Food safety:
In the plant and throughout your organization
Table of Contents

3 Clean as a Whistle
American bakeries have perfected the art of high-volume production. Now the focus is shifting to the science of hygienic design and efficient cleaning.

6 Food Safety and Compliance
Invest in food safety systems before you have a $10 million problem.

8 FDA Painted Into a Corner
A federal judge orders the agency to issue overdue food safety rules by Nov. 30 ... which looks unrealistic.

10 The Continuing Evolution of Food Grade Lubricants
Exclusive use of H-1 lubricants consolidates your inventory and removes lubes as a potential hazard.

13 Food Safety Plans
There are new requirements for registered facilities.

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Clean as a Whistle
American bakeries have perfected the art of high-volume production. Now the focus is shifting to the science of hygienic design and efficient cleaning.

By Kevin T. Higgins, Managing Editor

Time spent cleaning is time not producing, but higher hygienic standards for bakeries need not mean a drain on throughput.

Skimping on sanitation is not an option, of course. Continuous improvement in food safety is as central to today's food processing as increased automation. Customers and the industry itself are less forgiving of carelessness in cleanliness. While all industry sectors must raise their game, the impact is particularly profound in baking, where the visibly clean standard is giving way to cleaning to a microbial level, as outlined in the Food Safety Modernization Act (FSMA).

“The level of cleaning is going to change significantly under FSMA,” believes Greg Flickinger, vice president-manufacturing & corporate engineering at Snyder's-Lance Inc. (www.snyderslance.com), a Charlotte, N.C.-based snack foods manufacturer with a portfolio that includes cookies, crackers, pretzels and other baked goods. “The whole microbiology issue had not been on the table, but now we have more visibility to that side.” Not being able to see protein or bacteria on a food contact surface no longer is a defense for not removing them, Flickinger points out.

Many FSMA regulations aren’t likely to be phased in before 2015, but he has spent the past two and a half years preparing Snyder’s-Lance’s 10 bakeries for the preventive approach to food safety that will be required. Evaluation of existing equipment is part of the initiative, and when new machinery is ordered, sanitary design is the top criterion.

“Quite a partnership is evolving with the OEMs, who are designing equipment with angled surfaces and no unnecessary holes and harborage points,” Flickinger says. Capital expenditure limits prohibit replacing “heritage equipment,” so work teams are modifying the most problematic areas for accessible cleaning. Retrofitting comes at a cost, however: “We may have to spend more time cleaning,” he allows.

Reduced cleaning time usually is relegated to the soft savings column, although there is nothing soft in getting a line running 30 minutes faster. Increased capacity drove Canada Bread Atlantic in St. John’s, Newfoundland, to replace gyatory box screeners with presurized centrifugal sifters from Kason Corp. The 43 percent boost in throughput capacity wouldn’t have been meaningful if cleaning requirements were extended, and that is where soft savings really added up. The new sifters require only 10 minutes to clean compared to 90 minutes with the old screeners, according to the plant’s maintenance manager.

The industry template for sanitary design was set 10 years ago when the American Meat Institute (AMI), with input from meat and poultry processors, engineers and equipment manufacturers, unveiled its 10 principles of sanitary design. Those principles – no liquid- or product-collection areas, no niches, validated cleaning and sanitizing protocols, cleanable to a microbiological level, etc. – have been embraced by many industry participants, including OEMs catering to bakeries.

An example is Vemag, the dough divider and makeup system from Robert Reiser & Co. (www.reiser.com), Canton, Mass. The machine originally was engineered to pump sausage meat into casings. The heart of the system is a positive displacement pump that precisely meters materials between double screws. The AMI principles stipulate compatible materials of construction, and that is construed in meat to mean stainless steel food-contact points. Reiser fabri cates its tandem screws from stainless, regardless of whether they move sausage or dough.

“Within three to four minutes, all the machine surfaces can be exposed for cleaning, and the process is mostly tool-less,” says John McIsaac, Reiser’s vice president-strategic business development. The same polished surfaces, configuration of O-ring grooves and other details of construction can be found in dough dividers.

“High production bakeries really have been raising their game,” McIsaac adds. “One of the critical control points in baking is the divider. Under pressure from key customers, they’re taking swab tests, and a lot of the older equipment is not making the grade.”

