



Certech Registration Inc.



International Organic Standard – Natural and Natural Organic Cosmetic Certification

Certech Registration Inc.
260 Edgeley Blvd., Unit 4,
Vaughan, Ontario
L4K 3Y4
www.certechregistration.com

All rights reserved. Unless otherwise specified, no part of this standard may be reproduced or utilized in any form or by any means without permission in writing from Certech Registration Inc at the address shown above

Index

Number	Subject	Page
	Cover Page	1
	Index	2
1	Introduction	3
2	Scope and references	3
2.1	Scope	3
2.2	References	3
3	Definitions	3
4	Organics Management system	4
4.1	General requirements	4
4.2	Documentation requirements	4
4.3	Document Control	4
4.4	Control of records	4
4.5	Management responsibility	5
4.6	Planning	5
4.7	Personnel Requirements	5
4.8	Infrastructure and work environment	5
4.9	Review of requirements (legal and other) related to the product and packaging	6
4.10	Design and development	6
4.11	Purchasing	6
4.12	Verification of purchased product	6
4.13	Production Control	6
4.14	Rules on the ingredients and the composition of the finished product	7
4.15	Labelling	8
4.16	Preservation of product	8
4.17	Calibration	9
4.18	Monitoring and measurement of product	9
4.19	Nonconformance corrective and preventive action	9
Add 1	Acceptable ingredients	10
Add 2	Unacceptable ingredients	10
Add 3	Acceptable processes	11
Add 4	Unacceptable processes	12
Add 5	Certech audit processes	13
Add 6	Certech Registered Logos	14

1 INTRODUCTION

2 SCOPE AND REFERENCES

2.1 SCOPE

2.1.1 This document defines the criteria for organizations seeking to obtain Certech’s Natural, or Natural Organics Cosmetic approvals. Certech’s approach is limited to establishing that cosmetics are produced using certified ingredients (Certech does not certify ingredients) in an environment, using process, under controls that will assure the end customer that product is genuinely Natural Cosmetic or Natural Organic Cosmetic.

2.2 REFERENCES

The requirements specified within the following documents have been used to develop this standard. Reference to these documents does not indicate automatic conformance or compliance with all requirements specified within the referenced documents.

- 2.2.1 Consumer Packaging and Labelling Act
- 2.2.2 Canadian Food and Drugs Act
- 2.2.3 US Code of Federal Regulations (CFR). Title 7 Part 205 Natural Organic Program
- 2.2.4 FDA/CFSAN Cosmetics Good Manufacturing Practice guideline
- 2.2.5 CAN/CGSB-32.310-2006 Organic Production Systems General Principles and Management Standards
- 2.2.6 EEC Regulation number 2092/91
- 2.2.7 California Health and Safety Code, Article 7 “The California Organic Products Act of 2003”
- 2.2.8 ISO 9001 - Quality Management System – Requirements
- 2.2.9 ISO 14001 – Environmental Management Systems - Requirements

3.0 DEFINITIONS

Batch	A defined quantity of semi-finished or finished products, manufactured during the same series of operations of production, made from the same ingredients, stored at the same time, in the same conditions.
Contaminant	A substance not naturally present in the raw material or in ratios superior to those existing naturally and leading to a pollution (persistence, residues), and possibly to toxicity risks, i.e. heavy metals, hydrocarbons, pesticides, dioxins, radioactivity, GMO, mycotoxins, medicinal residues, nitrates, nitrosamines
Ingredients	All substances used in the preparation of the product (intentional or residual from processing).
Ingredient certified as Organic	Any product, coming from a plant or animal production, complying with the CAN/CGSB-32.310-2006 Organic Production Systems General Principles and Management Standards. The water added during the manufacturing of the finished product is deemed a natural ingredient.
Ingredient of natural origin	All natural ingredients processed following the permitted chemical processes as listed in this Standard and meeting the quality criteria also defined in this Standard
Natural	Existing in, or formed by nature; not artificial
Natural Cosmetic	All cosmetic products made out of natural ingredients (≥ 95%)

