Roles and responsibility of industry – joining the level playing field

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Swedish Chemicals Agency

Helena Casabona

Lilian Törnqvist

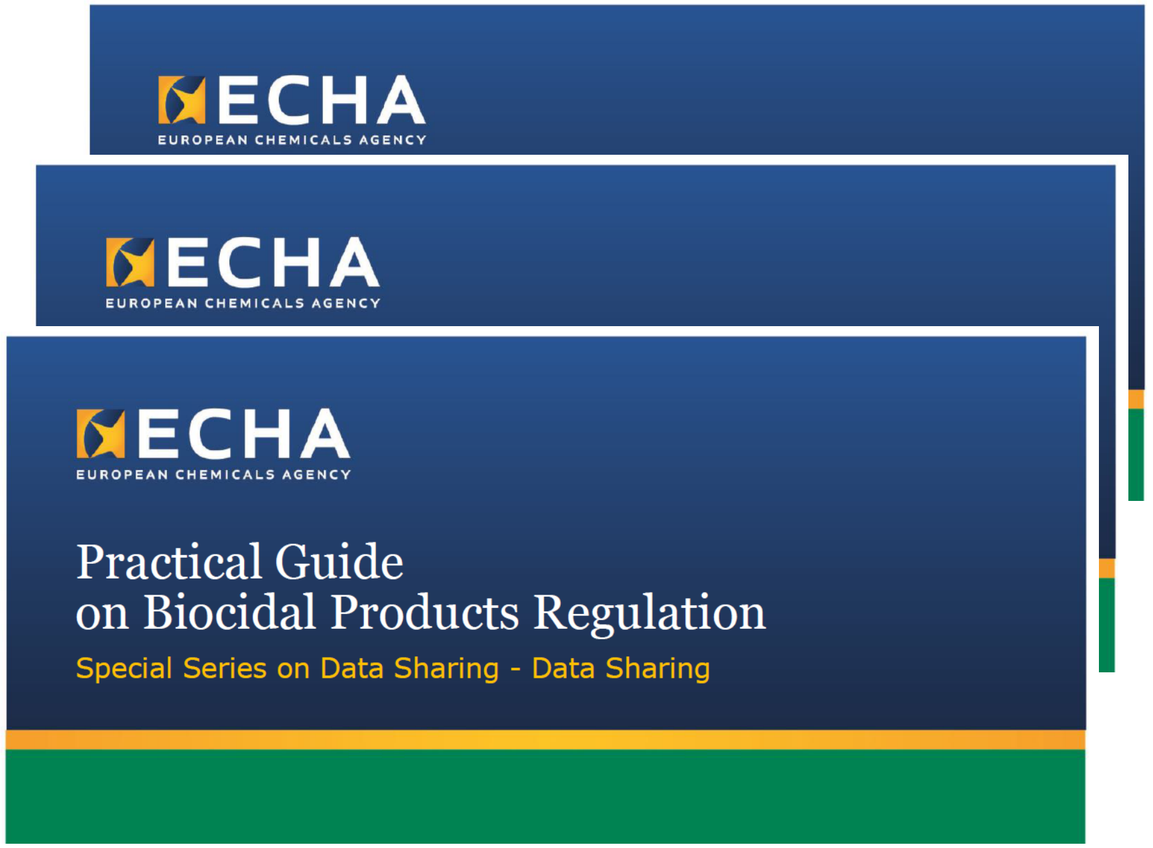
Content

- Obligations and possibilities
  - Data sharing and letters of access
  - Consortia
  - Technical equivalence
  - Other possibilities

- Ways forward

Practical guide on Biocidal Products Regulation

- Data sharing
- Letter of access (LOA)
- Consortia
- Technical equivalence
- Others….



- Developed by the European Commission in consultation with the Agency and the Member State Competent Authorities (the “MSCAs”), a sample of SMEs, representative associations, law firms and technical consultancies.

Practical guide on Biocidal Products Regulation cont´d

Why a practical guide?

- Practical guidance on one of the core issues: data sharing
- Explains the practical aspects of data sharing obligations, data sharing agreement through a letter of access and the role of consortia in the context of the BPR
- Is part of a special series of practical guides on data sharing for the BPR
- Should not be read in isolation. Other guidance documents are available from the Agency

Data sharing

Why data sharing?

- Art. 59 BPR: **Protection of data held by competent authorities**

  Data submitted for the purpose of the BPD or BPR shall not be used by CA or the Agency for the benefit of a subsequent applicant except where:

  - The applicant submits a letter of access
  - The time limit for data protection has expired

- Art. 62 BPR: **Data sharing**

  In order to avoid animal testing on vertebrates

Data sharing cont´d

What is data needed for?

- For dossier submissions under Articles 4 onwards of the BPR (approval of an active substance),

- For dossier submissions under Article 20 onwards of the BPR (authorisation of biocidal products),

- For dossier submissions under Article 95 of the BPR (for inclusion on the Article 95 List)

Data sharing cont´d

- The practical guide explains the following:
  - What prospective applicants and data owners should do in practice to prepare themselves for data sharing;
  - The way that negotiations should be conducted between parties; and
  - The possible outcomes of the negotiations

- Provides assistance to all parties involved in data sharing under the BPR, if no agreement is reached, the Agency can help

- Provides tips and guidance on how parties can conduct their every effort in order to reach an agreement on a fair, transparent and non-discriminatory sharing of data and their costs

Letter of access

Why a letter of access?

