. The periodic testing is used for certifying for the next production and shipping period.

On another note the current proposed Random Samples rule has some deficiencies. One technical problem is that the "population" is a forecast by the manufacturer and may change frequently and drastically. There may be time that the forecast is completed but then there are several additional orders later within the periodic testing period. There may be other time that the production order for the children's product is halted immediately such that the manufacturer will not be able to complete the original random samples plan for drawing random samples. The current proposed Random Samples rule does not cater for these situations. The proposed Random Samples rule also does not contain procedure that the manufacturer must follow if one or more samples fail during the periodic testing for manufacturer who produces children's products that continue to be distributed in commerce, and the manufacturer uses a procedure that randomly selects items from a list to determine which samples are the random samples used for periodic testing before production begins, and tests the selected samples as they are manufactured.

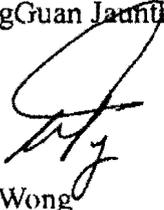
- 1107.23 Material Changes. If a children's product undergoes a material change in product design or manufacturing process, including the sourcing of component parts, the manufacturer must submit a sufficient number of samples of the materially changed product for testing by a third party conformity assessment body. Such testing must occur before a manufacturer can certify the children's product.

Manufacturer and overseas factory make frequent product improvement during production to enhance safety margin. The requirement to submit a sufficient number of samples of the materially changed product for testing by a 3rd party conformity assessment body period to certifying the change is costly and very time consuming. This will definitely deter the manufacturer and overseas factory's good intention to make continuous improvement effect to enhance the safety margin of children's product. We are extremely

worried that this will result in lower safety assurance of children's product. We would like to recommend that if the manufacturer and or the overseas factory have testing facility that conforms to ISO 17025:2005 – General requirements for the competence of testing and calibration laboratories, the manufacturer and or the overseas factory testing facility are allowed to conduct the certification of material change themselves.

Yours faithfully

DongGuan Jantway Toys Company Limited

A handwritten signature in black ink, appearing to be 'YK Wong', written over the company name.

YK Wong

General Manager

CC : The Board of Directors

PUBLIC SUBMISSION

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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0033
Comment from Silk Association of Great Britain

Submitter Information

Name: Adam Mansell
Address: United Kingdom,
Submitter's Representative: Adam Mansell
Organization: Silk Association of Great Britain

General Comment

See Attached

Attachments

CPSC-2010-0038-0033.1: Comment from Silk Association of Great Britain

Silk Association of Great Britain

5 Portland Place, London W1B 1PW
tel: 020 7636 7788 fax: 020 7636 7515
e-mail: sagb@dial.pipex.com website: www.silk.org.uk

28th July 2010

Mr Todd A Stevenson
Secretary of the Consumer
Product Safety Commission
4330 East West Highway
Bethesda
Maryland 20814-4408
USA

Dear Mr Stevenson

I am writing on behalf of the Silk Association of Great Britain, a UK trade association representing the interests of UK silk manufacturers and suppliers, regarding the CPSC's proposed new rule 16 CFR 1107 "Testing and Labelling Pertaining to Product Certification"

Although not directly affected by the Regulation we are very concerned that Regulation 16 CFR 1610 exempts fabrics made from certain fibres but that it does not exclude silk fabrics.

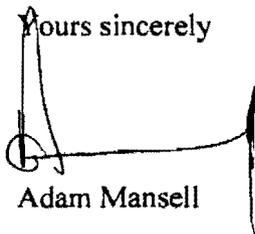
There does not seem to be a scientific reason for the distinction between fibres types. Silk is a protein based fibre and its reaction to fire is comparable to wool and is better than that of nylon, olefin or polyester.

We request, therefore, that silk be added to the exemption list. The use of silk poses no risk but the costs of testing is penalising American importers of silk products and textiles.

If you require further background information the European Silk Manufacturers Association has produced a detailed report documenting the burning behaviour of silk fabrics.

I look forward to hearing your response.

Yours sincerely



Adam Mansell

PUBLIC SUBMISSION

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Docket: CPSC-2010-0038
Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0034
Comment from Marcia Kinter

Submitter Information

Name: Marcia Kinter
Address:
SGIA
10015 Main Street
Fairfax, VA, 22031
Email: marcik@sgia.org
Phone: 703-359-1313
Organization: Specialty Graphic Imaging Association

General Comment

See attached file(s)

Attachments

CPSC-2010-0038-0034.1: Comment from Marcia Kinter



August 3, 2010

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East West Highway
Bethesda, MD 20814

RE: Docket No. CPSC-2010-0038

To whom it may concern:

The Specialty Graphic Imaging Association (SGIA) respectfully submits the following comments on the Consumer Product Safety Commission's (CPSC) notice of proposed rulemaking on Testing and Labeling Pertaining to Product Certification published in the May 20, 2010, *Federal Register*. SGIA represents companies engaged in the production of children's products, including wearing apparel, via the screen and digital print technologies, including the associated supplier base.

SGIA understands the need for a testing program to ensure that all children's products meet both the lead and phthalate content limits as set by the Consumer Product Safety Improvement Act (CPSIA). However, we do believe that the proposed rule does contain provisions that will be difficult for the small business community to comply with, both in terms of cost as well as understanding the provisions as currently stated. We offer the following comments on the proposed language.

Subpart C
General Requirements

SGIA concurs with the proposed language that allows the use of component testing to support product certification. This is extremely critical for those products for which a part has been exempted from testing and certification, i.e., textiles. To further clarify that the testing of children's products does not include those products previously exempted, we recommend that Section 1107.20 (c) be reworded as follows:

“(c) Except where otherwise specified by a children's product safety rule, a manufacturer may substitute component part testing for complete product testing pursuant to 16 CFR 1109 if the component part, without the remainder of the finished product, is sufficient to determine compliance for the entire product. *Component part testing can be used to substantiate compliance for those children's products where part of the product has been exempted from testing pursuant to Section 1500.91.*” (Italics indicate proposed language.)

Based on current practices in the marketplace, SGIA finds that the final customer relies on the literal translation of the CPSC's implementing regulations. If the regulatory language does not specifically state that component testing can be used to substantiate compliance in the instance where an exempt material is used, i.e., a printed garment, then the final customer will require that the final product, including the garment, be tested. Inclusion of the proposed language will further codify the position of

the CPSC regarding materials that are exempt from testing. Without this language, SGIA believes testing costs associated with the implementation of this proposal will increase tremendously.

Section 1107.21, Periodic Testing

While the proposal accepts the use of component testing for certification purposes, it remains strangely silent regarding its use for periodic testing. The CPSC requests information regarding possible avenues that can be used to maintain and substantiate compliance while reducing the costs associated with compliance testing. Use of component testing, especially for those products where the test does not need to be conducted on the entire product, i.e., those products containing an element that has been specifically exempted pursuant to Section 1500.91. The use of component testing as an element of a periodic testing program by manufacturers of children's products will create a much more manageable system. We recommend that Section 1107.21 (c)(1) be amended to include language allowing for the use of a component testing program to meet the periodic testing requirements. Specific regulatory language needs to be inserted into the text. SGIA can foresee customers requiring the development of a periodic testing program as a contractual requirement. The use of component testing to satisfy this requirement may not be allowed if specific language is not included in the final rule. It is our goal to provide as much flexibility as possible to the manufacturer of the children's product to meet its compliance obligations.

SGIA supports the concept of a low volume production exemption; however several questions have arose as to the application of this concept. First, if you have a facility that produces both children's and non-children's products, does the 10,000 production volume only apply to the children's products produced? We believe that it only applies to the production of children's products. To clearly state that this applies only to children's products, SGIA recommends that the word "children's" be inserted in Section 1107.21(d) as follows:

"For a *children's* product produced or imported...." (Italics added for emphasis.)

SGIA believes that the addition of this word clarifies the applicability of this section and will not penalize manufacturers who produce both children's as well as non-children's products in the same facility.

Second, does the low volume figure of 10,000 pieces apply to each unique print job or to the production of all possible children's products as at facility? The language clearly refers to "a product," and under the CPSIA, each product must be accompanied by a certificate. SGIA interprets that the low volume production number would be applied to each children's product produced at the facility that would be accompanied by a certificate. SGIA requests that the CPSC clarify the application of the low volume production exemption from periodic testing.

Section 1107.22, Random Sampling

The language proposed by the CPSC for the random sampling of products does not recognize either the use of component testing or those items that are exempt from testing pursuant to Section 1500.91. Random sampling for those products that include an exempt item, such as a textile, needs to include the ability to use component testing. The same arguments that support the use of component testing for final product certification exist for the use of component testing for random sampling. It is also unclear from this section if this section applies to products produced at low volumes. As this section is intimately tied to periodic testing, SGIA recommends that low volume productions be excluded from this section as well until the production limit of 10,000 pieces is attained.

Section 1107.24, Undue Influence

SGIA understands the need for this section, but finds the requirements for training extremely vague. Further, the CPSC does not include a definition for undue influence in Section 1107.2, Definitions. This is a compliance obligation that will impose a considerable burden on the small business community. When requiring training, it is imperative that the regulatory body clearly and succinctly describe what type of training is required. The current language states "... that appropriate staff receive training on avoiding undue influence ...". In this context, what is the meaning of undue influence and what would be the required training elements?

SGIA attempted to research based on the terms "training for undue influence" and "undue influence." Several definitions were located:

"The threat that a member will subordinate his or her judgment to that of an individual associated with a client, employer or other relevant third party because of the individual's (1) reputation or expertise, (2) aggressive or dominant personality, or (3) attempts to coerce or exercise excessive ..."

"Undue influence is power over someone else which is used to push the weaker person into making a decision which would not otherwise have been made."

Further, it is unclear as to what would encompass appropriate training. Would appropriate training be ethics training? Code of conduct training? Conflict of interest training? Before a training requirement can be imposed on the business community, the CPSC needs to clearly outline what needs to be included in a training program. An excellent example is provided by the Occupational Safety and Health Administration, in its Hazard Communication Standard (29 CFR 1900.1200). In this standard, the following regulatory text for its training program regarding hazardous chemicals in the workplace is provided:

1910.1200(h)(1)

Employers shall provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new physical or health hazard the employees have not previously been trained about is introduced into their work area. Information and training may be designed to cover categories of hazards (e.g., flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and material safety data sheets.

1910.1200(h)(2)

"Information." Employees shall be informed of:

1910.1200(h)(2)(i)

The requirements of this section;

1910.1200(h)(2)(ii)

Any operations in their work area where hazardous chemicals are present; and,

1910.1200(h)(2)(iii)

The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and material safety data sheets required by this section.

1910.1200(h)(3)

"Training." Employee training shall include at least:

1910.1200(h)(3)(i)

Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

1910.1200(h)(3)(ii)

The physical and health hazards of the chemicals in the work area;

..1910.1200(h)(3)(iii)

1910.1200(h)(3)(iii)

The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and,

1910.1200(h)(3)(iv)

The details of the hazard communication program developed by the employer, including an explanation of the labeling system and the material safety data sheet, and how employees can obtain and use the appropriate hazard information.

This example provides clear cut guidance to the regulated community regarding the elements of the required training program. Given the unclear regulatory language in the proposed text, the cost to develop an appropriate training program is difficult to gauge as it will require extensive discussions with CPSC staff to determine acceptable training guidelines. We do not believe that the current text provides enough direction to the regulated community as it is unclear as to which entity is conducting "undue influence", the manufacturer or the third party conformity assessment body. Until such a time as the CPSC provides further guidance and explanation, we recommend that this section be deleted in its entirety.

Third Party Testing of Children's Products

The CPSC requests comment on the requirement to develop and maintain records demonstrating compliance with the third party testing requirements. As long as the manufacturer can utilize existing documentation, i.e., the general conformity certificate with accompanying information, then there should not be an undue burden on the regulated community. However, if the CPSC intends to require that the manufacturer maintain documentation in a different format, then there will be a cost associated with maintaining this information.

Summary of Impact on Small Businesses

All proposed elements in this rulemaking will impact small businesses. SGIA has recommended language that, we believe, will clarify the intent of the proposal thereby reducing the impact. We do agree that the CPSC has created a proposal that incorporates, where possible, elements of a performance based approach to both testing and certification. However, SGIA remains convinced that the key element of component testing needs to be further integrated into the requirements for random sampling as well as periodic testing. Incorporation of component testing will provide a burden reduction to a small manufacturer.

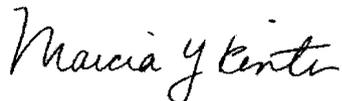
The provision exempting low volume production, i.e., 10,000 units, needs to be extended to the section regarding random sampling. Based on SGIA's reading of the proposal, the proposed language for random sampling is intimately tied to the requirements for development and implementation of a

periodic testing program. Therefore, if a periodic testing program is not required, we fail to see the applicability of a random sampling program.

Conclusion

SGIA welcomes the opportunity to provide comments on this important proposed regulation. This is a critical regulatory action as it will set the protocols for the certification of children's products. If you have any questions regarding our comments, please contact me at marcik@sgia.org or 703-359-1313.

Respectfully submitted,

A handwritten signature in cursive script that reads "Marcia Y. Kinter".

Marcia Y. Kinter
Vice President – Government & Business Information

PUBLIC SUBMISSION

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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0035
Comment from Stacey-Ann Taylor

Submitter Information

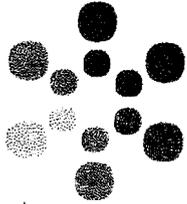
Name: Stacey-Ann Taylor
Address:
1500 Rhode Island Ave. NW
Washington, DC, 20005
Email: staylor@paint.org
Phone: 202-462-6272
Organization: American Coatings Association

General Comment

See attached file(s)

Attachments

CPSC-2010-0038-0035.1: Comment from Stacey-Ann Taylor



AmericanCoatings
ASSOCIATION

August 3, 2010

Office of the Secretary
Consumer Product Safety Commission (CPSC), Room 502
4300 East West Highway
Bethesda, MD 20814

**RE: Consumer Product Safety Commission – Testing and Labeling Pertaining to
Product Certification
Docket No. CPSC – 2010 – 0038**

Dear Sir/Madam:

The American Coatings Association represents a \$20 billion dollar industry in the United States, operating in all 50 states, and employing over 60,000 people engaged in the manufacture and distribution of paints and coatings. Annually over 706 million gallons of industry products are sold for application on architectural surfaces, in homes, offices and public buildings, by professional applicators and by homeowners and property owners who subscribe to the “do-it-yourself” approach. Not widely known but a fact of commercial production and manufacturing of consumer goods, the coatings industry’s products are applied to over 70 percent of the U.S. Gross National Product. From automobiles and appliances, to toys and electronic components, the continued availability of paints and coatings to protect and enhance these consumer products is critical to a large segment of the U.S. economy.

As described in the May 20, 2010 Federal Register notice, the Consumer Product Safety Commission (CPSC) issued a notice of proposed rulemaking that would establish requirements for a reasonable testing program and for compliance and continuing testing for children’s products. This proposed rule essentially attempts to codify guidance that CPSC previously issued describing the elements of a reasonable testing program. The rule would also allow manufacturers to have the option of applying a label to their products that reads “Meets CPSC Safety Requirements”.

Establishing the Requirements for a Reasonable Testing Program for Non-Children’s Products

ACA generally supports the Five Elements of a Reasonable Testing Program, as described in the proposed rule. CPSC has wisely provided general parameters for compliance with the reasonable testing program provision of the CPSIA, without requiring manufacturers to conduct a specific number of tests over a specific period time. As CPSC staff has noted on numerous occasions, each manufacturing process is unique. It will be up to individual manufacturer to determine how best to comply with the reasonable testing program requirement to ensure that every product is in compliance with applicable CPSC rules, bans, standards and regulations.

Optional Labeling to Show Product Compliance with CPSC Rules, Bans, Standards, etc.

Our main concern lies with the optional labeling rule. Allowing manufacturers to place an optional label on their products that states "Meets CPSC Safety Requirements" could give those manufacturers an unfair market advantage over those manufacturers who choose not to include the label. The fact is printing new labels or stickers will add an additional manufacturing cost and some manufacturers may decide against the label based on cost alone. However, this decision may lead some consumers to choose the product with the "Meets CPSC Safety Requirements Label" based on a false assumption that the product without this label is somehow less safe. Quite frankly, we expect some manufacturers to use this new label as a misleading marketing tool. We believe that some manufacturers will even alter the font type/size of the optional label statement for marketing purposes.

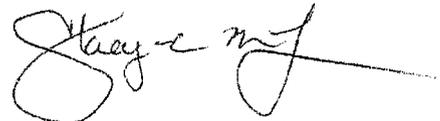
A number of our members were also concerned with the actual font size described in the proposed rule of "no less than 12 points" could be problematic on some small containers. In general, our industry is finding it increasingly difficult to modify our labels due to space restrictions. We strongly encourage CPSC to incorporate the font size requirements that are found in the Federal Hazardous Substances Act (FHSA) regulations into this rule.

ACA urges careful attention to these issues and the potential burdens they may present for all involved parties. ACA strongly urges the consideration of these comments and appreciates the attention of the Commission to these issues. Should you or your staff require further assistance please contact us at (202) 462-6272.

Sincerely yours,



Stephen R. Sides
Vice President
Science, Technology and Environmental Policy



Stacey-Ann M. Taylor
Counsel
Government Affairs

Comments submitted online via regulations.gov

PUBLIC SUBMISSION

As of: August 04, 2010
Received: August 03, 2010
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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0036
Comment from Alan Kaufman

Submitter Information

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Organization: Toys"R"Us, Inc.

General Comment

See attached file(s)

Attachments

CPSC-2010-0038-0036.1: Comment from Alan Kaufman



August 3, 2010

**Office of the Secretary
U.S. Consumer Product Safety Commission
Room 502
4330 East West Highway
Bethesda, Maryland 20814**

RE: CPSC Docket No. CPSC-2010-0038

Dear Sir or Madam:

Consistent with Toys“R”Us, Inc's commitment to children's product safety, we are writing to you to provide our comments regarding certain aspects of testing, certifying, and labeling of children's consumer products pursuant to the proposed Title 16, Code of Federal Regulations, Part 1107. We very much appreciate the opportunity to provide you with input on this important topic.

We believe strongly that the language of the Consumer Product Safety Act (CPSA) modifications embodied in the Consumer Product Safety Improvement Act of 2008 (CPSIA) leaves considerable latitude for differing interpretations of what constitutes a "reasonable test program", as well as what is required of manufacturers and importers with regard to assuring and certifying compliance with the requirements applicable to a given item. We also believe emphatically that, while the safety of children who use these products cannot be compromised, the Commission has clearly attempted to assure their safety while promoting sensible testing methodologies and protocols which do not create needless cost within the product supply chain, thus ultimately benefiting consumers.

Our specific comments follow:

A) "High Degree of Assurance" - §1107.2

We have no significant disagreement with the Commission regarding the definition of the term "High Degree of Assurance", except for the implication that a "demonstration" may somehow be necessary. We also believe that the language of the NPR, which uses 95% confidence limits as an example, has created significant confusion among industry and that clarity of Commission intent would therefore be achieved by the addition of some additional illustrative examples of what constitutes a "high degree of assurance". We therefore respectfully request that the Commission adopt the following definition:



"High degree of assurance means an evidence-based determination of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture. Acceptable determinations may be based on evidence derived through any appropriate tool or control methodology (or combination of tools and/or control methodologies), such as but not limited to:

- Design Validation
- Process Validation
- Manufacturing Process Control Audits
- Raw material validation and controls
- In-process manufacturing controls, measurements, and tests
- Component and material testing as defined at 16 CFR Part 1109
- Finished Product Testing"

B) Recordkeeping Requirements - §1107.10 and §1107.26

We find the proposed recordkeeping requirements at proposed §1107.10 and §1107.26 to be potentially unclear and/or unduly burdensome in two respects: that the records must be "available" in the English language, and must be maintained at a location within the United States. The Commission clearly has a strong interest that such records be provided to it within a reasonable time period upon request, and that any records submitted to CPSC be in English. Yet, since much manufacturing of consumer products occurs outside the United States, we believe that allowing maintenance of records in a local language at an offshore location (so that they will be of greatest utility to local compliance staff) should be allowed, subject to a reasonable requirement for production of those records in English to CPSC staff upon request. Further, neither the regulation cited in proposed §1109.5(i) (16 C.F.R. §1110.11(d)) nor CPSA §14(g) requires that the test records upon which certificates are based be maintained in the United States.

C) "Random Samples" versus "Random" Samples - §1107.22

While we have previously made comments on this topic, this is an area where we continue to differ with the Commission staff. Congress used the term "random samples" in section 14(d)(2)(B)(ii) of the CPSA as amended by the CPSIA. The Staff asserts that this phrase is to be interpreted as a two-word term and that the strict statistical meaning of it be applied (i.e. that each possible sample in the population as a whole has a mathematically equivalent probability of being drawn). However, we continue to be persuaded by the plain language of the statute and other factors (among them that Congressional representatives are typically not conversant with statistical nomenclature) that Congress' intent is that this phrase be interpreted as two individual words, i.e. as a sample which is random as "random" is commonly understood ("governed by or depending on chance"; in other words, a random sample is one selected so that it is representative of its population and in a manner free from overt bias). Frankly, it is far less important that a sample be truly random than that it be *reasonably* representative of the population from which it is selected.



