COMPLIANCE

Cosmetic products in Europe

EU Regulation EC 1223/2009

GUIDE

ABioSA GUIDE

SEPTEMBER 2021

The EU regulation for cosmetic products (EC 1223/2009) requires a Product Information File (PIF) for all cosmetic finished products made available on the European Economic Community market. This document must be read together with the ABioSA guide 'Product Information File: Regulatory documents and information needed to create a PIF'.

forestry, fisheries & the environment
Department:
Forestry, Fisheries and the Environment
REPUBLIC OF SOUTH AFRICA

THE ABS CAPACITY DEVELOPMENT INITIATIVE

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Economic Affairs SECO

Contents

This guide is part of a series of knowledge products produced by ABioSA. These knowledge products and other biotrade resources can be found at www.abs-biotrade.info/projects/abiosa/resources

A glossary of biotrade terms can be found at www.abs-biotrade.info/resources

Lisam was commissioned by the project ABioSA to develop and publish this guide. ABioSA is funded by the Swiss State Secretariat for Economic Affairs (SECO), integrated in the governance structure of the ABS Initiative, and implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH. Although every effort has been made to provide complete and accurate information, GIZ, SECO and Lisam make no representations or warranties, express or implied, as to its accuracy at the time of use.

Adrie El Mohamadi
Component Manager
The ABS Capacity Development Initiative
(ABS Compliant Biotrade in Southern Africa)
Center for Cooperation with the Private Sector (CCPS)

Deutsche Gesellschaft für
Internationale Zusammenarbeit (GIZ) GmbH
+27 12 423 7955 | +27 82 902 4083
adrie.elmohamadi@giz.de
www.giz.de & www.abs-biotrade.info

The ABS Initiative is funded by

Federal Ministry for Economic Cooperation and Development

Norwegian Ministry of Foreign Affairs

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Economic Affairs SECO

and implemented by

giz Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

Glossary

- **Claim** - A result that the cosmetic product advertises to uphold or deliver
- **Carcinogenicity, mutagenicity, and reproductive toxicity (CMR)** - A substance that is carcinogenic, mutagenic, or toxic to reproduction
- **Colourant** - A substance used to colour the cosmetic product
- **Cosmetic Product Notification Portal (CPNP)** - A free, online notification system created for EC 1223/2009
- **Cosmetic Product Safety Report (CPSR)** - A legal document provided by a scientific professional to ensure the safety of the cosmetic product
- **European Economic Community (EEC)** - A former regional organisation incorporated into the European Union in 1993
- **General Product Safety Directive (GPSD)** - A directive that establishes the essential requirements for consumer products that are not covered by specific regulations
- **Good Laboratory Process (GLP)** - A quality system concerned with the organisational process and conditions under which non-clinical health and environmental studies are managed
- **Good Manufacturing Process (GMP)** - A quality system concerned with ensuring that products are consistently produced and controlled according to quality standards
- **International Nomenclature Cosmetic Ingredient (INCI)** - A systematic name internationally recognised to identify cosmetic ingredients
- **International Organisation for Standardisation (ISO)** - An international standard-setting body composed of representatives from various national standards organisations
- **Leave-on product** - A cosmetic product that is intended to be kept on after use
- **Market surveillance** - An obligation of the Responsible Person to systematically monitor, prevent and investigate abusive, manipulative, or illegal practices within the European Market
- **Nanomaterial** - An insoluble or biopersistant manufactured material with an internal or external scale of 1 to 100 nm in the cosmetic product
- **Organisation for Economic Co-operation and Development (OECD)** - An organisation responsible for providing current and better policies to stimulate economic progress and world trade
- **Preservative** - A substance used to inhibit the development of micro-organisms in the cosmetic product
- **Product Information File (PIF)** - A regulatory document legally required for placing a cosmetic product on the European Market
- **Prohibited Substance** - A hazardous substance that is monitored, controlled, and/or disallowed in a cosmetic product
- **Responsible Person (RP)** - A legal person of the European member states that takes responsibility for many facets of cosmetic product deployment
- **Restricted Substance** - A hazardous substance that is monitored and limited in the concentration of the cosmetic product
- **Rinse-off Product** - A cosmetic product that is intended to be washed off after use
- **Safety Assessment** - A systematic collection of information on hazardous chemicals/products to afford an informed risk evaluation of the material
- **South African National Standard (SANS)** - A division of the South African Bureau of Standards, responsible for creating regulations and guidelines for industry

- **Scientific Committee on Consumer Safety (SCCS)** - An independent European Committee responsible for providing scientific advice to the European Commission on issues related to non-food issues
- **Serious Undesirable Effects (SUEs)** - Effects characterised by serious permanent/semi-permanent health problems
- **Software as a Service (SaaS)** - A software licensing and delivery model on which software is licenced on a subscription basis and is centrally hosted
- **Trace amount** - A volume or mass of a substance that is considered insignificant in the current concentration, usually 0.01% or 100ppm
- **UV Filter** - A substance which is used to protect the skin against UV radiation

Legislation: Background and requirements

The EU Regulation for cosmetic products (EC 1223/2009) requires a product Information File (PIF) for all cosmetic finished products made available on the EEC market.

A cosmetic product is defined by the regulation as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours".

The purpose of the Product Information File (PIF) is to ensure that all the supporting documentation is made available to support the assessment of human safety of the cosmetic product for its foreseeable use/s, and that it is kept updated.

A Responsible Person (RP) is defined by the regulation as a legal or natural person within the EEC responsible for ensuring compliance in accordance with the cosmetic regulation. By default, the RP is the manufacturer of the product (established within the EEC), though the manufacturer may designate a person established within the EEC as the RP. If the product is imported, each importer for the product is designated as the RP. The importer may designate a person established within the EEC as the RP. A distributor is the RP if they place a product under their name or trademark, or modify a product already placed on the market.

The RPs legal obligations are discussed below on page 6.

Unpacking the definition of a cosmetic product

The key aspects to consider for the cosmetic product definition in order to ensure compliance are the application site and the principle intended function e.g. a Leave-on hand sanitiser is **not** a cosmetic (main purpose is to sanitise).

A product may have a primary purpose and a secondary purpose; this distinction may not necessarily exclude it from being a cosmetic product e.g. toothpaste (keeps teeth clean and healthy but is not a medicinal product if the product is not presented as such). The product may also be a medicinal product, medical device, biocide, toy, food or chemical. Articles are not cosmetic products (e.g. cosmetic wipes (tissue is **not** cosmetic, lotion is), clothing with a releasing substance (the material is **not** a cosmetic, but the substance is)) – the General Product Safety Directive (GPSD) will apply. Examples of borderline products:

- Tattoos are **not** cosmetics
- Nutricosmetics are **not** cosmetics
- Body paint **is** a cosmetic

Borderline between cosmetic and medicinal products

If a product falls into the classification of both a cosmetic and a medicine, then the Medicinal Products Directive (Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001) will apply.