Fresh Start Bakeries, a McDonald’s bun supplier, installed a Vemag five years ago at its Ontario, Calif., plant. Additional installations have followed, though those purchase orders were driven not by sanitary considerations but by machine precision. Scaling accuracy is within 1 percent standard deviation. If a dough’s target weight is 68g, the unit operates in the 67-69g range, McIsaac says. “We are not the cheapest machine, but we deliver value by not giving away product,” says McIsaac.

USDA baking
Many of the ice cream sandwiches made in America rely on wafers supplied by Ellison Bakery, a family-owned operation in Fort Wayne, Ind., that also was the first licensee of Archway cookies (coincidentally, the brand is now owned by Snyder’s-Lance).

In terms of hygiene, “a bakery standard is not sufficient” when the customer is a USDA-inspected dairy, says plant manager Jon Ellis.
“We put a lot of emphasis on execution of correct procedures and on minimizing the potential for foreign-material contamination,” just-in-time production and close monitoring of metal detectors and other control points also play to that effort.

Ellison operates two bake lines in a 120,000-sq.-ft. facility that was expanded six years ago. Until then, production and packaging was done in an open-floor layout; with the added space, managers were able to isolate those operations.

“Twenty years ago, it was acceptable to do everything in the same area, but not anymore,” observes Ellison. Questioning accepted practices and migrating to higher standards is critical, particularly as the bakery seeks level 3 certification under the Safe Quality Food food safety standard. As part of the effort, audits of vendors are conducted regularly to verify that their safety programs are consistent with the bakery’s.

Consistency of finished goods also is a priority, and the bakery is locked into a continuous improvement cycle with its batch controls architecture. A Win SPC program was installed a decade ago and has undergone three or four upgrades and expansions to recipe management, even control and conveyor operating speed, Ellis reports. “Operators can make minor adjustments to forming, cutting, baking and cooling, but they can’t go out of a preset range.” A vision system tied to the program performs 10 quality measures, a major improvement in mind, but high throughput and minimal operator involvement were the key objectives. King points to the “lights out freezer” as an example. Pallets of finished goods move in and out “with the push of a button,” with inventory management software controlling an automatic storage and retrieval system that operates without human intervention.

Utility companies are inclined to subsidize self-generation and provide more favorable rates to big-usage customers who can go off line during peak demand periods. Those arrangements can mean the difference between building a peak-shaving plant or not.

Safety considerations should extend beyond the product to include the people who work in the plant, says King. Besides minimizing horizontal surfaces and overcoming the challenges of joining dissimilar materials such as steel and concrete without leaving crevices or fissures where vermin or rodents could enter, special attention was given to explosion-proofing in Clayton. Explosion panels surround the flour sifting area, which is further isolated from the production floor by a corridor. NEMA 4 enclosures and a separate air-handling system isolate areas for ingredient handling were designed with sanitation in mind, but high throughput and minimal operator involvement were the key objectives. King points to the “lights out freezer” as an example. Pallets of finished goods move in and out “with the push of a button,” with inventory management software controlling an automatic storage and retrieval system that operates without human intervention.

Another project distinction was the installation of three 1,000 KV diesel generators, which can power the plant completely off the grid. Back-up systems that deliver operating power are a growing trend, King suggests. Powerful storms like Hurricane Sandy and Oklahoma’s recent mega-twister are stoking interest in self-generation.

Sanitary design is a given with a greenfield project, suggests Brian King, president of AM King Construction Co. (www.amkingconstruction.com), Charlotte, N.C., but “the conversation always begins with, ‘What can we automate?’” When costs are attached to each possibility, the improvement list shrinks in proportion to the bakery’s appetite for investment.

King’s firm was the contractor for Northeast Foods’ Clayton, N.C., bakery, which came on line two years ago. Like Fresh Start, Northeast supplies McDonald’s, which wants frozen buns delivered to distribution centers instead of fresh buns to stores.

Conveyors suspended from roof trusses to facilitate cleaning and isolated areas for ingredient handling were designed with sanitation in mind, but high throughput and minimal operator involvement were the key objectives. King points to the “lights out freezer” as an example. Pallets of finished goods move in and out “with the push of a button,” with inventory management software controlling an automatic storage and retrieval system that operates without human intervention.

