

Are Dietary Supplements From All Countries Unsafe?

Rick Liva

In the past year, the press has peppered US citizens with multiple stories of tainted Chinese toys, foods, and other products. Those stories have prompted some degree of fear and concern about the overall safety of imported products from China. I have received many calls from customers and patients asking if the nutritional supplement products they take contain materials from China. Clearly, people have been alerted and are concerned.

An article was written in the October 5, 2007, issue of *The Wall Street Journal* entitled “China Strains to Police Quality.” The first paragraph states, “US Congressional investigators, after a two-week fact finding trip, concluded that China’s food safety system is broken and the US needs a stronger inspection system to keep out tainted products.” Unfortunately, in 2007 the US Food and Drug Administration (FDA) only inspected 1% of the 11.7 million shipments of imported food.¹ Obviously, FDA inspections are not the answer to fix the problem.

The Answer to This Dilemma Is Simple

China certainly has its share of problems with tainted food and other products. However, the problem is not limited to China alone. I submit that when it comes to the raw materials in dietary supplements, many countries have deficiencies. Products from other Asian countries, India, the European Union, Central and South America, and the United States may be contaminated or subpotent. I offer some examples from my experience in Table 1.

| Material | Problem | Sold By | Country of Origin | How Problem Found |
|--|---|---------------------------------|-------------------|--|
| Aloe | Low-quality aloe, 80% maltodextrin | French company, US distribution | US | Comprehensive testing profile for aloe |
| Bilberry extract 25% | Failed identity and assay | US company | Italy | Thin-layer chromatography testing and anthocyanidin potency assay |
| Black currant seed oil (1 st batch) | Rancid oil | Large US company, GMP certified | US | Peroxide and anisidine tests (rancidity markers) |
| Black currant seed oil (2 nd batch) | Rancid oil | Large US company, GMP certified | US | Peroxide and anisidine tests (rancidity markers) |
| Black currant seed oil (3 rd batch) | Rancid oil | US company, GMP certified | US | Peroxide and anisidine tests (rancidity markers) |
| Certified organic wild yam root | High aflatoxin content | US company | US | Aflatoxin assay |
| Curcumin extract 90% | Contained 1,2 dichloroethane, a Toxic solvent | US company | India | Solvent residue testing |
| Diindolymethane | Very high benzene content | US company | China | Solvent residue testing |
| Feverfew 0.5% | 0.4% active marker vs 0.5%, ie subpotent | US company | France | Potency assay |
| Magnesium ascorbate | Claims to be chelated in company info, instead is a dry blend of magnesium oxide and vit. C, ie, not chelated | US company | US | I asked if the product was fully reacted. They admitted it was not but sold it as such anyway. |
| Milk Thistle Extract 80% | High Aflatoxin Content | US Company | Italy | Aflatoxin Assay |
| Milk Thistle Extract 80% | High Acetone Content | US Company | France, Spain | Solvent Residue Testing |
| Potassium Ascorbate | Same | Same | US | I asked if product fully reacted, they admitted it was not but sold it as such |
| Silybin Concentrate | High Acetone Content | US Company | Argentina | Solvent Residue Testing |

If we did not submit these products to rigorous quality assurance testing, the problems would never have come to light.

With this in mind, the simple answer to fix poor-quality products is to mandate that manufacturing companies inspect, thoroughly test, and perform the necessary quality assurance due diligence before a product is ever released for sale. In August of 2007, Mattel announced 2 large recalls of lead-tainted toys manufactured in China. If they had done a simple and inexpensive test for lead before the toys were released for sale, the whole issue could have been avoided by rejecting the batch of toys.

I don't believe that any branch of the US. government will obtain the necessary funding and personnel to do a thorough job of inspecting and testing imported products. Therefore, it becomes the responsibility of the company that ultimately puts the product up for sale. That way each company assumes responsibility as Mattel should have done.

Lots of professional and retail product companies profess high quality. The word *quality* is splashed all over their marketing materials. Yet, most of them do not detail exactly what they do to assure the quality of their products and, just as important, what quality assurance measures they don't do or leave out. Of equal significance is whether or not the company will provide you with their test data as proof that they did what they say they do.

Just think for a moment how you would feel about a company that sells botanical products if a representative told you what quality assurance testing the company does and doesn't do. Of the 2 companies below, from which would you be more inclined to buy?

| Botanical Company #1 Quality Assurance Testing Profile | Yes Or No | Botanical Company #2 Quality Assurance Testing Profile | Yes Or No |
|---|----------------------|---|----------------------|
| Microbiology screen | Yes | Microbiology screen | Yes |
| Genus and species verification – identity | Yes | Genus and species verification – identity | Yes |
| Heavy metal screen | No | Heavy metal screen | Yes |
| Aflatoxin screen | No | Aflatoxin screen | Yes |
| Solvent residue screen | No | Solvent residue screen | Yes |
| Herbicide and pesticide screen | No | Herbicide and pesticide screen | Yes |
| Potency assay | No | Potency assay | Yes |
| Finished product potency test | No | Finished product potency test | Yes |
| Shelf-life stability testing | No | shelf-life stability testing | Yes |

Obviously, the second company would be more attractive and you'd get a good feeling about buying and prescribing its products to your patients.

Which company would potentially catch more quality issues with their raw materials, no matter what country they come from? Company #2 is much more likely than company #1 to catch and reject inauthentic, contaminated, and subpotent products because of the comprehensive scope of their quality assurance testing. *That's why I say the country of origin is moot. It is all about the quality assurance testing performed or not performed before the product is distributed and sold by the last company in the manufacturing chain.*

Make a Difference

The goal of all of these articles on quality assurance is to impress upon you the urgent need for quality standards. To help you do this, I developed and wrote a questionnaire for clinicians to query manufacturers and/or suppliers about their quality assurance practices. It is available at *IMCJ's* website, www.imjournal.com. In the menu bar on the left, click on "Quality Assurance" (located near the end), then click on "Manufacturer Quality Assurance Self-Audit Form."

I have had an opportunity to read and evaluate some of these questionnaires that were filled out by professional and retail companies. Here are some examples of the information that 5 companies provided:

- only 1 provided adequate documentation and copies of independent testing,
- 1 said they do everything but provided no documentation (it was only available if you visited them),
- 1 admitted to doing no testing whatsoever and just relying on a supplier's certificate of analysis,
- a few did finished-product potency testing but very little raw material testing.

I have been told by several clinicians that they sent the self-audit form to many companies and never received an answer. This is more than just a little disappointing. It brings to light that it is definitely a "buyer beware" marketplace.

Almost all clinicians buy and sell dietary supplement products. Thus, these same clinicians are the key to changing the paradigm. You will help everyone if you buy from companies that can provide scientifically valid evidence of comprehensive quality assurance testing of their raw materials and finished products.

Please send the "Manufacturer Quality Assurance Self-Audit Form" to each of your natural products manufacturers and/or suppliers and see what response you receive. It directs them to answer a series of questions, but also asks for documentation that helps provide verification that they are, in fact, doing what they claim to be doing. The questionnaire asks for proof as well as yes-or-no answers. It is easy to answer yes to a question on a form; it is more difficult to provide proof.

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