The Medicinal Products Directive defines a medicinal product as “any substance or combination of substances presented as having properties for treating or preventing disease in human beings”. A product may be considered a medicinal product if it is presented either for treating or preventing disease.

The following considerations need to be taken into account when deciding which regulation the product falls under:

- Claims and context of the claims
- How a product appears to the public
- The packaging and labelling
- The promotional material, advertisements and target market

Responsible Person (RP)

The Responsible Person is a legal or natural person within the EEC that is responsible for ensuring compliance in accordance with the cosmetic regulation.

The default RP is the manufacturer of the product (established within the EEC) or the importer of a product not manufactured in the European Economic Zone. The importer, the manufacturer or the distributor may appoint an independent RP. If the product is imported, each importer for the product is designated as the RP. A distributor is the RP if they place a product under their name or trademark, or modify a product already placed on the market. The RP must be resident in the EEC.

The Responsible Person's legal obligations are:

Ensuring the product is safe for the intended foreseeable use.

Ensuring the product is manufactured according to Good Manufacturing Principles (GMP). If the product is manufactured outside of the EEC, it is the responsibility of the RP to ensure that the product is manufactured according to GMP, which should include an audit of the manufacturing process.

Ensuring that the cosmetic product has undergone a Safety Assessment prior to it being placed on the EEC market. The Safety Assessment must be conducted by a suitably qualified Safety Assessor. Per EU regulations, this is a person that possesses as university qualification in pharmacy, toxicology, medicine or a similar discipline, or as defined by the member state. The Safety Assessor does not have to be resident in the EEC.

Keeping a Product Information File (PIF) for ten years following the date on which the last batch of the product was placed on the market. If the product is changed in any way - such as a change in raw material, raw material supplier, packaging, update in stability, change in label, change in formulation - the PIF must be updated accordingly and where necessary, the Safety Assessment must be updated.

Ensuring that all analyses of a cosmetic product are performed within the guidelines of GLP, and that appropriate reference is made to standards as published in the *Official Journal of the European Union*, where applicable (refer to EC provisions for GLP).

Submitting information electronically to the Commission – this is done through the Cosmetic Product Notification Portal (CPNP) (see page 11 for further details).

Ensuring the control of prohibited and restricted substances as listed in the Annexures of the Cosmetic Regulations:

- Prohibited substances (Annex I and II)
- Restricted Substances (Annex III)
- Colourants (Annex IV)
- Preservatives (Annex V)
- UV Filters (Annex VI)
- Assess the use of CMR substances within the requirements of the Regulation

Notifying the Commission of the use of nanomaterials in the cosmetic product that do not conform to Annex III; this must be done 6 months prior to placing the product on the market.

Defining traces of prohibited substances which are permitted within the requirements of Annex III based on their inclusion being technically unavoidable within good manufacturing practice.

Ensuring that the final cosmetic product has not been tested on animals for the purposes of proving cosmetic safety, and meet the requirements of the Regulation.

Ensuring the label of the final cosmetic product conforms with the Regulation.

Ensuring that product claims are substantiated and that the evidence is provided in the PIF.

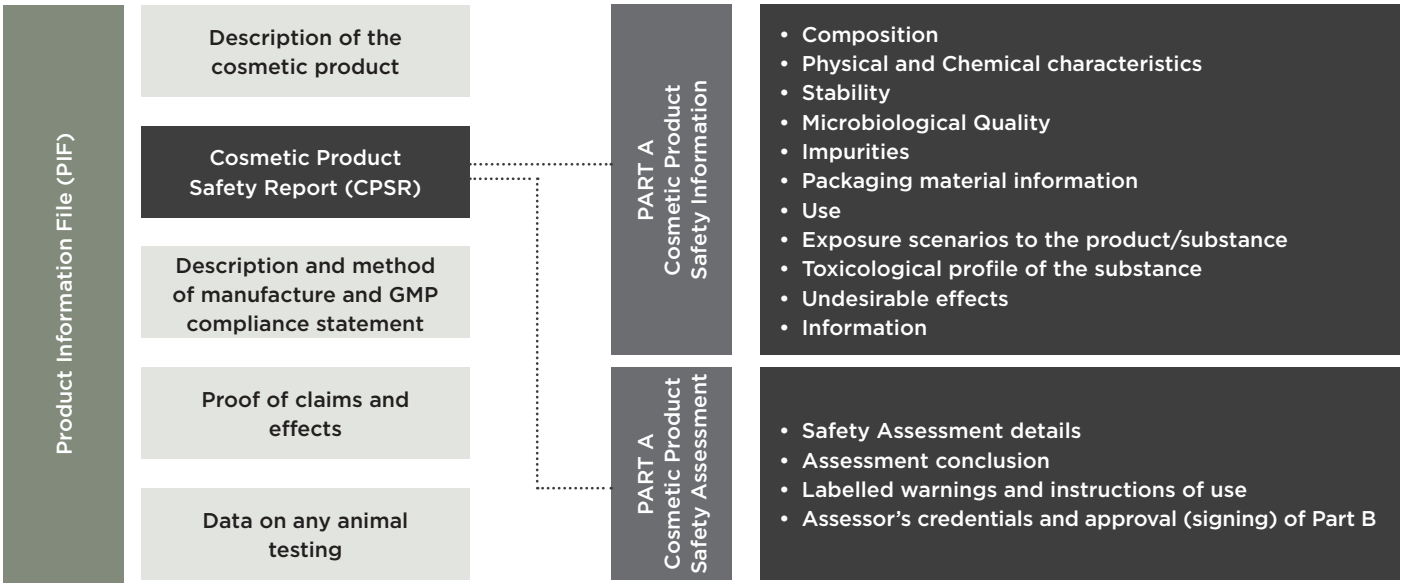
Ensuring access to information by the public, as required by the Regulation.

Market surveillance – records of customer complaints/compliments must be kept and added to the PIF; any medical findings against the product must also be added.

Notifying the authorities in the event of any Serious Undesirable Effects (SUEs).

Providing information to the authorities on the presence of particular substances in the product, as and when requested.

What is required for a Product Information File (PIF)?



