# Requirements for Certification Bodies

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**NATRUE – The international natural and organic cosmetics association**
Rue Washington 40 – 2nd floor
1050 Brussels
Belgium

Tel +32 261 329 30 - www.natrue.org - info@natrue.eu

# 1. Table of Contents

# 1. Objective of this Manual

This document specifies the approval and monitoring procedures and sets out the requirements for Certification Bodies to achieve and maintain approval to perform certification or approval according to the NATRUE Label scheme and to implement its related quality assurance system.

## 1.1 References

For Accreditation Bodies:

- ISO/IEC 17011 – Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies;
- IAF MD 7 IAF Mandatory Document for Harmonization of Sanctions to be applied to Conformity Assessment Bodies;
- IAF/ILAC A5 Multi-Lateral Mutual recognition arrangements.

For Certification Bodies:

- ISO/IEC 17065: 2012 – Conformity assessment — Requirements for bodies certifying products, processes and services (previously ISO/IEC GUIDE 65:1996);
- ISO/IEC GUIDE 68:2002(E). - Arrangements for the recognition and acceptance of conformity assessment results
- The NATRUE Label criteria and further supporting documents at www.natrue.org.

## 1.2 Glossary and terms of reference

**"Accreditation"** refers to the process of verification of performance and adequateness of NATRUE Approved Certifiers' activities executed by an independent entity appointed by NATRUE for such activity, namely Accreditation Body.

**"Agreement"** refers to the binding document between relevant parties.

**“Applicant”** refers to the body, natural or legal persons, applying to become a NATRUE approved certifier (NAC).

**“Approval”** refers to the process aimed at verifying compliance to the NATRUE standard by documentation review by a NAC and on-site audit where applicable. Approval scheme can be applied to formulas or raw materials.

**“Bottler”** refers to any natural or legal person in the supply chain, who is responsible for the action of bottling the bulk formula into its container. The Bottler may be a subcontractor.

**“Certification”** refers to the two-step process aimed at verifying compliance to the NATRUE Standard by documentation review and production site audit by a NAC.

**“Certification Body”** third-party conformity assessment body operating certification schemes

**“Chain of Custody (CoC) – identification within the supply chain”** refers to the sequence of responsibilities of operators for, and control of inputs and outputs as they move through each step in the relevant supply chain.

**“Cosmetics” or “cosmetic product”** includes any finished cosmetic product as defined by law. In principle all legal references in the NATRUE standard are related to reference EU law in force at the moment. In non-EU countries/regions references to cosmetic products may have to be adapted according to the corresponding national regulations in the countries in which the respective products will be marketed (e.g. concerning definition, composition, safety, efficacy and labelling requirements).

**“Distributor”** refers to any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the market; all legal or natural persons in the wholesale trade as well as retailers selling directly to the consumer are covered by reference to the distributor.

**“End user”** refers to either a consumer or a professional, using the cosmetic product.

**“Final certificate”** refers to the end point of the certification process, where the definitive NATRUE certificate is delivered by the NAC to the licensee.

**“Labeller”** refers to any natural or legal person in the supply chain, who is responsible for the action of labelling the final product. The Labeller may be a subcontractor.

**“Licensee”** refers to the person who undergoes certification or approval. This means that the licensee signs an agreement with the NAC of its choice, and therefore is subject to the certification or approval requirements, including to ensure

that other subcontracted parties, also comply with the requirements. The licensee must also sign the Label Usage agreement with NATRUE.

**“(making available) on the market”** means any supply of a cosmetic product for distribution, consumption or use in the course of a commercial activity.

**“Manufacturer”** according to the definition provided in Article 2(d) of the EU Cosmetics Regulation (EC) 1223/2009 means any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured.

**“NATRUE Approved Certifier (NAC)”** refers to the association approved Certification body which is appointed to perform Certification and approval activities aimed at verifying compliance to the NATRUE Standard. A certification bodies can only become NAC after successful accreditation by the accreditation body.

**“NATRUE Label”** or **“the Label”**, refers to the visual sign identifying compliance to the document NATRUE Label: requirements to be met by natural and organic cosmetics usually referred as “the standard” and is granted to certified finish products, raw materials and to approved formulas and raw materials.

**“NATRUE Label User”** refers to the legal representative of certified products and raw materials or approved formulas and raw materials. Label users also include approved formulas and approved raw materials for the use of the Label with the mandatory mention “NATRUE approved”.

**“Operator”** can refer to any natural or legal person involved in the supply chain.

**“Packager”** refers to any natural or legal person in the supply chain, who is responsible for the action of packaging the product. The Packager may be a Subcontractor.

