US Senate Passes The Food Safety Modernization Act:
Importers Beware!

The U.S. Senate passed the Food Safety Modernization Act (FSMA) of 2010. This bill directly enlarges FDA's legal and regulatory authority over food in nearly every sector. Very directly, this bill will substantially increase the regulatory compliance burden on foreign food manufacturers, farms, and food importers without a proportional affect on food safety. In addition to representing huge projected government spending, this bill will cause producers to raise food prices and it will noticeably-slow food imports without a significant improvement in food safety.

Benjamin L. England, a 17-year FDA-employee veteran and Food and Drug Law consultant and lawyer, warns food importers about the new U.S. Senate Bill 510 that is predicted to create unrealistic import-requirements in the near future. Benjamin England is the founding member of the law firm Benjamin L. England & Associates and the owner and founder of FDAImports.com, LLC, a consulting firm that regularly serves in the area of interpreting and applying the laws and regulations related to all FDA and USDA-regulated products.

Yesterday, the Senate passed the Food Safety Modernization Act (S. 510), as amended, by a vote of 73 to 25. This bill significantly increases FDA's authority over the food supply in the U.S. without examining the effectiveness of FDA's current surveillance and enforcement infrastructure. The bill will increase the price of food—indirectly, in the form of huge taxpayer expenditures and directly, in the form of higher prices—without a proportional improvement in food safety. It creates the perception of regulatory improvements, without cost-benefit analysis and without addressing FDA's inability to manage or support its current food safety regimen.

In response to foodborne illnesses traced to certain raw agricultural products (*E. coli* in U.S. spinach; and *Salmonella* in cantaloupes from Honduras, peppers from Mexico, and U.S. peanut butter and eggs), Sen. Richard Durbin (D- IL.) introduced yet more regulations to 'solve' the problem, and he received eight Republican and thirteen Democratic co-sponsors. If enacted, FSMA will be a failure primarily because it presumes that food safety will be enhanced through increased regulations without evaluating whether FDA is competent to execute the bill's mandate. Consider a few of the provisions against FDA's current practices.

FSMA requires FDA to establish and publish science-based minimum standards for 'safe production and harvesting' of raw agricultural fruit and vegetable commodities. It further requires FDA to establish and implement tracing, tracking, and reporting requirements for these commodities. It also requires FDA to establish and monitor Hazard Analysis and Risk Preventive Controls (HARPC), including standards related to in-transport food integrity. In other words, under the FSMA for the first time in history FDA would regulate farming (foreign and domestic)

by developing a Good Agricultural Practices (GAP) regime (a) governing what constitutes 'safe production and harvesting' and (b) tracking the farm industry's compliance with its new guidelines. FDA will then establish new HARPC guidelines and monitor compliance for all other food industries.

This is utopian-nonsense and statutory overreaching run amok. Using a very simple example we can see why the new mandates will prove to be a significant challenge for FDA to implement effectively. FDA currently maintains a database of "Registered Food Facilities." It is supposed to be composed of all firms, foreign and domestic, that manufacture, process, pack, or hold food for human or animal consumption. Presumably, there are hundreds of thousands of domestic and foreign facilities in this database: a mere collection of information related to facility type, location, contact information, etc. In October 2006, FDA performed its own audit of the emergency contact information of 400 registered facilities and the agency could verify only 39% facilities that contained accurate information. Three years later, in December 2009, the Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS) evaluated the accuracy of FDA's registration database by sampling 130 facilities that were required to register with FDA. The OIG found that 7% failed to register, or cancel their registration accordingly, and in each of these instances, FDA was missing critical emergency-contact information. Additionally, 48% of the sampled-facilities failed to submit accurate contact information, including 23% total that failed to provide accurate emergency contact information. The OIG found that 52% of the registered facilities' managers were unaware of the FDA registration requirements.

So FSMA will require FDA to create and track GAP and HARPC compliance when FDA—by its own admission—cannot even reliably maintain basic data-integrity, over a mere reporting database, on the information it already possesses (not to mention the fact that there appears no current estimate of 'how many facilities' aren't registered that should be.) Tracking accurate information on the location and contact information of facilities under FDA's jurisdiction ought to be the simplest task. This is a task FDA admits, and OIG confirms, that FDA cannot competently perform. Under FSMA, FDA will be required to monitor scientific and regulatory compliance of sophisticated processes related to food safety, of facilities it can't even identify, locate or contact?

