U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814-4408

Record of Commission Action
Commissioners Voting by Ballot*

Commissioners Voting: Chairman Inez M. Tenenbaum
Commissioner Nancy A. Nord
Commissioner Anne M. Northup
Commissioner Robert S. Adler

ITEM:

Proposed Rule: Requirements Pertaining to Third Party Assessment Bodies
(Briefing packages dated March 13 and 14 and April 13, 2012, OS No. 3786)

DECISION:

The Commission voted unanimously (4-0) to approve publication of the proposed rule in the *Federal Register,* with changes, that would establish requirements pertaining to third party conformity assessment bodies (or "laboratories") that are authorized to test children's products in support of the certification required by section 14(a)(2) of the Consumer Product Safety Act, as amended by section 102(a) of the Consumer Product Safety Improvement Act of 2008. Commissioner Northup filed the attached statement regarding this matter.

For the Commission:

Todd A. Stevenson
Secretary

* Ballot vote due April 27, 2012
(The vote in this matter was deferred from a decisional meeting on April 11, 2012.)

Attachment: Statement of Commissioner Northup

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

COMMISSIONER ANNE M. NORTHUP

STATEMENT OF COMMISSIONER ANNE M. NORTHUP ON THE PROPOSED RULE FOR REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES AND THE FINAL RULE FOR AUDIT REQUIREMENTS FOR THIRD PARTY ASSESSMENT BODIES

May 11, 2012

The Commission's recent issuance of a proposed rule setting forth requirements for CPSC approved labs and a final rule governing the auditing of the labs adds to the growing bureaucratic morass created by the requirement that all children's products be third party tested to all applicable children's product safety standards. Building on its highly prescriptive rules governing when and how manufacturers and importers must third-party test, the Commission now dictates a new series of requirements that must be followed by the labs that perform the tests. In addition to the burdens placed on the businesses regulated under these rules, the Commission itself faces a huge drain on its resources to enforce them. This is all imposed under a regime of third party testing with an unproven track record of enhancing product safety and significant practical reasons to believe it will not. All of these resources, both private and public, could be better spent embracing newer technologies to ensure product safety.

Last fall, the Commission voted to issue a final rule establishing the protocols and standards for the third party testing of children's products to ensure continued compliance with applicable safety standards, both when there is a material change in the product, and periodically during production even in the absence of a reason to believe a certified product is no longer compliant. As explained in my statement at the time, that rule may be the most intrusive imposition of requirements on a segment of the manufacturing community ever. Its prescriptive mandates insinuate the Commission deeply into the production process of any company that manufactures a children's product for the United States market. The final rule, codified at 16 C.F.R. § 1107, requires manufacturers to undertake a complex analysis and formulate a detailed periodic testing plan or production testing plan, or obtain ISO/IEC 17025:2005 accreditation for an in-house laboratory. A detailed periodic testing or production testing plan must be written for each product manufactured at each manufacturing site, even where the product manufactured at the site changes frequently, such as on a daily basis.

Now it's the labs' turn. By requiring third party testing of children's products, the CPSIA created for third party conformity assessment bodies (as the labs are formally called) a captive market of manufacturers who must contract with labs to obtain test results in order to sell their products in the United States. But in order for the tests to count, the accreditation of the labs to perform the tests must be "accepted" by the CPCS.

Labs can be either "independent" (labs over which the manufacturer has no control with regard to scheduling, pricing, management, etc.), "firewalled" (labs owned by the manufacturer where costs and schedules can be controlled) or "government owned". All labs seeking acceptance of their accreditations must submit to the Commission a lengthy and detailed application form with supporting documentation, and must update the form whenever the information it contains changes. CPSC staff will review each lab's form and may ask additional questions.

It is even more complicated for a lab that is firewalled, which must additionally submit copies of its policies and procedures explaining how it will protect test results from undue influence and ensure notification to the CPSC of any attempt to exert undue influence on the lab; copies of documents showing the content of training programs administered to employees to protect against undue influence, as well training records detailing the circumstances of the training and containing lists and signatures of staff members that have undergone training; and, detailed organizational charts showing reporting relationships both inside and outside the lab. Acceptance of a fire walled lab requires a majority vote by the Commissioners, based on legal and technical memoranda prepared by staff addressing the relevant criteria and the evidence presented by the lab.

Labs seeking acceptance as governmental third party conformity assessment bodies must provide the CSPC with even more information detailing their organizational relationships, completed questionnaires and attestations, and memoranda addressing undue influence, covering specific issues and in the precise format dictated by the Commission.

Once a lab is accepted by the CPSC, it must separately apply for acceptance of accreditation for each additional rule and/or test method it later adds. It must also adhere to stringent record keeping requirements, including the retention of all internal documents describing testing protocols and procedures, and all test reports and technical records related to tests, for at least five years. An accepted lab must resubmit its application form and all accompanying documents at least every two years, as part of the audit process.

