UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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Memorandum

October 18, 2011

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM : Robert J. Howell, Deputy Executive Director for Safety Operations
DeWane Ray, Assistant Executive Director, Office of Hazard Identification and Reduction

SUBJECT : Response to Commissioner Anne M. Northup's Questions Related to Pending Proposals for Testing and Certification and Component Parts

This memorandum provides the U.S. Consumer Product Safety Commission's (CPSC's) staff's response to 16 questions provided by Commissioner Anne M. Northup in a memorandum dated October 6, 2011. These responses have not been reviewed by, and may not necessarily reflect the views of, the Commission.

Question 1

Does staff believe that third-party testing protocols are unaffected by the directive in H.R. 2715 that the CPSC consider ways to reduce the costs of third-party testing? Please explain your reasoning.

Response to Question 1

Staff notes that, in comparison to the proposed rule, it considered ways to reduce the costs of third-party testing when developing the draft final rule, and the draft final rule includes measures, not included in the proposed rule, that will likely reduce the cost of third party testing. For example, the draft final rule eliminates the requirement that records be kept in English and located in the United States. The draft final rule also provides for an extended period of 3 years (as compared to a maximum of 2 years in the proposed rule) between periodic testing for those parties using an ISO/IEC 17025:2005 accredited laboratory.

The cost of third party testing or of implementing a production testing plan was not the reason for extending the one year testing interval for periodic testing. Rather, when a manufacturer has a production testing plan or uses an ISO/IEC 17025:2005-accredited testing laboratory, the additional knowledge a manufacturer has about its product's manufacture and compliance

justifies a longer interval between periodic tests. However, manufacturers that chose one of those two options will likely experience reduced cost in complying with the periodic test requirements**.**

With respect to the directive in H.R. 2715 that the CPSC consider ways to reduce the costs of third-party testing, H.R. 2715 created a new section 14(i)(3) of the Consumer Product Safety Act (CPSA). Section 14(i)(3)(A) of the CPSA expressly requires the Commission to "seek public comment on opportunities to reduce the cost of third party testing consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation…" Section 14(i)(3)(B) of the CPSA then states that, after the public comment period,

> "but not later than 1 year after the date of enactment of this paragraph, the Commission shall review the public comments and may prescribe new or revised third party testing regulations if it determines that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations."

Staff thinks it is premature to say whether the public comments received pursuant to Section 14 (i)(3)(A) of the CPSA will lead the Commission to conclude that new or revised third party testing regulations are necessary or whether those comments will provide sufficient information to enable the Commission to make the determination described in Section 14(i)(3)(B) of the CPSA.

Question 2

The testing and certification briefing package states at page 137 that the effective date was set as 15 months after the date of publication in the Federal Register "so that parties can begin taking steps to develop internal processes, such as recordkeeping, and so that the CPSC and other interested parties can consider how H.R. 2715 interacts with the final rule."

What, other than the development of internal recordkeeping processes, can regulated businesses do in reliance on the final rule during the 15 month period before its effective date, without risking that a change to the rule based on comments received pursuant to H.R. 2715§2 would result in detrimental reliance? In answering this question, please specifically consider whether:

a. Manufacturers will be able to plan how continued testing will be conducted given that they cannot predict how the CPSC will interpret the requirement that "representative" rather than "random" samples must be selected.

b. Given that small batch manufacturers making covered products will have no way of knowing what "alternative testing requirements" will be imposed, they will be able to make advance arrangements to ensure an ability to satisfy these requirements.

c. Any manufacturer will be able to enter into the most economical long term lab contracts without knowing the extent to which HR 2715 regulations will reduce the quantity of third-party testing that will be required.

d. Given that design specifications (and associated investments) originate 12 months or more prior to manufacture or import (p. 136) companies will be able to calculate their testing costs in order to determine whether a particular product can be economically manufactured.