Natural ingredient/Raw Material	Any plant, animal or mineral product, directly coming from agricultural production, from harvest or from working, unprocessed or extracted by the exclusive means of the physical processes listed in Addendum 3, and meeting the quality criteria as defined in this Standard. Water added during the manufacturing of the finished product is deemed to be a natural ingredient.
Organic	Grown, cultivated and stored without the use of chemical fertilizers, herbicides, pesticides, fumigants and other toxins
Primary packaging	The products' original package, with its seal
Production	Group of operations carried out in the factory or the laboratory, for obtaining, conditioning and labeling the products targeted by these Standards
Range of products	Group of products, possessing common or similar characteristics, and which can be grouped together for planning and/or marketing purposes.
Secondary packaging	Any other container different from the original one

4 ORGANICS MANAGEMENT SYSTEM

4.1 GENERAL REQUIREMENTS

4.1.1 The organization shall establish, document, implement, and maintain effective control of its natural/organic cosmetic production in accordance with the requirements of this Standard.

4.2 DOCUMENTATION REQUIREMENTS

4.2.1 The organic management system documentation shall include:

- a) A description of the main elements of the organic management system
- b) Documents, including records, required by this Standard, and
- c) Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of processes that relate to its organic products

4.3 DOCUMENT CONTROL

4.3.1 Documents required by the organic management system and by this Standard shall be controlled. The organization shall establish, implement and maintain procedures to:

- a) Approve documents prior to use,
- b) Review, revise as necessary and re-approve documents,
- c) Ensure that changes and the current revision status of documents are identified,
- d) Ensure that applicable versions of documents are available where needed,
- e) Ensure that documents remain legible,
- f) Ensure that documents of external origin are identified and their distribution controlled, and
- g) Prevent the unintentional use of obsolete documents and apply suitable identification to them if they are retained for any reason.

4.4 CONTROL OF RECORDS

4.4.1 The organization shall maintain records to demonstrate conformity to the requirements of its organic management system, applicable legislation, and this Standard, and the results achieved. The organization shall have processes for the identification, storage, protection, retrieval, retention and disposal of records. Records shall be and remain legible, identifiable and traceable.

4.4.2 Records shall as a minimum be retained for:

- a) Raw materials, primary packaging materials, each lot/batch (quantity, type, processing, handling, transferring, holding, filling, sampling, controlling, adjusting, and reworking, disposition of rejection)
- b) Certification marks for finished goods
- c) Test results
- d) Sampling, controlling and adjusting
- e) Finished product sampling, lab controls, test results and control status
- f) Distribution records

As a minimum, required records will be retained for expected product life, plus 3 years or any applicable time lines dictated by local / government authorities

4.5 MANAGEMENT RESPONSIBILITY

4.5.1 Management shall ensure the availability of resources necessary to establish, implement, and maintain the natural/organic cosmetics production. Resources include human resources, specialized skills, organizational infrastructure, technology and financial resources. Roles, responsibilities and authorities shall be defined, documented and communicated in order to facilitate effective management.

4.5.2 A member of management shall be appointed to communicate with Certech Registration regarding certification and any changes in production, processes or ingredients

4.6 PLANNING

4.6.1 The organization shall plan and develop the processes needed for natural/organic cosmetics production. In planning natural/organic cosmetics production, the organization shall determine the following, as appropriate:

- a) The need to establish processes, documents, and provide resources specific to the product;
- b) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- c) Records needed to provide evidence that the natural/organic cosmetics production processes and resulting product meet requirements.

4.7 PERSONNEL REQUIREMENTS

4.7.1 The organization shall ensure that any person performing tasks for it or on its behalf that have the potential to adversely affect the product are competent on the basis of appropriate training, education, or experience, and shall retain related records. The organization shall identify training needs associated with its natural/organic products. It shall provide training or take other action to meet these needs, and shall retain associated records. The organization shall ensure persons working for it or on its behalf are knowledgeable of

- a) The importance of conformity with the natural/organic program and with the requirements of the management system,
- b) The potential impact on product conformity associated with their work, and the benefits of improved personal performance,
- c) Their responsibilities in achieving conformity with the requirements of the natural/organic management system, and
- d) The potential effects of departure from procedures.

