THE PASSION FOR CERTIFIED QUALITY
PREFACE
Public attention to products values in terms of components and processes is gaining more and more ground also in the cosmetic sector, in a similar way to what happened more than 20 years ago with organic food production.

The continuous use of chemical products may damage the skin permanently. The studies show that a great number of people are allergic to such cosmetics. On the contrary, organic cosmetics do not involve any chemicals and are made of natural and organic ingredients refreshing for the skin and its health. As the skin usually absorbs whatever is applied on it, on a long run, the cosmetics with high chemical content have been proven to be harmful for the skin. When used regularly the chemicals reach the bloodstream through the skin pores, causing in time significant damage to the entire body. In the same time the organic cosmetics do not cause any harm to the skin doing nothing else but turning you into a natural beauty.

Unfortunately a compulsory European Regulation to regulate the production of organic and natural cosmetic products is not available. This is why the main retailers and industries of cosmetic products implemented voluntary standards in order to harmonize control requirements and procedures. Bioagricert, which has worked for more than 25 years in the sector of organic food products certification, has implemented its voluntary standard for the control and certification of bio-organic and natural cosmetic products. The standard is a voluntary instrument to qualify processes and products and to give consumers the guarantee of a certified product.

Producing certified organic and natural cosmetic products means to answer responsibly to the market requests with simple and safe products which respect human health and the environment.

1. SCOPE AND FIELD OF APPLICATION
The present Standard is voluntary and it concerns the production, packaging, labeling and trading of natural and organic cosmetic products. The present Standard explains what is a “natural ingredient” and an “ingredient of natural origin”.

2. DEFINITIONS
Vegetal products = substances coming from agricultural production or wild harvesting that have not being processed or have been obtained with allowed processes listed in paragraph 3.3. Vegetal products may be used for the production of raw materials that will be used in the preparation of cosmetic products.

Animal products = Substances listed in paragraph 3.5.A. that have not being processed or that have been obtained through processes that are listed in paragraph 3.3.A. The animal products may be used for the production of raw materials that will be used in the preparation of cosmetic products.

Mineral products = Minerals coming from the extraction used as they are or modified through physical processes. Mineral products may be used for the production of raw materials that will be used in the preparation of cosmetic products.

Ingredient = raw material, product and/or additive included in the composition of finished cosmetic products (the ingredients may be natural, of natural origin, of synthetic origin, other allowed additives).

Natural ingredients = animal products (except for dead vertebrates), inorganic mineral products coming from extraction and included in paragraph 3.5.B., vegetal products, by products of vegetal products, mixtures of vegetal products of agricultural origin or wild harvesting or obtained through a physical process (included in paragraph 3.3.A), without any chemical process. Where necessary, PH regulators (3.4.C.) can be added and, in the case of certification of raw materials, the additives included in paragraphs 3.4.A and 3.4.C may be added. “Natural
ingredients” can be vegetal, animal, mineral (for example avocado oil, caffeine etc.). Enzymatic and microbiologic methods are also allowed to obtain “natural ingredients” but only if enzymes and microorganisms that are present in nature are used. The ingredients coming from biotechnologies are: vegetal, animal, micro organic preparations obtained through the fermentation of microorganisms, in vitro cells or cells cultivations and clones; genetically modified organisms or processes that are not allowed by the present Standard are not used.

Genetically modified organisms (GMOs), natural substances, enzymes and microorganisms should be conforming to the European Regulation for the production of organic products: Reg. EC 834/2007.

**Ingredients of natural origin** = substances coming from the vegetal, mineral or animal world that have been processed through a chemical process which is included in the list of allowed chemical processes as indicated in paragraph 3.3.B. Also the ingredients of natural origin listed in paragraph 3.5.D. are included in this category.

**Water used in the process** is allowed and it is included in the calculation of the percentage of total ingredients of the finished product but it is a different category of ingredient from “natural ingredients” and “ingredients of natural origin” because it is not included in the calculation of the percentages of the minimum requirements as indicated in paragraph 3.1.

**Water contained in raw materials** is included in the calculation of the percentage of the total ingredients of the finished product and it should be included, as indicated in paragraph 6.C, in the calculation of the minimum requirements as indicated in paragraph 3.1.

**Ionizing radiations** should not be used on raw materials and/or finished products because they are prohibited.

**Additives** = substances used to make a cosmetic product acceptable in terms of stability, functionality, safety and texture.

**Certifiable ingredient** = raw material and/or product coming from agriculture, animal breeding or wild harvesting that is still natural or has been processed through an allowed process that is listed in paragraph 3.3.A. and that is certifiable according to Reg. EC 834/2007.

**Certified organic ingredient** = certified raw material according to Reg. EC 834/2007 and/or NOP, JAS, IFOAM or other organic standards. Certified organic ingredients are usually “natural ingredients” or “ingredients of natural origin”.

**Physical method of extraction** = extraction of substances and active principles from the plant or part of it, fresh or dried, through physical methods that do not involve chemical modifications.

**Processing chemical method** = chemical process that involves a modification of the molecular structure. Only chemical processes listed in paragraph 3.3.B. are allowed.

**Allowed chemical or physical process** = physical process of extraction or chemical processing process that is authorized by the present standard in order to obtain respectively “natural ingredients” or “ingredients of natural origin”.

**Non allowed chemical or physical process** = use of a non allowed process to obtain one or more raw materials that cannot be used according to present standard.

**Natural cosmetic** = a cosmetic product that contains “natural ingredients” or “ingredients of natural origin”.

**Natural cosmetic with organic ingredients** = a cosmetic product that contains “natural ingredients” or “ingredients of natural origin” and also agricultural ingredients or ingredients from spontaneous harvesting that are certified organic.

**Organic cosmetic** = a cosmetic product that contains “natural ingredients” or “ingredients of natural origin” and also a high percentage of agricultural ingredients or ingredients from spontaneous harvesting that are certified organic.

