Press Release:

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CLARIFICATION WILL AVOID UNNECESSARY ANIMAL TESTS

Unnecessary animal tests will be avoided and costs to industry reduced as a result of a new clarification of the information requirements for manufacturers and importers of chemical substances under the REACH regulation.

The clarification is specific. It applies to companies manufacturing or importing substances at quantities greater than or equal to 100 tonnes (and 1000 tonnes) per year who need to provide information in their registration dossiers on the repeated dose toxicity or reproductive toxicity of their substance.

Put simply, companies who need to provide information based on long term toxicity studies[1], do not need to also submit the results of screening or short term studies[2] in order for their submission to be considered "complete" by the European Chemicals Agency. Companies are encouraged to consult the Agency's fact sheet for the complete clarification to enable them to decide which information they need to provide for their dossiers to pass the technical completeness check. The clarification is one further contribution for companies to consider as part of an integrated approach to obtaining the information necessary to determine the hazards and risks that their substances may present for human health and the environment.

When a dossier has passed the completeness check, a registration number is provided to the company who can then continue to manufacture, import and market the substance.

ECHA emphasises that the information requirements constitute the minimum information required for a technical dossier to pass the completeness check for the two particular hazard endpoints - repeated dose toxicity and reproductive toxicity - and that additional information may be necessary to comply with the REACH legislation and to ensure safe use.

Registrants who decide to submit testing proposals for the longer term studies without having completed the shorter ones **must** take account of that by including in the Chemical Safety Report and in the exposure scenario the interim risk management measures that they put in place and those they recommend to downstream users in order to manage the risks yet to be

[1] A 90 day repeated dose toxicity study or a pre-natal developmental toxicity study
[2] A 28 day repeated dose toxicity study or a screening for reproductive/developmental toxicity study

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explored. The responsibility for the safe use of the chemical lies with the manufacturers, importers and downstream users.

More information

Link to Factsheet: http://echa.europa.eu/doc/reach/reach_factsheet_testing.pdf

Questions concerning information requirements and the technical completeness of the dossiers can be submitted to ECHA via the helpdesk web form which is available at www.echa.europa.eu.

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