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The Food Safety Modernization Act — Global Impacts for Microbiological Food Safety

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The United States (US) is undergoing the most significant change in food safety legislation in 70 years with far reaching implications for the approach food manufacturers take to microbiological food safety, both within and outside of the US.

An Unacceptable Level of Foodborne Illness

Over recent years the US has seen a number of very high profile cases where outbreaks of food poisoning from contaminated products have had a nationwide effect, causing numerous illnesses, hospitalizations and deaths. The Centers for Disease Control and Prevention (CDC) has estimated that each year roughly one in six Americans (or 48 million people) are ill, 128,000 are hospitalized, and 3,000 die due to foodborne diseases[1]. The main causes of these issues are *Campylobacter*, *Listeria*, *Salmonella*, *Shigella* and Shiga Toxin producing *Escherichia coli* (STEC) (Figure 1).

Organism	Cases (No.)	Hospitalizations (%)	Deaths (%)
Campylobacter	6,486	17	0.2
Listeria	118	92	15.3
Salmonella	7,452	29	0.4
Shigella	2,801	20	0.1
STEC O157	445	35	0.7
STEC non-O157	690	15	0.0

Figure 1 ~ Number of cases in the United Sates in 2014 of culture-confirmed bacterial infections, hospitalizations and deaths, by key pathogens transmitted commonly through food — Data from the Foodborne Diseases Active Surveillance Network (FoodNet)[2].

Although it is acknowledged that the number of reported cases vastly underestimates the number of actual cases, it is useful to study reported cases as they can be used to track variations on a year-by-year basis. Each year the CDC publishes a progress chart that indicates whether the incidence of infection by each organism is reducing or increasing compared to a benchmark level derived from the illness figures obtained between 2006 and 2008 (Figure 2). The 2014 figures show that *Campylobacter* rates have increased by 13%, while there has been no change to the rates associated with *Listeria* and *Salmonella*. Rates from *E. coli* O157 have decreased, although there has been an increase in illnesses associated with non-O157 STEC[2]. This gives rather a negative view of the situation, with rates continuing to be above the CDC target.

Pathogen	Healthy people 2020 target rate	2014 rate	Change compared with 2006-2008
Campylobacter	8.5	13.45	+ 13%
E. coli O157	0.6	0.92	- 32%
Listeria	0.2	0.24	No change
Salmonella	11.4	15.45	No change

Figure 2 ~ Data from CDC 2014 food safety progress report[3].

In recent years within the US, there have been a number of high profile outbreaks of food poisoning, sometimes involving unusual food/pathogen combinations (e.g. *Listeria* in ice-cream and candy apples), as well as a number of outbreaks from foods containing imported ingredients (Figure 3).

Year	Food	Organism	Approx. number affected (deaths)
2015	Ice-cream	*Listeria monocytogenes*	10 (3)
	Frozen raw tuna	*Salmonella*	65 (0)
2014	Cucumbers	*Salmonella*	275 (0)
	Caramel apples	*Listeria monocytogenes*	35 (7)
	Bean sprouts	*Salmonella*	115 (0)
	Sprouted seeds	*Listeria monocytogenes*	5 (2)
	Cilantro (coriander)	*Cyclospora*	304 (0)
	Nut butter	*Salmonella*	6
	Sprouted chia powder	*Salmonella*	31 (0)
	Clover sprouts	*E.coli* 0121	19 (0)
	Ground beef	*E.coli* 0157	12 (0)
	Cheese	*Listeria monocytogenes*	8 (1)
	Raw cashew cheese	*Salmonella*	17 (0)

Figure 3 ~ Number of cases for select multi-state foodborne outbreak investigations in 2014-15[4].

A Paradigm Shift in Food Safety Approach

Part of the reaction to what was considered an unacceptable level of foodborne illness was the development of the Food Safety Modernization Act (FSMA). This act has been hailed in many quarters as the most significant change in food safety legislation in the US since the passing of the original Food, Drug and Cosmetic Act in 1938[5]. That act originally gave the authority to the US Food and Drug Administration (FDA) to oversee the safety of food and drugs.

