Borderline between cosmetics and medicinal, biocidal and other types of products

Pharm. Joëlle MEUNIER
Federal Public Service of Health, Food Chain Safety and Environment

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Borderline products

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I. Introduction

*Legal status*

< composition
<br>
< intended function
<br>
< presentation
<br>
> applying regulation

! Case-by-case

! Taking all the characteristics of the product into consideration
Introduction

Tools:

➢ Manuals and guidance documents of the European Commission

➢ Jurisprudence of the European Court of Justice

➢ National authorities (Belgium: Specific Commission)
II. Does a product fall under the cosmetic definition?

*Cosmetic product:* (Regulation 1223/2009)

“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”
Does a product fall under the cosmetic definition?

**Intended main function:**

- cleaning
- perfuming
- changing the appearance
- protecting
- keeping in good condition
- correcting body odours
Does a product fall under the cosmetic definition?

**Intended main function:**

✓ cleaning, perfuming, changing appearance, correcting body odours, protecting, keeping in good condition.

✗ products treating or preventing diseases

✗ repellents

This main function is **exerted** on the specified application sites: "with a view ... to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition"

✗ products for muscles, joints
Gel to suppress appetite

Suppresses your appetite immediately!
Body fat disappears remarkably fast!
Reduces Cellulite by 60%!

The revolutionary new way to overcome overweight, enables the active ingredients to reach into the bloodstream remarkably fast. Within ten minutes your appetite is suppressed and your body is being fully trimmed, resulting in top speed weight loss. Slimming without intensive exercise: that is what you have been dreaming of!

Causes waste products in your body to be released little by little. Therefore you should drink at least two litres of water a day, so that your body will be detoxified properly. Apply onto High-flow areas, such as your stomach area and the insides of your upper arms and upper legs. Rub gently with your fingers in a clockwise direction. To stimulate absorption a damp and warm towel can be applied to the area preceding the application. Full absorption is accomplished in two to four minutes. It should be applied two to four times daily to achieve the desired results.
Does a product fall under the cosmetic definition?

**Site of application:**

- ✓ External parts of the body
- ✓ Mouth

Not applicable:

- ✗ Products intended to be placed inside ears, nose, vagina
- ✗ Permanent make-up and tattoo inks injected
- ✗ Products injected or delivered by other invasive techniques into the dermis

*Substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product* (reg. 1223/2009, art. 2, 2)
Products for ears and nose
Application site: epidermis <-> dermis
Does a product fall under the cosmetic definition?

Substance/mixture:

✗ Not applicable: articles: wigs, clothes,...

✓ Substance /mixture with a cosmetic function to be delivered by an article (by wipes, tooth floss, patches, razors, ...) → cosmetics
III. Borderline cosmetics / medicinal products

Medicinal product defined in art.1(2) of the medicinal products directive 2001/83:

“(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.”
Borderline cosmetics / medicinal products

Protecting or keeping in good condition

<--> Prevention of disease or protection against contamination

Non-cumulation principle: Article 2(2) of medicinal products directive: “In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a “medicinal product” and within the definition of a product covered by other Community legislation the provisions of this [medicinal products] Directive shall apply.”
Borderline cosmetics / medicinal products

(a) Medicinal product by virtue of its presentation:

➢ Product presented for treating or preventing disease
➢ even if it has no known therapeutic effect

• Presentation: packaging, leaflets, advertising, oral presentation, websites, etc.
• Perception by the averagely well-informed consumer
Sun oil

- For sunbeds and sun. Five times quicker brown.
- Moisturizing. Softens the skin.
- Suits for itching, eczema, after the sun, etc.
Sun protection product

- Cancer
- Wrinkles
- Sunburns
Borderline cosmetics / medicinal products

(b) Medicinal product by virtue of its function:
- modifies physiological functions by a pharmacological, immunological or metabolic activity
- significant
- also when no medicinal claim

Case-by-case approach: pharmacological properties, concentration, route of administration, absorption, frequency of application...
Borderline cosmetics/medicinal products

Medicinal product
- by presentation/function:
  Arnica gel for bruises and bumps

- by function:
  * ansm decision: anti wrinkle creams with pravastatine and natrium alendronate
  * Cleaning damaged skin
IV. Borderline cosmetics / biocides

Biocidal products: defined in Regulation 528/2012:
Substance or mixture with active substance(s), in the form supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or exert a controlling effect on any harmful organism by means other than physical or mechanical.

