

TECHNICAL STANDARD FOR THE CERTIFICATION OF ECO-ORGANIC & NATURAL ANIMAL CARE PRODUCTS

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1 INTRODUCTION

The Institute for Ethical and Environmental Certification (ICEA) has drawn up the following standards in order to define the expected requirements for animal care products with "organic" or "natural" claims and to allow all interested parties to access the certification of their products.

2 PURPOSE OF THE DOCUMENT

The purpose of this standard is to define the characteristics and voluntary certification requirements for animal care products that may use the declarations and marks:

- a) ORGANIC ANIMAL CARE
- b) NATURAL ANIMAL CARE

3 REGULATORY REFERENCES

- UNI CEI EN 45020:2007 – Standardisation and related activities - General vocabulary
- UNI ISO EN 14024:2001 – Type I environmental labelling
- UNI CEI ISO 17030:2006 – General requirements for third party marks of conformity
- UNI CEI EN ISO/IEC 17065:2012 – Requirements for bodies certifying products, processes and services
- UNI EN ISO 19011:2018 – Guideline for Management Systems Audits

4 SCOPE

The standard applies to products for animals intended to external surfaces (epidermis, hair system, teeth, etc.) in order to clean, perfume, change the appearance, protect, maintain in good condition or correct smells.

The standard is intended for pets.

Cosmetic products, medicines, veterinary products and medical devices (disinfectants, insect repellents, etc.) are not covered.

5 EVALUATION PRINCIPLES

The objectives of these standards are:

- To promote the use of natural raw materials from organic farming;
- To allow the use of ingredients of animal origin only if their production does not involve the killing of the animals themselves and provided that they have been bred in full compliance with animal welfare principles;
- To reduce the environmental impact of manufacturing processes;
- To ensure clear and non-deceptive information;
- To take measures to protect and monitor the use of compliance marks in accordance with the requirements of this standard.

6 RAW MATERIALS

ICEA products for animal care can include among their components:

1. Raw materials of vegetable origin
2. Raw materials of animal origin
3. Raw materials of inorganic origin
4. Raw materials derived from chemical synthesis processes
5. Water

6.1 General criteria for raw materials

6.1.1 Principle of precaution

If a product or process can have potentially dangerous effects and scientific evidence does not allow the risk to be determined with sufficient certainty, ICEA reserves the right not to authorise them.

6.1.2 Genetically Modified Organisms (GMOs)

The use of raw materials derived/containing Genetically Modified Organisms (GMOs) is prohibited, except for ingredients from biotechnology (e.g. enzymes, probiotics) produced by genetically modified microorganisms, provided that they are appropriately confined.

6.1.3 Nanomaterials

Nanomaterials are assessed according to the EU Cosmetic Regulation 1223/2009.

6.1.4 Raw material evaluation

- (a) The use of substances or preparations to which one of the following hazard indication codes or combinations has been assigned in accordance with EC Reg. 1272/2008 is not permitted.

Hazard indication	Description	
H300	Acute toxicity (oral), hazard categories 1 and 2	Lethal if ingested.
H310	Acute toxicity (dermal), hazard categories 1 and 2	Lethal for skin contact.
H330	Acute inhalation toxicity, hazard categories 1 and 2	Lethal if inhaled.
H340	Germ cell mutagenicity, hazard categories 1A and 1B	May cause genetic changes
H350	Carcinogenicity, hazard categories 1A and 1B	May cause cancer
H350i	Carcinogenicity, hazard categories 1A and 1B	May cause cancer if inhaled
H360F	Reproductive toxicity, hazard categories 1A and 1B	May damage fertility.
H360Df		May harm the foetus. Suspected of damaging fertility
H360FD		May damage fertility. May harm the foetus.
H360Fd		May damage fertility. Suspected of damaging the foetus.
H360D		May harm the foetus.
H370	Specific target organ toxicity (single exposure), hazard category 1	Causes damage to organs
H372	Specific target organ toxicity (repeated exposure), hazard category 1	Causes damage to organs
EUH070	Toxic by eye contact	

Hazard indication	Description	
H400	Dangerous for the aquatic environment - Acute danger, category 1	Very toxic to aquatic organisms.
H410	Dangerous for the aquatic environment - Chronic danger, category 1	Very toxic to aquatic organisms with long lasting effects.
H411	Dangerous for the aquatic environment - Chronic danger, category 2	Toxic to aquatic organisms with long lasting effects.
H412	Dangerous for the aquatic environment - Chronic danger, category 3	Harmful to aquatic organisms with long lasting effects.
H413	Dangerous for the aquatic environment - Chronic danger, category 4	May be harmful to aquatic organisms with long lasting effects.
H420	Dangerous for the ozone layer, hazard category 1	It damages public health and the environment by destroying the ozone layer of the upper atmosphere

