

EU Competition Briefing

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REACH: Key Competition Issues

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Overview

REACH¹ (the EU chemicals regime) raises a range of competition (antitrust) issues which are coming to the fore now that registration activities begin in earnest. With tough sanctions in place for breaches of competition law (prosecutions and fines) and active enforcement action by the European Commission and national authorities, data owners need to consider the possible pitfalls which REACH presents. Equally, data access purchasers may rely on competition law arguments when negotiating access and compensation fees.

This article examines possible anticompetitive behaviour in the context of the data sharing rules under REACH. We identify conduct which has the object or effect of preventing, delaying or making it more difficult for potential REACH registrants to fulfil their obligations (and which therefore restricts or affects competition in the EU chemical market). This conduct could be unilateral or part of a concerted practice or agreement amongst data owners.

REACH requires EU manufacturers and EU importers of substances to gather information on the properties of their chemical substances and register that information in dossiers filed with the European Chemicals Agency (ECHA)². Non-EU substance manufacturers and formulators may also register through an EU-established “Only Representative” (such as Steptoe). If registration is not completed within the applicable deadlines REACH’s “no data, no market” principle applies. Those companies who “pre-registered” by 1 December 2008 benefit from extended registration periods. (Under certain circumstances, there is a very limited scope for “late” pre-registration.)

¹ Visit Steptoe’s REACH Resource Center at www.steptoel.com/REACH.

² EU manufacturers and EU importers can register chemical substances on the European Chemicals Agency (ECHA) website at http://echa.europa.eu/home_en.asp.

Potential registrants are organising themselves in Substance Information Exchange Forums (SIEFs). SIEF participation (which is mandatory) is designed to facilitate data sharing for registration and agreement on classification and labelling. Access to existing studies is key in order for SIEFs to assess possible information gaps and determine the need to conduct additional studies (with the approval of ECHA where required) to complete registration.

Two sets of possible anticompetitive practices by data owners are considered:

- a refusal to exchange information or withholding relevant data; and
- engaging in strategic pricing behaviour in a way which may have the effect of making data access unattractive for requesting parties.

Refusal to grant access to data

Data exchange is typically a competition law concern when it is liable to remove inherent market uncertainty as to the future conduct of competitors and thereby facilitates their collusion. Practices likely to breach competition rules include information exchange on actual prices, terms of sale, allowances, credit terms, costs of production or distribution, inventories, sales performance and future technology plans. Communication and cooperation required between competitors under REACH should therefore not be used as a forum for cartel behaviour among SIEF or consortia participants. (Consortia are created by industry participants on a voluntary basis, in contrast with mandatory SIEF participation.)

A separate set of concerns arise where data exchange is used or has the effect to hinder, raise barriers to or defer entry of substance manufacturers or importers into the market. We focus here particularly on consortia activities.

How to challenge refused data access

Under REACH, data owners in the SIEF who refuse to supply requesting SIEF participants with vertebrate data are prohibited from proceeding with their own registrations and may be subject to penalties. For studies not involving vertebrate animal testing, data owners may refuse to disclose studies without fear of being denied registration (though the ECHA's Data Sharing Guidance³ invites Member States to apply penalties in such circumstances). A complaint to national enforcement authorities may be a first port of call if negotiations do not succeed.

³ ECHA's guidance on data sharing is available at http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.htm?time=1244545376.

Under EC competition rules, a collective refusal by consortium members to grant access to studies may amount to an unlawful boycott contrary to Article 81 of the EC Treaty. While this behaviour appears less likely to arise in the context of studies involving vertebrate testing, this would seem more likely for non-vertebrate studies.

Alternatively (absent evidence of a boycott), consortium members' collective refusal to provide access to studies may be caught by Article 82 EC, which prohibits the abuse by one (or more) undertaking(s) of its (their) dominant position. If the consortium enjoys significant market power in relation to the relevant substance, a refusal to supply is likely to be found restrictive and unlawful if it:

- relates to a study that is objectively necessary for other potential registrants to complete registration and compete effectively in the market or the substance;
- is likely to lead to the elimination of effective competition in the market; and
- is likely to harm consumers.

A defence that non-consortium members could have conducted their own study may not be sufficient to counter an allegation that the consortium committed an abuse of its dominant position. This is particularly the case if the time and resources necessary to complete the study would prevent a SIEF member outside the consortium meeting its registration deadline or cause it to abandon the registration. Mere inconvenience to a data access purchaser is, however, unlikely to form a successful basis for an allegation of anticompetitive behaviour.

