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## Specialty Insurers May Thrive On New Food Regs

By Nick Brown

Law360, New York (January 25, 2011) -- While the Food Safety Modernization Act could present a golden opportunity for specialty insurers offering coverage for food recalls, the jury is out on whether the policies can be comprehensive enough to outweigh costs, experts say.

The FSMA, signed by President Barack Obama earlier in January, expands the U.S. Food and Drug Administration's health and safety enforcement authority, increasing food companies' exposure to liabilities like recalls and plant closures.

Since typical commercial general liability policies tend to exclude recalls, a niche market for food recall insurance will likely expand, according to attorneys and insurance executives who spoke with Law360.

But just how big a boost the industry gets will depend on the answers to a few looming questions about the cost-effectiveness of the policies, given how far they stretch.

Under the FSMA, companies must renew FDA registration every two years. If the FDA finds a reasonable probability that a product may lead to health risks, it can demand a facility's records without a subpoena, and may suspend registration and shut the facility down.

Such a finding is more likely than it was prior to the FSMA's passage because of an increased inspection schedule that submits high-risk facilities to inspections once every three years, according to Miriam J. Guggenheim, a food and drug partner at Covington & Burling LLP.

Moreover, the law makes the "reasonable probability" standard easy to satisfy by, among other things, defining a foodborne illness outbreak as any two instances of illness caused by the same product, said Joseph F. Bermudez, an insurance partner at Nelson Levine de Luca & Horst LLC.

The regulatory crackdown creates two major needs for companies: the ability to defend itself when the FDA drops its hammer, and the assurance of knowing it's covered if a recall does take place.

CGL and property policies generally don't fill either void, and that isn't likely to change, said Jonathan M. Cohen, a Gilbert LLP partner who represents policyholders.

"[Recall exclusions] are standardized provisions that have been in policies in one form or another for many, many years," Cohen said.

But specialty policies may fill both gaps, Bermudez said.

They will generally cover Class 1 and Class 2 recalls, sometimes in both voluntary and involuntary capacities, he said.

They will also help teach companies to defend themselves in the face of FDA action and potentially avoid a recall that otherwise would have taken place, he said.

In addition to mandating hazard mitigation plans and allowing the FDA to demand a facility's records without a subpoena, the FSMA gives suspended companies only two days to convene a hearing to seek reinstatement. And it usually requires the submission of a comprehensive corrective action plan as a condition for the reinstatement.

That can be a lot to keep track of, especially for smaller companies without deep in-house expertise, Bermudez said.

Specialty policies pair companies with expert consultants for crash courses on preparing hazard plans, readying corrective action plans and preparing for hearings within 48 hours of a suspension — an invaluable resource, Bermudez said.

XL Insurance, one of the largest specialty underwriters, started developing recall policies in the mid-1990s.

"We've changed the product, and it has evolved over the years," Ed Mitchell, XL's global product recall manager, told Law360. "The consulting aspect, especially, has evolved with it."

But if the policies aren't necessarily new, they're certainly starting to get more attention, Cohen said.

Some of that attention is coming from companies that passed on specialty policies before the FSMA came into the picture, according to Marialuisa Gallozzi, a partner who represents policyholders in Covington & Burling's insurance practice group.

"I don't think there's any question they're going to become more common, and I think policyholders who didn't explore them before, or who explored them and concluded they didn't want to pay for them, are likely to go back and re-examine," she said.

But for all their potential value, lawyers aren't quite ready to advise their clients to rush out and buy the policies en masse.

They may make sense for some producers, but no one can definitively call them a slam dunk until a few key questions are answered, lawyers said.

The topic of cost remains wide open, with experts unable to agree on a ballpark but admitting specialty policies won't come cheap.

Depending on a company's size and insurability, as well as the specifics of the policy, yearly premiums could range from a few thousand dollars to more than \$1 million, Mitchell said.

Food companies generally perceive the policies to be expensive in the context of the scope of coverage, Gallozzi said. Potential recovery may be limited, and policyholders are often required to shoulder a share of the loss, she said.

Many of the policies are triggered by actual contamination, and would not cover a company whose products were safe but were nonetheless subject to an ingredient-driven recall like the one caused by Peanut Corp. of America's contaminated nuts in 2008, Gallozzi said.

In addition, the companies more likely to be able to afford coverage — large producers with deep in-house resources — may not be the ones who need it.

"Many huge companies do almost everything that this act requires already, so in that sense it doesn't necessarily add a whole lot," Cohen said.

It is still unclear whether smaller companies — the ones more likely to benefit from guidance — will even be subject to the same rules.

While the FDA will not be limited in its recall authority, certain exemptions in the FSMA will spare small producers from many of the law's provisions. Many of the details of the law's execution remain up in the air.

The FDA has given itself 18 months to promulgate regulations, but the food industry is concerned the agency will lack the resources to meet the deadline, forcing companies to comply without guidance on how to do so, Guggenheim said.

That makes the job harder for underwriters who rely on a clearly defined regulatory landscape to write narrowly tailored policies, Mitchell said.

One question that particularly interests insurers is the standard the FDA will use to determine whether a food or facility is "high-risk" — a label that makes a company more susceptible to inspections and potentially less insurable.

"If you're a U.S. food producer and suddenly you find you're in a high-risk facility, that affects the decisions you make for your company when it comes to managing risk," Mitchell said.

Businesses aren't the only ones thinking about costs. The FDA, too, must study the cost of enforcing the rules, Bermudez said — a factor that will impact the agency's regulatory approach and, by extension, the importance of having coverage.

Even if policies are affordable, some companies may choose to forgo them for the simple reason that they don't consider themselves at risk, whether due to high safety standards or the fortuitousness of dealing in low-risk products, attorneys said.

Other companies may decide to pass on insurance coverage and seek consultation services from independent compliance consultants — an industry sure to expand after the passage of the FSMA, Bermudez said.

But despite these arguments, insurers don't lack for confidence. They see opportunity in the passage of the FSMA, and the threats to the viability of specialty policies, at least to Mitchell, are not serious.

Mitchell claims that XL has worked to extend coverage to adulterated ingredient recalls, pointing to the company's launch in June of a policy that covers loss even when an insured's product is not contaminated itself, as was the case with many of the products included in the PCA recall.

Each year, about 30 percent of XL's specialty coverage buyers are first-time buyers, and the company only expects that number to rise in 2011, Mitchell said, adding that he did not anticipate a concomitant rise in premiums.

For lawyers who represent food producers, specialty coverage is certainly worth considering, but it's a step or two shy of being a sure bet.

"Brokers and insurers are expecting interest to grow, and it probably will," Gallozzi said.

"But there is a range of players in this industry, and what makes sense for one company might not make sense for another. "

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