Responses to Question 2a, 2b, 2c, 2d

a. CPSC staff proposes a definition of representative samples in the Notice of Proposed Rulemaking (NPR) and proposes several examples of how representative samples can be drawn. This information, along with that in § 1107.21 and the manufacturer's knowledge about its manufacturer's processes should allow advance planning for periodic testing.

b. With regard to small batch manufacturers, H.R. 2715 states that the Commission may not require third party testing of a covered product by a third party conformity assessment body (laboratory), within the limits established by subparagraph (C), until such time as the Commission has provided either an alternative or an exemption. When implementing any alternative testing requirements, the Commission could consider an effective date that would allow time for a small batch manufacturer to make whatever arrangements would be necessary to meet the requirements.

c. While staff has no knowledge of the specifics of any contracts or other long term agreements between manufacturers and testing laboratories, it seems reasonable to expect that a contract could be constructed to include a volume-based pricing tier structure that would build some flexibility into the agreement. This would permit a manufacturer to negotiate a contract based on any final rule approved by the Commission while allowing for modification, as needed, should the rule change before becoming effective.

d. It is likely that any forecast or calculation of testing costs, calculated prior to the finalization of any testing and labeling rule, will not be accurate if the testing requirements change significantly.

<u>Question 3</u>

The testing and certification package states at page 74 with respect to an importer's reliance on a foreign manufacturer's certification, that "due care by the importer involves ensuring that the foreign manufacturer conducts periodic tests."

Please explain how staff anticipates an importer will be able "to ensure" that a foreign manufacturer conducts periodic tests. In doing so, please address (a) how an importer is to judge whether the testing is conducted with an appropriate frequency, given that the proper frequency depends on production details that may be unknown to the importer; and (b) whether it would be deemed sufficient for an importer to review the foreign manufacturer's periodic testing plan.

Response to Question 3

There are several approaches that may serve as evidence of due care by an importer to ensure that a foreign manufacturer, that has provided a foreign manufacturer's certification, conducts periodic testing as specified in the draft final rule. The requirement should be specified in the importer's purchase order to the foreign manufacturer, clearly communicating the requirement to

conduct the required periodic testing and requiring submission of the foreign manufacturer's periodic testing plan. Simply reviewing the foreign manufacturer's periodic testing plan does not satisfy the requirement, as this approach lacks evidence that the periodic testing plan has been implemented. An importer may need to conduct occasional site visits to his supplier's manufacturing facility to examine evidence that the required periodic testing has been properly performed or may need to verify the authenticity of the supplier's test reports by contacting the testing laboratory for verification. An importer may also wish to occasionally submit samples from product received from the supplier for testing, to compare the test results to those conducted by the foreign manufacturer.

Question 4

Continuing its discussion of importer's receiving certified product from a foreign manufacturer, the testing and certification package states that "if the importer has no knowledge of the manufacturer of the product, then it should treat each shipment as a discrete lot and subject it to certification testing because the importer does not know whether material changes have been made…"

Please explain how an importer is to satisfy the requirement that "sufficient samples" of a product be tested to support certification, when the determination of what constitutes sufficient samples depends upon details of the manufacturing process, materials, suppliers and product of which, based on the predicate of the quoted language, the importer is unaware.

Response to Question 4

In the absence of any knowledge of the manufacturing process, materials, suppliers, and product, the importer should consider the units in the discrete lot as the population and determine the sample size based on this population. The calculation of sufficient sample size can be made based on the importer's determination of a high degree of assurance of compliance of the product.

Question 5

Page 88 of the testing and certification package, in the context of addressing the change to the NPR increasing the third party periodic testing interval from one to two years for manufacturers who have implemented a production testing plan, states: "This increase in the maximum testing interval was not based on the costs of third party testing or on the costs of implementing a production testing plan."

Do you mean by this that the decision to increase the testing interval under those circumstances was not intended to reduce the costs of third party testing, but was motivated by other input? If so, please explain staff's motivation in choosing to afford manufacturers with a production testing plan a minimum third party testing interval of two years.

Response to Question 5

The sentence, quoted above from page 88 of the preamble of the final rule, was written in response to a commenter's suggestion

> "that we consider the costs involved in establishing and maintaining a reasonable testing program, and noted that a reasonable testing program reasonably warrants a more relaxed periodic testing frequency standard, particularly when the manufacturing process inherently results in uniform production, with very little variability in the composition or quality . . ."

