

BIO ECO **COSMESI AIAB**

REGULATORY
DOCUMENT
ED. 02 / REV. 6



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1. INTRODUCTION

**BIO ECO
COSMESI
AIAB**



AIAB, ASSOCIAZIONE ITALIANA PER L'AGRICOLTURA BIOLOGICA (ITALIAN ASSOCIATION FOR ORGANIC AGRICULTURE), HAS DRAWN UP THE FOLLOWING REGULATIONS TO ALLOW ALL PARTIES CONCERNED ACCESS TO THE CERTIFICATION OF THEIR PRODUCTS, WITH THE AIM OF INCLUDING THE BIO ECO COSMESI CONFORMITY WORDING AND THE MARK ENVISAGED IN ARTICLE 10 OF THESE REGULATIONS ON THE LABEL.

Certification will be entrusted to an external and independent certification body (hereinafter CB). The CB's technicians will verify compliance with these regulations by all parties concerned.

This specification is intended to be in continuous evolution, subject to updates and improvements. Annex 1 has been drafted on the

basis of the inventory of cosmetic raw materials listed in the Decision of the European Commission as of 9 February 2006 (2006/257/EC), so subsequent additions or amendments to said inventory by the European Commission will trigger the need for further adjustments. The use of the raw materials included in Annex 1 must be assessed by the CB.

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2. PURPOSE OF THE DOCUMENT



AIAB USES THESE REGULATIONS TO PURSUE THE FOLLOWING AIMS:

to make it possible, also in the field of personal care, to use products with a low environmental impact, capable of expressing the greatest possible protection for the consumer's health, as well as meeting consumer expectations by means of a correct, transparent and complete definition of Bio Eco Cosmesi;

to define the minimum requirements for Bio Eco Cosmesi products to be granted the label;

to minimise:

- the presence of non-eco-friendly raw materials in products and packaging;
 - the presence of non-plant-based raw materials that may cause allergy or irritation, or which are proven to be potentially harmful to human health;
 - the environmental impact due to packaging (packaging from renewable raw materials or recyclable materials, or used in a system which involves the return of empties is promoted);
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to promote:

- the use of raw materials from organic farming or certified wild harvesting;
- the consumption of organic cosmetics, enabling the consumer to easily and immediately recognise certified cosmetics.

3. PRINCIPLES



IN ORDER TO FULFIL THE PURPOSE OF THESE REGULATIONS, THE PRODUCTION OF COSMETICS **GUARANTEES FINISHED PRODUCTS THAT ARE NON-AGGRESSIVE, ENVIRONMENTALLY FRIENDLY AND PRODUCED WITH LIMITED USE OF CHEMICAL PROCESSES**

The factors prioritised in the choice of raw materials to be included in the list of substances not to be used to obtain the Bio Eco Cosmesi mark were:

**POOR
DERMO-COMPATIBILITY**

**TOXICITY AND
UNDESIRABLE EFFECTS
ON HUMAN HEALTH**

**POOR
ECO-COMPATIBILITY**

THE FOLLOWING SUBSTANCES ARE INCLUDED IN THE LIST OF SUBSTANCES NOT TO BE USED:

PEG, PPG derivatives
(surfactants, solubilisers, emollients, solvents etc.)

ethoxylated compounds
(surfactants, emulsifiers, solubilisers etc.)

surfactants that are aggressive and not particularly skin-friendly

substances that may cause environmental and ecological damage

compounds that can generate nitrosamines
(carcinogenic substances)

animal derivatives such as collagen, tallow, placenta etc.

silicones and silicone derivatives

acrylic polymers
(emulsifiers, rheology modifiers,
filming agents, antistatic agents etc.)

preservatives such as formaldehyde and its carriers,
thiazolinones, phenylmercury by-products, carbanilides,
borates, halogenated phenols, halogenated cresols

4. TERMS AND DEFINITIONS



OPERATOR: natural or legal person responsible for compliance with the provisions of these regulations within the framework of the organic enterprise under its control.

CERTIFICATION BODY: independent third-party body that carries out inspections and certification in compliance with the provisions of these regulations.

RAW MATERIAL: substance included in the formulation of a cosmetic product.

