

STANDARD FOR ORGANIC AND NATURAL COSMETICS

REG COSM 002

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INTRODUCTION

The present Standard was felt necessary because of the current lack of any EU or national law regulating the organic cosmetics sector and the need of solving some gaps concerning production and trading processes of organic and natural cosmetics, such as:

- the lack of official standards on the cosmetic products made with vegetal substances coming from wild harvest or from organic agriculture;
- the consumer difficulty to recognize those cosmetics that contain considerable quantities of natural and that are manufactured through modern, eco-compatible techniques;
- the need of protecting, together with the consumers, those producers that use high quality vegetal raw materials and processes of low environmental impact.

This Standard draws the guidelines to follow along the production and distribution chain of organic and natural cosmetics.

AIMS

- To better safeguard consumers, by ensuring a strict control over used vegetal substances and production processes, thus distinguishing them from conventional products;
- To draw a link between cosmetic products and organic farming, so as to promote the use of vegetal raw materials coming from organic agriculture;
- To reduce the environmental impact by acting on the production chain and promoting the use of recyclable and biodegradable packaging;
- To give priority to products of natural origin instead of those coming from other sources;
- To ensure transparency to the consumer through a clear communication system;
- To improve the consumer “ethic” behaviour, increasing his/her consciousness on the criteria leading to choosing and using natural and organic cosmetics.

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GENERAL PRINCIPLES

Certified products must respect the following requirements:

ECOLOGY AND SUSTAINABILITY: it must be always preferable the use of raw materials that are quickly and easily biodegradable, easy to restore in the natural biological cycles and not toxic for both, consumers and environment. Products containing ethoxylate or propoxylate surfactants, GMO, enzymes genetically produced and petrochemical derivatives are prohibited. Production too must respect the principles of sustainability and of social equity.

EFFICACY AND SKIN COMPATIBILITY: it is advisable to submit to the Control Body (CB) laboratory analysis demonstrating product claims and products safety.

SCOPE

The Standard applies to:

- Raw-material Producers:
 - Natural materials;
 - Materials of natural origin;
 - Materials coming from organic farming in compliance with: EU regulation on organic production and/or equivalent standards, the present standard.
- Producers of semi-finished and finished products.
- Marketing companies.
- Subcontractors.

As the case may be, control and certification may concern the finished product, the process and/or the service.

The production process refers to either the entire production cycle or to part of it (eg. filling, bulk production, etc..).

The production of cosmetic products is regulated by legal provisions and good manufacturing practices. The requirements set out to the certification of organic and natural cosmetics add to these provisions, and their respect is a necessary, propaedeutic and indispensable condition.

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1. DEFINITIONS AND FORMULATION REQUIREMENTS

1. **Operator:** any company (see scope) requiring certification.
2. **Cosmetic Products:** any substance or preparation, other than medicinal products, which is intended for placing in contact with external parts of the human body (epidermis, hair system, hair, nails, lips, external genital organs) or with the teeth and the mucous membranes of the oral cavity, with a view exclusively to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours (Art.2, paragraph 1, letter a), EEC Reg. 1223/2009).
All the categories listed in Paragraph 7 of the above Directive are included within the meaning of this definition.
Cosmetics have no medical purpose and cannot claim any therapeutic effect.
3. **Ingredients:** any substance of natural or synthetic origin used in the composition of the finished product.
4. **Organic ingredients:** any product of vegetal or animal origin obtained with a production method in compliance with EU regulation on organic production, this Standard or equivalent ones.
5. **Natural ingredients:** any substance that is derived from vegetal, animal or mineral sources, not undergoing any chemical modification, and obtained only by means of physical processes listed in the list of Allowed Physical Processes.
The use of ingredients extracted from animals is prohibited.
The ingredients naturally produced by animals (Table 3) can be used if they don't come from species at risk and if their use does not imply a negative effect on the ecosystem.
6. **Ingredients of natural origin:** any vegetal, animal and mineral ingredient processed by means of the synthetic or biotechnological processes listed in the list of Allowed Production Processes. The ingredients of mineral and marine origin allowed are listed in the tables 4 and 5.
The ingredients obtained through biotechnological processes (vitro culture, cells culture, microorganism cloning and fermentation techniques) must be extracted from vegetal or animal raw materials GMO free and by means of techniques listed in the List of Allowed Production Processes.
7. **Synthetic ingredients:** any substance created *ex-novo* in a laboratory or on the base of natural analogous ones. This Standard prohibits the use of these substances, except for the ingredients listed in the tables 1 and 2 when used according to the Composition Criteria.
8. **Water:** It must be considered as a natural ingredient and it can't be certified.