Description of the cosmetic product
A description of the product according to the categories prescribed by COLIPA and SCCS (EC Scientific Council for Consumer Safety) is required. According to the SCCS **Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation** (10th revision), **these** categories apply.

Support for cosmetic product claims
The RP is responsible for ensuring that product claims are substantiated, and that the evidence is provided in the PIF. Some things to note:

- ***Legal compliance*** is assumed and may not be stated e.g. "Does not contain hydroquinone" (which is banned in the EU).
- ***Truthfulness*** – claims are not made falsely. If the product is listed as containing a specific ingredient, then it should. Claims on ingredients cannot be translated to the product unless proven scientifically using approved test methods for the product.
- Claims should be supported by ***appropriate supporting evidence***.
- Claims ***cannot denigrate opposition and ingredients*** that may be legally included in a cosmetic, e.g. this product does not contain parabens.
- Claims should be ***clearly understood*** by the end user.
- Tests should be conducted on human volunteers following ***ethical guidelines*** and products tested should have a ***Safety Assessment prior to human trials***.

Refer to the **Technical Document** on cosmetic claims (3 July 2017), compiled by the EU Sub-working Group.

Good Manufacturing Practices (GMP) according to ISO 22716:2007/ SANS22716:2011
ISO 22716:2007/ SANS 22716:2011 provides guidelines that offer organisational and practical advice on the management of human, technical and administrative factors affecting the quality of products.

GMP covers multiple topics and describes the relationship between these topics. These topics include:

- Management commitment and continual improvement
- Risk management
- Quality management system
- Site and facility management
- Product and raw material control
- Personnel training and competency

Why is GMP important:

- Ensures products have been produced according to appropriate quality and safety standards.
- Saves costs, thus increasing profits. By following GMP you lower the risk of waste, errors, employee injuries, etc.
- Creates a positive company image and reputation and gives confidence in the products produced.

For detailed summary and guidance on GMP, refer to the GMP knowledge product.

Animal testing

- Prohibited for cosmetic products and ingredients where animal testing was conducted to meet the regulatory requirements for cosmetics.
- Animal testing ban on finished cosmetic products has applied since 11 September 2004.
- Animal testing ban on ingredients or combination of ingredients has applied since 11 March 2009.
- For new ingredients developed for use in a cosmetic product, safety data needs to be derived from non-animal alternative methods (OECD methods and approved by the SCCS). The EU reports annually on alternative test method development and validation – such as the validated OECD test methods. Users will have to check the SCCS Guidelines to determine the tests required, then refer to **OECD**.
- Pre-existing data gathered prior to the 11 March 2009 deadline for an existing cosmetic ingredient can still be used.
- Animal test data relating to chemical substances developed for uses other than cosmetics (e.g. food, medicines, biocides, etc.) can be used as supporting data of an ingredient intended to be used in a cosmetic product.
- For the data required for the Cosmetic Product Safety Report (CPSR), refer to the ABioSA guide 'Product Information File: Regulatory documents and information needed to create a PIF' (Lisam, 2021).

Good Laboratory Practice (GLP)
The non-clinical safety studies referred to in the Safety Assessment carried out after 30 June 1988 for the purposes of assessing the safety of a cosmetic product shall comply with EEC legislation on the principles of Good Laboratory Practice, or with other international standards recognised as being equivalent by the EEC or the European Chemicals Agency (EC 1223/2009). All deviations from this set of rules should be explained and scientifically justified in the PIF (SCCNFP/0633/02) (SCCS Notes of Guidance, 2017, 10th revision). Safety studies conducted on chemicals must comply with the GLP **Directive 2004/10/EC**, which requires EU countries to take all measures necessary to ensure that laboratories carrying out safety studies on chemical products that comply with the **OECD Principles of Good Laboratory Practice**; Directive 2004/10/EC replaced Directive 87/18/EEC.

Labelling guidelines for a cosmetic product

1. The name or registered name and address of the Responsible Person (RP) where the PIF can be readily accessed (to be underlined if there are several addresses).
2. Country of origin for imported cosmetics.
3. The label must be in the regulated language/s of the EU member in which the product is made available to the end user.
4. Nominal contents of the product (given by weight (g) or volume (ml)). The net contents of a product must be labelled i.e. the net quantity of product at the time the packaging is filled with the cosmetic product. This is not required for ingredients below 5 g or 5 ml, single use packs such as sachets or capsules, or for free samples. If products are sold as a collection of items, this should be stated, e.g. 10 sachets.
5. The “e” mark (which indicates that the pre-packaged product fulfils EU Directive 76/21/EEC) must be shown if the product is filled according to the “average fill system”, which is defined in weights and measures legislation (1976) e.g. “200ml e”.
6. Particular precautions for consumers to take note of must be advised as a minimum (in particular, the requirements in Annex III and VI of the Cosmetic Regulation 1223/2009), along with any additional precautions, depending on the components, sources of raw materials and potential vulnerable population exposure.
7. Batch number or reference number to identify the cosmetic product (if the label is too small, then it may appear on the packaging or the Z-label).
8. The function of the cosmetic product.
9. The list of ingredients as per the regulatory requirements, preceded by the word “ingredients” - if the label is too small, it may be on packaging or Z-label. The list of ingredients and the order and wording of the ingredients is supplied in the PIF. If an INCI name is not available for an ingredient, a common nomenclature name may be used. Once an INCI name becomes available, the label must be updated within 12 months of the date of it being made available by the EEC in the glossary in the *Official Journal of the European Union*.
10. If the packaging is too small, the information in points 5-8 above may be provided on an enclosed or attached leaflet, label, tape, tag or cord, and **Figure 1** must then be included on the package.
11. For soap, bath balls and other small products, where it is impossible to provide for a leaflet (Z-label), a notice shall appear in immediate proximity to the container in which the cosmetic product is exposed for sale.

12. If products are packaged at point of sale, EU member states will provide labelling requirements – refer to each member state's legislation for the particular requirements.

13. The language for the information is prescribed by each individual member state.

14. Products must comply with additional national laws, in the language required.

15. Specific labelling/warnings must be used to prevent misuse of the product, taking into account the hazardous components and routes of exposure. The Safety Assessor will provide a statement for any particular warnings and instructions based on additional hazards.

16. Cosmetic products and packaging should not mimic a foodstuff - refer to regulation **87/357/EEC**.

17. Date of minimum durability may be indicated by the appropriate symbol or the words 'best used before the end of', as well as the conditions which satisfy this guarantee (where applicable). This is mandatory for products with stability tests < 30 months or minimum durability < 30 months. In this case, the symbol reflected in **Figure 2** is used.

