Navigating Cosmetic Borderlines in the EU

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Session Outline

1. **The Regulatory Challenge – and the EU's answer to it**
2. **Interplay between CPR and bordering regimes**
3. **Classification Logic & Criteria**
   - Application of EU Cosmetics Regulation definition
   - Assessment of secondary function
   - Application of the other regulation definition
   - Determination of the applicable legislation(s)
4. **Arbitration Mechanism – EU Commission WG on Borderline Products**
5. **Tips and Tricks**
6. **Conclusions**

Product classification

The Regulatory Challenge and the EU's answer to it



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Daily life situations are often not black/white

Reality sits on gliding scales; not on defined ‘borderlines’.

- Food vs. nutritional supplement
- Moving from A to B vs doing sport
- Cleanliness vs. desinfection
- Health vs. disease

  overweight → obesity → metabolic syndrome
  bad oral state → gingivitis, rotten teeth → cardiovascular issues
  dry skin → cracked skin → inflammation, infection
  skin impurities → severe acne
  bad hygiene → transmission of infectious diseases

Secondary benefits of everyday activities

Nobody questions the health benefits everyday ‘healthy lifestyle’ – without classifying it as ‘medicinal’.

- Balanced, healthy diet is more than providing energy.
- Physical activity is more than moving from A to B.
- Clean kitchen work plate is more than aesthetics.

Cosmetics are part of this:

- provide secondary benefits that go beyond ‘beautifying’,
- self-manage at the low end of the disease spectrum
- decrease the risk of progression to a medical condition

Can there be a downside ?

Confusion over drug/ cosmetic status can result in unintended over-treatment or under-treatment by consumers

Active drug product sold and used as a cosmetic →

- Medical over-treatement by consumers who do not have a medical issue
- Unfair competition with drug companies

Cosmetic Product sold and used a drug →

- Risk of medical under-treatment by consumers who have a medical issue

→ Need to maintain a clear regulatory separation of cosmetics and drugs !

Finding the right balance

- Broad definition of “medicinal product” or biocide
- Treat secondary health or hygiene benefits of cosmetics as medicines or biocides

→ Slow innovation, reduced consumer access

→ Larger costs for public health system (cosmetic problems are treated as medical problems)

VS.

- Broad definition of “cosmetic product”
- Treat secondary health or hygiene benefits as cosmetics

→ Fast innovation, easy consumer access

→ Lower costs for public health system (self care → reduced risk of medical problems)

A visionary definition of cosmetics – set in 1976

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** ....”

Allows cosmetics to be more than ‘beautifying’ and contribute to hygiene and public health – without being drugs