In all the 3 categories of cosmetic products, 5% in weight of additives of synthesis (listed in paragraph 3.4, points A, B, C, D) calculated on the finished product is allowed.

The surfactants that are used should be completely biodegradable according to Reg. 648/2004/CE.

For other terms used in the present standard, refer to Annex 6.A.
3. STANDARD

3.1 COMPOSITION AND PERCENTAGE

**NATURAL COSMETIC**

A cosmetic product that contains “natural ingredients”, “ingredients of natural origin” and water, where necessary, according to the definitions above. 5% in weight of additives of synthesis (listed in paragraph 3.4, points A, B, C, D) calculated on the finished product is allowed. In the finished product, at least 10% in weight of the whole ingredients should be “natural”; water should not be included in this calculation, except for the indications given in Annex 6.C. (When calculating the whole ingredients, include water). In this case the product will be labeled as **NATURAL COSMETIC** with Bioagricert Natural Cosmetic trademark.

**NATURAL COSMETIC WITH ORGANIC INGREDIENTS**

A cosmetic product that contains “natural ingredients”, “ingredients of natural origin” and water, where necessary, according to the definitions above. 5% in weight of additives of synthesis (listed in paragraph 3.4, points A, B, C) calculated on the finished product is allowed. At least 5% in weight of the whole ingredients that composes the final formulation should be certified organic to use Bioagricert bio-organic cosmetic trademark; in this percentage, water should not be included, except for the indications given in Annex 6.C. Furthermore, on the total of certifiable ingredients, up to a minimum of 70% in weight of organic ingredients that should be certified according to Reg. CE 834/2007, NOP, JAS, IFOAM or other organic standards, is allowed. Under derogation, 30% in weight of the certifiable ingredients can be non organic but only if they are not the same ingredients as the certified organic ingredients.

In this case the product will be labeled as **NATURAL COSMETIC WITH ORGANIC INGREDIENTS** with Bioagricert bio-organic cosmetic trademark. The % of organic ingredients on the finished product should be indicated near the trademark bio-organic cosmetic.

**BIO-ORGANIC COSMETIC**

A cosmetic product that contains “natural ingredients”, “ingredients of natural origin” and water, where necessary, according to the definitions above. 5% in weight of additives of synthesis (listed in paragraph 3.4, points A, B, C) calculated on the finished product is allowed. At least 10% in weight of the whole ingredients that composes the final formulation should be certified organic to use Bioagricert bio-organic cosmetic trademark; in this percentage, water should not be included, except for the indications given in Annex 6.C. Furthermore, on the total of certifiable ingredients, at least 95% in weight of organic ingredients should be certified according to Reg. EC 834/2007, NOP, JAS, IFOAM or other organic standards, is allowed. Under derogation, 5% in weight of the certifiable ingredients can be non organic but only if they are not the same ingredients as the certified organic ingredients.

In this case the product will be labeled as **BIO-ORGANIC COSMETIC** with Bioagricert bio-organic cosmetic trademark.

Once the operator sends the certification request, Bioagricert supplies some sheets to make easier the calculation of the % of ingredients.

3.2 PRODUCTION

As a pre-requirement, operators should be conforming with the laws and regulations that concern the production of cosmetic products on composition, quality, quantity, description of the product, labeling and any other aspect regulated by the National and European norms (as Law n° 713 of 11/10/1986, Directive 76/768/CEE of 27 July 1976 and New Cosmetic Regulation CE n.1223/2009 and following modifications and integrations) and by the Good Manufacturing Practices (G.M.P.) norms. Refer also to norm UNI EN ISO 22716 and Decree n.328 of 1987). Operators that apply for the certification should always control the whole production process and guarantee that all products always maintain a proper quality level and avoid any kind of contamination thanks to proper protection and cleaning practices.
3.3 PROCESSING PROCESSES

ALLOWED PROCESSES:
Principle: minimize the environmental impact, underline the eco compatibility by preserving the functionality.

