

# COSMOS-standard

## Cosmetics organic and natural standard Final – January 2010

### 1. Introduction

This Standard has been developed at the European level by BDIH (Germany), BIOFORUM (Belgium), COSMEBIO & ECOCERT (France), ICEA (Italy) and SOIL ASSOCIATION (UK) (hereinafter referred to as the founders) in order to define minimum requirements and common definitions for organic and/or natural cosmetics.

#### 1.1 Main objectives of COSMOS-standard

Addressing the excesses and failures of current developments is a key challenge for our society. Establishing a "sustainable development" that would reconcile economic progress, social responsibility and maintain the natural balance of the planet is a project in which the cosmetics sector is willing to be fully involved. The application of the principles of sustainable development in economic activity implies however changing patterns of production and changing consumption practices. Recognising these challenges, the responsibility of its actors, the organic and natural cosmetics sector clearly shows its ambition to go further in sustainable development with the setting at the European and international level of a new standard for organic and natural cosmetics.

To stimulate processes for sustainable production and consumption, the organic and natural cosmetics sector is using some simple rules governed by the principles of prevention and safety at all levels of the chain from production of raw materials to the distribution of finished products.

These rules are:

- promoting the use of products from organic agriculture, and respecting biodiversity;
- using natural resources responsibly, and respecting the environment;
- using processing and manufacturing that are clean and respectful of human health and environment;
- Integrating and developing the concept of "Green Chemistry".

This last point, new aspect of the COSMOS-standard is a key to the success of this ambition considering the specificities and constraints of the formulation of cosmetic products (particularly versus food products).

With this "green philosophy" and this desire to actively contribute to sustainable development, the cosmetics sector is committed to define and implement a standard for organic and natural cosmetics. This Standard takes into account the current technological reality while infusing a dynamism that will lead to innovative developments.

To facilitate the translation of these rules at the level of a Standard, it is necessary to distinguish the five categories of ingredients contained in a cosmetic product (listed below in ascending order of human intervention):

1. water – vital and basic raw material in product development; its quality is essential;
2. mineral ingredients – interesting and necessary, but not renewable; they require clear environmental rules in their use, and in further processing;
3. physically processed agro-ingredients – already benefit from satisfactory European and other recognised standards on organic agriculture;
4. chemically processed agro-ingredients – certifiable by using agricultural organic raw materials and manufacturing processes that are clean and authorised, all under the umbrella of “Green Chemistry”;
5. other ingredients – this is the category to actively manage the transition from the current situation to the objectives and direction of this Standard.

This new COSMOS-standard's ultimate objective is to address the major issues essential to the environment and welfare of man on the planet. For practical purposes, it aims to ensure the transition between today's and tomorrow's possibilities of technological advances to promote the development of cosmetics ever more natural and organic. This is necessary for the respect of consumers who must be informed clearly and transparently so that they can themselves be an actor for sustainable development.

## **1.2 Copyright**

This Standard is the property of the above named founding organisations and shall not be copied, reproduced or otherwise used except with their express written permission.

## **1.3 Revision**

The organic and natural cosmetics sector is still developing and both technology and understanding are advancing. The COSMOS-standard will therefore be subject to periodic review and amendment in line with the objectives above, taking into account availability of ingredients and technology, and after full and open consultation with stakeholders.

## **2. Regulations**

The users of this Standard are expected to comply with all relevant legislation, including The EU LEGISLATION for COSMETIC PRODUCTS - European Directive 76/768/EEC as amended, The EU REACH REGULATION – Regulation n°1907/2006, and other local or national laws where appropriate.

## **3. Scope**

This Standard applies to cosmetic products marketed as organic or natural. They cover:

- Origin and processing of ingredients
- Composition of total product
- Storage, manufacturing and packaging
- Environmental management
- Labelling and communication
- Inspection, certification and control

## 4. Definitions

In the context of this Standard, the definitions below will apply.

« Agro-ingredient » - any plant, animal or microbial product derived from agriculture, aquaculture or wild collection/harvest.

« Catalyst » – a substance used to modify or increase the rate of a reaction without being consumed in the process.

« Chemically processed » - processed or extracted using chemical processes such as those listed in Appendix II (which are allowed) and Appendix III (which are not allowed).

« Contaminant » - a substance that is:

- not naturally present in the material, or
- present in quantities greater than those that exist naturally which could lead to pollution (persistence, residues) and toxicity risks.

Contaminants may be:

- heavy metals
- aromatic hydrocarbons
- pesticides
- dioxins & PCBs
- radioactivity
- GMOs
- mycotoxins
- medicinal residues
- nitrates
- nitrosamines.

« Cosmetic ingredient » - (taken from European Parliament legislative resolution of 24 March 2009) - any chemical substance or preparation of synthetic or natural origin used in the composition of cosmetic products. The following shall not be regarded as ingredients:

- impurities in the raw materials used,
- subsidiary technical materials used in the preparation but not present in the final product.

