

Product Notification on the CPNP commission portal for notifying product



Aline WEBER
Head of Regulatory Affairs



Obligations of the RP

1. Product classification and ingredients compliance
2. GMP compliance
- 3. Product Notification**
4. Product information file
5. Labelling - Claims
6. Cosmetovigilance



Situation under the Cosmetics Directive 76/768/EEC

- *Unharmonised & multiple notifications throughout the EU*
- Notification to the Competent Authority
- Notification to Poison Centres



Regulation (EC) No 1223/2009 *Harmonised EU System*

- Central notification at European Commission level
- Notification required for new products and existing products still on the market
- Responsible person and distributor obligations



Who needs to notify – and to whom ?

- Responsible Person - *Prior to placing new product on the market and for existing products*
- Distributors – *When distributor translates the labelling on his own initiative for sale in another Member State*



What needs to be notified? *Responsible Person (RP)*

- Product category
- Product name(s)
- Responsible person - name and address
- Country of origin (*import only*)
- Member State where product is placed on the market
- Details of physical contact person in case necessity
- Nanomaterials – identification, exposure conditions
- CMRs (1A & 1B) – identification
- Frame formulation
- Original labelling (*only once*)
- Photograph of original packaging - if reasonably legible (*only once*)



What needs to be notified? *Distributor (when translating the labelling)*

Only required when a Distributor places a product which has already been placed on the market by RP in a Member State (MS) & from its own initiative, place it in another (MS) and translate the labelling

- Category of cosmetic product
- Product name in the Member State of dispatch
- Product name in the Member State in which it is made available enabling its specific identification
- The Member State in which the cosmetic product is made available
- Distributor name and address
- The name and address of the responsible person where the product information file is made readily accessible



Who has access to the notified Information? MS and **Poison Center**

- Product name(s)
- Responsible person - *name and address*
- Country of origin (*import only*)
- Member State where product is placed on the market
- Details of physical contact person in case necessity
- Nanomaterials – identification, exposure conditions
- CMRs (1A & 1B) – identification
- Original labelling (*only once*)
- Photograph of original packaging - if reasonably legible (*only once*)
- **Frame formulation**



1-Product Category

- Categorisation
- • 4 Level 1
- • 22 Level 2
- • 82 Level 3



2. Product Name(s)

- Cosmetic name or names, enabling its specific identification“ i.e. enabling the differentiation of products of the same product line
If the same product is on the market under different (translated) names, all names in the different languages have to be notified



3. & 4. Responsible Person and Contact Person

- Responsible Person : filled out automatically byCPNP
- Contact person details to contact in case of necessity



5. Country of Origin

- For imported products only
- If the same product is being “made in”in two or more countries ---> the system currently requires separate notifications



6. Member State where product is placed on the market

- One-off action
- Only one country needs to be identified, i.e. the country of first making available



7. Nanomaterial

- Identification
- Name - INCI
- CAS number
- EC Number (EINECS or ELINCS)
- IUPAC Name
- INN
- XAN
- Exposure type : Rinse off/ Leave on
- Exposure route
- Oral
- Dermal
- Inhalation



8. CMR (1A or 1B)

- Definition: Substances classified under chemical legislation as:
- Carcinogenic
- Mutagenic
- Reprotoxic
- Identification only
- Name, CAS #
- Only the CMR from “harmonised” classification
- (Annex VI of Regulation on Classification and labelling CLP)



9. Frame Formulations

- Frame formulations consist of lists of category / function of certain ingredients and their maximum concentration in the cosmetic product
- Additional indication of specific substances with exact concentration (high concern for poison centres)
- Alternatively : notification of Exact Formula or Concentration Ranges



10. Original Labelling

A one-off operation *Label*:

- refers to a copy of the artwork of the outer packaging of the product if there is a primary container and an outer packaging.... otherwise it is the artwork of the primary container”

Original:

- “refers to the first language / country version of the product that was placed on the market ...

If the product was simultaneously launched in several countries, you can chose which version you notify”



11. Photograph of Packaging

A *one-off* operation

- Photograph of packaging - *if reasonably legible* “Refers to a photograph of the outer packaging of the product if there is a primary container and an outer packaging Otherwise it is the photograph of the primary container”



Article 16 (notification of nanomaterials)

- ✓ In addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person 6 months prior to being placed in the market, except where they have already been placed on the market by the same responsible before 11 January 2013



Poison Information Centres (PIC)

- ✓ Any body established by member States and who can access the CPNP portal for the purposes of medical treatment.
- ✓ They can consult all the details of the notifications submitted by Responsible Persons (and Distributors).
- ✓ Draft notifications are not accessible to Poison Centres.



Competent Authorities (CA)

- ✓ In charge of market surveillance, market analysis, evaluation and consumer information regarding cosmetic products.
- ✓ They can consult all the details of the notifications submitted by Responsible Persons (and Distributors), except their composition.
- ✓ Draft notifications are not accessible to Competent Authorities.