How to ensure that you have access to useful data

REACH provides a narrow scope for data owners to claim protection, with justification, of their legitimate business secrets or IP rights, enabling them to opt out of the general requirement to submit a joint dossier. The right to opt out does not apply to the data sharing obligations. However, use of this opt-out may limit disclosure to such an extent that requesting participants are not in a position to evaluate the relevancy and reliability of a study. ECHA's Data Sharing Guidance recommends that, in the event of a dispute, the parties appoint an independent third-party to evaluate the appropriateness of a confidentiality claim and the relevancy and robustness of the studies concerned. Those recommendations are non-binding and might well be ignored by data owners. However, if there is evidence of a boycott or if consortium members enjoy significant market power, requesting parties might successfully argue that the refusal to give adequate disclosure constitutes a competition law

infringement and that therefore sensitive business information (even that protected by IP rights) should be made available in a meaningful format so as to allow requesting parties to proceed with registration.

How to ensure you only pay for data you need

Consortium members may “bundle” a requested study with other studies, offering the package to SIEF members for a global fee. This practice is common under other EU chemicals regimes (such as biocides and pesticides) but is restricted under REACH, which expressly provides that registrants “are only required to share in the costs of information that they are required to submit to satisfy their registration requirement”. There may be scope for bundling nonetheless, on the basis that the requested data *requires* accompanying data to be comprehensible (the two are *tied* by necessity). Consortia which hold significant market power will need to ensure that all tying practices can be objectively justified.

Strategic pricing behaviour

An excessive price for data access may place the requesting party at a competitive disadvantage.

Price calculation and cost sharing methods

REACH provides that parties must make “every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way” (similar to the well known “FRAND” test used by competition and IP lawyers). Only those studies that provide a sufficient degree of reliability and relevancy qualify for financial compensation. Whilst REACH obliges data owners to provide proof of costs, it does not dictate how this is to be demonstrated. For example, there is no express requirement to itemise each cost element.

ECHA’s Data Sharing Guidance sets out three possible alternative cost-allocation methodologies (though parties remain free to agree on any cost-allocation model):

- equal sharing according to the number of parties;
- proportional sharing according to production or sales volume; or
- methods combining a mixture of the two previous methods.

Concerted action, collective dominance and excessive pricing

EC competition rules prohibit anticompetitive agreements or concerted practices. SIEFs and consortia cannot therefore be used to facilitate cartel activities (such as price-fixing) or be party to restrictive schemes aimed at excluding actual or potential competitors. It may be possible to insist upon third-party access to the results of studies carried out jointly (within or outside consortia) applying the same principles used concerning technology licensing. The European Courts of Justice have upheld the principle that IP owners who hold a dominant position must license their technology under Fair Reasonable and Non-Discriminatory terms (FRAND) (see Case T-201/04 *Microsoft v Commission*). As a rule of thumb, the stronger the combined market share of the consortium's membership, the more important it is for the consortium to establish and operate objectively defensible data access and pricing criteria. If a consortium is the only available source for certain data, it might be argued that it or its members have a duty under competition law to provide data access (under FRAND terms) to other SIEF participants.

Potential complainants, unsatisfied with allegedly excessive pricing, might rely upon the three cost-allocation methodologies set out above. They may also demand that a consortium provide details on the data valuation method, the cost parameters taken into account and the relationship between costs expended and fees charged to data access purchasers. Based on this information, the requesting party should be in a position to verify that the fee is commensurate with the costs associated with the data.

Finally, entry or membership fees to the consortium may also affect competition in the relevant product market. An excessive entry fee may be an alternative method of excluding or arbitrarily discriminating against potential entrants. In general, the costs of entry into a consortium should be objectively justifiable (normally a reflection of prior administration costs incurred). Consortia should not attempt to limit or discourage access to the consortium via high entry fees (or ambiguous, discriminatory or excessively demanding membership conditions).

Avoiding price discrimination

Any differentiated treatment between consortium members and non-members as regards costs payable to a consortium will have to be objectively justified:

- Efforts and resources that each member has dedicated to a consortium's activities are a reasonable basis for cost differentiation. However, precise valuation of "sweat equity" is notoriously difficult to achieve and data sellers and access purchasers should both be attentive to this element in any pricing formula.
- Cost sharing structures based on volumes supplied in the EEA⁴ - the larger the supplier, the higher the fee - are acceptable. Careful thought needs to be given to how companies in the same corporate group (but not paying members of the consortium) will be treated.
- It remains to be seen whether a "risk premium" on top of the cost of data generation (a sum currently common in biocide and pesticide data compensation negotiations) will sustain scrutiny under REACH.

Next steps

Companies within and outside consortia need to prepare themselves for the very real competition issues which REACH's data sharing and compensation regime presents. Whilst REACH envisages some level of arbitration by the ECHA and enforcement of compensation claims by national courts, there are a number of situations where requesting parties may have no alternative than to use EC competition rules as a "sword" to access data on reasonable terms.

Our next REACH webinar: "REACH: Next Steps in Registration and TSCA Reform" will be held on 23 June (1600-1730 CEST (10:00 - 11:30 am EDT). To register, visit <http://www.steptoel.com/news-events-1083.html>.

⁴ More information about the European Economic Area (EEA) can be found at http://ec.europa.eu/external_relations/eea.

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