Note - The water added during the manufacture of the finished product is therefore a separate ingredient.

« Cosmetic product » - (taken from European Parliament legislative resolution of 24 March 2009) - any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

« Derivative of GMO » - any substance which is produced from or by a GMO where the GMO is the source organism of the substance or is involved directly in the last process that accomplishes an essential conversion of the substance.

« Manufacturer » - (taken from European Parliament legislative resolution of 24 March 2009) - any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark.

« Manufacturing » - group of operations carried out in the factory or the laboratory, for obtaining, preparing, processing and labelling products.

« Mineral » - raw material obtained from naturally occurring substances formed through geological processes, but excluding fossil fuel-derived materials.

« Mixture » - (taken from European Parliament legislative resolution of 24 March 2009) - a mixture or solution composed of two or more substances.

« Moiety » - a specific segment of a molecule.

« Nanomaterial » - (taken from European Parliament legislative resolution of 24 March 2009) - an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure (ie primary particle), on the scale from 1 to 100 nm.

« Organic » - production system that complies with Regulation n° (EC) 834/2007 or other recognised international or national organic standards and certified by an IFOAM accredited or internationally recognised (according to ISO/IEC Guide 65) certifier. When referring to organic in this Standard other terms that mean the same in other languages are also included and are subject to the same limitations.

« Physically processed » - processed or extracted using physical processes such as those listed in Appendix I (which are allowed).

« Primary raw material » - any product of plant, animal, or microbial origin, as well as minerals, which is used as raw material in the manufacture of cosmetic ingredients.

« Rinse-off product » - (taken from European Parliament legislative resolution of 24 March 2009).- a cosmetic product which is intended to be removed after application on the skin, the hair or the mucous membranes.

« Substance » - (taken from European Parliament legislative resolution of 24 March 2009) - a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

« Total product » - the total finished cosmetic product including all ingredients (water, mineral ingredients, physically processed agro-ingredients, chemically processed agro-ingredients and other ingredients).

## **5. General**

### **5.1 Precautionary principle**

When there is scientific evidence that an ingredient, technology or process could pose a health or environmental risk, then the precautionary principle will be applied and it will not be allowed. For this reason, the following are not allowed:

#### **5.1.1 Nanomaterials**

Nanomaterials are forbidden. It is recognised that there may need to be exceptions and applications for exceptions supported by technical dossiers will be considered.

### **5.1.2 Genetically modified organisms (GMOs)**

Primary raw materials or ingredients that are GMOs or derivatives of GMOs are forbidden. Contamination of primary raw materials or ingredients with genetically modified material must not be above 0.9% for that primary raw material or ingredient, and may only be above the reliable detection limit of 0.1% if adventitious or technically unavoidable.

### **5.1.3 Irradiation**

Gamma and X-ray irradiation are forbidden.

## **5.2 Animal testing**

Cosmetic products must not be tested on animals. Cosmetic ingredients must not be tested on animals except where required by law.

## **6. Origin and processing of ingredients**

In this Standard, the ingredients of a cosmetic product are classified in five categories:

- Water
- Minerals and ingredients of mineral origin
- Physically processed agro-ingredients
- Chemically processed agro-ingredients
- Other ingredients.

Each ingredient category is subject to requirements. Detailed requirements and calculation rules for organic percentage of ingredients are given below.

The same classification will apply for the origin and composition of a single cosmetic ingredient or a mixture of cosmetic ingredients. Manufacturers of ingredients must provide the corresponding percentages on the technical documentation.

### **6.1 Ingredients categories**

#### **6.1.1 Water**

The water used must comply with hygienic standards (CFU less than 100/ml) and may be:

- potable water
- spring water
- water obtained by osmosis
- distilled water
- sea water.

Water may be treated with the physical processes allowed in Appendix I.

#### **6.1.2 Minerals and ingredients of mineral origin**

Minerals may be used as long as they are pure and natural and preferably from environmentally sound extraction processes.

Only ingredients of mineral origin listed in Appendix IV may be used and they must comply with relevant legislation.

Minerals and ingredients of mineral origin may be treated with the physical processes allowed in Appendix I.

### **6.1.3 Physically processed agro-ingredients**

Included is any physically processed product of plant, animal, or microbial origin that complies with the conditions below.

- only primary raw materials of plant, animal or microbial origin that have been extracted using the physical processes listed in Appendix I are allowed
- only primary raw materials that respect the requirements of the Convention of International Trade in Endangered Species of Wild Fauna and Flora (CITES) are allowed.

It is forbidden to use:

- plants or plant materials that have been genetically modified
- primary raw materials extracted from living or slaughtered animals.