- (b) In derogation from point (a), the use of essential oils classified with the hazard statement codes or combinations thereof listed in point (a) is permitted for a total maximum concentration of 0.3%.
- (c) In derogation from the provisions of point (a), the use of ingredients classified with the indication of danger H412 is permitted if individually present in quantities of less than 0.010 % w/w in the final product.
- (d) In derogation from point (a), the use of the following ingredients classified with the indication of danger H412 is permitted even if they are present in concentrations higher than 0,010 % w/w in the final product:
- surfactants
 - perfumes (maximum limit 0.8%)
 - peracetic acid and hydrogen peroxide used as bleaching agents.
- (e) The use in quantities > 0.1% w/w in the final product of substances or preparations to which one of the following risk phrases or combinations thereof has been assigned or may be assigned at the time of application for certification according to EC Reg. 1272/2008 is not allowed:

Risk code	Description	
H351	Carcinogenicity, Risk category 2	Suspected to cause cancer.
H361fd	Toxicity for the reproduction, Risk category 2	Suspected to impair fertility. Suspected to damage the foetus.
H361f		Suspected to impair fertility.
H361d		Suspected to damage the foetus.
H362	Toxicity for reproduction, supplementary category — Effects on breastfeeding or through breastfeeding feeding	It may be dangerous for breastfed children.
H371	Specific toxicity for target organs (single exposure), Risk category 2	It may damage the organs

- (f) The use of ingredients is not allowed, except for essential oils and enzymes, classified with the following hazard indication code according to EC Reg. n.1272/2008:

Risk code	Description	
H334	Airways sensitization, Risk category 1	It may provoke allergic or asthmatic symptoms and respiratory difficulties if inhaled.

- (g) The use of ingredients, with the exception of essential oils and perfuming substances, in quantities exceeding 0.3% w/w in the final product to which the following hazard indication code has been assigned in accordance with EC Reg. n.1272/2008 is not permitted:

Risk code	Description	
H317	Skin sensitization, Risk category 1	It may provoke a skin allergic reaction.

(h) All raw materials and mixtures shall comply with the following criteria:

Parameter	Criteria
Acute oral toxicity	LD50>2000mg/Kg
Aquatic toxicity	LC50 or EC50 or IC50>1mg/l
Relationship between biodegradability/eliminability and aquatic toxicity	Allowed only if: <70% and >100 mg/l >70% and >10 mg/l >95% and >1 mg/l

The above criteria must be evaluated according to the following methods:

- When subjected to one of the following test methods OECD 301A, OECD 301E, ISO 7827, OECD 302A, ISO 9887, OECD 302B, or ISO 9888, the percentage of degradation must be at least 70% within 28 days;
- When subjected to one of the following test methods OECD 301B, ISO 9439, OECD 301C, OECD 302C, OECD 301D, ISO 10707, OECD 301 F, ISO 9408, ISO 10708 or ISO 14593, the percentage degradation must be at least 60% within 28 days;
- If tested with OECD 303A test methods, the percentage of degradation must be at least 80% within 28 days.

The following categories of ingredients are exempt from this requirement:

- Essential oils;
- Preservatives, as toxicity is closely linked to its own functionality. Preservatives are permitted when they have bio accumulative potential with values < 500 BCF or < 4 log Pow;
- Substances and preparations, such as alkalis and acids, which do not meet this requirement due to their pH value;

(i) Substances of Very High Concern (SVHC) as defined in Article 59(1) of Regulation (EC) No 1907/2006 may not be used. Evidence (e.g. safety sheets, declarations) must be provided at the time of certification attesting the absence of all substances included in the substance list.

6.2 Raw materials of vegetable origin

The allowed raw materials of vegetable origin are:

- a) raw materials from organic farming certified according to EC Reg. 834/07 or equivalent standards (e.g. NOP, JAS, COR);
- b) raw materials from conventional agriculture only in cases where the certified ingredient cannot be found on the national market. Raw materials from conventional agriculture are allowed as long as they are not GMO or derived from GMO.