The two sentences of the *response* to the commenter's suggestion on page 88 of the preamble of the final rule indicate staff's agreement with the commenter's premise and explain that

> "When a manufacturer implements a production testing plan and conducts production testing, such testing provides more information about a product's manufacture and compliance with the applicable children's product safety rules, which justifies allowing a longer period of time between periodic tests. If a manufacturer uses an ISO/IEC 17025:2005-accredited testing laboratory for testing to assure continued compliance, the maximum periodic testing interval is extended to three years."

Thus, staff indicated its agreement that, as the commenter noted, "a reasonable testing program reasonably warrants a more relaxed periodic testing frequency standard" and the response indicates that the final rule does allow for more relaxed periodic testing frequency under certain conditions. The sentence in the response to the commenter regarding cost indicates that the cost of third party testing or of implementing a production testing plan was not the reason for extending the one year testing interval for periodic testing. Rather, when a manufacturer has a production testing plan or uses an ISO/IEC 17025:2005-accredited testing laboratory the additional knowledge a manufacturer has about its product's manufacture and compliance justifies a longer interval between periodic tests. However, manufacturers that chose one of those two options will likely experience reduced cost in complying with the periodic test requirements**.**

Question 6

Page 111 of the testing and certification package states the following: "A manufacturer or importer who issues a finished product certificate that is based on test reports from a third party conformity assessment body over whom undue influence has been exercised provides a basis for the CPSC to deem the certificate invalid. We will hold the finished product certifier responsible for exercising due care that component part or finished product manufacturers or suppliers have not exercised undue influence over third party conformity assessment bodies."

Please explain how staff envisions an importer would exercise the due care referenced in the quoted passage. In providing that explanation, please address whether:

a. *The duty of due care would be satisfied by an importer obtaining a copy of the component part or finished product certifier's undue influence policy;*

b. *The duty of due care requires a manufacturer or importer to obtain documents signed by the component part or finished product certifier's employees reflecting that they attended undue influence training;*

c. *The duty of due care requires any other affirmative action on the part of the manufacturer or importer, and if so, what affirmative action, and under what circumstances.*

If a manufacturer or importer does exercise such due care and a determination is made that a component part or finished product certifier has exerted undue influence over a third party conformity assessment body, will the certificate the importer obtained from the component part or finished product certifier not be deemed invalid by the Commission? What other potential consequences to the importer or manufacturer in the event of undue influence by a component part or finished product certifier over a third party conformity assessment body are affected by the importer's exercise of due care that the component part or finished product certifier has not exercised undue influence over third party conformity assessment bodies?

Response to Question 6

If a manufacturer or importer intends to rely on test reports or certifications as all or part of the basis for issuing a finished product certificate, due care must be exercised to ensure that those test reports or certificates are not a result of the exertion of undue influence on a third party conformity assessment body. Due care requires a manufacturer to use that degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances. Accordingly, the concept of due care will vary depending on the circumstances and the industry in question. The number of actions taken regarding due care against undue influence may vary based on the type of product under consideration and the finished product certifier's determination of prudence and competence.

Depending on the industry in question, the risk of undue influence, and the manufacturer or importer's relationship with the supplier, due care requires that some affirmative action be taken to ensure the absence of undue influence. Thus, under certain circumstances due care may require one or more of the following: obtaining a copy of the component part supplier's or finished product certifier's undue influence policy; reviewing documents signed by a supplier's employees reflecting undue influence training; specifying in a purchase order or contract what procedures must be implemented to guard against the exercise of undue influence on a third party conformity assessment body; or specifying which third party conformity assessment bodies must be used for product testing. This list is illustrative and is not intended to represent all possible actions that could be taken to guard against undue influence. What constitutes due care will vary based on the industry, the consumer product safety rules under consideration, and the circumstances involved.

Certificates that rely on test reports or certifications that were generated based on the exercise of undue influence on a third party conformity assessment body are invalid because the manufacturer or importer no longer has a basis, based on the affected test results, to issue a certificate. Enforcement actions will be based on the facts and circumstances of each case, including the effect of noncompliance upon public safety.