It is allowed to use ingredients of animal origin as long as:

- they are produced by animals but are not a part of the animal
- they have been obtained using only the processes in Appendix I
- they come from animals whose welfare has been protected.

### **6.1.4 Chemically processed agro-ingredients**

Included is any chemically processed product of plant, animal, or microbial origin that complies with the conditions below.

Only primary raw materials that respect the requirements of the Convention of International Trade in Endangered Species of Wild Fauna and Flora (CITES) are allowed to be used.

It is forbidden to use:

- plants or plant materials that have been genetically modified
- primary raw materials extracted from living or slaughtered animals.

It is allowed to use ingredients of animal origin as long as:

- they are produced by animals but are not a part of the animal
- they have been obtained using only the processes in Appendix I,
- they come from animals whose welfare has been protected.

Chemically processed agro-ingredients may contain mineral moieties.

Note – alcohol and other by-products of fermentation are chemically processed agro-ingredients.

The following requirements apply to manufacturers of chemically processed agro-ingredients who should follow the principles of green chemistry for all the sequence of reactions that are needed to make each ingredient (Environmental Protection Agency Green Chemistry Programme, USA, 1998; [www.epa.gov/greenchemistry](http://www.epa.gov/greenchemistry)).

The manufacturer of chemically processed agro-ingredients:

- must only use the chemical processes listed in Appendix II (an indicative list of those not allowed is in Appendix III) and must use renewable resources.
- may use ingredients derived from culture or fermentation and other non-GMO biotechnology, the cultures must use only feedstock from natural vegetable or microbial raw materials without using genetically modified organisms or their derivatives.
- must comply with the following quantitative requirements for their chemically processed agro-ingredients:

Principle	Requirement
Atom economy	Yield of the last reaction step: Minimum 50% Reaction mass efficiency = (weight of desired product(s) / weight of all reactants) x 100
Non-persistent products	1) Minimum requirement for Aquatic toxicity: LC50, EC50, IC50 > 1 mg/l  2) Relation of biodegradability to aquatic toxicity: - Aquatic Toxicity: EC50 > 10 mg/l (daphnia) - Biodegradability: > 70 % (or 60 % if CO2 produced is measured) (OECD 301) or - Aquatic Toxicity: EC50 = 1-10 mg/l (daphnia) - Biodegradability: > 95% (OECD 302); > 70 % (or 60 % if CO2 produced is measured) (OECD 301)  3) Substances, known to be bio-accumulative and not biodegradable (do not pass OECD 301; => TEGEWA classification III = high waste water impact) are prohibited

With the current state of development of green chemistry, it is not yet possible to specify limits or requirements for all principles. For the following principles, manufacturers of chemically processed agro-ingredients must supply information about how the principle is applied or measured:

Principle	Requirement
Energy economy (low energy use)	Information point (can be for the factory as a whole)
Absence of temporary modification (intermediary reactions)	Information point
Method of analysis (eg real time analysis)	Information point
Lower waste production	Information point (can be for the factory as a whole)
Limitation of accident risk	Information point

However, green chemistry is still in development. As the principles and practice of green chemistry evolve, these will be further elaborated and incorporated into this Standard.

#### **6.1.5 Other ingredients and moieties**

Certain other ingredients are allowed as long as there are no effective natural alternatives available to ensure the safety of consumers or efficacy of the product. Only those listed in Appendix V are allowed.

During a transition period of 60 months after this Standard comes into force, a limited number of other ingredients, moieties and processes for some specific ingredients are allowed since fully natural alternatives are not yet available to ensure the efficacy of the product. Only those listed in Appendix VI are allowed.

## **6.2 Calculation rules for organic percentage**

The calculation rules below must be used to determine the proportion of organic content for each cosmetic ingredient. Organic refers to production system that complies with Regulation n° (EC) 834/2007 or other recognised international or national organic standards and certified by an IFOAM accredited or internationally recognised (according to ISO/IEC Guide 65) certifier.

Physically processed agro-ingredients or chemically processed agro-ingredients not falling within the scope of the previously mentioned recognised organic production systems, must be certified according to this Standard for a manufacturer to claim they have organic content that complies with this Standard. For these ingredients to be certified, there is no minimum percentage of organic content.

For all ingredients, the actual organic percentage, calculated according to this Standard, must be provided on the technical documentation.

### **6.2.1 Water**

Water cannot be calculated as organic. This includes water that is:

- added directly, or
- added indirectly as mixtures with or components of other ingredients, for example minerals, physically or chemically processed agro-ingredients.

The liquid (juice) content of fresh plants is not considered as water. Please refer to 6.2.3 for extracts and reconstitution of dried or concentrated ingredients.

### **6.2.2 Minerals and ingredients of mineral origin**

Minerals are not within the scope of Regulation (EC) 834/2007. Minerals and ingredients of mineral origin cannot be calculated as organic.