Products deriving from species at risk of extinction are not allowed and it is requested that they comply with the requirements of the International Trade Convention on Threatened Species of Wild Fauna and Flora (CITES); only species belonging to appendix II and III are allowed, considering the relevant limitations, which can be consulted from the link <http://checklist.cites.org/#/en>

6.3 Raw materials of animal origin

The allowed raw materials of animal origin are:

- a) raw materials from certified organic farming according to EC Reg. 834/07 or equivalent standards (e.g. NOP, JAS, COR);
- b) raw materials from conventional farming only in cases where the certified ingredient cannot be found on the national market.

Not allowed:

- a) raw materials of animal origin whose production involves the killing of the animals themselves. By way of derogation, raw materials of animal origin derived from the processing of food industry by-products shall be permitted;
- b) products derived from species at risk of extinction. It is requested that they comply with the requirements of the International Trade Convention on Threatened Species of Wild Fauna and Flora (CITES); only species belonging to Appendix II and III are allowed, considering the relevant limitations, which can be consulted from the link <http://checklist.cites.org/#/en>

6.4 Raw materials of inorganic origin

The permitted raw materials of mineral origin are listed in Appendix 1.

6.5 Raw materials derived from chemical synthesis processes

a) Surfactants

For surfactants, documentation is required to prove the plant origin of the alkylic chains used in the synthesis processes, so as to prove the natural origin of the raw materials supplying the carbon chain that distinguishes these molecules.

b) Other raw materials

Raw materials approved according to Cosmos evaluation criteria are allowed.

6.6 Water

Drinking water or demineralised or osmotized water can be used.

6.7 Palm oil and ingredients derived from palm oil

Palm oil, palm kernel and the ingredients listed below must be organic certified or in accordance with the Standard Roundtable on Sustainable Palm Oil (RSPO) at one of the following levels: Mass Balance, Certified Segregated Identity, Identity Preserved.

The following ingredients used in certified products must be certified:

- Palm oil
- Palm kernel oil
- Glycerine, cocamidopropyl betaine and coconut betaine
- Fatty acids: stearic acid, palmitic acid, myristic acid, lauric acid.
- Fatty alcohols: ethyl alcohol, cetearyl alcohol, stearyl alcohol, lauryl alcohol.
- Esters based on fatty acids or fatty alcohols: ethyl palmitate, ethyl phosphate, myristyl myristate,
- glyceryl (mono-) stearate and glyceryl oleate.
- Triglycerides: C8-C10 caprylic/capric triglyceride and C10-C18 triglycerides.

When a raw material is composed of a mixture of ingredients all included in the above list, compliance with RSPO will be required for all of them. If, on the other hand, a commercial mixture contains both some of the ingredients in the above list and other ingredients not included in the list (e.g. an extract) then none of the ingredients must be RSPO certified. This derogation is not valid if the raw material is mixed with water.

7 PRODUCTS

This Standard includes two levels of certification for finished products:

- ORGANIC ANIMAL CARE Products
- NATURAL ANIMAL CARE Products

7.1 Rules for the certification of ORGANIC ANIMAL CARE products

To obtain the ORGANIC ANIMAL CARE certification level it is necessary that at least 20% of the total product is organic.

Exceptions are rinse-off products, non-emulsified aqueous products and products with at least 80% minerals or mineral ingredients, for which at least 10% of the total product must be organic.

The calculation of the organic content of the product is given by the ratio between the sum of ingredients from organic farming and raw materials with organic content on the total ingredients net of water content according to the formula below.

$$\% \text{ organic content} = \frac{\sum (\% \text{ organic ingredients}) + \sum (\% \text{ organic content for raw materials made with organic ingredients})}{\sum (\text{all ingredients} - \text{water})}$$

An ingredient is considered organic if it is certified in accordance with EC Regulation no. 834/2007 or equivalent standard by an authorised and accredited certification body.

For raw materials produced with organic ingredients the actual organic content is considered, i.e. the weight of the as organic certified part on the total weight.

The weight of the support should not be taken into account when calculating the biological content.

7.2 Rules for the certification of NATURAL ANIMAL CARE products

To obtain the NATURAL ANIMAL CARE certification level, no minimum level of organic ingredients is required to be used. The use of organic ingredients is allowed.

The natural content of the product is calculated as follows:

$\% \text{ of natural origin} = (\text{weight of the whole product} - \text{weight of all non-natural and petrochemical ingredients}) / \text{weight of all ingredients} \times 100.$

The weight of the support should not be taken into account when calculating the natural content.

