

Harmonization in Food Safety Starts from Within

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SUMMARY

We can all agree that consumers should never have to worry about whether their food is safe. Where agreement doesn't exist, however, is in the "how"; how do we best monitor for chemical, biological and physical contaminants? How do we report and to whom? And how much regulation is too much?

Even as industry continues to debate the "how," prevailing sentiment is that the onus for ingredient and finished product safety is on manufacturers, both large and small, not on the myriad of regulatory bodies that now have jurisdictional oversight. After all, no regulator has sufficient resources to do anything more than perfunctory testing, and many agencies would readily admit they are drowning in data that, despite their intrinsic value, cannot be effectively accessed and used.

The answer must come *and is* coming from those best positioned to be stewards of food safety: the producers and manufacturers themselves. But this isn't a case of the "fox guarding the hen house," because there is no predator here. Each producer or manufacturer is accountable up and down an increasingly more transparent food supply chain. The consequences of a mistake range from crippling stock deflation for a mega brand to the complete shuttering of a smaller company affected by a recall on a national or international stage.

Now that the burden of proof has shifted to industry, each link in the supply chain has a proportional responsibility to supply safe product. Suddenly, it doesn't matter whether the Food Safety Modernization Act (FSMA) goes too far or whether the General Food Law Regulation in the European Union (EU) goes even farther. If the industry has a vested interest in delivering safe food, because the alternative is business-ending, they'll make investments that exceed what's required by regulation.

So what does all this have to do with harmonization, the subject of this article? Let's start by looking at what harmonization means.

Harmonization in food safety

Many industries have their eyes on the Trans-Pacific Partnership (TPP), and the food industry is no exception. On its website, the U.S. Dept. of Agriculture (USDA) states, "The TPP is an opportunity to advance U.S. economic interests in this critical region and to respond to the Asia-only regional trade agreements being negotiated by our competitors. A high-standard TPP agreement that addresses tariff and non-tariff barriers, including phytosanitary measures, will support expansion of U.S. agricultural exports and promote job growth."

Advocates for the dairy and poultry industries, among others, agree. Easing restrictions to global trade is important for future growth. But whether TPP is the catalyst for this growth isn't a subject for debate here. We accept that the opening of trade between nations, and among the thousands of food safety businesses within, is inevitable. But this is where the real challenge begins.

Critics of the law believe that an already loose net will get looser. For years, domestic seafood producers have complained of contaminated imports, including shrimp from TPP-participant Vietnam. How, these critics wonder, will opening trade help this long-standing problem? And

this is just one example among many. Simply put, there is no regulatory harmony between the eleven potential trade partners and the many other nations that are not part of TPP, so it's appropriate to wonder how standards will be monitored and met.

The same worries exist as the U.S. and EU hammer out terms of the Transatlantic Trade and Investment Partnership (TTIP), "an ambitious, comprehensive, and high-standard trade and investment agreement." Protests in the streets of Europe earlier this year don't portend well for TTIP, but that doesn't change the fact that strong political will exists to remove real and perceived shackles that prevent a free-flowing global food supply chain. Before this happens, however, proponents will need to win over those who question whether harmonization does indeed benefit consumers. In a recent article in the Huffington Post, authors Elizabeth Kucinich and Debbie Barker from the Center for Food Safety in the Washington, D.C. office wrote skeptically that "harmonization is code for low standards for food safety."

Without taking sides, however, we can at least concede that cross-jurisdictional harmonization will require negotiation and trade-off, so proponents and opponents

must accept something less than a perfect outcome. But everything we've explored so far looks at harmonization from the country or regulator point of view. What if, instead, harmonization capitalized on industry's willingness to accept the burden of proof and make harmonization about following data-driven business rules, instead of adherence to a hodgepodge of standards? In this case, could the outcome – in terms of food safety – actually be better? Perhaps.

Achieving data harmony first

You are only as strong as your weakest link. And if food safety is a chain, rather than a confederacy of monoliths, then weak links will stand out as the liabilities they are. A misstep by a single supplier can affect a brand's market cap significantly, and that single supplier is one recall away from bankruptcy. So, for any reputable food supplier, manufacturer or distributor, data-driven insights – as deep and detailed as possible – are actually prudent business insurance.