A statistically random sample, as outlined in the proposed §1107.22, would require that all production in a lot be complete prior to sample selection. Yet, it is much more typical for importers, who are purchasing a discrete lot of product, to require a minimum proportion (e.g. 10-20% or 100 pieces, whichever is larger) of the lot be complete before sampling. This allows testing to proceed while production is completed, preventing the need to stockpile large quantities of product awaiting test results. It also helps identify potential problems relatively early in a production run, helping to reduce the number of noncompliant products that are produced and the risk that they will be distributed inadvertently or by an unscrupulous party. Indeed, the current proposal may paradoxically act to increase the number of noncompliant goods which enter commerce. If sampling and testing cannot commence until a lot is complete or nearly so, economic operators may be tempted to ship prior to results being received; or if a failing result occurs the more unscrupulous may be tempted to "salt" this much larger noncomplying quantity into subsequent shipments rather than scrapping or reworking a smaller quantity to a compliant state.

While allowing early sampling of a lot creates an explicit sampling bias toward units which are produced early in the run, if the production process is reasonably well-controlled (i.e. provides a "high degree of assurance") there will be no assignable causes which would result in these units differing materially from those produced later; a requirement for sample selection from the production line using a standard selection protocol is sufficient to assure that the sample is indeed coming from the lot at issue (i.e. is not a so-called "golden sample") and has been selected without conscious selection bias other than that toward items produced early in the run. Thus, such a sampling scheme provides reasonably representative samples as Congress intended. We therefore respectfully propose that the first sentence of §1107.22 be changed to: "Each manufacturer must select samples for periodic testing by using a process that assures that such samples are reasonably representative of the production population".

We once again thank you for the opportunity to comment, and recognize that the Commission has a very difficult task as it works to assure the safety of children's products while attempting to also accommodate the needs of multiple stakeholders and supply chains. We thank you also for your continued partnership in the effort to improve children's product safety.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan P. Kaufman", with a long horizontal flourish extending to the right.

Alan P. Kaufman
Vice-President-Global Product Safety, Quality Assurance, and Compliance
Toys"R"Us, Inc.

PUBLIC SUBMISSION

As of: August 04, 2010
Received: August 03, 2010
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Docket: CPSC-2010-0038
Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0037
Comment from Pat Jennings

Submitter Information

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Fax: 706-428-3123
Organization: The Carpet and Rug Institute

General Comment

Flammability Testing of Youth Carpets:

Currently carpets and rugs, which includes youth carpets and rugs cannot be introduced into commerce in the U.S. unless the products comply with requirements and have undergone flammability testing in accordance with CPSC 16 CFR part 1630, Standard for the Surface Flammability of Carpet and Rugs (FF 1-70) and CPSC 16 CFR part 1631, Standard for the Surface Flammability of Small Carpets and Rugs (FF2-70).

The CPSC 16 CFR parts 1630 and 1631 contains detailed instructions regarding procedures for testing, frequency of testing, pass fail criteria, test reporting and test data retention procedures. Since all carpets and rugs must comply with the above testing procedures and requirements, there is no need of an additional flammability testing standard procedure to be established by CPSC specifically for youth carpet and rugs.

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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0038
Comment from Steve Pfister

Submitter Information

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Phone: 202-626-8193
Submitter's Representative: Jonathan Gold
Organization: National Retail Federation

General Comment

Attached please find the comments of the National Retail Federation on Testing and Labeling Pertaining to Product Certification (Docket No. CPSC-2010-0038)

Attachments

CPSC-2010-0038-0038.1: Comment from Steve Pfister



August 3, 2010

Todd A. Stevenson
Secretary
Consumer Product Safety Commission
4330 East-West Highway
Room 502
Bethesda, MD 20814

**RE: Comments on Testing and Labeling Pertaining to Product Certification
(Docket No. CPSC-2010-0038)**

Dear Mr. Stevenson:

The following comments are submitted on behalf of the National Retail Federation (NRF) in response to the Consumer Product Safety Commission's (CPSC) *Federal Register* notice titled: Testing and Labeling Pertaining to Product Certification (Docket No. CPSC-2010-0038). NRF appreciates the opportunity to provide feedback on the issue of testing and labeling pertaining to product certification.

We have provided comments previously to the CPSC on several of these topics, most recently on January 7, 2010 as part of Docket No. CPSC-2009-0095. We remain concerned about the draft regulation as published as it does not seem to change from what CPSC had originally published for comments last year. As we have stated previously, we fully believe that the CPSC needs to allow flexibility when developing a final regulation dealing with these issues due to the diversity and complexity of the products covered by the CPSIA and the diversity of the manufacturing systems already in place among retailers and suppliers. The CPSC needs to consider the current systems in place and build upon what industry is already doing and not look to overly burden industry with new excessively complex and expensive requirements.

As the world's largest retail trade association and the voice of retail worldwide, the National Retail Federation's global membership includes retailers of all sizes, formats and channels of distribution as well as chain restaurants and industry partners from the U.S. and more than 45 countries abroad. In the U.S., NRF represents the breadth and diversity of an industry with more than 1.6 million American companies that employ nearly 25 million workers and generated 2009 sales of \$2.3 trillion.

With regards to the draft rule as published, NRF has the following comments:

§ 1107.10(b)(2)(i) Certification Tests – While NRF agrees with the key elements of CPSC's defined "reasonable testing program," we remained concerned about some

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of the specifics. Specifically, we remain concerned about the requirement to perform certification testing on samples. We do not believe that a requirement to test pre-production samples should be included as part of a “reasonable testing program.” While it may be practical for large production runs, it is impractical when there is a seasonal item and the retailer/importer has only ordered a small limited run. In addition, if the samples test to meet all acceptable requirements, it will not matter, because the CPSC will not accept the test results on samples as test results for the final product. On the other hand, if the pre-production samples fail and the retailer/importer has the product re-worked by the manufacturer to correct any defects, and the production units test to meet all applicable standards, then why should it matter if the samples failed as long as the final product meets the requirements? We believe that sample testing should be optional but not required.

§ 1107.10(b)(5) *Recordkeeping* – While we believe recordkeeping needs to be part of a reasonable testing program, we are concerned about the amount of recordkeeping that is required as part of the *Federal Register* notice. The requirements would lead to a massive undertaking for any manufacturer or importer, especially if all of the records must be maintained within the United States. If the retailer can access the records electronically, does that count towards the records being maintained in the U.S.? We question how the CPSC defines the lifespan of a product. We ask for clarification on the term “for as long as the product is in production or imported.”

§ 1107.20 *General Requirements* – We appreciate the recognition by the CPSC that it should be left up to the manufacturer to determine the number of units that would be needed to “provide a high degree of assurance that the products comply with the applicable consumer product safety rule.” However, we remain concerned about the statistical sampling example that CPSC provides in the discussion of the proposed rule. We still do not believe this is appropriate as was pointed out by participants in the CPSC’s Product Testing Workshop and other comments provided previously on this proposed rule.

§ 1107.24 *Undue Influence* – While we understand and agree that parties must prevent attempts by parties to exercise “undue influence” over a third party conformity assessment body, we question as to what the CPSC considers to be sufficient. What must be considered as part of the annual training? Will a written manual suffice?

§ 1107.40 *Labeling consumer products to indicate that the certification requirements of section 14 of the CPSA have been met* – In our previous comments, NRF agreed with the CPSC that “the party certifying the consumer product is responsible for ensuring that the product complies with all applicable consumer product safety rules or similar rules, bans, standards, or regulations under any other act enforced by the Commission and that only the party certifying the product’s compliance, or its authorized representative, may affix the label to the consumer product.” We also agree that “the label should be affixed before the consumer product is placed on the market and should be affixed to the product packaging or, if there is no packaging, to

the product or on a tag or other material included with the product.” This should be done at the point of manufacture when the finished product is packaged.

While we appreciate the CPSC providing the text of the language that should appear on the label, we are concerned about the CPSC specifically stating the font that must be used. As we stated in our earlier submission, we do not think the CPSC should specify specifics such as size, color, font or location as these will depend on the product. There’s a potential that the specified text type and size will not be compatible with the different internal systems developed by retailers and manufacturers to meet the needs of the affected product. To specify any requirements other than what works with a firm’s own internal systems would have absolutely no benefit at all.

Conclusion

NRF welcomes the opportunity to share our thoughts on the CPSC’s *Federal Register* notice, Testing and Labeling Pertaining to Product Certification. If you have any questions, please contact Jonathan Gold (goldj@nrf.com), NRF’s Vice President, Supply Chain and Customs Policy.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve Pfister". The signature is fluid and cursive, with the first name "Steve" written in a larger, more prominent script than the last name "Pfister".

Steve Pfister
Senior Vice President
Government Relations

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Docket: CPSC-2010-0038
Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0038
Comment from Steve Pfister

Submitter Information

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Email: goldj@nrf.com
Phone: 202-626-8193
Submitter's Representative: Jonathan Gold
Organization: National Retail Federation

General Comment

Attached please find the comments of the National Retail Federation on Testing and Labeling Pertaining to Product Certification (Docket No. CPSC-2010-0038)

Attachments

CPSC-2010-0038-0038.1: Comment from Steve Pfister



August 3, 2010

Todd A. Stevenson
Secretary
Consumer Product Safety Commission
4330 East-West Highway
Room 502
Bethesda, MD 20814

**RE: Comments on Testing and Labeling Pertaining to Product Certification
(Docket No. CPSC-2010-0038)**

Dear Mr. Stevenson:

The following comments are submitted on behalf of the National Retail Federation (NRF) in response to the Consumer Product Safety Commission's (CPSC) *Federal Register* notice titled: Testing and Labeling Pertaining to Product Certification (Docket No. CPSC-2010-0038). NRF appreciates the opportunity to provide feedback on the issue of testing and labeling pertaining to product certification.

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the product or on a tag or other material included with the product.” This should be done at the point of manufacture when the finished product is packaged.

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Conclusion

NRF welcomes the opportunity to share our thoughts on the CPSC's *Federal Register* notice, Testing and Labeling Pertaining to Product Certification. If you have any questions, please contact Jonathan Gold (goldj@nrf.com), NRF's Vice President, Supply Chain and Customs Policy.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve Pfister". The signature is written in a cursive, flowing style with a large initial "S".

Steve Pfister
Senior Vice President
Government Relations

PUBLIC SUBMISSION

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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0039
Comment from Allan Adler

Submitter Information

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Fax: 202-347-3690
Submitter's Representative: Allan Adler
Organization: Association of American Publishers, Book Manufacturing Institute, Printing Industries of America

General Comment

See attached file(s)

Attachments

CPSC-2010-0038-0039.1: Comment from Allan Adler

Association of American
Publishers, Inc.



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August 3, 2010

Todd A. Stevenson
Office of the Secretary
Consumer Product Safety Commission
4330 East-West Highway
Bethesda, Maryland 20814

Submitted Electronically

RE: Comments on NPRM Docket Nos. CPSC-2010-0037 & CPSC-2010-0038

These Comments are submitted on behalf of the Association of American Publishers (“AAP”), the Book Manufacturers’ Institute, Inc. (“BMI”), and the Printing Industries of America (“PIA”) in joint response to both the Notice of Proposed Rulemaking (“NPRM”) on “*Conditions and Requirements for Testing Component Parts of Consumer Products*,” Docket No. CPSC-2010-0037, and the NPRM on “*Testing and Labeling Pertaining to Product Certification*,” Docket No. CPSC-2010-0038, that were published by the Consumer Product Safety Commission (“CPSC”) in the Federal Register, 75 FR 28208 and 75 FR 28336 (daily edition, February 26, 2009), respectively.

AAP is the principal national trade association of the U.S. book publishing industry, and represents some 300 member companies and organizations that include most of the major commercial book and journal publishers in the United States, as well as many small and non-profit publishers, university presses and scholarly societies. AAP members publish literary works in hardcover and paperback formats in every field of human interest, including trade books of fiction and non-fiction; textbooks and other instructional materials for the elementary, secondary, and postsecondary educational markets; reference works; and scientific, technical, medical, professional and scholarly books and journals. In addition to publishing in print formats, AAP members are active in the ebook and audiobook markets, and also produce computer programs, databases, Web sites and a variety of multimedia works for use in online and other digital formats.

BMI is a leading nationally recognized trade organization whose members are book manufacturers and companies that provide materials, equipment, and services to that industry. Our member companies produce the great majority of the books ordered by the U.S. publishing industry.

PIA is the world's largest graphic arts trade association, representing an industry with approximately one million employees. It serves the interests of more than 10,000 member companies involved in every stage of the printing industry from materials to equipment to production to fulfillment. General commercial printing--magazines, books, brochures, advertisements, and more--comprises the largest segment of the printing and graphic communications industry. Packaging printing, ancillary services, and digital printing also round out the industry's diverse product line.

Introduction

The submitters of these Comments recognize and greatly appreciate the efforts of the CPSC and its staff to implement the "children's product" testing and certification requirements of the Consumer Product Safety Improvement Act ("CPSIA") through rules that provide the manufacturers and private labelers of such products with the ability to reasonably avoid unnecessary costs and burdens while complying with CPSIA's purpose of ensuring the safety of such products before they are imported for consumption or warehousing, or distributed in commerce.

After participating in last December's Public Workshop on Product Testing and reviewing the NPRMs, the submitters have a better understanding of the complicated challenge the CPSC is confronting in attempting to develop requirements for the testing and certification of *all* products subject to *any* applicable safety rules, bans, standards, or regulations under the Consumer Product Safety Act ("CPSA") or any other statute it enforces. The submitters agree with CPSC "that it is difficult to develop rigid protocols for testing across all categories of products, manufacturers, and importers," 75 Federal Register at p.28339, and they applaud CPSC for acknowledging that "no one-size-fits-all testing program will be sufficient for all manufacturers." *Id.* at p.28342.

For these reasons, the submitters have reviewed the NPRMs with great sensitivity toward the expressed efforts of CPSC and its staff to find reasonably flexible, common-sense ways to implement the *intent* of Congress in imposing these requirements, especially where that intent would not be accurately reflected by a literal implementation of the statutory language Congress used to enact them. Indeed, as even leading Democrat and Republican sponsors of the legislation in both the House and Senate have publicly acknowledged, a literal implementation of CPSIA's statutory language would impose unanticipated and unworkable consequences in the form of unnecessary and excessive regulatory obligations on the manufacturers and importers of many children's products. See, e.g., *Letter of January 21, 2009 to Hon. Henry Waxman from Reps. Joe Barton and George Radanovich* ("[I]t is becoming clear that, without the rapid application of some common sense, the new law also holds potential to impose vast economic hardship without actually protecting anyone."). Short of amending CPSIA, legislators have called upon CPSC and its staff to avoid such consequences by finding practical, common-sense approaches for implementing the testing and certification requirements. See, e.g., *Letter of January 26, 2009 to Acting Chairman Nancy Nord from Senator Amy Klobuchar* ("I urge the Commission, once again, to implement pragmatic, common sense regulations that both ensure children's safety and spare countless businesses unnecessary disruption.")

In these Comments, the submitters have focused primarily on those parts of the proposed rules that would implement the CPSIA provisions which may embody the greatest risk of such unanticipated and unworkable consequences: the requirements for testing and certifying the total lead content in a children's product under Section 14(a) and (d) of CPSA, as amended by Section 102(b) of CPSIA. Specifically, the submitters ask CPSC and its staff to carefully consider how practical interpretation of certain provisions in the proposed rules, plus a few relatively modest changes in them, could result in a reasonably flexible, common-sense application of these requirements to an **"ordinary children's book"** (previously defined by the submitters and CPSC and its staff as "one that is made of paper and/or cardboard that is printed with inks or toners and bound and finished using a conventional method"), and to other **"children's paper-based, printed products"** that are comprised of the same raw materials and made by the same manufacturing process. Examples of other children's paper-based, printed products include flashcards, posters, bookmarks and worksheets.

The submitters ask CPSC and its staff to note that, in seeking a practical, common-sense regulatory approach for total lead content testing and certification of the children's products described above, the submitters are in no way abandoning their assertion, or waiving their right to seek a determination, that such products should be excluded from such testing on the grounds that the component materials that comprise them do not, by their nature and as treated in the manufacturing process, exceed the total lead content limits specified in Section 101(a) of CPSIA. See *"Children's Products Containing Lead; Determinations Regarding Lead Content Limits on Certain Materials or Products; Final Rule, 74 Federal Register 43031 (daily edition, August 26, 2009)*. While certain key component materials of such products have already been the subject of such affirmative exclusion determinations by CPSC, *id.*, the submitters are continuing to work with the suppliers of other component materials that did not qualify for exclusion determinations to compile additional technical data to present to CPSC in support of a request for reconsideration of the status of each of those component materials.

Discussion

As a threshold matter, the submitters understand that, under the critical requirement of Section 14(a)(2)(A) of CPSA, as amended by Section 102(a) of CPSIA, an ordinary children's book or other children's paper-based printed product, as a "children's product" subject to CPSIA's total lead content limitations, must be certified as complying with those limitations through the testing and certification of sufficient samples of the product by an accredited "third-party conformity assessment body."

However, the submitters agree with and support the central premise of the NPRM in Docket No. CPSC-2010-0037, *i.e.*, that reliance on the testing and certification of the *component materials* comprising a children's product – including when these activities are performed by the manufacturer or supplier of the component materials, rather than by the manufacturer or private labeler of the finished product – can be a reasonably cost-effective way for the manufacturers and private labelers of the finished product to certify the product's compliance with consumer product safety rules, including CPSIA's requirements relating to total lead content.

The submitters understand and support that, in some cases, the required certification for a children's product can be based on component materials testing, rather than testing of the finished product, if the component materials are tested by a third-party testing conformity assessment body. Since the proposed rules under Docket No.CPSC-2010-0038 would permit the private labeler importer of a children's product to base their product certification on a certificate provided by a foreign manufacturer if the latter certificate were based on testing conducted by a third-party conformity assessment body, it follows that such an importer may also rely on component materials testing conducted by the foreign manufacturer of the product or by the foreign suppliers of the component materials as the basis for their final product certification, provided that such component material certification is based on testing conducted by a third-party conformity assessment body. *Id.* at p.28337. It should similarly follow that a non-exempt component of a component material, which is combined with other elements in new ratios to create variations of the component material (e.g., such as the pigmented inks that serve as a mixing base which, in similar base formula combinations, can create a variety of spot ink colors), can itself be the subject of component material testing that would permit certification of both the tested component and the larger component material of which it is an element.

The submitters also understand, appreciate and support that the proposed rules for product testing and certification would permit the manufacturer to voluntarily establish a "reasonable testing program" ("RTP") if they think their children's product could safely be subject to the requirement for third-party conformity assessment body testing only once every two years, rather than annually. *Id.* at p.283348-28349.

While the submitters appreciate and support these proposals to help reduce the substantial costs entailed in annual third-party conformity assessment body testing, they believe the flexibility that CPSC and its staff have tried to build into the proposed rules to help minimize testing and certification costs and burdens can be reasonably enhanced by the acceptance of practical interpretations and applications of certain aspects of the proposed rules and, perhaps, a few targeted practical revisions in them.

"Ordinary Children's Books" as "Products" for Testing and Certification Purposes

The statutory definition of "children's product" in Section 3(a)(16) of the CPSA may provide a useful (albeit overbroad) set of criteria for determining what consumer products are subject to CPSIA's total lead content limitations, but it is unhelpful in determining how CPSIA's total lead content testing and certification requirements should be implemented in practice by the manufacturers and private labelers of the thousands of diverse "children's products" that are subject to those requirements.

In the submitters' discussions with CPSC and its staff regarding the definition of "ordinary children's book" or "other children's paper-based printed product" for CPSIA purposes, all parties have acknowledged that what constitutes a "book" or such other "printed product," as well as what distinguishes one "book" or such other "printed product" from another for CPSIA purposes, must focus on the nature of a "book" or such other "printed product" strictly in manufacturing terms, rather than in terms of its authorial content or any other intellectual characteristic. In other words, the usual means of distinguishing one unique "book" or "other

children's paper-based printed product" from another by reference to their respective authors, publishers, subject matter, and manner of content presentation have no meaning or utility for CPSIA's testing and certification purposes, where distinguishing one children's "product" from another depends entirely on the nature of the component materials that comprise the finished "product" and the nature of the manufacturing process that produces the finished product from those component materials.

While the proposed rules speak of "samples" and "units" of children's products in setting forth protocols for the total lead content testing and certification of such products, there is no guidance in either CPSIA or the proposed rules regarding how or even whether a manufacturer or private labeler can or should distinguish one "ordinary children's book" title or "other children's paper-based printed product" from another for purposes of "product" compliance. At the heart of the issue is that each "ordinary children's book" title or "other children's paper-based printed product" is manufactured in the same manner from a core set of component materials that are simply combined in a different product design.

The assignment of a unique International Standard Book Number, or "ISBN," to each individual book title also identifies the publisher of that particular edition of the book title and thus serves as the conventional marketplace way to distinguish one individual book title "product" from another for purposes of doing business in the publishing industry's supply and distribution chain. However, an ISBN is of little help in performing the function of determining what constitutes the specific "children's product" for CPSIA purposes of total lead content testing and certification. Unique ISBNs may apply to separate book titles which are manufactured in exactly the same manner using component materials that are the same in all material respects, or they may apply to separate book titles that look very similar but in fact are the result of different manufacturing processes using different component materials; either way, the unique ISBNs assigned to each book title will not signify anything about whether any two individual book titles are identical or different "children's products" in terms of their respective component materials and manufacturing processes.

