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Food safety in the legislative grinder

By Rod Leonard

There are two things most likely to upset the public, according to Otto Von Bismarck, the German politician who created the modern German state in 1871: one is to watch sausages being made, the other is watching the creation of laws.



Rod Leonard

Even Bismarck would have been horrified by The Food Safety Enhancement Act of 2009, approved by the House of Representatives just as the House left for its August recess. The legislation is intended to give new authority to the Food and Drug Administration (FDA) to prevent a repeat of FDA's failure to protect consumers in recent years from contaminated peanut butter, fresh lettuce laced with bacteria, and foods from China containing chemicals banned in U.S. foods.

The legislation, however, proposes to spend more federal dollars for less consumer protection and has created a spectacle of industry lobbyists shouldering aside the public interest. For students of government, this legislative process provides a classic case study of the territorial competition for power among the committees of Congress where none cede authority.

Divide and weaken

The legislation had two strikes against it from the start. The proposal took shape in a series of compromises among a tightly-knit group of consumer and non-government organizations. They sought to ride a wave of public outrage over multiple failures in food safety management to pass a bill for a single food safety agency. A merger of FDA and the Food Safety and Inspection Service (FSIS) of the Department of Agriculture (USDA) would provide the core of a single agency charged with safeguarding food. This concept briefly intrigued President Obama, who had the foresight to opt out, avoiding the train wreck now in progress. USDA currently regulates meat and poultry, as well as eggs and freshwater fish. FDA regulates everything else.

Without the White House leading the way, major legislation has little future in Congress. This reality led the single agency advocates to scale back their ambition. Their proposal now appears to be an effort to reform and embolden FDA's food safety program; but it also nibbles around the edges of USDA food safety responsibilities, as well as those of other federal agencies. The American food industry, recognizing the opportunity offered by a congressional battle over legislative turf between the Committee on Agriculture and the Committee on Energy and Commerce that oversee FDA, moved immediately to gut and grind up

rules that would have helped protect consumers from unfit food.

The House bill originally required farmers to register with FDA as food producers, paying a registration fee of \$500 each. Meat and poultry processing plants now regulated by FSIS would also register with FDA at \$500 a pop. Compliance with FDA standards of production would be a requirement for all parties who register.

These and other features of the House legislation affecting farmers were challenged by Rep. Collin Peterson, chair of the agriculture committee, who threatened to block the bill. Rep. John Dingell, representing the Committee on Energy and Commerce committee handling the FDA reform bill, agreed to the amendments proposed by Peterson. The amendments effectively remove provisions of the reform bill affecting food and agriculture where USDA has jurisdiction.

Similarly, the House Ways and Means committee with authority over the U.S. Customs and Border Protection (CBP) agency objected to FDA reform proposals to regulate customs brokers handling food imports into the U.S. Those provisions were stripped from the reform legislation and replaced with language directing FDA to develop an import tracking system with CBP agents.

The original bill would have cost about \$2 billion over a five-year period, of which \$1.4 billion would have been raised from fees. Congress would have had to agree to about \$120 million in additional appropriations annually to finance the reform measures. The effect on revenues and expenses from the changes agreed to with Agriculture and Ways and Means are unclear, but potential funding increases could be significant, in any event.

How much food safety protection?

The question is: How much food safety protection will the American public get by paying for this reform package? The answer: Probably not much, if any. Much of the change the House wanted to legislate could be done by FDA under current law, if FDA regulators used their present authority to ensure that industry produced safe and wholesome food.

In fact, the new bill could leave the public more vulnerable to food borne disease. For example, FDA will be mandated to operate a risk-based food safety system. What does risk-based mean?

In the first place, it means regulatory assumptions about risk justify government decisions not to inspect food, including imported foods. Establishing a risk-based system entails the development of regulations to place all food production in one of five categories, ranking food makers and producers from the least risky to the most risky. The bill mandates that FDA concentrate human and technical resources on the most risky category of foods and food processor facilities. However, an increasing number of incidents of horticultural products (traditionally low-risk) contaminated with pathogens of animal origin (traditionally high-risk) has undermined the justification for this categorization and for the rationale to reduce government inspection and testing of food.

