ECHA
EUROPEAN CHEMICALS AGENCY

Practical Guide on Biocidal Products Regulation

Special Series on Data Sharing - Introduction to the BPR and SME considerations

LEGAL NOTICE

Practical Guide on Biocidal Products Regulation: Special Series on Data Sharing - Introduction to the BPR and SME considerations

Reference: ECHA-15-B-03-EN
Cat No.: ED-04-15-164-EN-N
ISBN-13: 978-92-9247-153-8
DOI: 10.2823/080158
Publ.date: April 2015
Language: EN

This document will be available in the following 23 languages: Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish.

If you have questions or comments in relation to this document please send them (indicating the document reference, issue date, chapter and/or page of the document which your comment refers) using the Information request form. The feedback form can be accessed via the 'Contact ECHA' page at: http://echa.europa.eu/contact

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

DOCUMENT HISTORY

Version	Comment	Date
Version 1.0	First edition	April 2015

PREFACE

This Practical Guide provides an overview of the Biocidal Products Regulation (EU) No 528/2012 (the BPR), data sharing and SME considerations. It is part of a special series of practical guides on data sharing for the BPR, including also Practical Guides on Data Sharing, Letters of Access and Consortia.

This Practical Guide should not be read in isolation. Other guidance documents are available from the Agency and reference to them is encouraged.

The Special Series of Practical Guides has been developed by the European Commission in consultation with the European Chemicals Agency (the "Agency") and the Member State Competent Authorities (the "MSCAs"), a sample of SMEs, representative associations, law firms and technical consultancies.

Table of Contents

List of Abbreviations

The following text conventions are used throughout the Practical Guide.

Standard term / Abbreviation	Explanation
AH	Authorisation holder
AS	Active substance
BPD	Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (Biocidal Products Directive)
BPF	Biocidal product family
BPR	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 (Biocidal Products Regulation)
EU	European Union
LoA	Letter of access
MSCAs	Member State Competent Authorities responsible for the application of the BPR, designated under Article 81 of the BPR
PT	Product Type
R4BP	Register for Biocidal Products
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
SBP	Same biocidal product
SMEs	Small and Medium Sized Enterprises

List of Terms & Definitions

For the purposes of the Practical Guides, the definitions in Article 3(1) of the Biocidal Products Regulation (EU) No 528/2012 (BPR) apply. The most relevant definitions are reproduced below, together with other standard terms used in the Practical Guides.

Standard term / Abbreviation	Explanation
Access	The term is used to means the right to refer to data/studies when submitting applications under the BPR, further to an agreement reached with the data owner. Depending on the content of the data sharing agreement, it can also mean the right to inspect hard copies of studies and/or the right to obtain hard copies of studies.
Agency	European Chemicals Agency, established under Article 75 of REACH
Article 95 List	The list of relevant substances and suppliers published by the Agency under Article 95(1) of the BPR
Biocidal product family	A group of biocidal products having (i) similar uses; (ii) the same active substances; (iii) similar composition with specified variations and (iv) similar levels of risk and efficacy (Article 3(1)(s) BPR)
Chemical similarity	A check which can be made prior to the adoption of the approval decision for an active substance, which assesses the substance identity and chemical composition of an active substance originating from one source with the aim of establishing its similarity regarding the chemical composition of the same substance originating from a different source.
Data submitter	The company/person which submits the data to the Agency/MSCA in connection with an application under the BPD or BPR
Every effort	The level of diligence required when negotiating the sharing of data according to Article 63(1) of the BPR
Existing active substance	A substance which was on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development (Article 3(1)(d) BPR)
Fast track	One method of obtaining an LoA for Article 95 purposes which envisages limited negotiations and a short written data sharing agreement. Also described as an *"over-the- counter"* transaction
Letter of access	an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by competent authorities, the Agency, or the Commission for the purposes of the BPR (Article 3(1)(t) BPR)
New active substance	A substance which was not on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development (Article 3(1)(d) BPR)
Prospective applicant	Any person which intends to perform tests or studies for the purposes of the BPR (Article 62(1) BPR)

