



**REPORT FOR THE
INTERNATIONAL COOPERATION ON COSMETICS REGULATION**

MICROBIOME AND COSMETICS: WORKING DEFINITIONS & MICROBIOLOGICAL ASSESSMENT CONSIDERATIONS¹

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7. Ministry Food and Drug Safety (MFDS), Republic of Korea
8. US Food and Drug Administration (US FDA), United States
9. Indonesian Food and Drug Administration (BPOM), Indonesia
10. Ministry of Health (MOH), Israel
11. National Institutes for Food and Drug Control (NIFDC), People Republic of China
12. Saudi Food & Drug Authority (SFDA), Saudi Arabia
13. Thai Food and Drug Administration (Thai FDA), Thailand
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16. Taiwan Cosmetics Industry Association (TWCIA), Chinese Taipei
17. Cosmetics Europe (CE), Europe

¹ ICCR's focus is on cosmetics, the definition of which varies between jurisdictions. Due to these differences in legal definitions, some products that are considered cosmetics in one jurisdiction may be considered quasi-drugs, over-the-counter (OTC) drugs or natural health products in another.

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18. European Federation for Cosmetic Ingredients (EFFCI), Europe
19. Japan Cosmetic Industry Association (JCIA), Japan
20. Korea Cosmetic Association (KCA), Republic of Korea
21. Independent Beauty Association (IBA), United States
22. US Personal Care Products Council (PCPC), United States
23. Persatuan Perusahaan Kosmetika Indonesia (PERKOSMI), Indonesia
24. Israeli Association of Cosmetic Manufacturers, Israel
25. Thai Cosmetic Manufacturers Association (TCMA), Thailand

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1. SELECTED ABBREVIATIONS AND DEFINITIONS

ICCR	International Cooperation on Cosmetics Regulation
JWG	Joint Regulator – Industry Working Group
ToR	Terms of Reference

2. BACKGROUND

The International Cooperation on Cosmetics Regulation (ICCR) held its 14th Annual Meeting (ICCR-14) from December 7-9, 2020, virtually. At this meeting, the ICCR Steering Committee endorsed the Microbiome Joint Regulator-Industry Working Group (Microbiome I JWG) report “Microbiome and cosmetics: survey of products, ingredients, terminologies, and regulatory approaches” for posting to the ICCR website.² In addition, the ICCR Steering Committee agreed, with the full support of the Industry Associations, that the topic of the Microbiome should remain on the ICCR agenda and that a new Joint Working Group (Microbiome II JWG) be formed to work on other microbiome topics as they relate to cosmetics.³

3. PURPOSE

The ICCR-14 report of the Microbiome I JWG (ICCR 2021) highlighted that the topic of cosmetics working on the human skin (or mucosal) commensal microbiome to achieve a cosmetic function is evolving rapidly in the marketplace worldwide. The Microbiome I JWG conducted a survey of cosmetics in the marketplace which showed the types of products, ingredients, and approaches that are most relevant to microbiome-related technologies in cosmetics. The Microbiome I JWG report further noted that there is no consistent terminology relevant to cosmetic ingredients and/or finished products working with the microbiome. However, for reporting consistency, the JWG found it necessary to develop a set of categories and descriptors that could be used to cluster and categorize microbiome-related products, their ingredients, and other relevant approaches, in a cosmetically relevant context. Finally, while there are no unique regulations in the ICCR jurisdictions on this emerging class of cosmetic products, standard cosmetic requirements and guidelines must be considered including products having live and viable microorganisms. Building on these learnings, the Microbiome I JWG recommended that further research be undertaken to establish a common working vocabulary and relevant definitions. It was also

² <https://www.iccr-cosmetics.org/topics-documents/14-microbiome>

³ Further information on ICCR-14, along with previous meetings and reports, may be found on the ICCR web site: <https://www.iccr-cosmetics.org/>

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recommended that current microbiological limits for cosmetics be assessed in the context of products with intentionally added microorganisms.

