By Guest Author: David C. Kennedy, Ph.D.
As mentioned in the previous post, FDA requires that food testing methods be scientifically valid. FDA starts with this deeply fundamental premise, but does not dictate a prescribed solution. This is in contrast to other regulatory agencies, notably the EPA Clean Water Act, where the analytical methodology is specified statutorily. However, this lack of prescription has caused a significant amount of confusion and anxiety in the regulated community. Questions arise: "What is a scientifically valid method? How will I know one when I see one? How do I develop one? Are all scientifically valid methods equally valid?", and so forth.

The question of what is a scientifically valid method does not have a canned answer. Entire books have been written on the subject of scientifically valid analytical methods. The question of scientific validity is largely situational, but three important characteristics stand out: specificity, accuracy, and precision. For the moment, let's just focus on "specificity" and how it relates to the scientific validity of food testing methods for the purpose of assuring safety and quality.

Specificity is the ability of an analytical method to measure only the specific component of interest contained within a mixture of components. Many historically used food testing methods are based on older analytical technologies that suffer from a lack of specificity. They are not sufficiently able to distinguish between the analyte(s) of interest and all the other myriad components in a complex food matrix. This creates the potential for food to become accidentally contaminated – or even intentionally adulterated – without being detected. This vulnerability is perhaps best exemplified by the notorious melamine milk adulteration incident of 2008. This tragedy is directly connected to the use of a non-specific analytical method (the Kjeldahl method) to measure the protein content of food.

The Kjeldahl method for total nitrogen has long been used to measure the protein content of food. Sadly, unscrupulous people added melamine – a toxic, nitrogen-containing chemical compound – to food ingredients as a means to fraudulently increase the apparent protein content of the product. Since the Kjeldahl test is lacking in "specificity", the nitrogen content of the melamine was reported as protein. This resulted in the deaths of children who consumed infant formula made from the adulterated product. In response to the crisis, a new modern HPLC test – with a high specificity for melamine – was developed which now provides infant formula manufacturers a scientifically valid means to detect melamine contamination

in ingredients and products.

Many older food testing methods share this lack of specificity and this makes them vulnerable to intentional adulteration. The need for improved specificity has been a major factor in the drive for food method modernization and the use of analytical techniques such as chromatography that are inherently more analyte specific. Better specificity goes to the heart of the intended purpose of FSMA. In the next posting we will dig deeper into the issue of specificity, the "sweetspot" of chromatography.

To find more scientifically valid food testing applications for Pesticide Residues, Veterinary Drugs, Mycotoxins, Dietary Supplements, Fatty Acids, Sugars, and more . Download your copy today @ www.phenomenex.com/foodguide.

About David C. Kennedy, Ph.D.

David C. Kennedy is a Phenomenex Business Development Manager.
He is a graduate of Iowa State University with a BS degree in chemistry and a PhD degree in analytical chemistry. His professional career has spanned over 45 years with a focus on food safety and environmental monitoring. He has had sequential assignments in industrial R&D, contract testing laboratories, and in the manufacture of analytical instrument and consumables.