Cleaning



Protecting



Perfuming



Keeping in Good Condition



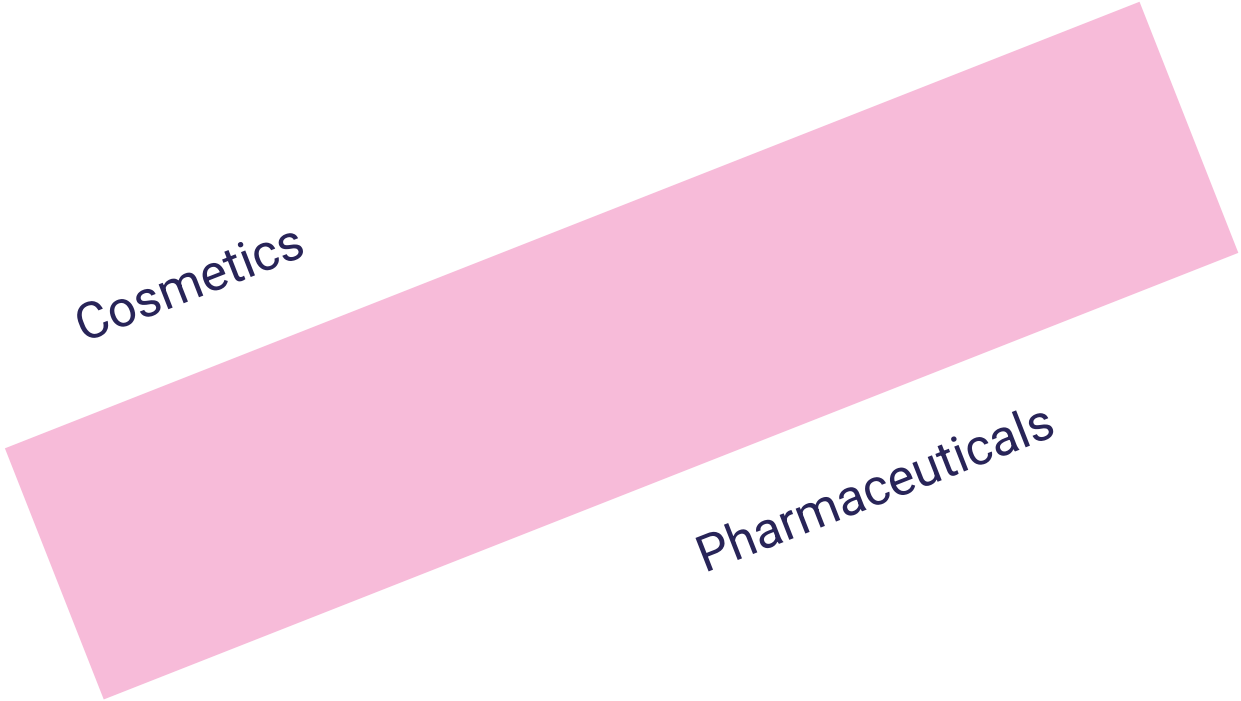
Changing Appearance



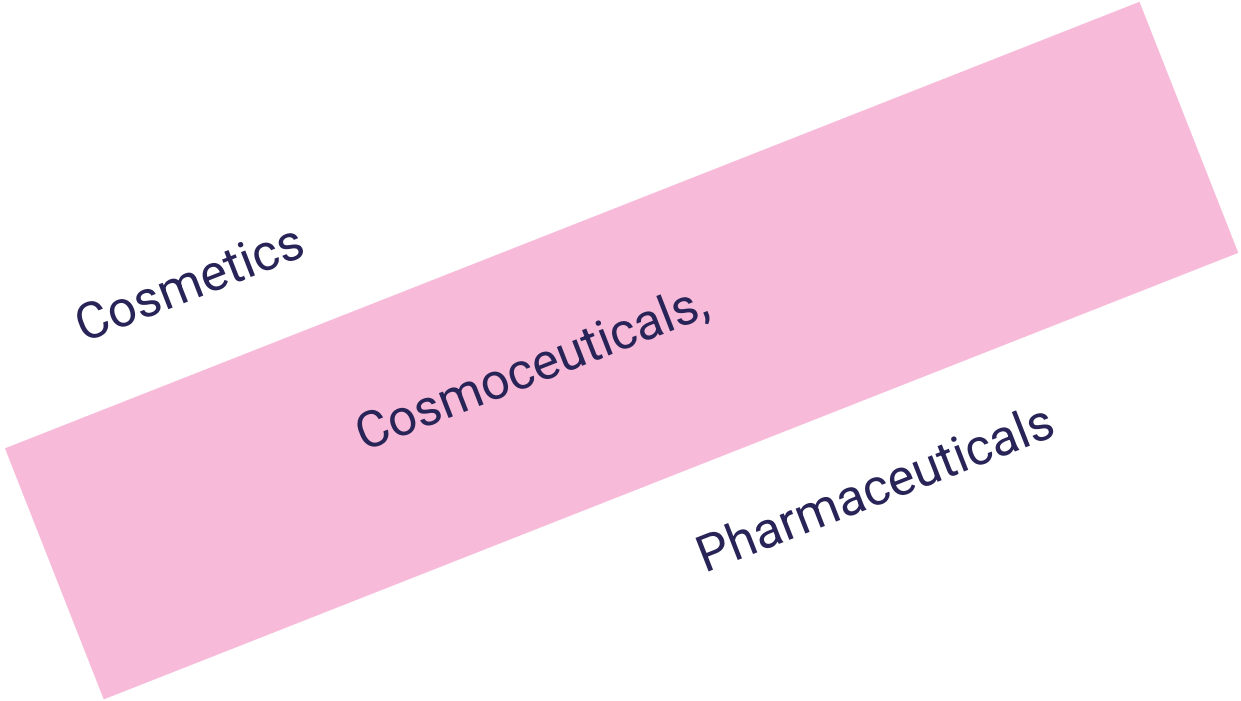
Correcting Body Odours