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The production procedures can use all kind of water (source, drinking, osmotic, demineralized through resins with ionic exchange, distilled, etc.) provided that analytical reports ensuring its quality are available. The presence of chlorides is allowed only if within the limits specified in the rules in force, as far as the drinking-water is concerned.

- 9. Plant fraction:** sum of plant ingredients of the product (i. e. oils, plant extracts, fats, etc.).
- 10. Hydrolats:** when using vegetable or animal derivative products from organic farming (in compliance with EU regulation on organic production this standard or standards deemed equivalent), only the share coming from the certified raw material will be considered for the calculation of the organic portion.
- 11. Surfactants:** They must be biodegradable, respecting the Regulation (EEC) N. 648/2004 of the European Parliament and Council.
The alkyl chain must be of proved natural origin.

Biodegradability levels for surfactants	Testing method for “complete biodegradability”
At least 60% within 28 days	Letter A - Annex III – EEC Reg. 648/2004
At least 70% within 28 days	Letter B - Annex III – EEC Reg. 648/2004

- 12. Smelling substances:** Essential oils, flavours and natural perfumes can be part of the composition of a Natural and Organic Cosmetic.
Flavours are as defined in the article 3, paragraph 2, letter c), and d) of the Reg. (CE) no. 1334/2008.
The definition **natural fragrances** refers to blends of natural essential oils, with or without the addition of natural isolated pure molecules.
The use of smelling substances has to follow the IFRA (International Fragrance Association) advices.

13. Prohibited substances:

- Substances listed in the Annex.II to Reg CE 1223/2009
- Synthetic raw materials;
- Silicone polymers;
- Ingredients from petrochemical industry;
- Synthetic perfumes, preservatives, synthetic antioxidants and colourings;
- Substances accumulating in the body or causing allergies and dermatitis;
- GMO;
- Agents such as EDTA and NTA;
- Surfactants with alkyl chain of not proved natural origin;
- ethoxylate or propoxylate surfactants.

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2. COMPOSITION CRITERIA

The following criteria must be respected for any product submitted to the “Ecosmetica quality” certification process:

Organic Raw material: it must be a vegetal or animal ingredient, in a pure form or blended, complying either with the EU regulation on organic production, or this Standard or any other deemed equivalent. Such raw material may also contain max 5% weight/weight of the ingredients listed in the Tables 1 and 2.

Natural raw material: it must be extracted from vegetal, animal or mineral sources by using only allowed physical processes (see attached list) and without undergoing any chemical modification. Adding up to max 5% weight/weight of the ingredients listed in the Tables 1 and 2 is allowed.

Raw material of natural origin: it must be obtained from vegetal, animal or mineral substances by means of allowed chemical or biotechnological processes (see attached lists). Adding up to max 5% weight/weight of the ingredients listed in the Tables 1 and 2 is allowed.

For each raw material used, the operator shall send to the CB:

- Technical and safety data sheet;
- Certificate of Conformity (if any).

In case of raw materials not certified according to this standard, the CB may ask to fill in the Raw Material form (MD COSM 014), so as to assess their conformity.

