August, 2012

http://www.leavittpartners.com/global-food-solutions

Product Tracing: When Regulatory Compliance is Inadequate

By: Jennifer McEntire, PhD

I remember receiving a phone call late in the spring of 2008 while working at the Institute of Food Technologists (IFT). FDA was giving me a heads up about a new project they wanted IFT to lead on traceability (they used that term at the time but have now shifted to "product tracing"). I had no idea where to start. I considered myself a food safety person, but as FDA was describing their challenges in obtaining, deciphering, and analyzing paperwork documenting the movement of a product suspected of causing foodborne illness I began to feel overwhelmed. "This isn't food safety," I thought. "This is about procurement, and sales, and IT systems." And I was right. And wrong.

About the Author

Dr. Jennifer McEntire is the person FDA entrusted to evaluate product tracing practices in the food and feed industry in 2008, guide FDA-contracted mock tomato pilots in 2009, and conduct the FSMA-required tracing pilots in 2011-12. She earned her Ph.D. in food science from Rutgers University and previously served as a Director at the Institute of Food Technologists (IFT).

Continued outbreaks, varying in nature (different organisms, different foods, different parts of the world) exemplify deficiencies in the ability to track the movement of food throughout the supply chain. When an outbreak occurs (or when a traceback is initiated due to known or suspected contamination), the food safety/quality assurance staff at a firm are engaged. Product contamination is a food safety issue. But after the fact, when you need to know where a product came from and where it went, is this still food safety? I don't think it's worth debating the answer, since in all likelihood, the food safety person will be involved. So what should a food safety person do? My advice is: make friends, both within your firm and within your supply chain. Product tracing is a complex challenge that requires a multitude of individuals, departments and organizations working collaboratively within a company, and further requires communication with the teams assembled by your supply chain partners. **While a system-wide approach to product tracing is needed, improvements can be made without breaking the bank.**

Traceback versus recall

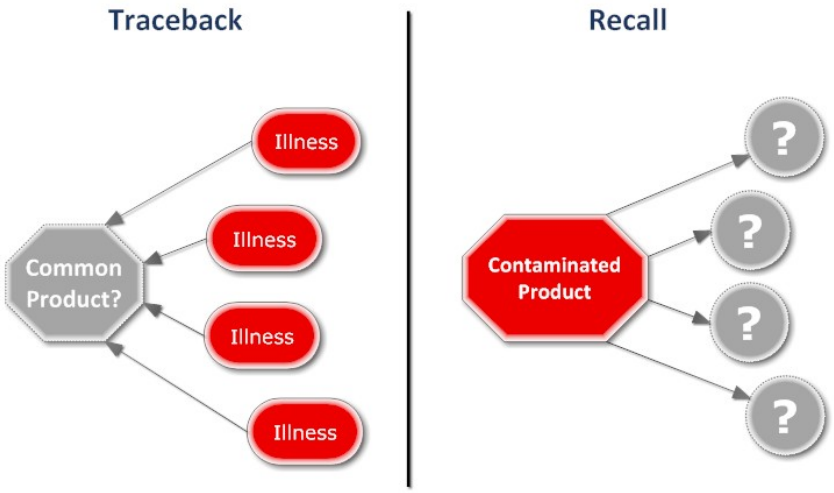
My apologies to anyone who has heard my rant on this issue for the past year, but I find that the confusion around traceback and recall: what regulators are looking for (to conduct a traceback) and what industry is accustomed to dealing with (recalls); is at the root of much of the challenge when talking about the need to improve the product tracing process. Products can be traced through the supply chain from the point of origin to the consumer (as one would trace during a recall, to determine the location of recalled product in the supply chain) or from the consumer to the point of origin (to determine what the common origin or common point is that is causing people to become ill during a traceback). Both require good recordkeeping. Both must be conducted quickly and accurately to protect public health. But they are different.

Do you have $10M to spare?

Because that's the average cost of a recall. And surveyed manufacturers had an average 2 recalls in the past 3 years.

Deloitte Consulting 2010. Recall Execution Effectiveness: Collaborative Approaches to Improving Consumer Safety and Confidence

A colleague of mine recently stated that the recall process was more difficult and complicated than the traceback aspect. I tend to disagree. First of all, industry is unfortunately pretty accustomed to conducting recalls. Firms generally have recall plans in place and conduct mock recalls regularly. As long as a firm can account for the distribution (or destruction, or other disposition) of all product, one step forward, they are in good shape (recognizing that this is not an easy feat). Rarely do firms conduct mock tracebacks, since the "origin" is likely more than one step back. The challenge faced by regulators is not to trace a product from a single location back to the point of origin—but rather to trace several products back and determine if they have anything in common. It is truly putting together pieces of a puzzle, which is a tremendous challenge when products are not described consistently between firms, when firms have aliases etc.