4.8 INFRASTRUCTURE AND WORK ENVIRONMENT

4.8.1 The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable. At minimum the following will be considered:

- a) Unobstructed placement of equipment
- b) Orderly storage of materials
- c) Cleaning and maintenance
- d) Surfaces kept clean and in good repair
- e) Floors, walls and ceiling smooth and easy to clean
- f) Fixtures, ducts and pipes – not contaminating product
- g) Sufficient lighting
- h) Suitable sanitary facilities
- i) Equipment and utensils – material & workmanship prevent build-up and corrosion
- j) Equipment stored in condition to prevent contamination
- k) Equipment cleaned and sanitized

4.9 REVIEW OF REQUIREMENTS (LEGAL AND OTHER) RELATED TO THE PRODUCT AND PACKAGING

4.9.1 The organization shall implement and maintain procedures:

- a) To identify and have access to the applicable legal requirements and other requirements applicable to its products
- b) To determine how these requirements apply to natural/organic products. The organization shall ensure that applicable legal requirements are taken into account in production of its natural/organic products.

4.10 DESIGN AND DEVELOPMENT

4.10.1 The design process shall ensure that the final formulation/specification includes only natural/organic ingredients as applicable and that the final formulation is documented. Design shall include review, testing as validation requirements.

4.10.2 Design formulation/specification shall be available to personnel performing manufacturing processes

4.10.3 Changes in design must be subject to re-qualification and must include communication with Certech Registration regarding changes.

4.11 PURCHASING

4.11.1 Organizations shall ensure that ingredients are purchased only from independently certified natural/organic sources.

4.11.2 All organic purchases shall be accompanied by a certificate of organic origin

4.11.3 Suppliers of natural/organic ingredients shall be evaluated prior to use to ensure that appropriate qualifications and certifications are in place

4.12 VERIFICATION OF PURCHASED PRODUCT

4.12.1 All purchased product shall be subjected to verification activities prior to being used on any certified products

4.13 PRODUCTION CONTROL

4.13.1 Strict configuration control will be established for all certified products. No changes to

ingredients will be accepted without re-qualification by Certech Registration

4.13.2 Production control shall ensure as a minimum:

- a) Documented instructions/requirements/methods
- b) Document formulations
- c) Approved ingredients and materials
- d) Second check for ingredient/measure
- e) Process status
- f) Equipment clean and in good repair
- g) Use of acceptable cleaning/sanitizing agents
- h) Weighing and measuring of raw materials checked by second person
- i) Suitable identification on containers
- j) Batch/lot controls and identification
- k) Wearing suitable clean/non contamination clothing
- l) No food, drink or alcohol

4.14 RULES ON THE INGREDIENTS AND THE COMPOSITION OF THE FINISHED PRODUCT

4.14.1 All ingredients shall demonstrate conformity to this standard

4.14.2 The ratios of ingredients in the finished product defined below takes into account the importance of the amount of added water included in the formulation of the cosmetic. Water is an ingredient of natural origin and is non-certifiable Organic.

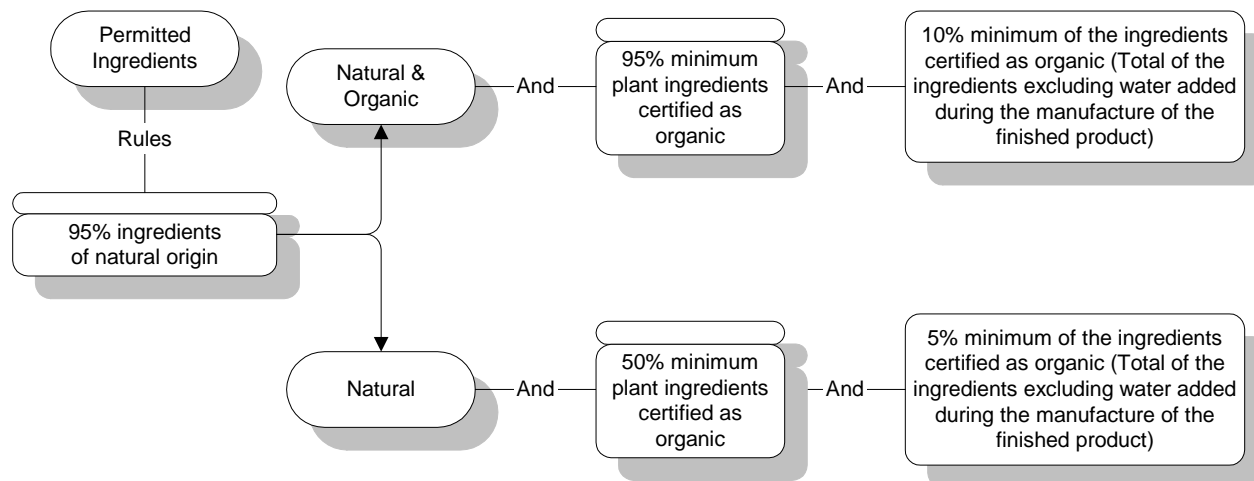
4.14.3 The quantity of natural ingredients or ingredients of a natural origin in the finished product must be a minimum of 95 % of the total ingredients.

