Recalling the Recalls of 2010

While no one industry is guiltier than another for recalling product, the food and pharmaceutical industries are not only the most notorious and memorable, but also the most wide-ranging and criticized. This year, as a matter of fact, the list ranges from shell eggs to pet feed to baby formula to black pepper to spinach to ice cream to Lipitor to Tylenol … and that’s not the half of it.

According to the World Health Organization, an estimated 76 million illnesses and 5,000 deaths occur annually in the United States as a result of food-borne illness, and these amounts continue to escalate, along with pharmaceutical-related recalls. One would think because these industries are becoming increasingly modernized with automation and sanitary technology that the problem of recalls would be waning. This is not the case … So let’s go through a couple of product categories that were hit especially hard this year by the dissemination of the news that product was contaminated, and unearth some ways in which these food and pharma snafus could have been prevented.

Food Contamination: The Wrongs of Wright County, SanGar & More

By Carrie Ellis, Editor

The connection between the two farms is that Wright County Egg supplied chickens and feed to Hillandale Farms, though samples of salmonella were found in the environment at both locations. Hillandale recalled approximately 170 million eggs, whereas Wright County recalled 380 million. After as many as 1,500 cases of salmonella poisoning reported, neither of the companies was permitted to sell shell eggs, unless they were sent to breaker facilities where the eggs could be

pasteurized to kill any present salmonella.
As reported on KTLA.com, Food and Drug Administration (FDA) inspectors attributed the salmonella to:

- Live rodents and mice in laying houses at both farms.
- Structural damage and holes in many locations at both farms, allowing wildlife access.
- Escaped chickens tracking manure through the houses.
- Employees not changing clothing properly when moving from one location to another and not sanitizing equipment properly.
- “Live flies too numerous to count” on egg belts, in the feed and on the eggs themselves at Wright County Egg.
- Dead and live maggots “too numerous to count” on the manure pit floor in one location at Wright County Egg.
- Manure piled 4 to 8 feet high in five locations at Wright County Egg, leaning against and pushing open doors that allowed wildlife to enter the laying houses.
- Non-chicken feathers in a laying house, and wild birds flying in and out of two facilities at Wright County Egg.
- Manure seeping through the foundation to the outside of the laying houses in 13 locations at Wright County Egg.
- Rusted holes in feed bins and birds flying over feed bins at Wright County Egg.

The last the public heard, the FDA had vindicated Hillandale on October 15 to the point that it could again ship product, but the jury may still be out on Wright County, with the FDA threatening that the company take action, or prepare its eggs to be seized or the company shut down. In contrast, Hillandale not only cleaned up its act, but also promised to execute more frequent testing for salmonella.

Keeping in mind that salmonella often originates from feces and/or contaminated water, it is easy to note how these egg farms landed themselves in hot water, bringing public sentiment to a boil over food safety. Therefore, there were many paths that these farms could have traveled in order to prevent the salmonella outbreak:

- Pasteurization, which is essentially the process of heating food to a specific temperature for a predetermined amount of time—enough to decelerate microbial growth, while additionally reducing the amount of bacteria and other microorganisms—then allowing it to cool down.
- Salmonella and/or microbiological testing, which can include drag or boot swabs (swabbing a building with material that can be thus tested), as well as egg and fecal sampling.
- Third-party auditing. Although Wright County had a third-party auditor (AIB Intl., which also audited Peanut Corp. of America, the company responsible for sickening hundreds and killing nine with salmonella-contaminated peanuts), the company should have researched its audit provider better,

making sure that its experience was to be trusted, its certifications approved and its auditing unbiased.
- Regular facility maintenance and cleaning. Many of the unsanitary conditions on both farms could have been easily avoided with a regular maintenance plan, especially concerning structural grievances, which helped lead to wildlife access to the laying houses, multiple piles of manure and general uncleanliness.
- Good manufacturing practices, discussed further in the sidebar.
- Lessening Listeria, E. Coli & Other Bacteria.

In October, a food cutting and processing unit by the name of SanGar Produce & Processing Co. continually asserted that state health authorities incorrectly traced listeria to its San Antonio, TX facility. Furthermore, the company accused a state health inspector of potentially contaminating the plant as a result of inappropriate attire, as well as touching surfaces.