4. INTRODUCTION

Consistent with the Recommendations of ICCR Microbiome I JWG (ICCR 2021) and endorsed by the ICCR -15 Steering Committee, a new Microbiome Joint Regulatory – Industry working Group (Microbiome II JWG) was formed in February 2021. In consideration of the work of the Microbiome I JWG, new Terms of Reference were endorsed and the JWG tasked with addressing the following:

- I. *Establish a common vocabulary to guide future ICCR discussions regarding microbiome-related topics in the context of cosmetics. [See Note 1]*
- II. *Examine if current microbiological limits are appropriate for products containing live or viable microorganisms that are intentionally introduced in cosmetic products and investigate whether additional considerations would be appropriate.*

NOTE 1: The JWG emphasizes that these working definitions are not intended to reflect official regulatory definitions, but to promote further ICCR discussions on this topic.

5. RESULTS AND DISCUSSION

5.1. Definitions related to the microbiome in the context of cosmetics

The vocabulary described below are based on state-of-the-art scientific literature and were established to guide future ICCR discussions regarding microbiome-related topics in the context of cosmetics, so they are not meant as legally binding. However, they are suggestions to support a clear understanding of skin microbiome related terms for regulators and other stakeholders in the cosmetic field.

All the terms below are described from the perspective of their use in the cosmetic sector.

MICROBIOTA:

Definition: The microbiota is the assemblage of microorganisms, such as bacteria, fungi, archaea, microalgae & protists present in a defined environment. This can be the human body or individual body sites, like the skin or the digestive tract. Definition based on *Berg et al., 2020*

MICROBIOME:

Definition: The microbiome is a characteristic microbial community occupying a reasonably well-defined habitat which has distinct physio-chemical properties. The microbiome not only refers to the microorganisms involved but also encompasses their theatre of activity, which results in the formation of specific ecological niches. This includes their genetic material, and also structural molecules, like enzymes, membrane lipids or polysaccharides. Definition based on *Berg et al., 2020*

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SKIN MICROBIOME:

Definition: The skin microbiome is present on the whole skin surface, including oral cavity and mucosal surfaces of the external genital organs. The composition of the skin microbiome is dynamic, site-specific but also differs from individual to individual. Definition based on *Byrd et al., 2018*

The skin microbiome includes also microorganisms found on e.g., the scalp, pilosebaceous follicles or sebaceous glands. It also comprises microorganisms detected in the epidermis or dermis as described by *Nakatsuji et al., 2013*.

It should be noted that the two terms “microbiota” and “microbiome” are not synonymous as the microbiota only refers to the microorganisms, whereas the microbiome also includes their functional potential. These 2 terms are mainly used in the scientific literature, whereas in the public domain both terms are often used interchangeably. Therefore, it is suggested that only the term “microbiome” be used in the JWG report, also in consideration of the widespread use of this term in the cosmetic field.

PROBIOTICS:

Definition: Viable (active or dormant) microorganisms added to a cosmetic product with an intended cosmetic benefit to the host *at the application site*, either directly or via an effect on the host microbiome, when utilized in adequate amounts.

Active microorganisms are usually defined as growing organisms, which increase their number and/or biomass (*Dyckmans et al., 2003*). Consequently, dormant microorganisms do not grow, but still keep their metabolic activity (*Joergensen & Wichern, 2018*). Definition based on *Hill et al., 2014*

POSTBIOTICS:

Definition: Inanimate ingredients of microbial origin added to a cosmetic product with an intended cosmetic benefit.

These components can either be cells or cell fractions, a filtrate of a fermentation or a metabolite of a microorganism. Definition based on *Aguilar-Toalá et al., 2018*

PARAPROBIOTICS:

Definition: Ingredients derived from inactivated probiotic microorganisms added to a cosmetic product with an intended cosmetic benefit. Paraprobiotics can either be inactivated microbial cells or components of cellular structures (e.g. cell walls), with or without metabolites. Based on the definition, paraprobiotics are a subgroup of postbiotics. Definition based on *Taverniti & Guglielmetti, 2011 & Salminen et al., 2021*

PREBIOTICS:

