

# Recommendations on preparing a Summary of Product Characteristics (SPC) for single biocidal products and biocidal product families

April 2022

# ABC

## Disclaimer

This document aims to assist users in complying with their obligations under the Biocides Products Regulation (BPR). However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Version	Changes	Date
1.0	First publication	5 April 2022

## Recommendation on preparing a Summary of product Characteristics (SPC) for single biocidal products and biocidal product families

**Reference:** ECHA-22-H-12-EN

**ISBN:** 978-92-9468-120-1

**Cat. Number:** ED-05-22-079-EN-N

**DOI:** 10.2823/49663

**Publ.date:** April 2022

**Language:** EN

© European Chemicals Agency, 2022

Cover page © European Chemicals Agency

If you have questions or comments in relation to this document, please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:

<http://echa.europa.eu/contact>

## European Chemicals Agency

P.O. Box 400, FI-00121 Helsinki, Finland

## Table of Contents

<b>PREFACE</b> .....	<b>4</b>
<b>LIST OF ABBREVIATIONS</b> .....	<b>5</b>
<b>1. ADMINISTRATIVE INFORMATION</b> .....	<b>6</b>
1.1 Trade name(s) of the product (BP) / Family name (BPF).....	6
1.2 Product type(s) (BPF).....	6
1.2 Authorisation holder (BP) / 1.3 Authorisation holder (BPF).....	6
1.3 Manufacturer(s) of the product (BP) / 1.4. Manufacturer(s) of the biocidal products (BPF)	7
1.4 Manufacturer(s) of the active substance(s) (BP) / 1.5. (BPF) Manufacturer(s) of the active substance(s).....	7
<b>2. PRODUCT COMPOSITION AND FORMULATION</b> .....	<b>8</b>
2.1 Qualitative and quantitative information on the composition of the product (BP)/of the family (BPF) .....	8
2.2 Type of formulation (BP) / 2.2. Type(s) of formulation (BPF).....	9
<b>3. HAZARD AND PRECAUTIONARY STATEMENTS (BP) / 3. HAZARD AND PRECAUTIONARY STATEMENT OF THE META SPC (BPF)</b> .....	<b>10</b>
<b>4. AUTHORISED USE(S) (BP) / 4. AUTHORISED USES OF THE META SPC (BPF)</b> .....	<b>11</b>
4.1 Use description .....	11
4.1.1 Use-specific instructions for use .....	12
4.1.2 Use-specific risk mitigation measures.....	12
4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment .....	12
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging....	13
4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage.....	13
<b>5. GENERAL DIRECTIONS FOR USE</b> .....	<b>14</b>
5.1 Instructions for use.....	14
5.2 Risk mitigation measures.....	14
5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment .....	14
5.4 Instructions for safe disposal of the product and its packaging .....	15
5.5 Conditions of storage and shelf-life of the product under normal conditions of storage ...	15
<b>6. OTHER INFORMATION</b> .....	<b>16</b>
<b>7. REFERENCES</b> .....	<b>17</b>

## Preface

An authorisation of a biocidal product – be it a single biocidal product or a biocidal product family – includes the so-called Summary of Product Characteristics (SPC) as laid down in Article 22 of the Biocidal Products Regulation (BPR, EU No 528/2012). Consequently, the SPC is an important result of the authorisation process, not only for the authorisation holder but also for Competent Authorities in the Member States (MSCAs), including enforcement authorities. The quality of the SPC is therefore of utmost importance with respect to its content, but also related to aspects like clarity and readability.

With this background, this recommendation on how to prepare an SPC has been prepared to support applicants as well as MSCAs. The document serves as a compilation of various agreements made in the Coordination Group, Biocides Competent Authority meetings and Biocidal Products Committee meetings related to the content of the SPC and aims to help the reader in preparing a clear and comprehensible SPC, which follows the legal obligations.

