



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

This document has been electronically
approved and signed.

Memorandum

Date: October 14, 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 : Technical Staff's Response to Commissioner Nancy A. Nord's Questions
Related to Pending Proposals for Testing and Certification, "Representative"
Proposal, and Notice for Public Comment Concerning H.R. 2715

This memorandum is the U.S. Consumer Product Safety Commission's (CPSC's) technical staff's response to 12 questions provided by Commissioner Nancy A. Nord in a memorandum dated September 29, 2011, and to an additional question provided by Commissioner Nord's office in an e-mail message dated October 5, 2011. The CPSC's Office of General Counsel is providing separate responses to the Commission that will address the legal aspects of these questions. These responses have not been reviewed by, and may not necessarily reflect the views of, the Commission.

A, Questions Provided in September 29, 2011 Memorandum

Question 1

Please provide staff's understanding of the difference between "regulations" and "standards and protocols".

Response to Question 1

The CPSC's Office of General Counsel will provide a response to this question.

Question 2

The rule suggests that periodic testing could be required more frequently than every year in certain circumstances. Do we have the authority under this rule to require more frequent testing, outside the context of a compliance action brought either for violation of an underlying

safety standard or for distributing in commerce a defective product? If so, please explain more fully the source of and the limitations on that authority.

Response to Question 2

The CPSC's Office of General Counsel will provide a response to this question.

Questions 3, 3a, and 3b

Is it accurate that staff was directed by the Chairman's office to remove the provisions dealing with low-volume production?

- a) Do we have the authority in light of HR2715 to include low volume production provisions similar to what was in the NPR in this final rule? In the best opinion of the staff, would the low-volume production provisions as included in the NPR apply more extensively than the normal batch provisions of H.R. 2715?*
- b) Does the staff continue to think that a low volume production provision such as in the NPR would be helpful in addressing the costs and burdens imposed by this rule?*

Response to Questions 3, 3a, 3b

Yes, the Chairman's office directed staff to remove the low volume production provisions in the final rule.

- a) The CPSC's Office of General Counsel will provide a response to this question as it relates to the *legal* authority for the inclusion of the low volume production provision.

In technical staff's opinion, the low volume production provision in the Notice of Proposed Rulemaking (NPR) would apply more extensively than the small batch provisions of H.R. 2715. The low volume production provision was intended to provide some relief from the third party testing costs by not subjecting products to the periodic testing requirement until 10,000 units of the product had been produced or imported. Once 10,000 units had been produced or imported, the product would have been subject to the periodic testing requirements, which require periodic testing at least once every one, two, or three years, depending upon other testing conducted by the manufacturer. The low volume production provision in the NPR did not relieve the manufacturer from the requirement to certify the product on the basis of third party testing, nor did it relieve the manufacturer from the obligation to obtain third party testing after a material change to the product.

The small batch provisions of H.R. 2715 exempt, with some exceptions, qualifying small batch manufacturers from 1) third party certification testing, 2) third party testing after a material change, and 3) periodic testing; and they provide, in many cases, qualifying small batch manufacturers with more relief than the NPR low volume production provision. However, manufacturers that had total sales from consumer products that exceeded one million dollars in the preceding calendar year are not considered small batch manufacturers even though they might have some low volume products. These manufacturers would not be provided any relief by the small batch provisions of H.R. 2715, but would have been provided relief by the low volume production provision in the NPR from the periodic testing requirement until 10,000 units had been produced or imported.

- b) Staff believes that the low volume production provision in the NPR could be considered independently of the small batch provisions of H.R. 2715. The low volume production provision could provide some relief from periodic third party testing costs for some manufacturers who, as discussed above, have low volume products but had revenue from the sale of consumer products that exceeded one million dollars in the previous calendar year. The provision would allow the manufacturers of low volume products to spread the cost of the initial third party certification tests over more units before having to obtain third party periodic tests on the product.

Question 4

Will we have to amend the rule to accommodate HR 2715? Do you expect that the amendments would go beyond the “representative v. random” issue?

Response to Question 4

It is premature to say whether implementation of H.R. 2715 would necessitate further amendment(s) to the final rule on “Testing and Labeling Pertaining to Product Certification.” We do not know what information we may receive as a result of the notice inviting comment on the issues specified in H.R. 2715 or on the proposed rule regarding representative sampling, and it is conceivable that further implementation of H.R. 2715 may suggest a need for further rulemaking. Whether such future rulemaking would necessarily affect the final rule on “Testing and Labeling Pertaining to Product Certification” is unknown.

Question 5

The statement has been made that the test results from a sample deemed “reasonably representative” may not, in fact, be representative of the population of manufactured units. Please explain and clarify.

