



USP'S FOOD CHEMICALS CODEX

A Way to Enhance Food Safety Standards?

By Ben A. Firschein and James C. Griffiths, Ph.D.

The Food and Drug Administration (FDA) and the Congress wrestle daily with the challenging issue of improving U.S. food safety in the global marketplace. Several widely publicized recent incidents illustrate potential risks to food. Wheat gluten from China was deliberately adulterated with melamine, which caused significant toxicity in pets and may also have affected poultry and swine destined for humans. There is also the risk of food-borne pathogens, as demonstrated by outbreaks of *E. coli*-contaminated spinach.

Food safety is an important issue for the United States Pharmacopeial Convention (USP), an independent, not-for-profit public health organization that sets quality and safety public standards for medicines, dietary supplements and food ingredients. USP's food standards and related programs can help strengthen the safety net for foods and be a part of a comprehensive solution to the current food safety challenges.

For nearly 200 years, USP has helped to improve the safety of drugs and other articles by establishing public standards. Most of these standards support end product testing to assure

that a food or drug article has good quality and has requisite safety and benefit. USP standards are developed by hundreds of domestic and international volunteer experts, and thus are widely recognized in the United States and elsewhere because they are authoritative, science-based, and are developed through a transparent and credible process.

For drugs, USP's *United States Pharmacopeia (USP)* and *National Formulary (NF)* are official compendia under the Federal Food, Drug, and Cosmetic Act (FDCA).¹ By law, prescription and over-the-counter medications available in the United States must meet standards for quality, purity, and strength published in *USP-NF*. These standards are enforced by the FDA, and at times by the States and foreign governments. The public-private partnership between FDA and USP created by the FFDCFA has worked to help assure the integrity of the U.S. drug and drug

ingredient supply for more than 100 years.

USP recently acquired the *Food Chemicals Codex (FCC)*, a compendium of food ingredient standards formerly published through the fifth edition by the Institute of Medicine. USP has just released the sixth edition of that publication and plans full publication biennially with one supplement in alternate years. While currently recognized in the United States in regulation but not in law, *FCC* is relied on by manufacturers and regulators throughout the world as a source of reliable quality standards for food ingredients.

Current Food Safety Efforts

As the U.S. Congress and FDA look for solutions in an era of scarce resources, policymakers will increasingly turn to standards-setting and other organizations for assistance and partnership in implementing approaches to food



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safety. Many authorities in industry and the nonprofit world already have come forward to offer their expertise.

Food safety efforts presently include the Action Plan for Import Safety of the Interagency Working Group on Import Safety;² FDA’s Food Protection Plan;³ the Report of the Subcommittee on Science and Technology of FDA Science Board⁴ and its subsequent recommendations to the Congress;⁵ recommendations of the U.S. Government Accountability Office;⁶ bilateral meetings the administration is holding in China;⁷ Congressional hearings, oversight investigations and proposals; industry plans, such as the Grocery Manufacturers Association’s (GMA’s) Four Pillars;⁸ and ideas by public interest organizations to modernize food safety laws and protect against foodborne hazards⁹ and the risk of intentional adulteration or, even, bioterrorism.¹⁰

Common themes appear to be that food regulations are generally weak, existing Good Manufacturing Practices (GMPs) are inadequate to control quality, and that FDA lacks resources to sufficiently monitor food imports. There is increasing recognition that standards-setting organizations and third-party programs enhance food safety. USP shares these perceptions, and believes that it and other private

organizations could assist the government in addressing food safety concerns.

USP’s Standards-Setting Activities

USP would like to work closely with stakeholders, FDA and the Congress to find ways that the organization’s standards-setting and related activities could be useful in the broader discussion on food safety. USP believes that increased legal recognition of publicly available food standards—such as those provided by USP in its compendia for dietary supplements and food ingredients—combined with expanded use of verification programs, could be part of the answer.

USP’s experience in the area of drug quality standards is illustrative of the sort of role it might play in the foods arena if the Congress were to increase recognition for food standards. USP’s drug compendia, the *USP* and *NF*, provide monographs for more than 4,000 drug substances, excipients, drug products, medical devices, and dietary supplements. There is a separate monograph for each drug, for example, Acetaminophen,¹¹ containing the name of the ingredient or preparation; the definition; packaging, storage and labeling requirements; and the specifications, i.e., the tests,

procedures, and acceptance criteria. Beyond these documentary standards, USP also provides more than 2,000 highly characterized chemical reference materials—official USP Reference Standards—that are used in end-product testing. These physical standards should be thought of as national primary standards, which may be used for calibration of house or working standards by manufacturers or other testing bodies.

Taken together, the specifications in monographs in the *USP* and *NF* function, along with GMPs and allied approaches, to help ensure manufacturing quality and consistency. The specification can be thought of as a kind of “chemical yardstick” to help ensure that each batch coming off the assembly line has the same strength, quality and purity as all other comparable batches.

USP–NF standards are revised to keep abreast of evolving practices and challenges, and can also help safeguard against intentional and accidental adulteration. For example, USP’s recent revision of its monograph on glycerin will help prevent potentially fatal health hazards associated with adulteration of drugs with diethylene glycol, an ingredient in antifreeze.