4.14.4 The quantity of ingredients from pure synthesis in the finished product cannot be greater than 5% of the total ingredients. Ingredients must comply with the Acceptable Ingredients List in Addendum 1.

4.14.5 The natural plant ingredients must originate directly or after processing (following the Acceptable Processes per Addendum 3), from products certified natural organic.

4.14.6 Materials used for packaging materials shall be at minimum recyclable

4.14.7 Diagram showing acceptable ingredients percentage:



4.15 LABELLING

4.15.1 Labeling on principal package shall include:

- a) Product name, identity and net contents
- b) Information panel
 - b.1) Name and address manufacturing firm
 - b.2) List of ingredients, in order concentration (Descending)
 - b.3) Guidance on safe use
 - b.4) Raw material identification

4.15.2 All labeling shall conform to legal requirements in the country of sale

4.15.3 Labels shall be fully checked prior to application

4.15.4 Finished products shall bear permanent Certification marks

4.15.5 Claimed Essential Characteristics - After product presentation the following characteristics should appear with the references to Certech:

- % of the total ingredients of a natural origin - (minimum 95 % by weight or fluid volume)
- % of the total ingredients emanating from Organic Agriculture (not to be less than 10% for the Natural and Organic label and to 5 % for the Natural label by weight or fluid volume)

4.15.6 The ingredients complying with the Organic Agriculture mode of production must be mentioned in the list of ingredients followed by an asterisk, referring to the indication: "Ingredients from Organic Agriculture". All of the ingredients and the indications concerning them, as quoted above, must be printed identically (color, format and font).

4.15.7 The products defined by this document and those which meet its conditions, are granted the right to use "Natural Cosmetic" Or "Natural and Organic Cosmetic", following the "Rules on the ingredients and composition of the finished product" set out in 4.14

4.15.8 The right to use Certech's 'Natural Cosmetic' and Natural Organic Cosmetics' logos is dependent upon maintaining current certification by Certech, and is limited to cosmetics specifically identified within certification scope.

4.16 PRESERVATION OF PRODUCT

4.16.1 Measure to preserve product shall include:

- a) Procedures to prevent contamination, mixing, and deterioration
- b) Containers closed and bagged or boxed
- c) Product and ingredients shall be stored off the floor
- d) Storage shall include correct conditions (Temp, light, etc.)
- e) Shelf life controls shall be auditable
- f) Product shall be periodically tested for contamination filth/microorganisms

4.17 CALIBRATION

4.17.1 The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

4.17.2 The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

4.17.3 Where necessary to ensure valid results, measuring equipment shall

- a) Be calibrated/verified at documented intervals, or prior to use, against standards traceable to national or international standards; where no such standards exist, an acceptable scientific basis shall be used for calibration or verification.
- b) Be adjusted or re-adjusted as necessary;
- c) Be traceable to enable the calibration status to be determined;
- d) Be protected from adjustments that would invalidate the measurement result;
- e) Be protected from damage during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected (including recall).

When computer software is used to verify processes or product its ability to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

4.18 MONITORING AND MEASUREMENT OF PRODUCT

4.18.1 Monitoring and measurement shall include:

- a) Samples – adequacy of mixing, absence (non presence) of hazardous organisms and chemical contamination
- b) Confirmation of conformance to specification
- c) Retained samples – defined period
- d) Water supply tested to ensure non presence of unacceptable ingredients (Herbicides and Pesticides) and harmful bacteria
- e) Fresh as well as retained samples tested for adequacy of preservation against microbiological contamination
- f) Checks to ensure that only approved ingredients and materials are used
- g) Second checks to verify ingredient measure
- h) Weighing and measuring of raw materials checked by second person
- i) Final product or its ingredients shall not be tested on animals

4.19 NOCONFORMANCE CORRECTIVE, AND PREVENTIVE ACTION

4.19.1 The maintain procedures for dealing with actual and potential nonconformities and for taking corrective and preventive action. The procedures shall define requirements for

- a) Identifying and correcting nonconformities and taking actions to mitigate their affect,
- b) Investigating nonconformities, determining their causes and taking actions in order to avoid their recurrence,
- c) Evaluating the need for actions to prevent nonconformities and implementing appropriate actions designed to avoid their occurrence,
- d) Recording the results of corrective actions and preventive actions taken, and
- e) Reviewing the effectiveness of corrective actions and preventive actions taken. Actions taken shall be appropriate to the magnitude of the problems and the environmental impacts encountered.