Compliance versus best practice

When I began exploring industry product tracing practices in 2008, one of the common assurances I heard was "we're in compliance with the recordkeeping regulations stemming from the Bioterrorism Act." And based on my assessment, this was generally true. **But being compliant and being adequate are two different things.** The recordkeeping requirements established by FDA in 2005 are inadequate to quickly and effectively trace food products. The exemption of the ends of the supply chain (the restaurants and retail stores where tracebacks often start, and the farms that could be the origins of a product) really limit the utility of the more robust information collected by the middle of the supply chain. Additionally, the unclear, fuzzy language around capturing lot information at manufacturing and relating those lots to finished products compromises internal tracing, without which, tracking throughout the supply chain is impossible.

FSMA confusion

Perhaps some of the confusion related to what FDA currently requires, as well as what they will require, stems from the fact that the food safety bills progressing through the House and Senate in 2009 and 2010 differed substantially in the authorities granted to and limitations imposed upon FDA with respect to product tracing. A substantial amount of misinformation abounds and the table below attempts to clarify what FSMA does and does not say, as well as provide commentary around whether or not FSMA language substantially changes the vision of the approach firms should take as they strive toward excellence, efficiency, and cost effectiveness.

Did you know?

Just over half of surveyed firms reported they were **fully compliant** with existing product tracing regulations.

Based on 2012 Commerce in Motion study of 129 food, life science and CPG firms

What FSMA Says	What FSMA Doesn't Say	Best Practice Considerations
Additional recordkeeping requirements for High Risk Foods (TBD); timing TBD	All firms/foods need to change what they are doing	All firms should evaluate product tracing capabilities. Low risk today ≠ low risk tomorrow
FDA can't prescribe specific technologies for the maintenance of records	Electronic recordkeeping is currently mandated	Flexible, interoperable, electronic recordkeeping solutions are ideal
Public health benefits must outweigh industry costs	FDA will require expensive solutions	Industry should make changes that have a positive ROI (in addition to public health benefit)
Maintain 24 hour timeframe in which to provide records	FDA will require records more quickly than current requirements	Faster is better, as long as you are right
FDA can't require a full pedigree or information beyond immediate subsequent recipient	You will need to have full supply chain visibility	Your supplier's supplier impacts your brand. Visibility has value.
FDA can't require product tracking to the case level	Product tracking at the lot level, with barcodes on cases, is prohibited	The right degree of granularity should be determined based on tracing objectives

As firms consider how they should address their product tracing challenges, “compliance” will likely be a low bar. This is principally because FSMA only authorizes FDA to require additional records for “high risk foods”. Although FDA has not yet released this list, FSMA identifies the factors that need to be considered as FDA develops this list, which includes the association with major outbreaks.

GS1

Love 'em or hate 'em GS1 is a force to be reckoned with when it comes to product tracing. The produce, meat and poultry, seafood and other industries have endorsed the GS1 identification system and one of the GS1 bar codes, the GS1-128, as part of the recommended tracing systems for their industries. It is unfortunate that there is so much confusion around GS1, which I think results in a fair amount of undue acrimony. Personally, I do not lump GS1 in with the host of third party technology providers offering trace-specific solutions. GS1 is not a competitor to the "trace-so-and-so" company. GS1 facilitates the development of consensus based standards. We have GS1 to thank (well, it's predecessor) for the development of the bar codes that allow us to check out at the cash register more readily than punching in the cost for every item. As a not-for-profit, GS1 serves as a valuable resource for product tracing information and a source of standards.

Is Electronic the Answer?

Ultimately, yes. There is no other way around it. I understand the prevalence of paper. In some cases, it may be a while before paper-based systems can be economically upgraded to electronic systems. Nevertheless, as companies discuss long term planning and system upgrades, electronic recordkeeping must be part of the discussion. You don't want to be pinpointed as the weak link during an investigation. As previously noted, conducting a traceback is akin to piecing together a complex puzzle (unlike a jigsaw puzzle, you don't even know how many pieces you are starting with or what the ultimate picture will look like). Assimilating all this information cannot be expeditiously or efficiently done by matching up pieces of paper. I know this from first hand experience.

How long to do a recall?

51.6% - Days or weeks to recall a specific lot

48.4% - Can recall a single lot within hours

Based on 2012 Commerce in Motion study of 129 food, life science and CPG firms

Are there work arounds? Of course! Optical character recognition is improving, allowing computers to scan and interpret hand written information (although I have seen some scribbles that make me question if a computer can really decipher something that my human eye cannot make out). Looking longer term this is an interim solution and should not be considered an end game.

