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## Product Classification

# Borderlines between medicines, cosmetics and biocidal products

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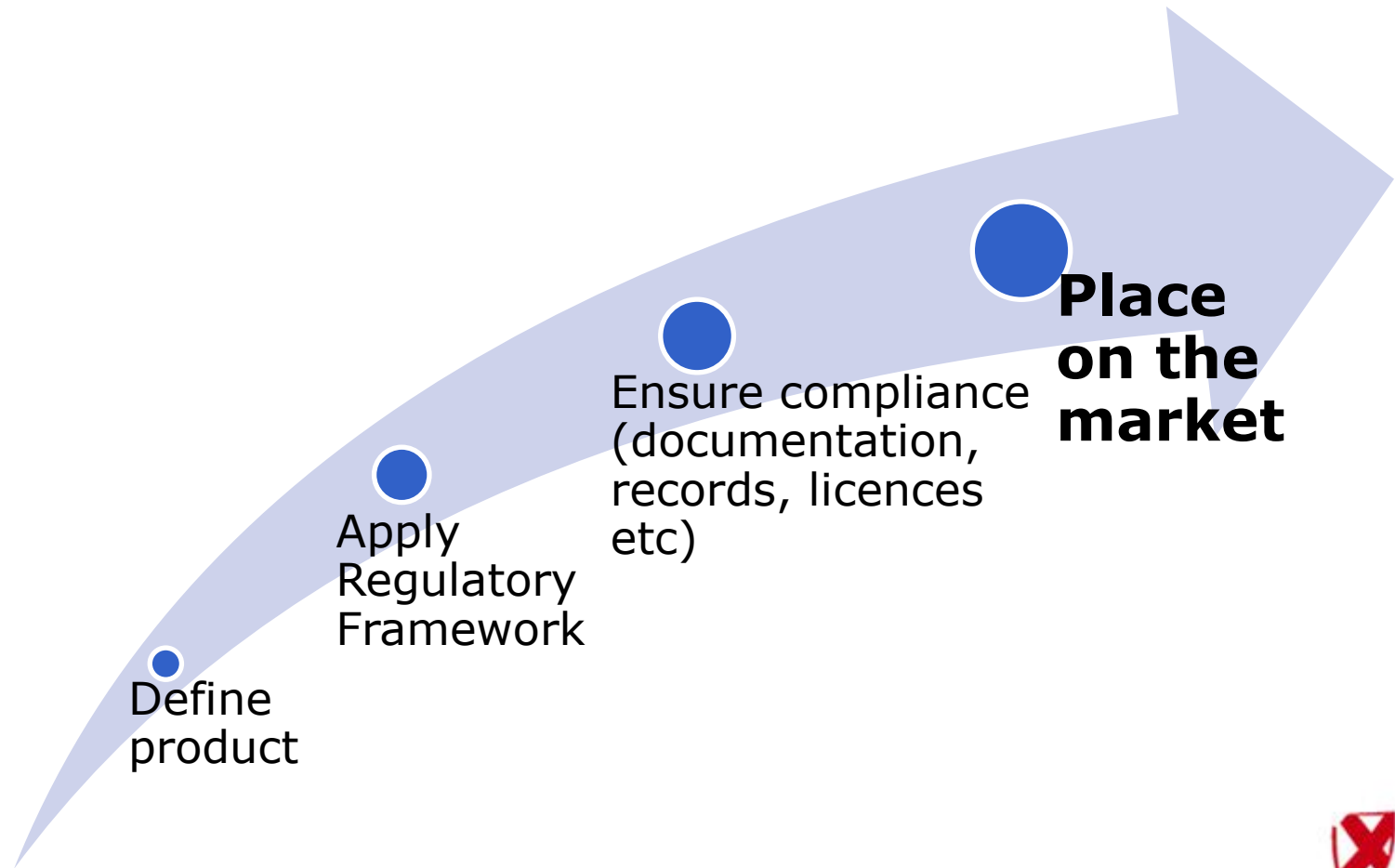
# Overview

- Key aspects – define your product
- Some examples of borderlines
  - Hair loss products
  - Antibacterial hand washes
  - Tooth Whitening Products
- Reference/ Guidance Documents



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# Key aspect to classification ...



