

This English document was not actually used for guideline and just for translation of original JCIA guideline.

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To members of Japan Cosmetic Industry Association

Kazumasa Hanagata
Chairman of the Distribution Committee,
Japan Cosmetic Industry Association (JCIA)

**Regarding JCIA Guideline on Labelling of Natural, Natural-origin, Organic and
Organic-origin Contents According to ISO 16128**

The international standard for natural and organic cosmetic ingredients and products, which had been discussed by the International Organization for Standardization (ISO) Technical Committee in charge of cosmetics (TC217), was published as ISO 16128. This publication has two parts: ISO 16128-1 (Part 1: Definitions for ingredients), which was published in February 2016, and ISO 16128-2 (Part 2: Criteria for ingredients and products), which was published in September 2017. ISO 16128 allows us to calculate indexes/contents related to natural and organic ingredients/products in cosmetics.

While ISO 16128 provides definitions (calculation procedures), it does not provide how to label natural and organic contents on cosmetic products. Therefore, the Japan Cosmetic Industry Association (JCIA) has established the following guideline regarding label on natural and organic contents, in order to make consumers easily understand information related to natural and organic contents of cosmetic products.

We hope our members to utilize JCIA guideline, when they label natural and organic contents according to ISO 16128 on cosmetic products.

**Guideline on Labelling of Natural, Natural-origin, Organic and Organic-origin Contents
According to ISO 16128**

1. Scope

(1) This guideline applies to cases where the *natural content*, *natural origin content*, *organic content*, and *organic origin content* of products that are defined in and calculated on the basis of ISO 16128-1 and ISO 16128-2 (hereafter referred to as ISO 16128) are labelled on cosmetic products, free samples of cosmetic products, and advertisements for cosmetics.

(2) The word “cosmetics” in this guideline refers to cosmetics (excluding toothpaste, soap, and hair dye) specified in Article 2(3) of the Pharmaceuticals and Medical Devices Act and medicated cosmetics (excluding medicated soap), underarm deodorants, talcum powder, hair restorers (hair tonics), and depilatories, which are among the quasi-drugs specified in Article 2(2) of the Act.

2. Labeling requirements

(1) The *natural content*, *natural origin content*, *organic content*, and *organic origin content* of cosmetic products that are defined in ISO 16128 shall be translated to Japanese as follows:

natural content:

natural origin content:

organic content:

organic origin content:

These terms will hereafter be collectively referred to as *content*.

(2) The content shall be calculated on the basis of definitions and calculation procedures provided in ISO 16128 and shall be labeled in percentage form.

(3) The label shall state explicitly, in the vicinity of the content, whether the calculation includes formulation water or excludes formulation water. When the calculation includes formulation water, the percentage of formulation water in the content can be also labeled.

(4) The label shall state explicitly, in the vicinity of the content that the content complies with ISO 16128.

(5) Because ISO 16128 doesn't define *natural cosmetic products* or *organic cosmetic products*, labels such as “Natural cosmetic products in compliance with ISO 16128” and “Organic cosmetic

products (ISO 16128)” shall not be provided.

(6) With complying with the Act and other relevant regulations, labels and advertisements that can mislead consumers into believing the relevance between the content and the safety, efficacy, quality, or function of the product, shall not be provided.

3. Materials for justification

Providing cosmetic products with any contents, the following materials for justification for labeled content for each product shall be prepared and kept.

(1) Ingredients

a. Natural and natural origin ingredients

(i) For every ingredient purchased, a certificate issued by the manufacturer/supplier of the ingredient and such shall be kept.

A certificate shall include the index* of the ingredient. It can also include the origin, manufacturing process, and the grounds for calculation of the index of the ingredient, if necessary.

* The index of the ingredient shall be expressed from 0 to 1.

Such information can be added to the existing documents about ingredient specifications, which have already been provided by manufacturers/suppliers.

(ii) For an ingredient produced by the cosmetic product company itself, a production record and cultivation record, and, if necessary, the grounds for calculation of the index of the ingredient shall be kept.

b. Organic and organic origin ingredients

(i) For every ingredient purchased, the following documents shall be obtained from the manufacturer/supplier of the ingredient and kept.

- For a domestic ingredient, copies of an organic certificate for animals or plants used as a starting material of the ingredient, in accordance with the Japan Agricultural Standard (JAS) issued by the Ministry of Agriculture, Forestry and Fisheries (MAFF), or an equivalent organic certification

- For an imported ingredient, copies of an organic certificate for animals or plants used as a starting material of the ingredient, stipulated by the law of the country of origin, or an equivalent organic certification

- The index of the ingredient. It can also include the origin, manufacturing process, and the grounds for calculation of the index of the ingredient, if necessary.

Such information can be added, to the existing documents about ingredient specifications, which have already been provided by manufacturers/suppliers.

(ii) Ingredient produced by the cosmetic product company itself

- Copies of an organic certificate for animals or plants used as a starting material of the ingredient, in accordance with JAS issued by MAFF or an equivalent organic certification shall be kept.
- A cultivation and production record certifying that the ingredient is *organic* or *organic origin* shall be kept. And, if necessary, the grounds for calculation of the index of the ingredient shall be also kept.

c. Examples of certificates for ingredients

Examples of certificates (*natural* or *natural origin*) : see Appendix 1

Examples of certificates (*organic* or *organic origin*) : see Appendix 2

(2) Products

With following JCIA voluntary standard “Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices”, production records that can justify for the content of the product shall be prepared and kept.

Appendix 1

Examples of certificates (*Natural/Natural origin*)

This ingredient conforms to be a natural ingredient/derived natural ingredient according to ISO 16128.

1. Name of the ingredient (Trade name)

2. Name of the component (s)

3. Essence of the ingredient

This ingredient is a 20% aqueous solution of XXX, which is obtained by extraction/concentration/separation/etc. of...

4. Natural index/Derived Natural Index of the ingredient

Natural index: 0.8

Derived Natural Index: 0.92

The index above includes 0.8 of water*

* Formulation water defined by ISO 16128.

5. Note

(Describe the grounds for the index of the ingredient, such as its origin, composition, chemical formula, production method, and calculation, as required.)

MM/DD/YYYY

XXX Corporation

Examples of certificates (*Organic/Organic origin*)

This ingredient conforms to be an organic/derived organic ingredient according to ISO 16128.

1. Name of the ingredient (Trade name)

2. Name of the component (s)

3. Essence of the ingredient

This is an essential oil obtained by expressing the peel of XXX, which is organically cultivated through an organic agricultural method based on organic certification standard, in a farm certified as an organic farm by YYY association.

4. Organic index/Derived Organic Index of the ingredient

Organic Index: 1

Derived Organic Index: 1

5. Certification acquired

ZZZ farm is certified as an organic farm by YYY association

6. Production method (Cultivation method)

Organic agricultural method based on JAS organic certification

7. Note

(Describe the grounds for establishing the index of the ingredient, such as calculation, as required.)

MM/DD/YYYY

QQQ Corporation

An organic certificate for animals or plants used as a starting material of the ingredient, in accordance with a Japan Agricultural Standard (JAS) issued by the Ministry of Agriculture, Forestry and Fisheries (MAFF), or an equivalent organic certification is attached.