Borderline Products
Regulatory Framework

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Introduction
The Science Never Stops
• Scientific progress allows cosmetic product innovation going deeper than just ‘superficial’ effects

• Growing recognition that products do more than ‘beautifying’ and actually contribute to hygiene and public health

• But, are these still cosmetics?

Depends on your definition of “cosmetic”
Classical Definition of Cosmetics (US 1930s)

Cosmetics:
(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and
(2) articles intended for use as a component of any such articles; except that such term shall not include soap.

Drugs:
articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease...and articles (other than food) intended to affect the structure or any function of the body

Relatively narrow concept
More active products → (OTC) Drugs
e.g. Sunscreens, Antiperspirants, Fluoride-Toothpaste
(On the plus side, drug claims are allowed)
Modern Definition of Cosmetics (EU 1976/2009)

Cosmetic Product:
...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.

Broad concept of cosmetic

Include ‘Protection’ and ‘Keeping in Good Condition’ as cosmetic functions
But soes not cover protection of disease or protection against contamination*
More active products → covered by cosmetics definition
(On the downside, drug claims are not allowed)
Assessment Criteria

Does my product fall in the definition of a cosmetic?
Three fundamental criteria

‘cosmetic product’ means 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 …
Three fundamental criteria

or mixture intended to be placed in contact with the various 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…”
Three fundamental criteria

substance or mixture

intended contact with certain defined 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..."
Three fundamental criteria

substance or mixture

intended contact with certain defined parts of the human body

with a certain defined exclusive or main functions
Three fundamental criteria

I) Physical/chemical form

II) Intended application site

III) Primary function

§C-321/14 §
All criteria must be fulfilled. Not sufficient to present the product as a cosmetic (e.g. via a labelling statement)

§C-1221/89 §
Must be a case-by-case assessment
I) Physical/Chemical Form

- Cosmetics must be substances or mixtures
- Articles are not cosmetic products - even if they are applied to the skin and fulfil a cosmetic function
- Substances or preparations intentionally released from an article can be cosmetics (e.g. lotion in a cosmetic wipe)
- The “article part” of such a composite product falls under the General Products Safety Directive (GPSD)
Some examples

Wigs 
False eyelashes 
Glue-on artificial nails 
Dermal Needle Roller 

Cosmetic Wipes : (tissue)/ (lotion)
Cosmetic Patches (patch)/ (lotion)

* Clothes releasing substances : (tissue)/ (lotion)
* Tooth picks/floss releasing fluoride: (pick/floss)/ (lotion)

* To support claims, need to demonstrate release to the skin / teeth!
II) Intended application site

• Clearly specified and limited.

• In addition – Article 2.2 clarifies:
  
a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product.

• However, certain degree of dermal penetration, inhalation or accidental ingestion is acknowledged and accepted for cosmetics.

§C-321/14 §
The list of application sites is exhaustive, not indicative. e.g. Products applied in the eye cannot be cosmetics.
Some examples

‘real’ tattoos 👎
Washable, temporary “tattoos” 👍
Body Paint 👍
Slimming pills 👎
Nutro-cosmetics 👎
Products intended for ‘Dermal Rollers’ 👎
Tooth whitener injected in tooth 👎

Cosmetics Europe
the personal care association
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III) Primary Function

- EU definition implies that cosmetic products can have secondary, non-cosmetic functions.
- The non cosmetic function cannot be the primary function, it must be secondary to the cosmetic function.
- To determine the primary function it is necessary to consider:
  - Manufacturer intention
  - Presentation / Labelling / Advertising / Claims
  - Mode of action / composition
  - Consumer perception

§ no cosmetic-specific court case §
But ample guidance by the EU Commission
Also, need to take into account average, well-informed consumer (C-227/82)
Some examples

Nail Glue remover 👍
Antibacterial / hygienic hand wash 👍
Leave-on hand sanitiser 👎
Products to detect dental plaque 👎
So, your product falls in the definition of a cosmetic product.