**“Preliminary certificate”** refers to the document with which the licensee is granted the provisory use of the Label, in anticipation of the receipt of the Final Certificate

**“Standard”** refers to the latest version of the NATRUE criteria document named: NATRUE Label: requirements to be met by natural and organic cosmetics.

**“Subcontractor”** refers to the natural or legal person who is contracted by NAC to perform review/approval and inspection on his behalf or by a licensee to perform a defined task within the CoC on its behalf (e.g. bottling, relabelling etc.).

**“Third-Party Manufacturer”** refers to the natural or legal person who is contracted by licensee to produce its finish products, raw materials or formulas. The Third-Party Manufacturer is considered as a Subcontractor.

## 2. Principles

The NATRUE requirement for Certification Bodies are built upon the ISO/IEC Guide 65: 1996 (now withdrawn and updated to ISO/IEC 17065:2012) “General requirements for bodies operating product certification systems” and the 2008 IROCB (International Requirements for Organic Certification Bodies), and considering that certification according to the NATRUE Label scheme has certain characteristics that may differ from certification of products and services covered by ISO/IEC Guide 65 and IROCB, as well as including sector and NATRUE specific requirements..

The main accreditation partner for the NATRUE Accreditation Program is IOAS – International Organic Accreditation Service, since it specialises in organic accreditation and operates worldwide. The cooperation is based on a corresponding agreement concluded between NATRUE and IOAS. However, NATRUE reserves the right to establish cooperation with other accreditation partners, if in line with the overall strategy of NATRUE. In this event NATRUE will apply the same requirements on all accreditation partners.

## 3. Requirements for Accreditation Bodies

Accreditation bodies must comply with the requirements of ISO/IEC 17011. Conformity assessment - General Requirements for accreditation bodies accrediting conformity assessment bodies and any subsequent revisions are expected to follow the procedures and requirements as detailed in this manual. Accreditation Procedure shall include the following as a minimum:

- Review of the applicant Certification Body procedure and documentation
- Audit to the headquarter or main office of the applicant Certification Body
- Witness audit of a representative manufacturing plant
- Ongoing monitoring of the Accredited Certification Body, including at least one up-to-date accreditation visits every second year to an office conducting NATRUE Label Certification and at least one witness audit or review audit every second year
- During the first assessment and re-assessment to verify files and formulas of certified licensees depending on the number of operators evaluated by the CB:
- 0-100 operators: 5 files + 5 formulas
- 100-200 operators: 8 files + 8 formulas
- 200-500 operators: 10 files + 10 formulas

- 500-1000 operators: 15 files + 15 formulas
- >1000 operators: 20 files + 20 formulas
- The CBs with less than 10 operators and/or CBs with less than 10 certified / approved products, the requirement of 5 files and 5 formulas applies for a two year period

## 4. Scope

The procedures and requirement as outlined in this document are applicable for all applying Certification Bodies as well as for already NATRUE Approved Certifiers. The procedures and requirement as outlined in this document are applicable for all applying Certification Bodies as well as for already NATRUE Approved Certifiers.

Certification shall be granted for finished products (Natural Cosmetics, Natural Cosmetics with Organic Portion, Organic Cosmetics) intended for the end-market (consumers, B2C).

Formula approval shall be granted to product formulations that are intended to be presented to potential brand owners (no marketing at this stage, B2B).

Certification or approval shall be granted for raw materials, as defined in the latest version of the NATRUE Criteria and in section 7.2.1 of this document and following Annex 3.2 RM Approval decision tree.

## 5. Application and Monitoring procedure

### 5.1. Application Procedure

Applications for approval should be sent to NATRUE AISBL – 40, Rue Washington 4, 1050 Ixelles, Brussels – Belgium via mail to info@natrue.eu to the attention of the Label Officer.

Application will be considered only if they contain:

- Duly completed application form
- Legal name and status, address and legal representative of the applicant
- List of all offices and branches
- A summary of the relevant professional qualifications and experience of the applicant designed personnel for the NATRUE Label scheme
- Declaration that, if accredited, the applicant agrees to:

- Operate in compliance with this document
- Enter into a formal contract with NATRUE (Commitment Declaration) and commit to the specified Fees
- Take contact with NATRUE to participate in a NATRUE Criteria Explanatory Session

After acceptance of the application by NATRUE, the Certification Body must apply to the accreditation body for further accreditation procedure.

## 5.2 Accreditation Procedure

The Accreditation body decides if accreditation to the NATRUE Label scheme based on procedures and requirements of this document will be granted to the applicant. If the accreditation is granted, the applicant becomes NATRUE Approved Certifier (NAC).

