The Food Safety Modernization Act: Hazards Analysis and Risk-Based Preventative Controls (HARPC).

A look at what you might be doing this next year.

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The FDA *Preventive Controls for Human Food* rule was published in September 2015 and is considered final. This rule caps several years of development of a major enhancement to food safety within the Food Safety Modernization Act (FSMA). Essentially FDA is now mandating a food safety program (system) for all food manufacturers.

Compliance dates. Small companies with less than 1 million dollars in annual sales (globally) will have three years to comply. Medium companies with more than 1 million dollars in annual sales (globally) but less than 500 employees will have two years to comply. Large companies with more than both 1 million dollars in annual sales and 500 employees will have only 1 year to comply. Facilities that only store packaged non-hazardous foods (e.g. low Aw) are subject to less stringent requirements. Details can be found in the FDA website and FSMA documentation.

Written plan with detailed hazard analysis. The major emphasis of the *Preventive Controls for Human Food* rule is that covered facilities ***must*** establish, document and implement a food safety system that includes a hazards analysis and risk-based preventive controls (HARPC). The HARPC written food safety plan includes an elaborate hazards analysis of all ingredients and each step in a food process. Operators must assess the impact of biological, chemical (including radiological) and physical hazards present naturally, unintentionally added or intentionally added. The FDA cites providing flexibility for the owner, operator, or agent in charge of the facility to either prepare the written food safety plan or have that plan prepared, in whole or in part, on its behalf.

Qualified individual. The FSMA HARPC rule defines that all HARPC plans be written and managed by a "qualified individual". A person may be designated as a qualified individual after completing training in the development, documentation, and management of HARPC food safety plans. At the present, the best training option is to attend an FSPCA (Food Safety Preventative Controls Alliance) workshop and receive a certificate of completion. Alternatively persons may demonstrate that they have the knowledge and experience of HARPC and the *Preventive Controls for Human Food* rule. The specifics of how one would demonstrate their knowledge and experience are not clear at this time.

Preventative Controls. For each hazard identified, operators must establish preventative controls to ensure those hazards are minimized or prevented (remain under control). Under HACCP the main preventative controls were critical control points. These remain in HARPC but are grouped as "process controls". HARPC under FSMA specifically enhanced several key preventative controls areas to address known hazards that have led to outbreaks of foodborne illness. These include allergen control, sanitation (environmental) control, supply chain control, and recall (traceability). These controls do not necessarily have to be "critical" and may be operational controls incorporated into prerequisite programs.

Effectiveness. Beyond the written food safety plan (hazards and preventative measures), operators must demonstrate plan effectiveness. This is done via effective monitoring, corrective actions, and verification. Under FSMA HARPC the FDA advocates verification activities such as product testing and environmental monitoring when these are needed to verify preventative controls where a hazard is likely. For example, an operator producing ready-to-eat foods susceptible to *Listeria monocytogenes* have an effective environmental monitoring program if *Listeria monocytogenes* is not controlled in another manner.

For the candy and confectionary industry a common hazard may be *Salmonella*. In a similar fashion to *Listeria monocytogenes,* an operator must demonstrate *Salmonella* control in one or more areas including supply chain, process, or environmental. This might include requiring suppliers to provide certificates of analysis on ingredients tested for the presence of *Salmonella*. Alternatively, a lethality step can be built into a process control ensuring its destruction. Lastly, *Salmonella* in the confectionary industry can be an environmental pathogen. An environmental *Salmonella* testing program may need to be implemented to ensure that the pathogen does not take up residence in the facility. If present, effective sanitation controls must be employed to eradicate it. Confectionary companies may also choose to hold and test finished products for *Salmonella* as a verification tool to provide data on the effectiveness of all of the *Salmonella* controls.

Supply chain control. The FSMA HARPC rule specifically mandates that an operator have a risk-based supply chain program. Operators must perform a hazards analysis on ingredients and supplies to determine if there are any hazards of concern and if they can (or must) be controlled or minimized at the supply chain level. Once again, *Salmonella* is a prime example of a hazard in confectionary ingredients. As a result operators should consider methods to ensure suppliers are making efforts at controlling identified hazards. This might include setting supplier (ingredient) standards, receiving ingredients only from approved suppliers, and verifying *Salmonella* sensitive ingredients are free of *Salmonella* via testing demonstrated in Certificates of Analysis.

The FDA has stated in the final rule that a facility will not be required to implement a preventive control when an identified hazard will be controlled by a subsequent entity such as a customer or other processor. An example might be dried spices and

flavorings. The nature of these ingredients often leaves them highly contaminated with spores and in some cases *Salmonella*. If the buyer of these spices places them in a food product that is cooked to a lethality, then the supplier of the spices need not demonstrate control over the hazards. However, the supplier must disclose that the food is "not processed to control (identified hazard)" and obtain written assurance from its customer regarding certain actions the customer agrees to take.

Allergen Control. A large proportion of recalls in the last few years has been due to allergen concerns. The FDA *Preventive Controls for Human Food* rule requires that an operator perform and document a hazard analysis to determine if there is any hazard related to allergens in their products or facility. The FDA rule lists only the eight major food allergen proteins for the USA. However, it is prudent to consider all allergens related to the countries of sale. If allergens exist, the operator must document and implement preventative measures. The most obvious is allergen labeling. Supplier controls and environmental (sanitation) control may be applied here as well. Regarding environmental control, the FDA rule and new GMPs define a more accurate term for allergen hazards, "cross-contact". This is a better term than "cross-contamination". Since the presence of an allergen that is listed on the label is not a hazard (contamination).

