U.S. CONSUMER PRODUCT SAFETY COMMISSION

4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814-4408

Record of Commission Action
Commissioners Voting by Ballot*

This is a DRAFT RCA.
It will be replaced by a Final RCA.

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

ITEM:

Draft Final Rule: Requirements Pertaining to Third Party Assessment Bodies
(Briefing package dated January 16, 2013, OS No. 5973)

DECISION:

The Commission voted unanimously (3-0) to approve publication of the final rule in the *Federal Register*, with changes, that will establish requirements pertaining to third party conformity assessment bodies (or laboratories) whose accreditations are accepted 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. Chairman Tenenbaum and Commissioner Adler voted to approve publication of the final rule with the same adopted changes. Commissioner Nord voted to approve publication of the final rule with changes that were not adopted. Commissioners Nord and Adler issued the attached statements regarding the matter.

For the Commission:

Todd A. Stevenson
Secretary

* Ballot vote due February 21, 2013
(The vote in this matter was deferred from a decisional meeting on February 20, 2013.)

Attachments: Statement of Commissioner Nord
Statement of Commissioner Adler
Supplemental Statement of Commissioner Nord
The Adopted Changes of Chairman Tenenbaum and Commissioner Adler
The Changes Proposed and Not Adopted of Commissioner Nord

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COMMISSIONER NANCY A. NORD

Statement on the Commission's vote to approve a final rule establishing requirements pertaining to third party conformity assessment bodies

February 21, 2013

Today, the Consumer Product Safety Commission voted to issue regulations for laboratory accreditation under our children's product testing and certification program. Although I generally support the regulation, some of its elements deserve comment.

First, one element—the test for whether a laboratory is "controlled" by a manufacturer—is excessively stringent in view of the extent (or absence) of the problem it addresses. This requirement continues a reflexively proscriptive, hyper-regulatory approach to addressing problems without fully considering more thoughtful options or even verifying that there is a problem at all. Second, we should provide some further clarity on testing that occurred before relevant rules were approved. While that issue is not addressed in the final rule, I am pleased that the staff plans to further address it in the near future. Finally, some of the provisions in this rule could be misinterpreted to require duplicative record-keeping. I explain below why I do not believe this is necessary.

Controlling "Control"

This rule presents a key example of the compulsion to over-police: overreacting to a hypothetical problem that, if it exists, is already adequately addressed by statute and other regulatory provisions. The Consumer Product Safety Improvement Act requires us to "establish protocols and standards . . . for safeguarding against the exercise of undue influence" over labs by manufacturers.[1] The CPSIA permits us to approve a company's in-house lab, but only if we go through an extensive added review to ensure its work is as sound as an independent lab's would be.[2] By statute, that review is triggered whenever a lab "is owned, managed, or controlled by a manufacturer."[3]

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[1] 122 Stat. 3016 § 102(b) (codified at 15 U.S.C. § 2063(d)(2)(B)(iv)).

[2] 122 Stat. 3016 § 102(b) (codified at 15 U.S.C. § 2063(d)(2)(D)).

[3] *Id*.

In drafting the rule, our staff proposed language that captured the plain meaning of the law. It viewed a manufacturer as controlling a lab if it could appoint a majority of the lab's board of directors (or other governing body), appoint the presiding official of that body, or hire, fire, or set salaries for lab personnel. This approach made sense, and tracks other areas of law that address controlling interests: If a manufacturer controls the people who do the testing or the people above them, then it controls the lab. That (along with the other protections found in ISO 17025) should have been sufficient to make sure that any lab that should be subject to the firewall requirements would be.

Unfortunately, my colleagues did not accept staff's recommendation. Instead, the final rule applies firewalled-lab status if a manufacturer can appoint *any* member of a lab's governing body. The argument is that even a single board member with manufacturer ties can be so persuasive as to steer the lab in directions that benefit the manufacturer. This solution in search of a problem ignores the realities of the marketplace.

