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GLOBAL RISK & REGULATION NEWS

Preliminary definition developed for titanium dioxide-type substances

Agreement achieved at industry-funded workshop on PSLTs

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Experts from industry and academia have developed a preliminary definition for a group of substances expected to have the same toxicity profile as titanium dioxide.

Concern about 'poorly soluble, low toxicity' particulate substances (PSLTs) is high, following the EU's classification of **titanium dioxide** as a carcinogen. During the heated public debate that preceded the EU's final decision, industry stakeholders said that PSLTs, including titanium dioxide, should be grouped for the purposes of hazard assessment.



However, there is no generally accepted, technical definition despite widespread use of the term.

The definition that has now been put forward was developed at an industry-funded workshop on the toxicology of PSLTs and is described in a report in *Inhalation Toxicology*. It has two parts, one addressing solubility and the other addressing toxicity.

In broad terms, a substance would be 'poorly soluble' if it has a dissolution rate in the lung that impacts on the rate at which particles are mechanically cleared by macrophages – cells that engulf foreign bodies as part of the body's immune response. However, the report provides various "observations and conditions" that make this part of the definition "more specific".

For example, labs would need to measure particle dissolution *in vitro*, under biologically relevant conditions, which would mean at a pH reflecting the intracellular environment and using a throughput system that allows for flow of material.

The report also mentions several specific substances in reference to the solubility part of the definition. It says that titanium dioxide and carbon black would be poorly soluble according to its terms, but zinc oxide and copper oxide "clearly" would not.

Regarding 'low toxicity', the report says that the critical endpoint should be chronic inflammation, because this underlies other responses, such as fibrosis and hyperplasia. It also says that "the most adequate dose metric still needs to be established".

"We made a huge step forward with the definition, but it's not yet finished," said Paul Borm, one of the two organisers of the workshop and a consultant specialising in particle toxicology.

The toxicology aspect, in particular, requires further discussion. Dr Borm said that organisations with the power to facilitate adoption of the definition in legislation should mediate this, such as the OECD or the International Organization for Standardization (ISO).

to the definition, because of the detail required.

Workshop

Overall, the workshop covered four topics:

defining and grouping PSLTs;

lung particle overload;

the relevance of the rat as a model for PSLT inhalation toxicology; and

the human health hazards and risks posed by PSLTs.

In addition to the 15 designated experts present, 15 individuals attended as 'observers', including Tim Bowmer, chair of Echa's Risk Assessment Committee (Rac) and Andrew Smith from the UK's Health & Safety Executive.

A spokesperson for Echa said that "the meeting was not directly related to any ongoing work item at Echa. We were interested in the science behind the discussion, but given that PSLT is not a substance, or a recognised group of substances, no new direct regulatory connections to [the agency's] work emerged".

Workshop sponsors:

the International Carbon Black Association (ICBA);

the Titanium Dioxide Manufacturers Association (TDMA);

metals trade association Eurometaux;

the International Antimony Association;

the International Magnesium Association;

Vliegasonie, a Dutch company that markets mineral residue materials from coal power plants; and

the Iron Platform.



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