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# Define Product

<b>IMB responsibility</b>	<b>Other agencies</b>
Human & Veterinary Medicines (Including THMPs)	Biocides (PRCD, Dept of Agriculture Food and the Marine)
Medical Devices	General Products (National Consumer Agency)
Cosmetics	Food Supplements (FSAI)

Need to refer to legal text for product definitions



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# Legislative texts – medicinal product definition

Article 1 of Directive 2001/83/EC as amended by Directive 2004/27/EC

- Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- 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



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# Cosmetic Product Definition

## Article 1 of Directive 76/768/EEC

- ...substance or preparation 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 teeth and the mucous membranes of the oral cavity,

with a view exclusively or mainly to **cleaning** them, **perfuming** them, **changing their appearance** and/or **correcting body odours** and/or **protecting** them or keeping them in **good condition**...



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# Key differences between medicine and cosmetic ...

## Cosmetic product

- Must not exert a pharmacological, immunological or metabolic action
- Must not be presented as having properties for treating/ preventing a disease
- External application
- Cannot be ingested, implanted or inhaled



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# Biocide definition

## Article 2 of Directive 98/8/EC

- Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, **intended to destroy, deter, render harmless**, prevent the action of, or otherwise **exert a controlling effect on any harmful organism by chemical or biological means.**



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# General Products

## Article 2 of Directive 2001/95/EC

- Any product – including in the context of providing a service – which is intended for consumers ...and is supplied or made available ... in the course of a commercial activity, and whether new, used or reconditioned.



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# Borderline cases...



Dental Floss



Facial Wipes



Dermal Patch

Are these cosmetic products?

1 – Yes

2 – No

3- It depends



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# Borderline cases ...



Lip Plumper



Eyelash Growth  
Enhancer



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# Borderline cases



Childrens  
Cosmetics



Chewing Gum  
releasing agents

Manual on the scope of application of the Cosmetics Directive, version 8:

[http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/manual borderlines of en.pdf](http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/manual_borderlines_of_en.pdf)

# Hair loss products

Claims include:

- Treat or prevent hair loss
- Stimulate hair growth
- Stop, slow down or reverse hair loss



Do you consider the claims listed to be associated with:

1. a cosmetic product or
2. a medicinal product?



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# Non- medicinal claims for hair care products

- Promote or strengthen existing hair growth
- Nourish thinning hair
- Consider route of administration - cosmetic Vs food supplement



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# Antibacterial hand washes – classification?

Cosmetic Vs Biocide Vs Medicine?  
Intended Use?  
Ingredient list?  
Claims?

## Intended Use

In line with a cosmetic  
product definition or is it to  
prevent cross contamination?

## Ingredient List

Biocidal active ingredients?  
Meet the restrictions of  
Directive 76/768/EEC?



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# Antibacterial hand washes – examples of claims

- Kills 99.9% bacteria
- Germ kill
- Kills bacteria, fungi, viruses
- Suitable for hand disinfection
- disinfectant



Would you consider the above claims to be associated with:

- 1 - A Cosmetic product, or
- 2 - A Biocidal product?



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# Antibacterial products – classification?

- Cosmetic, medicinal, biocide?
- Antiseptic claims – used to treat or prevent infections
- Disinfection claims – for hygiene purposes/ prevention of cross contamination
- Clean, protect, correct body odours - Cosmetic



Liquid Soap Bottle Labels

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# Status of cosmetic – biocide borderline products

- National guidance was drafted in 2011
- Outcome of Public Consultation – query to EU Commission on secondary claims
- EU Commission currently in discussions
- Hope to have clarification over the coming months
- IE – consider the product presentation, intended use and composition – if in doubt, contact the IMB and PRCD for guidance.



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# Hydrogen Peroxide in Tooth Whitening products



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# Current Legislation

The use of **toothpastes, mouth rinses** and tooth whiteners containing **up to 0.1%** hydrogen peroxide does not pose a risk to the health of the consumer. Toothpastes and mouth rinses should not contain more than 0.1% hydrogen peroxide.