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Awareness of the combustibility of dust was high when the Clayton plant was on the drawing board. Only two years had passed since the Imperial Sugar mill in Savannah, Ga., exploded, killing 16 and badly injuring scores of other workers. Like sugar, flour particles can easily meet the sub-420 micron threshold for ignition in a confined space.

While risk assessments of flour sifters and other vulnerable areas are ongoing at many bakeries, NFPA standards can leave plants vulnerable when transporting flour, maintains Nick Hayes, president of Volkmann Inc. (www.volkmannusa.com), Bristol, Pa. “The standard excludes confined areas of less than 8 cubic feet. ‘That’s not adequate,’ Hayes insists. ‘I don’t want to be standing next to a 65-gal. drum when it explodes.’ The manufacturer of vacuum conveyors is the first supplier in its category to receive ATEX certification from TUV, the German equivalent of UL.

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In recent years, a rash of product recalls has caused significant long-term damage to many brands. These recalls cover everything from serious health and safety risks to misrepresentation of a product’s performance or composition. The causes of these recalls stem from a wide variety of issues, including material tampering, improper labeling, inaccurate food-preparation instructions, cross-contamination, inadequate plant health and safety, false marketing claims, and inadequate shelf life.

Food safety and compliance keep many food company executives awake at night — and for good reason. According to the Recall Execution Effectiveness joint study by the Food Marketing Institute (FMI), the Grocery Manufacturers Association (GMA), GS1 US, and Deloitte, "the average cost of a recall participating food and consumer product companies is $10 million, in addition to brand damage and lost sales.”

Yet many companies are not willing to invest heavily in food safety and compliance, until they’ve had a problem. Food poisoning outbreaks are rare, for any given company; but when they occur, they harm the company for a long time. The study additionally reveals, "a company with poor recall execution processes could see declines of up to 22 percent [in their stock valuations] within two weeks after the recall announcement.”

PREVENTION IS BETTER THAN A CURE

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For instance, entire farm stocks were slaughtered — many unnecessarily — during the mad cow (bovine spongiform encephalopathy) disease scare in the UK in the mid-1990s, and again in the UK during the foot-and-mouth outbreak in 2001. In both instances, the UK also suffered from a dramatic drop in its meat export trade. Had better traceability been used to track the stock, many of the animals wouldn’t have had to be destroyed.

In an apparent case of life imitating legislation, in 2010 the largest egg recall in US history occurred just as the US Senate began considering the Food Safety Modernization Act (FSMA). This act, which was signed into law in January 2011, gives the US Food and Drug Administration (FDA) the power to enforce tough, new requirements that address food safety issues through preventative controls, inspection, compliance, ensuring imported food meets US standards, mandatory recall authority, and strengthening partnerships between food safety agencies.

Safety, however, is not the only reason for potential recalls. Consumers now demand more information on the composition, origin, and handling of the food they eat. While dietary restrictions (such as peanut allergies) can also be safety issues, other issues relate to more personal preferences (such as gluten free, zero trans fat, and genetically modified ingredients). The label and any claims it makes must match what is in the product. Failure to comply might not necessarily bring government action, but it can result in lawsuits and irreparable, bad publicity—all of which can make consumers wary.

The increase in recalls and the wide range of causes behind those recalls highlight the need for more than just internal improvements at process manufacturing companies. They also point out the need for manufacturers to be more vigilant about anything that could result in a product safety issue or recall.

With stricter food legislation being enacted around the world, the pressure to maintain food safety and compliance effectiveness must match what is in the product. Failure to comply might not necessarily bring government action, but it can result in lawsuits and irreparable, bad publicity—all of which can make consumers wary.

Food Safety and Compliance
Invest in food safety systems before you have a $10 million problem.

By Infor...

Food Safety and Labeling Laws

Recently Passed Food Safety and Labeling Laws

United States Food Safety Modernization Act (FSMA)
Canada Amendments to the Food Allergen Labelling Regulations
South Africa R446

FIVE PROCESSES THAT IMPACT RECALL READINESS

To be prepared for a recall, you need to have a framework in place that is built around these five processes.