The marketplace role of ISBNs in distinguishing one individual book title "product" from another argues for their use in CPSIA total lead content compliance *certification*, as the publishing industry's supply and distribution chain already utilize this form of individual product identification for children's books as they do for books in general. It also makes sense under the proposed rules, including from the consumer's perspective, as a way of directly linking compliance issues to a specific children's title.

However, for purposes of conducting total lead content compliance *testing*, using ISBNs is not the preferable way to distinguish one individual ordinary children's book title "product" from another. Many different ISBNs may in fact be the same "product" in all material respects – they only differ in elements that are irrelevant to lead testing (such as in the words on the page) or in other immaterial respects. Accordingly, submitters believe that having accredited third-party conformity assessment body testing for a finished book would constitute finished product testing for all ISBNs that do not materially differ from the tested book with respect to compliance with CPSC safety standards. This approach is supported by the NPRM, which states that samples need to be "identical in all material respects," and defines that phrase as meaning that there is "no

difference with respect to compliance to the applicable rules between the samples and the finished product.” Proposed rule section 1107.2.

During the period between required accredited third-party conformity assessment body testing of such ordinary children’s book products or other children’s paper-based printed products (i.e., two years under the proposed rules), the manufacturer or private labeler could rely upon those test results for certification of the subsequently manufactured book titles or other children’s paper-based printed products, provided that each manufacturer had established a reasonable testing program consistent with proposed rule section 1107.10(e) and there were no “material changes” in the product design or manufacturing process with respect to non-exempt component material elements, including the sourcing of non-exempt component materials, that could affect the ability of those books or other children’s paper-based printed products to comply with the total lead content rules. Of course, if such a “material change” were to occur during those subsequent two years, then each manufacturer implicated by the change would be responsible for exercising “due care” to ensure that reliance on anything other than retesting of the finished product would not allow a noncompliant ordinary children’s book or other children’s paper-based printed product to be distributed in commerce.

Such an approach to product testing involves substantially fewer tests (and related costs) than the “test each ISBN” approach, and it properly bases the definition of “product” for testing purposes on those component materials that have not yet been determined by CPSC to qualify for an exclusion from total lead content testing requirements (i.e., spot inks; saddle stitching wire; metal and plastic coil bindings; stamping foils; accessible non-animal-based adhesives; and film or other laminates). As CPSC and its staff are aware, the other component materials comprising ordinary children’s books and other children’s paper-based printed products have been determined by CPSC to not be subject to such testing requirements (i.e., paper; four-color CMYK process inks; varnish, water-based or UV-cured coatings; book binding threads; animal-based glues; tanned and dyed leather; textiles; and non-accessible adhesives/binding materials).

The submitters believe that CPSIA and the proposed rules would allow manufacturers and private labelers of ordinary children’s books or other children’s paper-based printed products to implement a testing scheme as outlined above. It is critical that this be permitted in order to mitigate the costs attendant to the massive amount of testing that could be mandated by CPSIA in connection with these children’s products.

Apparently, CPSC and its staff, in examining the impact on manufacturers of the proposed rule on product testing for purposes of the Regulatory Flexibility Act, did not include the book publishing and printing industries represented by the submitters in the relevant table (Table 2 – Manufacturers) published as part of the NPRM, *id.* at p.28353. The submitters urge CPSC to revise their table and the resulting calculations of costs attributed to CPSIA testing requirements in order to better appreciate the potential impact on the book publishing and printing industries, which are represented by the NAICS codes 511130 and 323117, respectively. According to the most recent available data from the same source used by CPSC and its staff, i.e., the U.S. Census Bureau, some 2,965 small book publishers (out of a total of 3,052 firms) and 477 small book printers (out of a total of 498 firms), for a combined total of 3,442 small firms out of a combined total of 3,550 firms), need to be added to CPSC’s previous totals to include the small

manufacturers represented by the submitters. See “*Number of Firms, Number of Establishments, Employment, Annual Payroll, and Estimated Receipts by Enterprise Employment Size for the U.S., All Industries: 2007*,” http://us_6digitnaics_empl_2007.xls, at U.S. Census Bureau, Statistics of U.S. Businesses (SUSB), Latest SUSB Annual Data 2007, www.census.gov/econ/susb/.

Reasonable Testing Program

The submitters appreciate and intend to take advantage of the opportunity to establish “reasonable testing programs” (“RTP”) as a way to bring their own knowledge and control of the manufacturing and importing of ordinary children’s books and other children’s paper-based printed products to bear on the problem of minimizing their costs and burdens in complying with CPSIA’s total lead content testing and certification requirements.

The submitters agree with CPSC and its staff that, “[b]ecause the requirement for a reasonable testing program would apply to a wide variety of product types and manufacturing processes, it [should be] designed to be scalable to production volumes and adaptable to the specifics of the product.” *Id.* at p.28345. And because, in the case of children’s products, the establishment of an RTP would be a *voluntary* undertaking by the manufacturers, the submitters fully endorse CPSC’s view that “[a] manufacturer may develop the scope and details of each element of a reasonable testing program based on the manufacturer’s knowledge and expertise regarding the product and its manufacturing processes.” *Id.* At minimum, the submitters understand this to mean that “[a] manufacturer may tailor the tests to the needs of the individual product, and the tests do not need to be the same tests that are specified in the applicable rules. The proposed rule would leave decisions on procedures such as the number of samples to test, up to the manufacturer provided that the testing plan provides a high degree of assurance that noncompliant products are not introduced into the stream of commerce.” *Id.* at p.28339.

Similarly, the submitters understand that, in meeting the “product specification” requirement for an RTP, the manufacturer may utilize vendor certifications and other forms of documentation to describe the product in sufficient detail to both identify the product and distinguish it from other products made by the manufacturer. *Id.* at p.28345. Such materials can also support the “production testing plan” that is required for each manufacturing site as part of an RTP. The specific technology used to support a production testing plan would be within the manufacturer’s discretion, exercising “due care” under the proposed rules, and such plans can include the use of process management techniques with nondestructive measurement methods that are “tailored to the needs of an individual product,” instead of conducting recurring product performance tests, under proposed rule section 1107.10(b)(3).

With those views in mind, the submitters offer the following suggestions regarding RTPs:

Duty of “Due Care” – Both sets of proposed rules in the two NPRMs refer to a duty of “due care” defined as “the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances.” The proposed rules in each docket, however, target this “duty” to only a few of the aspects of their provisions that call for the manufacturer to exercise judgment or discretion based on the manufacturer’s knowledge of the product and manufacturing process. See, *e.g.*, proposed sections 1107.10(b)(2)(ii) and

1107.23(a) regarding “material change” in the product’s design, manufacturing process, or sourcing of component parts; proposed section 1107.10(b)(4)(i) regarding “remedial action” deemed appropriate by the manufacturer to assure compliant products in response to a sample’s failed test; proposed section 1109.5(h)(1) regarding reliance by finished product certifiers on a component part certificate or component part test result.

In some instances, this defined duty of “due care” is coupled with a CPSC-created standard of “high degree of assurance,” which is defined as “an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture,” and is linked to a number of proposed provisions, including its application to the various elements of a “reasonable testing program” under proposed section 1107.10 and the various requirements for certification of children’s products.

The submitters appreciate CPSC’s recognition that both the “due care” standard of conduct and the “high degree of assurance” standard for compliance are anchored in the judgment and knowledge of the manufacturer. For that reason, both standards should have general applicability to all elements of compliance with the proposed rules for implementation of CPSIA’s testing and certification requirements. Manufacturers should not be left to wonder whether more than their exercise of reasonable judgment and practice, based on their manufacturing experience and sound knowledge of the product, is required for those aspects of the rules that do not explicitly reference these standards.

Frequency of Accredited Third-Party Conformity Assessment Body Testing – As noted earlier in these Comments, manufacturers that voluntarily establish an RTP “consistent with” Subpart B of the proposed rules in Docket No. CPSC-2010-0038 would have to submit their children’s product for third-party conformity assessment body testing at least once every two years, rather than annually. *Id.* at p.28348-28349. The submitters appreciate the recognition by CPSC that the establishment of an RTP would provide sufficient additional safety compliance testing to warrant some relaxation in CPSIA’s general requirement for *annual* third-party conformity assessment body testing in the absence of such an RTP. However, the submitters urge CPSC to consider that the costs involved in establishing and maintaining an RTP reasonably warrant more of a relaxation of that testing frequency standard, particularly where – as with ordinary children’s books and other children’s paper-based printed products – the product has no history of presenting safety issues involving total lead content and the manufacturing process inherently results in uniform production, with very little variability in the composition or quality of the finished product.

CPSC has already acknowledged that Section 14(d)(2)(B)(i) of the CPSA, which requires “periodic testing” of children’s products for compliance with all applicable children’s product safety rules, including CPSIA’s total lead content rules, does not require all such periodic testing to be conducted by a third-party conformity assessment body. *Id.* at p.28348. It has also acknowledged that the appropriate periodic testing interval “may vary for a manufacturer depending on the manufacturer’s knowledge of the product and its manufacturing processes.” *Id.* at p.28349. Moreover, in proposing relief for “low-volume manufacturers,” which would include many of the submitters’ members, CPSC has already acknowledged that a periodic testing frequency standard is not essential to the safety scheme by dispensing with periodic testing

altogether in the case of manufacturers that produce or import no more than 10,000 units of a product. See proposed rule section 1107.21(d).

In light of these considerations, the submitters urge CPSC to permit a manufacturer with an RTP in place to rely upon knowledge of their own product and manufacturing process to determine when to obtain third-party conformity assessment body testing of ordinary children's books or other children's paper-based printed products under a testing frequency standard of at least once every four years. Assurance against abuse of the manufacturer's duty of "due care" under such a standard would be provided by the proposed rule implementing Section 14(d)(2)(B)(i) of CPSA, as amended by Section 102(b) of CPSIA, which would require third party conformity assessment body testing to occur in response to a "material change" in the product design or manufacturing process, including the sourcing of component parts, that could affect the product's compliance, regardless of when such a change occurs.

Random Samples – While recognizing that "there are alternative approaches for deciding whether something represents a 'random' sample, *id.* at p.28349, CPSC nevertheless has proposed to implement the requirement for testing "random samples" of children's products in a manner that requires each manufacturer to have a selection process that assigns each sample in the production population an equal probability of being selected for testing. Apparently, CPSC proposed this requirement on the basis of reference to a single dictionary definition of "random sampling," *id.* at p.28340, and its belief that, "[i]f the products selected for testing are not randomly selected, there is no statistical basis for inferring the compliance of the untested products." *Id.* at p.28349-28350.

The "random sampling" presentation at the CPSC Staff Public Workshop on Product Testing last December demonstrated how incredibly complicated this approach to testing random samples will make compliance for many manufacturers. However, it is not at all clear that such a difficult requirement is mandated by or even consistent with Congressional intent in the statutory requirement to establish protocols and standards "for the testing of random samples to ensure continued compliance." Section 14(d)(2)(B)(ii) of CPSA, as amended by Section 102(b) of CPSIA.

Given its most straightforward reading, the statutory requirement for the "testing of random samples to ensure continued compliance" seems to be simply concerned with using some form of blind sampling to determine whether the selected samples themselves are compliant with CPSIA, not with determining a "statistical basis for inferring the compliance of the untested products." If Congress had intended this far more complicated reading of the statutory requirement, it would have used more specific language to make that intent unmistakably clear, given alternative approaches that exist for simply ensuring that the selection of samples is not intentionally manipulated to produce a certain result or representation regarding the product being tested.

But, even if CPSC were correct about the intent of Congress in requiring the "testing of random samples to ensure continued compliance" regarding the untested products, CPSC should allow manufacturers to exercise "due care" judgment in utilizing alternative approaches to such testing in light of the wide differences in practical capabilities for compliance that exist among the numerous manufacturers of the thousands of children's products subject to CPSIA's

requirements. While the proposed rules would define the “production population” for purposes of such testing and allow manufacturers to use a procedure that randomly selects items from a list to determine which samples are the random samples for testing before production begins, CPSC also notes that manufacturers “may select additional samples based on the manufacturer’s knowledge of the product and its production to provide greater assurance of compliance.” *Id.* at p.28350. The submitters believe this is a sensible idea which CPSC and its staff should develop further to permit alternative approaches to selecting “random samples” for testing.

Undue Influence – While acknowledging the value of requiring manufacturers to establish procedures to safeguard against the exercise of “undue influence” by a manufacturer over a third-party conformity assessment body, the submitters urge CPSC to drop its proposed requirement for appropriate staff to receive “annual training” on avoiding such undue influence. Proposed rule section 1107.24(b)(1). Given current economic circumstances and the significant additional costs and burdens that the proposed rules will generally impose upon manufacturers of children’s products, the “annual training” mandate, along with its participation attestation requirement, are unnecessary and excessive elements that should be eliminated from the proposed rules.

Requirements for Children’s Product Certificates and Recordkeeping – The statutory requirements for certificates in Section 14 of CPSA, as amended by Section 102(b) of CPSIA to incorporate a new subsection (g), imposes strict and detailed requirements for both the *contents* and *availability* of certificates of conformity that document compliance of a children’s product with CPSIA total lead content limitations as demonstrated through test results. Although those statutory requirements were enacted without consideration of component materials testing, which was not specifically addressed by CPSIA and would only be permitted pursuant to adoption of CPSC’s proposed rules, CPSC has proposed rules regarding the content and availability of certificates that follow the strict requirements of CPSIA as these would be made even more complicated by the need to address component material test results and certificates as the basis for finished product certificates.

As a result of CPSC’s helpful effort to formally permit component material testing as a basis for certification of conformity for the finished children’s product, the certificate based on accredited third-party conformity assessment body testing, which must be issued by the manufacturer and private labeler of any children’s product that is subject to CPSIA’s total lead content testing requirements, must not only comply with the requirements of Section 102(g) of CPSIA but also with the requirements for a finished product certifier’s reliance on component materials testing certification.

Thus, a finished product certifier could rely on a test report showing passing test results for one or more component materials used in the product, based on accredited third-party conformity assessment body testing conducted by another person. However, the requirements for the issuance of component materials certificates, with detailed information regarding the underlying component materials testing results, to be added to the other information required for inclusion in the certificate accompanying the finished children’s product would create logistical nightmares for the manufacturers and private labelers of children’s products, including ordinary children’s books and other children’s paper-based printed products.

While the submitters do not object to the proposed “recordkeeping” requirements in section 1107.26 of the proposed rules in Docket No. CPSC-2010-0038, they would strongly urge CPSC to note that compliance with these requirements should make it unnecessary for the manufacturer or private labeler of the finished children’s product to ensure that every certificate required under Section 102 of CPSIA (notably component materials testing certificates, in certain cases) accompanies the product or shipment of products and is furnished to each distributor or retailer of the product.

Although the wording of Section 102(g) of CPSIA regarding requirements for certification differs from that of Section 103 of CPSIA regarding requirements for tracking labels, the submitters urge CPSC to adopt certificate requirements that reflect the key concept in the tracking label provisions, which require that the manufacturer (as well as the “ultimate purchaser”) of the finished children’s product should be able to “ascertain” certain information similar to that required to be included in certificates of conformity.

Thus, instead of actually having to include within the accompanying certificate the date and place of manufacture, the date and place where the product was tested, each party’s name, full mailing address, telephone number, and contact information for the individual responsible for maintaining records of test results, plus a list of each component material that was tested, by material number or other specification, along with identification of the corresponding test report or component material certificate on which a certification for the finished children’s product is based, the certificate could, like the “tracking labels” mandated for children’s products under Section 103 of CPSIA, use codes or other means to point all interested parties to a source where such information can readily be found. This could be contact information for the manufacturer or private labeler (which, in the case of ordinary children’s books, would be the publisher), including a URL for the publisher’s or manufacturer’s web site where the information could be accessed.

This “ascertainable information” approach to ensuring the public availability of safety information needed to determine the origins of a particular children’s product relevant to a product recall has already been authorized by Congress and CPSC for “tracking label” purposes. Viewed in terms of the comprehensive recordkeeping requirements in section 1107.26 of the proposed rules in Docket No. CPSC-2010-0038, compliance with the important requirement for component materials testing “traceability,” which underlies the ability of a finished product certifier to rely on component materials testing certification, would be workably assured and an “ascertainability” standard for the availability of required information would provide a more reasonable way of facilitating transparency and disclosure in the service of children’s product safety compliance.

Component Material Testing and Traceability

With respect to requirements for documentation by a component materials testing party other than the finished product certifier, the submitters note that the proposed rule would require such documentation to include “identification of a lot or batch number for which the testing applies.” Proposed rule section 1109.5(f)(2). The submitters urge that this requirement should be understood to allow a component certification to apply to all of the same materials from a

particular supplier, rather than just the tested lot or batch, unless and until there is a material change in the tested materials that requires further testing. The certification would thus represent the product line as produced by the manufacturer, rather than just those units produced by a particular lot or batch.

Conclusion

The submitters would be happy to respond to any questions that CPSC and its staff may have regarding these Comments.

Respectfully Submitted,



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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0040
Comment from Alison Manhoff

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General Comment

Please see attached file.

Attachments

CPSC-2010-0038-0040.1: Comment from Alison Manhoff



founded 1881

August 3, 2010

Office of the Secretary
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Submitted electronically via www.regulations.gov

Re: **Docket No. CPSC-2010-0038: *Testing and Labeling Pertaining to Product Certification***

To the Commission:

The Consumer Healthcare Products Association (“CHPA”) appreciates the opportunity to provide comments on the Consumer Product Safety Commission’s (“CPSC” or “Commission”) proposed rule, “Testing and Labeling Pertaining to Product Certification,” published in the Federal Register on May 20, 2010. Founded in 1881, CHPA is a national trade association representing leading manufacturers of over-the-counter (“OTC”), non-prescription medicines and dietary supplements.

PPPA Regulated OTC Medicines and Dietary Supplements are Not Children’s Products

Many CHPA members manufacturer products with packaging regulated under the Poison Prevention Packaging Act (“PPPA”). The food and drug products manufactured and distributed by our member companies are specifically exempted from the definition of “consumer products.” Consumer Product Safety Act, P.L. 92-573, Sections 3(a)(5)(H) and (I). Therefore, the only food and drug products that fall within the scope of the Commission’s regulatory authorities are those for which the Commission has imposed packaging requirements pursuant to the PPPA. P.L. 91-601. These products are specifically enumerated in 16 CFR §1700.14. Further, the Commission’s regulatory authority over such products is limited to the packaging.

While some of these OTC medicines and dietary supplements may be labeled for use in children, they are not considered children’s products under CPSC laws and regulations. As stated in CPSC’s April 10, 2010 proposed rule on the “Interpretation of ‘Children’s Product’” “products that incorporate performance requirements for child resistance are not children’s products as they

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are designed specifically to ensure that children cannot access the contents.” Interpretation of “Children’s Products,” 75 Fed. Reg. 20,533, 20,534 (April 10, 2010). While the drug or supplement product may be labeled for use in children, the packaging of the products regulated by the Commission is specifically designed to prevent access to the drug or supplement by children.

Proposed Subpart C- “Certification of Children’s Products”- is Only Applicable to Children’s Products

As you are aware, the CPSA establishes different testing requirements for “children’s products” and “nonchildren’s products.” As currently written, some of the provisions in Subpart C, “Certification of Children’s Products,” are not explicitly limited to children’s products. This is inconsistent with the intent of the provision and requires clarification. For example, the provision on periodic testing (proposed §1107.21), references Subpart B of the proposed rule which relates to testing programs for nonchildren’s products. We recognize that Subpart B states that children’s product manufacturers can voluntarily establish a reasonable testing program consistent with the requirements for nonchildren’s product manufacturers but the reference in Subpart C could lead to confusion. To clarify, §1107.21 should be revised as follows:

- (a) Each manufacturer [of a children’s product] must conduct periodic testing...
- (b) If a manufacturer [of a children’s product] has implemented a reasonable testing program...
- (c) If a manufacturer [of a children’s product] has not implemented a reasonable testing program...
- (d) For a [children’s product] produced or imported at low volumes....

Additional revisions should be made to the other provisions in Subpart C that do not explicitly qualify the term “manufacturer” with “of a children’s product.” As intended by the title to the subpart, “Certification of Children’s Products,” the entirety of this subsection is only applicable to manufacturers of children’s products.

Existing PPPA Testing Standards Meet Requirements for a Reasonable Testing Program

We support the Commission’s efforts to establish requirements for a reasonable testing program for nonchildren’s products. As you are aware, 16 C.F.R. 1700.20 outlines the rigorous testing protocol for products required to be packaged in child resistant packaging pursuant to the PPPA. We strongly believe that these requirements meet the definition of a “reasonable testing program.” Since implementation of the PPPA in the early 1970’s, these requirements have dramatically reduced the number of deaths caused by unintentional ingestion of medicines by children. CPSC, Poison Prevention Packaging: A Guide for Healthcare Professionals (2005),

available at <http://www.cpsc.gov/cpscpub/pubs/384.pdf>. As noted in the Commission's online Frequently Asked Questions document:

The child resistance and senior friendly testing data (also known as protocol data) obtained in accordance with the procedures described under 16 C.F.R. 1700.20 may be used by the importer or domestic packager to support its certification. **The packager can rely upon this data as the basis for the reasonable testing program.** There is **no expiration date on these tests and no requirement to retest** so long as the tests adequately reflect the current packaging used.