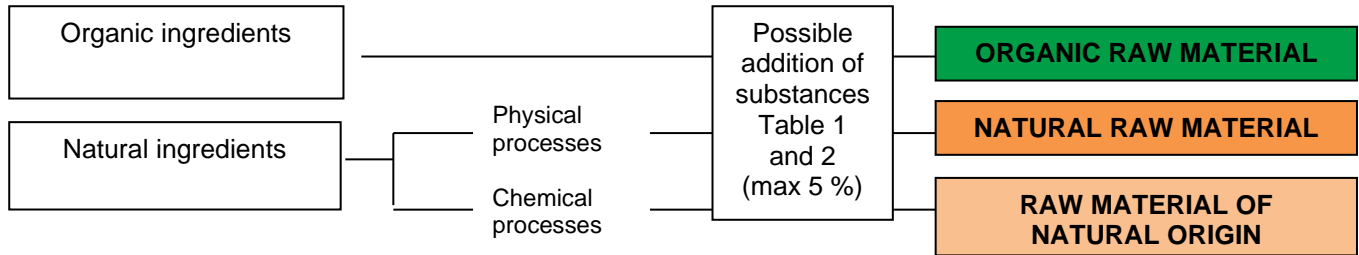
Organic Cosmetic: it must contain at least **95%** of natural or natural origin ingredients. Up to max 5% of synthetic ingredients (table 1 and 2) is allowed, including those contained in the raw materials.

Besides, at least **95%** weight/weight of plant raw materials on the total of vegetal ingredients must be organic grade. The minimum quantity of organic ingredients on the total of ingredients in the finished product is **10%**.

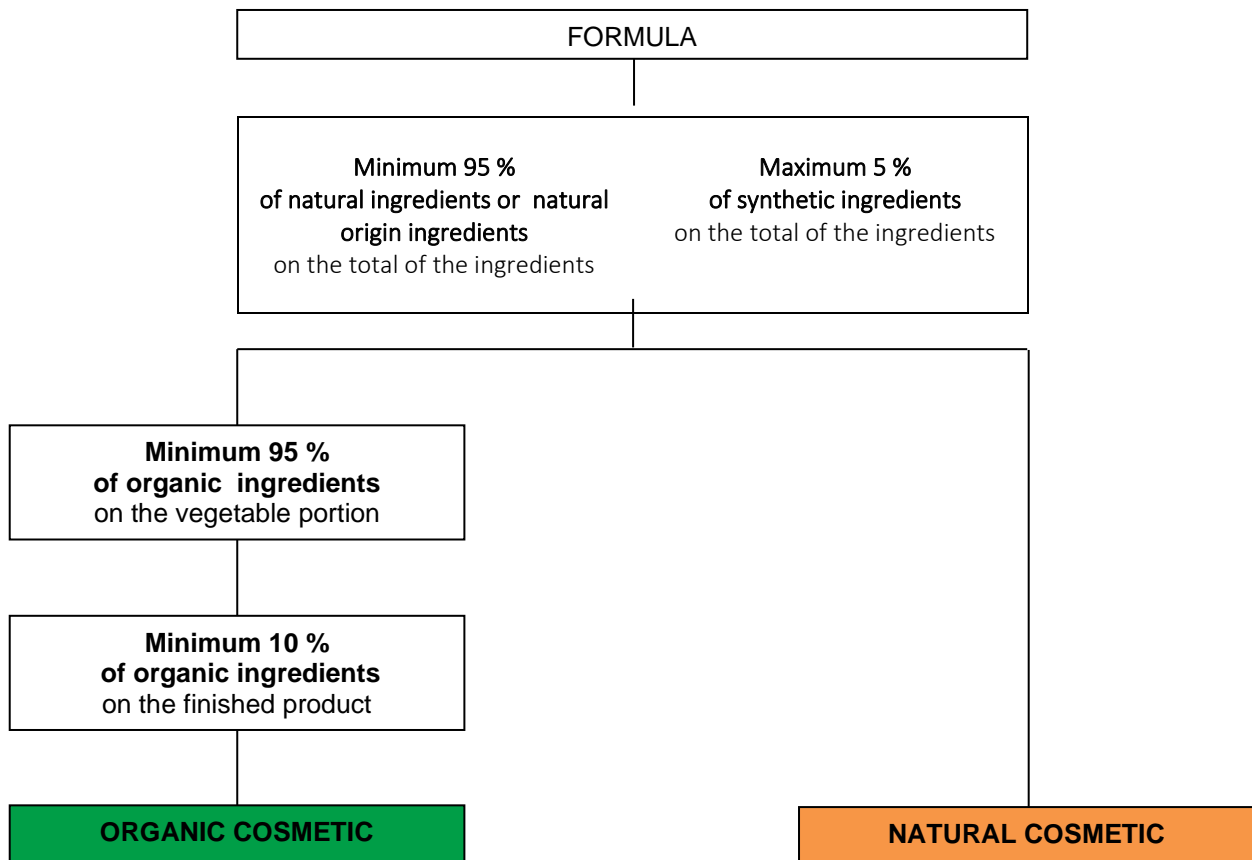
Natural cosmetic: it must contain at least **95%** of natural or natural origin ingredients. Up to max **5%** of synthetic ingredients (table 1 and 2) is allowed, including those contained in the raw materials.