Germany  
Medical Device



UK  
Cosmetic



Spain  
Dental Device

# Key area for 2012

- Directive 2011/84/EU – implementation Oct 2012
- Products containing up to 0.1% H<sub>2</sub>O<sub>2</sub> can be made available to the consumer
- Products containing between 0.1% and 6% H<sub>2</sub>O<sub>2</sub> can only be made available to dental practitioners
- Products containing >6% H<sub>2</sub>O<sub>2</sub> **Prohibited**
- Distributors must ensure product meets requirements in terms of labelling and must only supply to dental practitioners



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# Labelling requirements for $\text{H}_2\text{O}_2 > 0.1\%$

- Contains hydrogen peroxide
- Concentration of  $\text{H}_2\text{O}_2$  present or released indicated as %
- *'Avoid contact with eyes, rinse immediately if product comes into contact with them'*
- Not to be used on a person under 18 years of age
- **To be only sold to dental practitioners.**
- For each cycle of use, the first use to be carried out only by dental practitioners



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# Summary

- Ensure product classification is appropriate
- Apply appropriate regulatory framework
- If in doubt – seek advice
- Place safe, compliant product on the market

## Guidance Documents:

[http://ec.europa.eu/consumers/sectors/cosmetics/cosmetic-products/borderline-products/index\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/cosmetic-products/borderline-products/index_en.htm)

<http://www.imb.ie/EN/Cosmetics.aspx>



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# Borderline Products Guidance

The screenshot shows a Windows Internet Explorer browser window displaying the European Commission's website for Consumer Affairs. The page is titled "Borderline products" and is part of the "Cosmetic-products" section. The navigation menu includes "Cosmetic products", "Reference documents", "Useful links", "Questions and terms", "Acronyms", "Glossary", "Questions and answers", "News", "Events", "Contracts Grants", "Publications", "Public consultations", and "Speeches".

The main content area is titled "Borderline products" and contains the following text:

**Borderline products**

In practice, it may sometimes be unclear whether a product is a cosmetic product in the sense of the Cosmetics Directive or whether it falls under other sectoral legislation. This decision is to be taken on a case-by-case basis.

However, the Commission has published a number of guidance documents to facilitate the application of Community-legislation in these cases. These include a "manual" on the application of Art. 1 Cosmetics Directive, i.e. the definition of "cosmetic product" (see below) and various guidelines on the borderline other sectoral legislations.

Please note, however, that only the text of the Directives is authentic in law. The text of the Directives is applicable where there are differences between the provisions of a directive and the contents of these guidance documents. The interpretation of Community law is ultimately the responsibility and privilege of the European Court of Justice. The analysis set out in these guidance documents does not in any way preclude a different interpretation by the European Court of Justice in a particular case, and does not in any way commit the European Commission.

[Manual on the scope of application of the Cosmetics Directive 76/768/EEC \(Version 8.0, June 2011\)](#) [238 KB]

Guidance documents on "borderline products":

- [Guidance Document on the Relationship Between the General Product Safety Directive \(GPSD\) and Certain Sector Directives with Provisions on Product Safety](#)
- [Guidance Document agreed between the Commission services and the competent authorities of Member States for the biocidal products Directive 98/8/EC and for the cosmetic products Directive 76/768/EEC borderline between Directive 98/8/EC concerning the placing on the market of biocidal products and Directive 76/768/768/EEC concerning cosmetic products](#)
- [Manual of decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products](#)
- [Guidance Document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83 as agreed between the Commission services and the competent authorities of Member States](#) [80 KB]

The browser's address bar shows the URL: [http://ec.europa.eu/consumers/sectors/cosmetics/cooperation-trade/index\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/cooperation-trade/index_en.htm). The taskbar at the bottom shows the Start button, several application icons, and the system tray with the date and time: 18:35, 19/09/2012.



# IMB Publications

The screenshot shows a Windows Internet Explorer browser window displaying the Irish Medicines Board (IMB) website. The address bar shows the URL <http://www.imb.ie/EN/Cosmetics.aspx>. The website header features the IMB logo and navigation links: Home, About Us, Consultation, Events, Glossary, Legislation, Links, News, Publications, Recruitment, Register. A search bar is also present. Below the header is a red navigation bar with tabs for Safety & Quality, Human Medicines, Veterinary, Medical Devices, Blood, Tissues & Cells, **Cosmetics**, and Patients & Public. The main content area is titled 'Cosmetics' and includes a 'Cosmetic Product' section with a definition and a 'Substances intended to be ingested, inhaled, injected or implanted...' section. On the right side, there is a 'Latest Information' sidebar with a list of links: Publications - (7) (circled in red), Links - (2), Consultation - (1), News - (4), Events - (2), and Provide Feedback. The Windows taskbar at the bottom shows the Start button, several application icons, and the system tray with the date 25/09/2012 and time 09:40.



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