ADDENDUM 1 – ACCEPTABLE INGREDIENTS

Anti-Microbial Agents Used In The Finished Product	
Benzoic Acid, Its Salts And Esters	Propionic Acid And Its Salts
Benzylic Alcohol	Salicylic Acid And Its Salts
Formic Acid And Its Sodium Salt	Sorbic Acid And Its Salts
Other Types Of Synthesized Ingredients	
Disodium Phosphate	Sodium Borate
Magnesium Hydroxide	Sodium Carbonate
Potassium Carbonate	Sodium Hydroxide (Soda)
Potassium Hydroxide	Sodium Silicate
Sodium Bicarbonate	Titanium Dioxide
Animal Ingredients	
Beeswax	Lactose
Butyris Lac	Lanolin
Caprae Lac	Mel
Lac	Ovum
Lactis Proteinum	Propolis Cera
Lactoferrin	Royal Jelly
Lactoperoxydase	Shellac
Ingredients Of Natural Origin	
Aluminum CI77000	Magnesium Chloride
Ammonium Diphosphate Ci77742	Magnesium Oxide Ci77711
Bismuth Oxychlorure Ci77163	Magnesium Sulfate
Calcium Carbonate Ci77220	Manganese Bis Orthophosphate Ci77745
Calcium Sulfate (Gypsum)	Manganese Diphosphate Ci77742
Chromium Oxides Ci77288 77289	Manganese Sulfate
Copper CI77400	Potassium Sulfate
Copper Oxide	Prussian Blue Ci77510
Copper Sulphate	Silver CI77820
Cupric Sulfate	Silver Chloride
Dicalcium Phosphate Dihydrate	Silver Sulfate
Hydrated Silica	Sodium Fluoride
Iron Hydroxide	Sodium Monofluorophosphate
Iron Oxides Ci77480, 77491, 77492, 77499	Sodium Sulfate
Iron Sulfate	Titanium Dioxide Ci77891
Lazzurite CI77007	Zinc Oxide Ci77947

Magnesium Carbonate Ci77713	Zinc Sulfate
Marine Origin	
Algin	Potassium Alginate
Carrageenan	Xantophyll

ADDENDUM 2 – UNACCEPTABLE INGREDIENTS (Acceptable limit = Not detectable)

Ingredients	
Diethanolamine (DEA)	Synthetic Colorants
Cocamide DEA	Synthetic Perfumes
Triethanolamine (TEA)	Synthetic Anti-oxidants
Olefin sulfonate	Synthetic Emollients
Cocamidopropyl betaine	Synthetic Oils and Fats
Sodium Myreth Sulfate	Synthetic Silicones
Parabens	Genetically Modified Organisms (GMO)