SUMMARY TABLE OF THE COMPOSITION CRITERIA

RAW MATERIALS



COSMETICS



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Note: The total of the ingredients includes water added during the production process.

3. LIST OF PRODUCTION PROCESSES

These processes have been selected according to the following criteria:

- formation of biodegradable molecules;
- respect of the cosmetic characteristics of the natural active substances;
- waste management and energy consumption management.

Issuing a comprehensive list of processes' operational systems is very difficult. In general, however, any chosen method has to comply with the above-mentioned criteria.

Production processes cannot use chlorine compounds (chlorine gas or its by-products).

The following lists will be updated according to the scientific and technological acquisitions and to the future regulative changes.

	PHYSICAL PROCESSES
	Adsorption (on inert substrate, according to Standards) Atomization Centrifugation Decantation – Stabilisation Decoction Bleaching - Deodorisation (on inert substrate, according to the Standards) Deterpenisation (with fractional distillation in vapour stream) Digestion Distillation in vapour current Drying (progressive without evaporation or naturally under the sun) Extraction (with water or solvent) Crushing – Milling Filtration and Purification (ultrafiltration, dialysis, electrolysis) Infusion Freeze-drying Maceration Blending Percolation Hot pressure Cold pressure Sifting Pressing Thermal sterilisation Hydration Refining Rectification Roasting
ALLOWED PROCESSES	

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	CHEMICAL PROCESSES
	Alkylation Amidification Calcination (of vegetal residues) Carbonisation (resins and oily vegetal fat) Condensation/Addition Esterification Etherification Fermentation (natural/biotechnological) Hydration Hydrogenation Hydrolysis Neutralisation (to obtain Na, Ca, Mg, K salts) Oxidation/Reduction Reactions to obtain amphoters Saponification
ALLOWED PROCESSES	

	Deodorisation (on a substrate of animal origin) Deterpenation (other than with steam) Ethoxylation Ionising radiation Nanotechnologies Sulphonation (as main reaction) Techniques using genetic engineering Treatments with ethylene oxide Treatments using Mercury Use of enzymes derived from GMOS
NOT ALLOWED PROCESSES	

	EXTRACTION SOLVENTS
	Vinegar Purified, distilled, osmotic water Alcohol Supercritic CO ₂ Vegetal Glycerine Lactose Honey Vegetable fats and oils Sugar Other organic certified solvents
ALLOWED SOLVENTS	
	Note: When possible, the use of the above mentioned raw materials as

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	organic grade has to be preferred.
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4. PURITY CRITERIA

The following basic principles must be respected for ingredients and finished products:

- **No ionising treatments;**
- **No GMO** (Genetically Modified Organisms);
- **Absence of Nitrosamines** (neither individual ingredients nor their compound can ever produce nitrosamines).

The Operator must undertake any possible measure to prevent that ingredient and finished products contain, either deliberately or not, the following:

- Heavy metals;
- Carcinogenic hydrocarbons: benzene, toluene, xylene and polycyclic aromatic hydrocarbons (PAH);
- Pesticides: insecticides, fungicides, herbicides, acaricides, soil sterilants, growth regulators;
- Dioxins, PCBs (polychlorinated biphenyl) and PCDD/Fs (polychlorinated dibenzo-furan)
- Mycotoxins;
- Medicinal residues (synthetic antibiotics, anabolic steroids, etc...);
- Nitrates from vegetal products
- Amidoamines (> 0.5%) ed Ethanolamines (> 0,5%);
- 1,4 Dioxane;
- Quaternary ammonium salts;
- Ethylene and propylene oxides.

If accidental contamination is found, the relevant raw material or finished product must be quarantined and a notification must be sent to the Certification Body (CB).

5. LABELLING AND INFORMATION

Any information, advertisement and claim concerning both, the company and/or the products, must be true and not misleading the consumer.