Standard term / Abbreviation	Explanation
Review Programme	The work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Article 89 of the BPR
Related reference product	In the context of an SBP authorisation, this is the biocidal product or product family which has already been authorised, or for which the application has been made, which the SBP is identical to
Right to refer	Means the right to refer to data/studies when submitting applications under the BPR, further to an agreement reached with the data owner (the right is usually granted through an LoA). This right to refer can also be granted by the Agency following a data sharing dispute under Article 63(3) BPR.
Same biocidal product	A biocidal product/family which is identical to a related reference product/family, as per Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council
Standard Track	One method of obtaining an LoA which envisages detailed discussions on the rights covered by the LoA, together with a detailed written data sharing agreement
Technical Equivalence	Mean similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 54 of the BPR (Article 3(1)(w) BPR). Technical equivalence is a requirement for a product authorisation application but is not a requirement for an application under Article 95 of the BPR and is not a legal pre-requisite for data sharing under Article 62 and Article 63 of the BPR

1. Overview of the BPR

1.1. Introduction

(a) Any company/person involved at any stage of the supply and/or use chain in the biocides market in the European Union or in the European Economic Area (referred together in this Practical Guide as the "EU") will likely be affected by the BPR which concerns the "*making available on the market and use of biocidal products*".

(b) The BPR establishes a system concerning the approval of active substances – which are the key ingredients of biocidal products – and the subsequent authorisation of biocidal products containing those active substances, in the EU. Actors up and down the supply chain – whether non-EU manufacturers exporting to the EU, EU importers or manufacturers, etc. – will need to be aware of the various procedures which will allow them to continue operating on the EU biocides market.

(c) This Practical Guide provides an overview of the BPR, including its provisions regarding data sharing. It specifically looks at the place/role of SMEs which, just like other operators in the EU biocides market, are subject to the BPR's rules. The Practical Guide is accompanied by three sister Guides which focus on (i) how the data sharing provisions work in practice, (ii) what letters of access can be negotiated between parties and (iii) the role of consortia, if any, in the overall BPR data sharing process.

1.2. Background: what is the BPR?

(a) Biocidal products, by their very nature, may be harmful to humans, animals and/or the environment. The EU has adopted the BPR in order to set out a comprehensive system of governance of biocidal products to ensure that the potential risks of harm posed by them are in balance with their expected benefits. The BPR provides detailed rules regarding how to conduct scientific assessments of the risks posed by both active substances and biocidal products. It also provides rules regarding how companies/persons are to obtain authorisations from the relevant authorities before they can make available on the market or use a biocidal product anywhere in the EU.

(b) The BPR entered into force on 1 September 2013 and thereby replaced Directive 98/8/EC (the "BPD"[1]), which is now repealed. The BPR maintains the two-stage regulatory approach established under the BPD with some important changes:

- **Approval**: active substances are subject to an approval process at EU level, the aim of which is to be included on an EU-approved list of active substances. That approval signals that the European Commission concluded after a peer review/risk assessment process that the active substance is sufficiently safe and efficacious, as set out in the BPR, to be made available and used on the EU market.
- **Authorisation**: the biocidal product must be authorised by the relevant MSCA in whose territory it will be made available and used, or by the Commission (in case of a Union authorisation). The granting of an authorisation is the signal that the biocidal product meets the requirements of the BPR as regards safety and efficacy and can be made available and used in that Member State/the EU.

(c) All types of businesses – whether multi-national companies, an SME, incorporated as a limited company, operating as an association of companies or trading independently, for example – and which are involved in the following activities, should establish their rights and obligations under the BPR:

[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market; OJ L 123, 24.4.1998, p.1

- If they manufacture one or more active substances in the EU.
- If they import one or more active substances from a country outside the EU.
- If they manufacture one or more biocidal products in the EU.
- If they import one or more biocidal products from a country outside the EU.
- If they sell, supply or otherwise make an active substance or biocidal product available anywhere in the EU.
- If they place a treated article on the market anywhere in the EU.[2]

(d) The first question that needs to be addressed is whether or not the BPR applies to the product of the company/person concerned. To establish that, reference needs to be made to the definitions in the BPR.

- The definition of active substance is given in Article 3(1)(c) of the BPR: "a *substance or a micro-organism that has an action on or against harmful organisms*".

