



U.S. Pharmacopeia
The Standard of Quality™

U.S. Pharmacopeia Working to Better Detect, Measure Melamine Adulteration in Food

Combating an International Public Health Threat

December 18, 2008—Globalization of supply chains for food and food ingredients has brought greater variety and lower prices for many. It has also provided opportunities for economic exploitation, as seen with the current, tragic news of infant formula and other food products adulterated with melamine. USP is working with regulatory agencies and industry to help address this serious threat to public health.

Melamine is an industrial chemical used in plastics that has no legitimate role in food ingredients, potentially causing harmful or fatal kidney failure if ingested. It can, however, artificially raise the apparent protein level of a food product, enabling it to pass standard quality tests. Melamine has been used for this purpose prior to the current milk and soy adulteration, as with the 2007 episode of melamine in pet food in which many companion animals in the United States sickened or died. These incidents highlight the continued importance of public, science-based standards for the quality and purity of food ingredients. The collaborative development of improved public standards gives manufacturers a better method of assuring the quality and safety of their products. It also helps reinforce public trust in the safety of the food supply.

Close collaboration among USP, FDA, and scientific and industry groups has resulted in updated, more sensitive test methods following two other recent incidents of economic adulteration: that of glycerin (a sweetener commonly used in such products as cough syrup and toothpaste) with diethylene glycol (used in antifreeze); and of the blood thinner heparin with oversulfated chondroitin sulfate (which can mimic anticoagulant properties). These collaborative efforts helped to re-establish the safety of the U.S. glycerin and heparin supplies.

USP is working on a similar collaborative effort to update the current, internationally used method of determining protein content in food and food ingredients. The current approach – the Kjeldahl method – tests only for total nitrogen content, the traditional signifier of protein. It is unable to distinguish between nitrogen coming from actual protein and that coming from other substances, such as melamine, that may be present in the item being tested. USP seeks to develop a method that determines nitrogen content generated just by protein. By not limiting the new test to isolating a specific adulterant (e.g., melamine), it will be possible to identify the presence of other protein-mimicking adulterants as well. In other words, the test will not be “tricked” as readily as the Kjeldahl method that is the current standard. Once this more sophisticated methodology is thoroughly established and is practical for use in quality control laboratories, USP will modify its standards to include the new test.

USP’s open, public process for setting science-based standards is thorough and extensive, including input from a wide variety of stakeholders. This can be a lengthy process, but is done in the interest of consistently sound science that supports public health. USP will provide further information as its work evolves. For updates on the availability of this information, please contact Laura Provan at lnp@usp.org or 301-816-8268.

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