Despite the allegations from SanGar, according to the Associated Press (AP), “The state health department traced six of ten known cases of listeriosis during an eight-month period to celery processed at the SanGar plant. The agency shut down the plant and ordered the company to recall all the products that has passed through the plant since January.” The facility also handles lettuce, pineapple and honeydew.

Upon further investigation, inspectors revealed that there were certain sanitation problems at the plant, such as condensation leaking over a food production area. On November 5, it was confirmed. Listeria was discovered in several areas. The FDA cited multiple violations, per an AP article, including failure to:

- Take necessary precautions to protect against contamination of food and food contact surfaces.
- Store raw materials in a way that protects against contamination.
- Take apart equipment as necessary to ensure thorough cleaning.
- Take effective measures to protect finished food from contamination by raw materials and refuse.
- Keep foods that can support rapid growth of microorganisms at a temperature that prevents food from becoming adulterated.
- Provide adequate screening or other protection against pests.

Official & Unofficial Good Manufacturing Practices to Remember

There are so many cons to conducting a recall—brand

reputation, fines, decontamination, attributable sicknesses and possible deaths, stock depreciation and so on—that it behooves any company to do its best to avoid them. Remembering general good manufacturing practices is one good way to do that. Information on current good manufacturing practices (cGMPs) can be found on the FDA's website at www.fda.gov [1]. Below are a number of additional steps manufacturers can take to help mitigate the problems behind most recalls:

- Thoroughly examine and hold accountable your supply chain to minimize risk.
- Comply with all aspects of the FDA's Hazard Analysis and Critical Control Point

	(HACCP) program. • Diligently keep records of all goings-on at your facility. Enterprise resource planning, for example, is popular because it inherently grants certain food and pharmaceutical industry requirements, such as shipment and ingredient traceability, and inventory and location control. • Standardize auditing and testing criteria across all processes, plus select a lab with validated methods and ISO 17025 accreditation. Establish a quality control head and/or	

	working group that know best practices related to not only sampling, but also pathogen management and HACCP. • Create an environment in which a healthy workforce, healthy animals (if applicable), sanitary conditions, process controls, safe handling procedures, training resources, water quality and refrigeration control are encouraged. • Implement enough monitoring processes to keep an overall better eye on production quality.	

Food Irradiation & Anti-Bacterial Wash

Again, the SanGar anecdote reeks of obvious environmental misdeeds. However, one key way to protect food that hasn't been aforementioned is food irradiation, a procedure that exposes food to ionizing radiation, thereby killing microorganisms, viruses, bacteria and insects, and slowing spoilage. Although food irradiation is effective due to its ability to damage microorganisms' DNA, it's also the very reason some manufacturers worry about what effects it may have on product.

As a matter of fact, just more than 40 countries currently allow food-irradiated products into their markets. Many consumers argue that the safety of food irradiation hasn't yet been proven, or that it may encourage unsanitary processing

practices. However, all companies using this technology are subject to the same regulations as non-users, and the United Nations is pushing for global implementation.

Nonetheless, while food-irradiated microorganisms may die or become infertile, it doesn't imply that all problems are completely resolved. For example, Abbott was forced to recall several lots of Similac due to beetles and their larvae contaminating product. Had food irradiation been used, it may have killed many of the bugs involved, but their carcasses would still prompt an immediate recall. Similarly, while food irradiation aids in slowing spoilage, it cannot undo what has already been done. Thus, its benefits are somewhat limited.

In an even newer development, Chiquita Brands Intl. has unveiled a new wash to be used to kill bacteria like listeria, E. coli and salmonella on its bagged salads—namely its Fresh Express brand. Currently, the industry standard is rinsing with a chlorine wash; the new rinse, which contains no chlorine, is called FreshRinse.

According to the AP, "CEO Fernando Aguirre says the rinse dramatically improves food safety. Chiquita plans to share the rinse with its competitors. It will launch a campaign early next year to promote the rinse." FreshRinse has the ability to kill bacteria not only on the greens themselves, but also in the wash water. Chiquita says that it will begin to implement its new rinse by the end of this year or early next year.