Response to Question 5

The statement reflects the uncertainty of the “representative” nature of the sample that is imparted by the adjective “reasonably.” CPSC staff mitigates this uncertainty in its draft NPR in response to H.R. 2715 by adding the requirement 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.”

Question 6

Please explain the relationship between the small batch provision of H.R. 2715 and this rule.

- a) *Is creation of the registry called for in H.R. 2715 a condition precedent to a requirement for small batch manufacturers having to third party test (except for the test listed in H.R. 2715 section 2(a)(2))? If a small batch manufacturer registers with the CPSC, then are they exempt from third party testing until the agency promulgates alternative testing procedures?*

- b) *When and how will the registry be developed? What issues are currently facing the staff's development of this registry?*
- c) *Would you anticipate that any alternative testing procedures would be integrated into this rule as an amendment?*
- d) *When and how will these alternative testing procedures be developed?*

Response to Questions 6a, 6b, 6c, 6d

- a) The CPSC's Office of General Counsel will provide a response to both parts of this question.
- b) The process and software for registration of small batch manufacturers is currently being developed. Requirements are being identified that will enable the system to be integrated into the CPSC Business Portal. Completion currently is scheduled for late November or early December 2011. Staff faces the issue of ensuring that the interpretation and implementation of the statute are correctly addressed in defining the requirements and in designing and developing the registry system.
- c) Staff has not decided what the best approach would be for incorporating any alternative testing procedures. Options the Commission could consider include amending this rule, creating a new rule, or amending any existing rule, standard, ban or regulation that covers a product or product class that is subject to an alternative testing procedure.
- d) A Commission public hearing on alternative testing procedures is scheduled for October 26, 2011. After the public hearing, staff will assess the public comments received and provide a recommendation for Commission consideration. The schedule for assessing the comments and arriving at a recommendation will be dependent on the number and complexity of the comments received pursuant to the public hearing.

Question 7

H.R. 2715 requires that we seek public input into ways to reduce testing costs and burdens and develop recommendations within 12 months. The agency has now initiated that process. Do you see any reason why the schedule called for in the law cannot be met?

Response to Question 7

H.R. 2715 created a new section 14(i)(3)(B) of the Consumer Product Safety Act (CPSA). Section 14(i)(3)(B) of the CPSA states that "Following the comment period described in subparagraph (A), 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."

While staff strives to meet statutorily-prescribed dates for specific actions, various factors can affect its ability to act within a specific time period. For example, staff cannot predict 1) how many public comments will be submitted; 2) what the issues presented in the comments will be; or 3) whether, as a result of reviewing the comments, the Commission will decide that new or

revised regulations are needed, given the determination that is to be made under section 14(i)(3)(B) of the CPSA. Staff also cannot predict whether any new priority, such as an unexpected serious hazard associated with a consumer product, will arise and demand reallocation of CPSC staff resources.

Staff will certainly strive, however, to meet the mandated schedule. Upon the closing of the 75-day comment period, staff will review all comments, prepare responses, and develop recommendations for revisions to the Testing and Labeling rule, assuming the current draft final rule is approved by the Commission.

Question 8

In the rationale for the 15 month effective date, it is stated that this will give parties sufficient time to prepare internal processes to implement the rule. This extraordinarily long effective date suggests that, for many companies, extensive changes will need to be made to internal processes.

- a) *The Regulatory Flexibility Analysis recognized that the administrative costs of third party testing would add 15 to 50% to the costs of testing. Did the Analysis quantify in any way the costs of changing internal procedures to accommodate the rule?*
- b) *If the rule is amended close to the effective date, internal procedures may have to change again. How will the regulated community do the planning anticipated by the rule if we are planning to amend it in the future? How will we assure ourselves and the regulated community that they will have enough time to again update, amend or change internal processes that were put in place to accommodate the original rule?*

Responses to Questions 8a, 8b

- a) The statement in the regulatory flexibility analysis that the administrative costs would add 15 to 50 percent to the cost of testing was an acknowledgment, in response to a public comment, that there would be additional costs associated with the rule other than the costs that would be charged by conformity assessment bodies for third party testing. The additional costs cited by the commenter included the cost of samples destroyed or damaged in testing, transportation of samples, administrative costs for managing testing, administrative costs for managing the testing data, administrative costs for managing recordkeeping, an allocation of general management time, legal expenses related to testing, and so on. The commenter estimated that these costs would add 15 to 50 percent to the out of pocket costs for third party testing. However, staff has not specifically attempted to quantify the costs to manufacturers of changing internal procedures to accommodate the rule. These costs would likely vary substantially among manufacturers depending upon things such as the products that they manufacture and their current quality control and testing practices.
- b) If the rule is amended in the future, staff would recommend seeking public comments on the impact of the amendment(s) on the effective date.

