PRODUCT SAFETY LETTER

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Falvey Discusses Testing and Other Issues with *Product Safety Letter*

Companies need to pay attention to test methods associated with CPSC rules, urged former General Counsel Cheryl Falvey. Her recommendation came in an interview with *PSL* on her views of CPSC-related issues. She elaborated, ñDetails like calibration points and sample preparation have become increasingly important given the requirements for third party testing and the fact that these issues can mean the difference between passing and failing results.ò

She said the agencyôs biggest testing and certification challenge ñis deciding whether to respond to calls for relief from testing cost from manufacturers of products subject to regulations issued well before the passage of CPSIA, whether we are talking about the general wearing apparel rules, the mattress rules, the rules on carpets and rugs and deciding whether more specific guidance should be developed with regard to continued testing for those regulations.ò

A transcript of the interview is below.

What do you believe is the most challenging Section 102 testing and certification issue for industry? Are there different ones for different segments such as large versus small manufacturers or manufacturers versus retailers? What do companies need to do to address it?

Without a doubt, the cost of the testing and certification requirements has been a real challenge for businesses. Small businesses are certainly the most vocal about how the cost of testing and certification has affected their bottom line but the cost of the testing requirements seems to affect all manufacturers.

Another big concern for industry is the variability of test results between labs and even between tests done by the same lab on different products within the same lot. Manufacturers are disappointed that the Commission will not issue a statement addressing statistical uncertainty in testing results so they can know what to do when they get both a passing and a failing test result on products in the same lot. The practical effect of the rule, however, is that the manufacturer cannot certify the product until it establishes with a high degree of assurance that the product is compliant, which puts the burden on the manufacturer to decide whether the failure is representative of the batch or not. The manufacturer must investigate and take necessary steps to address the reasons for the failure. The current Commission has not provided any guidance on what level of statistical uncertainty it will or will not accept. The message to industry is to manufacture well under the limit. I am not aware of the cost of that having been quantified.

For these reasons, manufacturers need to pay attention to the test methods being developed to support the Commissionôs rules. Details like calibration points and sample preparation have become increasingly important given the requirements for third party testing and the fact that these issues can mean the difference between passing and failing results.

What are CPSC's biggest testing and certification challenges? What does it need to do?

The CPSCôs biggest challenge is deciding whether to respond to calls for relief from testing cost from manufacturers of products subject to regulations issued well before the passage of CPSIA, whether we are talking about the general wearing apparel rules, the mattress rules, the rules on carpets and rugs and decide whether more specific guidance should be developed with regard to continued testing for those regulations. To date, the Commission has tried to allow for flexibility in a broad rule that encompasses products subject to many different regulations. To drill down and tackle the cost issues on a regulation by regulation basis would impact the agencyôs resources at a time when resource challenges abound. A related challenge is that, moving forward, to amend any existing regulation, the cost of the testing and certification requirements

will be front and center in any rulemaking under sections 7 and 8 the CPSA, which requires cost benefit analysis. So the agency will face a challenge in handling the cost benefit analysis when it turns to updating any existing rules, especially to the extent the rule applies to childrenôs products.

Another challenge for the CPSC is responding to the calls for harmonization of the law in this country with the regulations in Europe and elsewhere. Harmonization of the various toy regulations, in particular, but more broadly, all of the requirements for childrenôs products, would help manufacturers paying for testing of the same product to multiple standards around the world. However, when Congress steps in a mandates a requirement such as a limit of 100 ppm total lead content for all childrenôs products, the Commission must enforce the law as written and cannot change total content limit, which looks at how much total lead is in the product into a limit that only looks at how much lead leaches out of a product, or a so called solubility standard. While it is tempting to legislate in certain areas to avoid the long process required for an APA rulemaking, when Congress does step in and legislate, it takes away the Commissionôs ability to step in and make changes over time and necessitates congressional action to harmonize regulations with other jurisdictions down the road.

What avenues for harmonization exist now that legislatures are stepping in and firming up the rules as laws?

When legislatures step in and mandate specific requirements the ability to harmonize ï whether itôs through voluntary standards or at the Commission level through the regulatory flexibility that we see sometimes ï goes away. Now there have been some indications of the Commissionôs commitment to harmonization in the durable infant product rulemakings where Commissioners will ask questions like ñWell how do they handle this issue in Canada or Australia or Europe?ò But the strict pronouncements by Congress with regard to the limits on chemicals does constrain the Commissionôs ability to harmonize.

What's the most common misperception about the testing and certification rules? What's the truth?