GMPs updated. The current GMPs found in 21 CFR 110 along with the new hazards analysis and risk-based preventative controls (HARPC) requirements have been placed into a new section 21 CFR 117. The Code of federal regulations 21 CFR 117 is organized into several subparts: A—General Provisions; B—Current Good Manufacturing Practice; C—Hazard Analysis and Risk-Based Preventive Controls; D—Modified Requirements; E—Withdrawal of an Exemption Applicable to a Qualified Facility; and F—Requirements Applying to Records That Must Be Established and Maintained. Subpart G is reserved.

Subpart A. One big change is that the term "shall" is replaced with "must". The mandate meaning is the same. All other references to "should" items were removed from the Code of federal regulations to FDA published non-mandated guidelines. Additional new definitions are listed in subpart A.

Subpart B. The existing 21 CFR 110 GMPs have been enhanced. Some of the previously non-binding provisions, such as education and training, are now mandated. Operators are now required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties including the importance of employee health and hygiene.

Subpart C. This section essentially outlines everything discussed above as requirements for HARPC including the written plan, qualified individuals, etc. An item not discussed above is the need for records (restated in subpart F), verification, and validation. HARPC requires written updates at least every three years in the absence of new or emerging hazards (in which case it would be sooner).

Subpart D. This section in part defines the submissions that need to be made to the FDA. First, all facilities must report whether they are a qualified (subject to HARPC) facility and what category they fall under (large, medium or small). This will be an online submission and will likely be in the same place where FDA food facility registration occurs. Secondly, qualified facilities must then submit a statement from an owner or person-in-charge stating that the facility is in compliance with all applicable food safety laws and regulations including HARPC. This would include adherence to other Codes of federal regulations such as (21 CFR) 163: Cacao products, 168: sugars and sweeteners, 170-177: food additives, 180-186 Generally recognized as safe ingredients or additives, and 189: Prohibited substances. There may be other state level regulations such as in California Transparency in Supply Chains Act that requires certain companies to report on their specific actions to eradicate slavery and human trafficking in their supply chains.

In earlier FSMA documentation the FDA has indicated that it will not require submission of written plans, certificates, or similar. It is not clear if this is still the case. The FDA or their representatives will likely request inspection of these documents during audits.

Subparts E and F. There are a few exemptions described in FSMA documentation. For example retail and foodservice facilities and facilities in compliance with Seafood HACCP, Low Acid Canning Regulations 21 CFR 113, or Juice HACCP are exempt from HARPC. Subpart E gives the FDA power to withdraw an exemption for a facility that may place it into a category that requires a full HARPC plan. Subpart F defines the records required and record retention. Basically, records must be accessible onsite for 6 months and must be kept for 2 years total.

Auditing. The new FSMA rules define a "qualified auditor" as someone with the knowledge and expertise (via education, training, or experience) to perform the auditing function. Examples of qualified auditors would be those individuals accredited by Global food Safety Initiative programs such as BRC and SQF. First party (self) audits are acceptable verification activities, but are generally not acceptable as evidence of food safety compliance externally. Second party audits are not specifically mentioned in FSMA and are presumed acceptable (inspecting a supplier); however in this case auditors should be "qualified" as designated above. Third party audits are best and a "qualified auditor" should always perform these audits.

HARPC and GFSI. The biggest question asked of the new FSMA HARPC rule is how does it work with operators that are already GFSI compliant. In this case operators have almost certainly met the enhanced food safety preventative measures for supplier control, environmental (sanitation) control, allergen control, recall, and have existing process control. It is recommended that the lead food safety manager receive HARPC training first. Then the operator will likely lack the new enhanced Hazard Analysis. This will need to be done. Then a simple alignment of existing preventive controls with those mandated by HARPC needs to be completed. Don't

forget that the new 21 CFR 117 mandates employee food safety training where needed. It may be advisable to align documentation terminology to HARPC verbiage. Hopefully, GFSI schema will incorporate HARPC quickly and provide guidance to this alignment. It is important to remember that the FDA has not made any specific interpretation that a GFSI complaint operation is evidence that an operator meets HARPC.

Summary. As a trainer and educator in HACCP and HARPC it is always beneficial to review the difference between a plan, program, and system. A plan is just that – a plan to do something. It might include documentation. A program is something that has a start and an end. A food safety program might have a documented plan and some implementation. A food safety system has a beginning, but no end. A documented plan, implementation, verification, and validation are all combined to judge effectiveness. Continuous improvement continues *ad infinitum*. Benchmarking with peers can be used to evaluate the progression from mere compliance to *best in class* to *world class.*

Disclaimer and reference: *this article was written from publically accessible information on FSMA, HARPC and from FSPCA meetings. Statements about the FDA or about how it might interpret something were taken from the Preventive Controls for Human Food final rule released September 2015. Readers are directed to the FDA website (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm) for their official documentation.*

About the author. Dr. Brian A. Nummer is a food safety extension specialist at Utah State University and is Director of the Retail-foodservice food safety consortium. He is a food microbiologist with more than 25 years experience. He has taught food safety workshops in many subjects including HACCP and now HARPC. Dr. Nummer is a "Lead" instructor for the FSPCA for HARPC and was a curriculum reviewer. HARPC workshops will be held in Utah throughout the year offered by Utah State University Cooperative Extension. The Retail-foodservice food safety consortium will provide HARPC workshops based in Las Vegas approximately monthly in 2015-2016. Find more information at Dr. Nummer's Retail-foodservice food safety consortium website: http://food-safety.guru.