



The Business Impact of Food Safety and Traceability Legislation

Positively Assured Traceability White Paper



Executive Summary

This white paper explores the apparent discrepancy in reactions to the National Animal Identification Scheme (NAIS) and U.S. House bill HR2749, and examines the technological implications of the HR2749 legislation.

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HR2749 and NAIS - The Confusing Tale of Two Food Safety Policies

by
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Over the last few years, we have witnessed much resistance to the National Animal Identification Scheme (NAIS), the six-year-old USDA policy initiative to reduce the catastrophic effects of a major animal disease outbreak on the livestock and meat industry. The ongoing negative reaction from so many quarters has stymied the U.S. animal identification program, and it now seems stalled. However, another policy initiative (U.S. House bill HR2749) breezed through the House of Representatives in the summer of 2009 and passed on the final day before the August recess, less than two months after its introduction, and now goes to the Senate. HR2749 passed with little debate, reasonably strong bipartisan support by today's standards, and very strong support from major food-growing Congressional districts.

In this white paper, we explore the apparent discrepancy between reactions to NAIS and HR2749, and examine the technological implications of the HR2749 legislation.

Strong Support for HR2749. Although there are more than 1,000 bills pending in the current U.S. Congress with the words "food safety" in their text, HR2749—sponsored by representatives John Dingell (D-MI), Henry Waxman (D-CA), and three Democratic colleagues—seems to have led a charmed life. It was assigned to only one House committee for review, and was passed out of committee with a unanimous voice vote. It then moved to the House floor, where it passed with little debate and no floor-introduced amendments in a lopsided 283-142 vote with eight members not expressing an opinion.

Contrast the broad support for HR2749 with the opposition juggernaut that currently faces implementation of NAIS. From our perspective, we see a number of reasons for the different reactions. One obvious difference between these two policies is that HR2749 focuses on food products regulated by the FDA, which regulates about 80% of the U.S. food supply, whereas NAIS comes from the USDA, which regulates meat, poultry, eggs, and fish, as well as other commodities that are not covered under HR2749.

The FDA-regulated industries have been stung by an apparent unceasing string of high-profile recalls, and the industry stakeholders for these commodities (fruits, vegetables, and manufactured foods)—throughout all production segments, from the first mile to the retailers—seem to recognize that the status quo just doesn't work anymore. They feel that something needs to be done, and, in general, seem to be backing the regulations put forward in HR2749.

The industries affected by NAIS, on the other hand, do not have this broad consensus about the risks they face, nor a strong desire to change, and they don't have clear industry leadership on this topic.

The level of willingness to change, and the strength of industry leadership, is the clear differentiator between the response to the two pieces of legislation.

Technology Implications

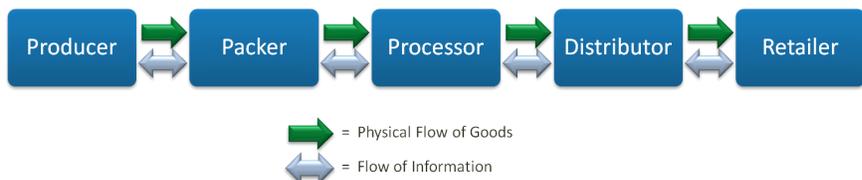
Other differentiators include:

- HR2749 is a congressionally initiated policy change whereas NAIS is generated by USDA staffers without detailed, legitimizing congressional legislation.
- HR2749 puts most of the responsibility for action on the downstream manufacturer and retailer whereas NAIS places most of the action on the first-mile and upstream livestock producer who has been very vocal in rejecting the NAIS risk message.
- HR2749 includes clear, detailed exemptions for the very smallest first-mile producer who sells directly to the consumer through roadside stands, farmer's markets, and Community-Supported Agriculture (CSA), so that these small growers won't feel they're being pushed out of business. NAIS is not clear about whether these small producers will be exempted.
- HR2749 has had broad industry endorsement and strong industry leadership from all stakeholder groups and is in synch with a parallel industry initiative (the Produce Traceability Initiative) whereas NAIS has few, influential industry champions and no parallel, detailed, industry-driven program.

Now that HR2749 has gone to the Senate for consideration, the Senate can choose to use this bill as its starting point, use a parallel Senate bill (S510 sponsored by Senator Durbin, five Republican Senators, and five Democratic Senators), move forward on one of the other numerous food safety bills pending in the Senate, or do nothing and let the HR2749 bill die in the 111th Congress. Of these options, using the S510 bill seems to us the likeliest, as there are relatively few major differences between that bill and HR2749, and the administration definitely has gone on record that they would do something to change the way the FDA regulates food.

So, if HR2749 and S510 appear to be the basic grist to be considered first by the Senate and then by a joint committee, let's look at the basic technology implications. The news here is that from a technology point of view, many of the proposed changes are in line with earlier policies but they are written more crisply and clearly. However, a few of the proposed changes are both broad and sweeping departures from previous policy, which have serious technology implications.

Beyond One-Up/One-Down. All of the proposed legislation to date, including NAIS, requires that a member of a supply chain know only the immediate upstream supplier of the ingredients and the immediate downstream customer that buys the product.



When one-up/one-down was first introduced in the Bioterrorism Record Keeping Act of 2002, many companies thought they only had to

keep a list of their suppliers and a separate list of their customers. The FDA published industry guidelines that made it clear that these two lists were insufficient, and that each company needed to be able to accurately describe which specific ingredients are included in which specific finished goods (see below). It is our experience that most companies cannot accurately meet this objective.