CPSC, Consumer Product Safety Improvement Act Frequently Asked Questions (posted 12/10/08), available at <http://www.cpsc.gov/about/cpsia/faq/faqs.html> (emphasis added).

The history of success of the PPPA procedures and CPSC's stated position on PPPA testing provides manufacturers complying with the PPPA laws and regulations a "high degree of assurance" that their products comply with the relevant applicable rules. *See* proposed § 1107.10(a). Similar to the existing testing programs listed in Table 1 of the Description of the Proposed Rule, the PPPA and its accompanying regulations establish a mandatory testing program that should not be superseded by proposed §1107.10. Therefore, PPPA products should not be required to adhere to the provisions of proposed §1107.10, as a "reasonable testing program" already exists for these products.

If the Commission disagrees with CHPA's position that PPPA products should be exempt from the proposed rule due to the existing mandatory PPPA testing program, we recommend the following changes to the proposed regulatory language of § 1107.10 (in addition to the revision to Subpart C- §1107.21 discussed above).

1. Retesting is Not Required for PPPA Products Unless There is a Change That Could Affect Compliance with PPPA Regulations

As stated by CPSC and noted above, PPPA packaged products do not require retesting unless there is a change that could affect compliance with PPPA regulations. Therefore, the language of proposed §1107.10(b)(3)(iii) should be revised to state:

The production testing must ensure that, if the samples selected for production testing comply with an applicable rule, ban, standard, or regulation, there is a high degree of assurance that the untested

products manufactured also will comply with the applicable rule, ban, standard, or regulation.

All references to testing intervals have been removed as in some instances, such as with PPPA products, time based interval retesting of a product is not necessary under a “reasonable testing program.” Stating that the “testing interval selected must be short enough” incorrectly implies that testing requirements should be based on time as opposed to being time-independent and pursuant to a change that could affect compliance to the applicable rule.

2. Product Specification Documentation Should Not Require Listing of Applicable Rules, Bans, Standards, or Regulations

Requiring product specifications to list “the applicable rules, bans, standards, or regulations to which the product is subject” is unnecessary as it is duplicative of information already included on the general conformity certificate for a product. This requirement would place a tremendous resource burden on manufacturers without any added value under a reasonable testing program for CPSC regulated products. Therefore, the introduction to §1107.10(b)(1) should be revised to state as follows:

Product Specification: The product specification is a description of the consumer product. A product specification should describe the product listed on a general conformity certification in sufficient detail...

3. Definition of “Identical in All Material Respects” Should be Revised for Clarification Purposes

The definition of “identical in all material respects” should be modified to clarify the intent of the rule. Specifically, the term as defined in § 1107.2 should be revised to state as follows:

Identical in all material respects means there is no difference between the sample and the finished product that could affect compliance to the applicable rules.

4. The Terms “Production Testing Plan” and “Remedial Action Plan” Should be Expanded to Include “Procedures”

Proposed §1107.10 should be revised to expand the terms “Production Testing Plan” and “Remedial Action Plan” to include procedures. As drafted, the term “plan” may be interpreted too narrowly to allow for the range of methods manufacturers may utilize to meet the underlying substantive requirements outlined in the proposed rule.

Specifically, the term “production testing plan” should be replaced with “production testing plan or procedures” throughout proposed §1107.10(b)(3) and anywhere else the term is used in the proposed rule. Further, the term “remedial action plan” should be replaced with “remedial action plan or procedures” throughout proposed §1107.10(b)(4) and anywhere else the term is used in the proposed rule.

5. Multiple Manufacturing Sites Can Have the Same Product Specifications and Production Testing Plan or Procedures

The provisions of §1107.10 should allow multiple manufacturing sites to share common product specifications and production testing plan or procedures. Specifically, § 1107.10(b)(1)(iii) should be revised to state:

Each consumer product must be covered by a product specification.

Further, §1107.10(b)(3)(ii) should be revised to state:

Each manufacturing site shall be covered by a production testing plan or procedures.

Manufacturers of PPPA regulated products may utilize the same product specification and/or production testing plan or procedures across multiple manufacturing sites. This is appropriate under the requirements for a reasonable testing program due to the nature of PPPA regulated products and limited requirements for retesting once the design of a product has been shown to meet the child resistance standards.

CHPA members thank the CPSC for the opportunity to provide our comments on this important issue. If the Commission has any questions or if CHPA can be of any assistance, please let us know.

Sincerely,



Alison Manhoff
Deputy General Counsel
Consumer Healthcare Products Association

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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0041
Comment from Donald Mays

Submitter Information

Name: Donald Mays
Organization: Consumers Union

General Comment

Comments attached.

Attachments

CPSC-2010-0038-0041.1: Comment from Donald Mays

***Consumers Union * Consumer Federation of America*
* Kids In Danger * Public Citizen *
* U.S. Public Interest Research Group *
* National Research Center for Women and Families ***

August 3, 2010

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, Maryland 20814
Via e-mail: <http://www.regulations.gov>
Docket No. CPSC-2010-0038

**Comments of Consumers Union, Consumer Federation of America, Kids In
Danger, Public Citizen, the U.S. Public Interest Research Group, and the
National Research Center for Women & Families to the U.S. Consumer
Product Safety Commission
on
“Testing and Labeling Pertaining to Product Certification; Proposed Rule”**

Introduction

Consumers Union of U.S., Inc. (CU), Consumer Federation of America (CFA), Kids In Danger, Public Citizen, the U.S. Public Interest Research Group, and the National Research Center for Women and Families (jointly “We”) submit the following comments in response to the U.S. Consumer Product Safety Commission (“CPSC” or “Commission”) in the above-referenced matter (“Notice of Proposed Rule”).¹ The CPSC has issued this Notice of Requirements pursuant to section 14(a)(1) of the Consumer Product Safety Act (CPSA) (15 U.S.C 2063(a)(1), as amended by section 102 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314. In this Notice, the CPSC publishes the proposed rule for testing and labeling requirements

¹ “Testing and Labeling Pertaining to Product Certification; Proposed Rule under Part 1107 of Title 16, Code of Federal Regulations” as Established by the Consumer Product Safety Commission,” Vol. 75, No. 97 Federal Register pg. 28336 (May 20, 2010).

pertaining to product certification as required by the CPSIA. We submit these comments in response to the CPSC's Notice of Requirements.

Background

Section 14(a) of the CPSA, as added by section 102 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-3144, directs the CPSC to establish requirements for the testing and certification of products subject to a consumer product safety rule under the CPSA or a similar rule, ban, standard or regulation under any act enforced by the CPSC and which are imported for consumption or warehousing or distribution in commerce. Under section 14(a)(1)(A) of the CPSA, the manufacturer (including the importer) or private labeler must issue a certificate that indicates compliance with all rules, bans, standards or regulations applicable to the product under the CPSA or any other Act enforced by the CPSC. Certification must be based upon a reasonable testing program and is known as the General Conformity Certification (GCC).

Section 14(a)(2) of the CPSA establishes requirements for children's products that are subject to a children's product safety rule. Children's products are defined as a consumer product designed or intended primarily for children 12 and younger. The manufacturer or private labeler must submit a sufficient number of samples that are identical to the product in all material respects to a third-party conformity assessment body accredited to perform such tests.

Section 14(d)(2)(A) of the CPSA requires the CPSC to initiate a program by which a manufacturer or private labeler may label a product as complying with certification requirements. This applies to all consumer products subject to a product safety rule by the CPSC.

Section 14(d)(2)(B) requires the CPSC to establish protocols and standards for: a program for testing children's products based on periodic testing, testing random samples, verification of compliance, and safeguarding against undue

influence on a third-party conformity assessment body. In addition, CPSC must define the elements of a reasonable testing program and establish protocols for continuing testing of children's products, and define the label that manufacturers can place on their products to indicate compliance with certification requirements.

On November 3, 2009, the CPSC staff issued a draft guidance document entitled, "Guidance Document: Testing and Certification Requirements Under the Consumer Product Safety Improvement Act of 2008". On December 10 and 11, 2009, the staff held a two-day public workshop to discuss issues relating to the testing, certification and labeling of products covered by Section 14 of the CPSA. We participated in the public workshop and offered comments at that time. The Commission has since issued responses² to the comments received at this workshop as well as to matters pertaining to implementation of Section 14 of the CPSA.

The Commission invites comments on the proposed rule as it applies to testing and labeling requirements pertaining to product certification.

Recommendations

We urge the CPSC to adopt the following recommendations in its implementation of testing and labeling requirements of certified products.

Need for specificity

We agree that the Commission's proposed five elements of a reasonable testing program are thorough, logical and appropriate. We are concerned, however, that the lack of specificity in some cases is prone to result in wide variations in the interpretation of these rules. Specifically, under the plan to define a "reasonable testing program," a manufacturer must develop a production testing plan that must be performed at such intervals to provide "reasonable assurance" that the

² Federal Register, Vol. 75, No 97 (May 20, 2010) pp 28337 - 28343

produced products meet all of the applicable safety rules by testing a “sufficient number” of samples. The terms “reasonable assurance” and “sufficient number” are likely to result in widely disparate interpretations. “Reasonable assurance” should be defined as a statistically significant number with a confidence level of 95 percent, based on testing enough samples to provide statistical validity. Setting a specific confidence limit better enables the Commission to enforce this section of the rule by avoiding subjectivity and by creating uniformity and consistency among manufacturers and conformity assessment bodies.

Under the Commission’s response to comments on existing testing programs, it states that: “If in a manufacturer’s determination, a prescribed testing program ensures with a high degree of assurance that the products distributed in commerce will comply with the applicable rules, then the manufacturer is free to choose that program for his product.” Again, the term “high degree of assurance” is subjective and subject to varied interpretations. A statistical confidence limit would help remove the subjectivity and set a specific threshold by which the CPSC can better enforce their rules. We are also concerned that this wording may lead some manufacturers to believe they are not required to test to the standard in all cases, as long as they interpret little risk of non-compliance or assume low risk of being discovered as having non-compliant products in the marketplace. It should clarify that testing to applicable standards is imperative and required by law.

Inconsistent language

We understand that is difficult to specify the exact number of products that must be tested in order to reach a “high degree of assurance” that the product is in compliance. We note, however, that the CPSC’s response to the comments cited in the section on *Additional Third Party Testing Requirements for Children’s Products* states that “the sample size for periodic testing will depend upon the number of samples that need to be tested to provide that statistical assurance.” While we do agree with this statement, we would also like to note the

inconsistency between the language used in this section and the language found in the section entitled *The Reasonable Testing Program*. The language there specifies that the testing intervals must provide “reasonable assurance” that the product meet applicable safety rules. There is a difference between “high degree of assurance” and “reasonable assurance.” To reiterate our recommendation above, we believe that the testing program should be statistically based such that a confidence level of 95 percent must be achieved to indicate compliance. This requirement would eliminate the possibility of testing only a single sample to indicate compliance.

Upstream controls

We do agree that manufacturing process controls, product risk assessments and design hazard analysis are appropriate elements for manufacturers to use in developing a reasonable testing program for safety assurance. These tools should not, however, be used as part of a compliance program. The international standards for quality management and controls, such as ANSI/ISO/ASQ 9001, are currently not rigorous or specific enough to ensure that downstream products are compliant. Additionally, we are not aware of recognized standards for risk assessment that can be universally applied. Until such standards are developed, strengthened or widely recognized, compliance must be determined based on final product testing.

Low-volume production limits

We do not agree with the Commission's limit for random sampling of low-volume production, currently set at 10,000 units or less. Our analysis of CPSC–announced recalls in calendar year 2009 shows that 47 percent of the recalls were for unsafe products of 10,000 units or less. Although most of the recalls were not due to compliance issues, it is clear that even small production runs have safety problems. We recommend reducing the threshold to 1,000 as the product run limit for which random sampling would not be required. Even at that lower limit, our analysis of 2009 recalls shows that 22 percent were for 1,000

units or less. Although we would prefer an even lower limit, we understand the practical limitations with random sampling of even smaller production runs.

Product labeling

We agree with the Commission's approach to labeling products to indicate compliance with the rules. For such a labeling program to be effective, it must be easily and universally recognized by consumers who can intuitively interpret its meaning. We recommend that the CPSC's labeling program should include guidelines for the type, style, color, and font of such labels, and should consider use of symbols or a mark rather than words or initials as proposed. Symbols would also help overcome language barriers for communicating compliance. The guidelines should allow variations in the label's size to accommodate products of different physical dimensions, but the general appearance of the label must remain consistent. We also recommend that the labels appear both on the product packaging as well as on the product itself as a permanent mark. For toys, we recommend that the labels be used to communicate not only compliance with the standards, but also the appropriate age range for the toy. The European Union uses a universal mark that indicates the inappropriate age ranges of a toy if it presents a choking hazard. The CPSC's program could expand on that concept by recommending labeling that caregivers can use to separate toys intended for siblings of differing ages, while also preventing them from buying toys that may be inappropriate for the age of the child for which the toy is intended. This could help enhance toy safety by reducing children's exposure to inappropriate toys.

Frequency of Periodic Testing

Under proposed section 1107.21, Periodic Testing, we recommend that the Commission require that children's products be tested by a third-party conformity assessment body at least every year, not every two years, as proposed. Many changes can occur over time in the manufacturing process, materials, test standards, and test protocols that could cause products tested infrequently to

drift away from compliance with applicable safety rules. More frequent independent testing would better be able to keep this in check.

Use of XRF

We recommend against the use of XRF testing as an alternative to ICP for certification of compliance. Although XRF can be an effective screening tool, variations in equipment, operators, and materials being tested can result in widely disparate measurements. In some cases, the errors provided by XRF measurement can be more than ten fold the levels measured by more accurate ICP methods.

We understand the concerns raised by very small/home manufacturers of toys regarding lead testing requirements. We believe that the lead screening needs of the vast majority of these very small and home manufacturers will be satisfied by the component parts rule, and by the Commission's prior exemption from lead testing a wide category of materials such as textiles, feathers, fur, and children's fabric products (see 74 CFR 43031).

If you do consider using XRF testing as an acceptable tool for compliance testing, we recommend that you impose the follow restrictions: In the case of non-layered, homogeneous materials of at least 5mm thick and that do not have a surface coating, XRF could be used as an alternative to ICP testing provided that lead is "not detected" when the product is tested by XRF. If lead is detected, the product should be tested by ICP. This would only apply to low volume production runs of less than 1,000 units.

Respectfully submitted,

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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0042
Comment from Ed Desmond

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General Comment

See attached file(s)

Attachments

CPSC-2010-0038-0042.1: Comment from Ed Desmond



Toy Industry Association, Inc.

www.toyassociation.org

August 3, 2010

Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

**RE: TIA COMMENTS NOTICE OF PROPOSED RULEMAKING ("NPR"):
Testing and Labeling 75 Fed. Reg. 28336, to be codified as 16 CFR Part 1107
CPSC DOCKET Number: 2010-0038**

Dear Mr. Stevenson:

We appreciate the opportunity to comment on the Consumer Product Safety Commission's ("CPSC" or "Commission") proposed rule that would establish requirements for a reasonable testing program and for compliance and continuing testing for children's products. The proposed rule would implement section 14(a) and (d) of the Consumer Product Safety Act ("CPSA"), as amended by section 102(b) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA"). TIA has previously submitted extensive comments on a variety of CPSIA issues related to testing and certification of toys. These comments are providing our views on the proposed requirements of 16 CFR Part 1107. TIA reserves the right to supplement or amend its comments as appropriate.

TIA supports the overall direction established in the rule which allows companies who are exercising 'due care' as part of good manufacturing practices under an alternate test rule. We also support the opportunity to utilize component testing as an integral part of their quality assurance program. We welcome the two key changes from the initial draft of this regulation: the added flexibility on periodic testing if a manufacturer of children's products adopts a reasonable testing program, and the elimination of the verification requirement to test with a second third-party conformity assessment body. The Commission staff efforts in this regard are appreciated and deserve support. We are submitting the following suggestions for providing greater clarity in the proposed rule.

I. **Definitions in § 1107.2 should be Clarified**

The term "High Degree of Assurance" (§ 1107.2) is important, so we suggest that the Commission amend the proposed rule to avoid any misunderstandings based on its discussion of the definition in the Supplementary Information.

The proposed definition's reference to relying on "knowledge of a product and its manufacture" strikes us as helpful. We agree with CPSC's conclusion that a numerical target for defining what constitutes a "high degree of assurance" is misplaced in the context of Good Manufacturing Practices (GMP) based programs which are to be encouraged. An evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture is clearly preferable to establishment of a fixed

numerical target. The Commission staff has appropriately recognized that numerical targets as a basis for determining compliance with a high degree of assurance could result in greater testing demands on small manufacturers without any corollary benefit of quality assurance.

However, the proposed *explanation* of the definition may create particular problems at the initial-certification stage of a product. Vol.75 No.9 Fed. Reg. at 28344. Although the discussion on its face makes it clear that the CPSC will not define “high degree of assurance” statistically as a 95% level of confidence, its implication is that the Commission prefers that approach and considers it the default. This language may prompt third-party laboratories and retailers to adopt standardized testing protocols that demand large sample sizes, which will be a particular burden for the initial certification—which in many cases may not be warranted. We strongly favor the flexibility afforded by the proposed definition under §1107.2– *Definition of “High Degree of Assurance”* as being evidentiary based with recognition that manufacturers’ process control programs can often assure a high degree of assurance of product integrity and conformance and is preferable to numerical sampling targets. We believe the goal across a broad range of different products subject to different manufacturing requirements and material sourcing must be a standard that correlates a “*High Degree of Assurance*” with “evidence-based demonstration of consistent performance” which more appropriately relies upon process controls to assure conformance. While generally accepted process controls may include statistical sampling as part of process control programs, in and of themselves, they are not preferable to GMP. The Final Rule must be clear in this regard.

“Identical in all material respects” (§ 1107.2): The proposed rule defines this term to mean that “there is no difference with respect to compliance to the applicable rules between the samples and the finished product.” This definition is absolute in applying to *any* “difference with respect to compliance,” which makes testing requirements unnecessarily rigid and costly. Neither the statute nor any reasonable risk assessment requires such a standard. The regulation should instead define the term to mean the following or something similar: “*to a high degree of assurance, there is no difference between the samples and the finished product that is material to compliance to the applicable rules.*”

“Manufacturing process” (§ 1107.2): The proposed rule defines “manufacturing process” to include “*personnel used to create the component parts and assemble a finished product.*” (Emphasis added.) This may mean that any change in the employees who manufacture a part or product amounts to a change in manufacturing process, which in turn can be a “material change” that triggers further testing if it merely “could affect” compliance (as discussed further below). See §§ 1107.10(b)(2)(ii) & 1107.23; see also 15 U.S.C. § 2063(d)(2)(B)(i). Such a result would be overbroad. The Commission’s discussion of the proposed rule on material changes, in listing examples, appropriately does not provide one that involves a change in “personnel.” See 75 Fed. Reg. at 28350; see also *id.* at 28346. We accordingly would recommend that the Commission delete “personnel” from this definition. It should at least replace “personnel used” with “types of personnel used” or “personnel specially trained.”

II. Reliance on Good Manufacturing Process (“GMP”) Programs Should Be Encouraged in the Rule

The CPSIA neither defined the term “reasonable testing program” nor required the Commission to issue regulations defining it. Nevertheless, we believe such programs vary from industry to industry and within product categories. In this regard CPSC has broad administrative discretion to recognize the need for flexibility in construing reasonableness of particular programs. We also note that a reasonable test program is only considered reasonable and customary within an

industry and with due consideration of the product being manufactured. Inflexibility of the rules would presumably disallow a company's reliance on adherence to well recognized product based GMP programs and guidelines, because they do "not include any provision for a 'safe harbor' enforcement policy based on a manufacturer's participation in a voluntary or industry-sponsored program"

Since the rules require all manufacturers to develop and implement extensive internal compliance mechanisms, whenever an issue or recall arises, the CPSC will have to examine that company's unique compliance mechanisms to evaluate their adequacy. The draft rules should clearly allow for recognition of "safe harbors" based upon adherence to national standards for good manufacturing practices ("GMP"), international ISO standards governing GMP and industry based GMP category specific guidelines that manufacturers may utilize as evidence of their good faith commitment to attain a high degree of assurance that their products meet or exceed applicable federal safety standards. The staff has recognized that such programs may be considered as evidentiary in meeting the requirements under the NPR, but has not yet recognized it's authority to provide for such safe harbors claiming the CPSIA did not make such specific provision (pg. 28339 in preamble). However, we note that a specific statutory safe harbor is not a precondition to the authority of the agency under its rulemaking and enforcement authority to recognize such safe harbors. They should provide for such recognition.