### **6.2.3 Physically processed agro-ingredients**

a) For physically processed agro-ingredients, using only organic primary raw materials or only organic primary raw materials and organic solvents, the organic percentage is 100%.

b) For water-based extracts, the organic percentage is calculated as follows:

First step:

Ratio = [organic fresh plant / (extract - solvents)]

If the ratio is greater than 1, then it is counted as 1.

Second step:

% organic = {[ratio x (extract - solvents) / extract] + [organic solvents / extract]} x 100.

Conditions:

- Solvent should be understood as the quantity of solvent present in the final extract. Water is not considered as a solvent.
- If alcohol is used as an extraction solvent, it must be organic
- Mixtures of organic and non-organic primary raw materials are not allowed.

For water-based extracts using only water, the organic percentage is calculated as follows:

% organic = (organic fresh plant / extract) x 100

c) For non-water based extracts, the organic percentage is calculated as follows:

% organic = (organic fresh plant + organic starting solvents) / (fresh plant + all starting solvents) x 100

Conditions:

- If alcohol is used as an extraction solvent, it must be organic
- Mixtures of organic and non-organic primary raw materials are not allowed.

General conditions:

- If alcohol is used as an extraction solvent, it must be organic
- If a physically processed agro-ingredient is diluted with water, non-organic solvent or carrier or mixed with other additives after processing, the organic percentage will be reduced proportionately.
- To calculate the equivalent fresh weight of dried herbs in the calculation of organic content of extracts, it is possible:
  - either to use the actual dry to fresh ratio for the material (information to be provided)
  - or use the following ratios:
    - Wood, bark, seeds, nuts and roots      1 : 2.5
    - Leaves, flowers and aerial parts      1 : 4.5
    - Water fruits      1 : 8
- It is possible to reconstitute pure concentrates and dried powders to their natural state provided:
  - the reconstitution is done before adding to a formulation, and
  - the concentrate or powder must not contain any other ingredients, additives or carriers (for example, those mixed with carriers such as maltodextrin cannot be reconstituted).

Note – freeze drying preserves quality best.

To calculate the percentage of physically processed agro-ingredient in extracts if the fresh plant is non-organic, a calculation analogous to b) or c) above must be used by substituting organic fresh plant by fresh plant.

#### **6.2.4 Chemically processed agro-ingredients**

In chemically processed agro-ingredients, the organic percentage of that ingredient is calculated as the proportion (by weight) of the organic primary raw materials in that ingredient, taking into account all the starting primary materials used to make that ingredient:

$\% \text{ organic} = \frac{[(\text{all organic starting primary raw materials} - \text{organic starting primary raw materials in excess}) / (\text{all starting primary raw materials} - \text{all starting primary raw materials in excess})] \times 100$

Conditions:

- Non-reacting solvents are not considered as starting primary raw materials.
- Excess means the amount of starting primary raw materials that are recycled or later-on removed.
- If a chemically processed agro-ingredient is diluted with water, non-organic solvent or carrier, the organic percentage will be reduced proportionately.
- Any chemically processed agro-ingredient obtained by cleavage of 100% organic primary raw materials only would be counted as 100% organic.

Chemically processed agro-ingredients may be certified in their own right according to this Standard, however:

- there is no minimum percentage of organic content, and
- the percentage of organic content, as measured above, must be clearly displayed

## **7. Composition of total product**

This Standard covers two levels:

- Cosmetic products under organic certification
- Cosmetic products under natural certification

### **7.1 Rules for cosmetic products under organic certification**

#### **7.1.1 Ingredients**

- At least 95% of the physically processed agro-ingredients must be organically produced.
- At the end of a transition period of 36 months after this Standard comes into force, the remaining physically processed agro-ingredients must be organic if they are available (in sufficient quantity and quality).
- At the end of a transition period of 60 months after this Standard comes into force, at least 30% of the chemically processed agro-ingredients, measured according to the calculation in 6.2.4, must be of organic origin.

#### **7.1.2 Total product**

- At least 20% of the total product must be organic.
- By exception, for rinse-off products, non-emulsified aqueous products, and products with at least 80% minerals or ingredients of mineral origin, at least 10% of the total product must be organic.

### **7.2 Rules for cosmetic products under natural certification**

There is no requirement to use a minimum level of organic ingredients (however, see 10.3 for requirements for how you can identify organic ingredients on the product labels).

## **8. Storage, Manufacturing and Packaging**

### **8.1 Storage**

Storage areas must be clearly labeled to avoid any confusion or risk to the integrity of the products.

### **8.2 Manufacturing**

Different manufacturing processes must be separated to prevent contamination of organic or natural ingredients.

There must be a Quality Control System which includes:

- complete traceability of ingredients and final products
- manufacturing procedures throughout all stages
- ingredient and product testing, and
- analysis, manufacturing and storage records.

