



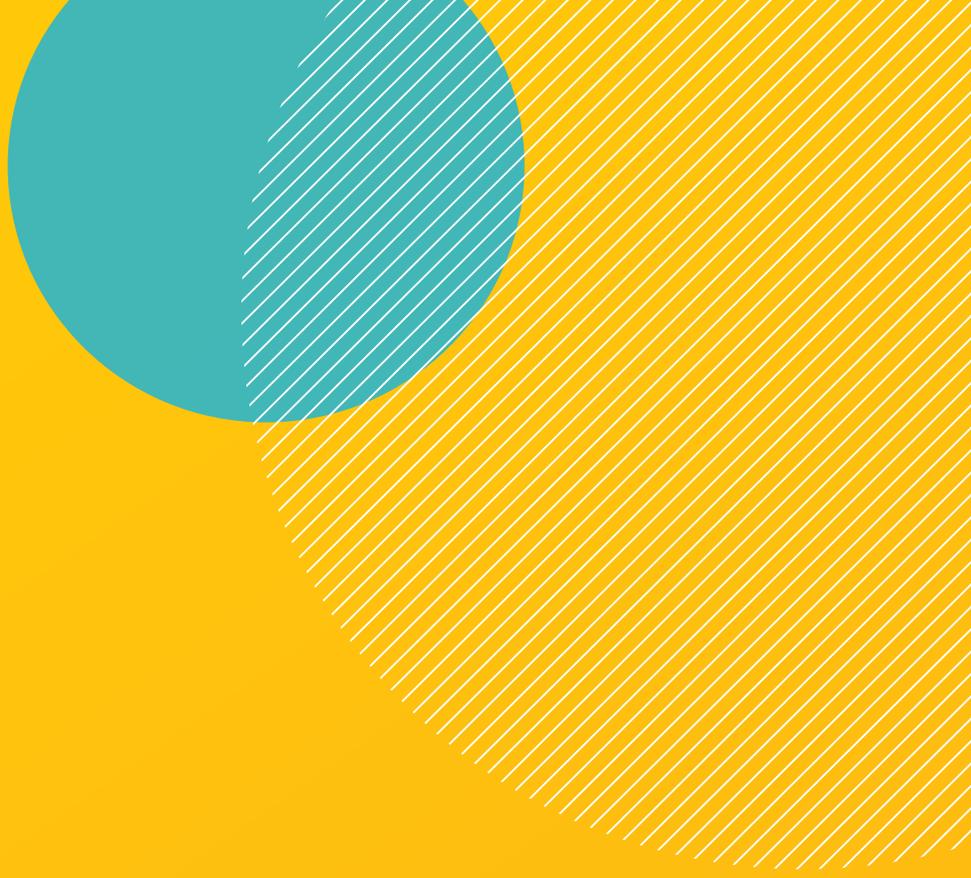
intertek

Total Quality. Assured.

CHEMICALS & MATERIALS SCIENCES

# REGULATORY ASSURANCE R&D SUPPORT

Helping you to achieve Total Quality Assurance



# Chemicals and Materials Sciences Regulatory Assurance and R&D Support

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With over 30 years of experience providing regulatory assurance, expert analytical services and R&D support, our scientists and regulatory experts work with global developers and manufacturers at every stage of a product's lifecycle, providing a flexible and knowledgeable resource to support your business.



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We go beyond just “testing”, responding accurately to your needs to help you to mitigate risks to your business

### **Regulatory Assurance and R&D Support: Helping you to achieve Total Quality Assurance**

Bringing products to market today means overcoming the challenges of new product development, manufacturing and compliance with global regulations. From chemicals to food contact materials, pharmaceuticals and medical devices, our assurance and analytical solutions will allow you to identify and mitigate risks associated with supply chains, product or raw materials quality and product performance.

With strengths in consulting and analysis we deliver assurance solutions for regulatory requirements such as food contact materials and chemical registration. Supporting product development and manufacturing, we also provide problem-solving, research support and analytical investigation programmes.

Ranging from product failure analysis, to supporting complex materials development, our scientists apply their industry knowledge to bring insight and assurance to your organisation, helping to accelerate development timelines across a wide range of products including polymers, coatings, catalysts, nanomaterials, petrochemicals, adhesives and surfactants. Our laboratories include facilities which operate to ISO 17025 Quality standards, accredited and audited by UKAS and also access to Good Laboratory Practice (GLP) or Good Manufacturing Practice (GMP) compliant facilities.

