

NEW CHEMICAL NOTIFICATION (NCN) PROGRAM

Keeping up with the ever-changing regulations and guidance for the chemical industry is challenging. If your product is a novel technology or application, the challenges are even greater. Developing a well thought out notification strategy is key to identifying the most efficient route to the marketing of any product.



Intertek's unparalleled understanding of the intricacies and processes of regulatory agencies and their requirements enables us to assist our clients in developing a successful notification strategy, follow through with the submission process, and act as a liaison with regulatory agencies as required.

Your Challenge

The regulations pertaining to new substance notification differ around the world and comprise a diverse set of hurdles including toxicological, environmental, and nano technological considerations. A clear understanding of the regulatory requirements is the key to enable you to bring your chemical to the global market. A clear strategy that outlines the chemical identity, details read-across and waiver arguments to replace the need for de novo testing, addresses the need for pre- and post-notification consultations with regulators, and includes preparation of thorough notification dossiers that prompt acceptance and assessment by regulators will ensure timely and successful product approvals.

Our Solutions

To ensure that our clients' products spend more time on the market and less time tied up in regulatory red tape, Intertek Assuris offers the following notification-related services to the producers, suppliers and users of industrial, commercial and consumer chemicals:

- Interpretation of notification schemes from scientific and regulatory perspectives;

- Classification of substances and/or products to determine the need for, and nature of, pre-manufacture/ pre-importation/pre-marketing notifications;
- Development of notification strategies that are designed to support not only regulatory compliance, but also the client's business objectives;
- Design and placement of testing programs to establish the safety-in-use of new substances in accordance with national and international notification requirements;
- Stewardship of testing programs including the development of test protocols and monitoring of studies within qualified contract laboratories;
- Regulatory submissions and study support
- Development of technical substantiation reports that defend the use of surrogate data, method variations or requests for waivers of test requirements, where permitted;
- Preparation of notification dossiers that are sufficiently detailed and quality controlled to ensure prompt acceptance and assessment by the regulatory authorities;
- Pre- and post-notification consultation with the regulatory authorities on matters relating to the notification and assessment of new substances; and
- Technical support for legal advisors to assist in the resolution of notification compliance issues.

The Intertek Advantage

Intertek Assuris has considerable expertise and experience helping companies to understand and comply with the requirements of new chemical notifications. We have provided advice to more than 500 chemical companies and has been directly involved in successfully clearing more than 400 New Substance Notifications. We have clients or projects in 120 countries across 6 continents. We currently have a full-time staff of over 80 regulatory and technical specialists, located in offices in the United States, Canada, Europe and Asia.

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.

FOR MORE INFORMATION

 chemicals.hers@intertek.com

 intertek.com/green/chemicals/