The content of the recommendation is applicable for simplified, national and Union authorisation. In relevant parts it is indicated if the instruction concerns only one type of authorisation.

The document follows the structure of an SPC for a single biocidal product. However, it is applicable for both single biocidal products and biocidal product families.

## List of Abbreviations

Abbreviation	Explanation
AH	Authorisation holder
AS	Active substance
AVK	Anti-vitamin K
BPC	Biocidal Products Committee
BP	Biocidal product
BPF	Biocidal product family
BPR	Biocidal product regulation (EU) No 528/2012
CA	Competent authority
CG	Coordination group
cMSs	Concerned Member States
H-statement	Hazard statement (from the CLP Regulation)
MR	Mutual recognition
MS	Member State
NA	National authorisation
P-statement	Precautionary statement (from the CLP Regulation)
PT	Product type
refMS	Reference Member State
RMM	Risk mitigation measure
RTU	Ready to use
SoC	Substance of Concern
SPC	Summary of Product Characteristics
UA	Union authorisation

## 1. Administrative information

### 1.1 Trade name(s) of the product (BP) / Family name (BPF)

<b>Trade name(s)</b>	

Instructions and agreements:

- In case the product would have more than one name, all names can be provided in this field (*CA-Sept14-Doc.5.4 – Final*).
- For Union authorisation (UA) trade names should not be translated, but rather all trade names in all Member states should be included in the English (master) SPC.
- For national authorisation (NA) this field in the SPC is MS-specific, so it will only include the name(s) authorised in that MS (*CA-May15-Doc.4.4 – Final.rev4*).

### 1.2 Product type(s) (BPF)

<b>Product type(s)</b>	

Instructions and agreements:

- In case the family would belong to more than one product type (PT), all PTs can be provided in this field (*CA-May15-Doc.4.6.a – Final*).

### 1.2 Authorisation holder (BP) / 1.3 Authorisation holder (BPF)

<b>Name and address of the authorisation holder</b>	<b>Name</b>	
	<b>Address</b>	
<b>Authorisation number</b>		
<i>Suffixes to the authorisation number linked to trade names</i>		
<i>R4BP asset reference number</i>		
<b>Date of the authorisation</b>		
<b>Expiry date of the authorisation</b>		

Instructions and agreements:

- Name and address of the authorisation holder (AH) are information imported from R4BP, not filled out in the SPC Editor. Thus, these fields are not visible when filling out an SPC in the SPC Editor.
- Authorisation number will be given and date of the authorisation, as well as expiry date of the authorisation, are set by the Member State granting the national authorisation or by the Commission when the authorisation is granted for Union authorisation, so these fields are not visible when filling out an SPC in the SPC Editor.

### 1.3 Manufacturer(s) of the product (BP) / 1.4. Manufacturer(s) of the biocidal products (BPF)

<b>Name of manufacturer</b>	
<b>Address of manufacturer</b>	
<b>Location of manufacturing sites</b>	