7.3 Accessories

The following criteria apply to accessories for the application of the product (e.g. wipes):

- for ORGANIC ANIMAL CARE products only certified organic cotton according to the main international certification schemes (GOTS; OCS100) is allowed.
- for NATURAL ANIMAL CARE products also certified non-organic cotton, lyocell and viscose may be used.

8 FILLING AND PACKAGING MATERIALS

The use of the following materials is prohibited:

- polyvinyl chloride (PVC) and other chlorinated plastics;
- polystyrene and other plastics containing styrene;
- materials or substances that contain, are derived, obtained or produced using genetically modified organisms;
- animal parts or substances produced by animals (e.g. leather and silk).

A declaration from the supplier/manufacturer must be provided to show that these requirements are met.

Only the following propulsive gases are permitted:

- air
- oxygen
- nitrogen
- carbon dioxide
- argon

Further details on materials are listed in Annex 2.

Only recyclable materials are permitted for primary packaging.

Some examples of correct application of the above criteria are:

1. label and cap of the same material as the bottle to allow correct recycling;
2. use of sprayers or monomaterial dispensers.

The secondary packaging material must be as small as possible, except when necessary depending on the characteristics of the product and the indication to the consumer.

9 LABELLING

Labels must comply with the mandatory sector standard (Regulation on classification, labelling and packaging (CLP- EC No. 1272/2008).

The phrase "topical product for animal use" must be indicated.

For the best consumer information, it is necessary to indicate the list of ingredients in descending order by weight and according to INCI nomenclature. Ingredients from organic farming must be associated with the phrase "from organic farming".

The percentage of organic and natural content of the finished product must be stated on the label.

It is allowed to report the presence of organic ingredients also in NATURAL ANIMAL CARE products as long as these claims are less prominent than the logo.

The claims on the label must be true.

Labels, graphics and information material relating to certified products must bear logos and wording that comply with these Standards and must be evaluated and approved by ICEA.

10 FINISHED PRODUCT MANAGEMENT SYSTEM

The company is required to implement a management system and adequate records that guarantee the traceability of ingredients, semi-finished and certified finished products at all stages of the production process.

The documentation to be collected and stored includes test reports on ingredients and products and documentation relating to the management of the production process.

Raw materials from organic farming and certified products must be correctly identified and stored so as to avoid any confusion or contamination of the products.

11 CONTROL METHOD

For the purpose of issuing the certificate and its annual maintenance, ICEA carries out inspections at the production, packaging and storage plants.

Inspections are conducted in accordance with the Control Plan with the aim of ensuring the compliance of the company's products and processes with the requirements set out in these Standards.

The Control has a sampling nature, can be with or without notice and is applicable during all phases of the company production processes implemented by the Client requesting certification.

The Control includes the Inspection of the company activity and the possible Sampling for the analytical test of the sample of matrix/product taken.

11.1 NUMBER/FREQUENCY OF INSPECTIONS

The type and intensity of the Controls is proportional to the Customer's characteristics (number and level of criticality of the production sites, number of products and any non-conformities and infringements detected).

In accordance with the Control Plan Requirements, ICEA ensures that:

1) at least one ordinary annual check is planned and carried out for all Clients under contract;

ICEA reserves the right to carry out additional Inspections (even unannounced) and/or to intensify the surveillance activity in case of serious non-conformities found during normal controls or reported by other interested parties.

11.2 TYPE AND CONDUCTION OF INSPECTIONS

In the start-up phase of certification, ICEA leads:

- a) the preliminary assessment of the application for certification to verify that:
 - the documentation is complete and correctly filled in;
 - the composition of the products is compliant;
 - the raw materials and their respective supply sources are compliant;
- b) The initial inspection has the purpose of:
 - ensure that the products for which certification has been requested are obtained in accordance with the requirements set out in these Standards;
 - ensure that the company's structures and management aspects comply with the requirements set out in these standards;
 - collect any product or raw material samples for testing or laboratory analysis.

During the entire period of validity of the certificate, annual surveillance inspections will be carried out.

The purpose of the surveillance inspection is to:

- verify that products placed on the market with references to the certificate maintain the conformity requirements;
- verify the maintenance of the adequacy of the structures and the organisation and management of the production process, as well as the full implementation of all the provisions of these standards;
- if changes have occurred in the product, the manufacturing process or the quality system, if they are likely to compromise the conformity of the product, check that they comply with this standard;
- verify that the granted trademarks are used on the product, in advertising and/or in catalogues in accordance with the Regulations for the use of the trademark;
- Take samples of product and/or raw materials, if deemed necessary for the conformity assessment of products, for laboratory testing or analysis.

