

Adulterated ingredients present costly, persistent global threat to dietary supplement manufacturers

To eliminate the problem, NOW Foods asserted itself as the non-adulteration champion. The company mitigated risks for retailers and consumers by creating a reliable, inexpensive screening for the booming supplement market. Its secret? Innovative software and world-class instrumentation manufactured by PerkinElmer that verifies the purity and integrity of ingredients in dietary supplements.



Ensuring Quality. The growth in dietary supplements creates a global market worth more than \$20 billion. Testing keeps adulterated materials out of supplements, increasingly part of daily wellness routines.

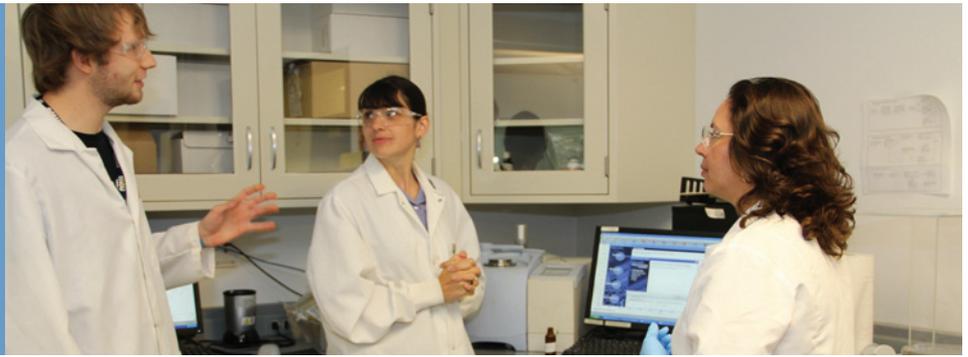
Challenge

Consumer reliance on dietary supplements as part of a daily wellness routine is escalating as the U.S. ages. People 60 and older will represent about 25 percent of the total population by 2030, up 9 percentage points since 2000. Baby Boomers want to stay young and are turning to vitamins, minerals and specialty formulations as their fountains of youth in a bottle.

A majority of U.S. adults take one or more dietary supplements every day, according to the National Institutes of Health. It's no wonder that the global nutraceutical ingredients market is worth an estimated \$20.8 billion and is forecasted to reach \$29.5 billion in the next five years. Body building, weight control and diabetes management are among the top segments.

But this bonanza has a dark side: Some global ingredient suppliers adulterate materials they sell to supplement manufacturers. Most common are "economic" low-cost fillers (added by suppliers as an illicit way to increase profit) and "enhancement" additives, or performance boosters that are sometimes added by unscrupulous manufacturers to deliver uncharacteristic performance results, often at a greater risk to consumer health. To complicate matters, new adulterants hit the supplement market as fluidly as fake Rolex® watches arrive on street corners in New York City.

“Everyone knew adulteration was a problem.”



NOW® Foods, based in Bloomingdale, Ill., wanted to attack the issue of adulterated food with unparalleled vigor. The company, which has built a reputation for producing high-quality nutrition supplements for health-conscious customers since 1962, needed to mitigate risk for the retailers who sell their products and the consumers who trust the brand.

“For our industry, it seemed that the mindset was that everyone knew adulteration was a problem, but the hope was that it would just never happen to them,” said Katrina Emmel, an analytical scientist at NOW® Foods. “But we wanted to take a leadership role on this issue. We wanted to know for a fact that this wouldn’t happen to us.”

Adulterated foods and supplements have caused numerous recalls, both voluntary and mandated by regulators. Among them:

- More than 300,000 people consumed melamine-laced milk and infant formula in 2008. Manufacturers added melamine, which can cause urinary stones and kidney failure, to artificially boost protein content, misleading potential customers about perceived product benefits.
- In 2011, St. Louis Rams® linebacker David Vobora won a lawsuit against a sports supplement-maker when he tested positive for a steroid after using one of its products. The lawsuit was validated when testing found that the product was adulterated with a banned steroid, methyltestosterone, which was misrepresented on the label as “steroid-free.”
- In Taiwan, a plasticizing chemical linked to fertility and liver dysfunction was identified in an ingredient used to make jellies, sports drinks and fruit juices in 2011. To protect consumers, regulators in China, Korea, Australia and the Philippines ordered contaminated products removed from the market.

“Recalls make everyone in the industry look like bad players,” said Andrea Champagne, an analytical scientist at NOW® Foods. “It has a severe psychological impact on the customers. People begin to think every similar product is unsafe.”

While the U.S. Food and Drug Administration orders that adulterated products be removed from the market, it also directed manufacturers to fix the problem, which it calls the industry’s biggest threat.

NOW® Foods seized an opportunity – especially in the popular segments of men’s virility, sports nutrition and weight loss – to become the non-adulteration champion not only for its customers but also for a vulnerable industry.

Addressing the threat meant creating a cost-effective solution – a test that could be repeated on a large scale and interpreted by in-house personnel without advanced science degrees. Rising to the challenge was worth it to Michael Lelah, technical director of NOW® Foods.

“To us,” Lelah said, “success was to allow not one single spiked ingredient to make its way through our facility – and certainly not to a customer.”

The answer was an in-house protocol. The real question, though, was how to create it – and with what.