Good ... BUT

This does not automatically mean that (only) the Cosmetics Regulation applies.
Characteristics of specific Borderlines

Cosmetics

- Biocides
- Pharma.
- Medical Device
- Toys
- Chemicals
- Food
Cosmetics/Toys

• Toy Directive and Cosmetics Regulation are cumulative

• A product can be simultaneously regulated by both legislations

• A cosmetic product with secondary function as toy needs to comply with both sets of requirements.
Cosmetics / Food

• Food legislation and Cosmetics Regulation are mutually exclusive
• The basic definitions are incompatible: intended ingestion vs. not intended to be ingested
• A secondary function as food is not possible for a cosmetic.
• Borderline issues can arise from accidental ingestion (i.e. at what stage does large accidental ingestion become intended ingestion?)
Cosmetics / Chemicals (CLP)

- Scope of CLP is ‘substances and mixtures of substances’
- Cosmetic Products - as defined in the Cosmetics Regulation – fall in principle into that scope
- However, “cosmetic products in their final state” are exempted from the requirements of the CLP
- Borderline can arise over the interpretation of ‘product in its final state’ (ingredients vs. finished product):
  - Cosmetic kits/DIY cosmetics,
  - Cosmetics mixed in the shop
  - Essential oils sold as cosmetics

§ no cosmetic-specific court case §
CARACAL Guidance on ‘product in its finished state’ CA/60/2017 rev.2
Cosmetics/Medical Device

- Medical Device legislation and cosmetics legislation are not cumulative (i.e. the Medical Device legislation excludes cosmetic products from its scope)

- A cosmetic product with secondary medical device function remains regulated only by the Cosmetics Regulation

- However, difficult to demonstrate that the medical device function is secondary to the cosmetic function. (Diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap)

  - Not frequently a borderline issue
Cosmetics/Biocides (1)

• Definition and scope of the Biocides Regulation (BPR) are very wide:

  • *any substance or mixture*, ... consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action...

  • ‘treated article’ means any *substance, mixture* or article which has been treated with, or intentionally incorporates, one or more biocidal products;
Cosmetics/Biocides (2)

• Products could easily fall in the definition of both, Cosmetics Regulation (CPR) and Biocides Regulation (BPR):
  • Cosmetic product containing a preservative or antimicrobial
  • Cosmetic product with a secondary biocidal purpose

• However, Art. 2 of the BPR excludes from its scope products regulated under the CPR

  Whereas (9): Where a biocidal function is inherent to the cosmetic function, or where that biocidal function is a secondary claim of a cosmetic product it should remain outside the scope of this Regulation.
Cosmetics/Biocides (3)

• As a consequence, cosmetics can have & claim a secondary biocidal function and remain only regulated by the CPR

• Borderline questions usually arise over primary vs. secondary purpose of the product

• Importance of consumer perception. Too strong claims can make the biocidal function becoming the primary function

→ In that case, no longer as cosmetic product!

Remember:
Claims are not limited to what is written on pack.
They include any communication made in the context of the product.
Cosmetics/Biocides (4)

Common understanding:

• Antimicrobial control of oral/skin microflora is a biocidal function.

• However, product remains exclusively regulated by the CPR if the biocidal effect is an
  • inherent property of a cosmetic product (e.g. soap, deodorant, …)
  • secondary benefit to a primary cosmetic purpose (e.g. hand cleanser, toothpaste)

• Claims going beyond the general personal hygiene can redefine the biocidal function as primary \(\rightarrow\) not a cosmetic (BPR applies)
  e.g. “control of infectious organisms”, “kills up to 99.9% of bacteria”, “disinfectant”, “antiseptic”, “antiviral”, “antifungal”

• Insect repellence is usually considered as a primary function \(\rightarrow\) (BPR applies)
Cosmetics/Pharmaceuticals
Cosmetics are not drugs but ...

