NOVEL FOODS

With the differing pre-market requirements and ever-changing regulatory landscape, developing a well thought-out strategy is key to identifying the most efficient route to market and becoming an industry leader.

Background

In several jurisdictions, foods or food ingredients that do not have a history of use within the community are considered as novel foods. Regulations governing novel foods are in place in the European Union, Canada, Australia/New Zealand, China, South Korea, and other countries. Each jurisdiction has specific regulatory requirements and processes.

In some jurisdictions, the demonstration of "substantial equivalence" to an existing approved ingredient can provide a quicker route to market than the full novel food procedure. This comparison may be based on composition, nutritional value, metabolism, intended use, and the level of undesirable substances.

Your Challenge

You need a clear understanding of the regulatory requirements for bringing your ingredient to the global market. Working with a partner who has expertise in dealing with the intricacies of international novel food regulations is essential.

In addition to ensuring that the appropriate information to support the safety and quality of your ingredient is submitted, your trusted partner can negotiate effectively with regulatory authorities, resulting in successful applications.

Our Solutions

Intertek Assuris offers the expert advice necessary to provide reliable advice in the area of novel foods.

Our services include:

- Assessing novelty status and availability of information to support a history of use
- Conducting feasibility assessments to determine whether sufficient data are available to support a novel food application or a not-novel opinion or substantial equivalence application
- Conducting comprehensive scientific literature searches to support safety of ingredients
- Where information gaps are identified, providing recommendations for the generation of additional data
- Design, placement, and management of pre-clinical and clinical studies, where needed
- Manuscript preparation for scientific studies.
- Conducting dietary exposure assessment using recognized food consumption databases
- Preparing novel food, GRAS, substantial equivalence dossiers or not-novel opinions
- Providing stewardship of submissions for regulatory approval, including liaising with government authorities

The Intertek Advantage

Intertek's scientific & regulatory consultants have been successfully delivering expert advice for over 30 years. Our dedicated teams of experts include all areas of dossier preparation (regulatory, chemistry and manufacturing, nutrition, efficacy, and toxicology). We have experience working with regulatory agencies world-wide, and we can prepare submissions and facilitate approvals in multiple jurisdictions. Our clients benefit from successful outcomes, reduced time to market, and decreased costs.

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices 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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