



DRAFT

HEALTH AND BEAUTY CARE STANDARDS

September 2004

INTRODUCTION

- **Why standards have been developed**

NASAA has developed Standards for the labelling of Organic Health and Beauty products in response to a perceived need to provide consumers with an independent verification system for the use of the word “organic” in relation to this group of consumables. These Standards will define requirements for the use of the NASAA label on health and beauty care products to provide a credible guarantee of organic integrity to the consumer.

There are currently no laws, international or national, that govern the use of the term “organic” in relation to health and beauty care products. As a response to this situation, NASAA will provide the benchmark for transparent and safe practices in relation to this developing industry.

This is a new area of compliance and regulation for NASAA and therefore the evolution of this Standard will be considered prospective and will be subject to refinement as knowledge and market conditions improve. All operators must be familiar with, and demonstrate compliance, to relevant sections of the NASAA Organic Standards.

- **Scope of the standards**

These Standards have been developed to cover products that are made from organic ingredients and include herbal, toiletries, body care products and cosmetics. They include both “therapeutic” and non therapeutic ingredients.

It is the responsibility of all applicants to comply with, and understand the regulatory requirements for the production of these consumables as defined in these Standards to permit the use of the NASAA name and logo.

- **Legislative context of cosmetics – when is a cosmetic a therapeutic good**

The Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulation 1991 is the legislative framework within Australia that defines a cosmetic as a “substance or preparation intended for placement in contact with any external part of the human body, including:

- a) the mucous membranes of the oral cavity and
 - b) the teeth
- with a view to:
- c) altering the odours of the body or
 - d) changing its appearance or
 - e) cleansing it or
 - f) maintaining it in good condition or
 - g) perfuming it or
 - h) protecting it”

Exempt cosmetic products under the above legislation are

- a) therapeutic goods within the meaning of the Therapeutic Goods Act (TGA) 1990 or
- b) free samples of a cosmetic product or
- c) testers of a cosmetic product

It is the responsibility of operators to be familiar with, and comply with, the relevant legislative framework. Verification of compliance with the TGA or Trade Practices

(Consumer Product Information Standards) (Cosmetics) Regulation 1991, will need to be demonstrated to NASAA, unless otherwise excluded.

Some ingredients used in cosmetics and toiletries, including perfumes and fragrances, may be classified as industrial chemicals. Any chemical substances used in a cosmetic product must be listed on the Australian Inventory of Chemical Substances (AICS) where relevant. Naturally occurring chemicals, being a substance that is extracted by manual, mechanical or gravitational means or dissolution in water or flotation or a process of heating for the sole purpose of removing uncombined water are excluded from AICS.

AIMS AND PRINCIPLES

In addition to the “Principles and Aims” of the NASAA Organic Standard, organic health and beauty care products shall:

- a) Be primarily composed of certified organic raw materials
- b) Be minimally processed in a manner consistent with the product to preserve its natural properties
- c) Be of high quality
- d) Cause minimum pollution and damage to the environment in their manufacture, use and disposal
- e) Be clearly labelled to provide the consumer with accurate information
- f) Not include harm to animals or involve testing on animals

1.0 RAW INGREDIENTS

General Principle

Standards:

- 1.1 All agricultural raw materials shall be certified organic in accordance with the NASAA Organic Standards.

Derogation:

Where organic sources of agricultural products are unavailable their substitute shall be a conventional agricultural product¹.

- 1.2 Agricultural raw materials that are subject to processing or preparation shall be done in accordance with the requirements of Section 9 of the NASAA Organic Standard. Specific requirements for health and beauty care products are outlined in Section 2 and 3 below.
- 1.3 The use of GMOs, or their derivatives as ingredients is prohibited.
- 1.4 The use of animal products is prohibited where harm, including death, is caused to the animal.
- 1.5 Colour additives, flavours and fragrances shall be certified organic and their manufacture and use subject to all other relevant requirements of this Standard. The use of colours, flavours and fragrances of non organic or synthetic nature are prohibited.
- 1.6 Current certificates shall be maintained for all certified organic ingredients.

