TARN-PURE

WHAT ARE THE EU "BIOCIDAL PRODUCTS REGULATIONS" ALL ABOUT AND HOW IS THEIR IMPLEMENTATION AND OVERSIGHT AFFECTED BY BREXIT?

Disclaimer - This is not intended to be a legal interpretation of the Biocidal Products Regulations ("BPR"). If you are reading this text, the chances are that your organisation needs either to manufacture, formulate or import a biocidal substance or product to supply or use in the territory of the BPR or the United Kingdom.

Tarn-Pure is a founding member of the Biocidal Copper Task Force and the EU BPR Silver Task Force. This means that we are one of only three organisations permitted to "first place on the market" copper and silver for use in biocidal applications covered by the Product Types we support.

(For further information please read the definitions of the Product Types and the current "Article 95" List published by ECHA, using the links that appear in the "**List of Important Websites**" as document 4 of this series).

The following paragraphs are presented to provide you with a brief but non-legal and non-technical overview of the road which has led to the creation of this new regulatory environment. They are intended as a guide that will allow you to make such further enquiries as you deem necessary to ensure that your business is compliant with the BPR.

History of the BPR

In the late 1980s the European Commission decided that it was necessary to harmonise the standards and regulate the conditions for the supply and use of biocides across all of the EU Member States. The objective was to ensure that all biocides placed on the market in the EU met common, minimum standards, are fit for purpose and safe for use.

This process resulted in the publication of the EC Biocidal Products Directive in February 1998 which created the Biocides Review Programme. The Commission allocated the conduct of these Biocides Reviews across all of the Member State Competent Authorities (MSCA). The task of performing the Review of Copper was assigned to the French body AFSSET (now ANSES). Silver was assigned to Kemi - the Swedish Chemicals Agency.

Industry then formed Task Forces, or consortia, to share the mandated cost of these Review programmes.

As this process commenced the European Parliament drafted primary legislation to supersede the Directive and, in March 2012, approved the Biocidal Products Regulation (EU/528/2012/) (the "BPR"). For the purposes of simplicity all references to the "Article 95" list and the "BPR" in this paper will include the UK's equivalent regulation which, at the time of writing, has not been published.

How to register on the Article 95 List to place biocides on the market

This regulation defines the terms under which a party may place biocides on the market in the territory covered by the BPR which, from 1 January 2021, includes the 30 Member States of the European Economic Area, "EEA", plus Switzerland.

Following the departure of Great Britain from the EU the BPR will be mirrored in UK law by new regulations that will contain the same provisions as the BPR but which will exclude any references to EU processes.

The essence of the BPR is to protect the industry participants that are funding the significant cost of these mandatory Reviews. It is a financial regulation drafted to ensure that only commercial organisations that have contributed to the cost of the Reviews may initially place biocidal active substances or products on the market. This protection permits the Review Programme Participants to profit from placing on the market the biocides they are supporting so that they may recover their significant investment in the regulatory approval process.

Clause 2 of Article 95 of the BPR states "As of 1 September 2015, a biocidal product consisting of, containing or generating a relevant substance included in the [Article 95 List] shall not be made available on the market unless either the substance supplier or the product supplier is included in the [Article 95 List] for the product-type(s) to which the product belongs."

Any business wishing to be included in the Article 95 list must submit an application to the European Chemicals Agency (ECHA) or the UK's Health and Safety Executive (HSE) in which it must identify how it complies with the relevant regulations.

Article 95 Clause 1, paragraph 2, states, inter alia: "A person established within the Union who manufactures or imports a relevant substance, on its own or in biocidal products ('the substance supplier') or who manufactures or makes available on the market a biocidal product consisting of, [or] containing [….] that relevant substance ('the product supplier'), may at any time submit to the Agency either a complete substance dossier for that relevant substance [or] a letter of access to a complete substance dossier…"

In order to submit a “complete substance dossier” in your own right you must be able to lawfully reference all of the data required to be contained within the dossier that has been deemed necessary by the Review body (the evaluating Competent Authority, or “eCA”).

In order to mitigate the costs of many parties conducting unnecessary duplicate studies the members of the Task Forces (the Review Programme Participants, or “RPP”s) negotiate, agree and pay compensation to the owners of all of the confidential studies that are required by the eCA for the purpose of conducting the relevant Review.

To achieve the desired outcome while retaining confidentiality of the data, the data owners submit the data to the eCA and the RPPs receive, through their Task Force, Letters of Access from the owners granting permission to reference this confidential data for the purpose of conducting the Review.

It is important to understand that the RPPs do not receive copies of the studies, have no rights to sell these studies or their contents and cannot pass on, assign or otherwise transfer access to these studies to any party unless this is done within the terms of their internal Task Force agreement.

Article 95 Listing for the Territory of the BPR

There are two ways that your organisation may secure sufficient rights to data citation to be able to secure inclusion in the EU Article 95 List as a Substance Supplier:

i. You must either join the relevant Task Force

The Task Forces themselves own the complete substance dossier citation rights and membership of the relevant Task Force confers the right to Article 95 inclusion.

OR

ii. You must purchase a Letter of Access which delivers citation rights for the Complete Substance Dossier from the relevant Task Force

The secretariats of each Task Force are the only parties permitted to issue to any applicant a Letter of Access to the data used to compile the “complete substance dossier” on behalf of the membership of the Task Force in question.

If you are interested in your party being included in the Article 95 List as a Substance Supplier in the EU for copper or silver please write to the relevant Task Forces for further information:

For Copper:

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

For Silver:

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

Article 95 equivalent listing for the Territory of the United Kingdom of Great Britain and Northern ireland

For details of the requirements for the listing of a Biocidal Active Substance or Product for placing on the market in the UK, please visit:

https://www.hse.gov.uk/brexit/biocides.htm

For further details please also read:

Letter of Access Explained

Product Authorisation Explained