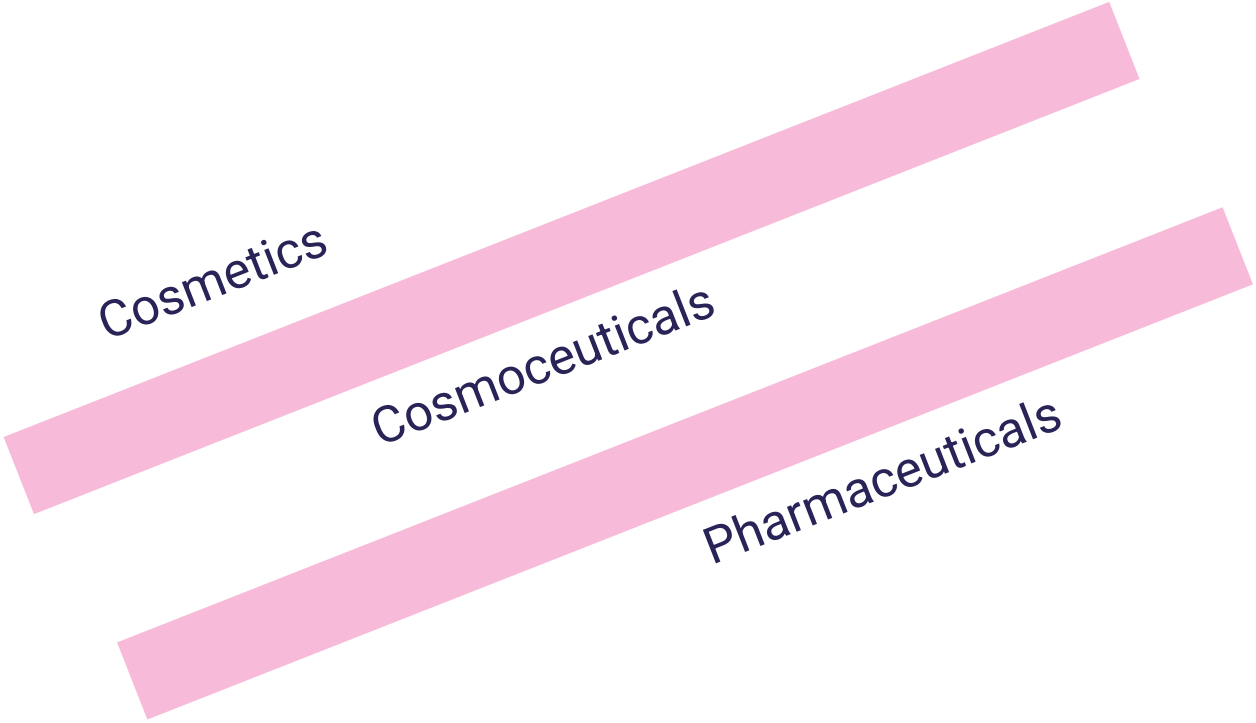
The challenge remains: How to manage the ‘grey zone’



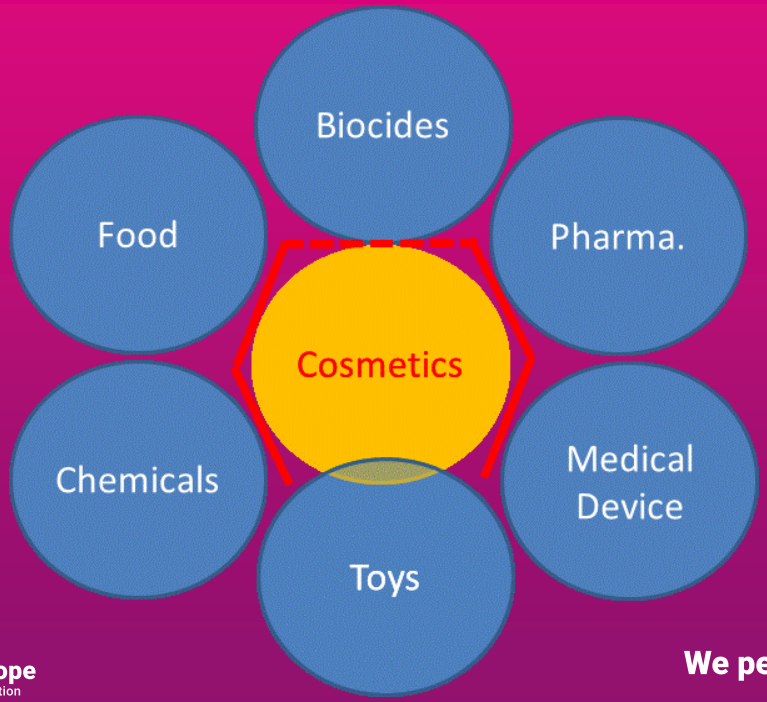
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Interplay between CPR and bordering regimes

