Client Alert

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The REACH Data-Sharing Regulation Is A Mixed Blessing

On January 6, 2016, the new implementing regulation on joint submission of data and data-sharing under the REACH Regulation[1] was published in the Official Journal of the European Union (EU) . The Data-Sharing Regulation (DSR) will enter into force on January 26, 2016[2] when compliance with the new rules will be required.

The DSR is a mixed blessing. According to the European Commission, experience has shown that the REACH provisions on data-sharing and joint submission "have not been used to their full potential, their implementation falling short of expectations."[3] The Commission believes that this state of affairs has been especially prejudicial to small and medium size enterprises. Indeed, there is no question that there have been cases in which data owners have used their powers in ways that are inconsistent with REACH's emphasis on fairness, transparency and non-discrimination.[4] But, the cure imposed by the Commission may be overkill.

Key Rights and Obligations

Under the DSR, potential registrants, a term that is not defined, and registrants are granted a series of new rights. Of course, this implies also that previous or co-registrants have corresponding obligations. The DSR is not concerned with the financing of the efforts necessary to comply with these new rights; it assumes that somebody will pay and that costs are shared later. As a practical matter, it will be up to consortia and data owners to figure out how they will arrange for and finance compliance.

One Substance, One Registration

REACH sets forth the "one substance, one registration" (OSOR) principle.[5] To improve the implementation of the OSOR principle, the DSR makes it harder for candidate registrants to submit their own registration dossier for a substance for which there already is a dossier or where other candidate registrants of the same substance are present. Subject to REACH's opt-out rules, European Chemical Agency (ECHA) must ensure that all registrants of the same substance are part of the same registration, and that all submissions of information regarding the same substance are part of the same registration.[6]

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[1] For an analysis of a wide range of issues arising under the REACH Regulation, see Lucas Bergkamp (editor), The European Union REACH Regulation for Chemicals: Law and Practice, Oxford University Press, 2013. Chapter 7 by Lucas Bergkamp and Nicolas Herbatschek discusses information and data-sharing requirements.

[2] Article 6, COMMISSION IMPLEMENTING REGULATION (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 3/41 (06.01.2016) (hereafter, the "Data-Sharing Regulation").

[3] Recital 2, Data-Sharing Regulation..

[4] Article 27(3), REACH Regulation.

[5] Recital 12, Data-Sharing Regulation.

[6] Article 3 juncto Recitals 12 and 14, Data-Sharing Regulation.

Data-Sharing

The bulk of the DSR deals with data-sharing. Under the DSR, a data-sharing agreement is required in all cases in which data must be shared between registrants of the same substance. It, therefore, does not cover read-across, other than that it *encourages* data-sharing in those cases.[7]

A data-sharing agreement involves "only persons or entities subject to REACH."[8] This clause is intended to clarify that the DSR does not apply to data that are owned or controlled by any entity that is not a participant in the relevant Substance Information Exchange Forum (SIEF), to which the REACH Regulation does not apply.

A data-sharing agreement must include: (a) the itemization of the data to be shared, including the cost of each data item, a description indicating the information requirements in [REACH] to which each cost corresponds, and a justification of how the data to be shared satisfies the information requirement; (b) the itemization and justification of any cost of creating and managing the data-sharing agreement and the joint submission of information between registrants of the same substance as required by [REACH]; and, (c) a cost sharing model, which shall include a reimbursement mechanism.[9] Registrants are required to document annually the costs incurred in relation to the operation of their data-sharing agreement, as well as any compensation received from new registrants.[10]

Cost-Sharing

A registrant is required to share only the costs of information that it is obliged to submit in connection with its REACH registration.[11] A cost sharing model is to include provisions for sharing any costs resulting from a potential substance evaluation decision, but it may not cover costs relating to establishing substance sameness. There is some flexibility in designing a cost sharing model, but if the parties cannot agree, cost must be shared equally.[12] Where a new registrant joins the data and cost sharing for a substance, proportional redistribution of costs, and, subject to some limited flexibility, reimbursement to each participant of their share of costs paid, are required.[13] Data-sharing disputes are handled by ECHA, which is instructed to take parties' compliance with the DSR into account.[14]

Retroactive Effect

A particularly tricky issue is the DSR's retroactive effect. If a potential registrant requests data-sharing, the previous registrants are required to provide proof of the cost of the pertinent existing studies, and "make every effort" to itemise all other relevant costs, including administrative costs, incurred before the DSR's effective date. If detailed documentation of costs incurred or compensation received before the DSR's effective date, is unavailable, parties to an agreement shall make every effort to collate proof, or to produce the best approximation, of such costs and compensation for each year since the commencement of that agreement. These obligations may well require substantial administrative efforts, which could result in significantly increased administrative costs.

[7] Recital 15, Data-Sharing Regulation.

[8] Article 2(1), Data-Sharing Regulation.

[9] Article 2(1), Data-Sharing Regulation.

[10] Article 2(3), Data-Sharing Regulation.

[11] Article 4(1), Data-Sharing Regulation.

[12] Article 4(3), Data-Sharing Regulation.

[13] Article 4(4), Data-Sharing Regulation.

[14] Article 5, Data-Sharing Regulation.

Waiver by Unanimous Consent

The DSR is mandatory and does not allow registrants to agree otherwise, except with their unanimous consent.[15] This regime probably works fine in most cases involving a small number of registrants. However, as the number of registrants increases, the number of passive registrants and "free riders" also increases. Some SIEFs include hundreds or even thousands of registrants.[16] At some point, obtaining unanimous consent becomes impossible as a practical matter. As a result, even where a regime that deviates from the DSR is in the interest of all registrants, it may not be applied. In other words, where the number of registrants is large, the DSR's regime is likely to impose substantial administrative costs that may well increase the cost share of all registrants.

Penalties

Sanctions and penalties are not included in the DSR. Under the REACH Regulation, Member States must adopt and apply penalties for infringement of REACH, including the data- and cost-sharing obligations. These penalties must be effective, proportionate and dissuasive. Insofar as breach of the DSR involves also a breach of REACH, these penalties may be imposed.

In addition, in some cases, administrative remedies might apply, such as the one set out in Article 30(3) of REACH. Under this provision, a registrant may proceed to register without vertebrate animal data, if the owner of the study refuses to provide either proof of the cost of the study or the study itself; this owner will not be able to proceed with registration until he provides the information to the other registrant. If the registrant already registered prior to the DSR's entry into force, this remedy does not apply.

Balance and Legality

Ultimately, the DSR did not get the balance right between the risks of data owners' abusing their position, and the risks of free riders imposing costs on others. It overregulates and eliminates the flexibility that is necessary to accommodate the multitude of data-sharing scenarios encountered in the real world. From a legal perspective, the key question is whether the DSR merely implements the provisions of the REACH Regulation, or goes beyond REACH and constitutes *ultra vires* regulation that creates new rights and imposes additional obligations.

Clearly, the REACH Regulation does not require an elaborate cost sharing model, annual accounting, and reimbursement. Nor does it require unanimous consent. Whether all of DSR's obligations will be deemed to be covered by the general REACH standards of "fairness, transparency, and non-discrimination," is an open question.

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[15] Article 2(2) and 4(5), Data-Sharing Regulation.

[16] For further discussion of SIEF and consortia management, see Lucas Bergkamp (editor), The European Union REACH Regulation for Chemicals: Law and Practice, Oxford University Press, 2013, Chapter 6 by Mike Penman and Martin Richards.