Are you aware which side of the border your product is?

Classifying correctly borderline type products

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Borderline

- 1 - What is the intended purpose of your product ?
- 2 – What is the directive or regulation that applies related to the intended purpose ?
- 3 – Is the product borderline ?
  - Based on its intended use ???
- • Based on its technical composition ???

COSMETIC PRODUCT DEFINITION

any substance or mixture

intended to be placed in contact with external parts of …

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;

CRITERIA

Aspect	• Substance or mixture
Application	• In contact with external …
Function or purpose	• Exclusively or mainly to cleaning, perfuming, them …

- Articles are NOT cosmetics
  - They may have some cosmetic function
- Substances or mixture released
  - are cosmetics
- Injected or ingested NOT cosmetics
  - (tattoo inks are injected)

BORDERLINE IS A CASE BY CASE HISTORY

CLAIMS

MANUFACTURER INTENTION

CONSUMER PERCEPTION (Remember CoJ)

INGREDIENTS

WAY OF ACTION

DEFINITIONS IN REGULATION

GUIDELINES from European Commission

File Modifica Visualizza Cronologia Segnalibri Strumenti Aiuto

Borderline products - Europ

ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en

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European Commission

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Borderline products

Sometimes it may be unclear whether a particular product is a cosmetic product under cosmetics legislation or whether it falls under other sectorial legislation. In the case of these "borderline products", the decision on a product's classification must be taken on a case-by-case basis.

The European Commission has published guidance documents to facilitate the application of EU legislation in these cases. They include a manual on the scope of application of the Cosmetics Regulation and the various guidelines on the borderline between cosmetics legislation and other sectorial legislation.

- Manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)) (Version 2.2, February 2016) (196 kB)
- Guidance Document on the relationship between the General Product Safety Directive (GPSD) and certain sector directives with provisions on product safety (500 kB)
- Manual of decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products (450 kB)
- Guidance Document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83 (66 kB)

Share

Share

MAIN CRITERIA

Only one classification – NON CUMULATION

- One product > one classification ECJ, “Upjohn“(cf. note 10), paras 30, 32; Cf. also ECJ, “Delattre” (cf. note 10), para. 22)

Choice is case by case

Exceptions (Cosmetics+toys)

Main labelling – intended use

Principles

Exclusion principle

- product cannot be in two categories
- (exception – cosmetic+toys)

Upgrade principle

- In doubt case the upper (more strict) rule is applied
  - (eg cosmetic vs medicine >> medicine)

Principles

Presentation principle

- The labeling and claim classify the product

Integration principle

- A secondary or ancillary action is allowed
  - Cosmetics + biocide
  - Medical device + medicine (substance)