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Changes for alternative suppliers
of biocidal active substances under the BPR

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Abstract With the entry into application of the Biocidal Products Regulation (BPR) on 01 September 2013 companies which were previously not involved with supporting active substances they supply now have the opportunity to become engaged in the regulatory process and must do so to remain in the market. This article looks at some of the options open to companies and the benefits and drawbacks of supporting an active substance through the EU biocides system.

INTRODUCTION

Under the Biocidal Products Directive (BPD)(1) companies could legally supply active substances into the EU market without having to be involved in the support of these active substances through the BPD Review programme, as long as another company or group of companies were doing so. These non-involved companies were termed somewhat pejoratively as "free riders" by companies who had invested in the EU review programme by supporting active substances either individually or as part of consortia. Under the BPD it was recognised that following evaluation of the active substance and its inclusion on Annex I of the BPD, any subsequent product authorisations would require formulating companies to seek letters of access (LoA) to the active substance dossier or to submit their own active substance dossier (called a third party dossier) to allow their products to remain on the market. As companies not involved in supporting active substances would not be able to issue these LoAs then this was considered to be the end of the road for any free rider companies.

With the introduction of the new Biocidal Products Regulation (2) companies which previously had not been involved in the regulatory process have been given the opportunity to become engaged and in fact must do so to remain on the market.

The BPR aims to ensure that the costs of the data on active substances are equitably shared. Therefore, all active substance manufacturers and importers placing active substances on the EU market must contribute to the costs.

From 01 September 2015 an active biocide substance will not be legally on the market in the EU unless the substance and supplier are listed on a positive list of active substance suppliers generated by the European Chemicals Agency (ECHA). To be included on this list companies must submit certain information to ECHA. Companies that have not already submitted their own dossier on an active substance under the BPD or the BPR must either submit a dossier, a letter of access, or, if all data protection periods have expired, a reference to an existing dossier to ECHA.

A provisional version of this list is available on the ECHA website but this provisional list does not currently include alternative suppliers.

Therefore, a biocidal product cannot be placed on the EU market after 01 September 2015 if the manufacturer or importer of the active substances contained in the biocidal product, or where relevant, the importer of the biocidal product, is not included in the list. This means that alternative suppliers are now obliged to become involved with the regulatory process.

OPTIONS OPEN TO ALTERNATIVE SUPPLIERS

Article 95 of the BPR (Transitional measures concerning access to the active substance dossier) states that, as of 01 September 2013, any person wishing to place active substance(s) on the Union market on its own or in biocidal products (the "relevant person") shall, for every active substance that they manufacture or import for use in biocidal products, submit to the Agency:

(a) a dossier complying with the requirements of Annex II, or where appropriate, with Annex IIA of Directive 98/8/EC; or

(b) a letter of access to a dossier as referred to under point (a); or

(c) a reference to a dossier as referred to under point (a) and for which all data protection periods have expired.

Some of the benefits and pitfalls of these various options are discussed below.

Option (a): a new dossier

For a dossier submitted complying with the information requirements in Annex II of the BPR or Annex IIA of the BPD it is required to submit the following (in line with Annex III of Regulation (EC) 1451/2007):

- Document II A summarising the intrinsic properties of the active substance,
- Document III A ((robust) study summaries),
- Document IV (original test reports),
- IUCLID dossier file,
- A reference list of the studies submitted,

- Listing of Endpoints (LOEP),
- Where relevant the decision from ECHA on the permission to refer to requested data in line with Article 63 must be submitted.

An applicant may propose to adapt the data as explained in Article 6(2) of the BPR. If data are waived a justification will have to be provided, it should be noted however that it is not allowed to submit a test proposal otherwise the dossier will not satisfy the data requirements and is therefore incomplete.