Question 7

According to the testing and certification package at page 163, manufacturers are considered small entities if they have fewer than 500 employees.

What percentage of small entities so defined also both produce "covered products" as defined by H.R. 2715 § 2 and are "small batch manufacturers" as defined by H.R. 2715 § 2?

Response to Question 7

The Census data upon which staff relies for industry statistics does not provide a breakdown of the volume of production by product for each manufacturer. Therefore, we do not know the percentage of manufacturers that would be considered "small batch manufacturers" and produce "covered products." However, if we assume that firms with fewer than five employees are the ones most likely to have less than one million dollars in revenue, and so would qualify as small batch manufacturers, between 40 and 60 percent of the manufacturers that are considered to be small might qualify as small batch manufacturers. As noted, we do not have any information on the volume of production by product for each manufacturer. Therefore, we do not know how many of the manufacturers that might qualify as small batch manufacturers also manufacture "covered products."

Question 8

Pages 166 and 168 of the testing and certification package provide estimates of the number of wholesalers and retailers of children's products that could potentially be impacted by the rule, and also acknowledge that an additional 206,000 non-employer businesses could include children's product wholesalers and that an additional 324,918 non-employer businesses could include children's product retailers. However, because the actual numbers of such non-employer businesses is "unknown", the costs the rule imposes on them are not taken into account in the Reg Flex analysis.

Is it therefore correct that the Reg Flex analysis has underestimated the cost impact on small businesses because these 530,918 potential non-employer small business wholesalers or retailers have not been taken into account, but you do not know to what extent that cost impact has been underestimated?

Response to Question 8

This is not a correct interpretation of the results provided in the regulatory flexibility analysis. The regulatory flexibility analysis demonstrates the impact of the rule on an individual small business, but does not attempt to aggregate impacts across entities. Wholesalers and retailers of children's products will be impacted by the rule if they are responsible for the testing and certification of a children's product because they either manufacture or import some products. In these cases, they are considered "manufacturers" and the examples used in the regulatory flexibility analysis, such as those discussed on pages 187 through 196 of the package, would be applicable to these firms.

Question 9

Page 167 of the testing and certification package states that more than 100,000 retailers could be considered small businesses, but that it is not known how many [are] engaged in importing or manufacturing children's products, and that they are therefore not considered in gauging the cost impact of the rule on small businesses. It is then stated with respect to these retailers that "[m]any firms probably obtain all of their products from domestic wholesalers or manufacturers and would not be directly impacted by the rule." Upon what is the quoted assertion based?

Response to Question 9

Based on our general knowledge of the industry, many small retailers rely upon wholesalers or other middlemen to obtain the product that they offer. These retailers would not be responsible for the testing or certification of the children's products that they offer. On the other hand, there are some small retailers that do import or manufacture some children's products. Because these retailers are responsible for the testing and certification of those children's products, the examples used in the regulatory flexibility analysis to illustrate the impact of the draft final rule apply to them. Consequently, while we do not know how many retailers manufacture or import children's products, the impact on small retailers that do manufacture or import children's products were implicitly considered in the regulatory flexibility analysis.

Question 10

Page 177 of the testing and certification package estimates three to five hours of record keeping per product. How was that estimate derived?

Response to Question 10

At the time when the Notice of Proposed Rulemaking was developed, we estimated that the recordkeeping would require about 2 hours per product. However, public comments provided alternative estimates, and we revised our estimate accordingly. For example, one commenter estimated that the recordkeeping requirements would require 3 hours for one category of products it manufactured and 5 hours for another, with an overall average across all products it manufactured of 3.5 hours. Another commenter stated that it required six employees to manage the recordkeeping for 1,700 products, which implies about 5 hours per product. Based on these and other comments, we revised upward our estimate of the average recordkeeping burden per product. Of course, the amount of time required for the recordkeeping for any particular manufacturer or product could be higher or lower than this estimate.

Question 11

Page 185 of the testing and certification rule explains that for purposes of calculating the cost impact of third party testing on small businesses, "the low to middle part of the ranges" for third-party lab testing costs was used.