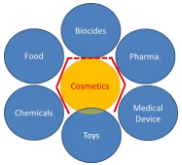


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Three different types of interplay



The two legislations are <u>mutually exclusive</u>

- Product cannot fall in both legal definitions or cannot be managed by both legislations at the same time
- Ex.: Food intended to be ingested / cosmetics not intended to be ingested
- Ex.: Cosmetics and medicines

The two legislations are <u>cumulative</u>

- Product falls in both legal definitions and both pieces of legislation need to be complied with
- Ex.: Toy make-up must comply with the EU Cosmetics Regulation and the EU Toy Directive

One legislation <u>defers to the other</u>

- Product falls in both legal definitions but one legislation excludes it from its application scope
- Ex.: Finished cosmetics are excluded from the application of Biocides Regulation, Chemicals Legislation (CLP), Medical Device Directive

Methodological approach to navigate the borderline

1) Assess whether the definition of the EU Cosmetics Regulation applies
2) Does the product have a secondary, non-cosmetic function ? If so, which product legislation could it fall into ?
3) Apply the definition of the other legislation
    - Mutually exclusive from cosmetics definition ?
    - Both definitions apply ?
4) If both definitions fit, determine which legislation(s) apply
    - Cosmetics Regulation
    - Other Legislation
    - Both

Classification Logic & Criteria

1) Does the cosmetics definition apply ?



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The EU Cosmetic Product Definition

‘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 cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;

Three fundamental criteria

substance 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 cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours”

Three fundamental criteria

substance or mixture

intended contact with certain defined parts of the human body

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;”

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

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 Regulation (GPSR)

Physical/chemical form

Some examples

Wigs 👎

False eyelashes 👎

Glue-on artificial nails 👎

Dermal Needle Roller 👎

Cosmetic Wipes : 👎(tissue)/👍(lotion)

Cosmetic Patches 👎 (patch)/👍(lotion)

II) Intended application site

- Clearly specified and limited and listed in the Cosmetics Regulation definition.
- 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.

- A certain degree of dermal penetration, inhalation or accidental ingestion is unavoidable and accepted for cosmetics

Intended application site

Some examples

‘Real’ tattoos 👎

Washable, temporary “tattoos” 👍

Body Paint 👍

Slimming pills 👎

Nutro-cosmetics 👎

Tooth whitener injected in tooth 👎

III) Primary Function

- EU definition allows that cosmetic products can have additional, non-cosmetic benefits
- These 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*

Usually, a single specific word in a claim is not sufficient to determine the primary function – need to look at the overall context.

