# BIOCIDAL PRODUCT DOSSIER

## APPLICATION FOR AN AUTHORISATION OF A BIOCIDAL PRODUCT

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# TYPES OF APPLICATIONS

First authorisaton of a biocidal product

Mutual recognition in sequence
Mutual recognition in parallel

Changes of biocidal products
(Major/Minor)

Simplified authorisation

Renewal of an authorisation

Same biocidal product application

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# First authorisation of a biocidal product
## Principle

The basic principle in the Biocidal Products Regulation ((EU) N° 528/2012 (BPR)) is that a biocidal product (BP) must be authorised before it can be made available on the market or used in the European Union (EU)/European Economic Area (EEA).

# FIRST AUTHORISATION OF A BIOCIDAL PRODUCT
## WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

An application for national authorisation can be made by, or on behalf of, the prospective authorisation holder (AH).

The AH may have a person/entity (e.g. consultant) handling the practical issues related to the application.

The AH is the person/entity established within the EU/EEA who is responsible for the placing on the market of a biocidal product in a particular Member State.

Applications for national authorisation shall be submitted to the competent authority of a Member State (Receiving Competent Authority).

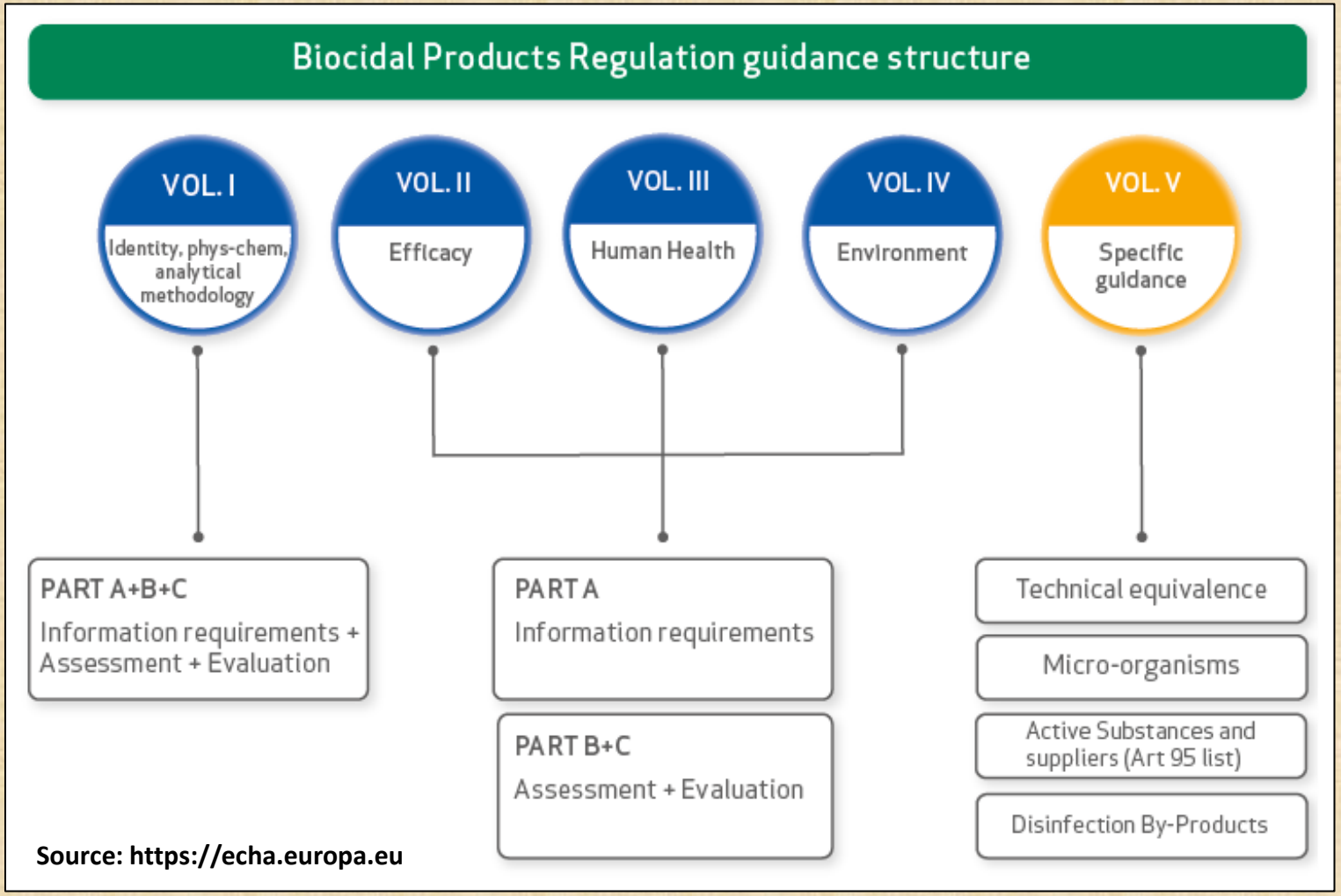
# FIRST AUTHORISATION OF A BIOCIDAL PRODUCT
## INFORMATION REQUIREMENTS (1)