a) PHYSICAL to obtain NATURAL INGREDIENTS

<table>
<thead>
<tr>
<th>KIND OF PROCESS</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSORPTION</td>
<td>Uniform penetration of a substance into another substance (on an inert support)</td>
</tr>
<tr>
<td>ATOMIZATION</td>
<td>The use of an atomizer allows the pulverization of the product</td>
</tr>
<tr>
<td>CALCINATION OF VEGETAL RESIDUES</td>
<td>High thermal treatment process applied to remove all volatile fractions</td>
</tr>
<tr>
<td>CENTRIFUGATION</td>
<td>Centrifugation is a process that involves the use of centrifugal force for the separation of suspension components with different densities</td>
</tr>
<tr>
<td>DECANTATION AND SEDIMENTATION</td>
<td>Decantation or gravitational sedimentation is the mechanical method used to separate the phases of a mixture or a suspension based on the spontaneous sedimentation due to different specific weights</td>
</tr>
<tr>
<td>BLEACHING</td>
<td>Process mainly based on physical bleaching by adsorption of colorant substances on natural supports</td>
</tr>
<tr>
<td>DECOTION</td>
<td>The solvent and the drug (part of plant) are heated for a determinate period (time)</td>
</tr>
<tr>
<td>DEODORISATION</td>
<td>Process used to neutralize, reduce or correct the odour of a substance eliminating the volatile compounds by adsorption on inert support and injection of low-pressure water vapour</td>
</tr>
<tr>
<td>DETERPENATION</td>
<td>Elimination of terpenes and sesquiterpenes from essential oils using water vapour fractional distillation. Deterpenated essential oils are obtained</td>
</tr>
<tr>
<td>DISTILLATION</td>
<td>The process allows the separation of different compounds in a mixture based on different boiling points</td>
</tr>
<tr>
<td>DESICCATION - DRYING</td>
<td>The removal of liquids, water or other solvents through evaporation</td>
</tr>
<tr>
<td>EXTRACTION</td>
<td>Separation of one or more compounds from a matrix using allowed solvents (water, vegetal glycerine, ethyl alcohol, vegetal oils, CO₂ supercritical: see the list of allowed solvents at the end of the table)</td>
</tr>
<tr>
<td>Process</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>FILTRATION and PURIFICATION</td>
<td>Operation used for the separation of solids from fluids by interposing a filtering medium through which only the fluid can pass while the oversize particles are retained. ULTRAFILTRATION: separation of solids from fluids by filtration under pressure which forces the liquid against a membrane of a certain porosity.</td>
</tr>
<tr>
<td>HYDRATION</td>
<td>Water addition</td>
</tr>
<tr>
<td>INFUSION</td>
<td>Variant of maceration, operation of aqueous extraction of vegetal compounds undergoing short boiling</td>
</tr>
<tr>
<td>LYOPHILIZATION</td>
<td>Treatment using low temperature and vacuum conditions which enable total water removal by freezing and reduction to dehydrated powder of the initial product maintaining its original characteristics</td>
</tr>
<tr>
<td>MACERATION</td>
<td>Extraction by diffusion and osmosis depending on temperature</td>
</tr>
<tr>
<td>MIXING</td>
<td>The physical combination of the particles of two or more substances without the use of a chemical reaction</td>
</tr>
<tr>
<td>PERCOLATION</td>
<td>The free or under-pressure solvent passes a homogeneous layer of pulverized drug through a solid-liquid extraction based on osmosis or diffusion which demonstrates to be more dynamic than maceration</td>
</tr>
<tr>
<td>PULVERIZATION AND COMMINUTION</td>
<td>Process in which solid materials are reduced to powder by shredding, grinding, abrasion, friction</td>
</tr>
<tr>
<td>RIFINING</td>
<td>The physical process of purification of a substance or product by means of decantation, centrifugation, filtration, bleaching or deodorization</td>
</tr>
<tr>
<td>RECTIFICATION</td>
<td>The physical process which allows the correction or the refining of a substance</td>
</tr>
<tr>
<td>HEATING/ BOILING</td>
<td>Thermal treatment of materials</td>
</tr>
<tr>
<td>SIEVING</td>
<td>Special sieves having serial position allow the granulometric separation of the particles</td>
</tr>
<tr>
<td>COLD AND WARM PRESSING</td>
<td>Extraction based on cold or warm pressing using hydraulic presses</td>
</tr>
<tr>
<td>STERILIZATION</td>
<td>Is performed using high pressure thermal treatments (temperature may comply with active thermolability principles)</td>
</tr>
<tr>
<td>ROASTING</td>
<td>Process that exposes the product to heat with variable temperature between 120°C and max 140°C</td>
</tr>
<tr>
<td>TOASTING</td>
<td>Procedure that submits the substance to a slow and strong heating to induce dehydration and toasting</td>
</tr>
</tbody>
</table>
FERMENTATION (NATURAL, BIOTECNOLOGIC NON GMO)  
A series of biological processes with partial destruction of organic compounds and accumulation of simple compounds using enzymes and microorganisms (living bacteria and fungi)

HYDROLYSIS BASED ON MICRORGANISMS AND ENZYMES  
Hydrolysis: is the chemical reaction during which one molecule is split into two parts by the addition of a molecule of water  
Enzymatic hydrolysis generates the formation of an acid and a base resulting from an initial interaction between a salt and water

Solvents and extractive substances allowed for extraction in relation with "bio-organic" cosmetic certification  
a) Ethyl alcohol of vegetal origin  
b) Organic glycerine, in case of glycerine no restriction regarding the use of non-organic vegetal glycerine is applied whenever the organic form is not available  
c) Organic vegetal fats and oils  
d) Water  
e) Organic honey  
f) Organic sugar  
g) Organic vinegar  
h) Organic lactose  
i) Other organically certified solvents  
l) Liquid CO₂ for supercritical fluid extraction  
In the case of "Natural Cosmetic", the above solvents can be non organic.

b) CHEMICAL, to obtain INGREDIENTS OF NATURAL ORIGIN  
The chemical processes used to obtain "ingredients of natural origin" are chosen for the very low environmental impact and safety towards consumer.

<table>
<thead>
<tr>
<th>KIND OF PROCESS</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACYLATION</td>
<td>The process of adding an acyl group to a compound</td>
</tr>
<tr>
<td>ALKYLATION</td>
<td>The transfer of an alkyl group from one molecule to another</td>
</tr>
<tr>
<td>AMIDATION</td>
<td>Chemical reaction through which an amide is obtained</td>
</tr>
<tr>
<td>CARBONIZATION</td>
<td>Conversion of an organic substance into carbon</td>
</tr>
<tr>
<td>CONDENSATION</td>
<td>Chemical reaction in which one or more compounds unite eliminating water or other simple molecule with low molecular weight</td>
</tr>
<tr>
<td>ESTERIFICATION</td>
<td>Chemical reaction to obtain an ester, a chemical compounds derived by reacting an acid with a hydroxyl compound</td>
</tr>
<tr>
<td>ETHERIFICATION</td>
<td>The process by which a large quantity of alcohol is transformed into ether</td>
</tr>
<tr>
<td>PHOSPHORYLATION</td>
<td>The addition of a phosphate (PO₄³⁻) group to a protein or other organic molecule</td>
</tr>
<tr>
<td><strong>GLYCOSYLATION</strong></td>
<td>The enzymatic process that attaches glycans to proteins, lipids, or other organic molecules</td>
</tr>
<tr>
<td>-------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>HYDRATION</strong></td>
<td>The addition of a water molecule to another molecule</td>
</tr>
<tr>
<td><strong>HYDROGENATION</strong></td>
<td>The reaction of alkenes with hydrogen</td>
</tr>
<tr>
<td><strong>HYDROLYSIS</strong></td>
<td>A chemical reaction during which molecules of water (H₂O) are split into hydrogen cations (conventionally referred to as protons) and hydroxide anions in the process of a chemical mechanism</td>
</tr>
<tr>
<td><strong>NEUTRALIZATION</strong></td>
<td>(To obtain Na, Ca, Mg, K salts) A chemical reaction in which an acid and a base interact with the formation of a salt</td>
</tr>
<tr>
<td><strong>OXIDATION/REDUCTION</strong></td>
<td>Oxidation is the loss of electrons or an increase in oxidation state by a molecule, atom, or ion. Reduction is the gain of electrons or a decrease in oxidation state by a molecule, atom, or ion.</td>
</tr>
<tr>
<td><strong>AMIDIFICATION AND QUATERNIZATION</strong></td>
<td>The processes to create amphoters</td>
</tr>
<tr>
<td><strong>REFINING</strong></td>
<td>The process of purification of a substance to improve its characteristics for a better use</td>
</tr>
<tr>
<td><strong>SAPONIFICATION</strong></td>
<td>A process that produces soap, usually from fats and lye. In technical terms, saponification involves base (usually NaOH) hydrolysis of triglycerides, which are esters of fatty acids, to form the sodium salt of a carboxylate</td>
</tr>
<tr>
<td><strong>SULPHATION</strong></td>
<td>The replacement of a hydrogen atom of an organic compound with a sulphate functional group, or the replacement of the hydrogen atoms of two molecules to form a sulphate</td>
</tr>
<tr>
<td><strong>TRANS-ESTERIFICATION</strong></td>
<td>The process of exchanging the organic group R” of an ester with the organic group R’ of an alcohol</td>
</tr>
</tbody>
</table>

