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August 3, 2010

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

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 sites 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.

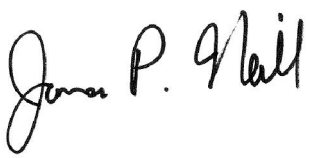
SUMMARY

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,



Jim Neill
Vice President, Product Safety