2.0 NON AGRICULTURAL INGREDIENTS

¹ Note that the inclusion of agricultural conventional products is to prohibit the substitution with synthetic alternatives

General Principle

The use of non agricultural ingredients shall be based on their essential need.

Standards

- 2.1 The use of minerals that are unmodified and not subject to chemical processes are subject to approval from NASAA. The following minerals are acceptable:
 - Sand
 - Kaolin clay
 - Salt
 - Pumice
- 2.2 The use of non agricultural ingredients shall comply with the requirements of Annex 4 “Acceptable additives of Non Agricultural Origin” as defined in the NASAA Organic Standard.
- 2.3 The use of talc is prohibited.
- 2.4 The use of ascorbic acid and tocopherol are permitted for use as anti oxidants.

3.0 EXTRACTION AND PROCESSING METHODS OF RAW INGREDIENTS

General Principle

Extraction and processing methods of raw materials, where employed, shall preserve the nature of the product. Agricultural solvents used in extraction processes should be derived from certified organic sources.

Standards

- 3.1 The following extraction methods are permitted:
 - Cold extraction
 - Pressure and pressing
 - Distillation using water or steam
 - Percolation
- 3.2 Extraction using certified organic solvents such as alcohol, oils, glycerine, honey, and sugar are approved for use.
- 3.3 CO₂, and potable water are approved extraction solvents of non organic source.
- 3.4 The following extraction solvents are prohibited:
 - Mineral oils
 - Benzene
 - Hexane
 - Propylene glycol
 - Butylene glycol
 - Petroleum derived solvents
 - Non agricultural solvents other than those listed in 2.3 above
- 3.5 The use of Ionising radiation, electron beaming and GMOs is prohibited.

4.0 MANUFACTURING PROCESSES

General Principle

The manufacture of organic health and beauty care products are designed to preserve the essential characteristics of ingredients and minimise environmental impacts.

Standards

- 4.1 The use of biological, mechanical and physical processing methods are permitted.
- 4.2 Biological processing methods that use GMOs or their derivatives are prohibited.
- 4.3 Hydrogenation² of oils is prohibited.
- 4.4 The use of chemical processing methods and surfactants shall be approved on the basis of a full technical report being submitted to NASAA addressing the following criteria:
 - Biodegradability
 - Toxicity
 - Necessity
 - Purpose
- 4.5 The following chemical (surface active agent) processes are prohibited for use:
 - Sulphonation³, ethoxylation⁴ and propoxylation

5 PACKAGING

General Principle

Packaging of health and beauty care products shall be strictly necessary and chosen as a result of their relative benign environmental impact, and ability to be recycled. Packaging material shall not provide a medium of contamination to the enclosed product.

Standards

² Hydrogenation is where oil undergoes heat and or chemical extraction processes to remove the oil from the seed and to clarify and deoderise it. This process denatures the oil and changes the molecular structure

³ Sulphation and sulphonation are the most widely used processes for the production of synthetic anionic surface active agents derived from a wide range of synthetic and natural products. Although the original derivatising agent, sulphuric acid, is still used in very basic processes or for specialized applications, sulphur trioxide is the reagent of choice for high volume production of the common anionic surfactants

⁴ Ethoxylated and Propoxylated surfactants and emulsifiers contain either ethylene oxide, propylene oxide or a combination of both. Ethoxylated materials usually end in "eth" as in Laureth, Myreth, etc. Ethoxylated ingredients may also be listed as PEG, POE or contain the word "ether" on a product label. Ethoxylated ingredients are generally used to increase the water solubility or emulsifying ability of a raw material. In the process of ethoxylation, a by-product called 1,4 dioxane can be released. The problem lies in 1-4 dioxane, which is recognized by the FDA (USDA) as a very powerful carcinogen, at very low levels. Harsh surfactants may inhibit the activity of skin cell enzymes, breaking the Membrane Coating Granules (MCG) found in the lower horny layers of skin. These side-effects reduce the water-binding capacity of skin, and contribute to dysfunctional keratinization (growth) of skin cells. The result can be skin that doesn't form properly, looks dull and dry, and even chaps and peels