### **8.3 Packaging**

**8.3.1** To minimise the direct and indirect environmental impacts of packaging during its life cycle, it is required to:

- minimise the amount of material used
- maximise the amount of material that can be reused or recycled, and
- use materials with recycled content where possible.

It must be demonstrated during inspection that this has been done for each packaging format used.

**8.3.2** Packaging must be reviewed against standard 8.3.1 at least every three years and it must be demonstrated that it has been done, for example by keeping minutes of review meetings, or having a formal policy requiring this.

**8.3.3** It is forbidden to use these materials in packaging:

- polyvinyl chloride (PVC) and other chlorinated plastics
- polystyrene
- materials or substances that contain, have been derived from, or manufactured using, genetically modified organisms

It must be proven that these materials have not been used, for example by having written confirmation from the supplier.

**8.3.4** It must be ensured that any environmental information, claims and symbols on packaging are clear, truthful and accurate.

**8.3.5** Only the following propulsive gasses may be used:

- air
- oxygen
- nitrogen
- carbon dioxide
- argon.

## 9. Environmental management

### 9.1 Environmental management plan

An environmental management plan must be put in place which addresses the whole manufacturing process and all the residual products and waste resulting from this. It must be implemented effectively.

As part of the environmental management plan, a waste management plan must be put in place which addresses manufacturing waste, including gaseous, liquid and solid waste. The waste management plan must aim to reduce, reuse, recycle waste products on an efficient and rational basis.

Note - compliance with ISO 14000 or national legislation that already covers this will be accepted.

It is required to:

- sort cardboard, glass, paper and all other waste materials
- recycle or process this waste, and
- send all other waste to a specialized recycling firm which deals with specific packaging that it is not possible to recycle.

It is recommended to conduct a carbon audit of your operation.

### 9.2 Cleaning and hygiene

It is required to use cleaning materials in which the ingredients comply with this Standard.

In addition, the following disinfection materials can be used:

- vegetable derived alcohol
- iso-propyl alcohol
- amphoteric surfactants
- hydrogen peroxide
- mineral acids and alkalis, and
- any other ingredients listed as accepted in this Standard.

## 10. Labelling & communication

### 10.1 General rules

Labelling and communication must be clear and must not mislead consumers.

### 10.2 For products under organic certification

Products under organic certification:

- must be labelled with the term 'COSMOS-ORGANIC'.
- must indicate on the label the body responsible for certification or control of the last process in manufacture of the product by its name, code or logo and/or indicate the seal of the standard setting body.
- must indicate on the label the percentage of organic origin ingredients by weight in the total product, as "x% organic of total".
- must indicate organic ingredients and those made from organic raw materials in the INCI list. This should be limited to the wording: "from organic agriculture" for physically processed agro-ingredients and "made using organic ingredients" for chemically processed agro-ingredients or similar expressions using the same typing as used for the INCI list.
- may also indicate the percentage of organic origin ingredients by weight in the total product without water and minerals (as defined in 6.2.1 and 6.2.2), as "y% organic of total minus water and minerals".

Note – you may give prominence to either of the percentage indications.

The product must not be called "organic", for example, "organic shampoo", unless it is at least 95% organic, measured as a percent of the total product.

For products that are less than 95% organic, it is allowed to make reference to the organic ingredients on the label and in promotional literature, such as "Shampoo with organic jojoba oil".

Note – some national laws do not allow a product to be called "organic" if it is less than 100% organic.

### 10.3 For products under natural certification

Products under natural certification:

- must be labelled with the term 'COSMOS-NATURAL'.
- must indicate on the label the body responsible for certification or control of the last process in the manufacture of the product by its name, code or logo and/or indicate the seal of the standard setting body.
- must indicate organic ingredients and those made from organic raw materials only in the INCI list. This must be limited to the wording: "from organic agriculture" for physically processed agro-ingredients and "made using organic ingredients" for chemically processed agro-ingredients or similar expressions using the same typing as used for the INCI list.
- may indicate the percentage of organic origin ingredients by weight in the total product, as "x% organic of total".

- may indicate the percentage of organic origin ingredients by weight in the total product without water and minerals (as defined in 6.2.1 and 6.2.2), as “y% organic of total minus water and minerals”.
- You must not make any claim relating to organic, either ingredients or percentages, on the front of the packaging.

#### **10.4 Supporting literature**

If any reference to organic or natural products or ingredients are made in advertising or supporting literature they must comply with the appropriate rules in 10.2 or 10.3.

#### **10.5 Organic in the name of a company or product range**

If the company name or product range includes the word organic, the use of that name or branding in conjunction with certified products must not be such that it might mislead the consumer.