The FSMA was signed into US law on January 4th 2011 by President Obama. Its aim is to strengthen the food safety system by enabling the FDA to focus its attention more on preventing food safety problems, rather than relying primarily on reacting to problems as they occur. It will also give the FDA new enforcement powers that have been designed to achieve higher rates of compliance with prevention-based/risk-based food safety standards and to enable a better response to, and control of, problems when they do occur. More importantly for those exporting food products into the US, the FSMA also gives the FDA the ability to ensure that imported foods are produced to the same standards, and have similar controls to foods produced within the US.

The Detail — What is in the FSMA

A glance at the full text of the FSMA[6] shows its coverage of the complete food chain and perhaps its apparent complexity.

The FSMA is divided into four parts, known as titles:

I. Improving capacity to prevent food safety problems
II. Improving capacity to detect and respond to food safety problems
III. Improving the safety of imported foods
IV. Miscellaneous provisions

It is useful to examine each of them and, when reading them, to remember that these will apply to both home-produced and imported foods.

Title I: Improving Capacity To Prevent Food Safety Problems

Title I of the act actually alters the US approach to food safety—from being a response to a problem, to being the application of preventative measures. This part of the act incorporates a requirement for producers to use hazard analysis and risk-based preventative control measures. This means a full hazard analysis should be conducted, then a plan created to ensure that all foreseeable hazards are significantly minimized or prevented. Control measures would have to be monitored and corrective actions taken if the preventative controls malfunctioned. From a microbiology perspective, this would include: reviewing what organisms might be present in an ingredient or food matrix; to what extent they might be able to survive and grow in the production environment and cross-contaminate the product; as well as the potential for survival and growth during distribution, and retail or domestic storage. Once such a hazard analysis has been completed, producers have to put in place suitable preventative controls that significantly minimize the microbiological risks.

Title I would also provide the FDA with access to records relating to the production of any food likely to cause serious health effects. It requires food producers to register with the FDA, and to regularly renew those registrations; it specifically covers standards for the safety of fresh produce, and has rules for the safe transportation of foodstuffs. Fresh produce has been particularly highlighted for a number of reasons: not only are the amounts consumed increasing but, coupled with this, there is an increasing variety of raw materials being sourced; it is a difficult product to "treat" to eliminate microbial hazards, and a number of outbreaks and illnesses have been associated with it[7].

Title II: Improving Capacity to Detect and Respond to Food Safety Problems

Title II moves into the area of what actions to take when food safety problems are believed to have occurred. It includes a requirement for the ability to track and trace foods. It gives the FDA the ability to stop the distribution of foods and to inform the public if there is a belief that a product is adulterated, misbranded or liable to cause harm to consumers. Here traceability becomes an important factor. Producers must be able to identify all individual components that go to make up multi-component foods, to be able to trace both where they were sourced from, and where each batch has been sent. This will allow effective withdrawal or recall of contaminated materials, if any are found.

Title III: Improving the Safety of Imported Foods

This title of the act expands the authority of the FDA over imported food products. It allows the refusal of imports without prior FDA inspection and requires producers to meet US standards. Perhaps the most significant part is the Foreign Supplier Verification Program (FSVP). This requires importers to verify that food imported into the US has the same level of public health protection as food produced within it. The responsibility for ensuring the application of the FSVP falls on the body or company that is importing the ingredient or product. The importer is required to undertake actions that assure proper control of hazards and that corrective action systems are in place at the foreign manufacturer, and that they (the importer) have a verification system in place to check and gain adequate assurance that all hazards are controlled (examples could be periodic testing, visits and audits of foreign suppliers).

Title IV: Miscellaneous Provisions

This title covers the provisions of funding to the FDA to carry out their activities, ensures that correct staffing levels are in place, and provides protection for any person engaged in food production from any adverse actions or discrimination if they disclose information relating to food safety issues (i.e. whistleblower protection).