• Health conditions are often not black/white scenarios

• May initially present as a cosmetic condition that can develop into a medical condition; e.g.
  – bad oral state → gingivitis, rotten teeth
  – dry skin → inflammation, infection
  – skin impurities → severe acne
  – bad hygiene → transmission of infectious diseases
  – frequent sunburn → increased risk of skin cancer

• Recognition that cosmetics can be used to self-manage at the lower end of the spectrum and thus help to prevent progress to a medical condition

• Public health interest in quick, easy access to such products – and their rapid innovation
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Cosmetics/Medicinal Products (1)

Perspective of the Cosmetics Regulation

Cosmetics Regulation:
• *Cosmetics defined by their primary function.*
• *Additional clarification: Not applicable to products that … are exclusively intended to protect from disease.*

→ Cosmetic product with a secondary health benefit remains within the definition of a cosmetic.
Definition of a medicinal product:

- **Presented** as having properties for treating or preventing disease

OR

- May be used with a view to **restoring, correcting or modifying physiological functions** by pharmacological, immunological or metabolic action, or to making a medical diagnosis.
Cosmetics/Medicinal Products (3)

Medicinal product by virtue of presentation

- Any product presented like a drug falls in the drug definition, regardless of its actual activity
- Need to protect consumers from products that do not have the effectiveness they expect
- No differentiation between primary vs secondary purpose of the product.
- Criterion is the perception by an ‘average, well informed consumer’ based on overall product presentation, form, marketing, …

§ C-227/82 § § C-219/91 §
§ C-319/05 § § C-211/03 §
§ C109/12 § § C-140/07 §
§ C-220/98 § § C-1121/89 §
§ C-313/94 § § C-60/89 §
Cosmetics/Medicinal Products (4)

Medicinal product by virtue of function

- Pharmacological properties must be real
- They can be ‘side effect’ of a non-drug primary purpose
- Case-by-case analysis, considering composition, use pattern, distribution, familiarity to consumers, risks
- Main criterion: Can the product be administered with a view of making a medical diagnosis, or to resporing, correcting or modifying physiological functions?

Modification must be
- Significant/appreciable
- have a beneficial effect

§ C-211/03 §  § C-27/08 §  § C-109/12 §
§ C-60/89 §  § C-150/00 §  § C-88/07 §
§ C-308/11 §  § C-227/82 §  § C-1121/89 §
§ C-319/05 §  § C-140/07 §  § C-290/90 §
Cosmetics/Medicinal Products (5)

• Assessment may conclude that the product falls under the definition of both, cosmetics and medicinal products (i.e. primary cosmetic function and secondary drug function).

• Medicinal Products legislation and Cosmetics legislation are non cumulative

• A product cannot be regulated at the same time by both laws.
Cosmetics/Medicinal Products (6)

Medicinal Products Directive

Whereas 7: Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics, this (medicinal products) Directive should not apply.

Art 2. 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 Directive shall apply.
Cosmetics/Medicinal Products (7)

• As a consequence, cosmetics can have & claim a *secondary* health benefit and remain only regulated by the CPR

• Borderline questions arise over
  • presentation of the product as a drug (claims, consumer understanding → consumer use as / instead of a drug)
  • which purpose, cosmetic or drug is the primary purpose
  • significance of effect on metabolism/physiology
  • nature of physiological/metabolic effect (beneficial or adverse)
Cosmetics/Medicinal Products (8)

In practice:

• Cosmetic products can have and claim health benefits if – beyond doubt – the primary purpose of the product remains a cosmetic purpose.

• As soon as the nature / presentation of the health benefit casts doubt over the primary purpose of the product → drug legislation applies

• Consequently, only ‘soft’ benefits and claims are acceptable
Medicinal Products / Cosmetics borderline

Some examples

• Helps in the prevention of caries
• Hydrating skin care that can be used on atopic skin
• Bath – helping to relax sore muscles
• Soothes irritated, itching skin after sun exposure
• Prevents caries
• Treats caries
• Hydrating skin care for atopic skin, allowing to reduce the use of corticosteroid treatment
• Bath to treat joint pain / swollen legs / muscle ache
• Treats sunburn / prevents skin cancer
Thank you for your attention!