Probably the most common misperception is that there needs to be a certificate for product to enter the country and that without one the customs agent at the border will refuse admission. That is not true. The certificate needs to be readily available so that Customs, if they ask for it, can see it. But thereôs a misperception that if you donôt literally have that certificate somehow the shipment is going to get stopped. It is **not** a required entry document.

Another common misperception is that an importer certifying a product cannot rely on testing performed by a foreign manufacturer. The Commissionôs component part rule was extended by the Commission to allow a foreign manufacturer to provide allow an importer to certify the product based on test results from the foreign manufacturer covering the finished product or any component part. Calling the 1109 rule a ñcomponent partò rule is somewhat of a misnomer because it allows a foreign manufacturer to test the finished product and pass that test to the importer for its use in certifying the products it imports. While the 1109 rule put some due diligence requirements on the importer, the Commission expanded the breadth of 1109 to try to address some of the concerns about redundant and duplicative testing being done by two or more importers by allowing the foreign manufacturer to pass along its test reports for use by multiple importers. Test reports of the same or substantially similar products that come from a CPSC recognized accredited third party testing lab can be shared by all importers of those products or components.

What are the most promising ideas in CPSC's ongoing effort on testing costs? Why?

Establishing a list of equivalent tests will help make clear what testing CPSC will and will not accept and would likely provide immediate cost savings. If you comply with X as long as itôs done by a CPSC-approved lab, CPSC might accept it because itôs even better. That is how industry has traditionally dealt with state regulation that may vary; you have to comply with the toughest state. I think thatôs a promising avenue and helps deal with some of the problems of harmonization.

I am just not sure whether the laboratories have already done this in practice. Forcing work in this area will help clarify for the labs what minor variations in methods are acceptable and perhaps more importantly identify areas where harmonization efforts should move forward on an international basis, and where Congress may need to step in if CPSC were to pursue harmonization.

Here's a list of specific testing and certification topics. What's your advice or at least observation related to each?

Material changes

This is an area where no matter how may rules are written, good process management in the factory is the only way to make sure that a material change is not made unbeknownst to the importer here in the United States. A substitute fabric used to make childrenôs sleepwear could directly impact ability of that garment to comply with the flammability regulations. The rule requires a test when there is a material change but the heart of the issue still is identifying when a material change has occurred and that can be very hard to do when you are half a globe away from the manufacturing source. The CPSIA has been in effect for quite some time now, and it absolutely amazes me how many phthalate, lead paint and lead content violations the Commission still deals with at the ports after more than five years of publicity on these issues.

Periodic testing

The biggest issue here is how your material changes in component parts affect your periodic testing plan. The more frequent the changes to the product parts, the more complicated it can get to calculate when periodic testing is necessary. These two concepts are interrelated.

It is a challenge for industry because most products are made up of so many different component parts. If you are making changes in the supply of your component parts, figuring out how that would affect the timing of your periodic testing for the finished products is really a challenge. At some point, I can imagine, itôs just worth throwing up your hands and sending out the entire product for testing on a routine basis because the paperwork and tracking for all that would just be insufferable.

If you just take a simple example of a garment with zippers and buttons and trim and fabric ï or a doll with the same sort of components with eyes and outfits and all that ï and at some point you want to change the supplier for a component because you can get something better or cheaper, how do you factor that change into your plan? At some point, there are just too many components to the products.

Do you think manufactures are approaching it that way? Are they saying, "Well, we've got so many components, we're just going to have a regular churn of testing"?

I think thatôs where the size of the manufacturer really comes into play. I do think we need to remember that the component part rule, in some ways, was an attempt to help the small home crafters. They are the oneôs more likely to be using it, I would think.

It seemed, very early on as we were implementing the CPSIA, we would [for example] get a call from someone who was creating on their home computer or with a publisher a book with a CD to put their kids to bed. The CD would come in a jewel case, and the logical answer to their concerns was ñWell, just get the jewel case manufactured and certified for you or tested for you to show that it doesnôt have lead and youôll be fine. You donôt have to send the jewel case out for testing every time you get a new order in, especially if you only get two or three orders a month.ò

So it really was designed to provide relief, but now that weôve advanced and the rules have been written, when you actually try to apply them to large manufacturing organizations in foreign countries, it doesnôt necessarily seem realistic.

Representative samples

While I thought the change in the statutory language was helpful, I always felt that the definitions in the proposed 1107 rule already addressed the concern about random samples and allowed a company to do representative sampling without the statutory change.

Iôve always thought that this whole issue of representative samples is a bit of a red herring in part because the way the rule defines *high degree of assurance* as a concept of just making sure that the product youôre testing is ñrepresentativeò of what youôre selling. I know thereôs a lot of controversy over it, but to my mind the concept of ñrepresentativenessò has always been there.