18. If a room temperature stability test is available for the product for > 30 months stability (room temperature), there should be an indication of the period of time after opening and the symbol in **Figure 3** is used, followed by the period in months and/or years.

Figure 1

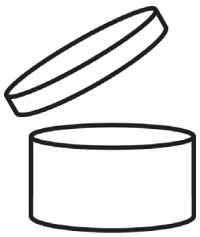


Figure 2

Figure 3

Cosmetics Packaging Safety Guidelines (final products and raw materials)

Certain **information** is required on cosmetic packaging (final products and raw materials) for the Cosmetic Safety Assessment and the PIF. These include:

- Details of the supplier, code of the product, description of the product, photos of packaging.
- Description of packaging materials used (to include all constituents e.g. polymer, colourants, any other agents used in the manufacture of the packaging component).
- GMP statement for the packaging manufacturing process (EU Good Manufacturing Practice (EC) No 2023/2006).
- Statement that the packaging material is suitable for the use in cosmetic raw materials and cosmetic final products.
- Provide a food contact statement for all the packaging components that the cosmetic product or raw material will be in contact with.
- Provide a statement if there are any substances that are > 0.1% identified as SVHC (REACH Regulation 1907/2006) and other substances of concern.
- Provide a statement for all heavy metals present (EU Directive 94/62).
- If the supplier is unable to provide the information of the migratable substances i.e. SVHC, heavy metals and other substances (a migratable substance is a chemical substance that is capable of transfer in detectable amounts from the packaging to the packed product; it is generally accepted that substances with a molecular weight greater than 1,000 Daltons are not migratable; inert, insoluble inorganic substances embedded in a polymeric matrix are not migratable) (Cosmetics Europe, 2019), then a migration study must be conducted by the cosmetic raw material/final product supplier.

How to register on the Cosmetic Product Notification Portal (CPNP)

CPNP is a free online notification system for the implementation of EC 1223/2009 on cosmetic products.

It is the responsibility of the Responsible Person to register the product prior to it being placed on the market.

The European Commission **website** provides a tutorial on how to request access to CPNP. It gives the following steps:

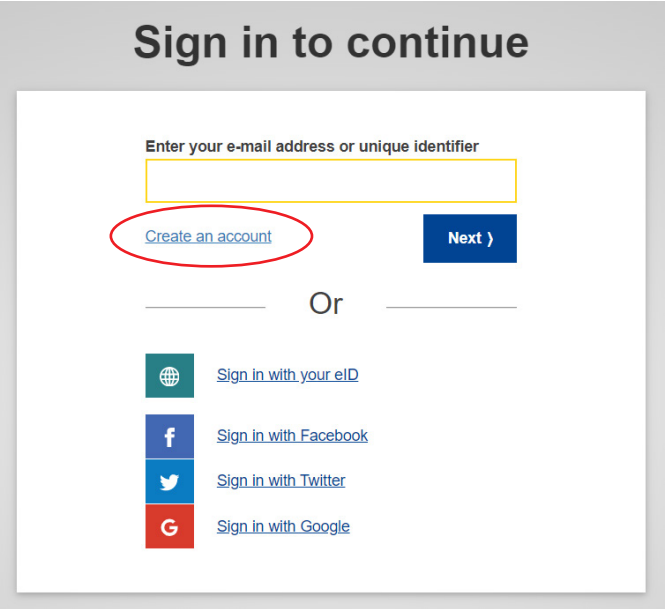
1. EU login account:
   a. If you already have a valid EU login account
   b. If you need to create a valid EU login account
   c. If you do not remember your EU login account
2. How to be defined as an organisation or request access in SAAS
3. How to enter CPNP

How to create an EU login account
Learn how to create your EU login account on EEC's user authentication service in six steps:

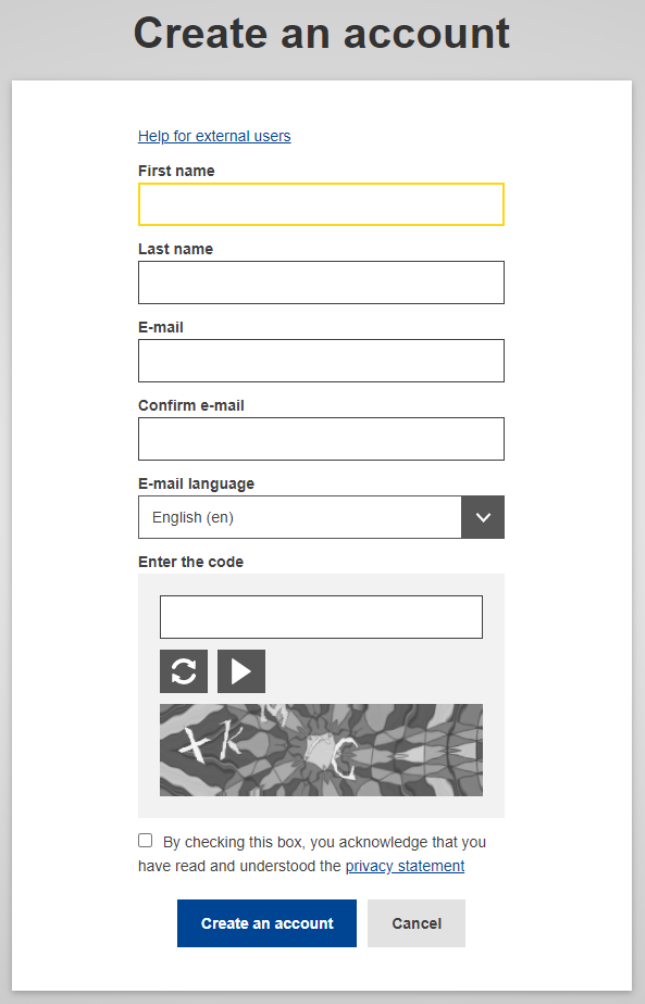
- Sign in
- Enter personal information
- Read confirmation message in your inbox
- Confirm registration sent via email
- Set password
- Log in

Step 1: Sign in

Create an account **here**.