EXAMPLE 1

Silver for disinfection uses; permethrin, geraniol or even a bacillus species for insecticide uses or lavander oil for repellent uses..

- The definition of a biocidal product is provided in Article 3(1)(a) BPR: "*any substance or mixture, in the form in which it is supplied to the user, consisting of or containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action*" and "*any substance or mixture, generated from substances or mixtures which do not themselves fall under the [*previous definition*], to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than a mere physical or mechanical action. A treated article that has a primary biocidal function shall be considered a biocidal product*".

EXAMPLE 2

Mosquito repellent, anti-fouling paint, wood preservatives, rat poison or sanitary cleaners..

If the product falls within the definition of a biocidal product referenced above, the BPR applies.

(e) The second question is whether or not the activity concerning the active substance/biocidal product is covered by the scope of the BPR. In short, if the active substance/biocidal product is manufactured for the EU market or imported/placed on the EU or a Member State market or made available anywhere in the EU/Member State market or used anywhere in that market, the BPR will apply.

[2] For more information on what a treated article is, refer to http://echa.europa.eu/web/guest/regulations/biocidal-products-regulation/treated-articles. Note that companies/persons placing treated articles on the market may be affected if those articles have a so-called primary biocidal function and require authorisation as biocidal products.

- The definition of "*making available on the market*" is provided in Article 3(1)(i) of the BPR: "*any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge*".

EXAMPLE 3

Selling directly to a customer or to a distributor; importing from outside the EEA; or giving free samples to customers.

- The definition of "use" is provided in Article 3(1)(k) of the BPR: "*all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation with a view to exporting the biocidal product or the treated article outside the Union*".

EXAMPLE 4

Storing biocides before use within the EEA; applying rat-poison; or generating and using *in situ* a disinfectant.

Again, if the activity falls within the definitions above, and if the product does as well, the BPR will apply.

1.3. What is the role of data under the BPR?

(a) Biocidal products are used for many different, important reasons – hygiene, eradication of pests, etc. Before they can be used, they must be shown to be safe and effective both for public health and the environment. This is where scientific data play a key role.

(b) Such data allows a decision to be made on whether the use of a biocidal product is safe and effective, and ultimately whether this biocidal product can be authorised for placing on the EU market.

(c) The sharing of such data underpins the BPR. There are two principal reasons.

- First, it is recognised that data must be generated in order to establish the safety and efficacy of a biocidal product. Unfortunately, but inevitably, such data often come from tests conducted on vertebrate animals. The BPR clearly provides that vertebrate animal testing must be reduced to an absolute minimum, and no such test can be repeated for the purposes of the BPR. Therefore, companies/persons who have already generated vertebrate animal test data must share those data with other parties.
- Second, sharing such data also addresses another issue: balancing the costs burden. It is not cheap to conduct a study, especially a vertebrate animal study. Under previous rules in the BPD, the law allowed the costs to be borne by one company/person (or a limited number of companies/persons) while their competitors were able to sell their products without contributing to the costs. The new rules under the BPR aim to ensure the equal treatment of all parties placing active substances on the market and the avoidance of the establishment of monopolies. In particular the BPR rules aim to establish a level playing field on the market for existing active substances (i.e. on the EU market on 14 May 2000 as an active substance of a biocidal product), by ensuring that the costs are shared equitably – both for those companies/persons that have invested in data

so far, and for those companies/persons that now require access to these data as well .[3] For vertebrate tests, and, in the case of applications for inclusion on the "Article 95 List"[4], for toxicological, ecotoxicological and environmental fate and behaviour studies for existing active substances, the Agency can enforce data sharing under certain circumstances.

(d) The legal requirement in the BPR concerning data sharing means that the owner of the data (the "data owner") and the company/person seeking to rely on its data for a purpose under the BPR (the "prospective applicant") must negotiate and come to a mutually acceptable arrangement. It means that data owners may need to accept that they may not be in absolute control of who can refer to their data; that small companies will have to deal with large companies/multi-nationals, perhaps for the first time; that actual or potential competitors have to come to an agreement on the sharing of data; and that discussions, which otherwise would not have taken place, will now have to take place.

