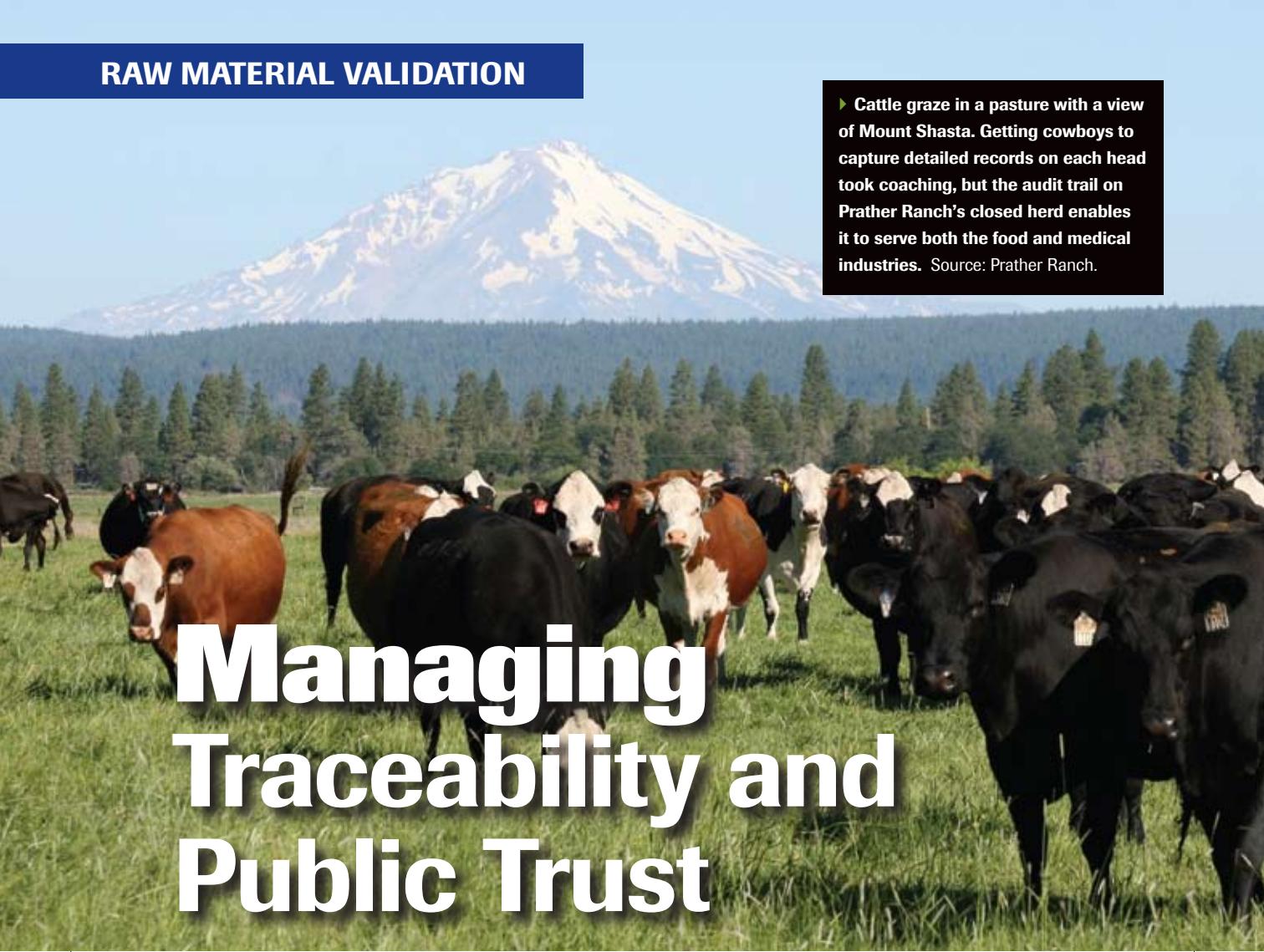


► Cattle graze in a pasture with a view of Mount Shasta. Getting cowboys to capture detailed records on each head took coaching, but the audit trail on Prather Ranch's closed herd enables it to serve both the food and medical industries. Source: Prather Ranch.



Managing Traceability and Public Trust

Validating the source and condition of raw materials is critical in maintaining public confidence in prepared foods. Based on recent events, the requirement is not being met.