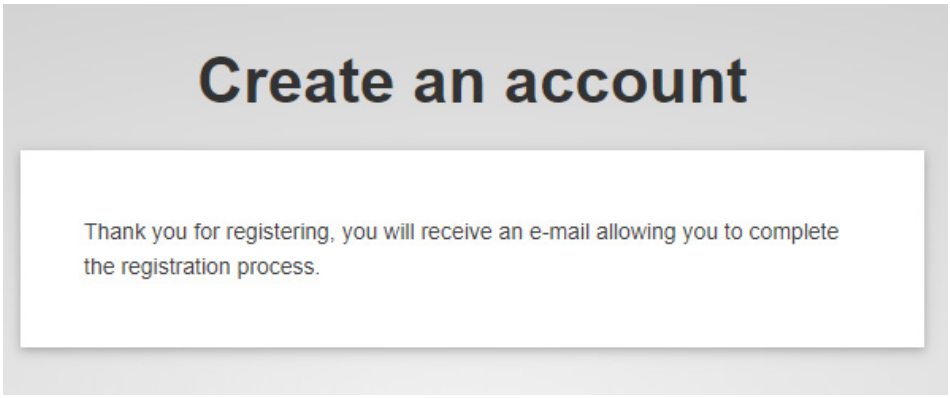


Step 2: Enter personal information



Step 3: Read confirmation message in your inbox

Once your login is created, the system will wait for your email validation. The system will send you an email to activate your account.



Step 4: Confirm registration sent via email

Go to your inbox and read the email sent by the system. You will receive a link in the email to confirm your registration. You have to confirm your registration within 24 hours of receiving the link.

To create your password, follow the link below:

this link

You have a maximum of 24 hr, starting from the time that this message was sent, to create your password, but you are encouraged to do so immediately if possible. After this time, you can make another request by following the same link: you will then need to re-enter your username and confirm your request.

If the above link does not work, you can copy the following address (make sure the complete address is copied!) and paste it into your browser's address bar:
https://webgate.ec.europa.eu/cas/init/initialisePasswordLogin.cgi?wayf.domain=external&wayf.remember=checked&wayf.submit=Select&uid=n007nxxe&resetCode=PN2rzNGJ4TIU

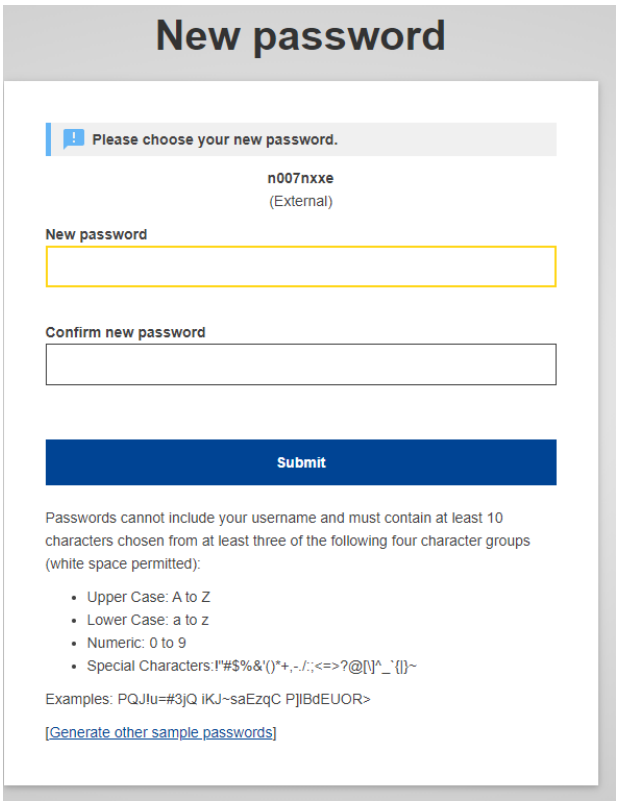
Instead of replying to this message, if you have a problem, please follow the help or contact information on the site where you were trying to register.

Note that it may take up to 5 minutes after reception of this mail before the above-mentioned site will recognize your registration.

Sent to you by EU Login

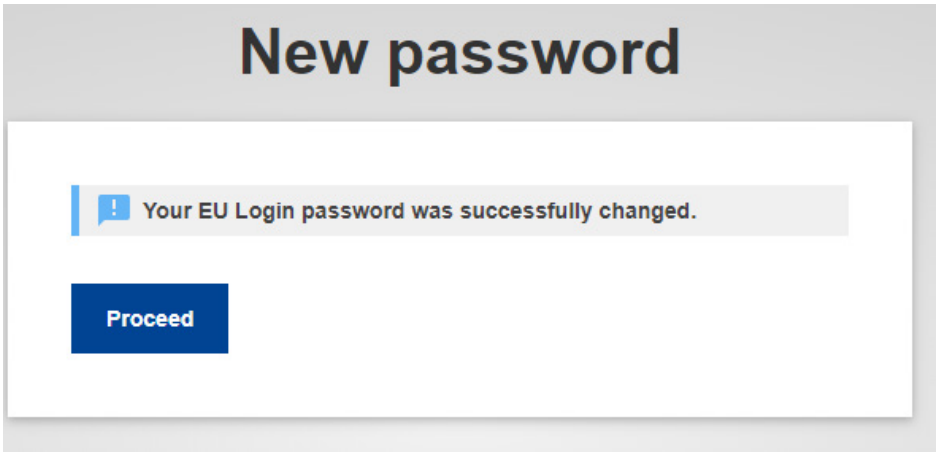
Step 5: Create a password

The system will require a strong password for security, as indicated below.



Step 6: Log in

You can now use your credentials to login.



