A PERIODIC REPORT FROM STEPTOE & JOHNSON LLP

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1. REACH: KEY COMPETITION ISSUES

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The authors acknowledge the valuable contributions of Laura Atlee, Craig Simpson and Jean-François Guillardeau.

Overview

REACH (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). 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.)

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 Guidance 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.

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 for 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 EEA - 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.

For further information on Steptoe's EU Competition group please visit our website.

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). Click here to register.

2. NEW CLASSIFICATION AND LABELLING REGIME

By Darren Abrahams, Bobby Arash and James Searles

Overview

Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation) is the EU's implementation of the UN's Globally Harmonised System for Classification and Labelling of Chemicals (GHS). GHS is intended, in part, to facilitate the global trade of chemical products by establishing common "building blocks" of a harmonised approach to classification and labelling. However, nations adopting GHS are not obliged to cover all the hazard elements it addresses (they can choose which building blocks to implement), so the EU's classifications may differ from those of other of other GHS implementing nations.

The CLP Regulation replaces the regimes contained in Directives 67/548/EEC and 99/45/EC concerning dangerous substances and preparations, and is designed to make minimal adjustments to REACH and other downstream use legislation.

Key changes

Hazard communication

The CLP Regulation applies the GHS hazard class system, with eight hazard categories (indicating severity). It also introduces new hazard symbols (pictograms) and other graphic elements including signal words ("warning" and "danger").

A new emphasis has been given to assessment of physical and chemical properties by aligning the classification and labelling system with the test methods and criteria set out in the UN's Recommendation on the Transport of Dangerous Goods, Manual of Tests and Criteria. For other properties (such as eco-toxicity and toxicity) the test methods remain those used under the prior EU regime. This will significantly change the manner in

which the hazards associated with chemical products is conveyed.

Supply chain obligations

Manufacturers, importers and downstream users must classify and label their substances or mixtures *before* placing them on the market (in the EEA). Manufacturers, producers of articles and importers are also required to classify those substances (in the articles) which are *not placed on the market* (under certain conditions).

Suppliers in a supply chain must "cooperate to meet the requirements for classification, labelling and packaging" and cooperate to complete any later changes to labelling "without undue delay". This is likely to have a significant impact on the contractual relationships between manufacturers, importers, downstream users and distributors.

Harmonised classification and labelling

Prior to the CLP Regulation, harmonised classifications and labelling procedures were set out principally in Title XI of REACH. Member States' Competent Authorities could submit proposals to ECHA for harmonised classification and labelling or propose amendments to already existing harmonised classifications and labels. The CLP Regulation introduces a new mechanism for establishing harmonised classification and labelling. Under these new procedures, the right to propose harmonised classifications and labelling has been extended to include industry (under specific conditions). Manufacturers, importers and downstream users may propose to:

- **ECHA**, a new harmonised classification and labelling provided that there are no entries in Part 3, Annex VI for that hazard class or differentiation covered by that proposal; or

- **a Member State Competent Authority**, new information which may lead to a change of the harmonised classification and labelling elements of a substance which is already listed in Part 3, Annex VI of the CLP Regulation (which the Member State then submits to ECHA).

In both cases, ECHA's Committee for Risk Assessment issues an opinion on the proposal to the European Commission (Commission) and also forwards comments received from concerned parties. The Commission then proposes a decision on harmonised classification and labelling which may be adopted under the Regulatory Procedure with Scrutiny (involving both Member States and the European Parliament). This new decision making process appears to offer greater transparency and an opportunity for industry to provide new information on substances and mixtures.

Packaging

In addition to complying with the CLP Regulation, packaging must also respect the applicable labelling rules found in EU legislation on the transport of dangerous goods:

(a) If a package consists of **inner** (including intermediate) **and outer packaging where outer packaging must be labelled** according to transport legislation, then: (i) the *inner* packaging *must* be labelled according to the CLP Regulation, and (ii) the *outer* packaging *may* be labelled according to CLP Regulation (the pictograms do not need to be repeated on the outer packaging).

(b) If a package consists of **inner** (including intermediate) **and outer packaging where outer packaging does not need to be labelled** according to transport legislation, then the inner and outer packaging *must* be labelled according to the CLP Regulation. If the outer packaging is transparent (or where the labelling of the inner/intermediate packaging is visible) then the outer packaging does not need to be labelled at all.

(c) **Single packaging** that meets the labelling requirements of transport legislation must be labelled in accordance with both the CLP Regulation and transport legislation (the pictograms do not need to be repeated).

Companies should be prepared for questions from customers who may not be familiar with the relationship between the two applicable regimes.

CLP Regulation timelines

The CLP Regulation establishes a complex transitional system for suppliers to convert their current classification, labelling and packaging to the new system, which is set out in the diagram at the end of this article. Until 1 December 2010, substances must be classified, labelled and packaged according to Directive 67/548/EEC. A similar transitional period is provided for mixtures, under which a supplier must, until 1 June 2015, classify, label and package mixtures according to Directive 99/45/EEC. Additionally, suppliers *may* choose to comply with the CLP Regulation during these periods, in which case they must also label and package their substances and mixtures applying its rules.

From 1 December 2010 until 1 June 2015, substances must be classified in accordance with the CLP Regulation and Directive 67/548/EEC. However, they only need to be labelled and packaged according to the CLP Regulation. If the substance was placed on the market before 1 December 2010 and classified, labelled and packaged according to Directive 67/548/EEC, the CLP Regulation provides a derogation until 1 December 2012 for labelling and packaging under the CLP Regulation.

The CLP Regulation provides a similar derogation for labelling and packaging of mixtures. If the mixture is placed on the market before 1 June 2015 then it does not have to be re-labelled and re-packaged according to the CLP Regulation until 1 June 2017.