► **Kevin T. Higgins**, *Senior Editor*

Mary and Jim Rickert are suppliers to both the medical industry and hungry carnivores, but what they really sell is quality assurance.

The Rickerts are managing partners of Prather Ranch, a sprawling 34,000-acre spread in California's Cascade Range. The ranch's herd of 1,500 mother cows is unremarkable in terms of numbers, and the dedicated slaughterhouse is picayune by industry standards. The USDA-inspected processing area operates only on Tuesday mornings, with fewer than 20 head handled.

Despite its modest size, Prather Ranch is an industry model in many ways. It began addressing BSE in cattle in 1990 and achieved ISO certification long before mad cow disease was part of the public dialogue. The ranch has a closed herd, with bull semen, organic rice and packaging the only feed and materials entering from the outside world. Organic and humane-handling certifications have been achieved. The most remarkable quality assurance, however, is the detailed record of each animal's genealogy, feed source and medical records. A HACCP card documenting the information is attached to each carcass on the kill floor.

► **The ID number on a ribeye steak can be traced back to complete documentation on the source animal, including vaccination history, birth date and genealogy, and live weight at various points.** Source: Prather Ranch.

Connoisseurs of dry-aged organic and natural beef are only part of Prather's customer mix. An even more demanding audience is medical and pharmaceutical buyers. The collagen in hides is harvested for cosmetic surgery. Pituitary glands, pericardium membranes and certain bone and tissue are extracted and sold to pharmaceutical companies who demand much more than an ear-tag number when validating raw-material sources.

Records are maintained in a database program called Cattle Pro, which was expanded and enhanced to document the fields where hay comes from, the results of irrigation-water testing, the methods and validation of every procedure in processing—enough



information, in fact, to keep three data-entry clerks busy. “I don’t know if it’s gotten any easier,” Mary Rickert says of the record-keeping. “We’ve gotten better at it, though.” The information is available on demand and, while the people who pay up to \$25 a pound for prime rib and other Prather cuts are unlikely to ask for them, their existence is a quality assurance measure that complements the flavor and tenderness of the meat.

Norway is magnitudes larger than Prather Ranch, but its largest meat processor, Nortura, which processes 200,000 tons of product per year, enjoys some of the same closed-loop advantages. Once on the retail shelf, a 2D code on the label can be photographed by a camera phone and, within seconds, the shopper receives a text message detailing the farm where the animal was raised, its slaughter weight and its medical and feed history.

DIY chemical analysis

Food pathogens and allergens aren’t the only threats to human health: chemicals and toxic metals accidentally or deliberately introduced can sicken or kill tens of thousands. Two of the biggest international scandals since 2007 involved melamine. In both cases, melamine was deliberately added to fool conventional tests of protein levels.

Pet food containing wheat gluten from China was the subject of a massive recall in April 2007. The chemical combined with cyanuric acid to form melamine cyanurate, an excellent fire retardant, but the cause of acute renal failure in many pets that ate it. The incident prompted instrumentation maker PerkinElmer Inc. to partner with Flora Research Laboratories to develop a protocol and methodology for using the Waltham, MA, firm’s gas chromatography/mass spectrometer to detect melamine levels down to 50 parts per billion (ppb), well below the 1,000 ppb deemed safe by FDA for infant formula.

Last September, Chinese dairy processor Sanlu began recalling infant formula laced with melamine that was blamed for the deaths of six infants and almost 300,000 illnesses.

Demand for PerkinElmer’s EcoAnalytix melamine analyzer increased in November when FDA began requiring testing of

Chinese imports containing milk-derived ingredients. Some legislators urged FDA to extend import testing to include eggs and fish products from China, America’s third largest food importer.

“Supply chains have become very global,” notes Alessandra Rasmussen, a PerkinElmer vice president who headed development of the system. More than 13 countries recalled baked goods, frozen desserts and other products containing Chinese milk powder with melamine last year. “People want access to more food variety, and that magnifies the issues of validation,” she says.

A technician proficient in mass spectrometry could forego PerkinElmer’s turnkey solution, though “the mass spec method and protocols as written by the FDA can be overwhelming,” observes Jim Kababick, owner of Grants Pass, OR-based Flora Research, an analytical lab registered with both FDA and the Drug Enforcement Administration. The complexity of sample preparation and standard operating procedures can be overwhelming, making guidance for in-house analysis essential.

Kababick is sanguine about EcoAnalytix cannibalizing some of his business. “There are so many people that have these problems, there’s no shortage of clients at all,” he says.