- In the following situations, the prospective applicant will not have to pay to share the required data:
  - Where it already owns the data or has the right to use it for a BPR purpose
  - Where the data endpoint concerned can be addressed with a data waiver or is not scientifically necessary
  - Where the data that are lacking are no longer data protected
- If the above does not apply a **letter of access (LoA)** may be needed.
- LoA is a document which states that data may be used for the benefit of a third party by CA, the Agency or the COM

Letter of access cont´d

- The practical guide explains the following:

  - The definition of a LoA under the BPR and the information it needs to contain
  - When a LoA is needed
  - What you need to be aware of as a prospective applicant or data owner
  - The process of obtaining LoA and the access rights
  - How the Agency/MSCA will use the LoA

Consortia

Why consortia?

- Allows companies to share costs. The costs could include:
  - The contracting of outside laboratories to conduct new studies;
  - The hiring of external technical or legal consultants;
  - The day-to-day costs of monitoring and steering the evaluation/authorisation process
  - The payment of authorisation fees to MSCAs or to the Agency.

- Reduces the risk of duplicative testing, as well as submission of different dossiers, requiring multiple assessments.

Consortia cont´d

- The practical guide explains the following:

  - What a consortium is
  - The rules for establishing/running a consortium
  - Advise on how to set up/join a consortium
  - Competition law issues
  - Practical issues
  - Biocidal products families and consortia
  - Same biocidal product and consortia

Technical equivalence (TE)

Why?

- Is required when the active substance to be used in a biocidal product (BP) differs from the reference source of the approved active substance by having a different manufacturing process, a different manufacturing location or a different manufacturer.

- According to art. 54 of the BPR the Agency shall determine the similarity of the chemical composition and hazard profile of active substances that may differ from the one that was evaluated for the purpose of approval (reference source).

- A positive decision on the TE of the active substance issued by ECHA is a required element in the application for a BP authorisation

Technical equivalence (TE) cont´d

Who and when?

- Manufacturers or suppliers of alternative sources of active substances who wish to sell their actives to product formulators or formulators themselves

- TE applications should be made well ahead of the foreseen submission date of the respective product authorisation application to accommodate for the time needed for the processing of the TE applications.

Other possibilities

- Biocidal product family approach

- A group of products with
  - Similar use
  - The same active substances
  - Similar composition with specified variations
  - Similar level of risk and efficacy

1 biocidal product family = 1 authorization
1 application

- Assessment of
  - Maximum risks
  - Minimum level of efficacy

Other possibilities cont´d

- Same biocidal product approach

- If a biocidal product or product family is **identical to** a reference product or product family you can submit an application for national authorisation of **a same product** to the Member State Competent Authority that authorised the reference product or is evaluating it.

- The authorisation is based on the evaluation of a single product. (Commission Implementing Regulation (EU) 414/2013)

- The validation shall include a check that the proposed differences between the same product and the related reference product concern merely information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

Ways forward

- Look at the ECHA webpage

http://echa.europa.eu/practical-guides/bpr-practical-guides

- Speak with your supply chain

- Don´t underestimate the preparation time, especially for data-sharing negotiations

- Do what you are best at

Possible timing for the full implementation of the Biocides Products Regulation in Serbia

2015

Industry: Preparation of applications

Start of pilot project; Mutual recognition

Industry: Preparation of applications according to ”Serbian review program”

New legislation in force

Stepwise Serbian implementation in the ”Serbian review program”

Industry: Preparation of applications according to EU program

Full implementation in Serbia

Transition time period, max 1 year?

Serbia Member State in EU 2020?

KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Active substances on Annex I

europa.eu/web/guest/informatio Biocidal Active Substances ...

Last updated 26-June-2015. Database contains 683 active substance-product type combinations for which approval has been sought.

EC Number		CAS Number	
Substance Name		Evaluating Competent Authority	
Type		Legal Act	
Approval Status	Approved		
Date of Approval (min)		Date of Approval (max)	
Expiry Date (min)		Expiry Date (max)	
Biocide ID		Biocide Asset Number	

☑ I have read and I accept the legal notice

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Showing 1 - 50 of 121 results. Items per Page 50 Page 1 of 3 First | Previous | Next | Last

Substance Name	EC Number	CAS Number	Type	Legal Act	Date of Approval	Expiry Date	Evaluating Competent Authority	Approval Status	Data	Related Authorised Products
(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3- methyl-2-nitroguanidine (Clothianidin)	433-460-1	210880-92-5	8 - Wood preservatives	Directive 2008/15/EC	01/02/2010	01/02/2020	DE	Approved		
(RS)-α-cyano-3phenoxybenzyl-(1RS) -cis, trans-3-(2,2-dichlorovinyl) -2,2-dimethylcyclopropanecarboxylate (Cypermethrin)	257-842-9	52315-07-8	8 - Wood preservatives	Regulation (EU) 945/2013	01/06/2015	01/06/2025	BE	Approved		
(Z,E)-tetradeca-9,12-dienyl acetate		30507-70-1	19 - Repellents and attractants	Directive 2011/11/EU	01/02/2013	01/02/2023	AT	Approved		

Issues/problems to clarify and prioritize – listed under the workshop

- Prepare a dossier
- Adaptation to the use of R4BP Register for Biocidal Products
- Draft the legislation
- Set up a review-program
- Find partners
- Proposed Serbian priorities related to the transition period
- Alignment with Article 95
- Etc.