Following the principles of mandatory data sharing, applicants must share and not duplicate studies and tests on vertebrate animals (which should be undertaken as a last resort). Because of this if you are developing a new dossier the first step is normally to undertake a data gap analysis against the dossier requirements. This will involve assessing any data that the company owns or has access to. Public domain data may be used in some cases particularly where a body of evidence approach is taken. Where data gaps are identified which cannot be subject to waivers for studies involving vertebrate animals (but optionally for toxicological, ecotoxicological and fate studies not involving tests on vertebrates) data sharing must be followed. Under the revision to the BPR (see below) the right to refer to data is extended to all studies required for the human health and environmental risk assessment, this now applies to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates.
Any active substance supplier intending to perform tests or studies may, in the case of non-vertebrate animal tests, and must, in the case of vertebrate animal tests, inquire with ECHA via R4BP 3 whether such tests or studies have already been submitted to any competent authority or to ECHA under the BPD or the BPR. ECHA will provide the prospective applicant with the contact details of the relevant data submitter. This inquiry step is a pre-condition before any data sharing dispute can be brought before ECHA because the relevant timelines for the dispute procedure are calculated from the date on which ECHA provides the contact details of the data submitter.
Where a request has been made in accordance with BPR Article 62 (2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results from the tests or studies requested by the prospective applicant.
An accurate and transparent evaluation of studies is a critical component of the data sharing process. The BPR makes reference to the REACH guidance on data sharing which outlines the principles to be used in determining the value of a study.
The prospective applicant is required to share only in the costs of information that it is required to submit for the purposes of the BPR, leading to the possibility of 'cherry picking' only certain studies.
Prospective applicants and existing data owners must make every effort to reach an agreement to ensure that the cost of sharing the information is determined in a fair, transparent and non-discriminatory way. All parties must fulfil their data sharing obligations in a timely manner.
If no agreement can be reached, Article 63 (3) of the BPR allows a prospective applicant to inform ECHA at the earliest one month after discussions commence, of the failure to reach an agreement with the data owner(s)/submitter(s) on the sharing of existing data in the context of an application dossier in preparation. Many companies think the-one month time period to be much too short for this to be achieved.
Provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred, ECHA will (within 60 days of being informed) give the prospective applicant permission to refer to the requested tests or studies on vertebrates. Where the prospective applicant and data owner cannot agree, national courts shall decide on the proportionate share of the cost that the prospective applicant is to pay to the data owner. The data owner shall not refuse to accept any payment offered and any acceptance is without prejudice, to his right to have the proportionate share of the cost determined by a national court. The decision of ECHA can be appealed under Art 77 of the BPR.

Option (b): a letter of access

Letters of Access (LoA) are, in principle a good option for alternative suppliers and regulators alike as it allows alternative suppliers to benefit from the effort already expended in developing and supporting dossiers by companies or consortia already involved with the review programme. It also means that regulators do not have to review large amounts of new data with possible negative impacts on endpoints and decisions already made. In addition, companies who have been involved with the process can share overall costs. It should however be recognised that the costs of a LoA for an alternative supplier may be very high. Details of what should be included in a LoA are provided in Article 61 of the BPR.
There are many reasons for the high LoA cost, notably that the LoA will include the cost of any data (study reports, etc., owned by the consortium or its members), dossier preparation, consortium management over many years, dossier evaluation fees and ongoing dossier support. In the case where alternative suppliers may seek to join an existing consortium they may also incur late joiner penalties, the inclusion of non-essential studies and, in some cases, multiple studies on particular endpoints which may inflate the overall cost.
It should be noted that the BPR makes explicit reference in Recital 58 to the objective "of avoiding the establishment of monopolies, of sustaining free competition between economic operators and of equitable compensation of the costs borne by data owners". The provisions of EU Competition Law therefore needs to

be considered by both data owners and alternative suppliers but is outside the scope of this article.
Submissions may consist of both a LoA and data for the endpoints not covered by the LoA.

Option (c): reference to a dossier for which all data protection periods have expired

Currently this is not thought to be an option as it is understood that no dossiers exist where all the data protection has expired. Companies following option (a) above may try to identify individual studies where data protection has expired but further to this the benefits of this option are currently somewhat academic.

Note: Article 95 does not require the prior establishment of technical equivalence via an application to ECHA under Article 54. However, regardless of the submission type (full dossier, LoA or a combination of both) information regarding the identity of the active substance as defined in Annex II of the BPR or Annex IIA of the BPD needs to be provided. ECHA does offer a chemical similarity and technical equivalence service. The chemical similarity check differs from the technical equivalence assessment under Article 54 of the BPR because a decision on the approval of the active substance has not yet been adopted and, therefore, the official reference source of the active substance is not yet established. The chemical similarity check service is an additional service provide by ECHA that was not foreseen under BPR, and is of a voluntary nature. The service is accompanied with a charge depending on the scope of the assessment to be carried out.

