Data sharing

Introduction

In order to reduce as far as possible the level of vertebrate testing conducted for the purpose of compliance with the Biocidal Products Regulation (BPR), the Regulation requires that such testing is only undertaken as a last resort and that no testing is repeated. With regard to this second point, a fundamental aspect of the BPR is the obligation to share information about active substances and products approved and authorised in the EU. Applicants who are required by the Regulation to undertake vertebrate studies must first contact the European Chemical Agency (ECHA) to establish whether such tests have previously been submitted and, where such tests have already been undertaken, the data holder should share the results of the studies with the prospective applicant in exchange for a level of compensation agreed in a fair, transparent and non-discriminatory manner. The prospective applicant may also request the sharing of data not involving tests on vertebrate animals and, in the case of a submission to be included on the list of approved active suppliers, must do so.

Inquiry

In order to initiate the data sharing process under the BPR, any applicant who intends to perform tests or studies involving vertebrate animals should submit an inquiry to ECHA using the software tool R4BP3. This should be done even if the prospective applicant is already aware of who the data holder is as a pre-requisite of any data sharing dispute subsequently brought is that an inquiry has been made.

For data involving tests not on vertebrate animals, an inquiry through R4BP3 is optional, unless the data requirement is for a submission as an alternative supplier under Article 95. In such cases, the submission of an inquiry relating to all necessary data is a legal requirement.

Following the inquiry, ECHA will screen dossiers submitted under both the BPR and the Biocidal Products Directive (BPD) and, if the tests or studies requested have been submitted, provide to the applicant details of the data submitter. If the data submitter is not the data holder, then the submitter must facilitate contacts between the prospective applicant and the data owner.

Data protection periods

Article 60 of the BPR defines the period for which data submitted under this Regulation and the BPD is subject to protection. Once this protection period has passed the data may be referred to by a prospective applicant without the requirement to pay compensation to the data owner. Data

protection periods are dependent upon the nature of the initial submission made and are summarised in the table below:

Submission type	Data protection period
Data submitted for substance/product-type combinations included in the review programme but not yet approved.	Protection period ends 31 December 2025
Data submitted under the BPR for the approval of an existing active substance	10 years from the date of entry into force of the relevant Commission implementing Regulation
Data submitted under the BPR for the approval of a new active substance	15 years from the date of entry into force of the relevant Commission implementing Regulation
Data submitted under the BPR for the renewal or review of the approval of an active substance	5 years from the date of entry into force of the relevant Commission implementing Regulation
Data submitted for the authorisation of a biocidal product containing only existing active substance(s)	10 years from date of authorisation of the biocidal product
Data submitted for the authorisation of a biocidal product containing new active substance(s)	15 years from date of authorisation of the biocidal product
Data submitted for the renewal or amendment of the authorisation of a biocidal product	5 years from the date of renewal of the authorisation of the biocidal product

Compensation for data

Where the stated test has previously been undertaken, and the data protection period given in the above table has not yet passed, the prospective applicant must request from the data owner the scientific and technical data relating to those tests. The prospective applicant and the data owner must then make every effort to reach an agreement on the sharing of the results of the tests or studies requested. The Regulation requires that the prospective applicant share in the costs of information they are required to submit in exchange for compensation determined in a fair, transparent and non-discriminatory manner.

Determining what is a ‘fair’ cost for data may not be easy, and whilst commercial and legal considerations may dominate, science should also play a part. An objective should be to avoid unnecessary arguments which can be both costly and time consuming, but reality may not be that simple. Although the perspective of ‘fair’ may well vary between those who hold data and those who need to pay for access, the below factors should be considered when setting costs.

1. Extent of access granted

Most data will not be formally exchanged in the form of test reports, but instead a Letter of Access (LoA) will be provided by data owners to demonstrate that the applicant has been granted the right to refer to the data in the owners BPR dossier. Where an applicant requests the rights to a test report, rather than simply a LoA, they should expect to pay an increased sum as they may then use the data for an alternative regulatory regime. The legal requirement however, and what will

occur in a majority of cases, is that the data owner provides the right for the applicant to refer to the data for compliance with the BPR through a LoA.

2. Old for new costs

It is generally considered 'fair' that old data is considered to be worth its replacement value today, regardless of whether the original cost was higher or lower than today's price. Research by Fleischer[1] into costs of testing in Europe has been cited as a guide to value data.

3. Quality of data

The value of data may be assessed on the quality of the test report. It is proposed that if a report scores 2 or less on the Klimisch scale[2], then it is of lower value. However, an alternative view is that any valid report that prevents the cost of a new study has equal value: for example, a positive response in a Buehler sensitisation test not performed to GLP in 1985 has the same value in terms of preventing a new study being performed as a GLP local lymph node assay (LLNA) performed in 2008.

4. Surplus data

Historical data may include end-points not essential for a submission under the BPR. Some such data may relate to specific markets, such as cosmetics, offshore use in oil extraction, the aerospace sector. Where a major supplier has invested heavily to demonstrate safe use in a high-risk scenario they may wish to recover a share of those costs from others in the same market. However, the BPR requires that the prospective applicant only be required to share in the costs of information they are required to submit under the Regulation.

5. Management costs

One of the most contentious costs when prices for a letter of access have been set under the REACH Regulation is that of management or administrative fees. Whilst the prospective applicant may be concerned only about access to the data, and not necessarily how its technical accuracy has been established, the initial applicant will often have to put a considerable about of time and resource into putting the dossier together. They may also incur expenses related to running new testing (visiting laboratories, monitoring work etc) or may have paid out for the use of consultants.

Determining if these expenses are 'fair' will be difficult and there will be the arguments about whether the work could have been done without consultants or whether so many visits to the test laboratory were needed.

Disputes

The data owner must accept any payment which is offered by the prospective applicant, however if this is not for the agreed sum, or no agreement is reached on the compensation to be paid, the data owner has the right to have the proportionate share of the cost determined by a national court.

If more than one month has elapsed since ECHA responded to an inquiry with details of a data submitter, and where the prospective applicant can demonstrate that every effort has been made to reach an agreement and that they have paid the data owner a proportion of the costs, ECHA will

grant permission for the prospective applicant to refer to the tests. Once again, if no agreement is reached, the proportionate share of the costs will be determined by a national court.

REACHReady References

[1] *Testing cost and testing capacity in accordance with REACH requirements*, Fleischer M (2007). Journal of Business Chemistry, Volume 4, Issue 3, http://www.wirtschaftschemie.de/journal/2007_iss3_96-114.pdf

[2] *A systematic approach for evaluating the quality of experimental and ecotoxicological data*. Klimisch HJ, Andreae E and Tillmann U (1997). Reg. Tox. And Pharm. 25:1-5