Furthermore, the FDA breaks out recalls into the following classifications:

- Class I recall: A case in which there is a reasonable probability that the use will cause serious adverse health consequences or death. An example would be E. coli contamination of meat.
- Class II recall: A situation in which the consumption of a product may cause temporary adverse health consequences or where the probability of serious health consequences is highly unlikely. One example might be an undeclared food dye that is known to cause mild allergic reaction in some individuals.
- Class III recall: A case where there is an error, but consumption of a product is not likely to cause adverse health consequences. An example would be an underweight product.

Regardless of which classification a recall is designated, there are well-defined processes for dealing with it that include prevention, identification, notification, removal, and replenishment. If you're unable to prevent a recall, the first and most critical step is to identify the affected products. You next need to notify everyone who's affected; make sure the affected products are removed from the shelves; and then get replacement products onto the shelves as soon as possible.

After prevention, timely, factual identification of affected products is the most critical of these processes. The faster you can identify and isolate contaminants, the less potential for consumer harm you face, and the lower the possible costs to your supply chain stakeholders. This challenge is made even more acute in today’s fast-paced and efficient supply chains, which can see ingredients distributed across multiple products, retail channels, and countries in a matter of hours.

Risk management is only part of the equation. You need to take a proactive approach as well. Detailed documentation of all your products’ ingredients and processes is the foundation of public trust. When you can show your customers online exactly what went into the product they are buying, or give an auditor direct access to your system to review your quality controls, you powerfully enhance customer trust and your reputation.

In addition, to differentiate yourself and to break out of the commodity pricing game, you may decide to follow the path that many manufacturers and food processors have taken—adding value through what the US Department of Agriculture (USDA) refers to as “credence attributes,” such as organic certification, kosher processing, and the labeling of “dolphin-safe tuna” and “fair trade coffee.” Credence attributes derive their premium value from the credence—the trust—that they invoke. They are content or process characteristics whose existence or absence can only be established by documentation. Consumers cannot taste the difference between oil made from genetically modified and non-genetically modified (GMO) corn. That’s why you have to be able to prove it.

Building a technology framework for improved recall effectiveness

To ensure that your organization is effectively prepared for a recall, you need to assemble a framework around the five key processes:

1. Prevention. The idiom, “an ounce of prevention is worth a pound of cure,” is one that food manufacturers and distributors should heed. Implementing ample preventive measures can go a long way toward avoiding many contaminants, such as:
   - Agrochemicals
   - Allergens
   - Carcinogens
   - Environmental contaminants
   - Plant contamination
   - Parasites
   - Pathogens
   - Pesticides
   - Processing contaminants

   Contaminants can come from many sources, including:
   - High humidity
   - Improper pH
   - Labeling errors
   - Manufacturing errors
   - Plant safety problems
   - Tampering
   - Temperature fluctuations
   - Unapproved ingredients

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FDA Painted Into a Corner

A federal judge orders the agency to issue overdue food safety rules by Nov. 30 ... which looks unrealistic.

By Eric Lindstrom, Keller and Heckman LLP, for Food Processing

O n June 21, a federal judge in California imposed concrete deadlines for the U.S. FDA to publish and finalize all remaining overdue rules to implement provisions of the FDA Food Safety Modernization Act (FSMA).

As background, FSMA was signed into law by President Obama on Jan. 4, 2011. FSMA granted FDA new authority, including a mandate to require science-based preventive controls throughout the food supply chain and enhanced authority regarding inspection, compliance, outbreak response and recalls.

FSMA set specific deadlines for FDA to publish proposed rules or guidance to implement certain provisions of the law, but FDA has failed to meet several of these deadlines. In August 2012, two consumer interest groups – the Center for Food Safety (CFS) and the Center for Environmental Health (CEH) – sued FDA in U.S. District Court for the Northern District of California to compel the agency to publish the overdue rules.