<p><u>Instructions and agreements:</u></p> <ul style="list-style-type: none"> <li>• Only sites where the manufacturing processes leading to the final biocidal product take place (except sites that perform filling operations) or, where they are different, those which allocate the production batch numbers referred to in Article 65(2)(d), should be listed in the SPC. Upon request from a Competent Authority (CA), for enforcement purposes for instance, the AH shall without delay provide information on the different sites involved in the whole manufacturing process, including contract manufacturers (<i>CA-May15-Doc.4.4 – Final.rev4</i>).</li> <li>• Contract manufacturers carrying out filling operations are subject to the relevant obligations referred to in Article 65(2) of the BPR and where relevant, to national legislation regarding the registration or authorisation of manufacturers of biocidal products (<i>CA-May15-Doc.4.4 – Final.rev4</i>).</li> <li>• Biocidal product family (BPF): All the manufacturers and manufacturing sites for any individual products within the family should be listed (<i>CA-May15-Doc.4.6.a – Final</i>).</li> <li>• The location of the manufacturing site(s) for the manufacturer(s) of the biocidal product (s) (BP(s)) has to be mentioned in the published SPC, i.e., it cannot be regarded as confidential in accordance with Article 66 of the BPR (<i>CA-May15-Doc.4.4 – Final.rev4</i>).</li> <li>• NA: The draft SPC submitted by the Reference Member State (refMS) to the concerned Member States (cMSs) in case of mutual recognition (MR) in parallel (or the SPC authorised in case of MR in sequence) should list all manufacturers of the product, so this would cover the manufacturers in all the MSs (<i>CA-May15-Doc.4.4 – Final.rev4</i>).</li> <li>• NA MR procedures: the authorisation in cMSs shall be subject to the same terms and conditions as in the refMS. Once the cMS has granted the national authorisation, the AH can notify an administrative change in order to add a new manufacturer in that MS, provided that the product composition and the manufacturing process remain unchanged. It has to be noted that this administrative change would not have any impact regarding the renewal procedure in accordance with Regulation 492/2014 (<i>CA-May15-Doc.4.4 – Final.rev4</i>).</li> </ul>
--

### 1.4 Manufacturer(s) of the active substance(s) (BP) / 1.5. (BPF) Manufacturer(s) of the active substance(s)

<b>Active substance</b>	
<b>Name of manufacturer</b>	
<b>Address of manufacturer</b>	
<b>Location of manufacturing sites</b>	

<p><u>Instructions and agreements:</u></p> <ul style="list-style-type: none"> <li>• The location of the manufacturing site(s) for the manufacturer(s) of the active substance(s) (AS(s)) has to be mentioned in the published SPC, i.e., it cannot be regarded as confidential in accordance with Article 66 of the BPR (<i>CA-May15-Doc.4.4 – Final.rev4</i>).</li> </ul>
--

## 2. Product composition and formulation

### 2.1 Qualitative and quantitative information on the composition of the product (BP)/of the family (BPF)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
		Active substance			
		Non-active substance			

#### Instructions and agreements:

- Content of AS should always be given as % w/w (not e.g., v/v). For details on expressing the content of the AS please refer to Q10 in *CA-May15-Doc.4.4 – Final.rev4*.
- Non-active substance(s) knowledge of which is essential for proper use of the product should be included. In the draft SPC in the application the applicant shall also indicate the exact function (e.g., solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of the non-active substance (*CA-Sept14-Doc.5.4 – Final, CA-May15-Doc.4.6.a – Final*).
- Do not indicate "Substance of Concern" (SoC) under the heading "Function" for non-active substances but include always "non-active substance" (*BPC-23 agenda item 8.2 and BPC-31 agenda item 8.4*).
- The question of which non-active substances should be considered as, knowledge of which is essential for the proper use of the product, should be addressed on a case-by-case basis according to the outcome of the risk assessment, which may depend on the properties and function of the non-active substances within the biocidal product. Non-active substances considered as SoCs should be listed in all cases (*CA-May15-Doc.4.4 – Final.rev4*).
- Express the content of non-active substance as the content of the non-active substance including any additives necessary to preserve its stability and any impurity derived from the process used (*CA-May15-Doc.4.4 – Final.rev4, BPC-31 agenda item 8.4 and BPC-33 agenda item 8.1*).
- For the following active substances: i) active chlorine released from sodium hypochlorite; ii) active chlorine released from calcium hypochlorite iii) active chlorine released from hypochlorous acid; and iv) active chlorine released from chlorine:
  - the content of available active chlorine is presented under the common name "Active chlorine released from [name releaser]", where the function is "Active substance" and neither CAS, nor EC number is indicated and
  - the content of the releaser (expressed as technical material) is presented where the common name is the name of the releaser; the function is "Releaser" and the concerned CAS and EC numbers – if available – are indicated. (*BPC-40 agenda item 8.3*)<sup>1</sup>.