Specifically, provisions in the rule should be addressed as follows:

1. *Product Specifications* (§ 1107.10(b)(1)(i)): The Commission should remove the requirement that the product specification "include any component parts that are certified pursuant to 16 CFR Part 1109." (Deleting this would require a corresponding change in proposed § 1107.10(b)(2)(i)(A).) It has not provided any reason for this requirement. See 75 Fed. Reg. at 28345 (background on this section). Nor is this requirement consistent with the Commission's explanation in its Supplementary Information that "a manufacturer is not required to specify every component or raw material of a product" and "is free to describe its product by model number, general description, photograph, etc., as long as the product is identifiable and differentiable from other products." *Id.* at 28338. Moreover, a product specification is often written during the design phase, before the manufacturer has a physical product, so it will be difficult at the time a manufacturer prepares the product specification to know which components will prove suitable for component-part testing pursuant to Part 1109. Cf. § 1107.10(b)(2)(i)(B) (providing that, in conducting certification tests, a "manufacturer may substitute component part testing for finished product testing pursuant to" Part 1109).

Under § 1107.10(b)(1)(iii), the Commission would require that each manufacturing site have a "separate" product specification, but it has not provided a persuasive reason for imposing this requirement. It is not clear why a single product specification would not suffice, particularly when the finished-product certificates—plus, for children's products, the tracking labels—will identify the place of manufacture. 15 U.S.C. § 2063(g)(1), as added by CPSIA § 102(b) (certificates); see § 2063(a)(5), as added by CPSIA § 103 (tracking labels). Thus, we would urge the Commission to remove this requirement or at least clarify that the rule's reference to a "separate" specification need not mean a "different" one.

This comment also applies to the requirement for having a "separate production testing plan" for "[e]ach manufacturing site." § 1107.10(b)(3)(ii).

2. *Certification Tests* (§ 1107.10(b)(2)(ii)): The proposed rule defines a “material change” as “any change in the product’s design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, *could affect* the product’s ability to comply with the applicable rules, bans, standards, or regulations.” (Emphasis added.) This definition is too broad; it will trigger excessive requirements for re-certification testing and correspondingly reduce the ability actually to use reasonable testing programs. *Any* change “could” affect compliance in some imagined scenario; the question should be whether that affect is at all likely. Thus, the definition should instead refer to changes that “*reasonably could affect*” compliance.

This comment also applies to § 1107.23.

3. *Production Testing Plan* (§ 1107.10(b)(3)(i)): The Commission should clarify what level of detail it is permitting in mandating that a production testing plan describe “the tests to be conducted or the measurements to be tested,” etc. We assume that manufacturers have the flexibility to create a testing plan that accounts for their making many kinds of products. Such flexibility would be consistent with the recognition in proposed § 1107.10(a) that a reasonable testing program covers multiple “consumer products.” For example, a plan could address testing by generic specifications of products (such as “die cast cars” or “fashion dolls”) or by the rule for which the manufacturer intends to test, or some combination of these factors or others. If, instead, the Commission expects a production testing plan to specify testing details for *each product* to be tested, then the documentation will be so burdensome as to make a reasonable testing program not economically feasible. The Commission’s welcome endorsement of process management techniques would become hollow.

III. Recordkeeping Requirements Must Not be Unduly Burdensome

The estimates for recordkeeping time and expense are severely underestimated, based upon most industry’s experience in meeting the requirements of the existing Interim Enforcement Policy which does not have the extensive recordkeeping requirements now proposed in the NPR. The industry’s experience with the current policy is that it is extremely burdensome, and the more extensive requirements contained in the new NPR would be even more costly and excessively burdensome. The draft rules would impose voluminous and unsustainable recordkeeping and documentation requirements on manufacturers of all sizes as it relates to reasonable testing plan documents, verification test plans, remedial action plans, etc. CPSC has specifically asked for input in this rule regarding the burden of recordkeeping and whether or not it adds ‘practical utility’. In the preamble (pg 28361) CPSC states that it will “*likely request access to these records only (emphasis added) when it is investigating potentially defective or noncomplying products.*” That would indicate that the collection of this information on every item is not necessary for the proper performance of CPSC’s functions. Having to integrate multiple systems to compile data that no one will look at across hundreds of thousands of products should not be needed as long as companies can provide reasonable data customary in a particular industry ‘upon request’.

The draft rule thoroughly underestimates the cost of compliance and recordkeeping such as this that will be unnecessarily required to document compliance with safety standards, particularly for small business that comprise 80% of the U.S. economy. Higher than the CPSC’s anticipated costs will be the inevitable result for industries to master and fulfill the recordkeeping requirements of the proposed rules. Some of the required record keeping is redundant and

unnecessarily duplicative, such as product specifications that are contained in test reports, and production plans for multiple factories. Fees for outsourcing these services could be significant and burdensome to many small businesses (Eighty percent of our members are small businesses).

CPSC's estimate of 200,000 -300,000 hours to manage recordkeeping equates to no more than 200 people across all industries impacted by CPSIA will be needed to manage the recordkeeping requirements, is woefully inadequate. Within our industry alone we estimate ten times that many persons have been engaged along the global supply chain to manage the data and recordkeeping associated with CPSIA's existing requirements. Although CPSC references a calculation of 100,000 to 150,000 products to which the recordkeeping requirements would apply, companies typically certify **each SKU** and there is recordkeeping for every version even if it is 'identical in all material respects'. There may be no need to re-test, but requirements still exist for all of the documentation. One member company, reported about 1700 individual products annually requiring testing, certification and recordkeeping, or >1% of the CPSC's entire estimated number of products across all affected industries.

Many companies have already been issuing Children's Product Certificates since November of 2008 in accordance with Section 14 (a)(1) of the CPSA. The requirements for those certificates have been clearly documented in CPSA sections 14(a) and 14 (g), listing the specific information that must be on the certificate. Companies have established processes, formats and in many cases, invested in IT solutions to prepare and transmit these certificates in accordance with the law. Retailers are relying upon such certificates as they can with the benefit of reduced liability under Section 19 of the CPSA as amended by the CPSIA. The Commission needs to clarify that the form of delivery of title, should not in and of itself, require additional testing, documentation and certification and that retailers can rely upon domestically located supplier certifications without duplication of testing and certification requirements.

Sec 1109.11(a) (3) of the NPR (Vol 75 No 97 Fed Reg 28208) mandates that Finished Product Certificates which are based on component testing must include on the certificate detailed documentation on each component: *"....the certificate required of certifiers under Sec 14(a) of the CPSA and Sec 1109.5(g) identifies each paint tested by color, location, formulation or other characteristic, the supplier of the paint, and if different, the manufacturer of the paint.*

A similar requirement is found in the component testing for lead section, Sec 1109.12(d), where *"...the certificate accompanying the children's product must list each component part that was tested by part number or other specification and for each component part, identify the corresponding test report, paint certificate.....on which the certification for the finished product is based."*

These requirements to provide detailed listing of all component information on the certificate add enormous complexity to the certification documentation process. CPSC has recognized the need for flexibility in testing processes. We request the same flexibility in how certifiers are allowed to manage their data and traceability in order to reduce paperwork and administrative burdens on manufacturers and importers of all sizes.

Specifically under § 1107.10(b)(5)(iii)&(iv), the Commission should clarify and slightly modify the requirements for record-keeping in three ways:

1. First, given the permissibility of maintaining records electronically (§ 1107.10(b)(5)(iii)), it is not clear what it means for records to be "maintained . . . at a location within the United

States.” It should be irrelevant where a server is located, so long as the records are “available . . . for inspection by the CPSC upon request,” which is not necessarily a function of location. *Id.* The ability to contact the custodian and the ready availability of the records upon such contact are the key factors. The Commission should delete this requirement or at least clarify it.

2. Second, it is not clear what it means for records to be “available in the English language.” May a manufacturer maintain records in an original language other than English, so long as it can promptly obtain a translation upon a request for inspection (while also allowing access to the original as a check)? The use of “available” rather than “kept” or “maintained” suggests that it may; so, by contrast, does the reference in 15 U.S.C. § 2063(g)(2) to certificates being “in” English. And allowing this option would reduce cost, as some manufacturers maintain records at the manufacturing facilities in local languages. The Commission should confirm that this practice would comply with the rules.
3. Third, the Commission should clarify the relationship between the requirement to maintain records and the proposed rule’s treatment of material changes as requiring re-certification and thus as effectively creating a new product (§§ 1107.10(b)(2)(ii) & 1107.23). To simplify record-keeping requirements, the record-keeping requirement should apply “for as long as the product, *without a material change*, is in production or imported by the manufacturer plus five years.” Otherwise, manufacturers of long-running products would have to maintain records in perpetuity, which would increase costs without assisting safety or compliance.

These comments on record-keeping also apply to proposed § 1107.26.

IV. Random Sampling

Under proposed section 16CFR 1107.22 under the NPR, Commission staff seems determined to interpret the term “random sample” in section 102 of CPSIA as a single phrase, rather than as separate words, when the plain language of the statute as well as the legislative intent and history would all indicate that this was not what Congress was attempting to implement.

“*Random sample*” has a very specific statistical meaning, i.e. a sample selected from a population in a manner such that each member of the population has an equal chance of being selected. A “sample” which is “random”, on the other hand, is one which is selected in a manner having no specific pattern, purpose, organization, or structure. It is clear that as Congress was, through this requirement, attempting to address the so-called “*golden sample*” problem, it is equally clear that it had in mind the latter construction of the term, and desired only that samples be selected in such a way that: there is no overt bias in the selection process which would operate to alter the representativeness (of the entire population) of the samples so selected. In fact, adhering to the proposed sampling method would allow a manufacturer to know exactly which sample would be selected for testing because it had been previously identified which would provide even greater opportunity for golden sampling.

Beyond this subversion of Congressional intent, there are some significant negative practical consequences which arise from the Staff’s misinterpretation. These are most acute in the case of an importer who purchases product from a manufacturer and takes possession prior to importation. In such a situation, the importer has an independent obligation to certify product compliance, but does not have full visibility to and knowledge of the manufacturing process; therefore it must treat each shipment produced for it by the manufacturer as a discrete lot. If a manufacturing facility were to sample when approximately 10-20% of the lot is finished, allowing

reasonably representative units to be selected and tested in parallel with the completion of production; if a “random sample” in the strict statistical sense is required, full sampling and commencement of testing cannot generally be accomplished until 100% of the lot is completed and available to be sampled. The problems thus created are:

1. The manufacturing facility often does not have room to store large or bulky items while the full quantity is produced, sampled, and testing is conducted, which may entail a period of weeks; and
2. If a test failure occurs, the amount of product which must be destroyed or reworked is multiplied, creating a perverse economic incentive for tampering. In this manner, the Staff’s approach may actually increase noncompliance over alternative approaches.

The random sampling rationale and process defined in the NPR also does not recognize variations in production processes or that such requirements are not realistically achievable across an enormously broad swath of industries without a major restructuring of many companies’ supply chain processes. Specifically, it assumes that all production is either non stop serialized product permitting continuous sampling or, non existent between re-test dates; It defines ‘*population*’ as the number of products manufactured or imported after initial certification of a product (which erroneously assumes that manufacturers know in advance exactly how many items they will produce over multiple production runs so that they could randomly assign numbers ahead of time for items to be pulled for testing); and, the proposed process does not recognize that testing methods at the labs require more than 1 sample so you cannot simply “*test the samples as they become available instead of waiting until all random samples have been selected.*” Sometimes large quantities of samples are required depending on the test requirements¹.

This approach presents a logistical nightmare in that it is not practicable to sample uniquely identified products on multiple lines and then store those samples until the number needed for testing 6 months later are available for a particular item.

In addition, such flexibility is sorely needed for batch based importers who may simply be buying product from overseas manufacturers and don’t possess the ability to sample from production runs. It should be clearly set forth that the alternate test rule is intended to provide flexibility and a benefit to manufacturers that directly or indirectly control their production processes and not as an additional requirement to importers of aggregated production batched for shipment into U.S. Jurisdiction, who can continue to test representative sample from shipments prior to U.S. import.

Throughout the Proposed Rule, and in most previous guidance documents or interpretations, CPSC has clearly stated that manufacturers “*may develop the scope and details of their reasonable testing program based on knowledge and expertise regarding their product and its manufacturing processes*” (pg. 28345 in preamble). We simply request that this logic be carried through to the sampling aspects of permitted alternate test programs. As CPSC has acknowledged there is no ‘one size fits all’ test program and there is not a single sampling plan that will work for everyone. Manufacturers, as part of their reasonable testing programs, should be allowed to define their sampling plans and rationales based upon customary practice for

¹ See Appendix 1.

particular products. These targeted sampling plans will be more effective than a blanket plan that attempts to target all manufacturing scenarios.

V. **Undue Influence (§ 1107.24)**

Since the term "undue" is not defined, nothing herein should be construed as prohibiting a manufacturer from exercising its customary and reasonable right to challenge erroneous test results based upon a belief that they are inaccurate. Such rights should be expressly distinguished from exercising undue influence.

The procedures that this provision requires would impose administrative burdens that exceed what is necessary to accomplish the statutory mandate of simply establishing protocols and standards "for safeguarding against" the exercise of undue influence on a third-party body. 15 U.S.C. § 2063(d)(2)(B). In particular, the requirements of annual training and signing of statements (which a company must in turn retain pursuant to § 1107.26) add substantial administrative burdens without materially adding to the effectiveness that a required minimum consisting of a written policy statement (§ 1107.24(b)(1)) and the notifications mentioned in proposed § 1107.24(b)(2)&(3) would accomplish. In imposing its burdens, the proposed rule appears to have been written in a vacuum: It does not take into account that the bodies to be safeguarded against undue influence will already be either independent of any ownership, management, or control by a manufacturer or at least firewalled from any undue influence, 15 U.S.C. § 2063(f)(2), added by CPSIA § 102(b); *and* that these bodies will be subject to the threat of withdrawal of accreditation if they nevertheless succumb to any undue influence, *id.* § 2063(e)(1)(A). This context confirms that the proposed rule is excessive. We would recommend deleting the requirements of annual training and of signing and retention of statements.

Thank you for the opportunity to provide comments on this important rulemaking. If additional information or data is required please contact the undersigned.

Sincerely,



Ed Desmond,
Executive Vice President, External Affairs

F.B. Locker, Esq., Counsel

APPENDIX 1.

For example Item 'X' is first produced on January 5th; Samples are randomly selected and sent to the lab for third party testing; and Certification is issued by manufacturer/importer and will be in place for 6 months when the next samples will be sent to the 3rd party lab based on the re-test period established in this manufacturer's reasonable test program. Manufacturer operates on a 'pull' system where new production is scheduled based on consumer demand. Supplier has 300 unique SKUs, each operating in a supply model as shown below.

Production Week (1-52)	Production Quantity	3 rd party test samples *	Comment
1	20,000	10-50	Children's Product Certificate issued based on results of 3 rd party test report
5	12500		Reasonable Testing Program processes in place
9	7500		Reasonable Testing Program processes in place
12	9200		Reasonable Testing Program processes in place
15	12,000		Reasonable Testing Program processes in place
18	14000		Reasonable Testing Program processes in place
24	10250	10-50	Samples pulled randomly from production run for 3 rd party test and new certificate

*quantity based on product type and input from lab as to #s of samples needed to complete tests

In this scenario, a manufacturer would not know precisely in Week 1 the 'population' over the upcoming 6 months, so is not able to randomly assign which samples are to be picked. Even if the manufacturer knew the exact production numbers for those 6 months, it would be a logistical nightmare to try to sample uniquely identified products on multiple lines and then store those samples until the number needed for testing 6 months later were available for this item – not to mention for 300+ other items also produced by this factory.

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Document: CPSC-2010-0038-0043
Comment from James Reed

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General Comment

See attached file(s)

Attachments

CPSC-2010-0038-0043.1: Comment from James Reed



August 3, 2010

Office of the Secretary
U.S. Consumer Product Safety Commission
Room 820
4330 East West Highway
Bethesda, Maryland 20814

**Re: Docket Nos. CPSC-2010-0038 and CPSC-2010-0037 -
YKK Corporation of America Comments to the Consumer Product Safety
Commission ("CPSC") Regarding Proposed Rules on Certification Testing and
Labeling and Component Part Testing**

My name is Jim Reed and I am Vice President and Chief Legal Counsel to YKK Corporation of America. YKK Corporation of America is a subsidiary of YKK Corporation, a global leader in the manufacture of fasteners such as zippers, buttons, snaps and webbing. YKK operates in over 70 countries/regions around the world, including the U.S., where it has over 1,800 employees, principally at manufacturing facilities in Macon, GA, Dublin, GA, Anaheim, CA, Lawrenceburg, KY and Oxford, AL.

YKK supports the Commission's efforts to create sensible regulations to implement the objectives of the Consumer Product Safety Act ("CPSA"), as amended by the Consumer Product Safety Improvement Act ("CPSIA"). YKK is a leader in its field and is committed to creating safe products of high quality. Although YKK does not manufacture children's products, some YKK components are used in children's products sold in the U.S. Consequently, YKK has a strong interest in ensuring its products meet and exceed the requirements of the CPSIA.

As a global manufacturer of component parts, YKK has a practical view into how the proposed testing regulations will work. Because the overwhelming majority of consumer products sold in the U.S. are produced overseas, nearly all of the work necessary to ensure compliance with the regulations will also be performed overseas. Since the cost of compliance for foreign manufacturers can be relatively high while the risks associated with non-compliance can be relatively low, it is important the Commission's regulations balance the need for a high degree of assurance of compliance with the need to develop a practical regulatory structure that foreign manufacturers can and will implement.

With this in mind, YKK offers its comments to the CPSC's proposed regulations under both 16 C.F.R. § 1107, Testing and Certification of Consumer Products and 16 C.F.R. § 1109, Component Part Testing. For ease of reference, the comments presented below are organized by the relevant sections of the proposed rules.

I. 16 CFR 1107 Testing and Certification of Consumer Products

A. 1107.2 Definitions, "High Degree of Assurance," – YKK believes that manufacturers would benefit from further guidance and explanation of how to achieve a "high degree of assurance" through their testing programs. The Commission's comments accompanying the proposed regulation refer to a 95% statistical significance level as constituting a "high degree" of assurance. However, that 95% confidence threshold is not mandated by the proposed rule. Does the CPSC consider 95% confidence to be a safe harbor level? What factors would permit a manufacturer to satisfy the "high degree of assurance" requirement with a statistical significance level below 95%? Could the CPSC provide an example of a situation where a manufacturer could still achieve a high degree of assurance with less than 95% assurance?

B. 1107.10 Reasonable Testing Program for Non-Children's Products - YKK believes it would be useful if the regulations addressed situations in which a certifier or testing party, acting in good faith, may challenge test results produced by a third party testing laboratory. In its comments accompanying the proposed rule, the Commission argues against simply "re-testing" a product that fails an initial test. YKK suggests clarifying this provision to indicate that some re-testing following a failing test result may be appropriate to ensure the testing party did not perform the test incorrectly. We recognize that re-testing is complicated by the fact that the initial test sample is destroyed by the ICP test method. However, the necessary destruction under ICP also creates a problem for the manufacturer that wants to challenge a report. YKK has experienced erroneous reports from third party testing labs from time to time. Challenging test results from an ICP test method has proven to be difficult and time consuming, often taking weeks to sort out. Thus, we suggest the Commission clarify that an acceptable remediation plan could include a good faith investigation into lab test results (even those of third party labs), which could also include retesting additional samples. This accommodation seems reasonable in light of the fact the regulations ensure that most manufacturers should have reasonable testing programs in place and will have a high degree of assurance that their products are compliant before a third party test is conducted.

C. 1107.10(b)(2)(i)(A) and Certification Testing of Raw Materials – This section indicates that only finished products or component parts listed on a product specification can be submitted for certification testing. This regulation appears to limit the extent to which a party may test subcomponents or raw materials. As discussed in more detail below, raw (or base) material testing is critical to manufacturers like YKK being able to develop programs to comply with the law. Please confirm it is not the intent of the rule to limit testing to finished products and component parts in situations where testing subcomponents or raw materials are sufficient to properly assess compliance, such as with chemical content tests.

Components such as fasteners are highly customized for different uses and different customers. Apparel manufacturers require their own button design, with various colors and styles that change with the fashion season. Buttons are typically composed of three or four different subcomponents, and zippers often have seven or more different subcomponents. YKK's zipper business in China must maintain over 374,000 different zipper sku's. Our button business must maintain over 10,000 button sku's. In addition, YKK has over 578 stock colors, and creates thousands of custom colors for its customers. In short, even component manufacturers have complex products with complicated production processes.

In order for companies like YKK to consider managing reasonable testing programs or third party testing, they must be able to test the base raw materials prior to actual production. YKK's hundreds of thousands of products can be seen as different combinations of a smaller population of subcomponents and raw materials. It is through working with this smaller population of subcomponents and raw materials where manufacturers like YKK can effectively manage quality in areas such as lead levels.

YKK can and does ensure that its products meet or exceed the lead levels imposed by the CPSIA. Our products currently have less than 90 ppm lead for surface coating and less than 90 ppm lead for content. We can ensure this quality because we (a) purchase high quality raw materials from reputable sources, (b) test samples of raw materials and parts as they come into our facilities, (c) manage and monitor production to control the risk of contamination, and (d) test selected samples post production. The ability to test raw materials, including base paint colors, prior to mixing and production is critical to our ability to comply with the proposed regulations. If we can ensure every item entering the production process has less than 90 ppm lead, then we can ensure that any combination of those materials will also be less than 90 ppm lead; therefore, raw material or base material testing can be effective in managing content and surface coat quality.