Why did you choose to use the low to middle range when it is expected that low volume manufacturers and importers are unlikely to receive the discounts made available to larger volume manufacturers and importers? Did you take into account whether small volume manufacturers are more likely to rely upon higher priced domestic labs, rather than lower priced Chinese labs?

Response to Question 11
The primary purpose of a regulatory flexibility analysis is to examine the impact of a rule on small businesses and to make a determination regarding the significance of the impact. We used the low to middle part of the ranges for third-party laboratory testing costs to show that the impact on firms is likely to be significant even when costs at the low to middle part of the ranges were assumed. Obviously, if a firm must pay higher testing costs, the impact would be more significant than that shown in the examples. However, the ultimate conclusion that the rule is likely to have a significant impact on a substantial number of small entities is unaffected by the choice of low to middle range versus a higher range estimate.

Question 12
Why, if as is stated at page 155 of the testing and certification package "matters regarding the small batch manufacturer's exception in H.R. 2715 are outside the scope of this rulemaking," did you assume when calculating the cost impact on small businesses of the third party testing requirement, at page 194, that small batch manufacturers would be completely exempted from, and therefore not be required to incur, the costs of third party testing to the phthalates, heavy metal of paints and lead in substrate standards? Isn't it true that the Commission is authorized to come up with "alternative testing requirements" for small batch manufacturers, and that while they may be exempt pending such rule making, they will only be permanently exempted when and if the Commission fails to promulgate such alternative testing requirements? Is it not therefore also true that the testing costs of small batch manufacturers could well end up being something between third party testing and no testing? Is it not also therefore likely that your assumption that they will be exempt understates the cost to small batch manufacturers of the testing and certification rule?

Response to Question 12
The regulatory flexibility analysis considered the impact on small batch manufacturers of the testing requirements that are required by the CPSIA and H.R. 2715 (see pages 127 – 133 of the briefing package). Any additional testing requirements that the Commission develops, under H.R. 2715, for small batch manufacturers are not included as part of the draft final rule. Obviously, because they have not yet been developed, their impacts cannot be assessed. If the Commission develops additional testing requirements for small batch manufacturers, the impact of those requirements on small batch manufacturers will need to be evaluated at that time. Any additional testing requirements that are established for small batch manufacturers will represent an incremental cost over what is assumed in the current regulatory flexibility analysis.

Question 13
Section 1107.21(b)(2) states: "The testing interval selected must be short enough to ensure that, if the samples selected for testing pass the test, there is a high degree of assurance that the other untested children's products manufactured during the interval comply with the applicable children's product safety rules."

Does the likelihood that passing test results for the samples selected will ensure compliance of the other untested products depend upon how the samples are selected? If so, how can a manufacturer determine the appropriate testing interval in connection with the preparation of a

periodic testing plan without knowing how the CPSC will construe the requirement that "representative samples" be used?

Response to Question 13
If the manufacturer's process is free from drift or variation that may influence the safety of the produced units during the interval, then this consistency of product would allow the manufacturer to meet the requirement in the NPR that "the manufacturer must have knowledge that, had other samples been chosen for testing, test results from those samples would have indicated the same compliance or noncompliance to the applicable children's product safety rule as the representative sample." Section 1107.21(b)(2) presents examples of factors that a manufacturer should consider when determining the testing interval for periodic testing. If the manufacturer chooses an interval where there is not continuity of product with respect to safety, then the proposed requirement for a representative sample will not be met.

Question 14
Page 20 of the component part rule preamble states that the inclusion of the phrase "willful ignorance" in the definition of the duty of due care "is not intended to be a substantive change because any party who is willfully ignorant of material facts, by definition, would not be exercising due care. However, we wanted the final rule to emphasize that a party cannot, and should not, purposely avoid knowing a business partner's testing and certification practices to benefit from an exception contained in section 19(b) of the CPSA."
Please explain what you mean by "purposely avoid knowing a business partners testing and certification practices," and in doing so, please address:

Whether the requirement not to "purposely avoid knowing" creates a duty to inquire about the testing and certification practices of the party providing test results or a certification in the absence of any reason to doubt their efficacy in ensuring continued compliance?