# Food Contact Materials Compliance Services

Comprehensive regulatory support through fast track and cost-effective approaches

Food contact regulatory requirements around the world are complex, with different regions requiring their own notifications including North America, Europe and China for new food contact substances as well as compliance specifications for food contact materials. Compliance is essential to achieve market entry while ensuring the safe use of your food contact material or article.

- Design and implementation of customised Food contact regulatory compliance programs
- Food contact materials Testing protocol development
- FCM Testing as per EU FDA and EFSA guidelines including (EU) No 10/2011
- Regulatory guidance and liaison with regulatory agencies when required
- Third party certifications

Our expertise spans the lifecycle of the project, beginning with an initial compliance review through to the notification of the new food contact substance, if necessary, which includes testing, regulatory support and a safety risk assessment until compliance is reached.

Through a strategic and methodical approach to gathering information, to regulatory considerations, and testing requirements and documentation can help you to achieve swift compliance, support notification or provide the analytical data and insight you need for your specific food contact materials. We liaise with regulatory agencies on a company's behalf when required. Our wide-ranging geographic presence and decades of regulatory knowledge have allowed us to create collaborative relationships with agencies around the world, accelerating the regulatory process.

## Non-intentionally Added Substances (NIAS)

As a requirement of the plastic food contact regulation (EU) No 10/2011, potential health risks in food packaging products or articles should be assessed in accordance with internationally recognised risk assessment principles. NIAS can include decomposition or



degradation products, impurities of starting materials or contaminants from recycling processes. Our scientists and regulatory experts, apply a stepwise NIAS assessment approach which includes:

- Gather, accurately, chemical composition information
- Analytical Screening investigations using a series of analytical approaches to determine all potential migration species (GC-MS, GC-Q-TOF, LC-MS, ICP-MS) to identify and semi-quantify the presence of NIAS.
- Identification of hazardous substances
- Exposure assessment. Migration studies and/or exposure assessment to define real exposure and estimated daily intake
- Final risk assessment on any potential health risk associated with the final material or article

Our experts provide Food Contact petitions and notification expertise for submission in the European Union (EFSA), USA (FDA), Japan (JHOSPA), South America (MERCOSUR), China, Canada, Australia, Switzerland, Philippines, South Korea and other countries

# REACH Registration Services and Compliance Support

A successful track record that has delivered REACH compliance for global clients

Strategic consulting, smart planning and efficient project-managed testing programs



European Union (EU) producers, users and importers of all phase-in substances manufactured or imported into the EU at and above 1 tonne per year which have not yet been previously registered need to prepare for the REACH registration deadline on the 1st June 2018.

With a successful track record supporting previous registration deadlines and in depth knowledge of REACH, our experts help your organisation to implement effective REACH testing and compliance strategies.

Our experts offer tailored REACH testing programs designed to facilitate a successful registration. We conduct substance identification testing, sameness and physico-chemical property testing and consultancy services and highly relevant technical guidance to ease your registration process. With strengths in data assessment we identify any data gaps in the information to complete a dossier and then put in place efficient strategies to address these gaps whilst minimizing unnecessary testing costs. Intertek's scientists generate high quality analytical services for structural and compositional information to meet the requirements of your dossier. This is underpinned expert technical dossier preparation and submission for both Lead and Non-Lead technical dossiers using the IUCLID software and REACH IT portal.

REACH delivery tailored to your company's requirements:

- Strategic consultancy/ Smart Planning – providing strategic 2018 REACH registration advice and guidance
- Consortia management and SIEF / consortia representation
- Collecting relevant data in the public domain
- Data evaluation and gathering
- Identification of analogues/read across/ grouping
- REACH testing programs:
  - o Substance identification testing,
  - o Sameness
  - o Physico-chemical property testing
- Design of Intelligent test strategies/ non-testing proposals – test study management and monitoring
- Exposure assessment /scenarios & PBT assessment
- Lead and Joint Registrant dossier preparation and submission of dossiers
- CSA / CSR preparation
- Reviewing and revising classification and labelling (EU CLP / UN GHS)
- Education and training
- REACH Only Representative

# Chemical Analysis and Materials Science Expertise

Expertise in chemical analysis and materials sciences, enabling you to power ahead safely

Our strength derives from the ability to combine an appropriate set of measurements for any given situation.