Annex V: biocidal product-types:
- disinfectants, biocidal products used for human hygiene purposes
- insecticides
- repellents ...
Borderline cosmetics / biocides

➢ **Exclusion provision**

➢ Protecting or keeping in good condition <--> protecting against contamination or infection by micro-organisms, fungi or parasites

➢ **primary biocidal function** → biocide or medicinal product

➢ **primary cosmetic function + secondary biocidal function** → cosmetic product
Borderline cosmetics / biocides

Cosmetics with a secondary biocidal function:
✓ anti-dandruff shampoos
✓ deodorants
✓ hygiene products with secondary antimicrobial claim

... 

Case-by-case approach based on composition, claims, general presentation, use instructions, intended function
Borderline cosmetics / biocides

- Soaps with primary biocidal function → biocides
- Antimicrobial products for food industry → biocides
- Lethal effect on parasites → medicinal products
- Repellents (mosquitoes, lice) → biocides
  * essential oils presented as repellent

Particular cases: New biocides regulation: 2 main functions: Ex: sun protection product containing repellent (insects, jellyfish)
Repellent

- Mosquitoes
- Wasps
- Gadflies

...
Borderline cosmetics/biocidal products

Elements to consider for antibacterial products:

- General presentation
- Claims, notably:
  - references to the killing of ... % bacteria
  - prevention of transmission of diseases, microorganisms
  - name of the product
  - medical symbols
- Rinse off <-> leave on
V. Borderline cosmetics/medical devices

Medical devices: intended to be used for the purpose of: - diagnosis, prevention, monitoring, treatment or alleviation of disease ...

- investigation, replacement or modification of the anatomy or of a physiological process ...

... does not achieve its principal intended action by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

*Intended function: specific medical purposes → Border medicinal product/medical device*
Borderline cosmetics/medical devices

Medical devices:
*Intended function: specific medical purposes*

New regulation (2020): includes some products without medical purpose, e.g.
- substances/combinations of substances for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction (excluding for tattooing).
Borderline cosmetics / medical devices

➢ **Tooth whitening/bleaching products**: 
Main function: changing the appearance of teeth → cosmetic

Manual borderline medical devices (05/2019):

... *discoloration of teeth may be caused by a disease. Nevertheless discoloration of teeth is not considered to be a disease in itself. Besides, application of tooth-whitening/bleaching products is not intended to treat the underlying disease; it only may mask a sign of an underlying disease → Not medical devices.*
Skin peeling products:

Manual borderline cosmetic products (04/2018):

Peelings that expose the deeper layers of the stratum corneum, or result into the complete removal of the stratum corneum significantly impact the skin physiology and barrier function. Such product could not be considered as a cosmetic product. Therefore, in order to decide about the qualification of a skin peeling product, the competent authorities have to consider all the characteristics of the product, and, in particular the claims, the depth of peeling per application and the frequency of application.

→ medical device or general product safety
VI. Borderline cosmetics / food

Food: defined in Regulation No 178/2002 as “any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans”

- not related to a specific purpose
- includes notably chewing gums

- Exclusion provision
Borderline cosmetics / food

Recital 5 of Cosmetics Directive: “products containing substances or preparations intended to be ingested, ... do not come under the field of cosmetics”.

Tablets and chewing gums to clean teeth or to reduce bad breath:
- Manual of EU Commission: Crucial point: is a product or a substance contained therein intended to be ingested? → case-by-case

! Different implementations by member states
Risk of confusion with food

Directive 87/357:
Forbidden if health risk
VII. Bordeline cosmetics/toys

- Make-up for children
  - cosmetics regulation
  - toys directive
    → no exclusion provision

- Make-up for dolls
  - toys directive
  - cosmetics regulation for composition & labelling

- Bath products with play value
  - toys directive

? Cosmetics regulation: yes if cosmetic function
VIII. Other borderline products

- **Muscle, joints creams**
  - Not cosmetic

- **Patches**
  - ? Cosmetic main function
  - ✗ Significant action on physiological functions; general activity <-> local activity.

- **Products stimulating hair growth**
  - Usually medicinal product

- **Products reducing hair loss**
  - Usually cosmetic product
IX. Conclusions

Legal status of a product:

- determined on a case-by-case basis
- depends on all its characteristics: composition, intended function, presentation