### 3.4 ALLOWED INGREDIENTS UNDER DEROGATION
Under derogation, the additives listed in points A, B, C, D, can be included in the formulation but the sum of their single percentages should be maximum 5% in weight on the total of ingredients of the finished product.

**A) PRESERVATIVES**
Natural preservatives are recommended. When they are not available, only the preservatives listed below can be used (applying the restrictions provided for by Annex VI of Directive 76/768/CEE and following integrations and modifications) always respecting the 5% derogation in weight of total additives (included in paragraph 3.4) on the finished product.

- Benzoic Acid and its salts* and ethyl esters
- Deidroacetic Acid and its salts *
- Formic Acid and sodium salt
- Propionic Acid and its salts*
- Salicilic Acid and its salts*
B) ALLOWED ADDITIVES
The use of additives that are not listed in the present standard is prohibited.
- Ascorbic acid and its salts and esters
- Citric Acid and its salts and esters
- Glicolic Acid and its salts and esters
- Lattic Acid and its salts and esters
- Malic Acid and its salts and esters
- Tartaric Acid and its salts and esters
- Calcium monophosphate and esters
- Bisodic Phosphate
- Lactoperoxidase – Glucosoxidase
- Magnesium hydroxide
- Potassium hydroxide
- Sodium silicate
- Sodium carbonate (washing soda, washing ash)
- Sodium hydroxide (caustic soda)
- Thymol (denaturant of ethyl alcohol)
- Tocopherol and its esters

C) pH REGULATORS
To regulate pH and for ion exchange, also inorganic bases and acids, like NaOH, KOH and HCl, can be used besides acids and natural bases or bases of natural origin and when it is the only possible solution.

D) FRAGRANCES
For Natural Cosmetic products, non natural fragrances are allowed under derogation, besides all fragrances indicated in paragraph 3.5.C, preferring natural identical fragrances with a maximum percentage of 0.8% in weight on the total ingredients of the finished product.

3.5 OTHER ALLOWED INGREDIENTS

A) ANIMAL INGREDIENTS
Parts of animal body or vertebrate animals organs are not allowed (as, for example, fresh animal cells, turtle oil, mink oil, marmot oil, animal collagen). Only ingredients that come from animal productions but have not compromised animal welfare or caused sufferance or suppression are allowed.
These ingredients are considered “natural ingredients”:
- Carmine CI 75810
- Bee wax
- Shellac
- Lanoline and its by products
- Milk and its by products
- Honey and its by products
- Royal Jelly
- Propolis
- Sericine
- Egg and its by products
B) MINERALS AND INORGANIC PIGMENTS

The use of the following substances is allowed by respecting the requirements of the law in force. These ingredients are considered “natural ingredients” both if they come directly from extraction and if they have been chemically or physically processed.