Any document, label, package and advertising material referring to production method or to the CB, must be approved before publishing it.

The use of the ECOGRUPPO ITALIA logo is regulated by:

- REG COSM 003 - Regulation on the use of the mark "Ecosmetica quality-organic";
- REG COSM 004 - Regulation on the use of the mark "Ecosmetica quality-natural".

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ORGANIC AND NATURAL COSMETIC

Labels of certified products must report, apart from the content required by law, the following information:

- The organic or natural status, with the pertinent entry: **“Organic Cosmetic”, “Natural Cosmetic”, “Organic Raw Material” or “Natural Raw Material”**.
- The logo identifying the certification type and the name of the CB;
- The authorization number given by the CB;
- INCI ingredients name, printed in the same colour, size and type; those coming from organic agriculture must be marked with an asterisk reporting the information **“Obtained through organic production method” or “From organic agriculture”**.

For “Organic Cosmetics” the following information is to be shown on the label, if its dimensions allow it:

- The words “X % of the ingredients is of natural origin”;
- The words “X % of the vegetal ingredients comes from organic agriculture”;
- The words “X % of the ingredients comes from organic agriculture”;



 <p>Organic Cosmetic Certified by ECOGRUPPO ITALIA S.r.l. Rel Op ___/___</p> <p>X % of the ingredients is of natural origin X % of the vegetal ingredients comes from organic agriculture X % of the ingredients comes from organic agriculture</p>	 <p>Natural Cosmetic Certified by ECOGRUPPO ITALIA S.r.l. Rel Np ___/___</p>
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ORGANIC AND NATURAL RAW MATERIALS

Labels of certified raw materials must report, apart from the content required by law, the following information:

- The organic or natural status, with the pertinent entry: **“Organic Raw Material” or “Natural raw Material”**;
- The logo identifying the certification type and the name of the CB;
- The authorization number given by the CB;
- The words “preserved with...”, reporting any preservative used;

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 <p>Organic Raw Material Certified by ECOGRUPPO ITALIA S.r.l. Rel Op ___/___ Preserved with _____</p>	 <p>Natural Raw Material Certified by ECOGRUPPO ITALIA S.r.l. Rel Np ___/___ Preserved with _____</p>
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RAW MATERIALS OF NATURAL ORIGIN

The words “Raw material of natural origin approved by ECOGRUPPO ITALIA”, as well as the orange logo – ECOSMETICA quality – (in accordance to the REG COSM 004) can be added on the label of the **raw materials of natural origin**.

6. PACKAGING

A primary packaging must respect the requirements of sustainability, particularly on the material it is made of (for plastics, recyclable polymers, such as PE, PP, PET, or compostable ones, such as bioplastics, must be preferred). Whenever possible, the operator has to use the minimum quantity of packaging necessary to ensure the functional performances.

The primary packaging cannot contain:

- PVC;
- Polystyrene foam.

Vaporizers, atomizers and sprays using pressurised gas such as propane, n-butane, isobutane or dimethyloxide are considered a potential risk; these containers are therefore not allowed.

Whenever possible, eco-friendly packaging, elimination of secondary containers and products refill have to be the first-choice solution. .

The different parts of the packaging should be easily divisible by material type, in order to make the relevant recycle easier (the actions the consumer has to carry out must be clearly reported on the product label or in an annexed leaflet).

The staff of the CB controls and approves the materials used for primary and secondary packaging.

7. REQUIREMENTS OF THE PRODUCTION SITES

All installations involved in the production process of the certified references must be notified to the CB, including those in toll manufacturing.

7.1 Storage

- **Storage facilities for ingredients and finished products**

Whenever the production unit adopts both the organic method and the conventional one, the storage areas assigned for organic raw materials, semi-finished and finished products must be physically separated and identified, so to avoid any possible commistion and/or contamination.

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- Tanks and storage containers

Tanks and storage containers for raw materials, semi-finished and finished products must be made of appropriate materials in order to not alter the substances they contain. They must have suitable openings so as to allow samplings and they must be easy to clean and sanitise.

7.2 Production processes

- Basic principles

Production processes must be as straightforward as possible, free from contamination and in conformity with those reported in the List of the Production Processes.