This April 22, the California court granted summary judgment to the consumer groups, stating that FDA had violated FSMA by failing to issue the required regulations in accordance with the deadlines in the law mandated by Congress. Initially, rather than imposing deadlines on FDA, the court ordered FDA to work with CFS and CEH to develop a mutually agreeable proposal setting forth deadlines for FDA’s issuance of the overdue rules. But FDA and the consumer groups could not reach agreement on an acceptable timeline. Consequently, the parties submitted separate, competing proposals to the court.

The plaintiffs’ proposal set May 1, 2014 as the deadline for all final regulations to be issued, with certain limited exceptions. The court found FDA’s proposal to be “inadequate,” as the court requested the agency to submit proposed deadlines that would form the basis for an injunction.

After balancing the parties’ competing concerns and proposals, the court concluded that a compromise deadline roughly in the middle of the two proposals was the correct course. Consequently, the court ordered FDA to publish in the Federal Register by Nov. 30, 2013, all proposed regulations that have not yet been published. For each rule, the public comment period must end by March 31, 2014, and FDA must publish all final regulations no later than June 30, 2015.

FDA now faces the task of publishing proposed rules, by the court-ordered deadlines, to implement the following provisions of FSMA:

• The foreign supplier verification program (Section 301 of FSMA)
• Preventive controls for animal feed (Section 103 of FSMA)
• Protection against intentional adulteration (Section 106 of FSMA)
• Sanitary transportation of food (Section 111 of FSMA)
• Accreditation of third-party auditors (Section 307 of FSMA)

Of the proposed rules referenced above, the foreign supplier verification program rules are the longest overdue. Under FSMA, FDA was required to issue the foreign supplier verification program implementing rules by Jan. 5, 2012. Foreign food manufacturers and distributors are still waiting to learn exactly how the agency’s proposal will affect imports and trade.

Complying with the court order likely will prove challenging for FDA due to factors such as the complexity of the required rulemaking, the agency’s need to consider and respond to public input on rules, the agency’s limited resources and the requirement for the Office of Management and Budget to review drafts of significant regulatory actions.

In addition to the regulations that are the subject of the order, FDA still must finalize currently published proposed FSMA regulations on preventive controls for human food and standards for produce safety; further adding to FDA’s burden.

It remains to be seen whether the agency can meet its newly imposed deadlines and avoid being held in contempt of court.  

Food Safety Is Job One.

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The Continuing Evolution of Food Grade Lubricants

Exclusive use of H-1 lubricants consolidates your inventory and removes lubes as a potential hazard. By Jim Girard, Vice President and Chief Marketing Officer, Lubriplate Lubricants-Fiske Brothers Refining Co.

For many years, the U.S. Department of Agriculture's Food Safety and Inspection Service Division (USDA/FSIS) reviewed the formulations of maintenance and operating lubricants, including lubricants, for use in official meat and poultry establishments that operate under USDA inspection. This "Prior Approval Program" as it came to be known, was the industry standard for determining food-grade lubricants. The USDA/FSIS' List of Proprietary Substances and Nonfood Compounds was the only source for food-grade and nonfood-grade lubricant reference for food and beverage processors worldwide. It listed lubricants in categories labeled H-1, H-2, H-3 and P-1.

True food-grade, USDA H-3 authorized lubricants are compounds that are permitted for use on equipment in locations in which there is potential exposure of the lubricated part to food. These instances are referred to by the USDA/FSIS as incidental contact. USDA H-2 authorized lubricants, usually containing non-food-grade ingredients, may be used around food-processing plants on equipment in locations in which there is no possibility of the lubricant or lubricated part contacting edible products. The USDA H-3 category refers to water-soluble oils. The machined part has to be cleaned and free of the emulsion before re-use.

Finally, the USDA P-1 category refers to lubricants that are to be used in accordance with the conditions set forth in the USDA's letter of acceptance. These lubricants should not be used in a food or beverage processing plant. The USDA/FSIS made its determination about lubricants based on the various Food and Drug Administration (FDA) Codes in FDA Title 21 Code of Federal Regulations (CFR). There are five codes in FDA Title 21 that dictate approval for ingredients for use in lubricants that may have incidental contact with food. See exhibit A for an explanation of those FDA Title 21 Codes. The USDA/FSIS' Prior Approval Program for Proprietary Substances and Nonfood Compounds was very effective. It served as a "watchdog" for the lubricants industry and protected the consumer against harmful substances that had the potential to contaminate food and beverage products.

