



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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COMMISSIONER ANNE M. NORTHUP

**STATEMENT OF COMMISSIONER ANNE NORTHUP ON THE VOTE TO
ESTABLISH PROTOCOLS AND STANDARDS FOR THE TESTING OF
REPRESENTATIVE SAMPLES TO ENSURE CONTINUED COMPLIANCE.**

July 23, 2012

My colleague Nancy Nord and I voted to amend the draft final rule establishing protocols and standards for the testing of representative samples to ensure continued compliance, and as a result, the rule failed by a 2-2 vote. Our amendment would have cut from the final rule a record keeping requirement that expands, without justification, the already enormous burden of complying with the CPSC's third party testing rule. I otherwise supported the substantive provisions of the rule.

Before the CPSC began to implement the new "prevention" regime of the Consumer Product Safety Improvement Act (CPSIA), members of Congress from both parties recognized that the law imposed immense cost burdens far in disproportion to any benefit attained through a reduction in risk. The CPSC received regular and vocal bipartisan exhortations to implement the law as "flexibly" as possible in order to minimize its adverse impact. It was in this climate, that Congress passed P.L. 112-28, which amended 15 U.S.C. § 2063(h)(2)(B)(1) by replacing "random" with "representative," to describe the type of sampling to be used when selecting products for periodic testing to ensure continued compliance.

CPSC staff properly recognized Congress' intent to define "representative" according to its common meaning. There is no scientific or manufacturing term of art that provides a definition of "representative" distinct from the one found in any dictionary. Meriam-Webster's dictionary defines "representative" as "serving as a typical or characteristic example." Therefore, the draft final rule would have reasonably afforded manufacturers the flexibility to select samples for periodic testing according to the methodology that best suited their product and production process, so long it provided a basis for inferring the compliance of the untested samples. As staff explained in the preamble to the draft final rule, "various methods can be used to determine that the selected samples are representative, depending upon the rule, ban standard, or regulation being evaluated." Draft Final Rule at 5.

Had the draft final rule stopped there, it would have had my support. Instead, it included costly new record keeping requirements not mandated by law and without adequate justification. The draft final rule would have required the creation and maintenance of:

Records documenting the testing of representative samples, as set forth in 1107(21)(f), including the number of representative samples selected and the procedure used to select representative samples. Records must also include the basis for inferring compliance of the product manufactured during the periodic testing interval from the results of the tested samples.

Draft Final Rule 16 C.F.R. 1107.26(a)(4).

CPSC's economists estimate the aggregate manufacturers' cost of compliance with this additional record-keeping to be \$32.3 million for the first year alone, and another \$1.3 million to \$6.5 million every year thereafter. And this cost is in addition to the enormous burden of the record keeping already required by 16 C.F.R. part 1107 – Testing and Labeling Pertaining to Product Certification. 16 C.F.R. § 1107.21 gives manufacturers three options for satisfying the requirement that, after initial certification, a third party lab conduct periodic tests of every component of every children's product to ensure continued compliance with all applicable children's product safety rules. Each of these options requires the creation and maintenance for five year of extensive records.

First, a manufacturer may opt to conduct periodic testing at least once a year pursuant to a Periodic Testing Plan, under 16 C.F.R. § 1107.21(b)(1). The written periodic testing plan must include the tests to be conducted, the intervals at which the tests will be conducted, and the number of samples tested. The manufacturer must also retain records of all third party periodic test results. Second, a manufacturer may choose to prepare a Production Testing Plan as described at 16 C.F.R. § 1107.21(c)(2), and conduct periodic third party tests a minimum of every two years. The Production Testing Plan must describe separately for every children's product and for each manufacturing site "the process management techniques used, the tests to be conducted, or measurements to be taken; the intervals at which the tests or measurements will be made; the number of samples tested; and the basis for determining that the combination of process management techniques and tests provide a high degree of assurance of compliance." The manufacturer must also retain copies of all production test results and all third party periodic test results. The third option permits manufacturers to conduct third party tests at three year intervals if, during the interim period, they conduct tests using a laboratory accredited to ISO/IEC 17025:2005(E). 16 C.F.R. 1107.21(d)(1). Manufacturers choosing this option must maintain the results of all tests conducted using an ISO/IEC 17025:2005(E) accredited laboratory, as well as all third party periodic test results.

I believe these extensive record keeping requirements already far exceed what is necessary to ensure continued compliance under the CPSIA and to facilitate enforcement. Yet the Commission would impose even more, requiring a written record of the procedure used to select the samples and a narrative explaining the basis for inferring compliance of the product manufactured during the periodic testing interval from the

results of the tested samples. I am unable to identify any benefit to imposing that additional recordkeeping burden that would justify the tens of millions of dollars it would cost. Given the number of products we regulate and the numbers coming in at the ports that are noncompliant and still result in no enforcement action, the odds of any manufacturer ever having to produce such documents is very slim. Imposing the high record keeping cost on all manufacturers so that a miniscule percentage could be reviewed during an investigation is unjustified. Moreover, the reasons offered by others are unpersuasive.