2. New Data Sharing Rules

2.1. Data protection

(a) The BPR sets out data protection periods; only data that are protected under the BPR must be compensated for. The protection periods are set forth in Article 60 of the BPR ("*Protection of Data held by competent authorities or the Agency*") and Article 95(5) of the BPR ("*Transitional measures concerning access to the active substance dossier*").

- For data submitted with a view to the approval of an existing active substance, the protection period is:
  - ten years from the first day of the month following the date of adoption of the approval decision for a particular product type for substances approved before 1 September 2015 (Article 60(2), first paragraph, of the BPR);
  - or until 31 December 2025 for existing active substances/ product type combinations included in the review programme, but not yet approved on 1 September 2013 (Article 95(5) of the BPR).
- For new active substances, the protection period is fifteen years from the first day of the month following the date of adoption of the approval decision for a particular product type under the BPR (Article 60(2), second paragraph, of the BPR).

(b) New data submitted and used for the renewal or the review of the approval of an existing or new active substance is protected for five years from the first day of the month following the date of adoption of a renewal decision (Article 60(2), third paragraph, of the BPR).

(c) The same protection periods apply for data on biocidal products (ten, fifteen and five years) from the first day of the month following the first decision concerning the authorisation of the biocidal product concerned. This rule applies for simplified authorisations, Member State authorisations and Union Authorisations.

(d) Once the applicable data protection period has lapsed, the data concerned can be referred to without compensation and relied on by the MSCAs and the Agency; the prospective applicant will not need to negotiate sharing of such data for the purposes of the BPR.

[3] See Recital (8) and Recital (58) of the BPR.
[4] For more information on Article 95 and the List, see section 2.2.

2.2. Data sharing rules under the BPR

(a) When compiling a dossier for submission to a relevant regulatory authority – the Agency or an MSCA – and it is discovered that some required data are lacking, the BPR states that vertebrate tests that already have been submitted to the Agency or a competent authority under the BPD or BPR may not be repeated for the purposes of the BPR (Article 62 of the BPR).

- **The obligation**: Article 62(1) of the BPR states that "*testing on vertebrates for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrates shall not be repeated for the purposes of this Regulation*". The BPR therefore forbids any company/person intending to perform tests or studies – the prospective applicant – to repeat vertebrate animal tests/studies. As a result, Article 62(2)(a) of the BPR says that if these data have already been submitted by somebody else in the context of either the BPD or the BPR, and are still protected under Article 60 of the BPR, the prospective applicant must request to share that data with the data owner. Negotiations will have to take place between the prospective applicant and the data owner with a view to sharing those data (for example, to negotiate a right to refer) and their related costs. If no agreement can be reached, the Agency can enforce data sharing via its dispute procedure (see section 4.2 of the Practical Guide on Data Sharing).
- **Article 95 applications – the extension**: Note that, for applications under Article 95, also toxicological, ecotoxicological and environmental fate and behaviour data (including data not involving tests on vertebrates) on active substances in the Review Programme must be shared when requested and this sharing can be enforced by the Agency via the dispute procedure.
- **The option**: If the studies which are missing are non-vertebrate animal data, a prospective applicant still has the option to request to share data with the data owner. However, in this case the Agency has no competence to enforce data sharing in case the parties cannot find an agreement (except as regards Article 95 of the BPR: see above).

(b) "***Every effort***": The key principle that applies to all data sharing negotiations under the BPR is that every effort is to be made by the parties to reach an agreement (Article 63(1) of the BPR – see section 3.2 of the Practical Guide on Data Sharing).