Primary Function

Some examples

Children’s Bath with "Play Value“ 👍

Anti-lice shampoo 👎

Alcoholic hand gel (leave-on) 👎

Antimicrobial handsoap 👍

Glue for artificial nails 👎

Classification Logic & Criteria

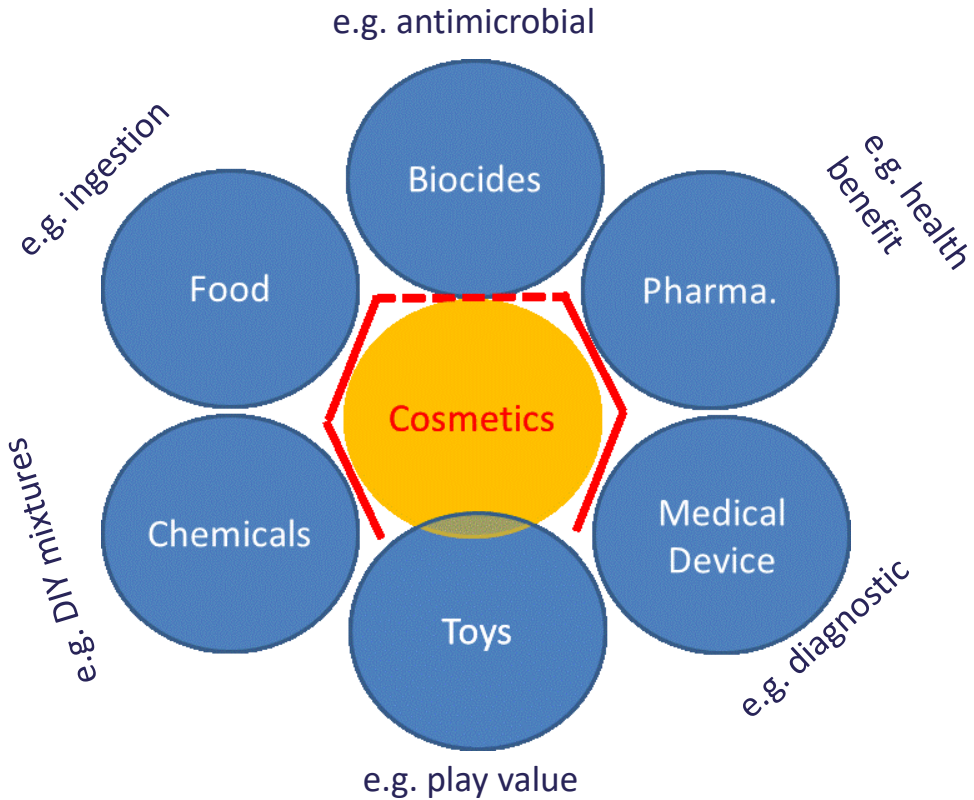
2) Does the product have a secondary, non-cosmetic function ? If so, which product legislation could it fall into ?



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Secondary Function



Classification Logic & Criteria

3) Does the other legal definition fit as well ?



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Definitions

Scope of the Toys Regulation:

Products that are designed or intended, whether or not exclusively, for use in play by children under 14 years of age (toys).

Can apply to a cosmetic !

Scope of Food Legislation

Substances/products intended or reasonably expected to be ingested by humans

Can't apply to a cosmetic !

Scope of the Biocidal products Regulation

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 with, or intentionally incorporates, one or more biocidal products;

Can apply to a cosmetic !

Definitions

Scope of the Chemicals Legislation (CLP) :

Substances, mixtures

Can apply to a cosmetic !

Scope of the Medical Device Legislation

*Instrument, apparatus, appliance, software, implant, reagent, **material** or other article intended … for specific medical purposes (diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation, compensation, investigation, replacement or **modification** of the anatomy or **of a physiological** or pathological **process or state**) not achieved by pharmacological, immunological or metabolic means.*

Can apply to a cosmetic !

Specifically listed aesthetic devices without medical purpose (includes dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction)

Can't apply to a cosmetic !

Definitions

Scope of the Pharmaceutical Legislation

Product **presented** as having properties for treating or preventing disease

OR

Product 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.

Medicinal product by virtue of presentation:

Criterion is the perception by an 'average, well informed consumer' based on overall product presentation.

Medicinal product by virtue of function:

Can the product be administered with a view of making a medical diagnosis, or to restoring, correcting or modifying physiological functions ?

Effect must be **significant/appreciable and beneficial**

Classification Logic & Criteria

4) If both definitions fit, which legislation(s) apply ?



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Which legislation applies ?

- Cosmetics / Toys → Cumulative; both legislations apply.
- Cosmetics / Chemicals (CLP) → only Cosmetics Regulation applies
- Cosmetics / Medical Devices → only Cosmetics Regulation applies

Which legislation applies: Cosmetics/Biocides (1)

- Products can 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 Biocides Regulation.