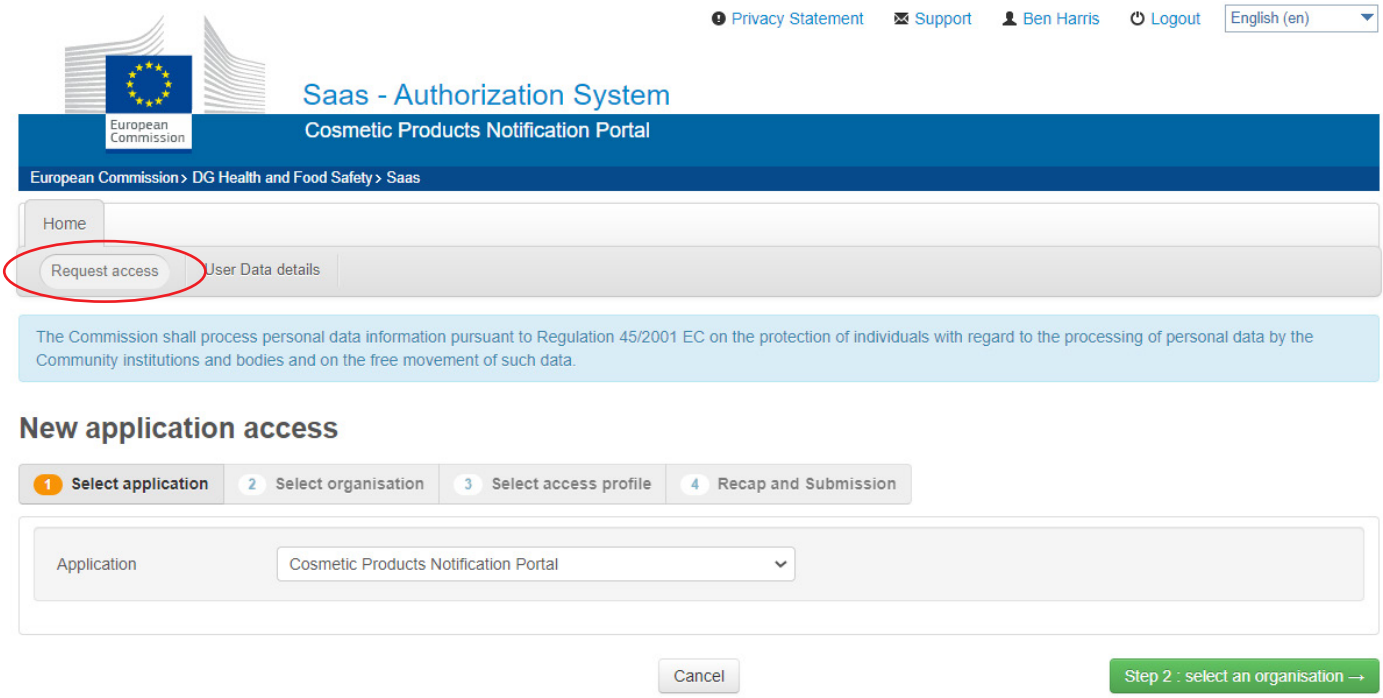
Log out by selecting the ‘Logout’ button in the top right-hand corner of the login page.

How to request access for you and your organisation on CPNP
See how to request access via the SAAS application in five steps:

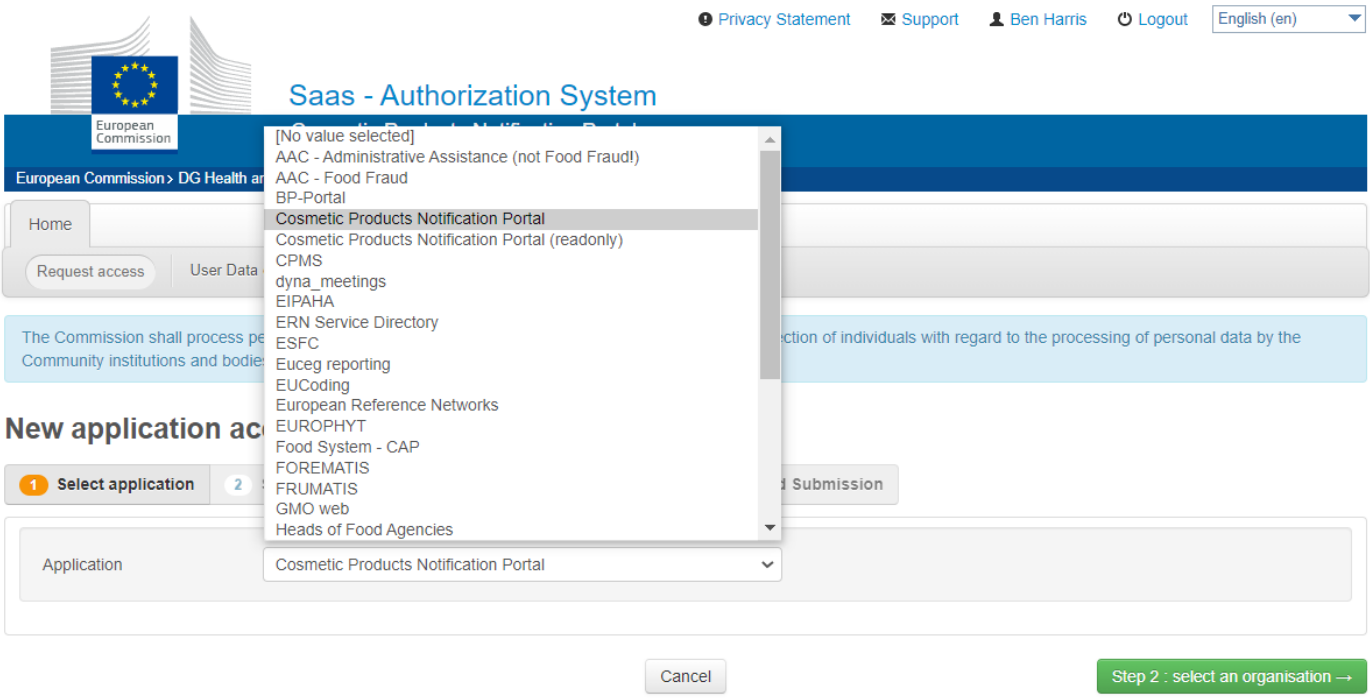
- Access to SAAS (request access page)
- Choose CPNP as application to request your access
- Select an organisation
- Search your organisation
- Create new organisation

Step 1: Access to SAAS

Go to **SAAS** and click 'Request Access' – you will need your valid EU login account to be able to request access to CPNP.