#### **10.6 Use of the name or term related to this Standard**

The COSMOS-standard term or name may be used in literature, advertising, publicity, etc:

- only in conjunction with the company name or brand if all the products of the company or brand are certified (for example, it can only be stated “we are COSMOS-ORGANIC certified” if the whole of the company’s range is COSMOS-ORGANIC certified)
- only in conjunction with the products that are certified, and
- only in a way that does not mislead the consumer, for example where it might mistakenly be associated with non-certified products.

Note – the danger of such a mistake arises in particular if the name is used in documents that are connected with the marketing of any non-certified products without a clear statement explaining the situation.

The requirements above are also valid for organisations that might not manufacture products but that are directly or indirectly involved with the COSMOS-standard (for example standard makers and certification bodies). This implies that standards makers or certification bodies must not implement the COSMOS-standard, COSMOS-ORGANIC, COSMOS-NATURAL terms (and translations) or any other terms including COSMOS in their logo, without prior consent of the founders or until there is an official COSMOS-logo.

## **11. Inspection, certification and control**

### **11.1 Inspection and certification**

To be certified for cosmetic ingredients or cosmetic products under natural or organic certification according to this Standard, it is required to:

- have subjected the manufacturing operation and the ingredients or products to inspection and certification by an authorised inspection/certification body; this includes any sub-contracted manufacturing plants that are used to process the ingredients or products
- hold a valid operational certificate from that body
- undergo an on-site annual inspection cycle which may include possible unannounced inspections and other additional inspections, and
- allow the inspection/certification body to take samples and carry out analysis (according to standard procedures) for ingredients or contaminants either on a random basis or in case of suspicion.

## **11.2 Approval of ingredients**

For non-organic cosmetic ingredients to be approved as acceptable for use under this Standard, it is required to:

- supply all information and documents needed for the approval as requested by the inspection/certification body, and
- declare to the inspection/certification body any changes to the processing of that ingredient that may affect its approval.

It is forbidden to label or otherwise indicate that approved cosmetic ingredients are certified according to this Standard.

## **11.3 Certification bodies**

Bodies certifying to this Standard must:

- be accredited to ISO/IEC Guide 65
- have cosmetics certification in the scope of their ISO/IEC Guide 65 accreditation (or at least have applied for inclusion of cosmetics in the scope which must be granted within 18 months)
- be authorised by the process set up by the European cosmetics standards working group to certify to this Standard
- submit to ongoing authorisation by the process set up the European cosmetics standards working group including any investigations they may undertake in case of complaint or suspicion, and
- cooperate with other authorised certification bodies to ensure common interpretation and implementation of this Standard.

# **12. Implementation of this Standard**

## **12.1 Coming into force**

This common and harmonised Standard comes into force from January 2010.

## **12.2 The founders**

The founders shall implement this Standard latest by 31<sup>st</sup> December 2014. Existing own standards for organic and/or natural cosmetics of the founders must comply with this Standard by this date.

Until 31<sup>st</sup> December 2014, the founders:

- shall implement inspection/certification to the COSMOS-standard but may choose to retain certain specific additional requirements of their own standards for organic and/or natural cosmetics that were valid at 31<sup>st</sup> December 2009;
- may arrange inspection/certification of products according to their own existing standards for organic and/or natural cosmetics. However, there must be no reference to the COSMOS-standard terms in relation to such products.

After 31<sup>st</sup> December 2014, the founders:

- must implement inspection/certification of products according to the COSMOS-standard without additional requirements;
- may continue to arrange inspection/certification for those products that were inspected/certified before that date according to their previous standards for organic and/or natural cosmetics, but there must be no reference to the COSMOS-standard terms in relation to such products.

### **12.3 Other certification bodies**

Other certification bodies must comply with the requirements in 11.3 before certifying to the COSMOS-standard. Once authorised, they must cease to certify cosmetic products according to their own standards for organic or natural cosmetics by 31<sup>st</sup> December 2014.

### **12.4 Products certified during the transitional period**

Products that are certified to the COSMOS-standard (including the transitional measures in 7.1.1 and Appendix VI) by 31<sup>st</sup> December 2014 may continue to be inspected/certified after that date according to the standard in force at the time of their certification.

## Appendix I

### PHYSICAL PROCESSES ALLOWED

The following criteria have been used to select these processes:

- processes which respect natural active substances that are present in ingredients;
- processes which encourage good waste management and energy use and take into account ecological balance.