Which legislation applies: Cosmetics/Biocides (2)

- 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 a cosmetic product !

Which legislation applies: Cosmetics/Biocides (3)

Practical application:

- Antimicrobial control of oral/skin microflora is a biocidal function.
- However, product remains regulated as cosmetic if the biocidal effect is an
  - inherent property of a cosmetic product (e.g. soap, deodorant, …) AND/OR
  - 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 → no longer a cosmetic → Biocides regulation applies

  e.g. “control of infectious organisms”, “kills up to 99.9% of bacteria”, “disinfectant”, “antiseptic”, “antiviral”, “antifungal”

Which legislation applies: Cosmetics/Medicinal Products (1)

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

Which legislation applies: Cosmetics/Medicinal Products (2)

- 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)

Which legislation applies: Cosmetics/Medicinal Products (3)

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 very ‘soft’ benefits and claims are acceptable that situated on the low end of the disease scale

Which legislation applies: Cosmetics/Medicinal Products (4) Some examples



- Helps in the prevention of caries
- Hydrating skin care that can be used on atopic skin
- Bath – helping to relax sore muscles
- Sooths irritated, itching skin after sun exposure



- Treats caries
- Prevents 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

Arbitration mechanism

EU Commission Working Group on Borderline Products



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Is it always clear and easy to identify under which definition(s) a product falls ?

- Surprisingly often, yes !
- However, mechanisms exist in case of doubts

a) COM has the legal power to ‘arbitrate’ between regulations qualify a specific product as cosmetic, pharmaceutical, medical device or biocide

b) EU Comission Working Group on Borderlines

EU COM WG on Borderline Products

- Comprises experts from COM, EU member states and industry; meets twice per year;
- Participants can bring up products over which they have a doubt regarding product status;
- Usually, these are ‘niche’ products without significant economic importance;
- However, they are very important to constantly confirm and re-define the borderline;
- **Conclusions are captured in ‘Borderline Manual’:**

  → **Guide industry to responsible behaviour**

  → **Support national authorities enforcement decisions**

Borderline Manual

1. *Type of Product – Substance or Mixture* ____ 3
   - 1.1. Tongue brushes releasing a substance or a mixture ____ 3
   - 1.2. Clothes releasing a substance or a mixture ____ 3
   - 1.3. Tooth picks and tooth floss ____ 4
   - 1.4. Patches ____ 4
   - 1.5. Washable, temporary “tattoos” ____ 5
   - 1.6. Wipes ____ 5
   - 1.7. Wig ____ 5
   - 1.8. Tattoo removal devices ____ 6
   - 1.9. Wet razors releasing substances/mixtures ____ 6
   - 1.10. Self-Tanning Concentrates ____ 6

Borderline Manual

2. Application site 7

2.1. Vagina 7

2.2. Ingestion (tablets) 7

2.3. Ingestion (chewing gum) 9

2.4. Oral drops, sprays or gels 10

2.5. Nasal sprays 11

2.6. Tooth whitening products, placed inside the tooth 12

Borderline Manual

3. Intended Cosmetic Purpose ____ *13*

3.1. Borderline with Toys ____ 13

3.1.1. Products which, according to their presentation, are destined to be used as make-up on dolls ____ 13

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3.1.3. Bath Products for Children with a Play Value ____ 14

3.1.4. Face paints, body paints, aerography ____ 14

3.2. Borderline with Biocides ____ 15

3.2.1. Leave-on products presented as “antiseptic” or “antibacterial” ____ 15

Borderline Manual

3. Intended Cosmetic Purpose _____ 13

3.3. Borderline with Pharmaceutical / Medicinal Products _____ 15

3.3.1. Products which, according to their presentation, are intended to exclusively or mainly relieve joint pain _____ 15