Across a breadth of industries we apply these strengths to investigate and test, to bring you the insight you need to address quality, performance, failure, litigation, contamination, and regulatory issues.

## INDUSTRIES

### Polymers and Plastics

Across a host of polymer development issues and applications such as packaging, automotive, toys, aerospace, electronics, we apply our industry knowledge and expert physical, mechanical, chemical, thermal, imaging analysis techniques to bring you the insight you need to progress product development, ensure compliance and achieve a successful market launch.

### Chemicals

Serving a diverse range of sectors from specialty polymer and nanomaterials to food additives, flavours and fragrances, our scientists can analyse the chemical composition or physical properties of your chemicals quality control testing, trace analysis, contamination and formulation analysis. Our regulatory experts have the expertise and experience to assist you and your organisation to comply with regulatory and safety requirements.

### Packaging

Though specialist knowledge of regulations and strengths in analysis of polymers, coatings, additives, inks, adhesives and multi-layered materials, we bring data-derived insight to support product development, failure or compliance requirements for a range of packaging materials such as plastics, glass, metals, paper, paperboard and textiles. Services include problem-solving, physical testing, barrier properties, weathering and quality testing to comply with national and international legislation

### Medical Devices

Our corrosion scientists, metallurgists, polymer experts and materials scientists apply strengths in fracture and failure analysis, surface chemistry and adhesion, microstructure, mechanical property relationships, chemical imaging and materials deformation to provide you with a flexible resource to respond to manufacturing contamination issues, in-field customer complaints or patent infringement challenges.

### Pharmaceuticals

Pharmaceutical development manufacturing support includes physical and chemical characterisation of raw materials and products. Across the supply chain, we provide rapid problem-solving analysis to address contamination and identify unknown impurities and investigate suspected counterfeit medicines.

### Nanomaterials

With Intertek as your partner, we can provide the chemical, physical and regulatory support you need to progress your nanomaterials development. Through characterisation of the nano-particle size, morphology, dispersion, uniformity, optical and physical properties, and chemical composition we have helped clients in sectors as diverse as cosmetics, polymer composites, pharmaceuticals, textiles, electronics and specialty chemicals such as insecticides or paints.





## EXPERTISE

### Materials Science Research

We have the facility to work with you on longer-term materials research projects, perhaps targeted at the development or optimisation of new materials. Our materials characterisation, chemical imaging, measurement and processing expertise (for example in the area of structure-property relationships) can complement your internal strengths allowing you to focus on your core business needs.

### Problem Solving

We apply our problem-solving skills where there is a need for to investigate a materials-related problem such as product quality, performance or processability. Our scientists define an appropriate set of measurements, conduct often multi-discipline analysis programs to derive data-driven intelligence to help you identify and understand underlying issues or source of risks.

### Method Development

Our highly skilled method development scientists have acquired years of experience, working across many types of products, methods and analytical technologies to ensure that the method for application to specific customer problems will be 'fit for purpose'. This has ranged from the adaptation of 'routine' measurements for novel sample types through to major projects on the development of on-line measurement tools.

### Failure Analysis and Investigation

Failure Investigation of polymers, blends, compounds, films, laminates, advanced materials and composites and, particularly, the end-user products manufactured from these materials is a core strength. Our intimate knowledge of raw material production processes, polymerisation technology, moulding processes and applications that vary from simple packaging films through consumer goods to advanced aerospace materials help clients to address performance and failure issues.

### Consultancy

Our scientists are national or international experts in their fields. We provide consultancy services ranging from short discussions and guidance through to more detailed programs, including the provision of reports on measurement issues and the supply of expert witness services for product dispute or litigation cases or Regulatory (REACH & Food Contact Materials) requirements

### Deformulation and Reverse Engineering

The ability to "pull apart" a chemical formulation is crucial in many applications; from quality assurance to competitor analysis. This is a core competency of the group, with the combination of methods such as XRD, NMR, Mass Spectrometry and Separation Science providing a powerful resource, enabling us to determine the components present in complex chemical mixtures or highly formulated materials.





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