

# U.S. GRAS

**Intertek understands the intricacies of the GRAS regulations and has successfully completed hundreds of GRAS food ingredient evaluations.**



In the United States (U.S.), food ingredients (including substances intended for use in animal food) are considered either as food additives, or are Generally Recognized as Safe (GRAS) for specific uses and thus are exempt from the premarket food additive approval requirements. The major difference between a food additive submission and a GRAS conclusion is the involvement of the U.S. Food and Drug Administration (FDA), which is required for the evaluation of the safety of food additives. For the conclusion of the GRAS status of uses of a food ingredient, the safety evidence is evaluated by independent scientists (an expert panel).

## Your Challenge

The complex and often extensive requirements for supporting the GRAS status of food ingredients necessitate expert advice in developing an effective regulatory strategy. A successful GRAS conclusion requires evaluation of a comprehensive dossier by a panel of experts, qualified by their relevant national and international experience and scientific training to assess the safety of the specific use of the ingredient.

While GRAS notifications to FDA are voluntary, a positive response from FDA provides assurances of safety to end users of the ingredient and is useful in importing ingredients manufactured outside of the United States. Regulatory and scientific experts are needed to prepare a complete GRAS notification and to act as a liaison with the Agency, ensuring a successful and timely launch of your ingredient.

## Our Solutions

Intertek Health, Environmental & Regulatory Services (HERS) offers the expertise necessary to provide reliable advice on GRAS.

### Our services include:

- Conducting feasibility assessments and assisting with the development of a successful regulatory strategy;
- Conducting literature searches and data gathering;
- Providing product development support;
- Identifying technical and scientific data gaps and recommending solutions;
- Coordinating the conduct of toxicological studies when required;
- Organizing and conducting pre-submission meetings with regulatory bodies, when appropriate;
- Facilitating the publication of pivotal data to meet the "general recognition" requirement of GRAS;
- Providing safety assessments;
- GRAS dossier preparation for expert panel review;
- Coordinating and facilitating expert panel review; and
- Preparing GRAS notification submissions to FDA.

## The Intertek Advantage

Intertek's scientific & regulatory consultants have been successfully delivering expert advice for over 30 years. With more than 80 professionals on staff, including many internationally-recognized scientists, regulatory specialists, and toxicologists, Intertek HERS is unparalleled. Our success record speaks for itself—more than 75% of

our projects come from existing clients or direct referrals. Our value lies in our successful outcomes and reduced time to market.

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 44,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

**Total Quality. Assured.**

## FOR MORE INFORMATION



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