But, in February 1998, things changed! In an official announcement published in the Federal Register, the USDA/FSIS said it was eliminating the Prior Approval Program. It pointed to the evolution of Hazard Analysis and Critical Control Point (HACCP) programs in which biological, chemical and physical hazards had to be monitored by food and beverage processors and both FDA and USDA inspectors. Lubricants are a potential chemical hazard in HACCP programs. Also, it was estimated that between $150,000 and $187,000 in USDA administrative costs could be saved by eliminating the Prior Approval Program. There were no fees involved for manufacturers that submitted their products for potential USDA use.

Food-grade FDA ingredient-compliant lubricants are significant in HACCP programs because if the food or beverage processor uses only H-1 food-grade lubricants, then the lubricants are not considered as potential chemical hazards. In addition to HACCP compliance, one of the solutions suggested by the USDA/FSIS was for food-processing plants to seek "letters of guarantee" from their suppliers, which would certify that the lubricants being used were manufactured with FDA Title 21-approved ingredients.

The elimination of the Prior Approval Program left the international lubricants industry in a quandary. There was a defined requirement for food-grade lubricants in HACCP plans, for instance. Lubricant manufacturers knew that food-grade lubricants must be manufactured with FDA Title 21-approved ingredients in order to eliminate them as potential chemical hazards in HACCP programs. But, what organization could be the industry "watchdog" to ensure compliance?

Three organizations came forth with plans for food-grade lubricant authorization and monitoring. The National Sanitation Foundation (NSF) Underwriters Laboratory (UL) and a Joint Working Group from three lubricant industry professional associations: The National Lubricating Grease Institute (NLGI), The European Lubricating Grease Institute (ELGI) and the European Hygienic Equipment Design Group (EHEDG). The NSF, an internationally respected, non-profit consumer products monitoring organization, developed an authorization program that mirrors the USDA/FSIS program and is guided by Title 21 of the FDA's Code of Federal Regulations. NSF registration is a formal procedure in which it reviews the lubricant formulations and certifies that they are in compliance with the various FDA Title 21 regulations. Once products are registered, the lubricant manufacturer may use the "NSF-registered" logo in its promotional literature and trade advertising.

Also, a very important feature of the NSF's program is that formulations and products are continually monitored for efficacy. In the USDA/FSIS system, lubricant manufacturers were "on their honor" to re-submit products if there were formulation modifications. There are fees for NSF evaluation and registration so the burden is on the manufacturer to make sure that its products are formulated with FDA Title 21-approved ingredients. Product submissions cannot be whimsical because of the justifiable fees involved.

Lubricant consumers may gain easy access to the NSF's registered lubricants and chemicals list by logging on to its website www.nsf.org/usda/listings.asp. Like the USDA/FSIS designation, the NSF designates food-grade lubricants, i.e., those lubricants approved for incidental contact, at NSF/H-1 registered. Underwriters Laboratory has not been as aggressive in defining its lubricants and chemicals authorization program although it has organized several informational meetings to which lubricant and chemical manufacturers were invited.

The NLGI/ELGI/EHEDG Joint Food Grade Lubricants Working Group has been very active in drafting an authorization program for food-grade lubricants. Like the NSF, the Working Group's program mirrors the former USDA/FSIS authorization program, and the ingredients used to manufacture food-grade lubricants must be FDA Title 21 approved compounds. The Group's plan is to obtain a German government-sanctioned DIN standard and then use the DIN standard as a base for an ISO (International Standards Organization) standard. The Group also acknowledges the importance of HACCP programs which call for the use of FDA ingredient-compliant H-1 food-grade lubricants.

Equally important as industry monitoring are the continual technological developments in the formulations of H-1/food-grade lubricants which must provide lubrication protection for food and beverage-processing machinery worth hundreds of thousands of dollars. Both petroleum-based and synthetic lubricants are available to effectively do the job.

Petroleum-based H-1/food-grade lubricants are developed with either technical white mineral or USP-type white mineral oil. USP mineral oils are the purest of all white mineral oils, and are the most oxidation stable, providing optimum lubrication against all other white mineral oils. FDA-compliant ingredients are added to the formulations to increase anti-wear capabilities, improve oxidation resistance and prevent rust and corrosion.

