The REACH implementing regulation on data sharing: A fairer approach?

Matthew Curl of **TSGE Consulting** looks at a key new element of REACH

Although European regulations go through extensive drafting, review and commenting processes, followed by a political process in the European Parliament, they may still not be clear on all points and, importantly, may not work in the way expected or intended. If a regulation falls short of expectations, the European Commission (EC) may issue an additional regulation to resolve any apparent shortcomings.

These additional regulations are referred to as 'implementing regulations'. In January this year, the EC issued an implementing regulation, EU 2016/9, 'on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006', i.e. REACH.

The background to this was apparently a steady stream of complaints from SMEs about the high cost of 'access' to REACH joint registrations and the perceived lack of transparency in how these prices had been determined.

The REACH regulation is clear that the costs relating to sharing information should be determined in a fair, transparent and non-discriminatory manner. Many joint registrants felt that this was not the case.

The EC concluded, in Recital 2 of the implementing regulation, that "provisions of Regulation (EC) No 1907/2006 on data-sharing and joint submission have not been used to their full potential, their implementation [is] falling short of expectations. This has been especially prejudicial to small and medium-sized enterprises". The EC therefore opted to publish the 'implementing regulation on data sharing', to which it is conveniently referred.

Although there are a number of legal question marks over aspects of the regulation, this article is not intended to be a legal review. I hope here to simply consider some of the provisions of the regulation and to relate these effects to lead registrants (LRs), data owners, consortia and non-lead joint registrants, i.e. sellers and buyers of access to data.

The purpose of the implementing regulation is to address transparency, fairness and non-discrimination, and to provide a framework for dispute resolution. The regulation also includes an article concerned with the principal of 'One substance, one registration', which is also related to data sharing.

Key points

The regulation is five pages long (including the recitals) and includes six articles. The first key point is that under the original REACH regulation the sharing instructions referred to 'information' and study data only.

The new implementing regulation includes a much broader set of costs. It refers to 'costs relating to sharing and jointly submitting information' and to 'sharing of information and associated costs'.

This broadening of the scope of the data sharing provisions is important. Although the costs of running studies could be upwards of €1 million, in many REACH registrations the cost of data may be small or even zero.

For example, many data requirements have been addressed from public domain data. In this situation, the cost of data is small, but it may have taken considerable effort by a number of specialist scientists to find the data, evaluate its quality and prepare suitable IUCLID robust study summaries.

In addition, a suitable chemical safety assessment might be the result of considerable work to prepare higher tier exposure and risk assessments. The data costs in that situation will be trivial compared to the 'associated costs'. Prior to the implementing regulation, these 'non-data access' costs were not always transparently identified but included in access fees. To the advantage of sellers and the disadvantage of buyers, these fees are now clearly to be included.

The Article on Transparency (Article 3) places a number of obligations on the seller in the form of the data sharing agreement. Data sharing agreements have been in place since joint registrations started in 2010. Many of these are based on CEFIC model agreements or agreements drawn up on legal advice. The implementing regulation requires a number of specific items to be included in the agreements:

- Itemisation of the data to be shared, including the individual costs
- A description of which end point the data addresses
- A justification for how the data addresses the end point
- Itemisation and justification of any cost to create and manage the data-sharing agreement and the joint submission ('administrative costs')
- A cost-sharing model, which shall include a reimbursement mechanism

It is interesting to note here that one of the criticisms by SMEs was that administration fees were commonly charged without much, if any, explanation or detail. This article provides more definition.

In the case where a data sharing agreement already exists – which is, in most cases, for a substance that has already been registered – the "parties to that agreement may, by unanimous consent, waive their obligation to itemise the data". However, the regulation goes on to state that a potential registrant shall not be bound by an existing waiver, unless he consents to it, and he still has the right to request the information.

Although this option is available, it is difficult to believe that unanimous consent could be obtained and, since a potential registrant still has the right to request the information, the information must be prepared ready for such a request. It therefore seems that there is no point in seeking unanimous agreement and a seller may as well prepare new agreements.

The implementing regulation intends to make data access more eqvilable

Article 3 also requires that sellers should document annually any further costs incurred in relation to the agreement. This effectively requires that each seller needs to prepare an annual report of the administration of the data sharing process. It is unclear whether this is required if the seller does not charge for this work, but its inclusion in the regulation is likely to encourage sellers to do this, even where they have considered it unnecessary previously.

The problem for many sellers is that they originally aimed to minimise the administrative burden, aiming for simplicity and low costs for themselves and the buyers. Their sharing agreements were relatively simple. Their selling prices were fixed, on the assumption that further administration costs would be minimal. This would provide long-term certainty for buyers. Sellers now find themselves in the position where they are obliged to undertake more substantial administration tasks and are virtually obliged to charge buyers for this work.

Article 5 on 'fairness & non-discrimination' reminds registrants that they only need to buy access to information to satisfy their own

obligations. An Annex VII registrant does not need to buy access to data required for an Annex IX registration. This is an established principle and follows the provisions of the original REACH regulation.

The implementing regulation also specifically states that administrative costs are subject to that provision. However, there is, at present, no guidance on what this means. You would not expect general administrative costs to be less for an Annex VII registrant than for an Annex IX registrant. It is also arguable that an Annex VII registrant would benefit from the scientific work of the LR to ensure that the substance did not attract, say, a reproductive hazard classification, even though reproduction toxicity is not an Annex VII test.

The implementing regulation recognises that any cost sharing model should include the possibility of future costs. This allows for the possible costs to address compliance checks, dossier evaluations and substance evaluations. All of this may incur considerable expense.

Article 5 is clear that costs should be transparent. This includes specific data costs and the other administrative costs, although Article 2 recognises that LRs and consortia members may not have specific cost records dating back prior to the publication of the regulation and allows sellers to make a 'best approximation' of historical costs.

Article 5 also requires some form of seller reimbursement mechanism. This needs to consider all past registrants, but may also consider future registrants. In reality, it is likely that buyers will have to wait until well after the 2018 deadline before they receive any reimbursement. Buyers may also like to consider that the regulation states that reimbursements do not need to be paid if the costs of the reimbursement are higher than the amount to be reimbursed.

Conclusions

The implementing regulation on data sharing puts clear obligations on sellers of access to REACH joint registrations. From the eyes of a buyer, the obligations are fair and reasonable. Based on my work over the past ten years or so, most data sellers will also agree with the principles. Most LRs will have the information on data, activities and costs, although not necessarily in a format ready for inclusion in an agreement.

In the majority of cases, it is likely that SIEF agreements or data sharing agreements will need to be revised or even replaced. The replacement documents should include detailed information specific to each substance. This work will inevitably involve legal advice as well as scientific work.

The requirement to include reimbursement mechanisms also complicates the financial management of the process, where funds may now need to be held for several years. Data and access buyers will expect to be provided with all the information required by the regulation, so LRs and consortia will need to prepare new agreements and data lists, describe their sharing models and devise a reimbursement mechanism.

They may also need to set aside funds for reimbursement. Let us not forget that reimbursement works both ways and a buyer may find they have further fees to pay come 2018.

It is likely that buyers will get a fairer deal. They will be better informed on how the costs are calculated and incurred and they are more likely to receive a reimbursement on the access fee. That is broadly the objective of the implementing regulation on data sharing.

Buyers are, however, unlikely to see any overall reductions in the costs of access, since sellers now have a more onerous administrative environment in which to operate, and the regulation clearly allows sellers to include these costs in their sharing models.

In this situation, time will tell if fairer means cheaper. It should perhaps be noted that there is no mention of reduced costs in the objectives of the implementing regulation.

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