On April 1, 2010, the CPSC staff issued a memo to the Commissioners stating that "some chemical tests may be performed on the raw materials used in the component part" The memo continued with a salient example of how resin may be tested in its raw form prior to entering the production process. This was valuable insight and direction, and YKK would suggest this concept be introduced and further explored in the actual language of the regulations and the commentary for further clarification.

D. 1107.22 Random Samples – YKK would like the Commission to provide more guidance on the question of random sample selection. As currently drafted, 16 C.F.R. § 1107.22 requires that all potential samples have an equal chance of being selected. However, from a practical standpoint, perfect randomness is nearly impossible to attain, given variations in product manufacturing schedules and the constraints imposed by the periodic testing requirements in the proposed rule. Such an absolute standard of randomness would not be practicable or cost effective in many manufacturing

circumstances. Thus, we believe a more reasonable and flexible approach to random sampling is warranted, one that companies can tailor to their specific products.

For example, YKK believes it would be appropriate to permit companies to apply reasonable random sampling methods within designated time periods corresponding to a product's production cycle. This approach may avoid confusion about how to maintain randomness while still meeting the time interval requirements for periodic testing. Notably, if the regulations require absolute randomness, then a periodic testing requirement that requires no less than one test every twelve months will actually require testing every six months in order to ensure the test occurs at least once every twelve months.¹ Thus, we believe the timing of random sampling should be clarified in the final rule.

E. 1107.24 Undue Influence – This section of the regulations imposes on manufacturers, importers and testing parties an obligation to provide annual training to their staff to avoid imposing undue influence on third party labs. YKK would like the Commission to consider eliminating this training obligation on manufacturers and importers, as the substantial costs associated with developing and implementing such training will likely far outweigh the benefits, particularly given the existing training requirement already imposed upon third party testing laboratories to detect, avoid and report any such pressure.

Section 14(d)(2)(B)(iv) of the CPSA states that the Commission must establish protocols and standards for avoiding the possibility of undue influence being imposed on third party labs. The Commission, however, has already addressed this by requiring third party labs to train their employees on how to recognize undue influence, avoid it and report it to the CPSC. This seems appropriate since the third party labs will be the most likely to recognize the undue influence.

Companies such as YKK have their own codes of conduct and require their employees to follow the law and not engage in unethical behavior such as exerting undue influence on testing labs. To impose an additional training obligation on both sides of the manufacturer/third party lab relationship seems redundant. The third party lab technicians are already trained on the issue, their accreditation depends on their compliance, and they will be a better barometer of such undue influence than the party alleged to have imposed undue influence. We believe this issue is adequately addressed in the third party lab certification regulations and need not be repeated here

¹ If absolute randomness is required, then manufacturers would not be able to schedule periodic testing, the date of periodic testing will be selected randomly any time during the period. If the intent is to have annual periodic tests, then the manufacturer will actually need to conduct tests once every six months to ensure the necessary test is conducted at least once in the twelve month time frame. For example, if a manufacturer requires complete randomness to select the date of an annual periodic test, then the manufacturer risks the interval between tests actually being the first day of Year 1, and the last day of Year 2; or, the last day of Year 1 and the first day of Year 2. Therefore, the potential time period between "periodic" tests could be as long as 729 days or as little as 1 day.

where the sizeable implementation costs spread across the global supply chain are excessive.

F. 1107.26 Recordkeeping (also, 1109.5(i) Recordkeeping for Component Parts) –

The recordkeeping requirements of the proposed regulations require that all test data, production plans, remediation plans, test results and remediation results be maintained in the English language. YKK feels this requirement may be overbroad, unnecessarily expensive and potentially dangerous. YKK understands the need for the CPSC to quickly determine the source of a potentially dangerous situation, however, it seems more appropriate to require all relevant data be translated into English at the manufacturer's or importer's expense when the CPSC conducts an investigation or otherwise requires documentation.

It is likely the overwhelming majority of all consumer products sold in the U.S. will be manufactured, tested and certified in non-English speaking countries. As currently drafted, the proposed rule will require millions of test reports and records be created and maintained in English, even though only a small fraction of a percent of these test reports will ever be reviewed by the CPSC or other third parties. Requiring that all testing and reasonable testing program documentation be created in English is extremely expensive for the manufacturer because they must find and hire English speaking technicians to perform the testing. More importantly, this requirement is potentially hazardous. For example, a quality assurance technician in Vietnam may be excellent at maintaining the quality of a product, and she may even have a passable grasp of English, but her English skills may not be sufficient to communicate precise technical findings in English. If she is nonetheless required to record her findings in English, then there is a risk the test results will be transcribed, described and maintained inaccurately. Thus, we ask that the Commission reconsider this English-only requirement in the proposed rule.

II. 16 CFR 1109 Conditions and Requirements for Testing Component Parts of Consumer Products

A. 1109.4(c) Component Part Certifier vs. 1109.4(k) Testing Party – From YKK's reading of the definitions and the requirements imposed on a component part certifier and a testing party, there does not appear to be any material difference between the two with respect to their testing and reporting duties. The testing party and the component part certifier both appear to be required to provide the finished product certifier essentially the same data in the same format. Thus, the only significant difference between a component part certifier and a testing party appears to be that a certifier assumes legal liability under the law and a testing party does not. What additional benefits would component part certifiers expect to receive for taking on the additional liabilities? What kinds of enforcement actions, if any, would a testing party be subject to if it failed to comply with the reporting and recordkeeping requirements

described in the proposed rules? It would be helpful if the regulations more specifically defined and differentiated the roles and duties of these two actors.

B. 1109.4(g) Component Part Certifier – Those working under the component part certification regulations would greatly benefit from a more detailed explanation of how a component part supplier assumes the role of a “component part certifier.” Since the word “certify” or “certification” is so prevalent in business communications in a variety of different contexts, it would be quite simple for a component part supplier to inadvertently be deemed a component part certifier when it was not its intention to become one.

The CPSIA and the rules around product certification have created new and important responsibilities for “certifiers,” which adds additional weight to the verb “to certify.” Industries such as the apparel industry have relied heavily for decades on certifications of compliance from vendors. Following enactment of the CPSIA, however, the term “certification” now carries significantly more weight. Consequently, there is much confusion in the marketplace as to what “certification” means in various contexts. For example, many purchase orders and standard terms and conditions in contracts and supply agreements continue to include boilerplate language referencing “certification,” but without an express reference to CPSIA compliance.

In order to avoid confusion in the marketplace, and to further support the voluntary aspect of the roles played by component part certifiers and testing parties, YKK suggests that the proposed rule be clarified to require any party seeking to be a component part certifier under 16 C.F.R. § 1109.5(g), or a testing party under 16 C.F.R. § 1109.5(k), to specifically state in writing that it is providing a certification or testing data as a certifier or testing party (as the case may be) under those regulations. Given the voluntary nature of the component part certifier and testing party roles, a component part supplier should not be compelled to act in either of those roles without expressly stating its intention in writing to assume the accompanying obligations under those specific regulations. Thus, we believe the proposed rules should be clarified to include the threshold actions a supplier should take to declare themselves a component part certifier or a testing party under the regulations.

C. 1109.4(m) Traceability and Subcomponents – The traceability requirements under the proposed component part testing rule will strengthen efforts to promote compliance. There remains, however, some ambiguity as to what constitutes a “manufacturer” under this provision. Many components are actually assemblies of several subcomponents. As stated above, zippers and buttons are components constructed from several subcomponents. YKK makes most of its own subassemblies for its components. Thousands of other smaller component “manufacturers,” however, are more accurately described as component “assemblers.” These “manufacturers” source subcomponents from various other manufacturers and assemble them. A zipper “manufacturer,” for example, may obtain sliders from one provider and zipper chain from another supplier. In order to confirm compliance and trace the components to their source, YKK suggests

the traceability requirement continue through the supply chain to subcomponent manufacturers, otherwise, the CPSC risks a break in the chain of accountability for the component.

D. 1109.4(m) Traceability - Component parts from various suppliers can be commingled prior to their introduction into the finished product. YKK recommends that the regulations surrounding traceability require manufacturers to maintain the integrity of different batches of components in the production process.

Notably, finished product manufacturers may receive discrete component shipments, but the shipments may be commingled with similar components from other sources ordered at different times. Since components generally do not carry identifying manufacturing data, the CPSC's requirement for traceability will be better understood if the traceability requirements specifically included instruction to maintain inventories in a way to avoid commingling components from different sources, or even commingled components ordered from the same source at different times. Commingling can threaten the integrity of component testing as a viable alternative testing procedure. Mixing a batch of non-compliant components with a batch of compliant components contaminates the entire lot without any way to sort them out again. The CPSC can discourage this from happening by requiring finished product manufacturers to manage their component inventories in ways that will avoid the use of commingled lots in a single finished production lot.

E. 1109.5(c) Test Method and Sampling Protocol – This rule requires component part certifiers and testing parties to "use the sampling protocols and test methods required under Section 1107." This appears from our reading to leave some ambiguity as to which specific aspects of an 1107 reasonable testing program such testers must maintain and which ones are not necessary.

It would be very useful for the CPSC to specify in this rule what aspects of the reasonable testing program under 1107 are required of a component part testing party. A reader may infer 1109.5(c) requires a testing party to maintain all aspects of a reasonable testing program, including the recordkeeping and reporting requirements. Section 1109, however, has its own recordkeeping requirements for testing parties, as well as its own disclosure/reporting requirements; therefore, it seems that there is some difference in what is required under 1107 and what is required under 1109. Clarity around this is most important to understand what aspects of a reasonable testing program a component part certifier or a component part testing party must have in place to properly provide certifications or test reports (as the case may be) to finished product manufacturers.

F. 1109.5(f)(7) Documentation by Testing Party – (Certification?) – This provision seems to require a testing party to "certify" that third party testing results meet the

requirements of Section 14 of the CPSA. Thus, it appears to conflict with other provisions in the proposed rule that establish testing parties as entities that conduct proper testing, but do not have to "certify" under the CPSA. This provision, therefore, causes some confusion on the extent to which a testing party is required to "certify." Additional clarity regarding the intent of this provision would be useful to better understand the level of "certification" a testing party must make.

G. 1109.11(a) Component Part Testing for Paint and Other Surface Coatings – Generally – Manufacturers do not just deal with single paints of a specific color. Many, like YKK, purchase base colors and mix them to create a specific color required for a specific product. YKK offers 578 stock colors, and develops thousands of custom colors each year for its customers. It would be impossible for manufacturers like YKK to test every mixed color it uses to paint its products. Just like raw material testing, it is important for all testing parties to be able to test base colors prior to them being mixed in the production process.

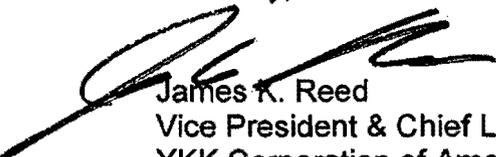
YKK only purchases base paints that contain less than 90 ppm of lead. As a result, YKK can ensure that no matter what the paint mix is, it will not exceed 90 ppm of lead. YKK also engages in internal testing to ensure the quality of those base paints. Finally, YKK ensures the paint is not contaminated in the production process. It would be useful; therefore, if the rules could specifically recognize that base paint testing under a controlled production process is acceptable under the paint testing regulations.

Also, this section appears to address paints as if they are components of a finished product. Components such as fasteners are also painted, so it would be useful if the surface coating rules applied equally to component parts and finished products. Similar issues of consistent application pertain to lead content testing for components and component part certificates under 1109.12(c) and 1109.13.

H. 1109.11(b) Test Reports – This rule indicates that a test report for paint must be commissioned by the finished product certifier. As stated above, however, components must also be painted. If it is the Commission's intent that paint on component parts be treated the same as paint on finished products, then we suggest that the proposed rule be revised to permit others, such as component part certifiers or testing parties, to commission test reports as well.

Thank you for the opportunity to comment.

Sincerely,



James K. Reed
Vice President & Chief Legal Counsel
YKK Corporation of America

PUBLIC SUBMISSION

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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

Document: CPSC-2010-0038-0044
Comment from Kim Mann

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General Comment

See the attached Comment of the Glass Association of North America. A supplemental filing may be made within the next 10 days on behalf of GANA.

Attachments

CPSC-2010-0038-0044.1: Comment from Kim Mann

BEFORE THE U.S. CONSUMER PRODUCT SAFETY COMMISSION

CPSC Docket No. CPSC-2010-0038

**16 CFR PART 1107, TESTING AND LABELING
PERTAINING TO PRODUCT CERTIFICATION**

COMMENTS OF THE GLASS ASSOCIATION OF NORTH AMERICA

The Glass Association of North America (“GANA”) submits these comments in response to the notice of the Consumer Product Safety Commission (“CPSC”) for proposed rulemaking, published in the *Federal Register* of May 20, 2010, 75 *Fed. Reg.* 28335 (May 20, 2010), proposing to establish requirements for reasonable testing programs for consumer products. GANA’s interest in this rulemaking proceeding is confined to those proposals applicable to nonchildren’s products, specifically to architectural glazing materials.

I. BACKGROUND

GANA is a nationwide trade association, based in Topeka, KS, representing the architectural glass and glazing industry. It has approximately 400 member companies engaged in the manufacture, fabrication, and installation of glass and glazing products for commercial and residential building applications. Its members’ glass and glazing materials, when installed in defined hazardous locations, are subject to the requirements of the CPSC’s safety standard for architectural glazing materials, codified at 16 CFR Part 1201, promulgated in January 1977. The industry’s primary glazing materials used for building installations subject to CPSC jurisdiction – doors and shower/tub enclosures – are tempered, laminated, and mirror (organic coated) glass (collectively, “safety glazing materials” or “safety glass”).

II. SUMMARY OF POSITION

GANNA readily acknowledges that Congress directs CPSC to act for the perceived safety interests of all consumers and, in this rulemaking proceeding, deserves credit for its well intentioned and generally carefully thought-out efforts to formulate guidelines for testing consumer products to accomplish this goal while, at the same time, without overburdening manufacturers. That formidable balancing act may in practice prove to be unachievable and inherently counter-productive in some instances, given the approach CPSC proposes to take in this proceeding. The proposed testing guidelines, framed as "requirements," will apply across the board to all consumer products subject to CPSC safety standards and will preempt all non-conforming existing "reasonable testing programs" of industries with consumer products, such as safety glazing materials, not subject to existing specific requirements for reasonable testing built into their safety standards. *75 Fed. Reg.* at 28344-45.

Most industry-developed testing programs, including the one for architectural glazing materials, have been crafted to accommodate the unique properties of the industry's consumer product and the unique processes by which it is manufactured. By discarding, without a product-by-product analysis, all existing reasonable testing programs of all industries, CPSC forces each industry to jam its unique product and manufacturing process into the rigid framework of the proposed testing program of Part 1107, despite claims of flexibility. Not all elements of the proposed reasonable testing program requirements will neatly fit all products or processes. As a result, CPSC stands to harm some manufacturers unnecessarily and unintentionally without improving the safety of their consumer products. Architectural glazing

materials manufacturing is just such an industry: its safety glazing materials do not fit comfortably within the proposed parameters of the reasonable testing program that CPSC seeks to prescribe in § 1107.4. Some additional flexibility is needed in the final rule in order to avoid substantial harm to many safety glazing fabricators.

Manufacturers of architectural glazing materials have, since January 1977, produced safety glazing materials meeting the 16 CFR 1201 safety standard, successfully certifying their compliance based upon industry-accepted and -devised “reasonable testing programs” established free from CPSC-set criteria. The general practice in the industry has been for most high-volume producers to rely upon third-party testing, administered through an independent testing organization, to satisfy the manufacturers’ obligations to certify based upon a “reasonable testing program.” Neither CPSC nor any other regulatory entity has ever expressed any concerns about the adequacy or appropriateness of these proven third-party or other customized glazing-industry testing and certification programs.¹⁴

Accepting CPSC’s determination, in the exercise of its discretion, to supersede the safety glazing industry’s long-established, reasonable testing program protocol with prescribed minimum requirements applicable to all testing programs for nonchildren’s consumer products, GANA finds encouraging and must applaud and fully support CPSC’s stated underlying objective and intent, repeated throughout its May 20, 2010 notice, to adopt reasonable testing program requirements that are flexible at their core:

¹⁴ See GANA Comments submitted January 11, 2010 in Docket No. CPSC-2009-0095.

[The proposed reasonable testing program] is designed to be scalable to production volumes and adaptable to the specifics of the product. A manufacturer may develop the scope and details of each element of a reasonable testing program based upon the manufacturer's knowledge and expertise regarding the product and its manufacturing processes.]

75 *Fed. Reg.* at 28345.

This commitment to flexibility, while admirable and most apparent in the loose phrasing of proposed § 1107.10(b)(3), leaving it up to each manufacturer to develop its own "Production Testing Plan," falls short of its promise. Unless modified as GANA requests below, the proposed testing program will – unnecessarily in GANA's view – compel the safety glazing industry significantly to revise its own accepted, proven reasonable testing program protocol. It will alter the type and nature and increase the frequency and cost of testing safety glazing materials, unnecessarily driving up the costs of production and, therefore the price, of these consumer products.

This promised flexibility begins to unravel at a critical juncture: the reasonable testing program requirements, as proposed, would not allow the manufacturer to rely upon successful production testing as the basis for resumption of glass production following adjustments in the operation of the manufacturing equipment undertaken to remedy a product test failure. This inflexibility is inconsistent with CPSC's express recognition that manufacturers may rely upon alternative testing during the production testing phase as long as the alternative tests are equally effective in detecting noncompliant products as certification testing. See 75 *Fed. Reg.* at 28346; proposed § 1170.10(b)(3)(iii)(A), (B).

For the reasons explained in GANA's comments below, GANA respectfully requests CPSC to modify its proposed regulations by eliminating from § 1107.10(b)(4)(ii) the requirement that manufacturers engage in another round of certification testing as a condition to resuming production when, pursuant to the manufacturer's remedial action plan, the manufacturer merely makes adjustments in its manufacturing-process equipment to remedy the cause of the test failure. Production testing should, in those circumstances, suffice.

GANa also clarifies that, within the safety glazing industry, constant adjustments to the manufacturing equipment at the initiation of and during the course of the manufacturing process are not deemed to constitute "material changes" for purposes of § 1107.10(b)(2)(ii).

GANa also urges CPSC to commence enforcement of the new reasonable testing program regulations no sooner than 12 months from the date CPSC publishes its final rule in the *Federal Register*. If CPSC adopts the new regulations as proposed, the safety glazing industry will require an additional 180 days, beyond the 180 days proposed, to implement the new reasonable testing program, including the acquisition of the specialized testing frame and related apparatus that certification testing requires each time a safety glazing manufacturer encounters a test failure during production testing.

III. GANA SPECIFIC COMMENTS ON PROPOSED PROVISIONS

To lend context to the safety glazing industry's principal concern about compliance with the proposed reasonable testing program requirements, a concern permeating three of the five elements – the "remedial action plan," "production testing plan," and "certification testing" – it is necessary to analyze the testing requirements that CPSC imposes upon manufacturers of

architectural glazing materials in 16 CFR Part 1201 and how they would apply to the proposed 16 CFR Part 1170 requirements and to review generally pertinent aspects of the safety glass-making process.

To engage in "certification testing" as CPSC proposes to define that concept, manufacturers of safety glazing materials not participating in a third-party testing program would have to build or acquire for each of their facilities a complex testing apparatus consisting of an impact test frame and subframe meeting the precise specifications set forth in 16 CFR § 1201.4(b), purchase a supply of a special type of leather punching bag, fill the punching bag with 100 pounds of lead shot, load the shot-filled bag impactor into the pendulum harness on the apparatus frame, and calibrate the mechanism to deliver the required impact forces, either 400 foot-lbs. or 150 foot-lbs. of energy. Each complete testing apparatus costs between \$25,000 and \$35,000 to build and an additional \$3,000 to \$5,000 annually to maintain.

The CPSC safety standard for architectural glass, 16 CFR § 1201.4(c)(2), requires the "samples" of laminated and tempered glass, if intended for use for certification testing in accordance with proposed § 1107.10(b)(2)(i), to be glass lites either 34" x 76" or, if the manufacturer does not make safety glass in sizes that large, the largest size it does produce. These "samples" are not likely to be randomly selected because most safety glazing materials fabricators do not ordinarily make production runs of glass in 34" x 76" dimensions although their equipment may be physically capable of doing so. The specimens produced for certification testing would have to represent every materially different type of safety glazing product that the manufacturer anticipates producing, in the largest size it manufactures, up to 34" x 76."

The plant equipment used to fabricate laminated, tempered, and mirror (organic coated) glass differs fundamentally from one safety glazing material to another, and each of their fabrication processes is also entirely different. Despite these basic differences, the oven, press roller, and autoclave (for producing laminated glass), the furnace (for producing tempered glass), and the cure oven, coating machine, and rollers (for producing mirror) all require dozens of minute adjustments, especially the autoclave, oven, and furnace temperatures, in order to produce quality safety glazing materials consistently meeting the standards set forth in 16 CFR Part 1201. During the production of safety glazing materials, manufacturers monitor a number of variable conditions – ambient temperature, plant humidity, water purity, airborne particles, coating thickness, equipment operation, etc. – that could adversely affect the quality of the glass or mirror batch and its performance as a safety glazing material. As these conditions change over time during the production day, the manufacturer constantly adjusts its oven, autoclave, or furnace temperature settings and other quality control instruments integral to the fabrication process in order to ensure the safety glazing materials coming off the end of the line continue to be quality product meeting the safety requirements of the CPSC standard, 16 CFR Part 1201, as well as customer specifications.