Proponents of the representative sample record keeping requirement argue that the act of creating these records will encourage manufacturers to think more carefully about sampling issues. However, it is not the Commission's responsibility to regulate good business practices, nor does it have the experience or expertise to gauge what is best for any particular business. The Commission should be concerned with promoting product safety by assisting businesses to understand their substantive legal requirements. The added record keeping burdens included in the Final Rule would have the opposite effect, by refocusing businesses away from complying with the rule and toward creating defensible documents. As a result, instead of making decisions based on their own experience and expertise, businesses would need to anticipate what CPSC investigators – with no business experience, let alone with respect to the particular product or manufacturing process -- might look for in the context of a defect investigation or enforcement action.

Some also say that the Commission needs the records for enforcement purposes, so that it can learn the sampling procedure and basis for it while investigating noncompliant product. But that information is available to the Commission even without the added burden of the recordkeeping requirement. The CPSC can learn the information orally or through written documents prepared by the target business when and if they are subject to an investigation.

Nor do I share the concern that permitting manufacturers to await a compliance investigation before being required to explain their selection would promote either inaccurate or fraudulent explanations. The risk of unintentional inaccuracy does not justify the record keeping requirement, because the substantive requirements of the representative sampling rule already create ample incentive for manufacturers who believe a contemporaneous record is necessary to create one. This is because even without the recordkeeping requirement, the rule would mandate that manufacturers use a sampling process from which the compliance of the untested products can be inferred. A manufacturer that cannot demonstrate that it used such a process would therefore violate the rule and be subject to civil penalties, as well as risk the recall of a far larger proportion of its production. As a result, there would already be strong incentive for manufacturers with selection processes too complex to be readily explained or recreated to prepare contemporaneous records, and they would be free to do so. But those manufacturers whose process and rationale for their selection process can readily be explained should not be required to incur the cost of creating unnecessary records.

With respect to the risk that businesses that do not create contemporaneous records will invent fraudulent explanations when investigated, the “cure” of mandatory recordkeeping doesn’t solve the problem. Business management willing to falsify the sampling procedure or basis when investigated is equally likely to do so at the outset in response to a record keeping requirement. Moreover, manufacturers are already spending huge amounts of money on third party testing. They have every incentive to make those tests worthwhile by ensuring that they provide results reflective of the compliance of the untested products. The unlikely possibility of a CPSC investigation is much less important to a business than protecting against product lost to recalls or confiscation at the ports, future scrutiny by the CPSC after a violation, bad publicity, and potential lawsuits. These concerns are the real incentive to select representative samples to ensure compliance of untested products, not a recordkeeping requirement. There is similarly little incentive for a manufacturer to select “golden samples” that pass tests, but do not ensure that the untested products are also compliant. A bad actor or a “fly by night” manufacturer more intent on getting past the testing phase than on selling a compliant product is not going to be reformed by a record keeping requirement that requires they document the procedure and basis for their random sample selection. Such manufacturers will circumvent the recordkeeping requirement through fraud or otherwise; while, ethical, conscientious manufacturers with good business practices would also unnecessarily bear the burden of the recordkeeping.

Finally, it has been argued that the CPSC needs records of the representative sampling procedure and basis in order to determine whether the entry into commerce of noncompliant product was caused by nonrepresentative sampling or inaccurate third party testing. But regardless of whether the CPSC were satisfied with a manufacturer’s explanation of its sampling procedure and basis, and irrespective of whether the manufacture maintained the records sought to be required by the Final Rule, laboratory error as a contributing cause could not be ruled out. There will therefore always be the need to investigate laboratories that tested samples from a batch or lot later determined to contain noncompliant product.

I was aware when Commissioner Nord and I voted for the Final Rule as amended that doing so would prevent the issuance of a Final Rule on the protocols and standards for the testing of representative samples to ensure continued compliance, because the two Democrats on the Commission would vote for the unamended version of the Final Rule. But I am confident that the Commission’s failure to issue the Final Rule will have no impact on product safety. 16 C.F.R. 1107.21 already requires that periodic testing be conducted pursuant to a plan that “ensure(s) with a high degree of assurance that children’s products manufactured after the issuance of a Children’s Product Certificate, or since the previous periodic testing was conducted, continue to comply with all applicable children’s product safety rules.” Periodic testing of product samples cannot provide a high degree of assurance that untested products are also compliant unless the tested samples are “representative” as defined in the Final Rule that failed to pass. Thus, the substantive requirements of the Final Rule are already subsumed within current regulations. I was therefore unwilling to pass what amounts to a redundant requirement, when the price of doing so was the imposition of tens of millions in unjustified costs.