

# Cosmetic Regulation in Andean Community

(Bolivia, Colombia, Ecuador, and Peru)



**Cristina ONCINS PALLAS**  
Regulatory Affairs Manager,  
COSMED



1



## LOBBYING FOR COSMETIC COMPANIES

- French National Agency for Medicines and Health Products Safety (ANSM)
- European Commission
- ISO, CEN, AFNOR
- Foreign countries authorities

## SHARED SERVICES

- Regulatory watch : 120 countries monitored
- Free Sale Certificates : <https://www.cosmedcvl.fr/>
- Training
- Purchasing group
- Events, Congresses


2


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### Uptdated database - Experts assistance

 **CHOOSE** your tailored solution

1 database France / Europe OR International  
2 databases France / Europe AND International

#### EUROPEAN DATABASE

- . French and E.U regulations
- . Specificities of E.U
- . Summary Tables of regulated ingredients
- . Product Information File
- . Assessment of ingredients
- . Notification of cosmetic product
- . Labelling, Claims
- . Cosmetovigilance
- . PAO tool
- . REACH, CLP
- . Actors' Obligations ...

#### INTERNATIONAL DATABASE


- . Classification of products: cosmetics, quasi-drugs, OTC, Natural Products
- . Fact sheets on regulations
- . Summary tables of regulated substances
- . Labelling, Claims
- . Registration / Notification of products ...
- . Comparative substances tables (UV filters ...)

 **NEW** COSMED REGULATORY monitoring in english  
A real asset for foreign subsidiaries and / or distributors

3

## TABLE OF CONTENTS

- 1) **Andean cosmetic legislation**
- 2) Definition and classification of cosmetics
- 3) Controlled substances
- 4) Labelling and claims
- 5) Mandatory Sanitary Notification (NSO)
- 6) Latest news: NSO holders, parallel importers and surveillance market

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L'ASSOCIATION DES PHARME DE LA PEAU COSMÉTIQUE

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4

## ANDEAN COSMETIC LEGISLATION



### SUPRANATIONALITY

- Andean Decisions and Resolutions are binding legal rules in all member countries of Andean Community.
- These are published in the Official Gazette of the Cartagena Agreement, without being required to be incorporated into national legislation of the member countries.
- In case of conflict between national law and Community law, Community law prevails

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5

## ANDEAN COSMETIC LEGISLATION

### Harmonization of cosmetic regulation

Decision 833 (2018): general framework

1

**COSMETIC REGULATION IN FORCE SINCE 1ST MARCH 2021**

2

Technical Regulation on the Labelling of Cosmetic Products (**draft**)

3

Technical Regulation on Cosmetic Good Manufacturing Practice (GMP)

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6

## COMPETENT NATIONAL AUTHORITIES



**BOLIVIA:** AGEMED - State Agency for Medicines and Health



**COLOMBIA:** INVIMA (National Institute of Medicine and Food) - Ministry of Social Protection



**ECUADOR:** ARCSA (National Agency for Regulation, Control and Surveillance Health) - Ministry of Public Health



**PERU:** DIGEMID (General Direction of Medicines, Supplies and Drugs) - Ministry of Health

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7

## TABLE OF CONTENTS

- 1) Andean cosmetic legislation
- 2) Definition and classification of cosmetics
- 3) Controlled substances
- 4) Labelling and claims
- 5) Mandatory Sanitary Notification (NSO)
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8

## DEFINITION OF COSMETIC PRODUCT

Any **substance or formulation intended to come into contact with :**

- ✓ the **superficial parts of the human body** (epidermis, body hair, nails, lips and outer genital organs)
- ✓ or **teeth and oral mucous**



**for the sole or principal purpose of**

- **cleansing,**
- **perfuming,**
- **modifying or improving** their appearance,
- **protect** them, keep them in **good condition** or
- **correct body odours.**