Synthetic H-3/food-grade lubricants available are primarily polyalphaolefin (PAO)-based fluids. They provide significant oxidation resistance versus petroleum-based H-1/food-grade oils. They also provide significantly better cold temperature operating capability. In combination with food-grade additives, PAO-based food-grade H-1 fluids are outstanding lubricants for air compressors, oil recirculating systems, hydraulic systems and gear reducers. Their initial high cost is more than justified by their long-range performance. Fluids that are 100 percent PAOs significantly outperform the PAO plus polymeric semi-synthetic fluids.

Polyalkylene glycol-based H-1/food-grade synthetic fluids are becoming very popular for applications where temperatures exceed 400°F/204° C up to 600°F/316° C. Bearings, chains and gear reducers subjected to these temperatures are candidates for polyalkylene glycol H-1 fluids.

H-1 food-grade greases may be either petroleum-based or synthetic. Aluminum complex is the most common thickener for today's food-grade greases, and produces a very sheer stable product. Aluminum complex-thickened greases also can withstand elevated temperatures. They are also very water resistant, which is vital for food and beverage-processing equipment because of post-shift equipment wash downs.

Recent developments with calcium sulphonate thickeners in combination with titanium dioxide for anti-wear protection and synthetic PAO-based fluids have expanded the capabilities of H-1/food-grade greases.

The most important aspect in the evolution of food-grade lubricant technology is that H-1/food-grade lubricants can now effectively handle every machinery lubrication application at a food and beverage-processing plant. This produces lubricant inventory consolidation, is good for the food and beverage-processing plant employees, and—most important—gives added protection to the ultimate consumer.
Food Safety Plans

There are new requirements for registered facilities.

By Leavitt Partners for Plex Online

The passage of the Food Safety Modernization Act in January 2011 will result in significant changes for FDA-regulated food manufacturers and processors. The cornerstone of the new law is a much greater focus on the need for preventive controls. Historically, the FDA has required control programs for seafood, juice and low acid canned foods. The new law will extend these types of requirements to all other types of FDA regulated foods.

By beginning to think about and plan for the new requirements now, industry will be able to maintain continuous compliance and ensure minimal disruption as new regulations come into effect. The requirements are that registered facilities develop and maintain a written food safety plan that includes a hazard analysis, identification, verification, and monitoring of preventive controls, and maintaining records to demonstrate compliance with the requirement.

Registered food facilities (with a few exceptions) will be required to develop a food safety plan that documents the facility’s:

* Prerequisite programs are in place to ensure food is produced in a safe and sanitary manner;
* Hazard analysis that identifies all potential risks throughout processing;
* Preventive controls that are implemented to mitigate risks;
* Monitoring of preventive controls to ensure they are properly implemented;
* Verification that the preventive controls have the intended reduction in risk; and
* Re-analysis of the hazards and preventive controls when there are significant changes in the process or every three years.

How FDA implements the new requirements in the law will have a significant impact on shifting the focus from reacting to foodborne illness to preventing illness from occurring in the first place. As FDA Commissioner Margaret Hamburg explains, “This law represents a sea [of] change for food safety in America, bringing a new focus on prevention, and I expect that in the coming years to have a dramatic and positive effect on the safety of the food supply.”

Part of the preventive controls provision will require registered facilities to develop and maintain a written food safety plan. Registered facilities include foreign or domestic facilities that manufacture, process, pack or hold food for consumption in the United States. FDA is required to establish the standards for conducting a hazard analysis and documenting preventive controls by July 2012. Likely, large facilities will be required to be in compliance first, followed by small facilities. Under the new law, FDA will have access to food safety plans, including related records, upon request.

Mike Taylor, FDA Deputy Commissioner for Foods pointed out in a speech on preventive approaches, “Food industry experts developed a system known as HACCP to build prevention into the processing of the food. HACCP is very much in line with good public health practice ... In food facilities, such as processing and packing plants, we will be proposing rules that are grounded in widely embraced principles of preventive process controls for food safety, similar to HACCP.”