Finally, from 1 June 2015, the CLP Regulation repeals both Directives 67/548/EEC and 99/45/EC and require that substances and mixtures are classified, labelled and packaged according to the new system under the CLP Regulation.

These transitional periods are to some extent aligned with REACH registration deadlines. However, those deadlines are triggered not only by tonnage thresholds but also by whether a substance has a certain hazard classification. Changes in the classification of a substance (as compared with the predecessor regime) may not become apparent until 2015 (when the CLP rules become mandatory). The effect of this could be that some substances escape the first REACH registration deadline (1 December 2010). This appears to have been overlooked during the adoption of the CLP Regulation. Registrants will need to make a strategic decision on how to address the application of the overlapping old and new regimes as part of any comprehensive REACH compliance activities.

Impact on the commercial sector

The CLP Regulation contains a range of welcome changes concerning procedural transparency and the potential for industry participation. However, new concerns arise, including the following:

- Some of the entries which have been transferred to Part 3, Annex VI of the CLP Regulation (without a new evaluation) are over 20 years old. There is a case for reviewing certain substances under the more transparent procedure of the CLP Regulation.

- The CLP Regulation imposes a significant additional cost on industry (related to the updating of Safety Data Sheets, labels and packaging, REACH registration dossiers, and generation of new studies for the new hazard classes, etc.)

Next steps

Companies should be actively engaged in *at least* the following measures:

- ensuring that adequate infrastructure and resources are in place to deal with re-classification, re-labelling and re-packing of substances and mixtures;

- assessing how obligations under the CLP Regulation affect current activities under REACH (for example, will a dossier update be required) and other downstream use legislation; and

- completing a compliance audit to ensure that labelling of packaging complies with both the CLP and transport of dangerous goods regimes.

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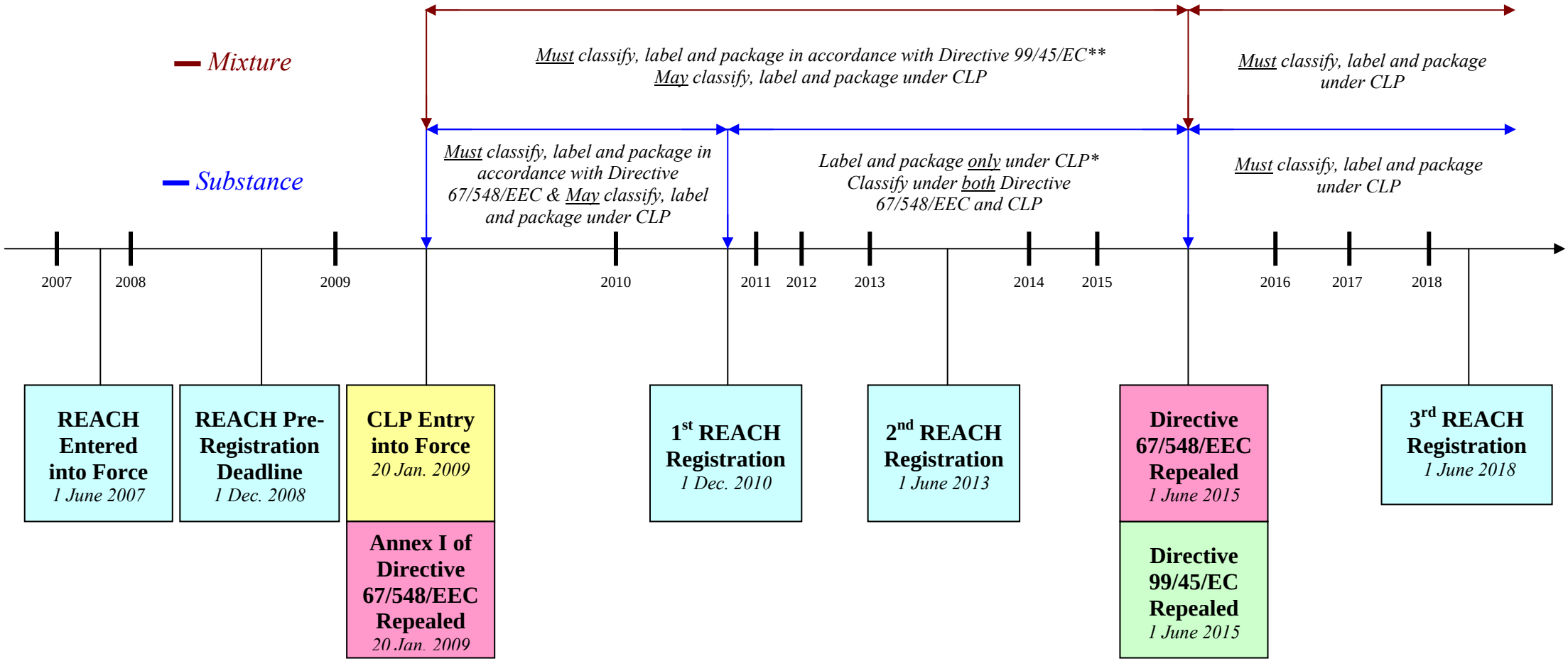
Classification and Labeling Timeline for Mixtures & Substances



** If the substance is placed on the market before 1 Dec. 2010, then it is not required to be re- labelled and re-packaged under CLP until 1 Dec. 2012.*

*** If the mixture is placed on the market before 1 June 2015, then it is not required to be re-labelled and re-packaged under CLP until 1 Jun. 2017.*

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If you have any questions concerning this briefing, please contact Darren Abrahams (dabrahams@steptoe.com).

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