<table>
<thead>
<tr>
<th>INCI</th>
<th>SUBSTANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alumina</td>
<td>Alumina (aluminium oxide)</td>
</tr>
<tr>
<td>Aluminium Sesquichlorohydrate</td>
<td>Aluminium Sesquichlorohydrate</td>
</tr>
<tr>
<td>Aluminum Chlorohydrate</td>
<td>Aluminium Chlorohydrate</td>
</tr>
<tr>
<td>Aluminum Hydroxide</td>
<td>Aluminium Hydroxide</td>
</tr>
<tr>
<td>Calcium Aluminum Borosilicate</td>
<td>Calcium aluminium borosilicate</td>
</tr>
<tr>
<td>Calcium Chloride</td>
<td>Calcium chloride</td>
</tr>
<tr>
<td>Calcium Fluoride</td>
<td>Calcium fluoride</td>
</tr>
<tr>
<td>CI 77510</td>
<td>Ferric Ferricyanide and Ferric ammonium Ferricyanide</td>
</tr>
<tr>
<td>CI 73015</td>
<td>Indigotine</td>
</tr>
<tr>
<td>CI 77000</td>
<td>Aluminium</td>
</tr>
<tr>
<td>CI 77004</td>
<td>Bentonite, Caolin</td>
</tr>
<tr>
<td>CI 77007</td>
<td>Ultramarines</td>
</tr>
<tr>
<td>CI 77120</td>
<td>Copper sulphate</td>
</tr>
<tr>
<td>CI 77163</td>
<td>Bismuth oxychloride</td>
</tr>
<tr>
<td>CI 77220</td>
<td>Calcium carbonate</td>
</tr>
<tr>
<td>CI 77231</td>
<td>Calcium sulphate</td>
</tr>
<tr>
<td>CI 77268:1</td>
<td>Vegetal carbon</td>
</tr>
<tr>
<td>CI 77288, CI 77289</td>
<td>Chromium oxide</td>
</tr>
<tr>
<td>CI 77400</td>
<td>Copper</td>
</tr>
<tr>
<td>CI 77480</td>
<td>Gold</td>
</tr>
<tr>
<td>CI 77489, CI 77491, CI 77492, CI 77499</td>
<td>Iron oxide</td>
</tr>
<tr>
<td>CI 77510</td>
<td>Prussian blu</td>
</tr>
<tr>
<td>CI 77711</td>
<td>Magnesium oxide</td>
</tr>
<tr>
<td>CI 77713</td>
<td>Magnesium carbonate</td>
</tr>
<tr>
<td>CI 77742</td>
<td>Ammonium and manganese diphosphate</td>
</tr>
<tr>
<td>CI 77745</td>
<td>Manganese bis orthophosphate</td>
</tr>
<tr>
<td>CI 77820</td>
<td>Silver</td>
</tr>
<tr>
<td>CI 77891</td>
<td>Titanium dioxide</td>
</tr>
<tr>
<td>CI 77947</td>
<td>Zinc oxide</td>
</tr>
<tr>
<td>Copper Sulphate</td>
<td>Copper sulphate</td>
</tr>
<tr>
<td>Dicalcium Phosphate Dihydrate</td>
<td>Dicalcium Phosphate Dihydrate</td>
</tr>
<tr>
<td>Ferric Sulphate</td>
<td>Ferric sulphate</td>
</tr>
<tr>
<td>Iron Hydroxide</td>
<td>Iron Hydroxide</td>
</tr>
<tr>
<td>Magnesium Aluminium Silicate</td>
<td>Magnesium Aluminium Silicate</td>
</tr>
<tr>
<td>Magnesium Chloride</td>
<td>Magnesium Chloride</td>
</tr>
<tr>
<td>Magnesium Silicate</td>
<td>Magnesium Silicate</td>
</tr>
</tbody>
</table>
C) FRAGRANCES AND AROMAS

Natural fragrances (essential oils) according to ISO 9235 standard should be used. For bio-organic cosmetic, neither fragrances of synthesis nor natural fragrances that have been chemically modified are allowed. Follow the in force regulation for the indication of fragrances and allergens on the label.

Allowed aromas are natural substances and products as defined by Directive 88/338 EEC. Respect the recommendations of the International Fragrance Association (IFRA) on the use of fragrances and aromas.

D) OTHER ALLOWED “NATURAL INGREDIENTS” AND/OR “INGREDIENTS OF NATURAL ORIGIN”

- Alginic acid and its salts
- Agar agar
- Carrageenan
- Carnauba wax
- Chlorophyl (E140-E141)
- Carob bean flour
- Guar bean flour
- Glycerol
- Tragacanth gum
- Arabic gum
- Karaga gum
- Xantan gum
- Lecithin
- Pectin
- Diatomaceous earth

* Each ingredient will be classified, case by case as “natural ingredient” or “ingredient of natural origin”, on the basis of the documents supplied by the operator.
E) INGREDIENTS OF BIOTECHNOLOGIC ORIGIN

Ingredients originating from non-GMO bacterial fermentation and obtained on vegetal nutrition substrate are allowed.

F) WATER

Water can be used without limitation but it should be purified, that means it should be deionized through ionic exchange resins or inverse osmosis. Water can be classified into the following categories: process water, added as ingredient of the cosmetic product formulation and water that is part of the raw materials used in the formulation. Process water is included in the calculation of the percentages of the ingredients of the finished formulation but not in the calculation of the percentages of the minimum requirements of “natural ingredients” and “ingredients of natural origin” as indicated in paragraph 3.1. Water as component of the raw materials is included in the calculation of the percentages of the finished formulation because it is part itself of the final formulation and it will be calculated according to the indication given in paragraph 6.C for the calculation of the minimum requirements requested in paragraph 3.1.

3.6 LABELING

Labels should be clear and satisfy all normative requirements (refer to Art. 8 of Law 713/86 and following modifications and integrations). In particular, labels should indicate:

- the name or the business name and the legal address of the producer or of the person responsible for placing the cosmetic product on the market;
- the quantity of product expressed in weight (g) or volume (ml). The indication is not compulsory for free samples, single-doses or particular packages as cases/kits;
- lot number;
- country of origin of the product for products made in extra EU countries;
- the function of the product, unless it is clear from the presentation of the product itself;
- direction of use;
- the date of minimum life of the product if it is less than 30 months or the PAO (Period After Opening);
- the list of ingredients of the product, indicated according to the INCI - International Nomenclature of Cosmetic Ingredients, in decreasing order of weight (consider the weight at the moment of incorporation). This rule remains valid for the substances that reach a concentration of 1% or higher; the ingredients that are less than 1% can be indicated in open order.

Additional indications:

compulsory on the label in order to declare the status of natural product, natural product with organic ingredients or organic product.

Bioagricert Control
Operator code: BAC yyyy yyyy
Product code (NC BAC)

Bioagricert Control
Operator code: BAC yyyy yyyy
Product code (BOC BAC)

Bioagricert Control
Operator code: BAC yyyy yyyy
Product code (BOCX BAC)

x % of organic ingredients
Legenda (do not put it on the label!):

<table>
<thead>
<tr>
<th>NC</th>
<th>Natural cosmetic</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOC</td>
<td>Organic cosmetic (bio-organic logo)</td>
</tr>
<tr>
<td>BOCX</td>
<td>Natural cosmetic with organic ingredients</td>
</tr>
</tbody>
</table>

In the INCI list of ingredients the star* should be placed near all ingredients from controlled organic farming.