This paper will outline who will be required to comply with the preventive controls regulation and the components and documentation that will likely be required as part of the food safety plan.

The Food Safety Modernization Act requires that all registered food facilities comply with the new preventive controls regulation, with a few exceptions. The law requires FDA to amend the definition of “retail food facilities,” which are exempt from registering under the 2002 Bioterrorism Act, to clarify that

<table>
<thead>
<tr>
<th>Farm</th>
<th>Foreign Manufacturer/ Processor</th>
<th>Domestic Manufacturer/ Processor</th>
<th>Retailer</th>
<th>Restaurant</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes*</td>
<td>Yes*</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

*Some manufacturers/processors may be exempt based on size and percent of sales that are direct to consumer.
direct sales to consumers includes “sales that occur other than where the food was manufactured, such as at a roadside stand or farmers’ market.” This ensures that roadside facilities and farmers markets are defined as retail food facilities and thus exempt from the preventive controls provision and the food safety plan requirement.

The law includes an exemption for “qualified” facilities and farms from having to meet the new preventive controls and food safety plan requirements. To qualify for an exemption from the preventive controls provision, a facility or farm must either be 1) defined as a “very small business” – a definition that FDA is required to define as part of the preventive controls rulemaking, or 2) in a category of sales where the average annual monetary value of the food manufactured, processed, packed or held at the facility over the last three years is less than $500,000 AND the value of food that is sold directly to consumers, restaurants or retail facilities that are within the same state as the facility or within 275 miles of the facility must exceed the value of food manufactured, processed, packed or held by the facility that is sold to all other purchasers.

While qualified facilities are not subject to the new preventive controls requirements, they will be required to submit to FDA documentation that demonstrates that they have identified hazards, implemented preventive controls and are monitoring to ensure the controls are effective or document that the facility is in compliance with State, local, county, or other non-Federal food safety laws and any additional documentation required by FDA. In addition, FDA may provide exemptions for certain facilities that are engaged only in production of food for animals other than man, storage of raw agricultural products (other than fruits and vegetables) intended for further distribution or processing or planting of food that is sold directly to consumers, restaurants or retail facilities that are within the same state as the facility or within 275 miles of the facility must exceed the value of food manufactured, processed, packed or held by the facility that is sold to all other purchasers.

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**Food safety plan components**

Likely, a food safety plan will involve a significant amount of documentation, including monitoring procedures and corrective actions, for the following components.

1. **Facility Information**: Facilities will need to document a description of the food, the methods of distribution and storage, the intended use and the intended customer for all products produced. Facilities will need to develop a process flow diagram that provides a simple description of the steps involved in processing each product.

2. **Prerequisite programs**: Facilities will be required to implement prerequisite programs. Each program will required to have a written plan, established monitoring procedures, established corrective action procedures, and an established recordkeeping system. Specific programs that will likely be required include:

   - Personnel: Establish written documents to outline personnel practices, including health and hygiene requirements.
   - Plant and grounds: Ensure all areas of the plant are clean and sanitary.
   - Sanitary operations (SSOPs): Establish a set of operating procedures to maintain a sanitary environment for the production of food.
   - Equipment: Ensure equipment is calibrated and functioning properly to mitigate food safety risks.
   - Production and process controls: Eliminate food safety risks by maintaining control of processes during production that control food safety risks.
   - Warehousing and distribution: Ensure procedures are in place to ensure sanitary warehousing and distribution of food products.
   - Allergen controls: Reduce the possibility of cross-contamination between major allergens (peanuts, tree nuts, milk, eggs, wheat, soybean, fish and shellfish) and non-allergen products.
   - Environmental monitoring: Control contamination in the processing environment to eliminate food safety risks from environmental contamination.
   - Product recalls: Ensure the ability to quickly locate and remove recalled product from the market.
   - Supplier control: Maintain control over food and ingredients by ensuring suppliers are taking appropriate controls to prevent food safety risks.
   - Product tracking: Ensure the ability to quickly identify both ingredients and finished products, both upstream and downstream, in the event of a public health threat or recall.
   - Consumer complaint system: Ensure consumer complaints are captured, analyzed, and appropriately addressed.

The flow diagram should cover all steps in the process, including receiving and storage of each ingredient.

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