While the CPSIA requires us to address the issue of manufacturer control over labs, this heavy-handed restriction seems unwarranted. There has been no demonstration that manufacturers commonly have board-appointment powers[4] at labs, that they are using any such powers, or such use can give them a voodoo-like hold over the labs though the boards. Both common sense and statute demand that we have some line for control, but there was no reason we could not adopt staff's proposal, which mirrors the approach of other legal fields.

What is more, the provision does not require any connection between manufacturer appointment powers and the products that the lab tests, nor does it require actual exercise of those powers. If *any* manufacturer *can* (not "does") appoint *any* board member, the lab can only be accredited as a firewalled lab, even if it does no work for the manufacturer with the appointment power. It borders on the absurd to suggest a board member would act contrary to her fiduciary duties to the lab to benefit a manufacturer for whom she does not even work.

If a manufacturer is actually using a lab's board member to steer decisions unfairly or improperly to its favor, then we can require a firewall. Until then, so long as a lab's board has a majority with no perceived manufacturer loyalties, it is not "controlled" by manufacturers in the common sense meaning of that term. I offered language to this effect; that my colleagues rejected it is dismaying.

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[4] I also feel this rule is too vague on the concept of appointment powers, providing no definition or guidance as to what that term means. That uncertainty would have been present under the staff's majority appointment approach, as well, but if *any* appointment power can trigger firewall requirements, it becomes crucial to know what an appointment power is.

Retrospective Testing

The final rule directly raises the issue of how we treat retrospective testing. When the effective date for the testing rule looms, manufacturers do not sit idle, waiting for the regulatory starter's pistol. They make products and send them to labs to be tested. In the rule we issued today, we recognize that reality with respect to a number of individual safety standards.

I believe that it would be helpful to have some plain-language clarity on that point in the form of a Frequently Asked Question (FAQ) document or some other type of staff guidance. Given that CPSC's rules take up their fair share of the near-quarter million pages in the Code of Federal Regulations, it is not reasonable to expect that all our labs and manufacturers will read each line. Giving them the opportunity to learn about the regulations in a manageable form will only enhance compliance, and I am glad that the staff intends to provide this clarity.

Record-keeping Redundancy?

This rule requires labs to retain testing records for five years. On its face, this is not a particularly odious provision. There need to be adequate records of tests so that, if something goes wrong, we can work with the labs and manufacturers to find out what and prevent it from happening again.

However, this requirement should be read in concert with our other rules. The periodic testing rule already requires manufacturers to keep test records for five years. In my view, our rules should be read so that, so long as the agency has reliable, ready access to these documents on demand, it does not matter whose file drawer they are in. If a manufacturer wishes to keep all the information in-house and provide it when we request, that should be fine. If a company prefers to effectively outsource that function to the lab, then, as long as it can deliver us the records quickly and completely, our ability to function is unchanged.

Contrariwise, one might read the record-keeping requirements as a new mandate to require another entity to keep the same records. I do not believe this is the best reading of the requirement. Such a reading would not benefit consumers, but add yet more costs to the supply chain that brings them the products they buy. The more sensible reading should govern here.

Conclusion

While I am generally supportive of the rule adopted today, as described above, I believe that certain elements should be different. My larger concern is that those elements reflect an instinct that adopts hyper-regulation as the answer, even where there is no question. We have no evidence that a manufacturer is using a single laboratory appointee to manipulate a laboratory's board into improper decisions, but we are acting

on unfounded suspicions nonetheless. For a science-driven agency tasked with problem-solving, this is a troubling overreaction.

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Statement of Commissioner Robert Adler on Approval of a Final Rule to Establish Requirements Pertaining to Third Party Conformity Assessment Bodies

February 22, 2013

On February 21, 2013 the Commission voted unanimously to issue regulations for laboratory accreditation under our children's product testing and certification program. Although the vote was unanimous, my colleague, Commissioner Nancy Nord, issued a statement, among other things, voicing objection to one revised section of the rule, claiming that it presented a "key example of the compulsion to over-police." I disagree with my colleague's characterization and want to clarify my support for the change in this provision of the rule.