For natural products with organic ingredients, place, near the trademark bio-organic cosmetic, the % in weight of organic ingredients on the total of the final formulation.

Under derogation, in some cases, the % can be indicated in the list of ingredients.

3.7 PRODUCTS USED FOR THE APPLICATION OF THE COSMETIC PRODUCTS

All the products used to apply cosmetic products on the skin (for example flannels, wet tissues, pads) should come from renewable raw materials.

3.8 REQUIREMENTS FOR PACKAGING

1. Packaging should be reduced to the minimum.
2. If possible, products should be made for multiple use.
3. If possible and available, use recyclable packaging materials.
4. Halogenated plastics cannot be used for packaging.
5. Packaging with compressed gas cannot be certified.

Within any fabrication, handling, filling process, the operator should always guarantee that the final products have not been contaminated with substances coming from processing, packaging material or storage.

3.9 ENVIRONMENT HEALTH

Production methods should respect the environment as much as possible; when possible, use biodegradable, recyclable and eco-compatible packaging.

3.10 PROHIBITED SUBSTANCES (examples)

- PEG, PPG and by products
- Ethoxylated compounds
- Compounds that may give rise to nitrosamines
- Animal derivatives such as animal-derived collagen, placenta
- Silicone and its derivatives
- Acrylic polymers
- Synthetic dyes
- Chemical UV filters
- Synthetic aluminium and silicium derivatives
- Synthetic perfumes (for bio-organic cosmetic)
- Mineral oils
- Benzene
- Hexane
- Propylene glycol
- Butylene glycol
- Animal glycerine
- Petrochemical substances used as ingredients or solvents
- Chelating agents based on EDTA and its salts
- Products treated with ionizing radiation and electron irradiation
- Authorized ingredients treated with prohibited processes
- Substances that may cause ecological and environmental damages
- Other ingredients and additives not authorized by the present standard
- All substances not allowed by the regulatory standard
3.11 TESTS ON ANIMALS
According to Law 713/86 and following modifications and integrations, test on animals are prohibited.

3.12 SOCIAL RESPONSIBILITY
Ingredients coming from fair trade commerce, third countries or Social Accountability companies are recommended.

4. GENERAL REQUIREMENTS FOR CERTIFICATION

The general requirements for the production of a cosmetic product conforming with this standard include:
- description of production processes for products and natural raw materials or raw materials of natural origin;
- respect of the minimum requirements for the production of natural ingredients and natural ingredients of organic quality and also respect of the maximum allowed percentages of additives of synthesis in the 3 categories natural cosmetic, natural cosmetic with organic ingredients and organic cosmetic;
- respect of the requirements concerning packaging processes and materials and products for the application of cosmetic products;
- respect of the requirements for production premises, machineries and tools according to the laws in force for cosmetic products;
- use of proper cleaning procedures for premises, machineries and tools;
- adoption of a cleaning program that should be followed anytime a product, especially if containing organic ingredients, is made according to the present standard;
- respect of the good manufacturing practices, like norm UNI EN ISO 22716, Colipa Guide Lines or Decree n.328/1987;
- use and maintenance of a load/unload register of organic raw materials that are used for the production of organic cosmetic products and natural cosmetic products with organic ingredients in order to guarantee the traceability of organic ingredients and demonstrate the use of the declared percentages;
- separation of storehouses for raw organic materials, organic semiprocessed products and organic finished products from storehouses for other raw materials, other semiprocessed products and other finished products.

A draft label should be placed to identify each raw material, semiprocessed products or finished products.

The applicant should also:
- supply all necessary documentation on raw materials and final products (see annex 6.B);
- help the auditor during the audit by giving any necessary information and supply any necessary document;
- complete and send Bioagricert Information Documents;
- supply a written and signed declaration of conformity with to the law in force on cosmetic products;
- supply a GMO free declaration;
- supply a clear and signed declaration on the non use of animal tests;
- inform the certification body if any evidence of toxicity has been found in the certified products;
- supply a written and signed declaration on the performance of challenge tests and microbiological tests on any finished product;
- keep a file for each product with the suppliers’ guarantees (analysis, certificates, origin of ingredients, processing processes etc.);
- describe, standardize and use an internal control plan that includes:
- on raw materials in entrance

<table>
<thead>
<tr>
<th>MINIMUM REQUIREMENTS TO CONTROL</th>
<th>MINIMUM FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control that the data of each supplier are communicated to Bioagricert</td>
<td>Each lot in entrance</td>
</tr>
<tr>
<td>Control of raw materials through: transport documents, certificates, chemical, physical, microbiological analysis issued by the supplier</td>
<td>Each lot in entrance</td>
</tr>
<tr>
<td>Control of transport documents, declarations of conformity issued by the supplier on the production process used to obtain natural ingredients and/or ingredients of natural origin</td>
<td>Each lot in entrance</td>
</tr>
<tr>
<td>Control the presence of certificates and declarations of conformity of the product according to Reg. EC 834/2007 and following integrations and modifications and/or according to the present standard or the equivalent ones</td>
<td>Each lot in entrance, only for ingredients from organic farming and/or conforming with the present standard or equivalent ones</td>
</tr>
<tr>
<td>Control that the information contained in the transport documents are complete; contact the supplier for further information</td>
<td>Each lot in entrance</td>
</tr>
<tr>
<td>Analytical tests on ingredients and raw materials coming from the outside in order to check their conformity</td>
<td>To be defined in the control plan prepared by the operator</td>
</tr>
</tbody>
</table>

- on the finished/final product

<table>
<thead>
<tr>
<th>Challenge test on the product</th>
<th>It should be done for each product formulation and only if necessary for the kind of product and packaging with which the product is sold to the final consumer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiological tests – at least TBC (&lt; 100 UFC/g), moulds and yeasts (&lt;10 UFC/g)</td>
<td>Each lot of finished product</td>
</tr>
<tr>
<td>Stability tests (heating/freezing cycles, etc.)</td>
<td>Each lot of finished product</td>
</tr>
<tr>
<td>Conformity with organoleptic parameters (colour, odour etc.)</td>
<td>Each lot of finished product</td>
</tr>
<tr>
<td>Conformity with physical parameters (pH, density etc.)</td>
<td>Each lot of finished product</td>
</tr>
<tr>
<td>The supplier makes available a sample made of 3 packagings for the certification body and keeps it for at least one year from the date of production</td>
<td>Each product that should be certified</td>
</tr>
</tbody>
</table>
5. CERTIFICATION PROCEDURE

Registration, Documentation & Certification
The certificate of conformity and the use of “bio-organic” and “natural” cosmetic trademarks guarantee the conformity with the requirements described above.

