

Microbiome

THE REGULATORY LANDSCAPE



Bloom Regulatory - A global approach to regulatory consultancy



Bloom Regulatory Ltd has been created in 2019 to provide regulatory support to companies offering cosmetics via a new global approach to regulatory consultancy.

A Global Approach to Regulatory

This new approach looks beyond regulatory affairs and considers as well other key challenges and opportunities to provide bespoke solutions to companies in a world of increasing commercial pressures.

Introduction



No available international guidelines on definitions or terminologies applicable to cosmetic ingredients that work with the skin’s microbiome. However regulators across the world are expressing interest in this topic.

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Probiotic: Viable (live or dormant) microorganisms added to a cosmetic product in order to achieve a cosmetic benefit at the application site, either directly or via an effect on existing microbiota.

Prebiotic: Non-viable ingredients added to a cosmetic product with the intention of being actively used as nutrients by the microbiota of the application site in order to achieve a cosmetic benefit.

Postbiotic: Non-viable ingredients comprised of inactivated microorganisms and/or soluble factors (products or metabolic by-products) released by live or inactivated microorganisms, added to a cosmetic product in order to achieve a cosmetic benefit at the application site, either directly or via an effect on the existing microbiota.

Why are regulators interested in this topic (Extract from the US FDA) ?

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- Are probiotics still alive in the cosmetics that have preservatives? [Efficacy](#)
 - Does the presence of probiotics have an effect on product safety? [Safety](#)
 - Is there an effect on product quality? [Safety / Quality](#)
 - What are the intended functions of probiotics in cosmetics? [Borderline / Efficacy](#)
 - Are there special considerations for manufacturing cosmetics containing probiotics? [Safety / quality / manufacturing](#)
 - How can cosmetics containing live microorganisms meet existing microbial contamination limits? [Safety](#)
 - Does the presence of probiotics in cosmetics affect the shelf life and storage products? [Safety / quality](#)
 - How are probiotic cosmetics regulated by other countries? [Global approach](#)



EU Regulatory Landscape



No specific regulations or requirements that govern cosmetic products or ingredients intended to work specifically with the skin's microbiome.

So... reference to the current regulatory landscape should be used for compliance:

- [1223/2009 Cosmetics Regulation](#) (products and ingredients)
- [REACH](#) and [CLP Regulations](#) (ingredients in these products).
- [Directive 2000/54/EC](#) biological agents at work (protection of workers from risks related to exposure to biological agents)

Similar principles in other jurisdiction such as Brazil, Canada, Japan, US, Israel, South Africa, South Korea, Taiwan, and Thailand.

Types of Products associated with Probiotics

skin care leave-on products

oral care

skin care rinse-off products

antiperspirants/deodorants

Types of Products associated with Prebiotic Ingredients

Skin Care – Moisturizers (Face & Body Cream / Face Serum / Face Mask / Body Lotion)

Skin Cleansers (Make-up Remover / Facial & Body Wash / Feminine Wash and Wipe)

Hair Care (Shampoo / Hair Mask)

Antiperspirant/Deodorant

Types of Products associated with Postbiotic Ingredients



Skin Care – Moisturizers (Face & Body Cream / Face Serum, Toner, Mist / Face Mask / Lip Treatment /Body Lotion)

Skin Care – Cleansers (Face & Body Wash / Scrub/Exfoliator / Feminine Wash)

Hair Care (Shampoo /Conditioner/serum /Scrub)

Make-up (Primer / Foundation /Mascara)

Oral Care (Toothpaste)

Antiperspirant/Deodorant

But also



Formulated without ingredients that may harm the microbiome (microbiome-friendly): no preservatives, no sodium lauryl sulfate (SLS), no mint, no synthetic ingredients etc.

Formula “gentle” to microbiome: 100% natural ingredients, mild to skin pH, “bound” water

Agenda

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1. Are prebiotics, probiotics and postbiotics allowed as cosmetic ingredients?
 2. Safety considerations
 3. The classification of the product – borderline challenges
 4. Claims substantiation

Are prebiotics, probiotics
and postbiotics allowed as
cosmetic ingredients?

Substance and mixture

*'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;*

substance' means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

'mixture' means a mixture or solution composed of two or more substances;

- Prebiotics and postbiotics?
- What about probiotics? the cosmetics definition does not mention viable microorganisms in its definition of 'substance'

Safety considerations

Products should be safe

USA: any topical product that contains live or dormant microorganisms beyond the acceptable limits in the Bacteriological Analytical Manual (BAM) Chapter 23 (<https://www.fda.gov/food/laboratory-methods-food/bam-methods-cosmetics>) is adulterated.

Canada: to follow the limits and methods outlined in the International Standards Organization (ISO) Standard on Cosmetics – Microbiology – Microbiological limits, ISO 17516:2014.

Japan: Standards for Cosmetics “Ingredients of cosmetics, including any impurities contained therein, shall not contain anything that may cause infection or that otherwise makes the use of the cosmetics a potential health hazard.”

Korea: using live micro-organisms in cosmetics is banned under the regulation on permissible limits of total aerobic microbes in cosmetics

Borderline Challenges

EU Cosmetic 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;*

1. Application site: What about the microbiota present at the application site?
2. **keeping in good condition** as long as it does not lead to a significant impact on the body’s physiological functions

Therapeutic / medicinal claims

Any therapeutic claims, which would imply a product modifies body functions, prevents or treats disease, are not allowed on cosmetic products

What about:

Redness

Atopic dermatitis

Eczema

Psoriasis

Broken skin

...etc



Claims Substantiation

Claims – Regulatory Landscape

Horizontal legislations

Unfair Commercial Practices Directive 2005/29/EC

Misleading and Comparative Advertising Directive 2006/114/EC

Vertical legislations

Cosmetic Products Regulation (EC) No 1223/2009

Common Criteria Regulation (EU) No 655/2013

Guidelines to Commission Regulation (EU) No 655/2013

Technical document

Technical document on cosmetic claims - Agreed by the Sub-Working Group on Claims (3rd July, 2017)

Self-Regulation

Member States Advertising Code e.g. UK Codes of Advertising Practice – CAP and BCAP codes

Cosmetics Association Guidelines (e.g. CE , CTPA...etc.)

Claims – key principles

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- Cosmetics are not drugs
 - Difficulty to discuss specific words or claims when taken in isolation, might prejudice the use of the same claim or words used in a different context e.g. treatment
 - General principles – key questions
 - “what has been claimed ?”
 - “is that claim supportable” on the basis of all available information ?
 - The substantiation should be available at the time of the claim

Claims substantiation

Relevant scientific data to back up such claims are needed.

The advertising authority in the UK will be very strict if they are making such claims on advertising materials (broadcast and non broadcast but also online) and will expect a very robust dossier - very few microbiome claims will be able to be substantiated.

Challenges:

Differences in microbial composition between benchmark skin

Identification of role these differences play

Define ways how to influence the microbial composition

Active interference with skin microflora

So...

- Efficacy claims on the skin microflora can only be secondary and need rigorous substantiation
- 'Help' is safer
- Microbiome friendly type claims