Definition: Substrates (e.g. carbohydrates or other nutrients) added to a cosmetic product to be utilized by the host microbiome, with an intended cosmetic benefit to the host. Whereas pro-, post- & paraprobiotics are defined by their microbial origin, the term prebiotic describes a functionality and is irrespective of its origin. For example, a postbiotic can also be (functionally) a prebiotic. Definition based on *Gibson et al., 2017*

MICROBIAL DYSBIOSIS:

Definition: An imbalance in the resident microbial population leading to possible loss of beneficial microbial organisms, increase in harmful microorganisms, change in the overall microbial diversity and/or change in functional composition and metabolic activities. Definition based on *Petersen & Round, 2014*

5.2. Microbiological limits for products containing live or viable microorganisms that are intentionally introduced in cosmetic products

Cosmetic products are not expected to be sterile. However, they shall not contain excessive amounts of microorganisms nor specified microorganisms that have the potential to affect product quality or consumer safety. Moreover, some cosmetic products are considered to have low microbiological risk⁴. The manufacturer should follow the Good Manufacturing Practices⁵ and take the necessary precautions to limit the introduction of microorganisms from raw materials, processing, and packaging⁶. Current microbiological limits are intended to address microorganisms unintentionally introduced (i.e., contaminants) into cosmetic products from raw materials, processing, or packaging, but not microorganisms which are intentionally added to products (i.e., probiotics). Therefore, applying current microbiological limits for probiotics which are deliberately and intentionally added to products would not be appropriate nor fit for purpose. Instead, when addressing the introduction of probiotics in cosmetic products, it is proposed that the determination of safe concentrations of such ingredients be established on a case-by-case basis. The following key considerations in this regard include:

- Microbiological assessment should be adapted to differentiate between intentionally added probiotics and microorganisms which are unintentionally present (i.e., contaminants).
- Preservation strategy should be adapted to ensure consumer safety, while allowing at the same time the viability of the probiotic in the formulation.
- Safety assessment of the probiotic for the intended cosmetic uses should be conducted as for any other cosmetic ingredient, considering the specificities of this new type of ingredients. Existing guidance and best practices derived from other sectors (food, pharma, etc.) should serve as a basis to develop suitable guidance for cosmetic applications.

⁴ ISO 29621 Cosmetics — Microbiology — Guidelines for the risk assessment and identification of microbiologically low-risk products

⁵ ISO 22716 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

⁶ ISO 17516 Cosmetics — Microbiology — Microbiological limits

6. CONCLUSION

Clarity in vocabulary is proposed from the perspective of their use in the cosmetic sector to provide for a consistent understanding of skin microbiome related terminology for regulators and other stakeholders in the field of cosmetics.

Cosmetics shall not contain excessive amounts of unintentionally introduced microorganisms nor specified microorganisms that have the potential to affect the product quality or consumer safety. The established guidance for acceptable quantitative and qualitative limits for cosmetic finished products (i.e., ISO 17516 Cosmetics — Microbiology — Microbiological limits) are not applicable to intentionally added microorganisms (i.e., probiotics), despite that currently such microbiological limits don't specifically address intentionally introduced microorganisms. However, the fundamental obligation of microbiological safety and quality remains.

While the Microbiome Joint Regulatory – Industry Working Group (Microbiome II JWG) has concluded the tasks described by the ToR, the topic remains of great interest and the JWG believes there remains relevant new items to discuss around the topics of microbiome and cosmetics:

- Firstly, ICCR jurisdictions are encouraged to consider and standardize, as appropriate, the vocabulary and terminology as outlined in this report when addressing matters related to the microbiome.
- Secondly, the JWG believes consumer friendly communications on the topic would be valuable and recommends the topic be advanced to the ICCR Communications Working Group for their consideration.
- Finally, there are technical challenges in assessing the microbiological safety of products that may contain both intentionally added and unintentionally present microorganisms. While the latter is outside the scope of the ICCR, the JWG encourages a dialogue with Standards Developing Organizations in order to develop an international standard to best address these challenges.

7. REFERENCES

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