Regardless of how well the company is able to preserve ingredient identity across their manufacturing floor, HR2749 ups the ante quite a bit by saying that each member of the supply chain must understand the full pedigree of the product before it reaches them (more than just one-up), and each company must understand the pedigree of who owns and handles the product after it leaves their control (more than just one-down).

Implementing full upstream and downstream visibility is possible, but unless this extended visibility is handled properly, it will destroy many of the existing commercial relationships that exist today. For example, the retailer who can look upstream to identify exactly which farms are growing the peaches they really want has the ability to bypass intermediate packers, processors, distributors, and brokers thus disintermediating the supply chain and creating substantial potential resistance to change. This is similar to the challenge we had during the Net boom, when a lot of exchanges and Net-markets were created in various commodities (e.g., e-STEEL) which created a disintermediary risk to the middlemen and brokers within the service chain.

Technically, it is possible to create networks that can provide this basic information when needed and still keep the upstream and downstream ownership information confidential so that supply chains are not disintermediated. Such networks have been built for other industries, and certain technology providers are in a position today to be able to deliver this functionality.

Identity Must Be Preserved Across Transformations. As mentioned above, the Bioterrorism Record Keeping Act of 2002 does require a manufacturer to be able to indicate which specific raw materials or ingredients from exactly which supplier delivery are included in a production batch, even when materials are stored in bulk storage and even when there is rework on the finished product. The difference between this earlier law and HR2749 is that HR2749 is, for the first time, very clear about what is required, whereas the earlier law was ambiguous.

The technology implication for food companies is that they need to make sure their system truly associates specific inputs with specific outputs. As noted above, our experience is that every company thinks they accurately do this today; however, when audited, gaps are usually found. Finding and fixing these gaps needs to be the first step food companies take when this legislation is passed.

Increased Responsibility for Knowing Good Upstream Practices. At no point in previous policy prognostication has a member of the food supply chain been held responsible for an upstream action. Under

HR2749, individual food companies will be responsible for knowing that product has been produced according to Good Agricultural Practices that have yet to be defined. The technology implication here is obvious: The network system that provides the e-Pedigree information before and after manufacture also needs to carry information necessary for the company to determine that Good Agricultural Practices were used, while still not disintermediating the supply chain. This task is trickier, although by no means impossible, and having this level of supplier compliance information available to the manufacturer will likely improve food safety.

Restaurants and Retail Grocery Now Included. In previous laws and rules, the retail endpoints were exempt from certain record keeping. That exemption is lifted in HR2749, and the retail grocer and the restaurant operator will now be responsible for knowing not only the e-Pedigree but also that Good Agricultural Practices were used.

Full Electronic Records and Immediate Access. The legislation is also very clear that the only records that really count are electronic ones and these must be immediately available to appropriate government agencies in the event of an investigation. Technically, this immediate access rule will require some companies that keep paper records to change the way they operate. It will also require some special data confidentiality safeguards to ensure government inspectors see only the data relevant to their investigation and not other commercially sensitive data. Again, meeting this goal is quite possible, but it must be done with care.

What makes all of this new policy highly compelling for food supply chain stakeholders is that, for the first time, the FDA will have the teeth to compel companies to act. They will have the right of subpoena, the right of mandatory enforcement, and the right of mandatory quarantine. Coupled with a whistleblower protection clause, the legislation will finally give the FDA the tools it has been requesting to do its job.

The good news for the operators within the produce industry is that compliance with the current industry-driven Produce Traceability Initiative (PTI) will automatically provide compliance with HR2749 and a likely combined bill that would go to President Obama's desk for signature. Other industries regulated by FDA would do well to look at the specifics of the PTI which has clear action items and clear date guidelines as a solid model.

Senate bill S510 is generally in agreement with all of these major policy shifts, so it is likely that if S510 is the bill the Senate focuses on as a way to address the issue, that participant in the food supply chain regulated by the FDA will need to prepare for some changes in the way they do business. Senate bill S510 does provide a few policy points that are not in HR2749, including:

- The Department of Homeland Security to work with food-testing laboratories to create a network for exchanging test data among labs;

- Case-level identification of all products leaving a manufacturer; and
- Within nine months of enactment, the DHS Secretary to have completed pilots on a traceability system for at least three commodities that have been involved in a high-profile recall.

The principal irony between the HR2749 legislative journey and the path NAIS has taken is that HR2749 goes much further in terms of government intervention and imposing requirements on the food industry, than either NAIS or the preexisting Bioterrorism Record-Keeping Act of 2002. HR2749, though, appears to have broad support while NAIS does not. HR2749 has now gone to the Senate, where it has been read twice and assigned to the Committee on Health, Education, Labor and Pensions. Our sense is that by Thanksgiving 2009 we should know which way the political winds will blow and whether the substantial change embodied in HR2749 will become the law.

Those responsible for technology and information systems within organizations need to start providing and managing electronic data records; put systems in place to monitor food safety inside their four walls as well as outside their enterprise—across their supply chain as well as at their customers; and establish processes to showcase transparency and responsiveness in case of any emergencies.

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About TraceGains, Inc.

TraceGains, Inc.'s Advanced Brand Protection solution minimizes corporate risk for companies in the food supply chain and maximizes the quality and profitability of finished goods. Advanced Brand Protection allows companies to determine how and which suppliers affect finished-good quality and profitability on a per-shipment basis, experience accelerated profitability through continuous product improvement, and leverage an authenticated supply chain for increased brand loyalty. For more information, visit www.tracegains.com.

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