

Posted on Sat, Oct. 09, 2010

Labels for some fish oil capsules leave countries of origin in doubt

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 The Kansas City Star

Pick up a bottle of fish oil capsules and squint hard at the label.

Chances are it won't say where the pills came from. But that's something you should know.

An investigation by The Kansas City Star calculates that fish oil imports from China, a country notorious for hazardous products, now account for roughly 20 percent of the U.S. market. And it's a big market, because one in five American adults now takes fish oil.

The Star also found that companies sidestep import labeling rules and that federal authorities let them.

No big recalls or health scandals have been linked to Chinese fish oil. And a spokesman for the People's Republic of China said his country's fish oil was of good quality.

But consumer advocates, a leading trade group for the supplements industry, and legal experts who have examined labeling laws agree: Consumers ought to be able to tell, at a glance, whether their fish oil capsules are coming from China.

Leo Hepner, an international consultant on food and dietary supplement ingredients, said that if he knew some fish oil capsules were manufactured in China, "I would prefer to buy something else."

And Sidney Wolfe, whose Public Citizen Health Research Group has advocated for consumer safety for decades, said, "People have a right to know."

U.S. manufacturers also sometimes have trouble meeting quality standards, Wolfe said, but he pointed out that China has had serious problems, including with drug ingredients.

A few years ago, nearly all fish oil consumed in the United States was manufactured domestically, with some made in Europe — where rules or laws governing manufacturing are strict.

But U.S. fish oil use has soared, making it the No. 3 dietary supplement and a nearly \$1 billion annual business. As sales increased, some U.S. companies started importing from Chinese facilities.

In its investigation, The Star reviewed every fish oil shipment from China to the United States over 1½ years. They amounted to about one-fifth of the U.S. market in 2009 and continued to increase the first half of this year.

The largest importers were asked to comment for this article, but most refused. The one company that did respond said it had gotten out of its Chinese importing business this year.

The Tariff Act of 1930 requires that imported products, including fish oil, be clearly marked for their "ultimate purchaser" with the last country where the product underwent a "substantial transformation."

Food and Drug Administration rules say supplement labels should include "a truthful representation of geographical origin." And Federal Trade Commission rules say they can supplement the Tariff Act when it fails to require the disclosure of countries that process or manufacture products.

But enforcement of import labeling is left up to yet another agency, U.S. Customs and Border Control, which has been letting the importers get around the law. Those companies assert that simply bottling the capsules in the United States "transforms" them into a U.S. product, so they don't have to be labeled as imports.

The Council for Responsible Nutrition, a leading supplements industry trade group, says the importers' interpretation is ridiculous, and it wants Customs to start enforcing the law.

The Chinese factories that make fish oil capsules for export to the United States are supposed to meet FDA standards. But the FDA, according to several sources, has never inspected any Chinese dietary supplement plants. An FDA spokesman said he didn't know whether the agency had inspected any Chinese factories.

Chinese companies also have shown little interest in having independent third parties inspect their plants or in joining industry groups dedicated to ensuring the quality of fish oil.

One such group is GOED — the Global Organization for EPA and DHA Omega 3s — co-founded by Robert Orr. His company, Ocean Nutrition Canada, has a solid reputation in the industry and is one of the largest refiners of fish oil in the world.

Orr said his group, which is open to companies around the world, would welcome Chinese firms.

"There's not a single Chinese manufacturer in GOED," he said. "You tell me why."

Careful processing of fish oil is important to keep it from becoming rancid. Without proper refining it can contain high levels of some nasty substances, such as PCBs and mercury.

In addition, lightly regulated plants introduce the possibility of products' containing odd contaminants or additives that no one would think to test for.

For example, in 2008 a contaminated ingredient from China showed up in heparin, a blood-thinning medicine that was linked to 149 deaths. The previous year, dogs and cats died after eating pet food made with wheat gluten from China that apparently contained melamine, a toxic compound.

