TARN-PURE

BPR LETTERS OF ACCESS EXPLAINED

So what IS a Letter of Access?

In Tarn-Pure's experience, the words 'Letter of Access' ("LoA") causes more confusion than probably any other phrase used throughout the BPR.

This note seeks to explain:

- What is a "Letter of Access"?

- Why is it needed?

- How is the LoA obtained and at what price?

NB - in order to understand some of the acronyms, it is recommended that you read our paper "Biocidal Products Regulations Explained" first.

Disclaimer

An important disclaimer - Tarn-Pure only supports elemental silver and elemental copper in the EU Biocides Review, so we only speak to these two substances. Furthermore, this text is not intended to be a legal opinion, it is provided as non-technical background reading for parties who have to make difficult commercial decisions and who may need an introduction to a regulatory process about which they may know very little. It is imperative that interested parties refer to professional advisors for any formal advice.

This version is published just before the United Kingdom of Great Britain and Northern Ireland leaves the European Union. Oversight of the BPR in the remaining 31 Member States of the Territory of the BPR (The 30 Member States of the EEA plus Switzerland) rests with ECHA and the 31 "Member State Competent Authorities" ("MSCA"). Oversight of the regulatory process for the authorisation of the marketing of biocides in the UK will vest in the Competent Authority for the UK, which is the Health and Safety Executive ("HSE"). For sake of simplicity the term MSCA in this document encapsulates all 32 bodies involved in regulatory oversight of the supply and use of biocides.

Introduction

The Biocides Review Programme calls for the submission of a "Complete Substance Dossier" to facilitate the review of a biocide by the evaluating MSCA. A Substance Dossier contains data from studies that provide information on the effect that the active substance has on the environment and human health so that the evaluating MSCA may determine the forms and concentrations which may be safely placed on the market.

What is a Letter of Access?

A Letter of Access ("LoA") is simply a document, issued on behalf of the owner of confidential data that is being used in the biocides review programme, to a party that needs to cite the data, confirming that permission to share the data has been lawfully granted.

The confusion arises because there are two different uses for LoA:

1. Permission to cite data for approval or listing of a Biocidal Active Substance

2. Permission to cite data to secure Biocidal Product Authorisation

ECHA's explanation for LoA may be viewed through this link:

https://echa.europa.eu/documents/10162/21742587/pg_letters_of_access_en.pdf

Any party that wishes to place on the market an Active Substance requires access to the relevant Complete Substance Dossier.

This would normally be acquired either to permit the recipient to reference the data in another substance review or to permit the recipient to apply for inclusion in ECHA's Article 95 List, which is the method by which the outside world can see that you are authorised to make available the biocide to the market.

Why is it needed?

All Substance Dossiers are very costly to create and require that the owners either spend a lot of money on tasking new studies or buy permission to refer to studies owned by other parties to avoid unnecessary duplication of effort.

The regulations mandate that Industry must fund the cost of creating or acquiring all relevant studies. Industry must also pay for the costs for the eCA to review the data. The EU

parliament has therefore stated that any party wishing to avail themselves of the benefits that fall from the review of this data must share in the cost of the regulatory process.

If you are a Review Programme Participant ("RPP") then you already either own or have secured lawful access to all the data required by the eCA to approve your active substance or your biocidal product.

There are however two methods of accessing the Review data if your need for access to cite confidential data has only just become apparent.

If you are "late to the party" and are not a RPP, you may acquire data citation rights by joining the relevant Task Force or consortium.

If however you do not wish to participate in the Review Programme yourself then you may, instead, buy the rights to cite all date used in the Review by paying compensation to the owner. Once compensation is paid then the owner will issue to you a Letter of Access.

How is your LoA obtained and what does it cost?

The first thing that you need to know is that there are two different LoA. The rights they confer are very different, as is their cost.

The two LoA offer access to the same data set but with different restrictions and permissions.

The more comprehensive, and therefore much more expensive, LoA confers the lawful right to cite access to all of the confidential data in the Complete Substance Dossier used for the Review of the biocidal active substance in question.

If you can demonstrate citation rights to, or joint ownership of, these studies for any biocide you may apply to be listed by ECHA as an authorised Substance Supplier under Article 95 of the BPR.

The only party that can issue LoA to a Complete Substance Dossier is the owner. This would normally be the Task Force or consortium that is funding the Review of the Biocidal Substance.

It is possible however to secure citation rights but only for the purposes of applying for Product Authorisation.

Product Authorisation is the final step in the process of securing approval to market your biocidal product. It requires registration either with your domestic MSCA or ECHA and your application for Product Authorisation must demonstrate that you are using a biocidal active substance which is approved and for which you have permission to cite the data used in the Review. Evidence of citation rights is evidence the you have contributed to the cost of the Review Programme and is the final piece of the jigsaw puzzle that you need so that you may place on the market and use your biocidal products.

Product Authorisation is described in more detail in a separate paper included in this series.

Acquiring LoA to Data to secure Article 95 Listing

Article 95 Listing requires that you must either own, or cite access to, a Complete Substance Dossier, for which permission to cite may only be issued by its owner.

The only complete substance dossier for copper that has thus far been submitted to ECHA is owned by the Biocidal Copper Task Force; and the only complete substance dossier for silver that has thus far been submitted to ECHA is owned by the EU BPR Silver Task Force. These two bodies are the owners of these “Core” dossiers and are the only parties that are able to issue the relevant LoA.

Tarn-Pure is therefore unable to issue to you, under any terms or at any price, a Complete Substance Dossier LoA because we do not have this within our gift.

In order to obtain the required rights to the appropriate data you must either:

i. Join the relevant Task Force, because membership confers all necessary citing rights

Or

ii. Acquire a Letter of Access for “Substance Supply” from the relevant Task Force

Or

iii. Prepare and submit to ECHA your own complete substance dossier

If you wish to enquire about the terms to acquire the LoA required for Substance Supplier status, the contact details for each secretariat are shown below.

For Copper:

The EU Biocidal Copper Task Force
℅ Regulatory Compliance Limited
Attn. Carol Mackie
6 Dryden Road
Bilston Glen
Loanhead EH20 9TY
Tel: + 44 131 448 1085/6

For Silver:

The EU BPR Silver Task Force
℅ Field Fisher Waterhouse LLP
Attn. Koen van Maldegem
l'Arsenal, Boulevard Louis Schmidt 29
B-1040 Brussels
Belgium
Tel: + 32 2 742 70 70

Acquiring LoA for Product Authorisation

There is however a cheaper and easier way to obtain the rights to sell biocidal products.

If you only wish to purchase biocidal copper or silver from a party who is already a Substance Supplier and then use it to manufacture, formulate or resell in a product that bears your brand name, then you will only need to cite access to the complete substance dossier for the purpose of applying for authorisation for your biocidal product(s); and you will then become a "Product Supplier".

If you only need to obtain citing rights to become a "Product Supplier" then you must buy your biocides from a listed Substance Supplier and you may acquire the right to make reference to the LoA owned by your Substance Supplier. These rights and obligations are conferred in Article 95.4, which states "A substance supplier or a product supplier included in the list referred to in paragraph 1 to whom a letter of access has been issued for the purpose of this Article or a right to refer to a study has been granted in accordance with paragraph 3 shall be entitled to allow applicants for the authorisation of a biocidal product to make reference to that letter of access or that study for the purposes of Article 20 (1)" The terms upon which an approved Article 95 Supplier may permit an applicant for the authorisation of a biocidal product to make reference to its relevant letter(s) of access or study (or studies) are subject to private commercial negotiation.

For further details please also read:

BPR Explained

Product Authorisation Explained