

A Global Overview on Cosmetic Regulations



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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, Congress




2

YOUR WORLDWIDE REGULATORY MONITORING

 **120** Countries monitored (Europe & international).
On-line available databases 24 hours, 7 days

 **1500** Updated factsheets and summary tables

 **48h** Deadline answer to your regulatory requests from a specialized team

 **7 days a week** Email alerts at each regulatory amendment



Updated 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. General information on regulations
2. Key points for cosmetics
3. Countries overview

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4

FREE SALES CERTIFICATES (FSC)



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5

REGISTRATION / NOTIFICATION / CERTIFICATION

NOTIFICATION

- European Union
- Canada
- Andean Community
- Turkey
- China

REGISTRATION

- Eurasian Economic Union
- Mercosur
- Israel
- Egypte
- China

CERTIFICATION

- Saudi Arabia
- United Arab Emirates
- Some countries in Africa

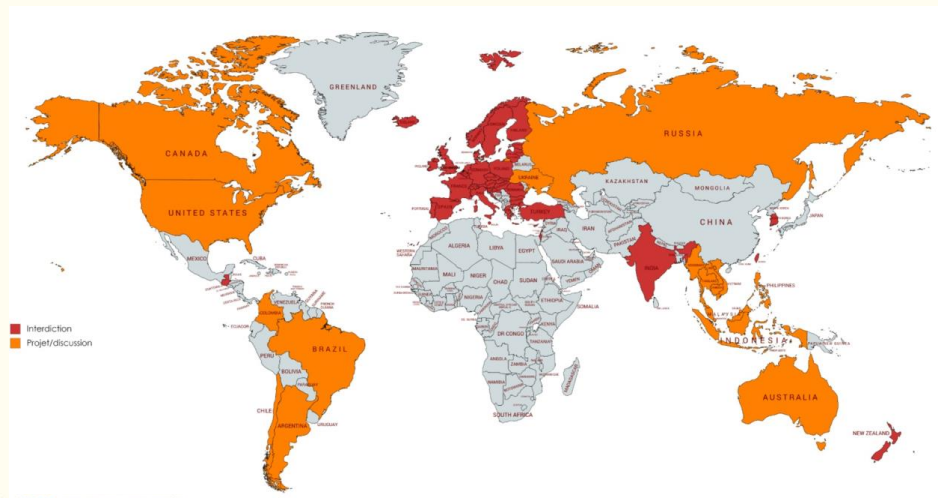


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6

ANIMAL TESTING



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7

TABLE OF CONTENTS

1. General information on regulations
2. Key points for cosmetics
3. Countries overview

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8

DEFINITION OF COSMETIC PRODUCT

Definition of cosmetics in your country \neq definition of cosmetics in the target country ?

Sunscreen

EU = cosmetic
 USA = Over The Counter product
 Canada = Natural Health Product or Drug
 Australia = Therapeutic Good
 Japan = cosmetic
 China = Special use cosmetics

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9

FUNCTION / TYPE OF PRODUCT

Population

- General population
- Babies
- Children
- ...

Application area

- Eyes
- Mucosa
- ...



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10

OTHER REGULATIONS

Environmental regulations

Microbeads

UV filters

Logos for recycling

REACH like regulations

Japan: some substance of
CSCL are banned in cosmetics
+ poison list

USA: TSCA, evaluation of D4
(cyclotetrasiloxane)

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11

TABLE OF CONTENTS

1. General information on regulations

2. Key points for cosmetics

3. Countries overview

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12

CHINA

2020-2021: Full change of regulation

- ⇒ Drafts still under consultation
- ⇒ Texts recently published (>10)
- ⇒ Text interpretation from authorities unknown
- ⇒ Uncertainty



2 categories of cosmetics:

- General cosmetics (notification)
- Special use cosmetics (registration)

Ingredients:

- Positive list (IECIC 2021)
- For new ingredients registration or notification
- Exhaustive information mandatory

Animal testing still mandatory. Exemptions possible for general cosmetics under certain conditions.