The applicant should:
A) satisfy every aspect described in the present standard.
B) Satisfy all requirements described in the previous paragraph.
C) Submit a technical dossier on the products that should include:
   - quali-quantitative formula with INCI for each ingredient, each finished cosmetic product in order to verify the percentages for the certification of the product itself;
   - certificates of conformity to the organic method, where necessary;
   - documents that prove that the ingredients come from natural products;
   - technical sheets and safety sheets of each ingredient used in each cosmetic product with the indication of: materials of origin, details (kind and description) on the processing processes (physical or chemical processes), extraction reports of natural substances/solvents of the used extracts, the parameters of the finished product (minimum requirements);
   - data concerning the controls of conformity on the finished product;
   - evaluation of the safety of the finished product (refer to article 10 bis Law 713/86 and following modifications and integrations);
   - existent data on the side effects caused by the product on human health;
   - description of the processing method, including the machineries used;
   - if present: tests on the effects of the product.

D) Have a management system of the natural and organic production with related descriptive documents, including at least:
   - a responsible person for the production system.
   - The application of good manufacturing practices (GMP).
   - A staff training program.
   - Identification of risks.
   - Sanitary control procedures.
   - Record keeping system (load/unload of raw materials, processing of finished product, distribution and sale, lots number, raw materials used).

E) Supply a copy of:
   - updated Notification of production and/or commercialization sent to the Ministry of Public Health;
   - labels of certified products.

For a better documents management:
   - keep records of processing done;
   - keep a catalogue with the formulations of the certified products, with approved labels that should be available during the audit;
   - keep all information documents sent to the certification body, for each certified product;
   - keep the evidences that prove the origin of the ingredients and the organic certification of the organic ingredients;
   - keep a copy of the Notification sent to the Ministry of Public Health and also any following modification;
   - keep the technical and safety sheets of raw materials;
   - keep a catalogue of all technical dossier and safety evaluations of each cosmetic product (edited according to the in force law); they should be available during the audit;
   - it is recommended the use of Bioagrict Software 4.0 for the management of organic products in entrance/exit.

The certification process is the following one:
   - request of an estimate for the certification and pre-evaluation of the ingredients of the product that should be certified;
   - acceptance of the estimate and sending of questionnaire and Bioagrict information documents;
   - acquisition of the data;
   - audit at the operator’s;
   - control if the products can be certified and eventual non compliances;
• sending of trademarks and Bioagricert (BAC) code that should be put on the labels;
• labels approval;
• issue of certificate of conformity.

The present standard can be applied both to finished cosmetic products and to cosmetic raw materials.

The Certificate of Conformity has 1 year validity.

The present version of this standard is the in force version.

The products that were certified according to the previous version of this standard remains conforming to the conditions laid down in the previous version until the stocks last.

The certification body and its staff guarantee that no information on the certified products will be communicated to third parts except for the compulsory information that should be communicated to Competent Authorities.

In case the operator does not respect the conditions and the requirements laid down in the present standard, the certification body may withdraw the certificate of conformity.

6. ANNEXES

A) OTHER DEFINITIONS

BAC = BioAgriCert, certification body

Cosmetic product, definition given by Law 713/86 = any substance and preparation, different from medicines, applied to the external part of human body (skin, hair, nails, lips, eyes, teeth etc.) for beautifying, preserving, or altering the appearance or for cleansing, coloring, conditioning, or protecting it. Cosmetic products do not have a therapeutic purpose and cannot boast of therapeutic functions. They are the products listed in Annex I of the law indicated above.

Finished product = completely manufactured cosmetic product which is ready for packaging, sale and delivery to the marketplace. In particular, in the present standard a finished product means all the ingredients that compose the product, including water of process, in order to calculate the ingredients percentages and decide if the product can be certified or not.

Natural identical ingredient = it is equivalent to a natural ingredient but it is produced with chemical synthesis.

GMP (good manufacturing practice) = GMPs are guidance that outline the aspects of production and testing of cosmetic products. Many countries have legislated that cosmetic producers must follow GMP procedures and have created their own GMP guidelines that correspond with their legislation; the basic concepts of all these guidelines remains more or less similar as their ultimate goal is to safeguard the health of the consumer, producing a good quality product. In particular for cosmetic product, in October 2007, the International Standard EN ISO 22716 was issued. Also the Decree 328 of 09/07/87 and Colipa Guide Lines can be taken as a reference.

GMO = genetically modified organism.

BAC information documents = documents and declarations sent to the operator from the certification body; the operator should complete them and send them back to the certification body in order to complete the certification process.

Technical dossier = collection of information as indicated in paragraph 5.C.

Dossier of finished product = (compulsory according to the law in force) it is the collection of data concerning raw materials and finished products with final evaluation on the safety of the finished cosmetic product. If it is complete with all necessary information, it may coincide with
Audit = inspection visit at the operator’s performed by a qualified auditor of the certification body. At least one inspection per year at each production premise is done, usually in the period during which the certified products are produced in order to issue/reconfirm the certificate of conformity.