COSMETIC PRODUCT: any substance or mixture intended for application to the external surfaces of the human body (epidermis, body hair, hair, nails, lips, external genital organs) or to the teeth and the mucous membranes of the mouth, with the sole or predominant aim of cleaning them, scenting them, changing their appearance, protecting them, keeping them in good condition or correcting body odours, as defined in Regulation (EC) 1223/2009.

ORGANIC COSMETIC: a cosmetic product that meets the requirements of these regulations.

ENVIRONMENTALLY FRIENDLY: something that can comply with ecological requirements, as it has a negligible impact.

SKIN-FRIENDLY: cosmetics that are well tolerated by the skin and mucous membranes.

ORGANIC FARMING: a method originating from or related to production carried out in compliance with the provisions of Regulation (EC) 834/2007 and Regulation (EC) 889/2008.

EQUIVALENT: capable of fulfilling the same aims and meeting the same principles, applying standards that ensure the same guarantee of conformity.

GENETICALLY MODIFIED ORGANISM (GMO): any organism to which the definition contained in article 3 of Regulation (EC) 1830/2003 applies.

IONISING RADIATION: treatment envisaged by Directive 1999/2/EC.

FERMENTATION: transformation of organic matter by microbial agents (yeasts, bacteria, fungi).

MICROPLASTICS: solid plastic particles, insoluble in water, measuring 5 millimeters or less, added intentionally to cosmetic products. Plastic is understood to mean polymers moulded, extruded or physically manipulated into different solid forms, which, during use and subsequent disposal, retain the forms defined in the intended applications (definitions from Italian Presidential Decree DPR 205/2017).

5. FIELD OF APPLICATION

The products covered by these regulations are those that fall within the scope of Regulation (EC) 1223/2009 as

amended and supplemented, and the raw materials that may be included in their formulation.

6. MAIN REGULATORY REFERENCES

Regulation (EC) 1223/2009 on cosmetic products and subsequent amendments;

European Commission Decision of 9 February 2006 (2006/257/EC) INCI and its updates available on the European Commission database (COSIng);

Regulation (EC) 834/2007 on organic production and labelling of organic products, repealing Regulation (EEC) 2092/91;

Regulation (EC) 889/2008 containing the methods of application of Council Regulation (EC) 834/2007 on organic production and labelling of organic products, with regard to organic production, labelling and controls;

Italian Presidential Decree DPR 205/2017 regarding the definition of microplastics;

Regulation (EU) 2018/848.



7. RAW MATERIALS

The list of raw materials (trade names) and corresponding ingredients (in INCI nomenclature) of cosmetic products subject to certification must be communicated to the CB, which will then assess their compliance with these regulations.

As regards the ingredients

included in the list of “ingredients” on the label under the heading “parfum”, the manufacturer of the raw material shall declare compliance with Annex I of these regulations, also considering the IFRA limitations.

As regards supports for the application of the cosmetic

product such as disposable wipes, in both single and multi-packs, and fabric masks, the use of materials of natural origin obtained by documented environmentally friendly production methods is preferable. Other supports will be assessed by the CB on a case-by-case basis.

7.1 PLANT-BASED RAW MATERIALS

Plant-based raw materials, meaning plants or parts thereof, should preferably come from certified organic farming or wild harvesting.

The organic production method must be certified in compliance with Regulation (EC) 834/2007 or equivalent regulations. Alternatively, plant-based raw materials may be certified in compliance with private standards recognised

by the CB as equivalent to these regulations.

The CB may, on a case-by-case basis, accept raw materials that differ from the above upon presentation of appropriate documentation by the operator. For every cosmetic product certified in compliance with these regulations, at least one certified organic raw material must be used. Plant-based raw materials

obtained from genetically modified organisms or irradiated with ionising radiation are to be excluded in all cases.

Plants or parts of plants are also excluded when their use could contribute to putting them at risk of extinction; the use of these raw materials is permitted if they are farmed.

The use of plant glycerine is allowed.



7.2 RAW MATERIALS OF ANIMAL ORIGIN

Raw materials of animal origin should preferably be certified organic so that animal welfare is effectively guaranteed.

The organic production method must be certified in compliance with Regulation (EC) 834/2007 or equivalent regulations. Alternatively, raw materials of animal origin may be certified in com-

pliance with private standards recognised by the CB as equivalent to these regulations.