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9

## CATEGORIES OF COSMETICS

- Cosmetics for children
- Cosmetics for Eyes area
- Cosmetics for Skin
- Cosmetics for Lips
- Cosmetics for Hair
- Cosmetics for Nails
- Grooming and personal hygiene ( **NEWS** also wet wipes & antibacterial gels <70% alcohol)
- Deodorants and antiperspirants
- Perfumery products
- Products for oral and dental hygiene
- Products for shave and aftershave
- Products for tanning and sun protection
- Depilatories
- Skin whitening products
- **NEWS** Insect repellents (human skin used)
- **NEWS** Others (approval by Resolution)

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10

## TABLE OF CONTENTS

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- 3) **Controlled substances**
- 4) Labelling and claims
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11

## CONTROLLED SUBSTANCES

The ingredients used in cosmetic shall be compliant to the bans, restrictions and conditions of use in the following international lists:

- ✓ Lists and regulations issued by the FDA (USA),
- ✓ Regulation (EC) No 1223/2009 (as well as its amendments)
- ✓ The Personal Care Products Council (PCPC)
- ✓ Cosmetics Europe

**As long as the competent national authorities do not make a decision under Article 5 (safety of ingredients), the member countries will use the least restrictive list.**

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12

## TABLE OF CONTENTS

- 1) Andean cosmetic legislation
- 2) Definition and classification of cosmetics
- 3) Controlled substances
- 4) **Labelling and claims**
- 5) Mandatory Sanitary Notification (NSO)
- 6) Latest news: NSO holders, parallel importers and surveillance market

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13

## LABELLING

For imported products, the instructions of use and warnings shall be translated in Spanish.

MANDATORY MENTIONS	REGULAR CONTAINERS	SMALL CONTAINERS
<b>Name of the responsible person in the Andean Community</b>	X	
<b>Name of the product</b>		X
<b>Nominal quantity</b>		X
<b>Specific precautions of use (for restricted ingredients if any)</b>	X	
<b>Batch number</b>	X	X
<b>Mandatory sanitary notification (NSO) number (except for Colombia*)</b>	X	X
<b>Ingredients list (INCI)</b>	X	
<b>Substances involving a sanitary risk</b>		X

\*As of March 5, 2021, the NSO (Mandatory Health Notification) number is no longer required on labelling in Colombia.

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14

## LABELLING

### Some new issues in Draft on “LABELLING” Andean Technical Regulation

- *Lifetime of products*
- *Use the NSO code: flexibility*
- *Use of stickers*
- *Other requirements based on ISO 22715 standard*



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15

## CLAIMS

Cosmetic products may not state therapeutic indications or any other indications which would contravene their definition.

 Anti-acne

 Antibacterial

 Anti-spot

 Antiseptic

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16



## TABLE OF CONTENTS

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- 4) Labelling and claims
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17

## MANDATORY SANITARY NOTIFICATION

The notification shall be done before the placement of the product on the market.

- ↳ Simplified register without the need for approval by the authorities
  - ↳ Communication under affidavit
    - ↳ Recognition in all Country Members
      - ↳ It is possible to amend the notification
        - ↳ Valid for 7 years

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18

# MANDATORY SANITARY NOTIFICATION

## *Requirements to apply NSO*

### General information:

- Name and address of the legal representative;
- Name and address of the producer and the holder of NSO;
- **NEWS** Name and address of the conditioner and packer (if any);
- Name of cosmetic product and **NEWS** generic name, the name of the cosmetic category and the trademark;
- Cosmetic form;
- **NEWS** Commercial presentation;
- **NEWS** Name of the technical manager - Pharmaceutical chemist

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19

# MANDATORY SANITARY NOTIFICATION

## *Requirements to apply NSO*

### Technical information:

- ✓ **Product description:** qualitative formula + quantitative formula of restricted substances **NEWS** and active ingredients;
- ✓ **NEWS** Nanomaterials substances (notify when appropriate): chemical name/ particle size;
- ✓ International nomenclature (or generic) of ingredients by **INCI**;
  - ✓ Organoleptic and physico-chemical specifications of the final product;
  - ✓ Microbiological specifications when appropriate;
- ✓ Justification of claims (cosmetic claims only);
- ✓ Label;
- ✓ How to use the product;
- ✓ Primary and secondary, if any, packaging materials;
- ✓ **NEWS** Description of the batch coding system for each manufacturer.

