



## Applied Research Center (ARC)

*Regulatory Support Services*



At NSF, we have the expertise to assist your company with a variety of regulatory support services. Our international network of quality and regulatory professionals can help your company to meet domestic and international requirements, providing you with guidance that will increase your speed to market.

### **Risk Assessments**

Our experienced toxicologists can conduct health-related risk assessments through the review and evaluation of comprehensive scientific literature, identification and resolution of data gaps and application of various toxicology and exposure modeling tools to support risk management decisions.

### **GRAS (Generally Recognized as Safe) Dossiers**

We can help in the preparation of regulatory submissions or self-affirmation, as appropriate. Our staff can assist in the compilation of the necessary documentation based on generally available safety data and information about the use and manufacture of the substance. We can also provide coordination of an expert panel to determine whether there is consensus among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use.

### **New Dietary Ingredient (NDI) Notifications**

If a company is planning to use an ingredient that was not marketed in the United States in a product prior to October 1994, the FDA requires that the company submit a safety assessment (NDI notification) verifying that the ingredient is safe for human use. This includes a review of the product use history and safety studies, development of toxicology data as appropriate, and preparation and submission of the NDI notification. Our in-house experts and external consultant scientists can assist with the compilation of the necessary scientific substantiation for a New Dietary Ingredient submission to the FDA.

To learn how ARC can support your business, contact [arc@nsf.org](mailto:arc@nsf.org) or visit [www.nsf.org/info/arc](http://www.nsf.org/info/arc)