How will risk-based criteria be applied to cookie dough plants following the contamination of Nestlé USA Toll House brand cookie dough by E. coli O157:H7? Nestlé's own contamination data is guarded as "confidential business information" even though 69 people were sickened, and 34 of those hospitalized, following consumption of the refrigerated cookie dough. The bill provides FDA authority to subpoena food safety data from companies after FDA suspects a violation; but a subpoena should not be required to obtain company data affecting public health. FDA inspectors should be able to obtain that data routinely and verify that data with their own testing to prevent contamination and other food safety hazards.

Staffing costs to pay experts in classifying companies, negotiating with company lawyers, managing classification records, tracking data—all of whom will be paid more as experts—will be higher than the cost of an equivalent, larger number of inspectors and technicians who inspect and test food. USDA's inspectors have told Congress that the same kind of food safety plans required in the bill have led to fewer government inspections of meat, poultry and eggs. Inspection verifies that other food safety programs are working to protect consumers. Less inspection is built into the design of the Food Safety Enhancement Act.

The likelihood that a risk-based system will not significantly improve food safety is implied by the legislation. The House bill acknowledges this prospect by including a provision to trace food causing illnesses—or death—back to its source. If the risk-based system has to depend on people getting sick before it can act, then the public is at risk and has no reason to feel safer. The House bill also promises to correct the scandalous failures of FDA to improve inspection of food imports, most clearly demonstrated by the recent deluge of Chinese products laced with melamine, a chemical that puts those who consume the substance at risk and deceptively raises the nutritional value of foods containing milk.

The rise in import food contamination begins with provisions of trade agreements that recognize foreign food safety systems as “equivalent” to U.S. systems, largely on the basis of a review of documentation supplied by the exporting government. Reducing import food contamination requires that trade negotiators eliminate the heavy burden of proof to show that government food safety regulations are “necessary” to protect the public. The right to regulate in order to protect public health should not be qualified by “risk-based” rules when contamination resulting from food industry practices has obliterated high- and low-risk categories.

Food safety reform prospects in the Senate

The House bill on FDA reforms now goes to the U.S. Senate, where the outlook is dim, for several reasons. Any Senate action in 2009 must wait until health reform and climate legislation is adopted. Senator Tom Harkin, chair of the Senate agriculture committee, has said he will not even plan to hold hearings on food safety until both health reform and climate legislation are enacted and signed by the president.

Even then, the bill's progress is uncertain. The shrunken carcass of the original legislation is likely less appealing to its supporters, who may not be willing to invest as much political energy as before to see it through the Senate. The food industry is already planning to ask its Senate friends for more changes. The United Fresh Produce Association (UFPA), for example, wants to change the registration fees, block product testing requirements, expedite imports and have industry help decide when to recall products. The Senate committee will consider an FDA reform bill sponsored by Sen. Richard Durbin that does not authorize fees to offset the \$2 billion cost estimate of the House bill by the Congressional Budget Office; nor would the Durbin bill include authority for FDA to set product standards for horticulture farms and other operations where contamination may originate.

All things considered, food safety reform legislation may be the political version of Cornelius Vanderbilt's book, "A Bridge Too Far;" a study of an ambitious World War II campaign that failed because of inept planning and execution. Conceived as a brilliant food safety strategy to gain a quick political victory in the early days of the Obama administration, the drive for a single **food** safety agency lost its momentum when Obama rejected the idea. Michael Taylor, a government official long associated with food safety policy, was operating in the White House as a food safety czar. He developed much of the legislative strategy, but suddenly disappeared as food safety czar only to appear as senior advisor to Margaret Hamburg, FDA's new administrator—a move that further deflated the policy momentum. Then the FDA reform legislation ran into Collin Peterson's buzz saw and was shorn of all the furtive efforts to add to FDA's regulatory reach at USDA's expense.

On balance, the push for food safety reorganization has set back any reasonable hope for long-term reform in food safety policy. A merger of food safety authority has been a 40-year goal of food and health activists, but the strategy would require delicate timing and skillful execution if the political power of the food industry were at a low ebb; but the food industry is riding high, and that condition isn't likely to change soon. Ultimately, the impetus for fundamental reform must come from the White House through the Department of Agriculture—a fool's bet today.

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