<sup>1</sup> The SPC editor has to be amended to make it possible to list "Releaser" under the heading "Function" and have it visible for dissemination purposes. Before this change is implemented to the SPC Editor, the "Function" in the disseminated document can only be "Non-active substance".



## 2.2 Type of formulation (BP) / 2.2. Type(s) of formulation (BPF)

Instructions and agreements:

- In case the family would have more than one formulation type, all types can be provided in this field (*CA-May15-Doc.4.6.a – Final*).
- For pre-impregnated wipes the formulation type could be specified as: AL (any other liquid) – RTU wipe.

### 3. Hazard and precautionary statements (BP) / 3. Hazard and precautionary statement of the meta SPC (BPF)

<b>Hazard statements</b>	
<b>Precautionary statements</b>	

#### Instructions and agreements:

- According to Regulation (EC) 1272/2008 This section shall only include P-statements triggered by the CLP legislation. List all P-statements triggered by H-statements (*CA-May13-Doc.5.4, CA-Sept14-Doc.5.4 – Final, CA-May15-Doc.4.4 – Final.rev4, CA-May15-Doc.4.6.a – Final, BPC-29 agenda item 8.3*).
- A P-statement that has been proven unnecessary in the risk assessment because of the intended use of the product should be left out of the SPC and of the label (*CA-May13-Doc.5.4, CA-May15-Doc.4.4 – Final.rev4, CA-May15-Doc.4.6.a – Final, CA-Sept14-Doc.5.4 – Final*).
- When the same sentence is triggered at the same time by the CLP Regulation and by the risk assessment, then a repetition of this sentence is possible both as a P-statement in section 3 and as a risk mitigation measure (RMM) in section 5 (*CG-44\_e-c P-statements for non-professional users*).
- P-statements should be completed (*BPC-29 agenda item 8.3*), e.g., P231 "Handle and store contents ...".
- Hazard statements should be interpreted broadly to encompass also "supplementary hazard statements" such as the EUH statements referred to in the CLP Regulation (*CA-May15-Doc.4.4 – Final.rev4*).
- Only those hazard statements should be listed which are necessary for labelling purposes, e.g., in case a product is classified as both H314 and H318, then H318 is not needed in the SPC, as it is already covered by H314 (*BPC-40 agenda item 8.4*).
- For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work) (*CA-Sept14-Doc.5.4 – Final CA-May15-Doc.4.6.a - Final*).

## 4. Authorised use(s) (BP) / 4. Authorised uses of the meta SPC (BPF)

### General instructions and agreements concerning all sections below:

- All instructions for use, RMMs and other directions for use that are valid for all authorised uses of a single biocidal product (*CA-Sept14-Doc.5.4 – Final*) or valid for all authorised uses within the meta SPC (*CA-May15-Doc.4.6.a – Final*) should not be included under this section, but under section 5.
- Please consult the agreed list of frequently used sentences in the SPC and their translations and use them, if appropriate (*available at <https://www.echa.europa.eu/support/dossier-submission-tools/spc-editor>*).
- Please make sure to explain all abbreviations used when they appear the first time (e.g. HDPE = high-density polyethylene, GMP = Good Manufacturing Practice etc.).
- The International System of Units should be used.
- Please give instructions in active rather than passive voice.
- Please try to keep the SPC clear and comprehensible and avoid repetition of the same information in different fields.
- PT14 anticoagulant rodenticides: Please use the agreed harmonised sentences for SPC AVKs (*CA-Nov16-Doc.4.1.b – Final*).