Whether the language is intended to impose on a certifier the duty to review the written testing and certification policies of the component part or finished product manufacturer or supplier, and if so, under what circumstances?

Whether the language is intended to impose on a certifier the duty to visit the facility of the component part or finished product manufacturer or supplier, and if so, under what circumstances?

What other duties the language is intended to impose on a certifier with respect to the testing and certification practices of a component part or finished product manufacturer or supplier, and under what circumstances?

What is meant by the term "business partner"?

Response to Question 14
A party exercising due care must use the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances. Accordingly, the concept of due care is flexible, and will vary depending on the circumstances and the industry in question. Regardless of this flexibility, a prudent and competent certifier, by definition, will not purposely or knowingly fail to inform themselves of material facts about a

supplier's testing or certification process, because at a minimum, due care requires that a certifier know something about the facts underlying a supplier's test report or certification before a certifier can rely on it to issue its own certificate. For example, a prudent and competent certifier would endeavor to ensure that the laboratory used to perform the testing was on the CPSC-approved list of third party laboratories to conduct that kind of testing.

In the examples provided above, insufficient information is given to provide a definitive answer for each circumstance. Generally, however, due care requires taking some affirmative step to ensure the validity of the test report or certification being relied upon. If the prudent and competent finished product certifier in the same line of business would inquire about the testing and certification practices of a party providing test results or a certification in the absence of any reason to doubt their efficacy to ensure continued compliance, then that is what constitutes due care in that circumstance.

Actions taken by a certifier to ensure the reliability of test reports from a supplier may differ depending on the nature of the component part supplied, the risk of noncompliance, the industry involved, and the nature of the relationship with the supplier. A long term relationship with a trusted supplier that receives a large portion of its profits from one manufacturer may not require the same level of inquiry or monitoring as that of a new supplier that provides parts to many different manufacturers infrequently. Depending on the industry and the facts, a certifier may take various actions in order to know something about the validity of the test reports or certifications being relied upon. Such actions must include receiving and reviewing the required documentation, and making inquiry regarding any discrepancies. Additional actions in furtherance of the due care obligation may include asking questions about testing and sampling procedures and the third party conformity assessment body the supplier uses, spot checking a supplier's test results, requesting written test procedures, or visiting a supplier's factory or third party laboratory.

The term "business partner" in the preamble means a party with whom you are conducting business. In the sentence on page 20, the term "business partner's" may be used interchangeably with "supplier's," "testing party or certifier's," or "another party's."

Question 15

Page 20 of the component part rule preamble states that "Certifiers and testing parties have an obligation to resolve known or knowable (in the exercise of due care) problems with testing or certification by another party before relying upon or passing on test reports or certifications."

Do you mean by this language that certifiers and testing parties have an obligation to resolve problems of which they should be aware based on the exercise of due care before relying upon or passing on test reports or certifications? If not, what additional duty is intended to be imposed by this language?

Response to Question 15

Yes, certifiers and testing parties have an obligation to resolve problems of which they should be aware based on the exercise of due care before relying upon or passing on test reports or certification.

Question 16

Page 33 of the component part rule preamble states that "[a] finished product certifier may rely upon test reports or component part certificates from another party, provided that such certifier exercises the degree of care that a prudent and competent person in the same line of business would exercise in accepting their validity and is not being willfully ignorant of information suggesting that a supplier is providing noncompliant products, invalid test reports, or falsified certifications."

Does the phrase "not being willfully ignorant of information suggesting" refer to information already in the possession of the certifier, or does it also refer to information that the certifier is under a duty to acquire? If it is information that the certifier is under a duty to acquire, what predicate knowledge of the certifier is required to trigger that duty of inquiry?

Response to Question 16

The phrase "not being willfully ignorant of information suggesting" could refer to information already in the possession of a certifier, or it could refer to information that the certifier had a duty to acquire. The "predicate knowledge" required to trigger the duty of inquiry is that knowledge that a prudent and competent person in the same line of business or endeavor would act upon to inquire further under similar circumstances.