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GLOBAL RISK & REGULATION NEWS

Downstream users urged to act on EU antimony evaluation

Warnings over consequences of changed classification

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Downstream users of antimony and its compounds have been urged to start preparing the information needed for an EU substance evaluation in March 2018. Lack of data could have serious consequences, speakers at a recent Brussels conference said.

Participants in the 2017 Antimony Day event on 29 November heard that the evaluation – to be carried out by Germany's Federal Institute for Occupational Safety and Health (Baua) – could result in the reclassification of three forms of antimony: antimony trioxide; antimony sulphide; and antimony metal.

Antimony substances are used extensively in flame retardants, and also in lead batteries, plastics, paints, glass and other ceramics.

Under the CLP Regulation antimony trioxide is currently listed as carcinogenic 2 – "suspected of causing cancer". The other two substances have no classification.

But delegates at the event, organised by the International Antimony Association (i2a), heard that reclassification to a carcinogen 1B category – "may cause cancer" – was a real possibility.

Speaking after the event Caroline Braibant, i2a's secretary general (pictured), said: "We are very worried about the impact, but we are trying to provide the most robust interpretation of toxicological evidence, and manage the possible downstream consequences of a possible reclassification."

Fears

Delegates to the conference included miners, producers, traders and users of various forms of antimony, and many expressed fears that a reclassification could drive up costs and force many SMEs out of the industry.

"The problem is the links that CLP has with many other pieces of legislation like REACH and the RoHS and toys Directives," Ms Braibant said. "Once a substance is in carcinogenicity categories 1A or 1B, its use may be restricted in a number of articles, no matter the physical form in which it is used or the actual exposure potential."

In an attempt to limit damage, i2a is promoting the idea that any change of classification could also specify a route of exposure.

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"Instead of having a reclassification via all exposure routes under CLP, if the authorities would agree on an inhalation effect only, this would allow continued use of antimony substances in any way when they are not generating dust," said Ms Braibant.

"One point where authorities and our industry could agree is that the issue is only one of inhalation," she said. "Any restrictions imposed downstream would only be applicable where there is a potential release or exposure to powders and dusts."

Raising awareness

Many downstream users are convinced, Ms Braibant said, that antimony substances are "nice to work with" and have never experienced adverse health impacts from it. Therefore they question why anything should change, she added. There is a "general lack of experience" of the CLP reclassification process in the sector and a belief that current risk management measures "are protective enough".

Further awareness raising is necessary to make industry realise a reclassification decision is subject to "rigid rules and will have a number of consequences".

Antimony compound stakeholders need to engage with the process, she said. "The best advice we can give industry is to generate or provide the exposure data they have. It may not change the reclassification, but it may ensure subsequent measures are not decided on a worst-case basis"

Evaluation work

Baua's decision to conduct the evaluation follows a US National Toxicology Program (NTP) [study¹](#) into the carcinogenicity of antimony compounds. This found evidence of lung tumours in exposed rats and carcinogenic effects on mice.

Baua's Mandy Lokaj told the conference the substances had been chosen on the grounds of:

- carcinogenicity;
- possible exposure of workers;
- high (aggregated) tonnage;
- high risk characterisation ratios;
- other exposure/risk based concerns; and
- wide dispersive use.

Antimony compounds have also been the subject of a 2017 EU pilot covering more than the three substances subject to evaluation.

Trialled for the first time this year, the so-called Colla approach has seen Echa, member state competent authorities and registrants working together on selected groups of substances. The antimony sector volunteered for the pilot to help prepare for the 2018 evaluation.

Nevertheless, despite close cooperation between the various sides, Dr Lokaj warned that industry needs to get its data in place, otherwise Baua would have to make worst case assumptions on the potential risk associated with antimony substances.



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