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20

## RECOGNITION OF THE NSO IN ANOTHER MEMBER COUNTRY

The registration in the second country is facilitated due to the presentation of the NSO notification from the first member country of marketing:

- Payment of the fee established by each member country
- Copy (in physical or electronic form) containing the NSO code assigned by the first member country of marketing
- Copy of the documentation required for obtaining the NSO in the first member country of marketing

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21

## FREE SAMPLES

Samples of no commercial value may circulate without an NSO number however, they must be the subject of a request to the competent authorities:

- Description of product: **name, producer's name, nominal content, form of presentation, country of origin;**
- **Purpose in which the samples will be used: scope and methodology of the market study / research of products / place and date that the study will take place**
- Payment of the corresponding fee



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22

## TABLE OF CONTENTS

- 1) Andean cosmetic legislation
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- 3) Controlled substances
- 4) Labelling and claims
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- 6) Latest news: NSO holders, parallel importers and market surveillance

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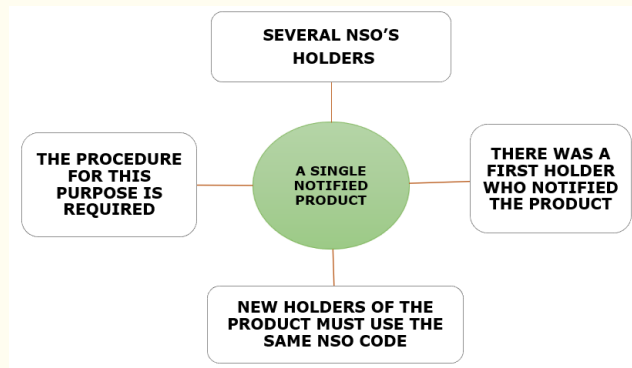


23

## NSO'S HOLDER

The holder of the NSO should have his **legal domicile in the country of notification or recognition** of the NSO.

The **responsible person** will be the NSO holder and all interested parties (in the case of multiple distributors in the Andean Community).



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24

## PARALLEL IMPORTERS

**Notification under the same NSO code = cosmetic product must have:**

- Same mark,
- Same qualitative and quantitative composition,
- Same generic name,
- Same producer & label

**Requirements of information:**

- Product name;
- NSO code to which it's requested to use;
- Name & address of the applicant;
- Name & address of the producer;
- Payment;
- Producer's Authorization depending of each Member Country (ex: not required in Colombia)

***NOTE Same obligations of the holder of the NSO on the quality and safety of the product. No possibility of making modifications, reformulations, additions or extensions to the NSO.***

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25

## MARKET SURVEILLANCE

### **Infractions and administrative penalties**

- Principle of proportionality;
- Internal administrative procedures of the MC;
- Penalties (**NEWS** new ones): partial suspension; temporary closing

### **Transparency and exchange of information**

- Share information between Competent National Authorities & General Secretariat - CAN;
- **NEWS** Information on health alerts, NSOs canceled and security measures taken;
- **NEWS** Using Andean virtual tool

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26

## MARKET SURVEILLANCE



**COLOMBIA : CAUTION with misleading packagings !**

Since 6 July 2021, packagings with non-functional empty spaces and false bottom, sidewalls, lid or covering will be allowed **provided the consumer is informed**.



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27

## MARKET SURVEILLANCE



**Good Manufacturing Practices** Technical Regulations for Cosmetics were issued on 17 June 2021 (**implementation on 17 December 2023**).

- ❑ The new Regulation is **based on the ISO 22716: 2007 standard**.
- ❑ For product notification (NSO) → a GMP self-certification by the NSO holder (legal representative of the cosmetic brand in CAN) is sufficient.

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28



**Thank you for your attention**