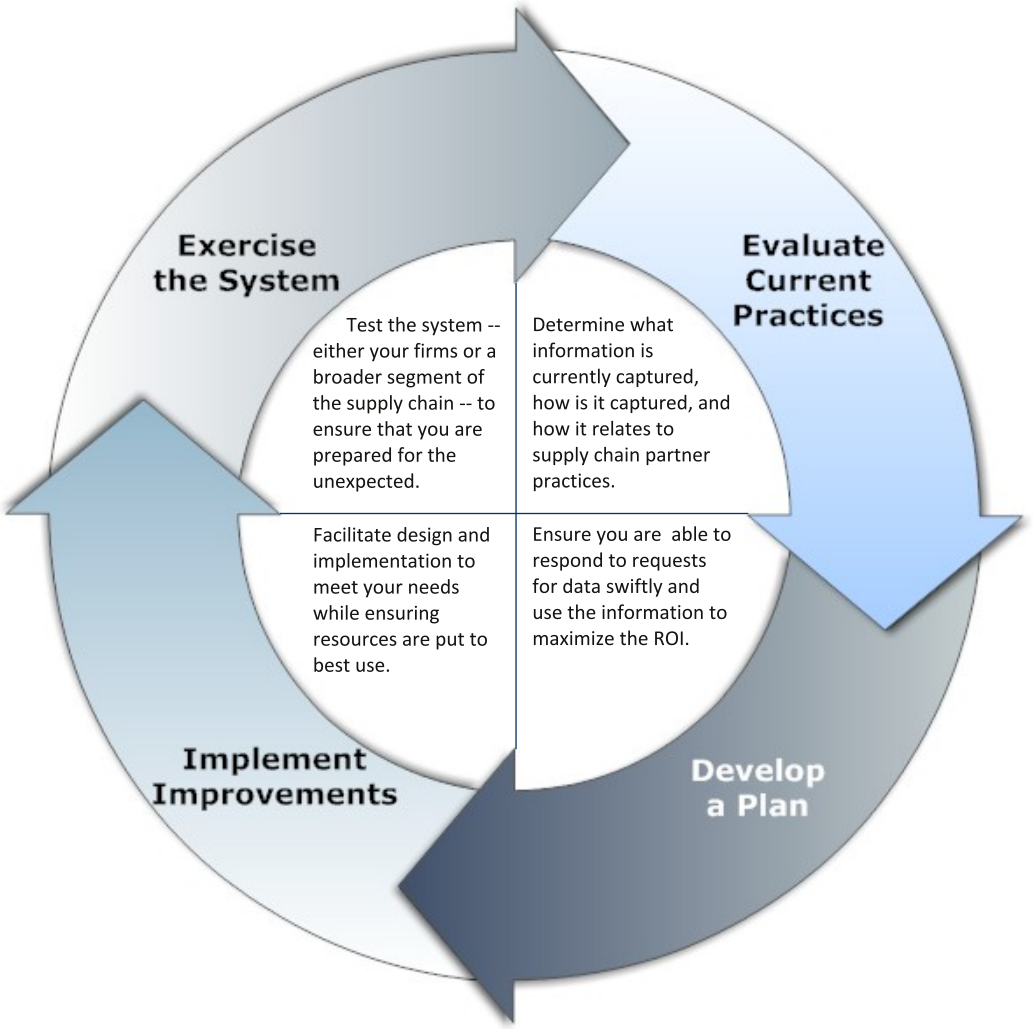
The Solution

When issues arise, it is easy to point out deficiencies in the system. It is much more difficult to provide concrete solutions. This is due, in part, to the fact that each company, and often each facility, operates differently. There are different systems in place, even within a facility—the receiving tickets may be electronic but the actual delivery time is written by hand; ERP systems may be used for some but not all parts of a process, etc. Even when appropriate and useful systems are employed to capture and record information, fitting the pieces of the puzzle together when systems don't talk to each other causes delays.

Less than 30% surveyed firms are very confident in their ability to trace **just 1 up/back**[1] and **less than half** don't have the capability to **track ingredients/allergens 1 up/back**[2]

[1]Based on 2012 Commerce in Motion study of 129 food, life science and CPG firms [2]Deloitte Consulting 2010. Recall Execution Effectiveness: Collaborative Approaches to Improving Consumer Safety and Confidence

Despite what some 3rd party technology providers purport, I don't believe that expensive solutions are necessarily the answer, and at a minimum, looking to technology providers is likely putting the cart before the horse. Before trying to solve a problem, you must first identify what exactly the problem is, what you are currently doing, and assess the gap. The best way to approach improving product tracing is to employ the ongoing process depicted below.



Summary

The food industry and individual firms are faced with two options when it comes to product tracing: wait until FDA makes clear requirements, or make changes now. There are pros and cons to each approach.

	Wait until FDA sets requirements	Make changes now
Pros	No wasted investment Defer resource allocation No need to retool if new system is mismatched with requirements	Improve brand protection Reduce liability Position the firm as "best in class" and increase market share/ confidence
Cons	May be the "weakest link" during issues May suffer interim inefficiencies	No current clear expectations - may not hit the mark May need to further invest as requirements are issued

Given the limitations FSMA imposes on FDA with respect to product tracing, it is unlikely that firms that make meaningful, appropriate investments now run the risk of being out of compliance when FDA requires additional recordkeeping for high risk foods. The decision to improve product tracing capabilities should stem from the recognition that it's good for your business and good for your brand. **Simply striving for the low bar of compliance is unlikely to position a firm well for future industry and consumer expectations.**

To learn more about how Leavitt Partners can help you understand the gaps you have and the other product tracing services we offer please visit Our Services or email Jennifer McEntire

Contact: Jennifer.mcentire@leavittpartners.com | 301-551-3601