(c) **What counts as a BPR purpose?** When Article 62 of the BPR talks of not repeating vertebrate animal testing "*for the purposes of this Regulation*", the word "*purpose*" refers to any procedure which requires a dossier of test and study data to be submitted to the relevant regulatory authorities under the BPR. Examples of those purposes include the following:

- **Biocidal Product Authorisations**: The data sharing rules apply where an EU manufacturer or importer of a biocidal product or someone who wishes to place a biocidal product on the EU market needs to obtain an authorisation or renewal, perhaps at a single Member State level or EU-wide (in the case of a Union authorisation). The procedure to follow can be found in Article 17 onwards of the BPR. This procedure requires the submission of two dossiers of data (on the active substance and on the biocidal product), or letters of access to those dossiers. If the prospective applicant does not have any access/right to refer to the required data – the data sharing rules apply and vertebrate tests cannot be repeated.
- **Active Substance Approvals**: The data sharing rules apply where a company/person is looking to have an active substance approved under the BPR (see Article 4 onwards of the BPR), or where that company/person is asked to submit more data with regard to an existing active substance under the review programme or to support an additional use or product type. This procedure requires the submission of two dossiers of data (on the active substance and on the biocidal product), or letters of access to those dossiers. If the prospective applicant

does not have any access/right to refer to the required data, the data sharing rules apply and vertebrate tests cannot be repeated.

- **Article 95 BPR Listing**[5]: Article 95 of the BPR establishes in practice that a company/person making available a biocidal product on the EU market must be able to show that the substance supplier or the product supplier is included on the Article 95 List, which can be accessed here: http://echa.europa.eu/information-on-chemicals/active-substance-suppliers.

  If such listing cannot be shown by 1 September 2015, then the product cannot be made available on the EU market as of that date (a supplier can still be added to the list at a later stage allowing the making available on the market from that point on). It is therefore critical that, at one link of the supply chain, either the product supplier or the substance supplier is included on the list. If a company is not already included on the Article 95 List and it wants to achieve that listing, it has to submit a complete substance dossier to the Agency or an LoA to a complete substance dossier (or a combination of both).[6] This is where data sharing will apply. Note that there is a critical difference where the purpose is for inclusion on the Article 95 List as the Agency can enforce data sharing beyond vertebrate animal data depending on the type of active substance concerned. Specifically, if the active substance is part of the review programme initiated under the BPD, the Agency can enforce data sharing also for "*all toxicological, ecotoxicological and environmental fate and behaviour studies (…) including any such studies not involving tests on vertebrates*".[7]

(d) **How to identify the data owner/submitter?** If a prospective applicant does not know who the data owner is, or whether the data it is looking for has already been submitted to the Agency/MSCAs, it can inquire with the Agency according to Art 62(2) of the BPR to receive the contact details of the relevant data submitters – see section 2.1 in the Practical Guide on Data Sharing for further details. Once the prospective applicant establishes that it requires the test/study and requests access from the data owner, data must be shared. In some cases, parties may know each other already and even may have been negotiating for some time. All their negotiations since 1 September 2013 fall under the obligation to make every effort to reach an agreement.

(e) **The dispute procedure**: In the event that negotiations are unsuccessful and the prospective applicant believes it has made every effort, the Agency can assist by granting a right to refer to the requested data, in certain circumstances – see section 4.2 of the Practical Guide on Data Sharing.

Now that the background to the BPR and data sharing within it have been set out, turn to the three sister guides on data sharing, letters of access and consortia for more information on how to achieve a successful negotiation of data sharing. Below, the Practical Guide outlines some considerations of specific relevance for SMEs.

[5] Article 95 of the BPR was amended by 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, OJ 2014 L103/22. Article 95 of the BPR applies to *in situ* active substances as well. For more on Article 95 of the BPR, refer to the Agency's guidance: http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation?panel=vol5partB#vol5partB.

[6] A reference to a complete substance dossier for which all data protection has expired will also be possible.

[7] The extension of scope is explained in recital 58 BPR and recital 24 to Regulation (EU) No 334/2014 in relation to the establishment of a level playing field on the market for existing active substances and the short timeframe for the Article 95 applications.

3. SME Considerations/Important Remarks Relevant for SMEs

As evidenced from its recitals, the BPR expresses a clear intention to cater for the specific requirements of SMEs. For example, recital 58 of the BPR states that "*a level playing field should be established as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs …*" SMEs can also benefit from a reduction of the fees payable to the Agency. This Practical Guide does not enter into the details of fee payments; refer to http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr for more information.