A. Equipment Adjustments to Remedy Test Failures Should Not Require New Certification Testing.

No element of a safety glazing fabricator's reasonable testing program should require the fabricator to successfully complete certification testing before resuming production each time it conducts an in-plant product test on a lite of safety glass and determines the resulting break pattern does not satisfy

the safety criteria specified in 16 CFR § 1201.4(e). The standard practice in the safety glazing industry today is, and has been for decades, to address these test failures, normally surfacing during quality assurance procedures most safety glass producers implement to evaluate break patterns, through minor adjustments in the oven, autoclave, or furnace temperatures. These standard adjustments would, under CPSC's proposed reasonable testing program requirements, become part of the manufacturer's remedial action plan and would, unless CPSC modifies § 1107.10(b)(4)(ii) as GANA requests below, require the manufacturer to issue a new product specification based upon successfully passing another round of certification testing.

Forced certification testing under these circumstances, with its mandatory use of the cumbersome testing apparatus specified in 16 CFR § 1201.4(b), would be inefficient, uneconomical, and, more importantly, unnecessary. Adjustments to the furnace, oven, autoclave, or other manufacturing equipment should not be classified as "material changes" in the manufacturing process for the reasons discussed below in Part III(B) below. Moreover, the safety glass fabricator's manufacturing process itself does not really change; rather, the operation of the equipment used in that process is fine-tuned or adjusted as necessary to prevent a recurrence of the manufacturing condition that caused the glass sample to break improperly, *i.e.* not meet the criteria set forth in 16 CFR § 1201.4(e) to evaluate the break pattern and assess compliance with the safety standard.

Requested change: CPSC should modify its proposed remedial action plan requirements by adding the following sentence at the end of § 1107.10(b)(4)(ii), after the second sentence: "Adjustments in the equipment or machinery to affect the product's ability to comply with any applicable rules or

standards shall not be considered a 'material change' in the manufacturing process for purposes of this subparagraph (b)(4)(ii), but will require the manufacturer, following those adjustments, to subject the product to its production testing plan and to achieve passing production test results before the manufacturer may resume production of that product."

This additional sentence would in effect relieve the majority of safety glazing materials manufacturers of certification testing obligations once the manufacturer detects a production test failure, subjecting the manufacturer instead to less onerous, less expensive, more efficient production testing, as long as the manufacturer does not alter its glass "design," components, or components supplier in order to correct the cause of that failure and achieve compliance with 16 CFR Part 1201.

Mandating certification testing following a production test failure would either inordinately delay resumption of glass production or require a significant majority of safety glazing materials manufacturers to spend tens of thousands of dollars each to acquire the test frames and other testing apparatus specified in 16 CFR § 1201.4(b) necessary to equip each fabrication plant to conduct certification testing. Most do not possess this testing equipment today. Instead, most safety glass producers currently participate in a voluntary third-party testing program administered by the Safety Glazing Certification Council ("SGCC"), a widely recognized non-profit organization that has since 1971 provided certification of safety glazing materials for the industry. SGCC in effect performs for the safety glazing materials fabricator electing to participate in SGCC's program what CPSC proposes to call "certification testing." SGCC approves the test apparatus of the SGCC designated third-party laboratory

which, in turn, performs the certification testing for the glass fabricator to support the fabricator's certification of compliance with 16 CFR Part 1201.

As part of its quality assurance program, to become part of its production testing plan under the proposed CPSC regulation, the SGCC-participant fabricator relies upon simplified, easy-to-administer, in-plant alternative tests that produce test results as effective in detecting noncompliant glass as the test frame and impactor prescribed in 16 CFR § 1201.4(b). These alternative tests – the center-punch test for tempered glass and the drop-ball and/or pummel tests for laminated glass – are conducted very quickly and inexpensively in the plant. If required, however, to perform certification testing before resuming production post-test failure, the SGCC participant would have no practical choice but to spend upwards of \$35,000 to acquire a test frame and related apparatus specified in 16 CFR § 1201.4(b) for each plant it operates – and many laminators and temperers operate multiple plants – because of the total commercial impracticality of shipping samples to SGCC designated laboratories to conduct certification testing following each equipment adjustment. They simply can not wait months or even weeks to get back in operation.²¹

Because these alternative safety tests, regularly used throughout the industry as part of the safety glass fabricator's "production testing plan," have been demonstrated to produce test results as effective in detecting noncompliant glass as the cumbersome, expensive test frame apparatus specified in 16 CFR § 1201.4(b), no practical, technical, or safety-related reason exists for requiring the fabricator to engage in certification testing as a

²¹ The unintended consequence of forcing the mass purchases of CPSC impactors may be to undercut the industry's use of independent third-party testing.

condition to resuming safety glass production – as long as the only “change” the fabricator makes, post-test failure, to correct the condition causing the test failure and to produce fully compliant glass again is to adjust the manufacturing equipment’s operation used in the manufacturing process.

B. The Safety Glazing Industry Does Not Construe Equipment Adjustments as “Material Changes.”

Safety glazing materials manufacturers as an industry have never considered the countless, continuous adjustments and fine-tuning occurring on an on-going basis during the manufacturing process as “material changes,” as CPSC proposes to define that term in § 1107.10(b)(2)(ii).^{3L} “Material changes” would trigger the proposed requirement in § 1107.10(b)(2)(ii)(B) for another round of certification testing. Consistent with industry’s understanding, GANA believes CPSC does not intend to classify these fluid, continuous equipment adjustments as the type of changes in the manufacturing process – even if deemed changes in that process – that should require certification testing even though arguably they may be designed to “affect the product’s ability to comply with the applicable ... standards,” namely to prevent altering the condition of the glass to the point that it would or might no longer meet the impact safety test requirements of 16 CFR Part 1201.

The safety glazing industry believes it is self-evident that mere adjustments in the manufacturing equipment – for example, adjusting furnace or oven temperatures in response to fluctuations in ambient air temperature – are not “material changes.” Otherwise, manufacturers of safety glazing materials would have to engage in incessant “certification testing” under

^{3L} GANA suggests CPSC shift this definition of “material change” to § 1170.2, **Definitions**, the location in the proposed regulations where the user would expect to find the definition of such a critical term.

proposed § 1107.10(b)(2)(ii)(B). Safety glazing manufacturers faced with certification testing would be required to shut down their manufacturing lines every time they made a minute “process” adjustment and to cease production until they successfully passed another certification or production test. For laminators, that would mean a production shut-down of at least five hours, the length of time needed to manufacture and “cure” a test specimen of laminated glass for certification testing. For mirror producers, that would require them to subject 15 mirror test specimens to 1,200 hours of accelerated weathering testing using the carbon arc, as required in 16 CFR 1201.4(d)(2)(ii). These patently absurd results would quickly drive up the cost of production and, therefore, the price of the finished laminated-glass and mirror product to the point that neither could compete with other glazing materials or substitute in-fill materials in the marketplace. It would be enough to put many laminated glass manufacturers out of business.

C. The Enforcement Date Should Be One Year From Publication of the Final Rule.

CPSC proposes to allow manufacturers only 180 days to comply with the new reasonable testing program requirements once they become final and the regulations are published in the *Federal Register*. That is not enough time for safety glazing materials fabricators to make the necessary revisions in their existing reasonable testing programs, especially if CPSC declines to modify proposed § 1107.10(b)(4)(ii) as GANA requests so as to permit production testing in lieu of certification testing as part of the fabricator’s remedial action plan to address test failures through adjustments in the fabricator’s autoclave, oven, or furnace. The glass industry will need an additional 180 days, a full year in total, to comply.

For most safety glazing materials fabricators the remedial action plans and recordkeeping requirements as proposed in new § 1107.10 go far beyond what they as fabricators are currently doing or are required to do. Compliance will require them to institute substantial, fundamental changes, including setting up new systems for tracking testing and keeping records, if the final version of the new rules is essentially the same as the one proposed.

The most significant factor driving the need for the additional 180 days is the lack of 16 CFR Part 1201-style impactor test frames and related testing apparatus at most plants of companies participating in the SGCC third-party certification program. These companies do not conduct certification testing in-house and, therefore, do not possess the necessary testing equipment to do so. They rely upon SGCC for that testing, but will not be able to continue to do so if the proposed remedial action plan regulation is not modified as GANA requests in Part III(A) of these Comments. If CPSC insists on certification testing following each test failure as part of the glass fabricator's reasonable testing program, every fabricator will have to acquire this specialized testing equipment for each plant it operates because the proposed regulation requires a certification test with the 16 CFR 1201 prescribed impactor. These frames must be custom-built from scratch and are very expensive – between \$25,000 and \$35,000 each. The particular leather punching bags prescribed in 16 CFR § 1201.4 are difficult to find, at least in the quantities the glass industry would require, and may have to be specially manufactured. And plant workers must be specially trained to perform the testing in accordance with 16 CFR § 1201.4, a very technically challenging undertaking except for experienced lab technicians.

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Testing and Labeling Pertaining to Product Certification

Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

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Comment from Michael Gidding

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General Comment

Please see the attached letter commenting on the proposed CPSC testing and certification rules

Attachments

CPSC-2010-0038-0045.1: Comment from Michael Gidding

August 3, 2010

**VIA E-MAIL AND
FIRST CLASS MAIL**

Office of the Secretary
Room 502
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

***Comments: Testing and Certification Rule
Docket No. CPSC 2010-0038***

On behalf of American Honda Motor Company, Inc. (Honda), I submit the following comment on the proposed rule establishing testing and certification requirements for consumer products subject to regulations that the Commission administers.

Proposed 16 CFR 1107.10(b)(5) establishes requirements for keeping records relating to the testing and certification of regulated consumer products. Proposed 16 CFR 1107.10(b)(5)(iii) would require that all such records be maintained in the United States. However, ISO 9001 requires manufacturers to maintain these types of records at the factory where a product subject to certification was manufactured. See ISO 9001:2008 (E) (4th ed.) section 4.2.4; see also, *id.*, at 7.1, 7.2.2, 7.3.2, 7.5.2, 7.6, 8.2.2, & 8.2.4. Rather than requiring foreign manufacturers to maintain duplicative and redundant records in the United States, the final rule should harmonize the Commission requirements with those of ISO.

The final rule should allow foreign manufacturers certified to ISO 9001 that have a corporate subsidiary or other substantial corporate presence in the United States to maintain these records solely at the place of manufacture. It should also require that those records be made available to the Commission for inspection, either in hard copy or electronically, through the U.S. subsidiary or other U.S. corporate entity within a reasonable time after the agency makes a request for them pursuant to section 16(b) of the Consumer Product Safety Act.

I appreciate the opportunity to comment on behalf of Honda. Please

contact me if you need additional information or if I can clarify these comments in any way.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Michael J. Gidding". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael J. Gidding
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Comment On: CPSC-2010-0038-0001
Testing and Labeling Pertaining to Product Certification

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Comment from Jim Neill

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General Comment

See attached file(s)

Attachments

CPSC-2010-0038-0046.1: Comment from Jim Neill



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August 3, 2010

Office of the Secretary
U.S. Consumer Product Safety Commission
Room 502
4330 East West Highway
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Re: Reasonable Testing Program (Docket No. CPSC-2010-0038)

Dear Secretary Stevenson:

The Retail Leaders Industry Association (RILA) appreciates the opportunity to offer comment on the Proposed Rule (16 CFR Part 1107) Testing and Labeling Pertaining to Product Certification. The members of RILA also want to thank commission staff for the meeting on June 1st, where the proposed rule was discussed.

By way of background, RILA promotes consumer choice and economic freedom through public policy and industry operational excellence. Our members include the largest and fastest growing companies in the retail industry--retailers, product manufacturers, and service suppliers--which together account for more than \$1.5 trillion in annual sales. RILA members provide millions of jobs and operate more than 100,000 stores, manufacturing facilities and distribution centers domestically and abroad.

RILA members are committed to placing the highest priority on the safety and quality of the products they sell to their customers.

STATEMENT OF IMPACT

I. IMPACT TO U.S. CONSUMERS

Every impact to retail has either a direct or indirect impact to consumers. RILA's commitment to and high priority on product safety is an important part of our relationship with the customer. The trust placed in retailers by guests in our stores is based on the expectation that the products offer good value. Good value encompasses two factors: safety AND affordability. As the recent economic challenges continue to be felt in the pocketbooks of our customers, CPSC must exercise care and deliberation in applying regulatory schemes such as testing, certification and recordkeeping that will dramatically increase the prices of products on store shelves without meaningfully increasing consumer safety. We implore the CPSC to consider the reduction in risk, if any, associated with each regulatory requirement

and impose only those that meaningfully enhance consumer safety in a way that makes increased cost and use of resources worthwhile.

II. IMPACT TO U.S. RETAILERS

The provisions of the proposed rule will not only affect individual U.S.-based companies as importers-of-record, they will affect tens of thousands of companies world-wide and hundreds of thousands of people.

As an example – within a given year, a major retailer currently works with over 1,500 direct suppliers who in-turn use over 4,500 manufacturing locations to produce products subject to CPSC enforcement. Over the course of the 5 years required for document retention, the total number of individual locations is over 10,000 in over 20 countries. Over 150,000 import purchase orders may be written in the average year for over 300,000 unique products. The number of individual production lots to support this diversity of product is estimated in the tens of millions, and retail units sold is in the billions.

The proposed provision having the largest immediate impact to the retail industry would be the record keeping requirements listed in §1107.10 paragraph 5 and §1107.26.

To meet the proposed provisions, a process to centrally maintain records for an estimated 300,000 items per year would need to be created. In addition, a method for making documents available in English in the United States would need to be scoped and created.

An estimate for the number of pages of documentation covering a portion of products for one large general merchandise retailer acting as importer of record would range from a low of 375,000,000 pages to over 1,000,000,000 pages per year.

An estimated set of records for each item would be based on the following requirements:

Full Specification - 150 to 200 pages

Certification Testing – 30 to 100 pages

Records for Production Testing Plan – 1000 to 3000 pages

This would include, but is not limited to:

- Inspection records
- Testing Documents
- Production Plans
- Quality Control and Process Documents

Periodic Testing – 50 to 200 pages

Records of Remedial action, if needed, would only add to the document count.

Moreover, training world-wide personnel to produce documents in English and / or creating dual language documents and implementing them through a world-wide supply chain would be unduly burdensome. In addition, we believe the requirement to have English language documents available within the United States does not offer additional confidence in product safety for U.S. consumers.

Current State

RILA asserts that its members are meeting the regulatory requirements for safe product now. However, the proposed rule for Testing and Labeling Pertaining to Product Certification mandates a formal structure for documents that is substantially different than existing processes, which have historically relied on a variety of solutions and record keeping languages and locations to achieve this compliant product.

RILA's members do not have current solutions to collect, capture, retain, file, and systematically make available for retrieval in the United States, the scope of documents required.

Currently, many documents resulting from individual production testing plans are created by and stored at the manufacturing site. Coalescing this information from its current locations and translating it from local languages in the highly-prescriptive format required by the rule will require extensive time, person power, and outlay of capital to purchase and develop electronic document storage systems.

Companies with existing electronic document storage systems for their teams responsible for product compliance will have to enhance those IT systems to accommodate these recordkeeping requirements. This includes the creation of an electronic library system with codes and views that can be accessed globally and by external vendors, filtered and sorted and represents a substantial cost for hardware, software, personnel and training. RILA members have estimated costs for basic infrastructure for enhanced systems could range from \$500,000 - \$3 million.

For companies that do not already have an established global product management tool with vendor access and security in place, the cost will be even higher in order to build electronic record-maintenance systems from the beginning level. In addition, companies must develop and execute training of global sourcing and vendor partners, including the development of appropriate templates that capture the data needed and can be easily translated into English.

Timing

For most major retailers the creation of a product beginning with a design specification originates 12 months or more prior to manufacture, import into the United States and retail sale. Retroactively applying all requirements of the proposed rule would be unduly burdensome. Compliant products currently on retailers shelves may not have any or all of the components of a reasonable testing

program. Generating this documentation “after the fact” is simply not possible. We respectfully request that the Commission apply the rule only to products whose development begins on or after 180 days after adoption. Accordingly, products would begin to be certified based upon a reasonable testing program with all accompanying documentation approximately 18 months following adoption of the final rule.

Furthermore, while the requirement of making documents available in English and in the U.S. upon request ultimately is feasible, sufficient infrastructure and processes to systematically provide this do not currently exist. Therefore, we respectfully request extra consideration for the time required to produce certain elements of the documentation from foreign locations and translate them for the CPSC. RILA members do not believe that translating and storing foreign manufacturing documents in the U.S. for every regulated product measurably increases product safety. We believe these documents could be stored in their existing location and obtained for CPSC upon request. Alternatively, a three-year stay of the requirement that documents be maintained in English and in the U.S. would allow a transition period to establish and implement appropriate infrastructure and processes for expanded recordkeeping. During the three-year transition, although records may not necessarily be maintained in English in the U.S., records will be made available upon request to the CPSC within a reasonable time. The stay could also allow the industry to develop and deploy lasting centralized solutions for document maintenance in the United States.

In addition, we request permanent consideration allowing certain manufacturing related documents to be maintained at the manufacturing site. This consideration would reduce the document burden for systems requirements measurably. For each retailer/importer these records would comprise the bulk of the document load for compliance with record keeping. We propose that these records continue to reside at the manufacturing site and be made available upon request.

To ensure compliance with the requirement to make records available in the English language, there are numerous readily-available translation services that can be employed around the world on an as-needed basis. Many retailers may also have internal multi-lingual staff who could prepare translations and ensure that when requested, the CPSC will have documents available in a reasonable time-frame and in English.

III. LAB CAPACITY AND EXECUTION

RILA’s members also have a concern about the testing capacity at the third party test labs as a result of this ruling. The fast-paced product development cycle used by retailers requires a five to ten day turnaround for product testing. Currently, without the ruling being implemented, retailers are already experiencing delayed turnarounds in product testing. It is not uncommon to have special request testing denied due to the current backlog of testing.

The proposed rule will have the potential to multiply the current volume of product testing by several fold and the concerns are very real that labs will be unable to accurately and efficiently provide the increased testing needed by retailer/importers to comply with this rule. RILA is suggesting the removal

of references to statistical sampling and the use of ANSI/ASQ Z1.4 and Z1.9 for determining the number of samples required for certification testing, production testing and periodic testing. The frequency of testing and the number of samples tested should be set or determined by retailers and manufacturers to assure compliance with all applicable rules, bans, standards and regulations at the time production starts and that compliance is maintained throughout production. In addition, retailers are concerned that increased testing demand may affect lab execution potentially, resulting in incorrect lab results, which may cause compliant product to be lost, or may allow non-compliant product to enter commerce.

Retailers and their vendor's factories typically are already using the approved third party test labs. The proposed ruling increases the volume of product testing as follows:

- Increased number of samples to comply with the sufficient number of samples required by 1107.10 (2) (i).
- Production Testing Plan 1107.10 (3). Retailers and most factories do not have their own test facilities and will be using the third party test labs.
- If Periodic Testing is elected in lieu of RTP, additional samples are required for product testing to comply with 1107.21 (c) (1) & (2).
- Referencing the use of statistical sampling, confidence levels and ANSI/ASQ Z1.4 & Z1.9 also implies a very significant increase in number of samples required for product testing.

Finally, if the capacity of the third party test labs is exceeded, retailers and manufacturers ability to meet the assumed effective date of the ruling could be jeopardized. RILA is asking that the lab capacity issue be taken into consideration when establishing the effective date of the ruling.

IV. PAPERWORK REDUCTION ACT

As you can see, this proposed rule has the very real potential to impose costly and time consuming data collection efforts worldwide. Using the number of items identified in Section II, and the hourly recordkeeping estimate and hourly rate estimates from p. 28361 of the Federal Register Notice, and applying an average burden of 1.5 hours per model, per prototype, per year, the estimated cost to a single major retailer is approximately \$22,000,000, without considering any material changes. The benefit to the agency's mission and consumer product safety itself is unclear. We urge the agency to strongly consider the tenets laid out in the Paperwork Reduction Act of 1995. While the CPSC stated in the proposed rule this will not add additional cost to the Federal Government, as we have just explained, the sheer volume of documentation created strongly suggests otherwise.

COMMENTS ADDRESSING REGULATORY FRAMEWORK

I. DEFINITION OF A HIGH DEGREE OF ASSURANCE

RILA members place the highest priority on the safety and quality of the products that they sell and are committed to achieving a high degree of assurance that the products they import are, in fact, compliant. However the definition of a high degree of assurance in the proposed rule lacks sufficient clarity.

High degree of assurance is defined in section 1107.2 as “an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture.”

In its discussion of that section (p. 28344) CPSC staff makes clear that no specific formula is mandated by this definition. It rejects an exclusive definition of “high degree of assurance” as a “95% probability that all product produced meets the requirements of the applicable rules.” It notes that if this were the requirement, it “...could result in greater testing demands on small manufacturers,” with the implication this would be undesirable. It also maintains that “there may be difficulty in applying statistical methods to all manufacturing processes.” However no specific examples are cited other than the use of statistical methods.