### 4.1 Use description

**Table 1. Use # 1 – name of the use**

<b>Product Type</b>	
<b>Where relevant, an exact description of the authorised use</b>	
<b>Target organism(s) (including development stage)</b>	
<b>Field(s) of use</b>	
<b>Application method(s)</b>	
<b>Application rate(s) and frequency</b>	
<b>Category(ies) of users</b>	
<b>Pack sizes and packaging material</b>	

### Instructions and agreements:

- Copy this section as many times as necessary (one table per use, together with any instructions for use, RMMs and other directions for use that are use-specific. The SPC of a single biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence (*CA-Sept14-Doc.5.4 – Final*, *CA-May15-Doc.4.6.a – Final*).
- Name of the use should provide a short or synoptic description of the authorised use, which is further detailed in the associated table below the name of the use. See some examples below for different PTs:
  - For PT 14: Mice – non-professionals – indoor; Rats – professional users – sewers – large blocks,
  - For PT 8: Wood staining fungi – professional users – spraying – outdoor,
  - For PT 19: Repellent – (adult) mosquitos – general public (above 12 years) – spraying

– outdoor.

The terms chosen for the description of the authorised use should facilitate the comprehension by final users and inspectors. This is of particular relevance for SPCs of single biocidal products with a number of authorised uses for which separate product labels can be placed on the market (CA-May15-Doc.4.4 – Final.rev4).

- The field “where relevant, an exact description of the authorised use” is intended to provide a more specific description of the use for those PTs where different uses are referred to within the PT description of Annex V to the BPR (e.g., repellent or attractant in PT 19; disinfectant of drinking water for humans or for animals in PT 5; insecticide or acaricide in PT 18, etc.). This field would be left empty for other PTs (CA-May15-Doc.4.4 – Final.rev4).
- Please note under the field “Application method(s)” the following fields “Method” and “Detailed description of the method” from the SPC editor are included. Unnecessary repetition should be avoided in these sections.
- Please note that in the SPC in Word/PDF format under the field “Application rate(s) and frequency” information noted in the following fields “Application rate”, “Dilution (%)” and “Number and timing of application” are included. In addition to the application rate, contact time should be given, where relevant. For RTU products the field “Dilution (%)” can be left empty.
- NA MR procedures: Where a target organism cannot be authorised by the refMS on the grounds referred to in Article 37(1)(e) of the BPR, such target organism should be included in the draft SPC proposed by the refMS (in EN) and be also reflected in the agreed SPC so that cMSs can authorise the product in conformity with it. The specific situation in the refMS should be clearly flagged in the agreed SPC (e.g., by adding a footnote “The target organism (or use) cannot be authorised in the refMS due to ....”). However, for consistency and in order to avoid any misunderstandings by the readers of the final SPC issued by the refMS, section 4 should list the authorised target organisms only (CA-May15-Doc.4.4 – Final.rev4).
- PT14 Pack sizes and packaging material: Please consult the Harmonised approach on how to report the packaging size and packaging materials of PT14 products in the SPC (CG-34-2019-18 AP 14.1.2).

#### 4.1.1 Use-specific instructions for use

Instructions and agreements: In case there are no use specific instructions, include reference to section 5.1..

#### 4.1.2 Use-specific risk mitigation measures

Instructions and agreements: In case there are no use specific RMMs, include reference to section 5.2..

- RMMs resulting from the risk assessment should be referred to in here, where they are use-specific, or under heading 5.2 where they are applicable to any of the authorised uses (CA-May15-Doc.4.4 – Final.rev4).

#### 4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Instructions and agreements: In case there are no use specific particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment, include reference

to section 5.3..

**4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging**

Instructions and agreements: In case there are no use specific instructions for safe disposal of the product and its packaging, include reference to section 5.4..

**4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage**

Instructions and agreements: In case there are no use specific conditions of storage and shelf-life of the product under normal conditions of storage, include reference to section 5.5..

## 5. General directions for use

### General instructions and agreements concerning all sections below:

- Instructions for use, RMMs and other directions for use under this section are valid for all authorised uses of a single biocidal product (*CA-Sept14-Doc.5.4 – Final*) or valid for all authorised uses within the meta SPC (*CA-May15-Doc.4.6.a – Final*).
- PT14 anticoagulant rodenticides: Please use the agreed harmonised sentences for SPC AVKs (*CA-Nov16-Doc.4.1.b – Final*).