As a result of China's past troubles, the supplements industry is becoming concerned about a potential scandal involving fish oil — one that could jeopardize all sales of the product.

"This industry is playing with fire," said Kenn Israel, vice president of marketing for Robinson Pharma, a supplements manufacturer in California. "It could kill the goose that laid the golden eggs."

A global business

Fish oil sales in the United States have risen rapidly in recent years, from \$35 million in 1995 to \$359 million in 2005 and just under \$1 billion last year, according to Nutrition Business Journal, a trade publication. They're expected to approach \$2 billion by 2014.

The supply chain for fish oil coming to the United States can be complicated, and no organization or agency tracks the product all along the way. That makes it difficult to specify how much flows through various countries at each stage.

The fish from which fish oil is extracted come from around the world, including cod from the North Atlantic and salmon off the Alaskan coast. It is known that most of the fish oil that arrives in the United States is from Peru or Chile, where anchovies and sardines are caught and cooked, and the oil is separated out.

The oil then is sent to refiners, who remove or reduce contaminants and do some other processing. Fish oil consumed in the United States may be refined domestically or in other countries, including Canada, Norway, Iceland and China.

The final stage, manufacturing, includes making the gelatin capsules and injecting them with fish oil. Done correctly, this stage follows proper techniques for manufacturing and storage, and it includes laboratory analysis of the ingredients and other steps to ensure purity and potency.

To see how much fish oil manufactured in China is coming to America, The Star reviewed all shipments of the supplement from China to the United States from January 2009 through July 2010. The information was compiled, at the request of The Star, by Datamyne Inc. of Miami, which specializes in trade data.

Dozens of Chinese and U.S. companies are involved, but a few account for most of the trading in fish oil. Just over 4 billion Chinese capsules were imported in 2009, some of which were then sent on to other countries.

Most of the larger U.S. importers produce dietary supplements for various retailers, making dozens of private or store brands.

One major importer in 2009 was Best Formulations Inc. in City of Industry, Calif., a contract manufacturer for thousands of branded dietary supplements at its California facility.

The company had become a partner in a Chinese plant that made fish oil capsules, which Best Formulations sold to a U.S. customer. Marketing director Eugene Ung did not name the customer but said the fish oil was of high quality and could be made in China at lower cost. However, he said, Best Formulations decided to sell its stake in the plant, in part because of the image of Chinese fish oil.

"It really devalues a brand," Ung said.

Other companies have more than picked up the slack, however. Shipments from China over the first seven months of this year showed fish oil imports on track to rise by 25 percent from last year.

NBTY's experience

One big fish oil importer, NBTY Inc. of Ronkonkoma, N.Y., is publicly traded, so it has to file some information with the Securities and Exchange Commission.

NBTY is one of the largest supplements manufacturers, with sales for all its products of \$219 million just in August. It is best known for its big-selling Nature's Bounty brand of vitamins and supplements and its chain of Vitamin World stores. But it's also a major producer of private and store brands.

In documents filed with the SEC, it said "competitive pressure" was making it tough to keep its 36 percent gross profit in the private-label business. NBTY said "improvements in supply management" would help it deal with that pressure.

The company didn't spell out those "improvements." But already this year, the **Datamyne** figures show, NBTY has more than doubled its total 2009 fish oil imports from China to about 1,800 tons.

Using that much of the cheaper Chinese product, industry sources estimate, could have saved the company at least \$2.4 million.

Dietary supplement manufacturers typically don't disclose the private or store brands they make. But two of NBTY's major customers are Costco and Walmart. The labels on their brands — Kirkland and Spring Valley — don't say where the fish oil comes from.

Costco officials declined to comment, but their brand is one of the few that is tested by an outside organization, USP.

USP, a nonprofit group that has been around for nearly 200 years, sets standards used in 130 countries for prescription and over-the-counter medicines and dietary supplements. USP, on Kirkland fish oil labels, says it "has tested and verified ingredients, potency and manufacturing process."