The specific provision that my colleague objected to is section 1112.11(b)(ii)(C), which states that a laboratory will be considered to be a "firewalled" laboratory, i.e., one that is owned or controlled, in whole or in part, by a manufacturer or private labeler, if --

> (C) A manufacturer or private labeler of the children's product has the ability to appoint <u>any</u> of the third party conformity assessment body's senior internal governing body (such as, but not limited to, a board of directors), the ability to appoint the presiding official (such as, but not limited to, the chair or president) of the third party conformity assessment body's senior internal governing body, the ability to hire, dismiss, or set the compensation level for third party conformity assessment body personnel, regardless of whether this ability is ever exercised. (Emphasis added)

The revision to which my colleague objected is the underlined word "any" above. As originally drafted by staff, the provision applied only when the manufacturer or private labeler had the ability to appoint a <u>majority</u> of the lab's senior internal body. She characterizes the rationale for the change in wording as being "even a single board member with manufacturer ties can be so persuasive as to steer the lab in directions that benefit the manufacturer."

That is my colleague's characterization, not mine. My reason is much simpler and has nothing to do with a board member's persuasive abilities. The issue is whether a lab that can be forced by a manufacturer or private labeler – against its will – to appoint a board member or senior executive can truly be considered independent. To me, the answer is simple— no. The classic definition of power is the ability to get someone to do something even when he or she does not want to do it. That is the point. A manufacturer's ability to make a lab take such a critical personnel action has nothing to do with the number of board appointees and everything to do with the power to bend the lab to the manufacturer's will.

Does a manufacturer's ability to influence a lab's senior personnel decisions constitute complete control of the lab? The answer is "maybe, but not necessarily." The test, however, is not whether the manufacturer totally controls a lab. The test is whether the customer controls the lab "in whole or in part." Where a manufacturer has the ability to control a lab's senior personnel decisions, there should be no question about that.

I would further note that the disagreement with my colleague is not whether a lab can be accredited to test for compliance with CPSC rules. Either an independent or a firewalled lab can be accredited. The point is that a lab that can be compelled by its customer to hire personnel favored by the customer cannot truly be considered independent. That said, I see nothing inherently wrong in such an arrangement so long as all parties recognize and disclose the underlying power structure. Nor does the CPSC regulation bar the lab from doing business. It simply places the lab in a different – and more appropriate – category.

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COMMISSIONER NANCY A. NORD

Further statement on the Commission's vote to approve a final rule establishing requirements pertaining to third-party conformity assessment bodies

February 25, 2013

As I have noted before, it had been longstanding practice at the CPSC for Commissioners' statements to discuss their votes, rather than use their statements to rebut those of their colleagues. Unfortunately, one of my colleagues does not subscribe to that view, and his statement on our recent vote to adopt requirements for third-party conformity assessment bodies (that is, laboratories) appears to be prompted entirely by mine. Since my statement has been challenged, I feel I must respond.

The staff presented us with a thoughtful definition of the kind of control that could lead to concerns about a laboratory's independence and warrant "firewalled" status: a manufacturer's ability (1) to appoint a majority of the governing body, (2) to appoint the presiding officer of the laboratory's governing body, or (3) to make staffing and compensation decisions about laboratory personnel. To assure that this definition was as complete as possible, I offered an amendment that would have required firewalling wherever a manufacturer had the ability to exercise a controlling influence over the management or policies of the governing body. This language mirrors the definition of "control" in other areas of law, but this compromise amendment was rejected.

Instead, the majority adopted an amendment states that an ability to appoint even a single member of the governing body would result in firewalled status. My colleague justifies this amendment as addressing a situation where a laboratory is being "forced . . . —against its will—to appoint a board member or senior executive." However, we have no evidence that kind of coercion is happening or would happen, as shown by our staff's language. Further, if it did occur, it would be contrary to the requirements of ISO 17025, a standard that applies to all our accredited laboratories.