Final Rules

Although the FSMA was signed into law in 2011, the details behind its requirements have remained broadly unknown. The complexity of the act has required the FDA to spend considerable time drafting measures and consulting with stakeholders, before the detail of the act could finally be published. However, through September and November 2015 the final rules[8] covering the requirements of the FSMA were published into the following forms:

Final Rule for Preventative Controls for Human Foods

This rule requires food producers to have produced a written food safety plan that includes: hazard analysis, preventative controls, and management of preventative controls (this includes monitoring, appropriate corrective actions and verification of the control measures). It is noted that product and environmental monitoring are possible verification activities. The rule also notes that "farms" are not subject to the preventative controls requirement. The compliance dates for this rule vary depending on the size of the business, from three years for very small businesses to one year for large businesses.

Final Rule for Preventative Controls for Animal Foods

This rule takes into account some of the unique aspects of animal food production and provides flexibility for the diversity in different animal food production facilities. Processors already implementing human food safety requirements do not need to put in place any additional preventative controls when supplying by-products for animal foods (except for preventing physical and chemical contamination). This rule requires similar hazard analysis, preventative controls and management of preventative controls as does the rule for human foods.

The animal foods rule does contain some interesting features for vertically integrated operations. For example, an animal farm which produces feeds that are supplied solely to its own animals is considered to be a farm and not subject to the preventative controls for animal food rule. However, there is a strong indication that the FDA will publish a future rule that will require some of these on-farm feed mill operations to establish preventative controls. As with the human foods rule, the compliance dates vary depending on the size of the business, and in this rule different dates are given for compliance to Current Good Manufacturing Practices (CGMP) and compliance for availability of preventative controls. The compliance dates are between three years for very small businesses to one year for larger operations.

Final Rule on Produce Safety

In consideration of the large number of food poisoning outbreaks in the US attributed to fresh produce, this rule is detailed and covers a varied range of "inputs" into the produce growth environment. Key inputs with specific requirements include: agricultural water (including microbiological criteria for waters and a requirement to test untreated waters used for certain purposes); soil amendments (manures and compost, with microbiological criteria set for pathogens in composts); sprouts (with microbiological criteria set

for pathogens in seeds, spent irrigation water or sprouts); animals in growing area (restricting access of wild or domestic animals to covered growing areas); worker training and health (preventing worker contamination of produce); and equipment, tools and buildings (establishing hygienic standards).

The rule has some exemptions, including produce that is not consumed in its raw state (i.e. always consumed after cooking) and produce for "own" use.

Again compliance dates vary according the business size, with very small businesses having four years whilst most farms will have two years.

Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

This part of the act covers foods imported into the US. The rule is very specific, an importer is the US owner or consignee of a food offered for import. If the latter does not exist, then it is the US agency or representative of the foreign owner at the time of entry.

The rule places obligations on the importer to take actions to: determine hazards; evaluate risk; approve verification activities based on risk; conduct supplier verification activities and undertake corrective actions. Some more specific requirements are covered later in this article.

This rule is of critical importance to those exporting foods into the US, and should be read in some detail. Compliance dates vary depending on the type of supplier, but for most importers it will be 18 months after the publication date of the rule.

Final Rule on Accredited Third-Party Certification

This rule covers the provision of a voluntary programme for the accreditation of third party certification bodies (auditors) to conduct food safety audits and issue certifications for "foreign" food and feed production facilities. Certification can be used by importers in the Voluntary Qualified Importer Program (VQIP) which can speed up the process on entry of foods into the US.

Imported Foods, Microbiological Hazards and Testing

One of the major initiatives of the FSMA is a need to ensure that imported foods meet the same standards as foods produced within the US. In 2011 it was estimated that 10.5 million[9] different lines of food were imported which represented around 16%[10] of all foods consumed. By 2013 this had risen to 19%[11].