- Volume 1: Identity/physico-chemical properties/analytical methodology
- Volume 2: Efficacy
- Volume 3: Human health
- Volume 4: Environment
- Volume 5: Specific guidance

(Guidance on Disinfection By-Products/Guidance on applications for technical equivalence/Guidance on active substance suppliers/Guidance on micro-organisms)

# FIRST AUTHORISATION OF A BIOCIDAL PRODUCT

## INFORMATION REQUIREMENTS (2)




https://echa.europa.eu/it/guidance-documents/guidance-on-biocides-legislation

# FIRST AUTHORISATION OF A BIOCIDAL PRODUCT
## TIMELINES AND DEADLINES

The application for NA can, in general, be made at any time after the decision to approve the active substance has been adopted.

The Member State Competent Authority evaluates the application and makes a decision on the authorisation within 365 days.

# FIRST AUTHORISATION OF A BIOCIDAL PRODUCT ISSUES (1)

If the applicant is not the data owner of the dossier(s) of the approved active substance(s) contained in the BP, then the applicant needs to provide information to demonstrate access to the relevant data of each of the active substance to fulfil the requirements set out in Annex II to the BPR.

**Letter of Access (LoA)**

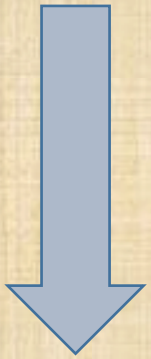
**Declaration (data protection period expired)**

**Waiving of information requirements by providing justifications**

**Alternative and equivalent studies**

# First authorisation of a biocidal product issues (2)

Active substance with different source



Technical equivalence

# FIRST AUTHORISATION OF A BIOCIDAL PRODUCT
## RESULTS

After finalising the assessment, the MSCA will update all necessary information related to the biocidal product (product assessment report and SPC) in R4BP 3 and either grant, or not grant, a NA.

NA for a BP can be granted for a maximum period of 10 years, which is renewable.

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# MUTUAL RECOGNITION OF A BIOCIDAL PRODUCT

## PRINCIPLE

The authorisation of a biocidal product (BP) can be recognised in other Member States (MSs) in accordance with the mutual recognition (MR) procedures to avoid duplication of the evaluation. There are two procedures: mutual recognition in sequence (MRS) which is relevant where there is an existing authorisation, and mutual recognition in parallel (MRP).

# MUTUAL RECOGNITION OF A BIOCIDAL PRODUCT
## WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

An application for mutual recognition can be made by, or on behalf of, the prospective authorisation holder (AH). If the prospective AH in the concerned MSs is a separate person/entity than the AH of the initial NA, they can also make the application, if they obtain the necessary rights to the required data on the active substance and BP.

The AH may have a person/entity (e.g. consultant) handling the practical issues related to the application.

The AH is the person/entity established within the EU/EEA who is responsible for the placing on the market of a biocidal product in a particular Member State.

Applications for mutual recognition shall be submitted to the competent authority of a Member State ('the receiving Competent Authority').

# MUTUAL RECOGNITION OF A BIOCIDAL PRODUCT
## TIMELINES AND DEADLINES

An application for MR, just like in the case of NA, can be made only after the decision to approve the active substance is adopted.

The Member State Competent Authority evaluates the application and makes a decision on the authorisation from the validation of the application by the evaluating competent authority.

# MUTUAL RECOGNITION OF A BIOCIDAL PRODUCT
## RESULTS

After finalising the evaluation and reaching an agreement between the reference MS and MS(s) concerned, each of the MSCAs update the information in R4BP 3 relating to this BP and grant an NA of the BP. Authorisation according to MRP should be granted for the same number of years in all MSs (e.g. up to 10 years).

For MRS, the validity of the product authorisation should also be the same as for the initial authorisation granted by the reference MS, unless the active substance is a candidate for substitution (i.e. maximum of 4 or 5 years).

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# CHANGES OF BIOCIDAL PRODUCTS

National authorisations (NAs) of biocidal products (BPs) issued by competent authorities of the Member States (MSCAs) are only valid for the approved terms and conditions stated therein.