There was no review of the impact of this change, nor was there any attempt to define its scope—for instance, limiting it to situations in which the company holding the appointment power is actually transacting business with the relevant lab. In other words, we are squashing an ant with a sledge hammer. We have created a hypothetical problem and crafted an overly broad solution to address it. And that is why, as indicated in my earlier statement, my larger concern is that this amendment reflects an instinct on the part of this Commission to hyper-regulate, to issue edicts that go beyond demonstrated need.

The CPSIA set a reasonable boundary between third-party labs and firewalled labs, requiring the latter to go to extra lengths to prove their independence. The boundary is "owned, managed, or controlled by a manufacturer."[1] We should have followed our staff's recommendations and left the line where Congress drew it.

[1] 122 Stat. 3016 § 102(b) (codified at 15 U.S.C. § 2063(f)(2)(D)).

Page 25 of Preamble:

(*Comment 19*) A commenter requests that the status of CPSC-accepted laboratories be disclosed publicly and that it should be readily ascertainable on the CPSC's website. The list of CPSC–accepted laboratories on the CPSC website at: http://www.cpsc.gov/en/Business--Manufacturing/Lab-Accreditation/, currently does not display whether a laboratory is categorized as independent, firewalled, or governmental. The commenter asserts that it is in the interest of commercial customers and consumers to display this information and that the proposed rule should be modified to require that in applying for acceptance by the CPSC, "a lab must accede to the public disclosure of its acceptance status" (independent, firewalled, governmental) on the website display of CPSC-accepted laboratories.

(*Response 19*) For the reasons stated by the commenter we agree to list the independent, firewalled, or governmental status of accepted laboratories on the CPSC website at Section 1112.19. While it is true that once its accreditation is accepted by the CPSC, a laboratory may conduct tests within its scope for children's product certification purposes, regardless of its status as an independent, governmental, or firewalled laboratory there is no restriction on the CPSC providing the public and manufacturers with this information.

It is important to note, however, that many of the CPSC-accepted governmental laboratories have a small portion of government ownership and little-to-no government involvement in their operations. These laboratories operate essentially as independent laboratories, but by law, they must be categorized as "governmental" because they have

partial government ownership, such as through a joint venture. Other governmental laboratories are associated with state-funded institutions. Because forms of governmental involvement can vary, listing a laboratory as "governmental" does not necessarily convey any meaningful information to the public. Yet, in the interest of transparency the Commission has chosen to provide the information in a similar manner to the way in which the CPSC lists firewalled laboratories.

As noted, the CPSC already lists firewalled laboratories on its website, despite the fact that the firewalled status applies only to a manufacturer or private labeler who owns, manages, or controls the laboratory. This practice will not change. (*See* http://www.cpsc.gov/en/Business--Manufacturing/Lab-Accreditation/.) In other words, the laboratory is considered independent for any other manufacturer or private labeler who may wish to use the laboratory's services.

Page 41 of Preamble:

A laboratory would be considered to be "owned, managed, or controlled" by a manufacturer or private labeler if one (or more) of three characteristics apply. The first is if the manufacturer or private labeler of the children's product holds a 10 percent or greater ownership interest, whether direct or indirect, in the laboratory, the laboratory would be considered firewalled. In this context, indirect ownership interest would be calculated by successive multiplication of the ownership percentages for each link in the ownership chain. We chose the 10 percent threshold ownership amount because it is our estimation that a manufacturer or private labeler who possesses less than a 10 percent ownership interest in a laboratory and does not otherwise exercise management or control

of the laboratory, presents a low risk of exercising undue influence over the laboratory. In addition, our experience using this threshold over the past 3 years indicates that applicants understand it easily and have been able to supply such information. We note that the Federal Communications Commission also uses a 10 percent ownership threshold in its ownership disclosure requirements for applications. *See* 47 CFR 1.2112. The rule also includes indirect ownership because an entity that owns a manufacturer or private labeler that, in turn, owns a laboratory, has the same potential for conflict of interest concerning the independence of the testing process as a manufacturer or private labeler who owns a laboratory directly.