Food imports were valued at $78 billion in 2007[10]. The main imported food groups were seafood (85% imported), fresh produce (50% imported) and fresh vegetables (20% imported). CDC data collected between 2005 and 2010 indicates imported foods were responsible for 39 outbreaks involving 2,348 illnesses[10]. This may sound like a small number, however, over half of these outbreaks (17) occurred in the last two years, leading to a concern that the rate could be increasing drastically. It is with this data in mind that

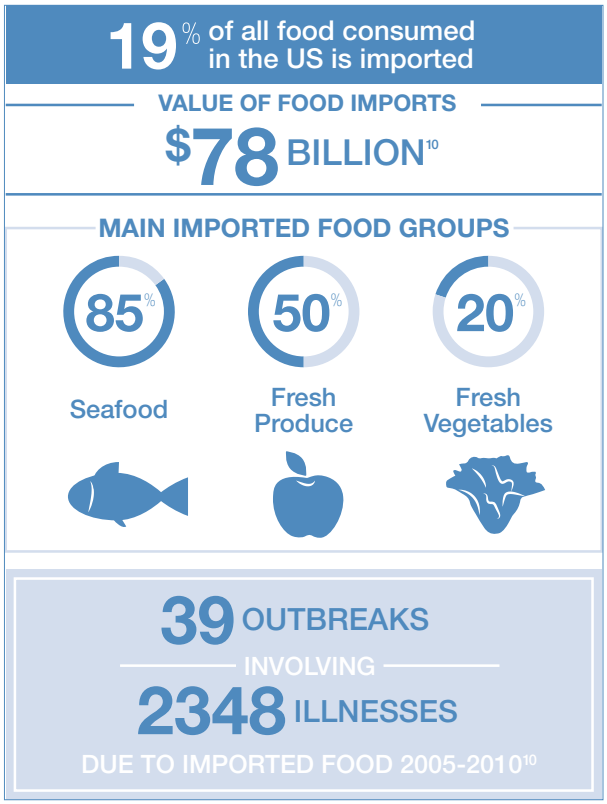

Figure 4 ~ Summary of reported figures for US food imports and associated foodborne illness

major sections of the FSMA have been focused on the monitoring and control of imported food products.

The major part of the act that covers imported foods is the FSVP. The final rules for this have now been published and it is clear that there are a number of actions that importers need to take. The basic requirements are:

- Review the compliance status of the food. This will involve background checks to establish any previous issues with that product or the supplier.
- Undertake a hazard analysis to establish what hazards might reasonably be expected within that product. This should be followed by a determination that the producer has in place suitable control measures for each identified hazard.
- Set up a verification activity. Here, it is the responsibility of the importer to set up a series of activities that will allow verification that the producer's control measures are working. As noted previously this could include visits to the production site, audits of facilities and control measures, independent sampling, and testing of the foods by the importer.
- Establish a corrective action procedure. If the importer obtains indications that the imported foods are not of the correct standard, then they should review them, investigate their cause and put in place corrective actions to prevent recurrence.

There is a requirement for importers to reassess their FSVP at appropriate intervals; at least every three years. If, however, the importer is aware of new information about hazards associated with the imported food, then the FSVP has to be reassessed more frequently.

Testing

It is clear that on many occasions within the FSMA, and certainly within the verification parts of the FSVP, there will be a need to test foods for particular hazards. There is recognition within the act that great care has to be taken to ensure that laboratory results are correct and properly define the presence, or absence, of a hazard. In order to build a foundation of high quality laboratory results, the FSMA Section 202 requires the FDA to set up a laboratory accreditation system. This initially needs the definition and establishment of "accreditation bodies" that are recognized by the FDA. The act notes that the accreditation bodies may operate outside of the US, as long as they meet US standards.

This brings in the next requirement. In order to accredit a laboratory, there must be a standard against which to audit and measure compliance. The act requires the FDA to set up such an accreditation standard, and defines that it shall ensure that:

- appropriate sampling and test methods are followed and that reports are true;
- internal quality systems are in place;
- a complaints and investigation system is in place;
- staff are appropriately trained to do their work.

While the final rules of the act have now been published, there appears to be little to help define the requirements for the qualification testing laboratories and acceptable methods that can be used within those laboratories. This leaves those testing foods within the requirements of the act with a dilemma. What will be the correct accreditation standard(s) that a laboratory has to work to and what method should they use?

Accreditation

The standard against which laboratories will be measured is, at present, unknown. It is certainly possible that, rather than inventing a new system, the well known ISO 17025 quality standard[12] could be employed. This would benefit many laboratories both in the US and around the world that are already accredited to this standard, but there are other potential issues with the FSMA that need to be resolved.