It is possible to apply for a change of the terms and condition of an authorization.

# CHANGES OF BIOCIDAL PRODUCTS

Three types of changes can be distinguished:

- administrative changes (a prior notification can be required or not);
- minor changes, which should not affect the conclusion with regard to the fulfilment of the conditions for authorisation; and
- major changes, when a need for reassessment of the risk and the efficacy can be expected to fulfil the conditions for authorisation.

# CHANGES OF BIOCIDAL PRODUCTS



**COMMISSION IMPLEMENTING REGULATION (EU) No 354/2013**

**of 18 April 2013**

**on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council**

**(Text with EEA relevance)**

# CHANGES OF BIOCIDAL PRODUCTS

*ANNEX*

**CLASSIFICATION OF CHANGES OF PRODUCTS**

TITLE 1

**Administrative changes of products**

*SECTION 1*

***Administrative changes of products requiring prior notification before implementation***

*SECTION 2*

***Administrative changes of products which can be notified after implementation***

TITLE 2

**Minor changes of products**

TITLE 3

**Major changes of products**

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# SIMPLIFIED AUTHORISATION OF BIOCIDAL PRODUCTS

## PRINCIPLE

A simplified authorisation procedure aims to encourage the use of biocidal products that are less harmful for the environment, human and animal health.

The application procedure is similar to the procedure for national authorisation except that there are fewer information requirements.

# SIMPLIFIED AUTHORISATION OF BIOCIDAL PRODUCTS

## INFORMATION REQUIREMENTS

All the active substances contained in the BP appear in Annex I to the BPR and comply with the specified restrictions.

The BP does not contain any substance of concern.

The BP does not contain any nanomaterials.

The BP is sufficiently effective.

The handling of the BP and its intended use do not require personal protective equipment.

# SIMPLIFIED AUTHORISATION OF BIOCIDAL PRODUCTS

## INFORMATION REQUIREMENTS

The SA of a BP is granted by the competent authority (CA) of the evaluating Member State (MS) and is only valid for the approved terms and conditions stated therein.

Mutual recognition by other MSs is not needed for an SA. A notification to the relevant MS(s) before actually placing the product on its territory is sufficient.

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# RENEWAL OF AN AUTHORISATION

The Biocidal Products Regulation ((EU) No 528/2012 (BPR)) states that an authorisation of a biocidal product (BP) can be granted for a maximum period of 10 years.

Article 31 of the BPR sets out the procedure for the renewal of a single national authorisation granted by the Member State competent authority (MSCA).

# RENEWAL OF AN AUTHORISATION

An application for the renewal of NA including those subject to MR shall be submitted at least 550 days before the expiry date of the NA.

# RENEWAL OF AN AUTHORISATION

After finalising the evaluation and, in the case of MR, after reaching an agreement between reference MS and MS(s) concerned, the authorisation shall be renewed for a maximum period of 10 years, unless the active substance is a candidate for substitution (i.e. maximum of 5 years).

For authorisations granted through MR, the maximum validity of the renewed authorisations should be the same in all the MSs where the product is renewed.

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# SAME BIOCIDAL PRODUCT APPLICATION

The following are the basic principles of the new Same Biocidal Product Regulation No 414/2013 (SBP regulation) as amended by Regulation No 2016/1802:

- a subsequent authorisation of the same biocidal product (SBP) can be granted based on the evaluation of a biocidal product already authorised or registered under the Biocidal Product Directive 98/8/EC (BPD);
- an already authorised under the Biocidal Product Regulation No 528/2012 (BPR).

The terms and conditions for the SBP authorisation will be based on the evaluation made on the reference BP

# SAME BIOCIDAL PRODUCT APPLICATION

Applications can be requested for authorisations of same biocidal products where there is already an identical product authorised or where the identical product is under evaluation and not yet authorised.

The biocidal product already authorised or under evaluation to be authorised is called the ‘related reference product’ (or the reference BP).

The precondition for authorisation of same biocidal products is that these products are identical within the limited variations of an administrative change.

# SAME BIOCIDAL PRODUCT APPLICATION

The content of SBP authorisation shall be identical with that of the reference biocidal product, except for the administrative changes that have been applied for. he authorisation of SBP will have a different authorisation number and may be changed, renewed or cancelled independently of authorisation related to the reference product.

# PRATICAL GUIDES

It is possible to check the Pratical Guides available on the ECHA website for more information on procedures.

Click here for the Practical Guides on Biocidal Product Regulation

# THANK YOU
# FOR YOUR ATTENTION