All EXTRACTIONS must be with natural materials with any forms of water or with a third solvent of plant origin, such as:

- ethyl alcohol
- glycerine
- vegetable oils
- honey
- supercritical CO<sub>2</sub> ABSORPTION (on an inert support that conforms to this Standard)

ABSORPTION ON AN INERT SUPPORT CONFORMING TO THIS STANDARD

BLEACHING - DEODORISATION (on an inert support conforming to this Standard)

BLENDING

CENTRIFUGING

EXTRACTION

PRESSURE

DECOCTION

DESICCATION - DRYING (progressive or not, by evaporation / natural under sun)

DETERPENATION (if fractionated distillation with steam)

DISTILLATION, EXPRESSION or EXTRACTION (steam)

FILTRATION and PURIFICATION (ultra filtration, dialysis, crystallisation, ion exchange)

FREEZING

GRINDING

INFUSION

LYOPHILIZATION

MACERATION

MICROWAVE

PERCOLATION

ROASTING

SETTLING AND DECANTING

SIFTING

SQUEEZING, CRUSHING

STERILISATION BY MEANS OF UV

STERILISATION WITH THERMAL TREATMENTS (according to a temperature respectful of the active substances)

ULTRASOUND

UV TREATMENTS

VACUUM

## Appendix II

### CHEMICAL PROCESSES ALLOWED FOR PROCESSING AGRO-INGREDIENTS

The following criteria have been used to select these processes:

- processes which allow the formation of biodegradable molecules;
- processes which respect natural active substances that are present in ingredients;
- processes which encourage good waste management and energy use and take into account ecological balance.

ALKYLATION

AMIDATION

CALCINATION of plants residues

CARBONIZATION (resins, fatty organic oils)

CONDENSATION / ADDITION

ESTERIFICATION / TRANS-ESTERIFICATION / INTER-ESTERIFICATION

ETHERIFICATION

FERMENTATION (natural / biotechnological)

HYDRATION

HYDROGENATION

HYDROLYSIS

IONIC EXCHANGE

NEUTRALIZATION (to obtain Na, Ca, Mg, K salts)

OXYDIZATION / REDUCTION

SAPONIFICATION

SULPHATION/SULPHATATION

#### USE OF PETROCHEMICAL SOLVENTS

Petrochemical solvents may be used during the transition period (60 months after this Standard comes into force). However:

- these must not be used as part of the chemical processing of organic agro-ingredients, and
- there must be no use of aromatic, alkoxyated, halogenated, nitrogen or sulphur based solvents with any chemical processing of agro-ingredients.
- solvents as defined above may only be used provided there are no effective natural alternatives and they are recycled and eliminated at the end of the process.

## Appendix III

### EXAMPLES OF PROCESSES NOT ALLOWED

Only the processes allowed in Appendix I and Appendix II are allowed. Those below represent a non-exhaustive list which only identifies the main ones.

ALKOXYLATION (including ETHOXYLATION and PROPOXYLATION) using ethylene oxide, propylene oxide or other alkylene oxides

BLEACHING - DEODOURISATION (on a support of animal origin)

DETERPENATION (other than with steam)

IONISING RADIATION

SULPHONATION (as main reaction)

TREATMENTS WITH ETHYLENE OXIDE

TREATMENTS USING MERCURY (MERCURIAL SODA)

USE OF PETROCHEMICAL CATALYSTS

## Appendix IV

### INGREDIENTS OF MINERAL ORIGIN ALLOWED

You may use these substances:

- for the specific uses listed
- or for general purposes if no specific uses are listed.

<i>Ingredients</i>	<i>Specific use</i>
Aluminium ammonium sulphate	
Aluminium CI 77000	Inorganic pigment / colorant
Aluminium hydroxide	
Aluminium oxide	
Aluminium sulphate	
Ammonium manganese diphosphate CI 77742	Inorganic pigment / colorant
Ammonium sulphate	
Bentonite	
Bismuth oxychloride CI 77163	Inorganic pigment / colorant (but must not be used in lip products)
Calcium Aluminium Borosilicate	
Calcium carbonate CI 77220	Abrasive / buffer / opacifier
Calcium fluoride	Ingredient for oral cavity hygiene – until 31 <sup>st</sup> December 2014
Calcium sulphate (Gypsum)	Abrasive / opacifier
Chromium oxides CI 77289, 77288	Inorganic pigment / colorant
Copper CI 77400	Inorganic pigment / colorant
Copper oxide	Active agent
Copper sulphate	Additive
Cupric sulphate	Additive
Dicalcium phosphate dihydrate	Abrasive agent / agent for product for the oral cavity hygiene
Disodium phosphate	Buffer agent
Hectorite	
Hydrated Silica	Abrasive agent / absorbant agent / opacifier / agent for viscosity inspection
Iron hydroxide	Additive
Iron oxides CI 77480, 77491, 77492, 77499	Additive
Iron sulphate	Additive
Kaolin	
Lazurite CI 77007	Inorganic pigment / colorant
Magnesium aluminium silicate	
Magnesium carbonate CI 77713 (Magnesite)	Absorbant agent / viscosity agent
Magnesium chloride	Additive
Magnesium hydroxide	Absorbant / buffer agent
Magnesium oxide CI 77711	Absorbant agent / buffer agent / opacifier
Magnesium silicate	
Magnesium sulphate	Agent for viscosity inspection
Malachite	
Manganese bis orthophosphate CI 77745	Inorganic pigment / colorant