► GC/MS instruments are bundled with a PSS injector and liquid autosampler, along with supporting software, in the EcoAnalytix system (inset), giving mass spectrometer technicians the ability to analyze food and beverage ingredients for trace metals and chemical contaminants.

Source: PerkinElmer Inc.

Owning the supply chain, from the herds to the individual cuts, makes the information delivery possible, acknowledges Ashleigh Stephenson, co-founder and chairman of Reva Systems, which supplies the RFID technology that makes Nortura's data collection system possible. The implementation underscores the importance of manufacturer-driven RFID initiatives: if Nortura had been responding to a retail mandate rather than seizing the chance to optimize the value chain and improve traceability, the project likely would not have succeeded, he believes.

"Norwegian consumers are quite particular about food quality, safety and the source of the food," Stephenson says. "Food producers are realizing there is a real benefit in terms of consumer perceptions of their products and their own efficiency in having a comprehensive traceability program in place. Neither retailer mandates nor pure regulation is going to motivate adoption of an RFID-based information system."

Contrast the Prather and Nortura controls with the confidence-shattering recall



in January and February of peanut butter ingredients and finished products from Peanut Corporation of America's (PCA) Blakely, GA, plant. As the extent of the crisis slowly expanded and the number of recalled products steadily mounted, one of the few track-and-trace success stories was the advisory issued to buyers of affected products at Costco. The club store generated millions of automated calls and letters to members who had purchased recalled products. Wegmans and Price Chopper supermarkets also leveraged their frequent-shopper databases to alert customers.

Standards vs. practices

Regulation 178/2002 is the European Union's equivalent of the track-and-trace requirements of the US Bioterrorism Act of

2002, which the FDA originally construed to require one-up, one-down traceability records that could be produced in a few hours. As the PCA recall entered its third week, it was painfully evident that standard had not been met.

The salmonella-related recall is arguably the worst domestic food recall of the 21st Century. Eight deaths and more than 500 illnesses were linked to the plant. Unlike the meat and vegetable public-health crises of the recent past, it involved a highly processed product. It also dramatized the industry's complex web. One producer's finished goods can weave through many channels to serve as a raw material for hundreds of other manufacturers.

While US and EU traceability standards are similar, US executions often suffer from a failure to designate a single responsible person. "When a problem occurs, QA, processing and maintenance all say they did their part, but when you stitch all those parts together, you see that everything wasn't done properly," suggests Vicki Griffith, global marketing director, food & beverage, for St. Paul, MN-based Lawson Software. Organizations assume data on raw materials, process steps, sanitation



► Packaged goods are conveyed past an RFID reader at a Nortura meat plant in Norway. An extensive reader infrastructure collects the data needed to drive product-specific information all the way to the retail shelf. Source: Reva Systems.

► **HACCP tags attached to carcasses at Prather Ranch's abattoir provide a process validation method. To avoid dislodging brain and nerve tissue, carcasses are not split into sides of beef.** Source: Prather Ranch.

procedures, etc. reside in ERP or another centralized system, but that almost is never the case. Typically, information is squirreled in unconnected databases, resulting in slow responses and lack of accountability. Traceability is “a company issue, not a departmental issue,” Griffith points out, yet that’s not how it is approached.

The hard-dollar cost of poor supply-chain tracking was quantified in an AMR Research study commissioned by Lawson last year. Only 11% of 251 food and beverage companies surveyed in the US and three European countries made it through 2007 without at least one product recall. While most were satisfied with their mock-recall performances, execution during actual events was spotty: it took an average of 48 days to identify a problem, and less than 40% of affected product was actually collected. Most US product recalls cost the organization more than \$20 million. Using AMR’s math, the peanut recall—at 1,351 US and Canadian products as of February 4, plus additional products made in Mexico, New Zealand and Singapore—will cost businesses well over \$1 billion.

CDC Software’s David Cahn seconds Griffith’s point about fragmented data, adding the problem is most pronounced outside the four walls of the plant. “Once product is on the truck and leaves the dock, that’s where the system of records falls down,” maintains Cahn, vice president-product strategy at the Atlanta firm. If integrated data systems are not driving “better analytics and front-end visibility,” however, they become costly exercises, rather than “compliance as a value proposition.”

“It takes a calamity to draw attention to certification of raw materials as a critical need,” he adds. “But the overall issue isn’t peanut butter this week or lettuce next week: it’s milk from China.”