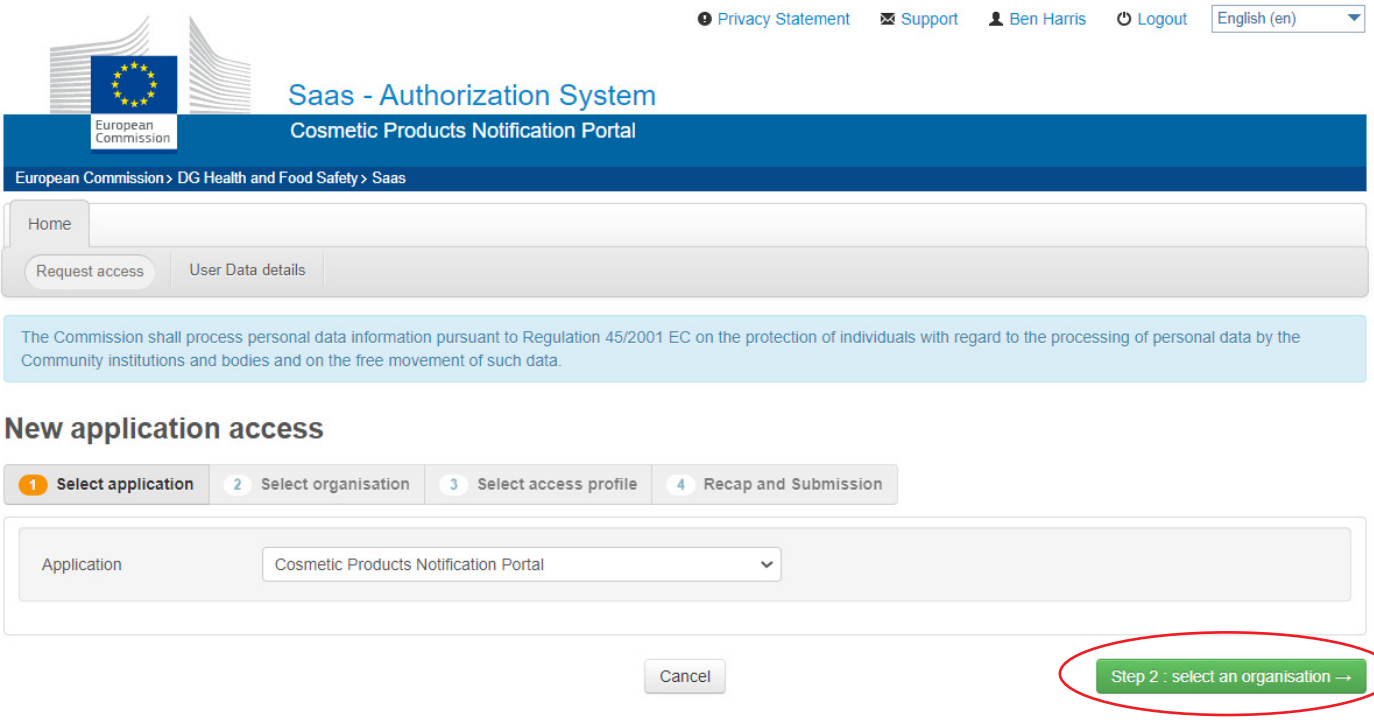


Step 2: Choose CPNP as application to request your access



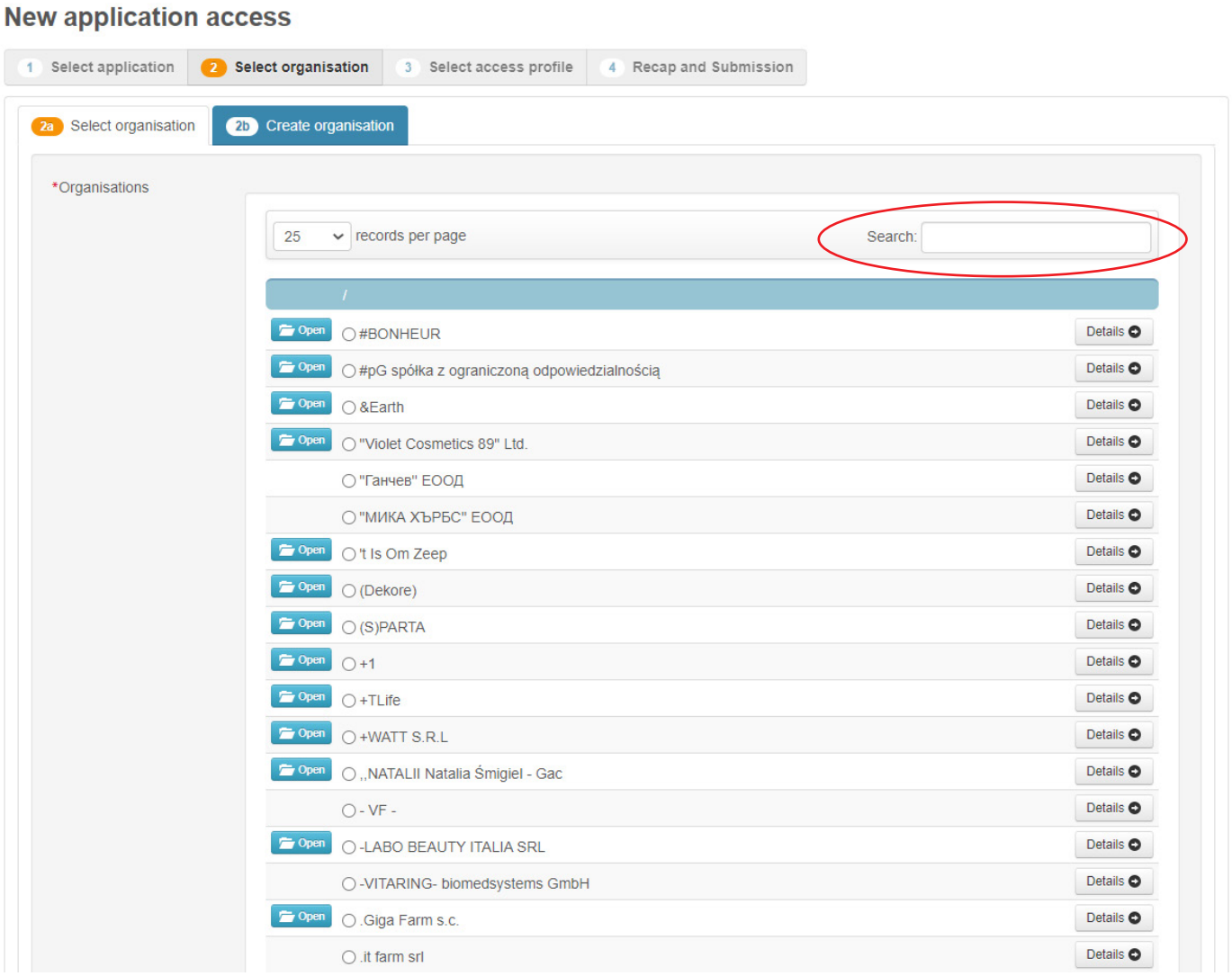
Step 3: Select an organisation

Select ‘Step 2: select an organisation’