The CB may, on a case-by-case basis, accept raw materials that do not comply with the above upon presentation of appropriate documentation by the operator. Raw materials of animal origin may not be used when produc-

tion involves the slaughter of the animal.

The use of glycerine of animal origin is forbidden.

The use of collagen is allowed if duly documented as originating from food production waste. Raw materials obtained from fermentation processes are allowed.

7.3 INORGANIC RAW MATERIALS

Inorganic raw materials are allowed, with the exception of those listed in the annex to these regulations.

When the cosmetic product is made up exclusively of natural inorganic raw materials (e.g., “bath salts”, “clay”, “thermal wa-

ters”, etc.), the CB may only grant compliance with these regulations for the purpose of completing the range of such products.



7.4 SYNTHETIC RAW MATERIALS

Raw materials produced by means of synthetic chemical processes are only allowed in cases where there are no viable alternatives and must meet the following criteria:

- ethoxylation of the raw material is not allowed;
- chemical sun filters are not allowed;
- microplastics, including glitters, are not permitted, either in rinse-off products or in products where rinsing is not required;
- substances listed in Annex I are not allowed;
- the CB reserves the right to approve the use of the substances listed in Annex I if requested, following the presentation of suitable documentation certifying that they are environmentally and skin friendly.

7.5 GMO

The use of ingredients obtained from genetically modified organisms is forbidden. The CB shall carry out special checks on the use of ingredients deriving from raw materials such as maize, potatoes and soya and others that pose a high risk.

7.6 RADIATION

Radiation of the finished product with ionising radiation and the use of ingredients that have been radiated are forbidden. UV radiation is allowed.

7.7 FRAGRANCES

Synthetic components not listed in the annex to the regulations are allowed in the perfumes used. Substances of natural origin, contained in plant extracts, are excluded from limitations in the above-mentioned "parfum" component, if they are non-GMO and do not come from endangered plants that are not farmed especially for this purpose.

8. PACKAGING

For primary packaging that comes into direct contact with the cosmetic (bottles, cans, etc.), only recyclable containers complying with Regulation (EC) 1223/2009 are allowed. In secondary packaging, materials that are hazardous to human health are not allowed,

but reduced and environmentally friendly packaging, preferably from natural and renewable raw materials, guaranteeing choices that respect natural resources, is allowed. The packaging material must be as minimal as possible, unless it is necessary due to the

characteristics of the product and for communication to the consumer. All materials used in the packaging of the cosmetic product must be assessed and expressly approved by the CB to verify compliance with these regulations.



EXAMPLES OF THE CORRECT APPLICATION OF THE ABOVE CRITERIA INCLUDE:

- **label and cap made of the same material as the bottle to allow proper recycling;**
- **use of single-material spraying or dispensing devices;**
- **in the case of products that have a multi-material spraying or dispensing pump in the container (containing metal elements, for example), it is desirable to market this article also in the “refill” version and to invite the consumer, with clearly visible wording on the label, to use the pump as often as possible. The presence of metal prevents proper recycling.**
- **Bakelite and PVC are not allowed in any packaging components, labels and/or as a holder or as product accessories (e.g., vial breakers, nipples, replacement caps etc.).**

9. LABELLING

For improved consumer awareness and information, it is compulsory to indicate the certified raw materials on the label and it is desirable to indicate their quantitative percentage on the finished product. AIAB and/or the CB will publish the list of certified products on its website to enable consumers to engage in responsible consumption. All labels and all informative

material relating to products certified in compliance with these regulations must bear the logos and wording referred to in article 10 and must be assessed and expressly approved by the CB before being printed. The CB approves the labels of the products subject to certification on the basis of the provisions of these regulations and issues written authorisation to print the compliant labels. Additional

compulsory information required by national and EU legislation on the labelling of cosmetic products remains the responsibility of the operator. Products bearing the references referred to in this article 9 which do not comply with the AIAB regulations for Bio Eco Cosmesi shall be withdrawn from the market at the expense of the person responsible for releasing them onto the market.