ADDENDUM 3 – ACCEPTABLE PROCESSES

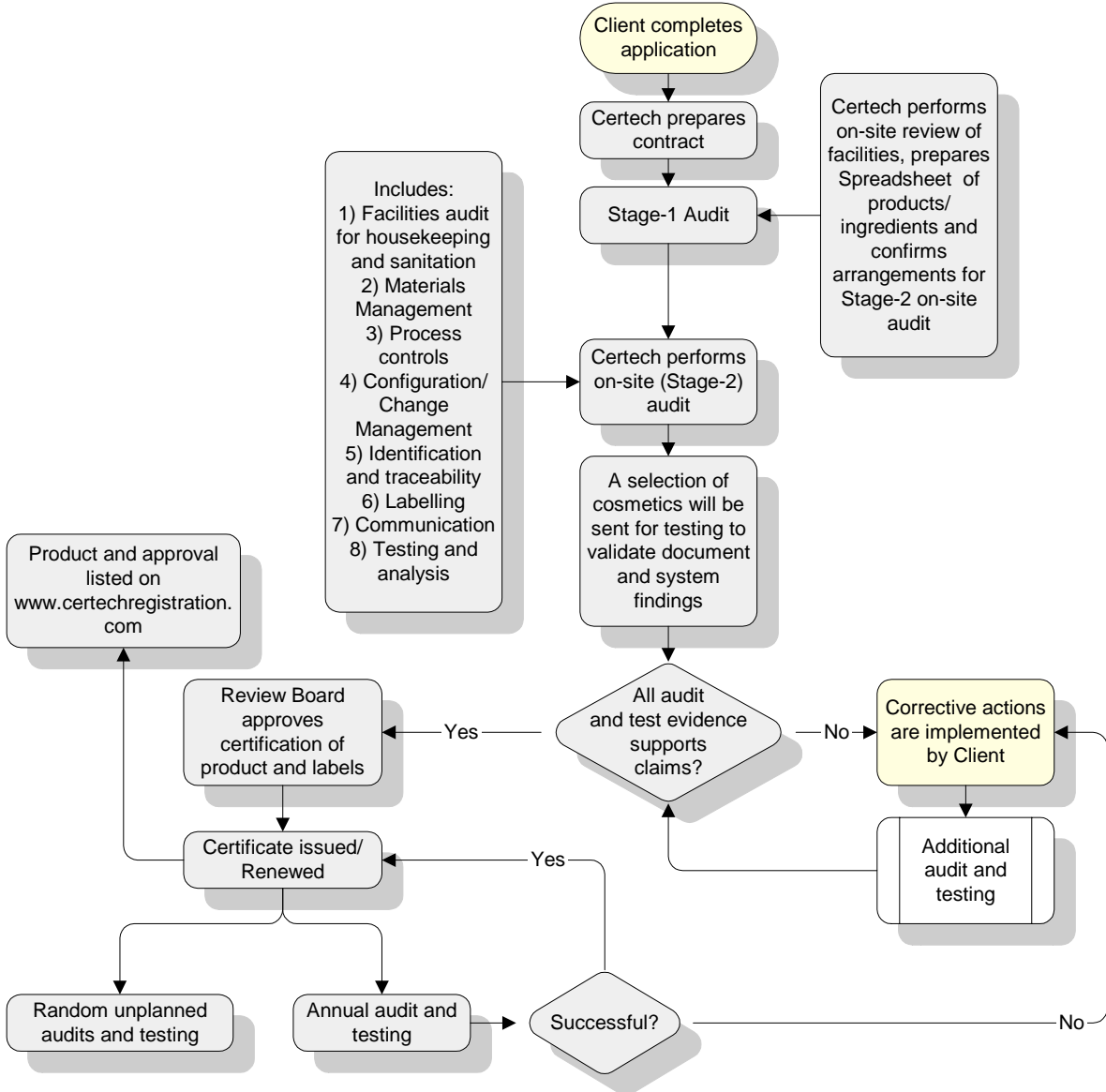
Physical
Absorption
Bleaching - Deodorization
Grinding
Centrifuging (Solid / liquid separation (spin-drying)
Settling and Decanting
Desiccation - Drying (Progressive or not by evaporation / natural under sun)
Deterpenation (if fractionated distillation with steam)
Distillation or Extraction (steam)
Expression
Extractions (with water or a third solvent : ethyl alcohol-organic glycerin-organic oils - CO2)
Filtration and Purification (ultra filtration, dialysis, electrolysis)
Lyophilization
Blending
Percolation
Cold Pressure
Hot Pressure
Sterilization with thermal treatments
Sifting
Chemical
Alkylation
Amidation
Calcination of Plants Residues
Carbonization (Resins, Fatty Organic Oils)
Condensation / Addition

Esterification
Etherification
Fermentation (Natural / Biotechnological)
Hydratation
Hydrogenation
Hydrolysis
Neutralization (To Obtain Na, Ca, Mg, K Salts)
Oxidization / Reduction
Processes For The Manufacture Of Amphoterics
Saponification
Sulphatation
Roasting

ADDENDUM 4 – UNACCEPTABLE PROCESSES

Bleaching - Deodorization (on a support of animal origin)
Deterpenation (other than with beam)
Ethoxylation (PEG,)
Irradiation
Sulphonation (As main reaction)
Techniques using Genetic Engineering
Treatments with Ethylene Oxide
Treatments using Mercury (Mercurial Soda)

ADDENDUM 5 – CERTECH AUDIT PROCESSES



Addendum 6 – Certech Organic & Natural Logos

