The REACH Implementing Regulation on joint submission of data and data sharing: is it fair, transparent and non-discriminatory?

Commission Implementing Regulation (EU) 2016/9 (Implementing Regulation) entered into force with retroactive effect on 26 January 2016, providing several new and important considerations and obligations for companies sharing data under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. The Implementing Regulation aspires to: (1) provide useful clarity on data sharing and data compensation under REACH by providing detail on the “fair, transparent and non-discriminatory” standard; and (2) reinforce the “One Substance, One Registration” (OSOR) principle.

Regarding “transparency,” Article 2 of the Implementing Regulation requires that parties “obliged to share information” under REACH “make every effort to reach an agreement on the sharing of the information.” This data sharing agreement must be “clear and comprehensible to all parties,” and must include:

- Itemisation of data to be shared, including the cost of each data item; a description indicating the REACH information requirements to which each cost corresponds; and a justification of how the data to be shared satisfy the information requirement;
- Itemisation and justification of any costs of creating and managing the data sharing agreement and the joint submission of information (i.e., administrative costs); and
- A cost-sharing model, which must include a reimbursement mechanism.

Regarding “fairness and non-discrimination,” Article 4 of the Implementing Regulation underlines the REACH rule that registrants are only required to share costs of information needed to satisfy their own registration requirements, and adds that this condition also applies to administrative costs.

Article 4 provides precise rules and requirements for cost sharing, which include: (1) the cost-sharing model applies to all registrants of a substance, including potential future registrants joining the data sharing agreement at a later stage; (2) the cost-sharing model must include provisions for sharing costs resulting from a potential substance evaluation decision; (3) the number of potential registrants estimated to register a substance, and the possibility of future additional information requirements for that substance, other than those resulting from a potential substance evaluation decision, must be considered in agreeing on a cost-sharing model; and (4) the aforementioned reimbursement mechanism “shall be envisaged in every cost-sharing model and shall include a method of proportional redistribution to each participant” for their share of costs paid where a potential registrant joins the data sharing agreement in the future.

Regarding the OSOR principle, Article 3 of the Implementing Regulation states:

- Without prejudice to the “opt-out” provisions in REACH Articles 11(3) and 19(2), the European Chemicals Agency (ECHA) shall ensure that all registrants of the same substance are part of the same registration; and
- Where ECHA permits a potential registrant of a substance that has already been registered to refer to information in accordance with REACH Articles 27(6) and 30(3), ECHA shall ensure that any subsequent submission of information by that potential registrant is part of the existing joint submission for the substance.

The Implementing Regulation amplifies and illuminates REACH data sharing obligations substantially, and arguably accomplishes its stated goals. The Regulation’s establishment of several new, important, and demanding measures means that manufacturers, importers, and Only Representatives must manage data sharing, data compensation., and OSOR-related matters more diligently and tactfully than before.

Despite industry’s criticisms of the Implementing Regulation, the Regulation potentially facilitates better deals, from a neutral perspective, for data under REACH. Under the Implementing Regulation, data buyers are better informed on how costs are calculated and incurred, and generally, the Regulation’s principles are not unduly burdensome on data sellers. Considering their central importance, the Regulation’s OSOR provisions are beneficial.

In conclusion, it appears that greater fairness, transparency, and non-discrimination lie ahead under REACH due to the Implementing Regulation, and short-term compliance difficulties are outweighed by this persuasive benefit.

William Blythe launches web shop for graphene oxide

Northwest chemical producer William Blythe is proud to announce the launch of its dedicated web shop for graphene oxide, GOgraphene, which can be found at www.go-graphene.com. Graphene oxide is an exciting novel 2D material that is currently widely researched in many different applications for its unique electrical, mechanical and thermal properties.

As an innovative specialty materials supplier, William Blythe has invested in developing a robust manufacturing technology for producing graphene oxide powders and dispersions. These are now for sale through the company’s web shop in gram-scale quantities, aimed at supporting global research into applications for this advanced 2D material. Further efforts are underway to provide larger volumes, with William Blythe being able to supply 1000 kg of product, before moving to the 10 tonne scale in 2018. Further product modifications are also under development.

Author: Marc de Pater, global marketing & sales director