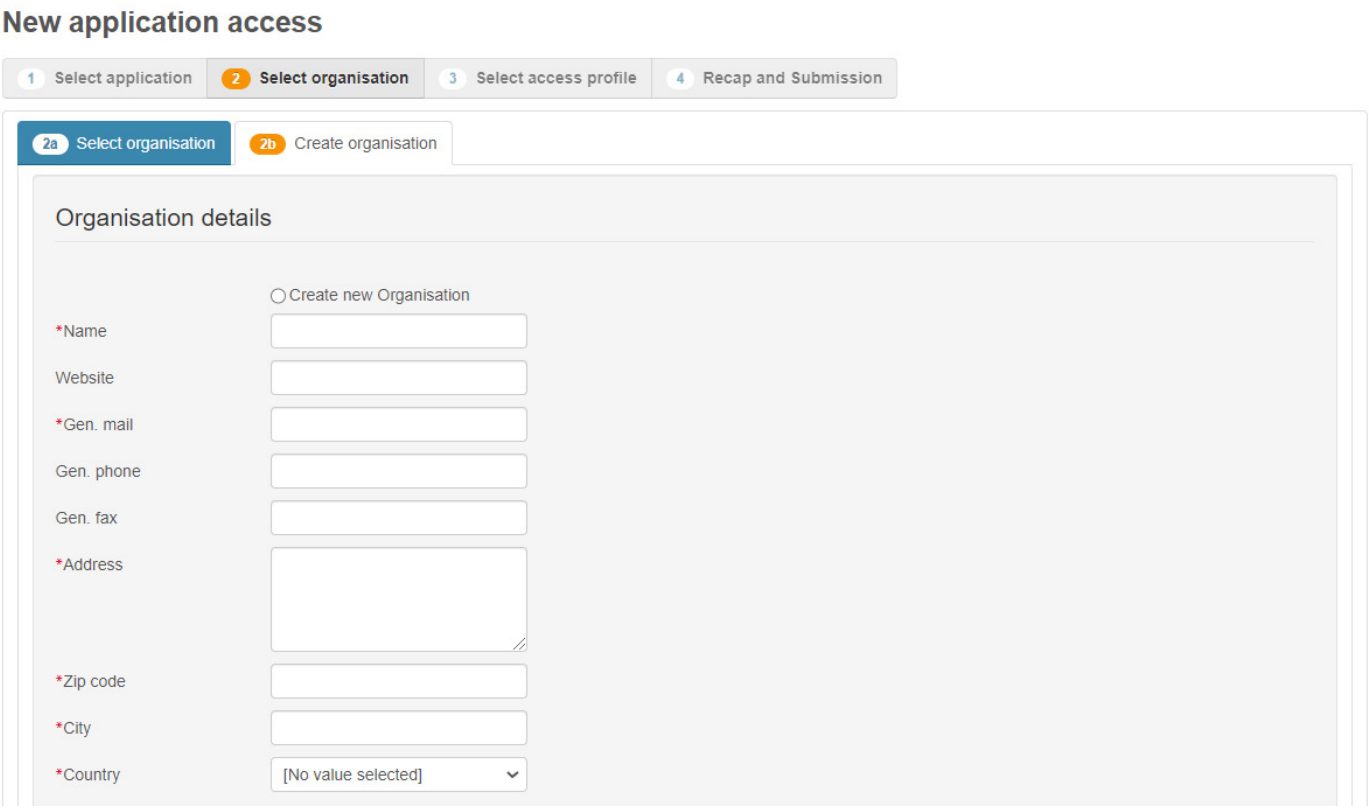
Step 4: Search your organisation

Search for your organisation in the search box. This step may result in two situations; either the search result contains your organisation, and you select it; or the result could not find your organisation and now you must create it.



Step 5: Create a new organisation

If your organisation does not exist, select ‘Create organisation’.



You can enter CPNP at any time **here**.

References

CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal L 353, 31/12/2008 p.1

COLIPA Guidelines: 'Consumer exposure to cosmetic ingredients', BB-97/007, 1997

Cosmetics Europe, Understanding the Label, accessed 28 July 2021, https://www.cosmeticseurope.eu/cosmetic-products/understanding-label/

Cosmetic Product Notification Portal, https://webgate.ec.europa.eu/cpnp/public/tutorial.cfm

Munro, I.C., Renwick, A.G., Danielewska-Nikiel, B., 2008. The Threshold of Toxicological Concern (TTC) in risk assessment. Toxicology Letters 180, 151–156.. doi:10.1016/j.toxlet.2008.05.006

European Commission, Good Laboratory Practice, https://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_en

European Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.

EU Legislation, COUNCIL DIRECTIVE of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre packaged products, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31976L0211&from=EN

EU Legislation, REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products

Hall, B., Steiling, W., Safford, B., Coroama, M., Tozer, S., Firmani, C., Mcnamara, C., Gibney, M., 2011. European consumer exposure to cosmetic products, a framework for conducting population exposure assessments Part 2. Food and Chemical Toxicology 49, 408–422.. doi:10.1016/j.fct.2010.11.016

ISO 22716:2007, Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices, https://www.iso.org/standard/36437.html

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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Steiling, W., Almeida, J.F., Assaf Vandecasteele, H., Gilpin, S., Kawamoto, T., O'Keeffe, L., Pappa, G., Rettinger, K., Rothe, H., Bowden, A.M., 2018. Principles for the safety evaluation of cosmetic powders. Toxicology Letters 297, 8–18.. doi:10.1016/j.toxlet.2018.08.011

Cosmetics Europe Advisory Document Information Exchange On Cosmetic Packaging Materials Along The Value Chain In The Context Of The Eu Cosmetics Regulation EC 1223/2009. 13 June 2019

Disclaimer:

This report has been compiled specifically for the use of the individual and/or entity to whom it has been addressed. If you are not the individual or entity to whom it has been addressed, you are not entitled to act in accordance with any of the advice and/or views which have been provided herein, without the authorisation of LISAM. Notwithstanding the aforegoing, this report is confidential, and has been compiled based on the facts and circumstances based on information gathered from third parties and provided as a summary to the entity to whom it is addressed, and no third party may make use of any view or advice, as provided herein, without the authorisation of LISAM.

Lisam Systems and Lisam South Africa liability will be limited to the repair of the Report supplied that does not comply in any way. No further damage claims or liability will be recognised. Lisam Systems and Lisam South Africa will not be liable for any direct or indirect damages to the customer or user of the supplied documents. Considering the nature of the services provided, the Lisam Report is subject to a best endeavours' obligation.

The Company undertakes to provide its services in accordance with standard professional practice complying with norms and other established standards, under the terms and conditions of the agreement between the parties, as well as in compliance with the legal and regulatory provisions that apply. Neither the Company, nor any of its directors or employees are liable nor responsible with regard to the services rendered to customers or third-parties, which is based on information supplied by the Customer or individuals that is not clear, is wrong, incomplete, misleading or false. The Company is neither an insurer, nor a guarantor, and declines to accept any liability in this respect. Customers seeking a guarantee against loss and damage must obtain appropriate insurance cover.