If the company does not deal with organic products exclusively, time and physical separation of the production processes must be respected. The operator is required to plan the relevant processing days and inform in advance the CB by fax or e-mail.

All necessary steps must be taken to ensure the identification of the lots, so as to prevent any contamination with conventional products.

- Supporting documents

The production process must be supported by a list of documents (as per forms provided by the CB) concerning flows, processes and commercial transactions. Any change must be immediately communicated to the CB.

The company is required to have a risk management plan (to assess critical points and put in place corrective actions) and procedures to record and manage complaints.

7.3 Cleaning and disinfecting of premises and of the production tools

Storage and processing facilities must be periodically cleaned and sanitised accordingly to a precise schedule.

Before every production cycle of the certified references the operator has to sanitise all supporting equipments; this activity must be recorded in a register given by the CB. The cleaning activities may be performed with:

- hydrogen peroxide;
- potable and/or demineralised water at different temperatures;
- ethyl alcohol (in case no other substance can be used);
- non-ethoxylated surfactants;
- vapour;
- other products (if previously authorized by the CB).

These substances cannot be stored in the areas dedicated to manufacturing.

The above-mentioned substances are to be used only as recommended by the producer. Such products are subject to controls about their source, composition, use conditions and level of safety. Products leaving persistent and non-biodegradable residues are not allowed.

7.4 Transport management

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All necessary measures must be employed to prevent any mixture and/or contamination by conventional products and other polluting agents during transport and temporary storage. Bulk products in temporary containers (not meant for selling) must be managed with care.

7.5 Emissions and waste management

The company has to develop an efficient and rational plan for emission containment and waste disposal. The standard ISO 14001, addressing various aspects of environment management, is accepted; otherwise, the operator must guarantee an environmental management system through internal procedures.

The operator must adopt procedures for:

- selective sorting of plastic, cardboard, glass, paper and other materials;
- recycling and waste recovery;
- disposal of packaging items and their delivery to specialized companies as per current regulations.

7.6 Energy management

The company commits, as far as possible, to develop a multiannual plan for the production or purchase of increasing amounts of green energy.

7.7 Staff management

With reference to the processes concerning certified references, the staff must receive an effective and documented training based on each role and function.

Three kind of training have to be imparted:

- **Start up:** with the aim of giving new employees the base information for becoming operative quickly and effectively;
- **Planned:** to update the staff about relevant and important subjects for the company. The company must organize at least one training session per year.
- **Extraordinary:** when workers deviate from correct behaviours and/or operational rules established in the company internal procedures.

The company management must always respect the principles of sustainability and social equity.

8. IMPORT

If the company sells on the National territory cosmetic products coming from foreign countries, the CB must receive a copy of the import notification to competent authorities, in compliance with Reg. CE 1223/2009.

9. CONTROL ACTIVITIES

TYPE OF COMPANY	A			B			
	Number of products			Number of sites			
	From 1 to 25	From 26 to 50	More than 50	1 site	2 site	3-5 site	> 5 site
Trading Company	0	0	1	1	2	3	4
Manufacturing unit	0	0	0	1	2	3	4
Production Company	0	1	1	1	2	3	4

The CB's activity consists of documentary checks and physical inspections at the production units notified by the Operator. Such tasks are carried out by CB's qualified auditors, so as to ensure proper competence, professionalism, impartiality and independence.

The number of annual controls is based on the company type, and is determined by the sum of factor "A" (number of references certified) and factor "B" (number of sites to be controlled), as reported in the following table:

Number of annual controls = A + B

Companies producing raw materials of natural origin are subjected to documentation checks only, according to which compliance to the current standard is assessed.

In order to implement an efficient control system and in addition to ordinary inspections at operators facilities, Ecograppo Italia sees a need to run some analytical testing on product samples. The sampling plan is based on the following criteria:

- No sampling is foreseen for operators performing marketing activities only, without any involvement in product manufacturing, packaging or labeling.
- Minimum one sampling within the validity period of the Conformity Certificate (3 years) for those operators involved either in product manufacturing or packaging or labeling. Where laboratory tests reveal positive findings for not allowed substances, an additional sampling will be made during the next inspection.

The inspector, however, shall have authority to decide for any sample taking if substantiated concerns raise during the inspection.