Therefore, in order to provide a balanced definition of high degree of assurance, other means to achieve this confidence level should be recognized in the final rule, including means that do not solely rely on product testing or statistical methods.

We are requesting acknowledgment in the rule that the manufacturer / importer could employ a variety of methods that provide objective evidence that their processes will produce a product with a high degree of assurance the “expected” outcome will be achieved – methods that do not necessarily involve statistical methods or testing any particular number of samples. These methods include appropriate quality assurance processes and risk management. Quality assurance processes can include factory/supplier evaluations, design reviews, manufacturing process control, process auditing, or similar controls or reviews. Risk management includes analysis of a given possible failure, the likelihood of the failure, and the potential consequences associated with the failure. All of these activities can be employed by the importer in order to maximize desired expected outcomes and minimize unexpected outcomes and is performed in a feedback loop that facilitates true root cause analysis and correct if there is a failure.

Please refer to the following examples for other possible means to reach a high degree of assurance:

Example 1:

A factory is evaluated by the importer prior to placement of an order based on defined process control criteria and a scoring system that indicates capability. The importer imposes a minimum score in order for the factory to be used for production. Factories that achieve a passing score are also required to

complete corrective action plans in order to improve specific process concerns. The RILA initiative for developing and supporting a Global Standard for Consumer Products, when fully implemented for the North American market, is one example of such an evaluation. The Global Standard for Consumer Products will set out minimum requirements for factories to demonstrate that they can consistently produce safe, legal consumer products of the quality required by retailers. The factory evaluation score is a strong indicator of the factory's ability to meet the requirements of production testing and other steps applied to that factory to reach a high degree of assurance. For example, if a factory earns a high score and therefore indicates capability to meet the importer's requirements for high degree of assurance, the importer could reduce frequency of testing, inspections and other similar activities because the factory has demonstrated capability. In summary, if the factory has the systems, processes and organizational structure that meet the criteria of the Global Standard for Consumer Products (or a similar factory evaluation standard), the importer has a high level of assurance that the factory is able to produce safe, legal and quality products.

Example 2:

A factory designates critical stages of the production process to execute in-line inspections. These inspections evaluate the product as it is being built to determine the likelihood that it will be compliant once it is completed. The inspection is proactive because the product or process can be stopped immediately if a problem or concern is detected, rather than at the end of the line for final inspection or at the 3rd party lab for testing.

Example 3:

A product is manufactured through a highly automated production process. The equipment and controllers have been verified and validated through formal qualification processes. Therefore a risk based approach can be used to reduce the frequency or volume of quality checks (which include testing) since the likelihood of a product failure is less than that of a manual process.

Similar flexible approaches to achieving a high degree of assurance have been recognized for some time by the Food and Drug Administration for pharmaceuticals and medical devices.

"It is through careful design and validation of both the process and process controls that a manufacturer can establish a high degree of confidence that all manufactured units from successive lots will be acceptable. Successfully validating a process may reduce the dependence upon intensive in-process and finished product testing." - GUIDELINE ON GENERAL PRINCIPLES OF PROCESS VALIDATION MAY, 1987, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health Food and Drug Administration.

This approach is further referenced in 21 CFR 820.

It is imperative that language be included in the final rule that clearly states that other methods such as these are acceptable. Without this clarity we are concerned that for practical purposes a single definition of “high degree of assurance” will be based solely on a “95 percent confidence”. We suggest the following substitute definition, which acknowledges, but does not mandate, a variety of methods to obtain a high degree of assurance:

High degree of assurance means an evidence-based determination of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture. Acceptable evidence-based determinations may be based on evidence derived through any appropriate process or control or combination of processes and/or controls, such as (but not limited to):

- Design Validation
- Manufacturing Process Control Audits
- In-process manufacturing controls, measurements, and tests
- Component and material testing as defined in 16 CFR 1109
- Finished Product Testing
- Raw materials certification
- Other controls or processes that provide information about the safety or compliance of a product

II. PRODUCT SPECIFICATION

1. We appreciate the acknowledgement that a product specification packet can be comprised of multiple documents within the record to meet requirements. As an example, at each manufacturing site a typical packet of documents could be comprised of:
 - A product design specification – conveys the overall aesthetic and material selection for the product and a visual representation of the expected product.
 - A testing protocol – conveys the overall performance and regulatory requirement specifications that the product may be required to meet, including listing all potential rules bans and standards applying to a product category.
 - Documentation of the final rules, bans, standards, and regulations that apply to the specific product.
 - Documents detailing the actual use of any certified components within the finished product (as applicable).

2. Finalization of product specification can be dependent on product development, manufacturing process development, sourcing, material selection, etc. We understand that it is acceptable for finalization of the product specification to be completed by the time the certification testing is conducted or even after some certification has been completed. We believe this is reasonable, as demonstrated by these examples (which are intended as illustration, but not as a limitation).

- a. Apparel Example:

The retail product is a children's polo shirt with buttons. During development, a manufacturer presents a set of design options all based on the same fabric, but with several options of buttons. The importer will not know until final assembly which button option they would prefer. The fabric has been chosen for the first stages of manufacturing and specified to meet requirements of 16 CFR 1610. However, depending on the button chosen – it is not known at the design stage whether certified (button) components will be used, or whether materials would be chosen which may be exempted (i.e. glass and wood) from testing at an approved laboratory to provide certification for lead. The cut and sew of the shirt is the first stage of assembly for the final product and can occur independently of the final assembly of the product (sewing on the buttons). A key decision regarding a material change is held until final assembly. The certification of the body of the shirt can take place separately thus ensuring certification to 16 CFR 1610 and further certification testing may or may not be necessary.

If a button is chosen that meets the requirements for component testing – all certification testing has occurred prior to the final spec release and has not increased risk to the consumer.

Three possibilities include:

- A plastic button is chosen that has met the requirements for component testing. If so, documents would be collected from the supplier to substantiate that the material aspects of the button affecting compliance with the CPSIA have been validated.
- A painted metal button is chosen that has not met the requirements for component testing. A separate set of certification tests and/or RTP requirements are completed for the button prior to assembly for the shirt. Once a high degree of assurance has been achieved that the material aspects of the button affecting compliance with the CPSIA have been validated, the specification can be finalized.
- A natural wood button is chosen that requires no additional testing.

In all cases, all testing related to the button certification has occurred prior to the final specification and has not increased risk to the consumer.

b. Non-Apparel Example:

The retail product is a wooden toy train. During development, a manufacturer presents a set of design options all based on the basic toy train, but with several finish options. The importer will not know until a date very close to import which finish option they would prefer until application. The wood and other components have been chosen for the first stages of manufacturing and specified to meet requirements of ASTM F963 / 16 CFR 1500. However, depending on the finish chosen – it is not known at the design stage whether certified paints, stains or other coatings will be used. The manufacture and assembly of the non-coated train is the first stage of assembly for the final product that would occur independent of coating the product. A key decision regarding a material change is held until the final production stage. Importers may wait until the last stage of production (prior to shipment) to make final decisions on color and finish as a result of last minute reaction to sales figures in order to best meet customer expectations and sales goals. The base train can be certified to meet all requirements with the exception of those related to the finish.

These examples could hold true for any scenario where a material component can be selected late in a segmented manufacturing process.

If it is required that a final specification be created prior to assembly of any final consumer product it would be unduly burdensome across the industry and result in:

- Increased cost of testing components that may not be part of the final product
 - Limiting design capabilities for fast-trend retailers
 - Longer lead time / inflexible supply chain
 - The specification documents produced prior to assembly may be obsolete at the production completion, due to the inherent specification modifications occurring during assembly
3. We appreciate the acknowledgement that if identical products are produced in separate manufacturing sites, the same initial specification may be used for each manufacturing site as long as each manufacturing site is noted on the separate specifications.
 4. Assuming that a product specification packet can be comprised of multiple documents, and the acknowledgement that new documents need not be created where proper revision control can be implemented, RILA requests that the CPSC confirm that the designation of certified components need not be included in the initial specification, so long as proper documentation is available validating the selection and use of certified components prior to import and issuance of the GCC.

5. Section 1107.10(b)(1)(i) requires the product specification to identify component parts that are certified pursuant to 16 CFR 1109. We expect that, depending on the manufacturer's location, the importer may not be able to specify a certified component at the product specification stage, because availability of certified components may vary from manufacturing location to manufacturing location. In addition, assuming that a certified component meets all of the requirements that final product certifier, using due care, must rely upon, there is no reason to require that certified components be identified at the product specification stage. Therefore, we request that Section 11107(b)(1)(i) be deleted.

III. CERTIFICATION TESTS

1. Certification testing requires a sufficient number of samples to provide a high degree of assurance of compliance. The rule also defines high degree of assurance as being evidence based. However, the CPSC cites ANSI/ASQ Z 1.4-2008 and Z1.9-2008 often, and there are multiple substitutes for achieving a high degree of assurance.

Use of the ANSI/ASQ standards is unduly burdensome when applied to certification testing. The frequency and sample sizes for certification testing should align to the amount of risk each product has to be compliant with all CPSC rules, bans, standards and regulations. If flexibility of sampling and testing frequencies is not allowed based on evidence-based and historical approaches to product quality; sampling and testing costs would be unduly burdensome.

The commission provided one example of sampling for lead testing when both the historical variability (standard deviation) and the historical mean of the variable (lead content) are known. The commission then acknowledges that when qualitative (attribute) or pass/fail testing is conducted, that sampling sizes will be larger. However, the commission did not provide examples regarding how large the sample sizes might be or provide a basis for choosing a level of inspection or AQL. There are many tests with qualitative results related to the validation of rules, bans, and standards. Additionally, in the example the CPSC provided, incorrect assumptions are made that both historical data are available and that the data can be captured in a resolution to allow variables inspection / sampling.

Currently, continuously variable data on commonly available testing reports from major CPSC approved laboratories is not available for lead content. Specifically data for samples with a result below the method detection limit cannot be included for calculations of the mean or standard deviation. These results are commonly captured as <Xppm, where X is the method detection limit. The CPSC's example is invalid unless the data can be captured and tracked in full resolution, which is not the current state.

An example of how the ANSI standards could be applied follows.

Application of ANSI Standards:

The retail product is a children's 100% Cotton, 3-button placket, Polo Shirt. 3.5 million units would be imported over eight months. The 10.5 million buttons required for the shirts are produced in lots of 1 million buttons.

Using an AQL of 0.010% (Non-conforming units are unacceptable) and that a level III inspection is chosen for a high degree of discrimination, 1250 tests would be required per lot for a total of 13,750 tests. Assuming \$25 USD per test and assuming a cost of \$0.05 per button, the cost of testing (\$343,750) far exceeds the cost of the material (\$52,500).

For a toy with many different plastic components, the sample scenario above is still viable, however due to the complexity and number of rules, bans, standards and regulations that may apply to this type of item; the testing cost, time and number of samples would increase a minimum 3 to 4 times.

Using an evidence-based approach based on historical performance and risk for the product type and manufacturing processes, a retailer may implement a program requiring:

- sample testing using materially identical components to be completed before production begins,
- require certification from samples selected during the start of production, and
- require periodic testing as the item remains in production.

At each of these stages, a representative set of samples would be pulled to cover all tests related to applicable rules, bans, standards and regulations.

2. We appreciate the acknowledgement for non-children's products that the testing conducted during execution of the production testing plan could additionally serve as Certification Testing within the Reasonable Testing Program (RTP).
3. We appreciate the acknowledgement for children's products that samples selected from a lot of finished product over 10,000 pieces, but produced in short time period may be used to satisfy both certification testing and periodic testing requirements together.

Example - For a child's solid-rubber ball, more than 10,000 finished products, that are materially identical could be made in less than one manufacturing shift. In this scenario, it would be appropriate to select samples when material changes occur, and or meet historically defined frequency intervals in order to maintain and validate that products meet all rules, bans, standards, and regulations.

IV. PRODUCTION TESTING PLAN

1. We appreciate the acknowledgement that a single production test plan that is available to both the manufacturing site and the importer of record (retailer) may be used. An example supporting this case follows:

For a plastic toy truck, the factory is required to develop a production test plan incorporating raw materials testing for analytical requirements, mechanical hazards, etc. Throughout the production lifecycle, the importer of record would validate critical elements using various process management techniques at the manufacturing site:

- factory audits / evaluations
 - ensures the factory has the capability to produce consistent product for the quantities required
 - ensures an evidence-based production testing plan (PTP) and industry accepted quality processes are satisfactorily implemented
- production inspections - validates PTP records are present and match specification, and
- periodic testing – assures adherence to all rules, bans, standards, and regulations, safety standards throughout production with a CPSC approved laboratory.

2. We appreciate the acknowledgement that a production test plan for a single product made in one manufacturing site but sold to several importers (retailers) may only have one production test plan. This is supported through the following example:

A large volume pen manufacturer produces pens for multiple retailers. The pen manufacturer has demonstrated to all retailers that they have an evidence-based production testing plan based on their internal knowledge of the variability of their processes and can provide evidence of compliance based on a high-degree of assurance to their customers that product meets all rules, bans, standards, and regulations.

V. REMEDIAL ACTION PLAN

We appreciate the acknowledgement that a remedial action plan can be a formal standard operating procedure (SOP) along with record keeping of each event.

For further consideration - When a particular component causes a product to become non-compliant to a rule, ban, standard, or regulation and the remedial action eliminates this specific component from the product, certification testing will not have to be repeated. Documentation can be provided ensuring that the non-compliant component has been removed and the product specification has been revised. There would be a standard operating procedure that requires a corrective action. In addition, a record

of the instance of noncompliance would be maintained providing evidence that the product has been corrected and is compliant. The following example supports this contention:

A doll has a bottle and pacifier as accessories. The doll and the pacifier are compliant, however the bottle is not. The removal of the bottle from the item would not require the other two compliant pieces to be recertified. If documentation shows the bottle is not present with the item, a change to the product specification would be sufficient and additional testing would not be necessary.

VI. RECORDKEEPING

1. RILA understands that the product specification is a record, and proper revision /version control of the product specification would fulfill the record keeping requirements. Therefore, we believe a newly generated product specification is not a requirement in the case of all material changes. Please confirm.
2. We appreciate the CPSC's consideration of electronic solutions. We recognize that the proposed rule all records must be EITHER physically present in the U.S., OR accessible electronically and printable in the U.S. to meet the recordkeeping requirement stated in §1107.10 paragraph 5 and §1107.26.
3. Per §1107.10 paragraph 5 and §1107.26 all records must be available in English. There are situations where documents pertaining to record-keeping requirements could be created in the local language and could be made available upon request in English in the United States within a reasonable period of time. See Section II, Impact to U.S. Retailers - Page 2
4. Due to record keeping volume (See Section II, Impact to U.S. Retailers – Page 2), the time required to scope, investigate, develop, integrate, and implement a comprehensive technology platform will be substantial. The sizeable financial investment necessary will likely be spread over multiple fiscal years. We are therefore requesting consideration of the following:

We propose that a three year stay be allowed for the requirement to maintain documents in the U.S. This will allow the industry to define and implement centralized document solutions for the volume of data / paper expected.

During the stay, if requested by the CPSC, the importer will collect the requested documents from their current storage locations within a reasonable time frame, and provide them to CPSC in the United States, and in English.

VII. RANDOM SAMPLES

The CPSC has stated in their response to public comments that the statistical definition of random sample is the most appropriate technical definition because it must be applied to generalize from the

tested samples to the compliance of the untested portion of the product population. RILA asserts that a “technical” definition was not the intent of lawmakers when the CPSIA statute was drafted. RILA maintains that the intent of the term “random” in the CPSIA was to eliminate the risk of bias or selective sampling in order to manipulate a desired outcome. Therefore, an importer/manufacturer can apply many practical means to achieve randomness and non-biased selection and achieve a high degree of assurance.

The CPSC proposed ruling discussion of high degree of assurance (p. 28344) rejects an exclusive definition of “high degree of assurance” based on a single statistical definition (“95% probability”). RILA requests that the CPSC allow the same non-prescriptive consideration in determining how to randomly select samples.

Specifically we request that the first sentence of §1107.22 be changed to read: “Each manufacturer must select samples for periodic testing by using a process that reasonably assures that such samples are representative of the production population and are selected in a manner free from overt bias”.

VIII. SAMPLE QUANTITY

RILA strongly suggests the language covering samples requires substantial clarity. As written, it proposes requiring testing with a “sufficient number of samples” to provide a “high degree of assurance” (for minimum certification testing), while maintaining that the sampling does not have to meet minimum standards of statistical confidence.

1. Section 1107.10(b)(i) for non-children’s products under a Reasonable Testing Program (RTP) would require manufacturers to submit a “sufficient number of samples” to provide “a high degree of assurance” of compliance to all applicable rules. As discussed earlier in the document we strongly believe that the definition of “high degree of assurance” must be clarified. As we mentioned, the comments accompanying the NPR recognized that “there may be difficulty in applying statistical methods to all manufacturing processes”. If so, then *testing with a sufficient number of samples to provide a high degree of assurance* should not be a mandatory element of an RTP for non-children’s products.

If testing a “sufficient number of samples to provide a high degree of assurance” is required when applying RTP to children’s products, please provide guidance on alternatives that certifiers may use to fulfill the duty to justify their plan were they to choose anything less than a random statistical sample. For example, the CPSC has historically relied on a sample of 12 or fewer units, without regard to the size of the production run. Likewise, certain statistical models used by auditors impose a maximum sample of 25 units, no matter the size of the cohort from which the samples are selected.

2. We ask CPSC to consider the many existing, successful quality assurance programs of U.S. manufacturers / importers who offer safe consumer products. It is essential to recognize that

most of them in major industries such as apparel employ statistical sampling very sparingly in the testing portions of these comprehensive programs, while still achieving a high degree of assurance that products comply with the rules. When they do use statistical sampling, it is frequently based on judgments about risks particular to a production manufacturing process.

We therefore request that the CPSC resolve this problem by deleting the requirement to test a “sufficient number of samples to provide a high degree of assurance” under a Reasonable Testing Program. The premise of a “reasonable testing program”---in order to differentiate it from the mandatory periodic testing required for children’s products not relying upon an RTP-- must be that for some specific products, testing will not be the basis for certifying to the applicable rule. The Commission appropriately acknowledges the implications of differences between product categories and industries attempting to develop programs under the proposed rule in the observation “*A manufacturer may develop the scope and details of each element of a reasonable testing program based on knowledge and expertise regarding the product and its manufacturing processes*” 75 Fed. Reg. 28,345 (May 20, 2010). This discretion must also extend to the sample selection methodology of our test programs provided that all population elements have a chance of selection and due care is exercised to avoid selection bias through documented procedures. The Commission should propose separate rulemaking for specific products that may warrant prescribed methodologies as has been done with bicycle helmets.

We believe this is the kind of evidence-based decision-making that CPSC envisioned in its rejection of a single definition of “high degree of assurance” within a reasonable testing program for non-children’s products.

IX. UNDUE INFLUENCE

Because of the scale of the retail supply chain (please refer to Section II, Impact to U.S. Retailers – page 2), the importer of record should not be responsible for undue influence initiated by people not directly employed by the importer of record (retailer). We understand that importers will only be responsible for training their own employees, and will not have responsibility for training the employees of other companies, such as manufacturers, vendors, freight handlers or laboratories. Please confirm our understanding.

As an example – A major retailer has 1000 staff members that reasonably could be in contact with the lab. The retailer also purchases from 1500 vendors producing at over 4500 factories. If each vendor and factory has 5 staff members who have contact with the lab, this would be a total of 30,000 staff for vendors and factories needing documented training annually. Employee turnover further complicates the issue.

Should an ethical violation be found, the importer of record has documented penalties that can be exercised and used as deterrents to undue influence.

In addition the CPSC has included undue influence training with lab accreditation.

Due care is exercised by the retailer to prevent undue influence by those parties in their direct employ, and the CPSC has taken due care to prevent undue influence on the part of the laboratories. The retailer should not be responsible in the case of undue influence by those not in their direct employ.

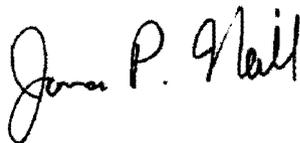
SUMMARY

As we have stated in this letter and in previous meetings with CPSC staff, while we are firmly committed to continue to provide safe products to our customers, we remain deeply concerned about the potential negative impact to U.S. businesses and to consumers if the rule is finalized without careful consideration of the points we have attempted to address here, including:

- Onerous documentation and recordkeeping;
- Impact to costs, which must ultimately be absorbed by U.S. consumers;
- Inadequate time to develop and execute a compliant system;
- Lack of flexibility to meet product specification requirements;
- Multiple options to attain a "High Degree of Assurance";
- Not allowing the same single production test plans to apply to both the manufacturer and importer;
- Precise undue influence obligations;
- Paperwork reduction.

We are confident that these concerns may be addressed in a way that will likely enhance and definitely not reduce the level of product safety in the marketplace. Thank you for allowing RILA the opportunity to comment on this important rule. If you would like to discuss further, I can be reached at 703-600-2022 or jim.neill@rila.org.

Sincerely,

A handwritten signature in black ink that reads "Jim P. Neill". The signature is written in a cursive, slightly slanted style.

Jim Neill
Vice President, Product Safety