Challenges presented by the BPR

Dr Richard Elsmore of JSC International looks at four of the thorniest issues in the new Biocidal Products Regulation

The Biocidal Products Regulation (BPR, 528/2012) has applied since 1 September 2013 and has repealed and replaced the Biocidal Products Directive (BPD, 98/8/EC). Although it is based on the principles laid down in the BPD, the BPR does introduce a number of new concepts that will impact how biocidal products and the active substances they contain will be regulated in the future.

As with many new pieces of legislation, the BPR presents a number of issues that both industry and the regulators must work through to resolve. This article examines some of the more contentious ones and how they may be addressed, notably the requirements for alternative suppliers of active substances, options for data sharing and data compensation and the obligations for treated articles.

**Article 95: Alternative suppliers**
The preamble to the BPR states that, in order to ensure the equal treatment of persons placing active substances on the market, they should be required to hold a dossier, or have a Letter of Access (LoA) to a dossier or to relevant data in a dossier, for each of the active substances they manufacture or import for use in biocidal products.

Biocidal products containing active substances for which the relevant person does not comply with this obligation should no longer be made available on the market, the BPR stipulates. In such cases, there should be appropriate phase-out periods for the disposal and use of existing stocks of biocidal products.

The details on how this will be achieved are covered in Article 95 of the BPR on transitional measures concerning access to the active substance dossier. This article is intended to address the situation where companies who were not involved with supporting active substances, sometimes referred to as ‘alternative suppliers’ or ‘free riders’, were still able to supply legally biocidal products containing active substances in it or, where relevant, the importer of the biocidal product, is not included in the list.

The provisional list includes only companies supporting active substances through the BPD review programme, those that have submitted dossiers on new active substances and those that have submitted third party dossiers. It is intended that this list will be updated as alternative suppliers make submissions. Alternative suppliers wishing to be included in the ECHA list will be exploring these options.

In many cases, the costs of joining an existing consortium or obtaining a LoA from an existing consortium have been very high. There are many reasons for this, notably that they 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. They may also include late joiner penalties, the inclusion of non-essential studies and, in some cases, multiple studies on particular endpoints which may inflate the overall cost.

Where agreement on joining an existing consortium cannot be made or where the costs of LoAs are thought to be excessive, alternative suppliers have the option to develop new dossiers either individually or under the umbrella of an alternative consortium. If a new dossier is submitted, sufficient time must be allowed for ECHA to undertake a compliance check.

A positive outcome from the compliance check is a condition for being placed on the ECHA list. At this stage it is unclear how long ECHA will need to complete this step. The development of new dossiers leads into the next set of contentious issues, that of compulsory data sharing (Article 62) and data compensation (Article 63).

**Article 62: Data sharing**
Under the BPR, testing on vertebrates should be undertaken only as a last resort and must not be repeated for the purposes of the BPR. Under Article 62, data sharing shall apply to data involving tests on vertebrates and may apply in the case of data not involving vertebrates.

Sharing data can be as contentious as sharing anything else.

**The transitionary measures for active substances, Article 95 (1), states that data sharing shall apply to all toxicological and ecotoxicological studies, including any not involving tests on vertebrates.** Under the EC’s proposal for a revision to the BPR, this is extended to include environmental fate and behaviour studies relating to substances in the review programme, including any such studies not involving tests on vertebrates.

Prospective applicants intending to perform new tests on vertebrate animals have an obligation to find out which tests and studies are already available, by submitting an inquiry through R4BP3 to ECHA. This must be done even if the applicant knows who the data owner is. Enquiries regarding studies not involving tests on vertebrate animals can also be made. ECHA will provide the contact details of the corresponding data submitters.

For companies that have spent many years developing data on their active substance, the concept of compulsory data sharing can be anathema but the principles of preventing unnecessary testing on vertebrates are not to be argued with. The ability of prospective applicants to ‘cherry pick’ key studies from existing dossiers appears to be accepted but, again, is not popular with data owners.

**Article 63: Data compensation**
Where a request has been made in accordance with 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 valuation 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.

ECHA has published an explanatory note that can be used to determine which sections of the REACH guidance on data sharing are relevant under the BPR. As a starting point, studies should be assessed in terms of their scientific quality (reliability, relevance and adequacy).

Next, a financial value can be determined taking account of correcting factors, which will lead to an increase or reduction of the values assigned, where appropriate. For companies that have been involved with REACH, the principles of data valuation...
should be familiar, but, to aid impartiality, it may be advisable to obtain an independent valuation. Agreements on data sharing may be replaced by the submission of the matter to an arbitration body and a commitment to accept the arbitration order. Compensation for data sharing must be determined in a fair, transparent and non-discriminatory manner, as per the guidance established under REACH.

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) allows a prospective applicant to inform ECHA at the earliest one month after discussions commence the failure to reach an agreement with the data owner(s) or submitter(s) on the sharing of existing data in the context of an application dossier in preparation. Many companies think the one-month period to be much too short for this to be achieved.

Raising a data sharing dispute with ECHA involves a prospective applicant submitting a web form and providing documentary evidence (copies of letters and other documents relating to the negotiation) demonstrating the efforts made by all parties compelled to reach an agreement on sharing data. This documentary evidence may consist of:

- Correspondence requesting the conditions of access to the data
- Correspondence from the data owner or submitter describing the conditions for the sharing of the data
- Correspondence challenging valid grounds the conditions imposed by the data owner or submitter
- Any further justification or modification of the conditions provided by the data owner or submitter
- Correspondence challenging these justifications that the other participants would consider unfair, non-transparent or discriminatory
- Notification of the previous registrant(s) by a letter and a proof of transmission that ECHA will be informed of their joint failure to reach an agreement

Based on the documentary evidence, ECHA can perform an informed and balanced assessment of the claim. A data owner must not refuse to accept any payment offered for data but any acceptance is without prejudice to his right to have the proportionate share of the cost determined by a national court.