Drug manufacturers, including those who source their ingredients from overseas, have a powerful incentive to use *USP–NF* standards to test their drugs. First and foremost, they know *USP–NF* standards provide assurance of quality. Additionally, if a manufacturer’s products do not conform to these standards, the products may be considered to be adulterated and/or misbranded and withdrawn from the market by FDA. This longstanding partnership

between FDA and USP has helped ensure the quality of pharmaceuticals in the United States.

Suggested Ways to Enhance Food Standards

USP's *FCC* similarly is a compendium of internationally recognized standards for purity and identity of food-grade substances that allows manufacturers of food and food ingredients to comply with standards that have been created and vetted by a rigorous and transparent scientific process. These standards are also accompanied by physical reference standards.

However, although the *USP* and *NF* are official compendia of the United States under the FDCA, *FCC* does not enjoy broad statutory recognition with respect to food and food ingredients. Instead, specific standards in particular editions of *FCC* are incorporated in selected FDA regulations for food and food ingredients. Thus, there is no general requirement that food ingredients used in the United States conform to *FCC* specifications.

This is different from the level of recognition for *FCC* in other parts of the world. For example, the laws in Australia, Canada, and New Zealand, mandate compliance with *FCC* standards, and Brazil recommends *FCC* as a source of standards for food ingredients. USP is working with food manufacturers and other stakeholders to gain greater adherence to these standards—an important step in ensuring food safety in the United States. Legal recognition of *FCC* in this country could be expanded to help ensure consistency and quality of food ingredients.¹²

Potential solutions to increasing legal recognition in the U.S. run from mandatory standards (requiring ad-

herence to *FCC* under the adulteration provisions of the FDCA), to providing a safe harbor under the adulteration provisions of the Act for voluntary industry compliance to *FCC*. The objective in either case would be to provide greater certainty and compliance to food quality standards, and thereby greater regulatory and public confidence. Each of these options might involve different responses from the regulated community, consumers, and lawmakers. To address this, USP has entered into a dialog with stakeholder groups and regulators, as well as our expert committee members and leadership, about the advantages and limitations of each approach.

in conjunction with ethical manufacturers, sound regulatory oversight, adherence to good manufacturing and distribution practices, and testing to private and public requirements would form a key component to overall U.S. food safety. USP could play a heightened role in protecting the food supply if legal recognition of these standards was enhanced.

USP Verification Programs And Food Safety

USP also offers verification programs¹³ that might be the kind of third party certification program that could help FDA monitor quality while conserving agency resources. We

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A related problem is that to the extent that *FCC* currently is referenced in specific FDA food and food ingredient regulations, it is often to an outdated edition of the compendium. This can cause problems for those seeking to embrace the latest standards and analytical technology and protect public health. It also creates difficulties for manufacturers who seek certainty in establishing compliance with regulations. USP would like to work with FDA and the Congress to address these issues.

In summary, USP compendial monographs and reference standards

know that these sorts of voluntary programs are being considered both by the Congress and the Department of Health and Human Services. Participation in USP's verification programs is voluntary and available to manufacturers worldwide. USP verifies the identity, strength, purity and quality of dietary supplement finished products, dietary supplement ingredients and pharmaceutical ingredients. Products and ingredients that pass all USP verification requirements—including a GMP audit, product and ingredient testing, and manufacturing documentation

review—are awarded use of a “USP Verified” mark.

In addition, USP labs in China, India and, soon, Brazil could play a helpful role in food importation safety. For example, USP, in partnership with the Natural Products Association (NPA), offers a voluntary testing program in China for dietary supplement ingredients.¹⁴ Under the ingredient testing program, a supplier in China or one of its customers in the United States contracts with NPA to test dietary supplement ingredients, designates the tests to be performed, and pays NPA for the service. The supplier samples its ingredient according to a sampling protocol provided by NPA, and NPA then blinds the sample and provides it to USP for testing, paying USP to conduct the tests. The results of the tests are posted on NPA’s website (unblinded), transparent to NPA members and selected others and samples of the same lot will be tested again (on a random basis) after they are received by the U.S. customer.

Solving the food safety issue will take many partners and a host of programs and great ingenuity. USP has come a long way since its founders first met in the old U.S. Senate chamber in 1820 to map out a way to establish drug standards. The organization hopes to be equally helpful and valuable to the Congress and FDA as a trusted partner on the issue of food safety. ▲

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- 10 See, e.g. testimony of Caroline Smith DeWaal, CSPI, before the United States Senate Commerce Committee, Jul. 18, 2007, “Imports from China Exploit Chaos in the U.S. Food Safety System,” http://www.cspinet.org/foodsafety/SenateTest_ChinaImports_071807.pdf. (Last visited Mar. 21, 2008).
- 11 USP–NF, (An Illustrated Guide to USP Standards Using the Acetaminophen and Acetaminophen Capsules Monographs), <http://www.usp.org/USPNF/acetaminophen.html>. (Last visited Mar. 21, 2008).
- 12 Such an effort to assure consistent quality of food ingredients would complement FDA’s efforts to set standards of identity for foods. FDA’s regulations at 21 C.F.R. § 131 *et seq.* ensure that products such as milk, peanut butter, and cheeses have consistent quality with respect to the name used to describe them.
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