Labeling, tracking and traceability

The Commission has allowed industry as much flexibility as possible here and sometimes it can be difficult to find a tracking label. I am not aware of a situation where the tracking label violation was the only thing the Commission was looking at ï those violations were usually coupled with a violation of an underlying standard. Whatever you call it tracking,

traceability, knowing how your product is made and what components have gone into it give you a way to limit the scope of a possible recall in the event that something goes wrong. Moreover, with all the state regulations regarding chemical content and the federal requirements that manufacturers understand their products down to whether any minerals came from conflict regions in Africa, traceability is a modern reality. The key takeaway here is that traceability is not going away.

Labeling and tracking and traceability have always been important even before the CPSIA in terms of limiting the scope of a recall when something goes wrong. My sense is that those activities have been embraced and the Commission has created substantial flexibility so that industries can handle it as it make sense for them.

Traceability is absolutely essential, in knowing your product, if a problem does arise, in containing the problem to a more manageable universe instead of having to recall all the product because you didnôt track the component thatôs causing the issue.

Itôs something that the Commission recognizes as important, and even the experience on something like Chinese drywall and the need to mark and track a product that then becomes fungible in the building supply chain, all but reinforced the need for traceability that the CPSIA had in it for childrenôs products. So I see it as something that will only continue to be with us moving forward and well beyond just childrenôs products.

Remedial action

Even though the provisions of the proposed rule on a reasonable testing program and the need for a remedial action plan in that RTP were not approved, it still seems like something that the Commission would view favorably if you have such a plan and might be a good factor for a compliance program in order to mitigate any penalty problem in the event a noncompliance arises.

Undue influence

Itôs a training issue. Even if itôs straightforward to explain, when it happens, itôs probably a pretty agonizing situation to go through in the corporate culture. Along with the ongoing compliance and ethics programs that companies have, they need to work this into those programs as a part of their training and recognize that when and if an employee does feel an issue arises with undue influence, they do need to take that very seriously to try to manage the situation as best they can.

Third-party lab selection

My observation is and what Iôm really surprised by is that there havenôt been more requests to approve firewalled labs. Because of the clamor about testing costs, I would think that more requests would have come in, especially with regard to companies that have been subject to regulations for years that have nothing to do with the CPSIA and that presumably already were doing that testing internally. Why wouldnôt they have asked for firewalled status, unless they had determined that using third-party labs was more economical? I was expecting to be inundated with firewalled lab applications, and we havenôt really seen that many?

Was it five? Ten?

A handful.

The testing and certification rules are likely to get the most attention in upcoming months due to the February effective date, but what other CPSIA issues will present challenges in the coming year?

Thereôs still an awful lot of work to be done under the CPSIA. In particular, the phthalates CHAP needs to complete its work. How that happens and the required rulemaking after six months is a major outstanding issue that needs to get done. The timing on that is a challenge.

The timing on the durable infant product regulations is just a constant stress on not just the resources of the agency but everyone involved in the process. There are a couple of those that involve products that are important and that everyone uses ï highchairs and stroller. Thereôs a lot of work there.

Beyond the CPSIA, what do you see as industry's biggest challenge in the upcoming year?

For those dealing with enforcement issues before the Commission, negotiating those under the new penalty amounts with this Commission may become increasingly difficult. One Commissioner has issued two public statements urging an increase in the size of the penalties. ï CPSIA issue in that they were raised to $15 million but as time goes on and the violations fall within the effective date of the new penalty amounts I suspect the negotiations of enforcement investigation will become challenging.

I think there are significant challenges with regard to chemicals in products and the patchwork of state regulations that need to be dealt with and may continue to increase over the coming years.

Some of the stuff they're addressing seems to be in CPSC's jurisdiction. Some of it probably is in EPA's jurisdiction. One federal agency can't address it alone, so…

There are issues that overlap with FDA, EPA and CPSC, which create concerns when it comes to chemical regulations in products and, frankly, efficacy in terms of what you can say in your advertising. And FTCôs Green Guides have come out and companies need to pay particular attention to what they say about the chemicals in their promotion of their products. Thereôs just an awful lot to it in terms of dealing with chemicals in products and how you advertise, market and sell them.

What about CPSC's challenges beyond the CPSIA?

The challenge in this budget environment is prioritizing their work. Weôve yet to see how all the budget issues are going to resolve, but assuming confidently that things will get worked out, thereôs still a need to prioritize the work.

There is a lot still to be done under the CPSIA and new issues that arise all the time and prioritizing the regulatory agenda consistent with the important ongoing agency compliance work will be the biggest challenge in the coming year.