3.3.2. Products which, according to their presentation, are intended to address "itching" 16

3.3.3. Product containing substances which restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action _____ 16

3.3.4. Products containing substances stimulating hair growth or reducing hair loss 17

3.3.5. Products that make eyelashes grow _____ 18

3.3.6. Products for in-grown hairs _____ 19

3.3.7. Products that make the lips swell _____ 19

3.3.8. Products reducing cellulite _____ 20

Borderline Manual

3.3.9. Substances applied with skin-patches 20
3.3.10. Products delivered through iontophoresis or similar mechanisms 21
3.3.11. Products delivered through invasive techniques, such as needle roller 21
3.3.12. Product to treat dry mouth 22
3.3.13. Products for superficial moisturizing of female genital organ in cases of extreme mucosal dryness 22
3.3.14. Topical breast augmentation products 23
3.3.15. Products claiming aromatherapy 23
3.3.16. Products for atopic skin 24
3.3.17. Products to reduce dark circle under the eyes, bruises or blue spots 24
3.3.18. Products with claims related to bruises, bumps and similar 25
3.3.19. Skin-whitening products 25
3.3.20. Products to relieve tired swollen and heavy legs 25
3.3.21. Anti-wrinkle products 26
3.3.22. Tattoo removal and tattoo fading products 27
3.3.23. Products with “healing the skin” claims 27
3.3.24. “Hot tanning products” 28
3.3.25. Products to remove “hard skin” 28
3.3.26. Products to change the appearance of skin reddened due a weak dilation or imperfection of capillary veins 28
3.3.27. Tattoo aftercare products 29
3.3.28. Products for acne and spots 29
3.3.29. Piercing care products 31
3.3.30. Mouthwashes and dental gels 31
3.3.31. Nail care products 32
3.3.32. Products against nail biting 32
3.3.33. Massage products 33
3.3.34. Products in a vial or ampoule 33

Borderline Manual - example

3.3.16. Products for atopic skin

150. **Question: Are products for atopic skin cosmetic products?**

151. **Answer:** According to common understanding, atopy is a type of hypersensitivity.

152. It seems that in the general meaning, atopy and atopic dermatitis are used as synonyms in relation to cosmetic products. This makes the notion of atopy ambiguous. WHO classified several diseases due to atopy: acute atopic conjunctivitis, allergic asthma, atopic dermatitis, neurodermatitis, etc.

153. In light of these definitions, the products using claims related to atopy seem to fall outside of the scope of the Cosmetics Regulation. However, the use of such terms as "atopy" or “atopic skin” should be assessed on a case-by-case basis.

154. For instance, products presented as “appropriate for/suitable to skins with atopic tendency/atopic skin” can be qualified as cosmetic products, if their purpose is to place them in contact with the various external parts of the human body (…) in order to exclusively or mainly clean them, perfume them, change their appearance and/or correct body odours and/or protect them or keep them in good condition. On the other hand, products presented as having properties to treat or prevent atopy/atopic skin cannot be qualified as cosmetic products.

Tips and Tricks



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Importance of claims

- Claims are important factor to inform consumers – or to confuse them – over the product status
- Claims are also what drives innovation !

→Claims set products apart from the rest of the market.

→ Claims allow consumers to find the product which suits them best – among a big range of different products with small differences.

Remember:

Claims are not limited to what is written on pack.

They include any communication made in

the context of the product.

Consumer perception counts

- Ultimately, the primary function of a products can be defined as the ‘reason why the consumer buys and uses the product’.
- Consumer perception counts !
- Claims on pack are not the only characteristic that a consumer perceives.
- Consider advertising, internet presence, sales channel, product design, …
- Your reference is a "reasonably well-educated, average European consumer“
- Control authority inspectors are also consumers !

Language and cultural aspects

- Who is this "reasonably well-educated, average European consumer“ ?
- Is he/she English, French, German, …?
- Although there is common, harmonised regulation for cosmetics, the EU is not a homogeneous block with one single language
- The regulation is applied in each country against a linguistic, cultural background
- The same wording may not mean exactly the same in each language

→Do your homework and check if your product could be misinterpreted locally

Conclusions



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Conclusion

- In the EU, cosmetic products have secondary benefits that positively support public health;
- Not by disinfecting or by treating diseases but by protecting the skin/oral cavity and keeping it in good condition, thereby reducing the risk of certain non-cosmetic problems;
- Such benefits can be claimed – provided that the claim does not create doubt over the primary cosmetic function of the product;
- Such products also drive industry innovation – but clear guidance is needed to avoid ‘crossing the borderline’
- EU guidance exists through the work of the Borderlines WG and its Borderline Manual

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Thank you for your attention !

Questions ?