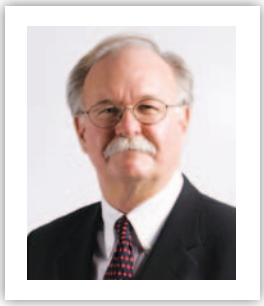

The Food Safety Modernization Act: Lessons for Canada

Despite all the hype, the new *Food Safety Modernization Act* (FSMA) signed into law by President Obama on Jan. 4, 2011, is a model of how not to make food safety law. The Americans laboured long and hard and delivered a mouse.

Under the FSMA, some powers of the Food and Drug Administration (FDA) are enhanced or clarified. For example, the FDA has powers to demand access to and copies of records when there is potential for serious health consequences (Canada has always had this). The FDA has also finally been given the power of mandatory recall after a Hearing (Canada has had this since 1997, without the right of a Hearing); and the FDA has the right to hold food products it has reason to believe are adulterated or misbranded (Canada has always had this).

But FMSA has two fundamental flaws, flaws so serious that the law may end up doing more harm than good. First, the Act provides a broad framework leaving to future regulations the real law. As everyone knows, the FDA is profoundly under resourced to carry out its existing mandate — and the House Appropriations Committee recently recommended $285 million in cuts — and yet FMSA requires it to bring in more than 12 Rulemaking regulations and more than 10 Guidance documents. The FDA has admitted it is already behind and that it may take many years before the regulations are enacted. In the meantime, there will be real legal uncertainty for industry and consumers as the new law will be fully enforceable with little guidance on how it will be enforced.

The most serious flaw is the profound disconnect between the rhetoric about major improvements in food safety and the complete absence of new resources to walk the talk. For example, FDA is required to do 600 foreign facility audits next year and to double the number of audits every year for five years. The FDA has admitted this is completely impossible. As Peter Hutt, the dean of American food law lawyers, has recently observed: "The lack of reality in the statute is staggering."

The import provisions of FSMA are the most relevant to Canadian exporters and, again, the law is confusing. Under section 301, every U.S. importer is required by January 2013 to carry out foreign supplier verification programs to provide assurances that the imported food meets the same level of public health protection as required of U.S. companies. Yet guidance on how this should be done will not be available on time.

In the meantime, effective immediately under section 303, the FDA has the power to require certification before the product can be imported. Certification can be provided by third-party auditors, but there are no guidelines on how this would be implemented or which entities would be acceptable third-party auditors. At the moment, the FDA is reluctant to accept private-sector audits done, for instance, under the Global Food Safety Initiative, even though they may be the best hope for improving food safety when there are more than 10 million importations of food every year into the U.S. under FDA jurisdiction carried out by over 150,000 importers.

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There are lessons here for Canada. Don't accept the facile argument that the state must move from reaction to prevention. The primary responsibility for food safety rests with industry — the role of the state is to make laws that it enforces, to audit industry's risk management systems, and to be very good at reacting swiftly and fearlessly to protect the public when there's a problem. Don't mislead your citizens by telling them that you're doing more than you are. And don't legislate what you can't enforce. ■

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