Walmart is NBTY's biggest customer, contributing 18 percent of its revenue, or nearly \$500 million annually for fish oil and other supplements. Walmart's Spring Valley brand of fish oil says it is either distributed or manufactured by U.S. Nutrition, a company that NBTY owns.

But where does it come from? Walmart, in an e-mailed response, said the information on its website about where Spring Valley fish oil originated and was assembled was correct. It says: "USA and/or imported."

Nagging doubts

A recent poll sponsored by the Pew Prescription Project, an initiative of the Pew Charitable Trusts aimed at promoting consumer drug safety, found that 70 percent of those surveyed in the United States had little or no confidence in Chinese drugs and would want to know whether that was where they were made.

Wang Baodong, the Chinese government spokesman, said that in the past there had been quality problems in about 2 percent of the many products exported by China. But that has much improved in the past couple of years, he said.

"Everyone in the Chinese government and relevant agencies are doing their best to see that all exports are of high quality," he said.

Hepner, whose company in London helps manufacturers select food and dietary supplement ingredients, remains skeptical. Chinese manufacturers in his industry are still all about production and not much about quality, he said, despite claims of improvements and meeting U.S. standards.

"I can say confidently, if they pretend they do, they are telling a story," he said.

A Kansas City company, CardioTabs, sells its own brand of fish oil capsules, which come from Norway. A co-owner of the company, James O'Keefe, who is director of preventive cardiology for St. Luke's Mid America Heart and Vascular Institute, said CardioTabs decided against using Chinese fish oil because "you don't know what you're going to get."

NSF, a standards and testing organization, and the Natural Products Association, a trade group, do audit some plants in China to see whether they meet FDA standards.

But only a handful of Chinese companies have participated in those groups' monitoring.

"There are very, very good ones, and there are very, very bad ones," said Ed Wyszumiala, general manager of the dietary supplements program for NSF, whose voluntary program checks whether dietary supplement plants meet FDA rules.

Orr, the GOED founder and Ocean Nutrition Canada chairman, said his company had tested Chinese fish oil.

He declined to share details of his results, but he agreed with NSF: Some "outliers" are mixed in with good companies, resulting in some problems with quality and consistency.

Hope for change

Buy a toaster in the United States, and if it was made in China it will say so. Buy an umbrella, and not only will it state what country it was made in but where all of its components were from.

Orr said labels similarly should tell consumers where the fish oil was refined and manufactured, and even where the fish were caught.

"How can you not want to do what is best for the consumer?" he said.

A few brands do say they're "Made in USA," but that's allowed only if the fish were domestic and virtually all of the processing, manufacturing and other parts of the supply chain are in the United States. A few others say they're from Norway, which has an excellent reputation in part because of regulations for producing fish oil.

But for fish oil capsules from China, consumers have been left with the importers' evasions.

However, that could change.

Stanley Hopard, an import specialist for U.S. Customs, said in an interview that, despite his agency's inaction so far, he thought imported fish oil capsules should have a country-of-origin disclosure on their bottle and packaging.

Exactly which country, he said, would depend on how much the fish oil was "transformed" at each stage along the way. But he rejected the importers' reasoning that just bottling the pills in the United States was enough to get around listing a foreign country.

He also said Customs would be happy to help importers figure out how to comply with the law if they approached his agency.

Pressure from the rest of the supplements industry also might get some action.

The Council for Responsible Nutrition, the supplements trade group that ridiculed the importers' legal stance, sought legal advice on the question about a year ago. Those lawyers concluded that the product should be labeled with the country where the fish oil was injected into the capsules.

That advice went out to the organization's members.

Steve Mister, the council's president, said in an interview that he was in favor of disclosing where fish oil was manufactured, and he wants Customs to enforce the law.

"A consumer should be able to look at the label and get the country of origin," he said

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