Section 202 says that the FDA has to set up a public registry of suitable accreditation bodies. This brings in an issue that is found in few regions of the world. Many countries will have only one officially recognized accreditation body with suitable recognition agreements to The International Laboratory Accreditation Cooperation (ILAC), which is a body that oversees mutual recognition of accreditation by different organizations. However, the US has eight such accreditation bodies, so which accreditation bodies become listed on the FDA registry will be very important to foreign suppliers. Will the list be limited to US based bodies or include others with links to ILAC? If a particular country's accreditation body is not listed by FDA, it is possible that no laboratory within that country will be able to test products to be imported into the US, as testing could only be done by laboratories that have been accredited by FDA listed accreditation bodies.

Test Methods

Of course laboratory accreditation will only cover tests that are listed within a laboratory's scope or schedule of accreditation; the laboratory may operate other methods, but these will not be accredited. The scope is the important document that states which tests are covered under accreditation. It will also indicate the basis of the method that is being used and the sample types on which that method can be used.

It is well known that different method types can give slightly differing results; this is the reason why many pieces of legislation that define criteria that are applied to foods (particularly microbiological criteria) will define the method that must be used to check that those criteria are not exceeded. As an example, in European legislation, microbiological criteria for foods are defined within European Commission Regulation 2073/2005[13]: this tends to reference International Standard (ISO) and European Standard (CEN) methods, or other rapid methods that have been formally validated and certified against these standard methods (and shown to give equivalent results), as the only test types that can be used. Thus in Europe most accredited food microbiology laboratories will have ISO methods, or methods validated against ISO methods, within their scope. If we now turn to the US, the methods used tend to be those recommended or indeed specified by the FDA. The FSMA is clear that "appropriate" methods have to be used. We have to wonder what an "appropriate" method may be. If only official FDA methods are considered, then any laboratory that does not have these methods within their accreditation scope would not be able to test under the FSMA, and this, of course, would include many accredited European laboratories.

Volume 36 Number 1 | January 2016

A Step Forward in Food Safety

Some Conclusions

The FSMA is a large and complex piece of legislation, but its goal of introducing hazard- and risk-based preventative control measures is a major step forward and will benefit food safety within the US. It is well understood that testing alone is not a valid method of controlling food safety; it is one of the tools that enables the analyzer to verify whether control measures are effective. In many situations where final product testing is used, the results will be available long after food has been shipped and in many cases consumed. The correct approach to managing the food safety risk has to be the application of preventative measures as required within the FSMA. Within Europe, legislation has required the implementation by food producers of the principles of Hazard Analysis and Critical Control Point (HACCP) system for many years. HACCP is a risk management approach centered on the use of preventative measures to maintain food safety. While testing is used within HACCP, it acts as one of the verification tools, to give users confidence that the system is working. Testing is not considered a control. European producers/exporters are therefore well placed as the FSMA progresses. This does not mean that changes will not have to be made, or a new system introduced if export to the US is required, but that the changes should not require a fundamentally different approach to risk management.

In September and November 2015 we saw the publication of the bulk of the FSMA final rules. These tackle, in detail, the requirements of the act for those producing human or animal foods within the US or those wishing to export to the US. It is clear that microbiological testing can form a major verification activity in support of the correct application of preventative measures. It is, however, also apparent that vagueness still surrounds the detailed aspects of microbiological testing. The act stated that laboratories would have to be accredited to a standard, it is still difficult to interpret what that standard should be and who would be an appropriate accreditation body. Likewise, with test methods, any definition of acceptable test methods seems to be absent from published information. While this is problematic within the US, it is more of a concern in other areas of the world, where the ISO 17025 laboratory quality standard is universally used. Will this be an acceptable standard within the requirements of the FSMA? If so, what methods would accredited laboratories have to use, ones that are currently within their scope of accreditation or other methods specified by the FDA?

The answers to all of these questions are not yet in place. How they are answered will have important and far reaching consequences as to where, how and by whom testing of food imported into the US can be undertaken in the future.

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