There are also a host of adverse actions that the Commission can take against the labs, including denial, suspension and withdrawal of acceptance. The proposed rule sets forth a detailed list of grounds for each potential adverse action, lengthy guidelines for whistleblowers to follow when alleging grounds for an adverse action, and a multi-phase procedure for the CPSC's investigation, evaluation, adjudication, and consideration of appeals of adverse actions.

In short, the third party testing requirement has now spawned a whole new regulatory regime, which imposes substantial costs on labs – most of which we can assume will be passed on to their captive manufacturer and importer customers – and will badly strain the CPSC's limited resources. And to what end?

As the regulatory burden associated with third-party testing continues to grow out of control, its benefits are speculative and likely overstated. Some argue that third-party testing before sale will result in fewer recalls. But most recalled products contain design or manufacturing defects that are unrelated to the Commission's product and material specific safety standards. Moreover, given the Commission's decision to reduce the lead in the substrate of children's products well below a level presenting any risk to health, recalls of products violating the new standard will not even necessarily protect against a real risk of injury.

Additionally, the manufacturers most likely to honor the third-party testing requirement are also the least likely to produce noncompliant products. Good corporate citizens wishing to maintain their market reputation have already improved their internal mechanisms to ensure compliance regardless of third-party testing requirements, but will also incur the cost of third-party testing consistent with their commitment to follow the law. Indeed, the CPSIA's micromanagement of a company's testing, certification and tracking of each and every component of a product will be less helpful than the sophisticated internal controls manufacturers are currently using and continue to develop and perfect. For instance, we have learned that since the discovery in 2007 that the lead paint in certain violative products was introduced through inadequately supervised component suppliers, manufacturers have reduced their number of suppliers, and now undertake more frequent internal testing. Component suppliers, in turn, take more care to ensure compliance because they are aware that manufacturers will not risk continuing to use a supplier who fails even once to provide compliant components.

In contrast, a "bad actor" with a casual attitude toward safety standards compliance will be just as casual about maintaining accurate records to support CPSIA-mandated certifications. 16 C.F.R. § 1107, when effective, will require a manufacturer to retest and issue a new finished product certificate every time a new batch of paint is used on any component of a product. Manufacturers wishing to avoid that burden will simply ignore component supplier changes and continue to use the results of older tests to support existing certifications. The CPSC does not have the resources to police manufacturers' internal record keeping controls and would not learn of a failure to comply with retesting requirements until it identifies a noncompliant product in commerce and undertakes an investigation. As a result, the detection method of ensuring compliance will remain the default for companies most likely to produce violative products, while those committed to ensuring compliance and already effectively doing so bear the unnecessary additional burden of third-party testing.

Today, the Commission also has enforcement tools vastly improved over those available even a few years ago. These are a more effective use of taxpayer dollars to ensure compliance with safety standards than is policing all children's product manufacturers for certifications to mandatory third-party tests and micromanaging the labs that perform the tests. The Commission now has authority to confiscate and destroy at the border products that violate federal safety standards. Since the advent of our agency's Import Surveillance Division in 2008, we have continued to increase the number of full-time CPSC investigators posted at key U.S. ports. We have also expanded cooperation with

CBP to maximize the number of products screened at all U.S. ports. Today, the Commission intercepts non-compliant toys through more extensive border control efforts; application of x-ray technology; and computer databases that search ship manifests before they reach port, flagging for inspection previous offenders and first-time shippers. Using this more detailed and timely information, and through closer cooperation with CBP, the CPSC seized and denied entry to 49% more shipments of noncompliant products in 2010 than in 2009.

The CPSIA also increased the incentive for compliance by increasing the maximum civil penalty amounts from $8,000 to $100,000 for each "knowing" violation and from $1.825 million to $15 million for any related series of violations. As a result, the average out of court settlement reached by the CPSC for violations of its statutes increased 61% between 2008 and 2009, and another 43% in 2010 over the amounts collected in 2009. The CPSC also can now more easily seek criminal penalties, and can require a company recalling a product to give a refund, replacement and/or repair, rather than allowing companies to select the remedy they prefer.

It is well recognized that these difficult economic times call for a regulatory regime that carefully balances the costs and benefits of executive agency action. And consumer product regulation, in particular, must take into account the desire of American families for a dynamic marketplace with new and more interesting products that are also safe and affordable. The requirement that all children's product manufacturers repeatedly third-party test every component of their products is a tremendously costly and not very effective means to prevent violative products from entering commerce. It also threatens to drastically reduce the availability of children's products for parents of modest means. Public and private resources should therefore instead be redirected toward the alternative production processes and enforcement methods that can achieve the same goal much more efficiently.