A common European approach to the regulatory testing of nanomaterials

Results in Brief

Unlocking the market potential of nanomaterials

EU-funded researchers have created a toolbox to help regulators assess and better address the safety of nanomaterials.

Nanomaterials are full of possibility yet, because of ongoing concerns about their safety, rules and regulations have prevented them reaching their full potential. ‘The innovative and economic potential of Manufactured Nano Materials is threatened by a limited understanding of the related EHS (Environmental Health and Safety) issues,’ says NANOREG Project Manager Aart Dijkzeul. ‘While toxicity data is continuously becoming available, the relevance to regulators is often unclear or unproven, and the shrinking time to market of new materials makes the need for action by regulators increasingly urgent.’

To remedy this, Dijkzeul and his team of researchers provided regulators and
legislators with a scientific evaluation of current data and testing methods. ‘By working hand-in-hand with global regulatory institutions, we successfully developed a toolbox for assessing the safety of nanomaterials,’ he says.

Dispelling uncertainty

Nanomaterials are chemical substances or materials that are manufactured at an incredibly small scale – down to 10 000 times smaller than the diameter of a human hair – and they are already being used in hundreds of products ranging from batteries and paint to anti-bacterial clothing and medical equipment.

However, to capitalise on the full market potential of nanomaterials, their safety must be guaranteed. ‘This means dispelling any scientific uncertainty about their effects on either humans or the environment,’ says Dijkzeul. ‘As these nanomaterials are often unique and have never been on the market before, assessments must be done on a case-by-case basis using globally recognised and approved methods.’

A practical toolbox

The project started by analysing existing knowledge and combining this with a study of the needs of regulatory authorities. This enabled researchers to identify knowledge gaps, including: characteristics that influence the risk of nanomaterials in the environment of humans; standardised methods to determine these characteristics; and nano-specific risk assessment strategies and approaches.

From these three main gaps, 16 regulatory needs were generated. These then formed the basis for researchers to develop the next generation of reliable and comparable experimental data on the environmental, health and safety aspects of nanomaterials. ‘The very-practical NANOREG toolbox, which contains relevant instruments to aid risk assessment, toxicity testing and exposure measurements, is meant to help organisations involved in the standardisation and regulation of nanomaterials,’ says Dijkzeul.

Getting nanomaterials to market

In order to ensure closer collaboration between regulatory authorities, industry and researchers, the toolbox was created in close cooperation with the European Chemicals Agency (ECHA), the European Committee for Standardisation (CEN) and the International Organisation for Standardisation (ISO). The project also created an international network of global standardisation institutions in the US, Canada, Australia, Japan and Russia. ‘We see this cross-border interdisciplinary approach as being one of the project’s greatest legacies, one that will significantly contribute to removing risk from the use of nanomaterials in industrial and consumer products,’ adds Dijkzeul.
Thanks to the work of NANOREG, the innovative and economic potential of nanomaterials will no longer be jeopardised simply because health and safety issues were not being fully addressed. ‘NANOREG has made it easier for regulatory and legislative bodies to do their jobs effectively based on scientific data and test protocols,’ concludes Dijkzeul. ‘Our more efficient risk management approaches ensure that the time it takes to get new nanomaterials to market will continue to shorten – with obvious benefits for consumers and manufacturers.

Keywords

NANOREG, nanomaterials, nanotechnology, REACH, EHS, ECHA

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