The second circumstance that signifies that a laboratory is firewalled arises when the laboratory and a manufacturer or private labeler of a children's product are owned by the same parent entity. In this instance, the manufacturer would not be a 10 percent owner of the laboratory, either directly or indirectly, but the interests of both entities would converge in a common parent. In such a case, the parent company would hold the interests of the manufacturer, and the laboratory should be firewalled to ensure that its testing processes are independent.

The third circumstance that results in firewalled status occurs when a manufacturer or private labeler of the children's product has the ability to appoint any of the laboratory's senior internal governing body (including, but not limited to, a board of directors); the ability to appoint the presiding official (including, but not limited to, the chair or president) of the laboratory's senior internal governing body; the ability to hire, dismiss, or set the compensation levels for laboratory personnel. The ability to appoint the president or any of the senior internal governing body or to make personnel decisions

indicates management and/or control of the laboratory. The preamble to the proposed rule discusses in more detail the development of the firewalled requirements in proposed §§ 1112.11(b)(1)(ii)(A)-(C). *See* 77 FR at 31109-10. The Commission has chosen to change the proposed rule's standard of "a majority" of a laboratory's senior internal governing body to "any" member of that body. It is not clear by what means an independent laboratory that has any internal directors appointed by clients can remain completely independent, regardless of whether this ability is ever exercised. This was the only change to proposed §§ 1112.11(b)(1)(ii)(A)-(C) of the final rule.

The fourth circumstance described in the proposed rule that would have resulted in firewalled status arises when the laboratory is under a contract to a manufacturer or private labeler of the children's product and the contract explicitly limits the services the laboratory may perform for other customers and/or explicitly limits which or how many other entities may also be customers of the laboratory. As discussed in the response to Comment 13 in section II.B. of the preamble, the Commission has decided to delete proposed § 1112.11(b)(1)(ii)(D) from the final rule

Page 90 of Rule

Subpart B -- General Requirements Pertaining to Third Party Conformity Assessment Bodies§ 1112.11 What are the types of third party conformity assessment bodies?

(a) *Independent.* Independent third party conformity assessment bodies are third party conformity assessment bodies that are neither owned, managed, or controlled by a

manufacturer or private labeler of a children's product to be tested by the third party conformity assessment body, nor owned or controlled, in whole or in part, by a government;

(b) *Firewalled.* A third party conformity assessment body must apply for firewalled status if:

(1) It is owned, managed, or controlled by a manufacturer or private labeler of a children's product;

(i) For purposes of determining whether a third party conformity assessment body is firewalled, "manufacturer" includes a trade association.

(ii) A manufacturer or private labeler is considered to own, manage, or control a third party conformity assessment body if any one of the following characteristics applies:

(A) The manufacturer or private labeler of the children's product holds a 10 percent or greater ownership interest, whether direct or indirect, in the third party conformity assessment body. Indirect ownership interest is calculated by successive multiplication of the ownership percentages for each link in the ownership chain;

(B) The third party conformity assessment body and a manufacturer or private labeler of the children's product are owned by a common "parent" entity; or

(C) A manufacturer or private labeler of the children's product has the ability to appoint any of the third party conformity assessment body's senior internal governing body (such as, but not limited to, a board of directors), the ability to appoint the presiding official (such as, but not limited to, the chair or president) of the third party conformity assessment body's senior internal governing body, the ability to hire, dismiss, or set the

compensation level for third party conformity assessment body personnel, regardless of whether this ability is ever exercised;

(2) The children's product is subject to a CPSC children's product safety rule that the third party conformity assessment body requests CPSC acceptance to test; and

(3) The third party conformity assessment body intends to test such children's product made by the owning, managing, or controlling entity for the purpose of supporting a Children's Product Certificate.