Where ECHA decides that, for example, the documentary evidence demonstrates that the data owners have not met their obligations to make every effort to share the data and its costs in a fair, transparent and non-discriminatory way, the prospective claimant will receive from ECHA permission to refer to the studies already submitted together with a copy of the studies disputed.

The data owners will have a claim on the claimant for an equal share of the cost incurred by him, which will be enforceable in the national courts. Claimants must obtain a decision from ECHA confirming that they have met their obligations before proceeding with the submission of their application. Data owners may bring an appeal under Article 77 of the BPR, which will have a suspensive effect.

The issue of compulsory data sharing and data compensation appears to have split industry into two camps of data owners and those seeking access to data. That said, in some cases a company might be both a data owner for one substance and trying to access data for another, thus finding itself in both camps.

Article 58: Treated articles

The BPR introduces the concept of treated articles. Under the BPR, these differ from the more familiar concept of articles under REACH and are defined as any substance, mixture or article which has been treated with, or which intentionally incorporates, one or more biocidal products.

The inclusion of treated articles within the scope of the BPR has been brought about by...
The definition of a treated article under the BPR is potentially very wide

following recent high profile cases where an unregulated biocidal active substance was used to preserve leather goods and resulted in cases of severe skin irritation. In addition, treated articles are now within its scope to avoid discrimination between those originating in the EU and those imported from third countries.

A treated article that has a primary biocidal function is considered a biocidal product and will require authorisation accordingly, while those simply making a claim relating to its biocidal properties will require specific labelling (Article 58(3)). This labelling will also be needed for treated articles containing active substances where the conditions of approval required of the active substance make reference to the need for specific labelling. At the time of writing, there are no examples, but this requirement is likely to be included in future approvals, e.g. for substances that are skin sensitisers.

A third class of treated articles would be products that are simply preserved with a biocidal product but for which no claims of a biocidal function are made. In this case, as long as the active substance does not trigger the labelling requirement, these products will not require specific labelling under Article 58(3).

There is still much discussion on the interpretation of a number of aspects of the BPR regarding treated articles; this is further complicated by proposed changes to the legislation. A draft guidance document has recently been agreed, having been under discussion for many months, although it is likely that it will need redrafting when the BPR is amended in 2014.

No treated articles may be placed on the market unless all the active substances contained in the biocidal products with which they were treated, or which they incorporate, are approved in accordance with the BPR. The reason for this is to protect human health, animal health and the environment, and to avoid discrimination between treated articles originating in the EU and those imported from third countries.

There are transitional measures concerning treated articles (Article 94). Treated articles that were on the market on 1 September 2013 may, until the date of a decision concerning the approval for the relevant product-type of the active substance(s) contained in the biocidal products with which the treated articles were treated or which they incorporate, continue to be placed on the market if the application for the approval of the active substance(s) for the relevant Product Type is submitted at the latest by 1 September 2016.

The labelling requirements of the BPR for treated articles do not fall under derogation and must be applied for treated articles that are placed on the market after 1 September 2013. A further requirement is that the supplier of a treated article must provide information on the biocidal treatment of the treated article within 45 days free of charge to any consumer who requests it.

Due to a number of factors, the situation regarding treated articles has been very unclear. This has been evident from the ongoing discussion over the interpretation of topics such as: what is and what is not a treated article; what constitutes a primary biocidal function; what is an acceptable claim of biocidal function; and, how complex articles (for example, cars and planes) should be included, amongst many others.

Proposed changes to the BPR have also resulted in uncertainty in this area. These discussions had delayed the finalisation of guidance documentation and led to further confusion in the marketplace.

Conclusions
Some of the new provisions introduced by the BPR will have a major impact on the regulation of biocidal active substances and biocidal products within the EU. The ability of companies that have, up until now, been able to legally sell active substances while not being engaged in the regulatory process will stop and the principle of ‘no data, no market’ introduced by REACH will now apply.

Companies that are in this position have several possible routes to become compliant but must be aware of the significant costs involved. Any action must be taken well before the 1 September 2015 deadline to allow them to appear on the ECHA approved supplier list; otherwise, continued supply cannot be ensured.

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 data applicants and data sharing provisions, include toxicological and ecotoxicological studies not involving tests on vertebrates. Under the proposed revision to the BPR, this is also likely to be extended to environmental fate and behaviour studies.

Data compensation routes also appear to favour companies seeking data, although only time will tell how amicably data owners and companies seeking access to data can reach agreement with each other and if ECHA will need to be involved.

The inclusion of treated articles within the scope of the BPR has led to considerable concern within industry. The definition of a treated article is so broad that it could be considered to cover many if not most articles in common use including complex articles. The lack of clarity and absence of agreed guidance has also hindered the implementation of certain aspects, such as product labelling, which will result in many products that are currently on the market being non-compliant.

Finally, the introduction of the BPR has introduced new challenges for both industry and regulators. There are undoubtedly other issues of concern which will continue to challenge those involved in the biocides industry and, as treated articles are now in the scope of the legislation, much more widely within many different industries.

References

Contact
Dr Richard Elsmore
JSC International Ltd.
Tel: +44 1423 520245
E-mail: richard.elsmore@jsci.co.uk
Website: www.jsci.co.uk