Question 9

Please describe more fully the “testing” that must be done as a part of a production testing plan. The rule states that this testing need not be the same tests that are required for certification

testing. Will calibrating machines on production line and testing to assure calibration is accurate, for example, count as production testing? What does the phrase “production testing must include some testing” mean? How and when will it be done and how will it be measured in a non-subjective manner?

a) What does the sentence “Any production test method used to conduct production testing must be effective in determining compliance.” mean? How will that effectiveness be measured?

Response to Questions 9, 9a

The draft final rule does not prescribe what the manufacturer must do for compliance; rather, the manufacturer would be responsible for developing a production testing plan that incorporates effective testing such that continual compliance with the requirements of the rule would be assured. The draft final rule leaves the manufacturer the flexibility to use the best practices of the company’s unique production process in developing a production testing plan.

Question 10

I would like to better understand the significance of “reserving” Subpart B rather than deleting it.

a) What was the staff’s preference on this matter? Was staff directed by the Chairman’s office to designate Subpart B ‘reserved’ as opposed to ‘deleted’?

b) What is the legal difference between reserving the section and deleting it?

c) If the Commission makes a decision to revisit this subject would it need to reinstate rulemaking with a reproposal or could the provision be brought back before us as a final rule? Does the decision to “reserve” rather than “delete” the provision change this result?

d) By reserving Subpart B, what is the status of the staff guidance on reasonable testing program, November 2009? Please provide a legal opinion on the status of this document.

Response to Question 10a, 10b, 10c, and 10d

a) Staff’s preference was to leave Subpart B in the draft final rule for Commission consideration. The direction to the staff from the Chairman’s office was to remove subpart B from the proposed final rule. Staff recommended reserving rather than deleting subpart B.

b) The CPSC’s Office of General Counsel will provide a response to this question.

c) The CPSC’s Office of General Counsel will provide a response to this question.

d) The CPSC’s Office of General Counsel will provide a response to this question.

Question 11

The statement that retailers can rely on certificate is in the preamble. Is there a reason not to emphasize it by putting it into the rule, being fully aware we do not exercise control over contractual arrangements but we can make clear that the agency believes and encourages retailers to rely on certificates from manufacturers/importers?

Response to Question 11

Technical staff has no opinion on the matter of adding this statement to the text of the rule. This is an option the Commission can consider.

Question 12

Is it possible to receive input on HR 2715 issues at the same time as re-proposing the testing rule, so that it is then amended and finalized within the same timeframe as the proposed effective date?

Response to Question 12

As indicated in the response to question 7, various factors - such as the volume of comments received, the issues presented in those comments, and unanticipated priorities that result in a reallocation of staff resources - can affect staff's ability to act by a particular date. Additionally, if the question implies that we would seek input on H.R. 2715 issues and develop a new proposed rule, it might be more efficient to seek input on H.R. 2715 issues and, after considering that input, develop a proposed rule. The proposed rule itself would be subject to notice and comment rulemaking. If the Commission chooses to re-propose, we note that the proposed rule on representative samples would then be unnecessary, as the concept of representative samples could be included in a re-proposal.

B. Question Provided in an E-Mail Message Dated October 5, 2011

Question

*In the briefing package and preamble to the proposed rule on "representative samples," Amendment to Regulation on Testing and labeling Pertaining to Product Certification Regarding Representative Samples for Periodic Testing of Children's Products, the following statement appears (mem. at *3; draft Federal Register notice at *6): "To be representative, 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 samples".*

[With respect to the above statement,] Is the word "knowledge" different from the phrase "basis for inferring compliance" as used in the draft proposed rule: "The procedure used to select representative product samples for periodic testing must provide a basis for inferring compliance about the population of untested products produced during the applicable periodic testing interval?"

If "knowledge" is different from "basis for inferring compliance", should the preamble be revised to reflect that, perhaps by using the following sentence: "To be representative, the manufacturer must have a basis for inferring 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 samples."

Response to Question

Yes, “knowledge” and the phrase “basis for inferring”, as they are used in the draft proposed rule, are different. The condition that provides the basis for inferring compliance of the untested samples from the representative sample’s test results is the manufacturer’s knowledge that the safety compliance determination resulting from a representative sample would have been the same had any other samples been selected for testing. It is the compliance of untested products that is inferred from the test results of the representative sample -- not the knowledge that the sample is representative as the sentence suggests. Staff’s opinion is that the preamble should not be revised as suggested in the question.