### 5.1 Instructions for use

#### Instructions and agreements:

- Describe the necessary instructions relevant for all uses in single biocidal product or all uses under meta SPC in biocidal product family like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance (*CA-Sept14-Doc.5.4 – Final, CA-May15-Doc.4.6.a – Final*).
- For non-professional / general public uses, the sentence P103 "Read label before use<sup>2</sup>" should be adapted to "Comply with the instructions for use" and included in this section (*CG-44\_e-c P-statements for non-professional users\_Final*).

### 5.2 Risk mitigation measures

#### Instructions and agreements:

- BP: Instructions for use, RMMs and other directions for use under this section are valid for all authorised uses of a single biocidal product (*CA-Sept14-Doc.5.4 – Final*).
- BPF: Instructions for use, RMMs and other directions for use under this section are valid for all authorised uses within the meta SPC (*CA-May15-Doc.4.6.a – Final*).
- Do not include RMMs like "The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management", as these are not regarded as use specific RMMs but obligations for the authorisation holder related to resistance management. It is a horizontal policy issue that needs to be further analysed, before such sentence can be included in the SPC or in the terms and conditions of the authorisation. (*BPC-35 agenda item 8.3*).

### 5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

<sup>2</sup> Please note that in the CLP the most recent P103 wording is „Read carefully and follow all instructions.“

Instructions and agreements:

- For non-professional / general public uses the spirit of the sentence P101 "If medical advice is needed, have product container or label at hand" could be adapted and included into this section (*CG-44\_e-c P-statements for non-professional users\_Final*).
- For first aid instructions please consult the "Guidance for harmonisation of first aid instructions in the authorisation of biocidal products" (*CG-43\_SE Guidance for first aid instructions\_Vf*).

## 5.4 Instructions for safe disposal of the product and its packaging

Instructions and agreements.

## 5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Instructions and agreements:

- For non-professional / general public uses the sentence P102 "Keep out of reach of children" should be adapted to "Keep out of reach of children and non-target animals/pets" and included in this section (*CG-44\_e-c P-statements for non-professional users\_Final*).

## 6. Other information

--

### Instructions and agreements:

- PT14 anticoagulant rodenticides: Please use the agreed harmonised sentences for SPC AVKs (*CA-Nov16-Doc.4.1.b – Final*).



## 7. References

### Documents agreed at CA meetings:

- CA-May13-Doc.5.4 - Final.rev1 - Classification and labelling of biocidal products
- CA-Sept14-Doc.5.4 - Final - SPC template reviewed
- CA-May15-Doc.4.4 – Final.rev4 - Q&A on SPC content
- CA-May15-Doc.4.6.a - Final - Updated SPC template for BPF
- CA-Nov16-Doc.4.1.b - Final - harmonised sentences SPC AVKs

Available at: <https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a>

Path: /CircaBC/SANTE/BPR - Public/Library/documents\_finalised

### Documents agreed at CG meetings:

- CG-34-2019-18 AP 14.1.2 Harm for reporting\_packaging size and material PT14\_vf
- CG-43\_SE Guidance for first aid instructions\_Vf
- CG-44\_e-c P-statements for non-professional users\_Final

Available at: <https://webgate.ec.europa.eu/s-circabc/w/browse/89efe476-1017-46af-8a31-6ad845f79d04>

Path: /CircaBC/echa/Biocides CoordinationGroup\_public/Library/General agreements

### Other documents:

- Frequently used sentences in the SPC and translations

Available at: <https://www.echa.europa.eu/support/dossier-submission-tools/spc-editor>

- SPC AVKs translations

Available at: <https://www.echa.europa.eu/support/dossier-submission-tools/spc-editor>)

- BPC minutes

Available at: <https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/meetings-of-the-biocidal-products-committee/2022>

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