Auditor = qualified inspector sent by the certification body in order to verify that operators respect the requirements of conformity.

Certification = process that leads to the issue of a certificate of conformity according to a standard and that adds value to a product and gives guarantees to consumers.

B) LIST OF DOCUMENTS THAT SHOULD BE SUPPLIED

- a written and signed declaration of conformity with the in force law on cosmetic products and the GMP
- a GMO free declaration
- a clear and signed declaration on the non use of animal tests
- quali-quantitative formula for each finished cosmetic product
- technical sheets and safety sheets of raw materials used
- certificates of origin of natural ingredients and of the ingredients of natural origin and of the physical or chemical processes to which they were subjected
- declaration of conformity of the certified products with chemical, physical and microbiological stability
- technical dossier of the finished product including the evaluation of its safety
- load/unload register of organic raw materials
- BAC information documents
- Copy of labels of certified products
- Register of production lots and distribution least of finished product

C) EXAMPLES OF CALCULATION OF NATURAL INGREDIENTS AND ORGANIC INGREDIENTS

Natural substances that contain water are considered with the following % in weight:

a) vegetal juices: 100% natural substance
b) concentrate of vegetal juices: only 100% concentrate juices (as natural substance), except for dilution water
c) watery extracts: only the vegetal part
d) hydroalcoholic extracts: the vegetal and the alcoholic parts (this one only if natural)

Examples:

\[ P + E \rightarrow \text{Plant residue} \]
\[ \text{Extraction solvent} \]
\[ + \]
\[ \text{F} \]
\[ \text{Extract/Hydrolate} \]

\[ P = \text{Mass of vegetal material used (in case, from controlled organic farming)} \]
\[ E = \text{Mass of the extraction mean used or of the water used for distillation} \]
\[ \text{F} = \text{Mass of the extract obtained (after extraction and filtration) or of the hydrolate obtained (after distillation)} \]
\[ X = \text{Part of natural ingredient or ingredient from organic farming of the extract/hydrolate [%]} \]
Case 1: Distillation or extraction of vegetal material from controlled organic farming with water or other substance of vegetal origin (not from controlled organic farming):
Extract/hydrolate: \( X = \frac{P}{P + E} \times 100 = X \% \) natural and from controlled organic farming
Oil (in case of distillation): 100 % natural and from controlled organic farming

Case 2: Extract of vegetal material with a mean of vegetal origin (natural, not from controlled organic farming)
Extract: 100 % natural, of which \( X = \frac{P}{P + E} \times 100 = X \% \) from controlled organic farming

Case 3: Extraction of vegetal material from controlled organic farming with a mean of extraction from controlled organic farming:
Extract: 100 % natural and from controlled organic farming
The vegetal residue remaining after distillation or extraction can be still further manufactured as natural ingredient or, in case, as quality from controlled organic farming.

Example 1: extraction of hypericum with a vegetal oil (natural, in case, from controlled organic farming):
P = 30 kg dried vegetal material (from controlled organic farming)
E = 90 kg vegetal oil (in case, from controlled organic farming)
F = 80 kg extract after filtration
Extract: 100 % natural, of which \( X = \frac{30}{30 + 90} \times 100 = 25 \% \) from controlled organic farming.
In case vegetal oil from controlled organic farming is used, the extract can be classified 100% natural and from controlled organic farming.

Example 2: production of a hydrolate through distillation rose petals with water (first distillation):
P = 300 kg fresh rose petals (from controlled organic farming)
E = 300 kg water
F = 300 kg hydrolate
Oil: 100 % natural and from controlled organic farming
Hydrolate: \( X = \frac{300}{300 + 300} \times 100 = 50 \% \) natural and from controlled organic farming

Example 3: production of a hydrolate through distillation of rose petals with water (first distillation):
P = 300 kg fresh rose petals (from controlled organic farming)
E = 1000 kg water
F = 1000 kg hydrolate
Oil: 100 % natural and from controlled organic farming
Hydrolate: \( X = \frac{300}{300 + 1000} \times 100 = 23,1 \% \) natural and from controlled organic farming

Example 4: production of an hydrolate through distillation of rosemary with water:
P = 1000 kg rosemary (from controlled organic farming, nearly dried)
E = 350 kg water steam (it is conducted until F = 350 kg)
F = 350 kg hydrolate
Oil: 100 % natural and from controlled organic farming
Hydrolate: \( X = \frac{1000}{1000 + 350} \times 100 = 74,1 \% \) natural and from controlled organic farming

Example 5: production of a floral water (without extraction of oil):
Same calculation of the part of natural ingredient or natural ingredient from controlled organic farming as in the case of hydrolates
7. TABLES

Natural cosmetic

“natural ingredients” + “ingredients of natural origin”

H₂O of process

Max 5% in weight of allowed additives under derogation (see paragraph 3.4) on the finished cosmetic product

At least 10% in weight of “natural ingredients” on the finished cosmetic products*

Natural cosmetic with organic ingredients

“natural ingredients” + “ingredients of natural origin”

H₂O of process

Max 5% in weight of allowed additives under derogation (see paragraph 3.4) on the finished cosmetic product

At least 5% in weight of organic certified ingredients on the finished cosmetic products*

On the total of certifiable ingredients at least 70% certified organic *

*Water, except for what indicated in Annex 6.C, should not be included in the calculation of these minimum requirements but should be included in the calculation of the % of the finished cosmetic product
Bio-organic cosmetic

“natural ingredients” + “ingredients of natural origin”

H₂O of process

Max 5% in weight of allowed additives under derogation (see paragraph 3.4) on the finished cosmetic product

At least 10% in weight of organic certified ingredients on the finished cosmetic product *

On the total of certifiable ingredients at least 95% certified organic *

*Water, except for what indicated in Annex 6.C, should not be included in the calculation of these minimum requirements but should be included in the calculation of the % of the finished cosmetic product
THE PASSION FOR CERTIFIED QUALITY