Human greed and indifference to public health was starkly displayed in China’s melamine-adulterated milk scandal last year. The chemical boosts protein readings in traditional nitrogen tests, and 22 Chinese dairies were found to be selling milk contaminated with melamine. The largest, Sanlu, knew of the problem by May but continued accepting and selling the milk until its New Zealand partner, Fonterra, became aware of the practice. Two death sentences and one life imprisonment were given to Sanlu executives, and hundreds of products containing Chinese milk worldwide were recalled.

Traceability systems alone wouldn’t have provided an early warning for melamine any more than they could have spotted salmonella in peanut butter. Chemical (or, with salmonella, biological) analysis is required, a costly procedure involving more expertise than is found in the typical food company lab. But pre-calibrated and formatted instrumentation is coming to market, and regulators are beginning to require importers to test for chemical adulterants (see related story on page 46).

Chemical and toxic-chemical poisoning from food is rarer than pathogen and allergen issues, though companies like Flora Research Laboratories are being retained for more food testing. Testing for pesticide residues in ginseng and tobacco is common, according to Jim Kababick, Flora’s owner. To help meet demand, his team designed a “solution package” with equipment supplier PerkinElmer to detect melamine. It can be programmed to detect other chemicals of concern. “If you’re going

to go back to a supplier and say, ‘There’s an adulterant in your product,’ you’re going to have to give them hard data to support it,” says Kababick.

“The bigger challenge is the unknown contaminant,” acknowledges PerkinElmer’s Alessandra Rasmussen, who developed the EcoAnalytix detection system in conjunction with Flora. “If a new danger is identified, the same technology can be used with a modified protocol, which is relatively easy to do.”

Mass spectrometers “are all over food labs in China,” adds Kababick, though having the tools and using them effectively are two different things. And a sampling program alone won’t provide the validation needed. A food safety information system is being deployed in China’s Henan Province, home to many of the country’s dairies and other food manufacturers. Helping to provide the traceability and regulatory-compliance recordkeeping is CDC’s Ross Enterprise and CDC Factory systems, which are deployed on a subscription as a service (SaaS) basis.

SaaS is also the delivery mechanism for Plex Systems Inc., an Auburn Hills, MI, supplier of on-demand manufacturing software. Coming from the automotive sector, the company branched into food recently with a deployment at Cuisine Solutions Inc., Alexandria, VA. Accessing Web-based programs eliminates issues of hardware maintenance, software updates and user licensing, notes Ron Zilkowski, Cuisine’s chief financial officer. Plex’s ERP package replaced a conventional system from JD Edwards.

Security concerns about SaaS give many IT professionals pause, acknowledges David Chidsey, a senior project manager at Plex who is involved in Cuisine's deployment. But the program is SAS 70 certified, an audited standard that is respected in IT circles, Chidsey says.

Raw materials arrive at Cuisine from hundreds of companies, "from mom and pops to international suppliers," according to Zilkowski. Slow cooked (up to 72 hours) and flash frozen after vacuum packaging, the center-plate items are sold through a variety of institutional accounts, including the US military. Traceability and pro-

cess validation is critical with the military, Zilkowski says, and their auditors like the fact the manufacturing system doesn't permit raw materials to move beyond a given step unless all protocols have been satisfied.

Some small-scale recalls of raw materials have occurred since Cuisine's plant opened in 2001, including a mushroom shipment suspected of containing glass. "Fortunately, that product was fairly traceable," says Zilkowski, and he's confident capabilities have been enhanced. "The military much prefers our track and trace capabilities now," he says.

Every food crisis draws new clients to validation solutions, though whether they view them as a cost of doing business or a way to improve operations depends on the organization. Dole Fresh turned to Reva Systems after the spinach recall of 2007, an event that cost the firm \$42 million. "You can buy a lot of RFID for that amount of money," Reva's Stephenson says.

Ideally, the investment returns more than recall assurance. When RFID tags incorporate temperature sensors, for example, a manufacturer knows instantly whether a delivery was subjected to temperature abuse. Freezing temperatures turn leafy greens black, and validating transport temperatures can mean the difference between accepting a bad shipment and turning it away at the receiving dock.

Detailed records are helping Prather Ranch make use of a genetic test for tenderness, a quality characteristic with obvious commercial value. An even stronger argument for validation systems is the ranch's understanding of the public trust it holds. ❖

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