

Nano Services



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Yordas Group is a leading global provider of scientific, environmental and regulatory consulting services.

Our unique collaborative approach is designed to build strong working relationships, allowing us to create a customised and integrated service specifically tailored to the needs of each individual customer. Yordas offers a range of comprehensive services relating to nanomaterials.

In light of the recent amendment to the REACH regulation covering nanoforms (Regulation 2018/1881 (amendment of REACH annexes)), importers and manufacturers of nanomaterials are required to provide detailed particle characterisation, hazard and risk information for all nanoforms placed on the market in the EU.

Registration dossiers must be updated before January 1st 2020. These changes to REACH have potential implications for anyone importing/manufacturing nanomaterials.

Yordas provides bespoke nanoparticle characterisation services designed to meet our clients' needs whilst satisfying the recent definition of 'nanoform' for REACH:

nanoform A form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm.

If you are placing nanoforms on the market, Yordas can provide guidance and assistance on fulfilling all your hazard, exposure and risk assessment obligations arising from this amendment to REACH.

Service Offerings

Testing Strategies

REACH states that different approaches to those used for bulk substances may be needed for nanoforms to satisfy the registration endpoints of REACH. In addition, the requirement to provide information for each nanoform could potentially lead to a large amount of testing being commissioned.

Yordas' experts have been part of the Partner Expert Group that assists ECHA with writing the Guidance for Information Requirements and are active members of EU funded projects focused on developing Grouping and Read Across strategies for nanoforms. We are in the fortunate position to use our position at the leading edge of research to be able to design strategies to identify sets of similar nanoforms and read-across strategies that will replace your testing costs. We are able to design the animalfree testing and use the latest research to scientifically justify these approaches. If testing is needed, Yordas uses our experience to design and commission the most appropriate study for your products.

European and Global Regulatory Advice

Yordas is a leading global provider of regulatory consultancy. Although REACH has the most detailed obligations for nanoforms, many other regulations have specific requirements from cosmetics to biocides. We can assist clients by providing advice, identifying and meeting broader regulatory obligations unique to nanomaterials.

Example regulations:

Cosmetics

Biocides

Taiwan (TCSCA)

Nanoparticle characterisation

Yordas offers a bespoke particle characterisation service, handling requests on a substance-by-substance basis, reflecting the complex nature of nanoparticle analysis.

1. *Initial scoping investigation*

A scoping assessment will evaluate existing information pertaining to a given substance, including any existing particle characterisation data.

Once this is complete, Yordas can provide guidance on the next steps to achieve compliance.

2. *Particle characterisation of nanoforms*

If no particle characterisation data exists for the client's substance, or if existing data is insufficient for the purposes of meeting the EC definition, then Yordas can offer a package of particle characterisation testing including:

- *Particle shape and morphology*
- *Number-weighted particle size distribution*
- *Volume specific surface area (VSSA)*
- *Composition and surface functionalisation*
(if no existing data can be produced)

3. *Updating registration dossiers*

Yordas can incorporate new and/or existing data into a particle characterisation report, which can be attached to existing registrations.

Exposure and risk assessment

The exposure and risk assessment of nanoforms can be more complex than other substances because of the possibility of transformation of the nanoform to another nanoform during the life-cycle of the substance. Yordas has been part of EU-funded projects that have been focused on identifying the nanoform and measuring exposure for workplace, consumer and environmental scenarios.

We have also been part of the development of new approaches to nanomaterial risk assessment that has guided the development of the amended regulations. Whether it be for regulatory obligations or to optimise your occupational safety programs, Yordas can provide the expertise to help you achieve your goals.

Expert Opinion

Even if you decide to rely on other SIEF members to lead the testing strategy to meet the requirements of the amended regulation, there will need to be a great deal of technical discussion between registrants to ensure the dossier covers all members products.

Yordas applies our experience to support our clients to ensure all their products are properly covered in any update to the registration dossier. We have supported clients through substance evaluation for both bulk substances and nanoforms.

Safety by Design

Safety-by-design is a concept that ensures that reducing hazard and risk to humans and the environment is an intrinsic part of product design and development.

Yordas uses our experience with risk assessment for nanomaterials to support your company to apply safety by design that will produce safer products and reduce the cost of development.

About Yordas



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