(c) *Governmental.* Governmental third party conformity assessment bodies are owned or controlled, in whole or in part, by a government. For purposes of this part, "government" includes any unit of a national, territorial, provincial, regional, state, tribal, or local government, and a union or association of sovereign states. "Government" also includes domestic, as well as foreign entities. A third party conformity assessment body is "owned or controlled, in whole or in part, by a government" if any one of the following characteristics applies:

(1) A governmental entity holds a 1 percent or greater ownership interest, whether direct or indirect, in the third party conformity assessment body. Indirect ownership interest is calculated by successive multiplication of the ownership percentages for each link in the ownership chain;

(2) A governmental entity provides any direct financial investment or funding (other than fee for work);

(3) A governmental entity has the ability to appoint a majority of the third party conformity assessment body's senior internal governing body (such as, but not limited to, a board of directors); the ability to appoint the presiding official of the third party

conformity assessment body's senior internal governing body (such as, but not limited to, chair or president); and/or the ability to hire, dismiss, or set the compensation level for third party conformity assessment body personnel;

(4) Third party conformity assessment body management or technical personnel include any government employees;

(5) The third party conformity assessment body has a subordinate position to a governmental entity in its external organizational structure (not including its relationship as a regulated entity to a government regulator); or

(6) Apart from its role as regulator, the government can determine, establish, alter, or otherwise affect:

(i) The third party conformity assessment body's testing outcomes;

(ii) The third party conformity assessment body's budget or financial decisions;

(iii) Whether the third party conformity assessment body may accept particular offers of work; or

(iv) The third party conformity assessment body's organizational structure or continued existence.

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§ 1112.19 How does the CPSC publish information identifying third party conformity assessment bodies that have been accepted?

The CPSC will maintain on its website an up-to-date listing of third party conformity assessment bodies whose accreditations it has accepted and the scope of each acceptance. The CPSC will update the listing regularly to account for changes, such as

the addition of new CPSC rules and/or test methods to its scope of accreditation, changes to accreditation certificates, new addresses, as well as changes to the status of a third party conformity assessment body due to voluntary discontinuance, suspension, and/or withdrawal. The CPSC will also list the firewalled or governmental status of accepted laboratories on the CPSC website.

CHANGES PROPOSED AND NOT ADOPTED BY COMMISSIONER NORD

p. 42 of Preamble

In the appropriate paragraph, insert underlined language and omit struck-through language.

The third circumstance that results in firewalled status occurs when a manufacturer or private labeler of the children's product has the ability to appoint a majority of the laboratory's senior internal governing body (including, but not limited to, a board of directors); the ability to appoint the presiding official (including, but not limited to, the chair or president) of the laboratory's senior internal governing body; ~~and/or~~ the ability to hire, dismiss, or set the compensation levels for laboratory personnel ~~.~~ ;and/or has the power to exercise a controlling influence over the management or policies of another person of the laboratory's senior internal governing body. The ability to appoint the president or majority of the senior internal governing body or to make personnel decisions indicates management and/or control of the laboratory. The preamble to the proposed rule discusses in more detail the development of the firewalled requirements in proposed sections 1112.11(b)(1)(ii)(A)-(C). *See* 77 FR at 31109-10. ~~Proposed sections 1112.11(b)(1)(ii)(A)-(C) of the final rule are unchanged from the proposed rule.~~ The Commission has chosen to change this provision from the proposed rule to strengthen the effort to avoid undue influence.

p. 90 of the Rule

In the appropriate paragraph, insert underlined language and omit struck-through language.

(c) A manufacturer or private labeler of the children's product has the ability to appoint majority of the third party conformity assessment body's senior internal governing body (such as, but not limited to, a board of directors), the ability to appoint the presiding official (such as, but not limited to, the chair or president) of the third party conformity assessment body's senior internal governing body, ~~and/or~~ the ability to hire, dismiss, or set the compensation level for third party conformity assessment body personnel ~~,~~ ; and/or has the power to exercise a controlling influence over the management or policies of another person of the laboratory's senior internal governing body.