TBA: Stinking Out the Supply Chain

By Luke Simpson, Associate Editor

Click to enlarge the recall timeline for Pfizer and Johnson & Johnson.

The pharmaceutical industry has a new enemy. TBA, formally known as 2,4,6 tribromoanisole, has infiltrated the supply chain, contaminated tens of millions of dollars worth of product, and caused irreversible damage to the reputation of drugmakers and their well-known brands. Johnson & Johnson and Pfizer have issued

nine TBA-related recalls since the problem first surfaced in December of last year. The issue in each case related to a musky or moldy odor coming from the packaging and/or the product itself. Some reports of nausea, vomiting and other related symptoms were also indicated.

TBA is formed when a chemical change occurs in 2,4,6 tribromophenol (TBP), a chemical used in wood preservatives, paint, insulating materials and other items. Its anti-fungal qualities have made it a popular treatment for wooden pallets in humid areas of South America. While TBP is illegal in the U.S., the trace amounts required to cause TBA contamination have found their way into the facilities used by Pfizer and Johnson & Johnson. It is also a common problem in the wine industry, where TBA causes a moldy smell or taste known as “cork taint.”

With the potential for this problem to expand into other facilities and industries, the FDA, and the pallet and packaging industry have responded with solutions and best practices aimed at mitigating the risk of further TBA outbreaks.

The Pallet Is Key

Stuck in the middle of the TBA problem is Bruce Scholnick, president of the National Wooden Pallet & Container Association. Scholnick hopes that new guidelines will help ensure that wooden pallets are free from contamination.

“We are developing a best-handling practice, which we hope will satisfy the pharmaceutical and food industries, as well as the FDA. The guidelines will have several components. First are the requirements for a new pallet manufacturer, in terms of sourcing wood material. If the wood is imported from South America, they will probably need to get certification from the supplier that says TBP is not being used anywhere around it,” states Scholnick.

“The second and biggest part is for the food and pharmaceutical environments. These manufacturers will need to ensure that they store their wooden pallets properly and that they utilize them properly. This includes keeping them inside and away from chemicals.
“Thirdly, when the pallet is returned to a recycler, pallets used for pharmaceutical and food products will need to be separated from pallets used in chemical or other industries. This will be the hardest part to track,” predicts Scholnick.

In the meantime, new wooden pallet providers should be able to provide certification that the wood used to produce their pallets is native or that chemicals haven’t been used on the pallet.

Pfizer has responded to the TBA recalls with a number of new requirements, including the use of plastic pallets for the transport of empty bottles. While the plastic pallet industry is capitalizing on the woes of its wooden counterparts, there is a third, lesser-known option for pallet material.

Pregis Hexacomb produces a pallet made from FDA-approved paper that acts almost exactly like a normal pallet. It can hold up to 8,000 pounds, and is designed

specifically for pharmaceutical and food shipping applications.

“The pallet is clean—there are no chemicals and no treatments. It won’t impart any flavors, odors or taste to the product,” according to Pregis Hexacomb President Jeff Kellar.

Never Too Proactive

After the first reports of musky-smelling Tylenol products surfaced at the end of 2009, Pfizer reported that it was enhancing its monitoring of odor complaints, particularly those that referred to a musty smell. Soon after, the company detected an odor in unused bottles shipped from its Puerto Rico bottle manufacturer.

Pfizer and the bottle manufacturer launched an investigation into the contamination and attempted to minimize the conditions that cause TBA to form by increasing the ventilation at the Puerto Rico warehouse. It was not enough, and within a few months, Pfizer issued the first recall of its blockbuster cholesterol treatment Lipitor.

Further analysis at the bottle manufacturer revealed that TBA and TPB were in the air, insulation, paint and packaging materials, and in wooden pallets from a supplier that had stipulated the wood was not TBP treated. While Pfizer continues to work with its suppliers to reduce the possibility of TBA contamination, the events surrounding the Lipitor recalls serve as a reminder that you can never be too proactive in your quality control procedures and risk management planning.

For more information on recalls and recall prevention strategies, please visit www.fda.gov/Safety/Recalls/ [2].

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