Consider a parallel in the seafood industry: FDA regulations require the existence of an adequate seafood Hazard Analysis and Critical Control Point (HACCP) plan, but does not evaluate the plan's substance for adequacy or safety except in the context of administrative actions, such as import detentions, facility inspections, or import alerts. And it is well known that FDA inspects 2% or less of imported seafood entries. From 2009 to 2010, FDA inspected only 13 seafood firms in all of China. And FSMA pretends that FDA will evaluate adequacy and compliance of GAP and HARPC programs for all registered food facilities dealing in all food categories?

That FDA cannot and does not effectively inspect facilities to ensure food safety is not news to the FDA. There are at least 150,000 domestic facilities and 240,000 foreign food facilities in over 200 countries. Consider the following: the Office of the Inspector General (OIG) released an April 2010 study in which it found that, in 2007, FDA only inspected approximately 22% of the domestic facilities subject to inspection. (FDA records indicated that in 2007, there were approximately only 65,520 registered food facilities, suggesting that a huge number of domestic facilities are not registered). OIG also found that, of those domestic facilities inspected in 2007, FDA only found violations sufficient enough to warrant 'official action' in slightly more than 2% of those facilities inspected (i.e., 446 of 14,339 facilities). In 25% of those 446 facilities, FDA failed to reinspect within one year or to evaluate additional evidence to ensure the violations had been corrected. In other words, out of 150,000 domestic facilities, roughly 65,000 are registered, FDA inspected some 14,000, required corrections of about 450, and only followed-up on about 340 of those facilities.

Obviously, the foreign inspection record will be much worse considering the new FDA inspection requirements. FDA's internal guidance on its administrative procedures for conducting foreign inspections indicates that FDA expects foreign inspections to take approximately three weeks, and FDA records indicate that each inspection costs FDA about $14,000. Let's assume the same registration, inspection, and remedial action percentages as OIG found in 2007 (although we know they'll be much lower). This means FDA would inspect 25,800 foreign facilities (at a cost of over $361 million) require 516 facilities to take official action, and only follow-up with 387 of those facilities. In 2009, FDA had 2,165 "Full-Time Equivalent" employees in the field. Let's assume 50% of those employees were conducting foreign inspections (a pipe dream) and two employees perform each inspection. Since it takes 3 weeks per inspection, this means, in the rosiest of scenarios (ignoring farms), it'll take a little over three years to complete its *annual* inspections!

If the Congressional Budget Office (CBO) didn't estimate that FSMA will result in $1.4B outlay over a mere four years (2011-2015), this would be laughable. And surely this number, however staggering, is too laughably low, CBO 'upward revisions' being well known. What's worse: FDA appears unconcerned for the private compliance-costs this useless burden will place on food facilities.

I emphasize we are ignoring farms in creating our rosy scenarios because FSMA does not; by giving FDA the authority to establish and enforce produce standards related to fruit and vegetable farming, harvesting, packing and holding; an area previously reserved to USDA. I think we can safely grant that there are "a lot" of farms around the world producing food for the U.S. market; I mean, "a lot". Further, most of the recent food-based outbreaks originated with domestic farming operations; not foreign – yet under FSMA foreign farms will be subject to FDA's new produce safety standards and will have to prove compliance with the new requirements to gain (or at least maintain) access to the U.S. markets. Setting aside the exorbitant costs to American tax payers for creating and implementing a food system envisioned

by FSMA (which CBO has drastically underestimated), the question no one seems to be asking is: What happens if foreign farms decide not to participate? What happens to the U.S. food supply or the cost of food in the U.S. then? Will FDA feed us all?

Benjamin England, founder of FDAImports.com, LLC, firmly believes that the FDA is aggressively over-stating their ability to comply with the FSMA's new inspection mandates. While addressing and interpreting FDA, USDA, Customs, and other related agency-regulations, it is FDAImports.com, LLC's experience that the FDA will be unsuccessful in their upcoming inspection ventures. Founded by Benjamin England, who gained over 17 years experience working directly for the FDA, FDAImports.com, LLC considers itself expert in the interpretation and application FDA laws and regulations.