NEXT STEPS

All submissions made to ECHA will go through a compliance check to confirm that the information submitted is complete and complies with the requirements of Article 95 (1). This compliance check will confirm if:

- the information provided (directly and/or indirectly through a LoA) covers all the endpoints needed, including justifications for the adaptation of information requirements. This must include all of the requirements of Annex II of the BPR or, where appropriate with Annex IIA of the BPD;
- the identity of the active substance supports the submission in any dossier is submitted;
- in the case of a LoA, that the identity of the active substance matches that covered by the LoA;
- in the case where studies were submitted ECHA will check whether the information provided for the endpoints required, including waiving statements, is adequate and of sufficient quality;
- a LoA is submitted, ECHA will check if the LoA complies with Article 61 of the BPR;
- the submission consists of a reference to a dossier for which it is claimed that all data protection periods have expired ECHA will check this claim.

A positive outcome of the compliance check is a condition for being placed on the active substance supplier list. ECHA will inform the applicant if the submission is non-compliant stating also the reason(s) for the non-compliance. It is unclear how long ECHA will require to perform the compliance check and the only advice from them is that alternative suppliers submit as soon as possible after 01 September 2013 to maximise the time for the compliance check. In case of a late submission ECHA cannot guarantee that the compliance check is finished before 01 September 2015, enabling them to decide before that deadline if the alternative supplier will be placed on the list. Recent indications from ECHA are that initial Article 95 submissions have been lower than anticipated indicating that alternative suppliers may be intending making applications nearer to the deadline. This may mean that if a last minute flurry of submissions is seen it is possible that the compliance checks may not be completed in time to allow companies to be included on the ECHA list before 01 September 2015.
The Commission has published an amendment to the BPR which contains several changes to Article 95. including the ability to apply for data sharing of environmental fate studies under Article 63(3) (3). This new Regulation entered into force on 25 April 2014 with some aspects being retrospectively applied from 01 September 2013. These amendments affect the way Article 95 is implemented and also the available guidance (4).

CONCLUSIONS

Article 95 of the BPR is intended to ensure equal treatment of persons placing active biocidal substances on the EU market and is aimed mainly at alternative suppliers. It provides companies supplying active substances who had previously not been engaged with the regulatory process the opportunity to become involved and to continue supplying into the EU market. It is recognised that the various options open to alternative suppliers will involve considerable cost and it is intended to ensure that all players contribute to the costs of the active substance approval process. Of the possible options open to alternative suppliers the ability to obtain a LoA (or join an existing consortium) should be considered as it offers benefits to new suppliers, existing data owners and regulators alike.
It is however known that costs being provided to alternative suppliers have in some cases been considered to be excessive and many companies are exploring the option of submitting their own dossiers. For companies seeking to gain access to specific studies, the compulsory data sharing provisions of the BPR and the transitional measures covered in Article 95 appear to favour applicants and data sharing provisions, including toxicological and ecotoxicological studies not involving tests on vertebrates.
This has been extended to environmental fate and behaviour studies under the revision to the BPR. Data compensation routes also appear to favour companies seeking data and it is likely companies seeking data will be involved in critically assessing the costs that they are being asked to pay.
It is certain that Article 95 presents a number of challenges to both industry and regulators alike but alternative suppliers must take action well before the 01 September 2015 deadline to allow ECHA to evaluate any submission and make a decision regarding placing them on the approved supplier list; otherwise, continued supply cannot be maintained.

REFERENCES AND NOTES

1. Council Directive 98/8/EC of 16 February 1998, Official Journal of the European Communities, 24 April 1998, L123/1.
2. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
3. Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market
4. Guidance on active substance suppliers GUIDANCE ON REGULATION (EU) No 528/2012 CONCERNING THE MAKING AVAILABLE ON THE MARKET AND USE OF BIOCIDAL PRODUCTS (BPR) Version 1.0 July 2013. http://echa.europa.eu/documents/10162/15623299/biocides_guidance_active_substance_suppliers_en.pdf

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