Solution

NOW® Foods took its first step by assessing what it already had. A crucial part of the company's progress was relying on instrumentation and software created by PerkinElmer, a global leader focused on improving the health and safety of people and the environment.

In its arsenal of instruments, NOW® Foods implemented and now operates the PerkinElmer® Spectrum™ One FT-IR spectrometer in a laboratory. Fourier Transform Infrared Spectroscopy, commonly referred to as FT-IR, collects data on solids, liquids or gases, obtaining an infrared spectrum that can be qualitatively analyzed.

FT-IR historically had been used for analytical testing of substances such as polluted soil and biodiesel blends, but NOW® Foods wanted to apply this instrumentation to an innovative method of material qualification.

Powerful software anchors testing method

What made the FT-IR data valuable was the unique AssureID™ software. AssureID compares similarities and differences in the spectral data and delivers an easy-to-read printout – an assessment of whether a sample “passed” or “failed” the test.

“FT-IR is one of the most established types of instrumentation we have in our facilities,” Champagne said. “The instrumentation itself is not the novel solution, but our approach using AssureID is.”

NOW® Foods knew that a test failure indicated that a target ingredient's spectral signature failed to match critical characteristics, indicating the presence of a foreign substance – an adulterated material.

“Since substances create unique wavelength patterns, our FT-IR suite generates what amounts to a molecular fingerprint,” said Jerry Sellors, IR business manager. “AssureID software effectively transforms a layman into a reliable high-tech detective by comparing the sample's FT-IR spectrum against authentic samples to decide if it is likely to be contaminated – just like an analytical spectroscopist in the lab.”

Powered by PerkinElmer, NOW® Foods knew it could create a powerful weapon in the global battle against adulterated materials. The tool could be quickly scaled, economically implemented and easily managed.

Alternative testing methods could have yielded the results NOW® Foods required. But at the cost of nearly \$1,000 for each test and a turnaround time of several days by expensive third-party chemists, the company needed a more efficient solution. NOW® Foods determined it could achieve answers in five minutes instead of five days – a valuable, reliable and speedy outcome for a business that manufactured products based on a just-in-time delivery model.

With PerkinElmer's hardware and software, testing couldn't be easier. NOW® Foods researchers place a sample in powder or pulverized form onto a metal plate. The instrument then runs the test in less time than it takes to toast a bagel. Using AssureID, the test detects the differences between the spectra of raw ingredients and adulterated materials with greater accuracy than more expensive testing methods.

“We honestly couldn't have overcome this challenge without PerkinElmer technology,” Emmel said. “The combination of AssureID and the Spectrum instrument allowed us to do this testing and analysis in a new and incredibly automated way.”

“The one thing that allows a relatively non-qualified technician to do this is the AssureID software platform,” Lelah said. “That's what makes the technology truly turnkey.”

To stay ahead of fraudulent suppliers who were aggressively formulating new ways of spiking ingredient lots, NOW® Foods needed a testing solution that could encompass all potential adulterants. PerkinElmer's Spectrum One made that possible. FT-IR analyzes core chemical structures of materials being tested. The shell of an adulterant may change; what's inside stays the same.

“The players who are adulterating these products are changing characteristics outside the core structure,” Lelah said. “They're not changing the core structure because that is what makes a certain material, like a steroid, work. What this means is that the ability to manipulate the chemistry of a substance does not impact our ability to detect it. We'll always be ahead of their shell game.”

FDA directs supplement industry to combat ingredient adulteration

NOW® Foods assesses internal resources

NOW® Foods creates adulterant test with PerkinElmer FT-IR hardware, AssureID software

NOW® Foods perfects adulterant test, implements for men's virility, sports nutrition and weight-loss supplements

NOW® Foods publishes results and test methods for industry to replicate, protect public

How NOW® Foods devised an efficient, innovative method to screen for adulterants in dietary supplements by using existing hardware and software.

Outcome

In more than two years of testing each ingredient lot of specific classes of ingredients susceptible to adulteration with this revolutionary method, the NOW® Foods team has detected no adulterated lots (confirmed positives). This not only protects the public from unknown adulteration, but also supports the quality of NOW®'s suppliers.

"It's important to identify potential problems at the earliest stage possible," Lelah said. "By catching any potential ingredient problems before they go into manufacturing, it's less costly for our suppliers to remedy and doesn't inconvenience retailers or consumers."

Sharing Success With Industry

NOW® Foods saved thousands of dollars per tested lot and significantly reduced waste. The new method, which eliminates the need for solvents, was the greenest

testing method possible. Since NOW® Foods' products are manufactured to a high quality and valuable price point, this method also allowed the company to keep its products affordable without compromising quality or integrity. NOW® Foods shared its success in food qualification with industry peers by publishing its methods for screening with FT-IR. As a result, the team has received interest from other businesses interested in adopting similar methodology for identifying adulterants.

The pioneering efforts of the NOW® Foods team led the industry in meeting its goal of providing "nutrition for optimal wellness" and enabling peers to combat the issue and take an active role in ensuring the integrity of consumer products.

A.B. Champagne, K.V. Emmel, Rapid screening test for adulteration in raw materials of dietary supplements, Vibrational Spectroscopy (2010), doi:10.1016/j.vibspec.2010.11.009

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