Manganese sulphate	Additive
Maris sal (sea salt)	
Mica (muscovite) natural CI 77019	
Potassium carbonate	Buffer agent
Potassium chloride	
Potassium hydroxide	Buffer agent
Potassium sulphate	Viscosity agent
Prussian Blue CI 77510	Inorganic pigment / colorant
Silver chloride	Additive
Silver CI 77820	Additive
Silver citrate	
Silver oxide	
Silver sulphate	Inorganic pigment / colorant
Sodium bicarbonate	Buffer agent
Sodium borate	Buffer agent
Sodium carbonate	Buffer agent
Sodium chloride	
Sodium fluoride	Ingredient for oral cavity hygiene – until 31 <sup>st</sup> December 2014
Sodium hydroxide	Buffer agent
Sodium magnesium silicate	
Sodium metasilicate	
Sodium monofluorophosphate	Ingredient for oral cavity hygiene – until 31 <sup>st</sup> December 2014
Sodium silicate	Buffer agent
Sodium sulphate	Agent for viscosity inspection
Solum diatomea (diatomaceous earth)	
Talc CI 77718	
Titanium dioxide CI 77891	Inorganic pigment / colorant / opacifier / UV filter
Tin oxide	
Zinc oxide CI 77947	Inorganic pigment / colorant / additive / UV filter – until 31st December 2014
Zinc sulphate	Antimicrobial agent / agent for product for the oral cavity hygiene

## Appendix V

### OTHER INGREDIENTS ALLOWED

These may be used in both ingredients and the finished product but only for the uses and conditions specified.

<i>Ingredient</i>	<i>Specific use and condition</i>
Absolutes, Concretes, Resinoids (extracted with other solvents than those listed in Appendix I)	Fragrance / Can not be certified as organic / Only for use in cosmetic products under natural certification
Benzoic acid and its salts	Preservative
Benzyl alcohol	Preservative
Carrageenan	Viscosity agent / gelling agent
Dehydroacetic acid and its salts	Preservative
Denatonium Benzoate and Tertiary butyl alcohol	Denaturing agent for alcohol / Where required by law
Lecithin	Emollient / emulsifier
Natural tocopherol (extracted with hexane)	Antioxidant
Salicylic acid and its salts	Preservative
Sorbic acid and its salts	Preservative
Tetra sodium glutamate diacetate	Chelating agent
Xanthan gum	Viscosity agent / gelling agent

Important: If other solvents need to be used than those listed in Appendix I, these solvents have to be recycled and completely removed or removed to technologically unavoidable and technologically ineffective concentrations in the finished product. In any event, there must be no use of aromatic, alkoxyated, halogenated, nitrogen- or sulphur-based solvents.

## Appendix VI

### OTHER INGREDIENTS, MOIETIES AND PROCESSES ALLOWED DURING THE TRANSITION PERIOD (60 months after this Standard comes into force)

<i>Ingredients</i>	<i>Specific use</i>
CI 75470 (Carmine from Cochineal)	Pigment
Silk amino-acids, hydrolyzed silk	Humectant, Hair conditioner, Skin conditioner – only for products under natural certification
Chitosan	Emollient, Film former – only for products under natural certification
Shellac, Shellac Cera	Emollient, Film former, Hair conditioner, Skin conditioner – only for products under natural certification

<i>Ingredients containing petrochemical moieties</i>	<i>Specific use</i>
Betaines	Amphoteric surfactant
Alkylamphoacetate	Amphoteric surfactant
Alkylglucosidecarboxylate	Anionic surfactant
Alkylcarbonate	Anionic surfactant
Carboxy methyl cellulose	Gelling agent / viscosity agent

Important: Those moieties must not exceed a total of 2% of the total finished product: In those ingredients containing petrochemical moieties the proportion of the petrochemical moiety is calculated as follows:

$$\left[ \frac{\text{(all petrochemical starting primary raw materials - petrochemical starting primary raw materials in excess)}}{\text{(all starting primary raw materials - all starting primary raw materials in excess)}} \right] \times 100.$$

<i>Processes on ingredients</i>	<i>Specific use and condition</i>
Gamma irradiation of clay types, kaolin and hectorite (Magnesium Aluminum Silicate), bentonite types, diatomaceous earth only where other sterilization techniques are insufficient	Sterilisation / Only for use in cosmetic products under natural certification

## Appendix VII

### European Cosmetics Standards Working Group members

#### **BDIH**

##### **Professional association / Standards setting body**

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#### **BIOFORUM**

##### **Professional association / Standards setting body**

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#### **COSMEBIO**

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#### **SOIL ASSOCIATION**

##### **Consumer association / Standards setting body**

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