10. THE MARK

THE AIAB BIO ECO COSMESI MARK IS SHOWN BELOW:



The AIAB Bio Eco Cosmesi mark may only be applied to the labels and advertising material of products which meet the requirements of these regulations; if the operator also places non-certified cosmetic products on the market, the certified product range must have a trademark and graphics which are clearly distinct from the non-certified products, so that the consumer can immediately recognise the certified products from the non-certified ones. In the case of companies whose trademark corresponds to the manufacturer's name, the same trademark may be retained, if the certified range is easily recognisable by the consumer.

11. CONTROLS AND SANCTIONS

The control of these regulations is carried out by AIAB, using licensed certification bodies accredited according to UNI CEI EN ISO/

IEC 17065:2012 "Conformity assessment - Requirements for bodies that certify products, processes and services".

If a CB does not comply with the requirements of these regulations, AIAB reserves the right to suspend its licence.

11.1 NON-CONFORMITIES

IN THE EVENT OF ANY NON-COMPLIANCE WITH THE REQUIREMENTS OF THESE REGULATIONS BY AN OPERATOR, THE CB SHALL REPORT SAID NON-COMPLIANCE. THESE REGULATIONS ENVISAGE TWO LEVELS OF NON-COMPLIANCE, RANKED IN RELATION TO WHETHER OR NOT CERTIFICATION IS AFFECTED:

IRREGULARITY: consists of non-compliance with formal aspects and the documentation envisaged which do not result in prolonged or manifest effects such as to lead to substantial changes in the status of the company and which in no way alter the operator's reliability. With reference to the principle of graduality, minor irregularities are distinguished from major irregularities mainly in that the former consist of a deficiency and the latter a lack of the requirements imposed.

INFRINGEMENT: consists of a manifest or prolonged non-compliance with the obligations imposed by these regulations, either due to the lack of certain elements that make up the documentation or due to the infringement of further obligations incumbent on the operator. With reference to the principle of graduality, minor infringements are distinguished from major ones mainly in that the former may be reversed.

11.2 PROVISIONS

Within the two categories of non-compliance, depending on the level of severity and the criterion of graduality, the following measures are applied: withdrawal, removal of indications of compliance, suspension of certification and removal of the operator.

11.3 CORRECTIVE MEASURES

If the operator subject to the control is found to be non-compliant with the standards imposed, said operator shall implement the necessary corrective measures at a time and in a manner to be established on a case-by-case basis, and shall promptly report their implementation.

12. ANNEXES

ANNEX 1 — LIST OF FORBIDDEN SUBSTANCES

THE LIST OF FORBIDDEN RAW MATERIALS WILL BE UPDATED REGULARLY.

This list has been drawn up using the European Inventory of Cosmetic Ingredients adopted by Decision of the European Commission of 9 February 2006 (2006/257/EC).

Substances not listed in this inventory that are added will have to be subject to specific assessment by the CB. AIAB reserves the right to update the annexes according to technical progress.



13. APPLICATION TIMES

THESE REGULATIONS ARE APPLICABLE FROM 01/04/2021. FROM THAT DATE UNTIL 30/06/2021 IT WILL BE POSSIBLE TO CERTIFY PRODUCTS CONFORMING TO BOTH ED. 02/REV. 04 AND TO THE PRESENT VERSION (ED. 02/REV. 06).

From 01/07/2021, newly approved products must comply with this version. The production of references that have already been certified in compliance with Ed. 02/Rev. 04 of the regulations may be continued; New products added to ranges certified previously in compliance with Ed. 02/Rev. 04 of the regulations may also be approved in compliance with the aforementioned version of AIAB Bio Eco Cosmesi regulations.



QCERTIFICAZIONI

Il tuo punto di riferimento nel panorama nazionale della certificazione di prodotto, sempre attento alle richieste e alle novità dei mercati.

Organismo autorizzato dal Ministero delle Politiche Agricole Alimentari e Forestali a svolgere attività di controllo e certificazione dei prodotti da agricoltura biologica. Certifica standard riconosciuti di organizzazioni qualificate e competenti. Non chiede percentuali sul fatturato. Il costo della certificazione è quantificato sulla base delle diverse realtà aziendali.



Per maggiori informazioni, contatta QCertificazioni:

Tel. +39 0577 327234

Fax +39 0577 329907

lettera@qc.bureauveritas.com

www.qcertificazioni.it

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