11.2 ELEMENTS SUBJECT TO ICEA INSPECTIONS

The inspections regard the following elements:

- Product/process/service related quality system;
- Document and data control;
- Provision and supplier qualification;
- Identification and traceability of the product and raw materials;
- Process control;
- Handling, storage, packaging, preservation, feeding and delivery;
- Non-compliant product check;
- Corrective and preventive actions;
- Complaints Management;
- Internal quality inspections;
- Staff training

12 METHOD OF DECLARATION OF CONFORMITY

ICEA marks and declarations of conformity with these standards are only applicable to certified products.

12.1 CERTIFICATION MARK

Licensees may use one of the following ICEA certification marks in relation to the type of product being certified. The certification mark must always refer clearly to the certified product and comply with the standards.



The use of the above logos is granted to products that meet the requirements of this standard and have obtained compliance for certification.

If the company also produces other non-certified products, the distinction must be clear so that the consumer can immediately distinguish between certified and non-certified products.

ANNEXES

Annex 1: ALLOWED INGREDIENTS OF MINERAL ORIGIN

Only the mineral ingredients listed below may be used and must comply with the relevant legislation.

Mono-, di-, di-, tri- or poly- etc. salts of the listed "mineral ingredients" are also allowed.

Aluminium Hydroxide
Aluminium Iron Silicates
Alumina
Aluminium Sulphate
Ammonium Sulphate
Barium Sulphate
Calcium Aluminium, Borosilicate
Calcium Carbonate, CI77220
Calcium Chloride
Calcium Fluoride
Calcium Hydroxide
Calcium Sodium
Borosilicate
Calcium Sulphate
Cerium Oxide
CI 77163 Bismuth Oxychloride
CI 77288 Chromic Oxide
CI 77289 Chromic Oxide hydrated
CI 77489 Iron Oxides
CI 77491
CI 77492
CI 77499
CI 77510 Prussian Blue
CI 77742 Manganese Violet
CI 77745 Trimanganese Bis(orthophosphate)
Copper Copper
Copper Oxide
Copper Sulphate
Diatomaceous Earth, Diatomaceous Earth Calcined
Dicalcium Phosphate Dihydrate
Ferrous Sulphate
Gold
Hydrated Silica
Hydroxyapatite
Iron Hydroxide
Magnesium Aluminium Silicate
Silicic Acid, Aluminium
Magnesium Salt
Magnesium Carbonate, CI 77713
Magnesium Carbonate Hydroxide
Magnesium Chloride
Magnesium Hydroxide
Magnesium Oxide, CI77711
Magnesium Phosphate
Magnesium Silicate Silicic Acid, Magnesium Salt
Talc,

Magnesium Sulphate
Mica, CI 77019
Potassium Alum
Potassium Carbonate
Potassium Chloride
Potassium Hydroxide
Potassium Iodide
Potassium Sulphate
Potassium Thiocyanate
Silica
Silver Silver
Silver Chloride
Silver Oxide
Silver Sulphate
Sodium Bicarbonate
Sodium Borate
Sodium Carbonate
Sodium Chloride
Sodium Fluoride
Sodium Hydroxide
Sodium Magnesium Silicate
Sodium Metasilicate
Sodium Monofluorophosphate
Disodium Fluorophosphate
Sodium Silicate Silicic Acid, Sodium Salt
Sodium Sulphate
Sodium Thiosulfate
Titanium Dioxide, CI 77891
Tin Oxide CI 77861
Ultramarines, CI 77007
Zinc Carbonate CI 77950
Zinc Oxide, CI 77947
Zinc Sulphate

Annex 2: PACKAGING MATERIALS

Fabric packaging and supports must meet the criteria for packaging.

Accessories sold with the products (e.g. brushes or applicators etc.) are not considered packaging to be checked.

List of accepted materials (not exhaustive):

- CA - Cellulose acetate
 - Cellulose
 - Ceramics
 - Glass
 - Metals like: Aluminium, iron, stainless steel, etc.
 - Paper / Cardboard
 - PE – Polyethylene
 - PET - Polyethylene terephthalate
 - PETG - Polyethylene glycol terephthalate
 - PLA - Polylactic acid
 - PP - Polypropylene
 - Rubber (of natural origin)
 - Wood
- Any other material of 100% natural origin (non-GMO).

If a material is not among those listed above, the technical documentation for revision can be evaluated.