Labelling: Chinese

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13

SOUTH KOREA

Products categories

- Quasi-drugs
- Functional cosmetics
- General cosmetics



- ⇒ Cosmetics: notification to the KPTA (Korean Pharmaceuticals Traders Association)
- ⇒ Functional cosmetics and quasi-drugs: registration and approval before marketing.

List of substances :

forbidden, restricted and positive lists for preservatives, UV filters, colorants

For functional cosmetics: list of recognised actives. Other actives may be used, but with longer approval periods and more testing.

Others:

- Regulation on customised cosmetics
- Regulation on natural and organic cosmetics

Labelling: Korean language + Korean INCI

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14

ANDEAN COMMUNITY

Members:

Bolivia, Columbia, Ecuador, Peru

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

- FDA
- Regulation (EC) No 1223/2009 (as well as its amendments)
- Cosmetics Toiletry & Fragrance Association (CTFA)

⇒ Mandatory sanitary notification

Labelling: Spanish

⇒ General texts for the area but specificities in each country



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15

EUROPEAN UNION

Regulation 1223/2009 fully applicable in the 27 EU countries since 2013.

Online **notification** for each product

Mandatory to have a responsible person for the EU market

Lists of regulated substances:

Banned, restricted, positive lists for preservatives, UV filters, colorants

Product Information File with a Safety Assessment of the cosmetic product

Labelling: language of the Member State



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16

JAPAN

Categories of products:

- Cosmetics
- Quasi-Drugs

No notification for cosmetics

Registration and approval mandatory for quasi-drugs

Substances:

- Standard for cosmetics: banned substances, restricted substances, positive lists for UV filters and preservatives
- Ordinance No 66: authorised coal-tar colorants

Labelling:

Japanese and Japanese INCI

Claims strictly regulated



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17

TURKEY

Regulation similar to the European Union

Online **notification** for each product

Mandatory to have a responsible person for the Turkish market

Cosmetic File with a Safety Assessment of the cosmetic product

Lists of regulated substances:

Banned, restricted, positive lists for preservatives, UV filters, colorants

Language: partly in Turkish



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18

USA

Responsibility of the manufacturers for the products safety
Control of the market by the authorities

Substances:

Banned and restricted substances
Positive list for colorants
CIR recommendations

Labelling:

English
INCI with some changes



No cosmetic file
Notification on voluntary basis
Good Manufacturing Practises only voluntary

CANADA

Mandatory statement for cosmetics

Critical list of ingredients which use is restricted or forbidden in cosmetics

Labelling: English and French

Categories of products:

- Cosmetics
- Natural Health Products
- Drugs

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19

EURASIAN ECONOMIC COMMUNITY

Members:

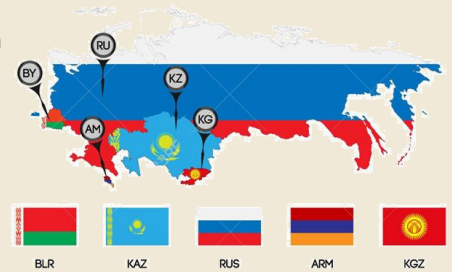
Russia, Kazakhstan, Byelorussia, Armenia, Kyrgyzstan

Regulation TR/TC 009/2011, based on the EU regulation

- ⇒ Registration or declaration of conformity
- ⇒ Lists of substances : banned, restricted, positive lists of UV filters, preservatives, colorants

Safety evaluation: toxicological tests in certified russian laboratory

Labelling: language of the member state



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20

INDIA

New regulation since December 2020
« Cosmetic Rules 2020 »



Registration of cosmetics: online registration, must be renewed every 5 years

BIS standards:

Lists of regulated substances (banned, restricted, positive lists for preservatives, colorants and UV filters)

Some types of products have specific standards to follow

Ban of animal testing
Testing for heavy metals

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21

Thank you for your attention



22