REGISTRATION MECHANISM



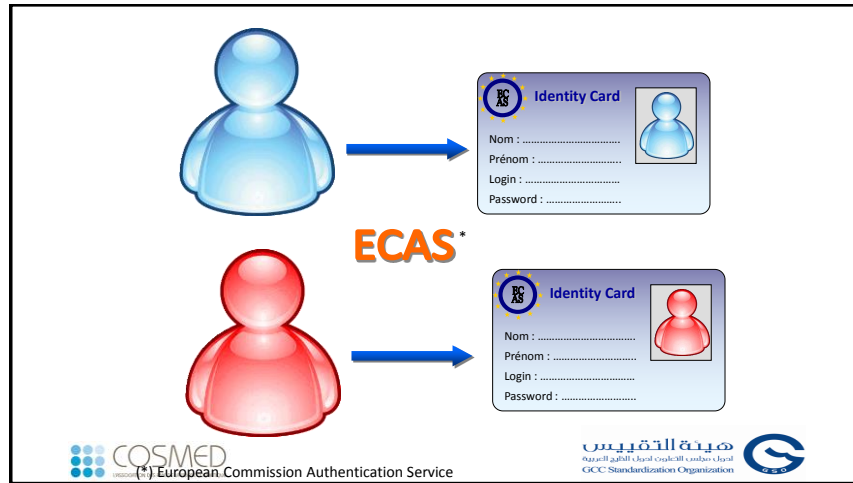
ECAS: Create a personal account (1)

- **ECAS:** European Commission Authentication Service
- This system provides the user with a login and password to connect to multiple European Commission applications.
- **URL:** <https://webgate.ec.europa.eu/aida/selfreg>

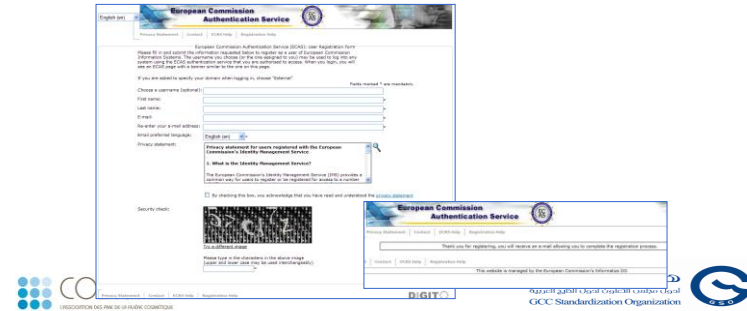


<https://webgate.ec.europa.eu/cnpn/>

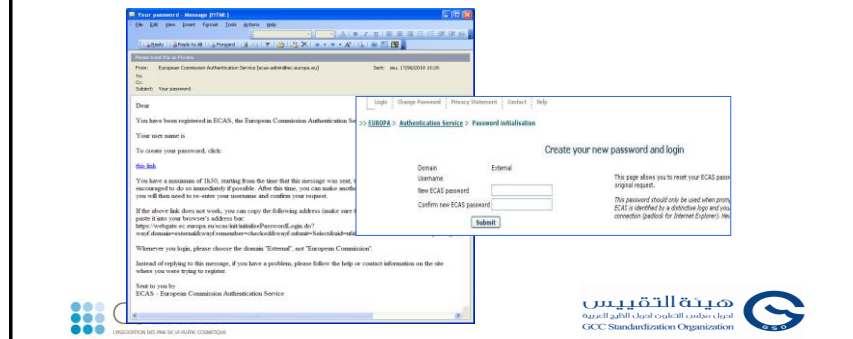




ECAS: Create a personal account (2)

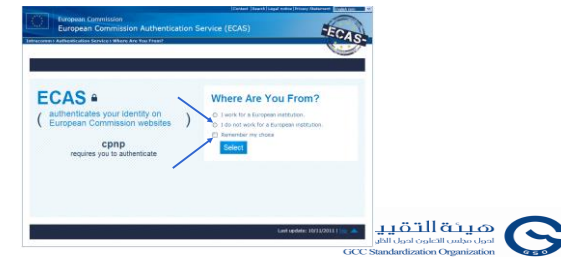


ECAS: Create a personal account (3)



ECAS: First login (1)

- URL: <https://webgate.ec.europa.eu/cnpn>



ECAS: First login (2)

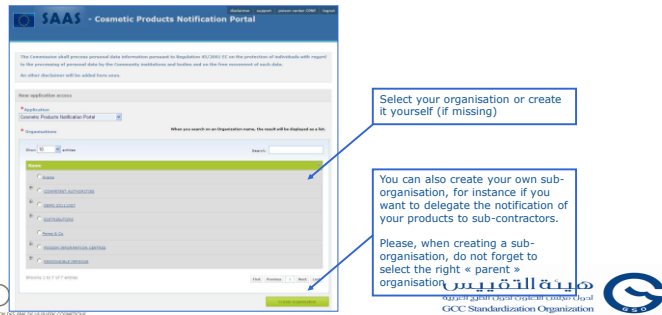


SAAS: Request an access to CPNP (1)

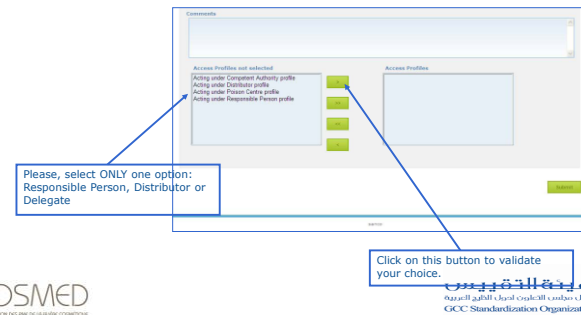
- **SAAS: SANCO Authentication and Authorisation System**
- This system provides the user with a profile and access rights for a specific European Commission application, in this case the CPNP.
- **Remark:** SAAS provides also administration interfaces to the Local Admin.
- **URL:** <https://webgate.ec.europa.eu/saas>



SAAS: Request an access to CPNP (2)



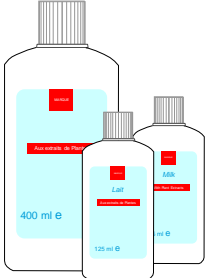
SAAS: Request an access to CPNP (3)





Advanced Search

[illegible]



Hints and Tips

- 1 Notification
- Notification of all translation of the product name
- Notification of one original labelling

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Thank you for your attention



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