- 5.1 Packaging must comply with the requirements of section 9.5 of the NASAA Organic Standard.
- 5.2 Packaging materials must not be capable of transmitting contaminants to food, nor must the adhesives or inks used on them
- 5.3 Organic produce shall not be packaged in reused bags or containers that have been in contact with any substances likely to compromise the organic integrity of product or ingredient placed in those containers.
- 5.4 All final packaging materials used must be food grade, clean, new or as new and of suitable design to protect the organic integrity of the product during transport and display.

6.0 LABELLING

General Principle

Labelling shall convey clear and accurate information to the consumer about the product and its constituent ingredients.

Standards

- 6.1 Labelling must comply with relevant legislative requirements.
- 6.2 Products shall be labelled as “organic” provided a minimum of 95% of the constituent ingredients (excluding salt and water⁵) are certified organic.
- 6.3 Products shall be labelled as “made with organic ingredients” in the product description where a minimum of 70% of the constituent ingredients (excluding salt and water) are certified organic. Use of the NASAA label is not permitted.
- 6.4 The percentage of organic content in each functional ingredient on the product shall be included on product labelling.
- 6.5 Where ingredients have been made by chemical processes, such ingredients shall only be described, or otherwise suggest, “made with organic ingredient(s)”. Labelling shall not indicate that the ingredient is “organic”.

⁵ The calculation of organic ingredients will be quite complex. E.g. should floral waters be excluded from the percentage organic ingredient. Should the final product calculation take into account the percentage organic content for each ingredient. As an example, an ingredient could be made from a mixture of organic and non organic ingredients (i.e. aloe vera is extracted using sodium hydroxide. Aloe vera constitutes 92% and NaOH constitutes 8%. The actual percentage of this ingredient in the product is 85%. The other final ingredients in the product are organic herbs (10%) and organic essential oils (5%). Therefore the total organic component of the ingredient is NOT 100%. It will be $92 \times 85/100 = 78.2\%$ (aloe vera) + 10% herbs + 5% essential oils = 93.2%. The product CAN NOT be labelled as “organic” only “made with organic ingredients”?

ANNEX 1 - DEFINITIONS

Anti Microbial Agents: ingredients that prevent or retard microbial growth and thus protect cosmetic products from spoilage.

Emulsifier: A substance which can be used to produce an emulsion out of two liquids that normally cannot be mixed together (such as oil and water). Emulsifiers are used in health and beauty care products

Ingredient: A substance that makes up part of the formulation of a product. Where an ingredient is itself composed of sub ingredients, such sub ingredients shall be considered in the final calculation of organic content of the finished product.

Preservative: A substance incorporated to prevent growth of microorganisms (refer to anti microbial agents). Organic preservatives include grapefruit seed extract

Raw Material: The original plant or animal material which is used to produce therapeutic or functional ingredients by extraction or other permitted processes.

Surfactant: a material that can greatly reduce the surface tension of water when used in very low concentrations. Contribute to the foaming and lathering properties of health and beauty care products.

Therapeutic Good: A 'therapeutic good' is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use, unless specifically excluded or included under Section 7 of the Therapeutic Goods Act 1989.

For the purposes of evaluation and assessment, a therapeutic good is a product for use in humans that is used in, or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury;
- influencing inhibiting or modifying a physiological process;
- testing the susceptibility of persons to a disease or ailment;
- influencing, controlling or preventing conception;
- testing for pregnancy; or
- replacement or modification of parts of the anatomy.

ANNEX 2 – Prohibited Products (this list is not exhaustive)