

Product Liability Regulation To Watch In 2011

By **Nick Brown**

Law360, New York (December 27, 2010, 12:11 PM ET) -- Product liability attorneys will be watching closely in 2011 as the U.S. Food and Drug Administration writes rules to implement legislation passed to revamp food safety regulation and beef up the agency's power to police producers domestically and abroad.

In addition to the Food Safety Modernization Act, product liability lawyers are also preparing for the implementation in 2011 of controversial provisions of the Consumer Product Safety Improvement Act, as well as consumer laws in Australia and Canada that could create major compliance headaches for U.S. manufacturers.

Here is the legislation to watch in 2011.

The Modernization Law

The Food Safety Modernization Act, which gives the FDA enhanced power to police producers domestically and abroad, continues a trend of increased regulatory authority and may be the FDA's counterpart to the CPSIA, attorneys say.

The bill, passed by the U.S. House of Representatives on Dec. 21 and awaiting the signature of President Barack Obama, provides the FDA with the funding and staff to focus on detecting and halting the distribution of contaminated food from both domestic and international facilities and farms.

Under the new law, the number of food safety facility inspections will rise significantly, attorneys say. The legislation has also given the FDA authority to order a recall of tainted food without producers' consent.

Importers will be required to vouch for the integrity of their suppliers and imported products, and the FDA can now mandate certification of high-risk foods and deny entry to products originating from facilities where U.S. inspectors have been denied entry.

"I see this as very akin to what the CPSIA does for the CPSC," said John F. Kuppens, partner at Nelson Mullins Riley & Scarborough LLP. "It gives the FDA more muscularity, more power to regulate food facilities."

In addition to recall authority, the law requires food production facilities to put together a preventative food safety plan, to which FDA regulators will have access. FDA officials will also be given more authority to go in and look at producers' safety records and facility documents in the event of a food safety emergency, and to yank certification and impose noncompliance fees if a producer runs afoul of the law.

"It places a little more of an onus on the food industry to comply," Kuppens said.

The law points to what Kuppens sees as a regulatory trend with significant momentum going into 2011.

"I think there's this movement generally of these regulatory agencies being given stronger regulations, and more power to enforce them," he said.

The Database of Shame

The provision of the Consumer Product Safety Improvement Act that establishes a public database for consumers to publicly report product-related problems is set to be implemented in March, and attorneys are bracing for the impact.

The database lets any consumer report a problem, and directs the Consumer Product Safety Commission to publicly post the report 10 days after its submission. While targeted companies will be notified ahead of any reports, 10 days is not much time to research and refute baseless claims, attorneys say.

"Posts are automatically published after 10 days, so there's a concern among industry that the CPSC won't be able to evaluate these claims in time to prevent baseless ones from initially being published," said Timothy L. Mullin Jr., principal at Miles & Stockbridge PC.

The CPSC is already stretched fairly thin, and may receive even less funding in 2011 amid a federal budget crunch, added Lee L. Bishop, counsel at Miles & Stockbridge.

Lawyers are also concerned that published reports could be used as evidence in court.

"It could completely change the way product liability cases are handled, because anyone is allowed to make reports, including people and groups that decide they have an agenda," said Beth Naylor, a product liability member at Frost Brown Todd LLC.

Companies will have to task certain employees with learning to use the site and investigating claims expeditiously, according to Holland & Knight LLP partner Charles E. Joern. That will be a challenge, as questions still remain as to exactly how the site will work, he said.

The next few months, added Mullen, will be crucial, not only for manufacturers, but the lawyers who represent them.

"We'll have to learn quickly, because this is a pretty big undertaking, and no one's seen it live," he said.

The 15-Month Rule

Attorneys will also have a watchful eye in 2011 on new product testing standards under the CPSIA, which could impact every step of the supply chain.

The so-called 15 month rule — which was named after lawmakers' attempt to promulgate it 15 months after the CPSIA's August 2008 enactment and would require companies to test products after they have been launched — is slated to become effective in February, Bishop said.

Under the rule, manufacturers will be required to have centralized remedial plans for products found to be noncompliant, which could alter the way manufacturers communicate with their suppliers, distributors and retailers, he said.

"The way the supply chain works, you have companies at each step that keep documents and have practices in place, but I don't know of any step that keeps information and data on every other step," he said.

How the testing will be done—and who will do it—remains unclear, as independent certification labs are generally only versed in design-stage testing, which is what current rules require, Bishop said.

"I don't know of any certified labs that do that right now," he said of post-launch testing.

Another rule, also currently slated to take effect in February, will set safety standards and require independent certification specifically for children's products, Joern said.

Complying with the new standards will be costly and, for smaller businesses, potentially more expensive than manufacturing, he said. But legislators, along with the CPSC, have said they are willing to discuss relaxing standards in 2011 if it will help small companies absorb the blow, he said.

"The CPSC has expressed willingness to extend stays currently in place if Congress is serious about considering changes," Joern said. "So it will be interesting [in 2011] to see what happens there."

The International Laws

With new consumer safety legislation in Canada, Australia and South Africa, companies face numerous challenges in 2011 to reconcile standards that vary between countries.

The Canada Consumer Products Safety Act took effect in December, while the Australian Consumer Law becomes effective Jan. 1. In South Africa, the Consumer Protection Bill will be implemented in March.

The laws all generally establish safety standards and reporting responsibilities, according to Kenneth Ross, of counsel at Bowman and Brooke LLP. But reporting thresholds are lower in some countries than others, creating conflicts that may have to be fleshed out in court, he said.

"Plaintiffs' lawyers may attempt to sue companies in the U.S. for failing to report problems that they reported in Australia, for example, where the reporting threshold is much lower," he said. "They can argue that even though it wasn't against the law not to report, the company knew about a safety issue and didn't do anything."

Counsel may advise manufacturers to play it safe and report all incidents to all governments, rather than risk being accused of ignoring a defect, Ross added. The upshot, he said, is that the average consumer will have more access than in the past to a wider range of information on a given product.

The international laws also mean manufacturers will have to keep track of data on a worldwide basis, a task that could be challenging, Ross said. Simply knowing where to forward a complaint — let alone reacting to it — will require extensive training, not only within a company but throughout its distribution chain, he said.

"What if a sales rep in India gets a complaint?" Ross said. "Does that person know whether that complaint warrants reporting? And if so, does that person know who in the company needs to be alerted to it?"

In general, he said, 2011 will be an educational year for manufacturers, and counsel should expect to be called on to steer clients through an increasingly global regulatory world.

--Additional reporting by Jessica Dye

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