Is harmony just about agreeing to minimum standards? Maybe. But lost in the discussion of what standards should be is how to measure them, track them inside and outside of an enterprise, and respond as quickly as possible if a breach of any kind occurs. This is where regulation – even if harmonized – doesn't help. What can help, however, is a management system that over-achieves and is actually voluntary: ISO 22000. And don't let voluntary imply less rigor: Adherents to ISO 22000 haven't taken the easy way out; they've committed to holding themselves and their partners to a higher standard.

As you'll see in the sidebar to this article, while there's no single formula establishing rigor across the global food supply chain, one solution is to rely on ISO 22000 within labs, whether those are onsite or contract. In particular, Trish Meek, Director of Product Strategy at Thermo Fisher Scientific and author of the sidebar, argues for laboratory management information systems (LIMS) because of their existing track record across food and beverage laboratories. In effect, LIMS and ISO 22000 together can form a circulatory system for managing a highly distributed food supply chain, with data as the lifeblood. What we'd have then is data harmonization first.

Data management for global compliance

While some food and beverage companies still rely on manual data capture in some parts of their laboratory operations, spreadsheets and manual data transcription will prove incapable of handling the large volume of data that must be discoverable and auditable for ISO 22000 compliance, or as evidence to any other regulatory authority. Only an enterprise-level integrated informatics solution can handle the volume of data required of the latest food safety regulations in a secure and defensible manner. Laboratory Information Management Systems have an established track record across food and beverage

laboratories for helping to manage the ISO 22000 process, and compliance efforts in particular. This makes a LIMS an essential part of any food or beverage company that markets and sells its products around the world.

With a LIMS managing workflow and process, as well as serving as the central source of data for all sample testing, from raw materials through to the final packaged product, food and beverage companies can be assured that the data will be defensible to regulatory authorities and that management will have the data necessary to routinely reduce the risk of contamination or to effectively manage a food recall if that should prove necessary. Most important, the money invested in building the brand will be secured, and the consuming public will continue to have confidence in the quality and safety of the food products being sold. Adherence to regulatory requirements is one very important part of the ongoing efforts to build and support a brand. If processes are not in place to capture non-conforming product before it reaches the public, then a recall is a very real possibility.

Enterprise-level integrated informatics – Built-in best practices

For food producers, the main benefit of using LIMS to manage ISO 22000 compliance is its ability to address compliance needs in multiple geographies. A standard ISO/LIMS strategy can be implemented in any country without sacrificing regulatory rigor or compliance. No matter how many laboratories are involved in a company's manufacturing processes, or where in the world they may be, the LIMS is capable of managing the levels of relationship complexity and connectivity with multiple sites and manufacturing environments. Enterprise-level LIMS can build ISO 22000 into the workflow structure so that adherence to these regulations are routine, not only in the lab but across the entire organization.

CONCLUSION

Once you harmonize the data, you're one step closer to protecting your flanks up and down your supply chain. Or, if you're a single link in that chain, you have a way to validate that your ISO 22000-driven processes and management systems enable you to immediately plug into a lucrative global supply chain.

Over the next several decades, the world will get progressively "flatter," and that brings both opportunity and risk. But whether harmonization is possible across disparate jurisdictions is moot. What's most exciting for our industry is seeing how it steps up, arming itself with data and technology such as LIMS to make it our mission to ensure that consumers never have to worry about whether their food is safe.

SIDEBAR

ISO 22000 and Integrated Informatics: Best Practices to Meet Global Food Safety Regulatory Challenges

Trish Meek, Senior Manager, Product Marketing Informatics and Chromatography Software, Thermo Fisher Scientific

In KPMG'S 2014 Food, Drink and Consumer Goods Industry Outlook Survey, 22 percent of the senior managers questioned said that "staying ahead of or navigating changes in the regulatory environment" would consume most of their time in the coming 12 months. Nearly 20 percent said that geographic expansion would be one of the primary areas of

investment in the coming months. Taken together, these two data points echo a common food industry refrain: We want to expand internationally, but we're increasingly aware of the difficulties and costs of doing so from a regulatory standpoint.

Navigating regulations and requirements on a country-by-country basis is fraught with challenges: Those of some countries are exceptionally strict and onerous, while those of others are developing and the regulatory framework is far from mature. So what's the best path forward? While there's no single formula for success, one path forward for participants in the global food supply chain is to rely on accepted international standards such as ISO 22000 as best practices for their lab operations.

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