TABLES

The following lists will be updated according to the scientific and technological acquisitions and to the future regulatory changes.

Table 1: Allowed synthetic antimicrobial agents

Ingredients	INCI name
Benzoic Acid, its salts and esters	Benzoic Acid
Benzyl Alcohol	Benzyl Alcohol
Dehydroacetic acid and its salts	Dehydroacetic acid
Propionic Acid and its salts	Propionic Acid
Salicylic Acid and its salts	Salicylic Acid
Sorbic Acid and its salts	Sorbic Acid

Table 2: Other allowed synthetic ingredients

Ingredients	INCI name
Bitrex® or Aversion®	Denatonium Benzoate
Citric acid and its salts and esters	Citric Acid
Disodium Phosphate	Disodium Phosphate
Magnesium Hydroxide	Magnesium Hydroxide
Potassium Carbonate	Potassium Carbonate
Potassium Chloride	Potassium Chloride
Potassium Hydroxide	Potassium Hydroxide
Sodium Bicarbonate	Sodium Bicarbonate
Sodium Borate	Sodium Borate
Sodium Carbonate	Sodium Carbonate
Sodium Hydroxide(soda)	Sodium Hydroxide
Sodium Silicate	Sodium Silicate
Titanium Dioxide	Titanium Dioxide

Table 3: Ingredients of animal origin

Ingredients	INCI name
Beeswax	Beeswax
Eggs and their derivatives	Ovum
Honey and its derivatives	Mel
Lanolin	Lanolin
Milk and its derivatives	Caprae Lac
Propolis	Propolis Cera
Royal jelly	Royal Jelly
Sericine	Sericine
Shellac	Shellac

Table 4: Ingredients of mineral origin

Ingredients	INCI name
Aluminium CI 77000	Aluminium
Aluminum Hydroxide	Aluminum Hydroxide
Aluminum Oxide	Alumina
Ammonium, Manganese Diphosphate CI 77742	Ammonium, Manganese Diphosphate
Azurite CI 77007	Ultramarines
Barium Sulfate	Barium Sulfate
Bismuth Oxychloride CI 77163	Bismuth Oxychloride
Calcium Aluminum Borosilicate	Calcium Aluminum Borosilicate
Calcium Carbonate CI 77220	Calcium Carbonate
Calcium Sulfate-Gypsum	Calcium Sulfate
Chromium Oxides CI 77289, 77288	Chromium Oxides
Copper CI 77400	Copper
Copper Oxide	Copper Oxide
Copper Sulfate	Copper Sulfate
Dicalcium Phosphate Dihydrate	Dicalcium Phosphate Dihydrate
Hydrated Silica	Hydrated Silica
Iron Hydroxide	Iron Hydroxide
Iron Oxides CI 77480, 77491, 77492, 77499	Iron Oxides
Iron Sulfate	Iron Sulfate
Kaolin	Kaolin
Magnesium Aluminum Silicate	Magnesium Aluminum Silicate
Magnesium Carbonate CI 77713	Magnesium Carbonate
Magnesium Chloride	Magnesium Chloride
Magnesium Oxide CI 77711	Magnesium Oxide
Magnesium Silicate	Magnesium Silicate
Magnesium Sulfate	Magnesium Sulfate
Manganese Bis Orthophosphate CI 77745	Manganese Bis Orthophosphate
Manganese Sulfate	Manganese Sulfate
Mica	Mica
Potassium Sulfate	Potassium Sulfate
Prussian Blue CI 77510	Prussian Blue
Silver Chloride	Silver Chloride
Silver CI 77820	Silver
Silver Oxide	Silver Oxide
Silver Sulphate	Silver Sulfate
Sodium Chloride	Sodium Chloride
Sodium Sulfate	Sodium Sulfate
Titanium Dioxide CI 77891	Titanium Dioxide
Zinc Oxide	Zinc Oxide
Zinc Oxide CI 77947	Zinc Oxide
Zinc Sulfate	Zinc Sulfate

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Table 5: Ingredients of marine origin

Ingredients	INCI name
Algin	Algin
Carrageenan	Carrageenan
Potassium Alginate	Potassium Alginate
Xanthophyll	Xanthophyll