Furthermore, the BPR places an obligation on MSCAs to provide advice to all interested parties, in particular SMEs, concerning their responsibilities and obligations under the BPR (Article 81(2) of the BPR), and the Agency provides advice to applicants (for the approval of an active substance or inclusion in Annex I to the BPR or for a Union authorisation), again in particular to SMEs (Article 76(1)(e) of the BPR). The Agency and the MSCAs have helpdesks which can be contacted by SMEs (and all companies/persons) with any specific BPR questions they may have.

The BPR does not, however, provide any specific rules obliging private parties, such as prospective applicants and data owners, to conduct themselves in a particular way when one or both of them is an SME. The closest that the BPR comes to this is with the obligation that the data sharing negotiations are conducted with every effort and that the cost compensation is calculated in a "*fair, transparent and non-discriminatory manner*". All the guidance above with regard to adopting a flexible approach to negotiations, recognising the particular set-up of the other party etc, are relevant in ensuring that these legal obligations are satisfied. This includes taking into account the status of an SME during the negotiations (i.e. that it potentially does not benefit from deep pockets or to have significant human resources or to have regulatory or legal knowledge, etc.) – is taken into consideration. Therefore, any party (data owner or prospective applicant) in a data sharing situation may wish to declare whether it is an SME or to ask whether the other party is an SME.

To establish whether a company is an SME, it can refer to European Commission Recommendation 2003/361[8]. Therein, the main factors determining whether a company is an SME are the number of employees and either the turnover or the balance sheet total.

Company category	Employees	Turnover		Balance sheet total
Medium-sized	< 250	≤ € 50 m	AND/OR	≤ € 43 m
Small	< 50	≤ € 10 m		≤ € 10 m
Micro	< 10	≤ € 2 m		≤ € 2 m

These ceilings apply to the figures for individual companies only. A company which is part of a larger multinational grouping may need to include employee/turnover/balance sheet data from that grouping too. Further information is available on the Agency's website "*How to determine the company size category*" which may be found at: http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/how-to-determine-the-company-size-category .

[8] Commission Recommendation 2002/361 of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, OJ L 124 20.5.2003, p. 36 .

Below, some of the issues that may be raised when dealing with SMEs in the context of data sharing and consortia are addressed:

- **Should a data owner differentiate between SMEs which already participate in the review programme (and which have incurred significant costs) and SMEs which only seek data access now?**

Data owners need to comply with the obligation of non-discrimination and shall not treat prospective applicants differently depending on the moment in time they request data sharing.

- **If special treatment is granted to SMEs, does this set a precedent for all economic operators? Could large companies rely upon the precedent as well?**

While special treatment for SMEs is not a requirement in the BPR for data sharing, a data owner may choose to grant such treatment and could also consider extending such special treatment to other companies/persons. If it does not do so, this other company may request a justification in accordance with the principle of fair, transparent and non-discriminatory cost sharing – see section 3.3 in the Practical Guide on Data Sharing for further details.

- **If and how should SMEs support/contribute to the ongoing (and future, unpredictable) costs of the review programme? Should buyers of data access have automatic access rights or not to future data; or should this only be the case for SMEs?**

The question of future rights ultimately forms part of the party-to-party negotiations and it will be up to them to come to that commercial arrangement. There is nothing that prevents such rights being acquired for as long as they are offered to similarly placed companies/persons on similar terms. There is also nothing in the law that says that SMEs should have an automatic right.

- **Can special treatment be given to SMEs in terms of payment terms, or for the amount of data compensation to be paid?**

The data compensation to be paid is calculated on the basis of a fair, transparent and non-discriminatory approach and that should be no different for SMEs or for any other category of companies.

Recognising the limits of companies/persons in special circumstances, including SMEs, however, may justify the application of different modalities of payment of the data compensation. Examples would include:

- Payment by instalment; and
- Payments based on royalties linked to, for example, turnover of sales of the relevant biocidal product. Such a payment method must be designed to pay a total agreed sum, taking into account potential reimbursements which might occur at a later stage, and should not be indefinite. As such sales would be considered commercially sensitive information, and in light of competition law, appropriate arrangements (for example an independent third party) should be made in order to prevent the disclosure of the exact turnover to the data owner/prospective applicant. Also, the additional running costs related to the appropriate arrangement should be carefully considered.

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU

ISBN