## 5.3 Grace period

### 5.3.1. Definition

The Accreditation Grace period allow the applicant to perform certification and approval against the NATRUE standard prior to completing full accreditation by a third-party, pending compliance with these Grace Period requirements. Accreditation Body can recommend the eligibility of an applicant to the Grace period, after which NATRUE can grant a limited license for the duration of the Grace period. The Grace Period aims to reduce barriers to entry for an applicant certification body interested in the NATRUE standard schemes.

### 5.3.2. Duration

The Grace period ends when the applicant has achieved the requisite full accreditation to the NATRUE standard within 18-months of initial application with the Accreditation Body. If the applicant fails to do so within the 18-months of initial application, the Grace period would be automatically be terminated.

### 5.3.3. Eligibility Criteria

In order to be eligible for the Grace period, a certification body needs to undergo the documentation review and should not have any issues outstanding in relation to Chapter 6.

# 6. General requirements

## 6.1. Responsibility

### 6.1.1. Legal structure

The structure of the certification body shall foster confidence in its certification operations. In particular, the certification body shall:

a. Have documents attesting to its status as a legal entity

b. Have documented the rights and responsibilities relevant to its certification activities

c. Identify the management (body, group or person) that has overall responsibility for the functioning of the certification body, including its finances.

### 6.1.2. Certification agreement with licensees

The certification body shall provide its certification service based on an agreement signed between the NATRUE approved certifier and NATRUE licensee. In particular, the agreement shall:

a. Include a description of the rights and duties of the NATRUE approved certifier and licensee offering certified/approved products, formulas or raw materials, including a commitment to comply with the relevant provisions of the certification or approval program

b. Specify requirements, restrictions or limitations on the use of the NATRUE logo and on the ways of referring to the level of certification granted in order to prevent misleading use or claims by providing the licensee with the latest version of the Agreement on the Usage of the NATRUE Label and its Annexes

c. Contain provisions for confidentiality to protect the clients' data

d. Contain provisions to allow the certification body to exchange information with NATRUE, other certification bodies and nominated Accreditation Bodies to verify information, especially the status of certified products, approved formulas or certified/approved raw materials, as part of its ongoing evaluation

e. Grant to both the certification body and its nominated Accreditation Body the right of access to all appropriate facilities, including to non-organic production in the unit or related units, and all relevant documentation and records, including financial records.

### 6.1.3. Approval agreement with licensees

The certification body shall provide an approval service based on an agreement signed between the NATRUE approved certifier and NATRUE licensee. In addition to the requirements listed above, with the exception of the application of 6.1.2 (e) for approval of non-organic raw materials and specified organic raw materials, the agreement shall:

a. Confirm that the Certification Body is authorised by NATRUE for the approval of raw materials

b. Enable the Certification Body to transfer to NATRUE for publication purposes, its contact details along with:

   - the commercial or trade name
   - the producer/manufacturer
   - the Chemical Name or INCI name of constituents
   - the purpose/function of the approved raw material
   - the percentage composition of the raw material according to the NATRUE label criteria classification system

c. Enable the Certification Body to exchange information related to approvals with other NATRUE approved Certifiers, particularly to verify the status or the conformity of the approved raw materials with the NATRUE standard. Should these exchanges concern confidential information, the Certification Body and licensee shall jointly and previously identify the information that can be transmitted in this framework (at least the trade name and manufacturer names should be shared).

### 6.1.4. Responsibility for certification and approval decisions

The certification body shall have final responsibility for granting, maintaining, extending, suspending and withdrawing certification of finished products, approval of formulas, and certification or approval of raw materials

Certification Bodies authorising approval of raw materials must ensure that up-to-date lists of these ingredients are available to NATRUE and the other authorised Certifiers on the allocated platform on the NATRUE extranet.

Raw materials or (a) substance(s) composite of the raw material, which have been approved on a confidential basis do not need to be disclosed to the other NACs (or

on the public NATRUE database) but at least the trade name and the producer's name must be disclosed.

In cases of conflicting decisions on conformity, the NATRUE approved certifiers concerned shall share their proofs of assessment with the aim of achieving a consensus decision. If this fails, the NATRUE Scientific Committee will consider all the proofs of assessment and shall decide whether the specific raw material or substance is acceptable or not.

#### 6.1.5. Acceptance of prior certification

Where finished products, raw materials or formulas have been certified or approved by another NATRUE approved certifier according to the NATRUE Criteria, the certification body accepts prior certification and approval in order to secure equal application of the NATRUE standard.

## 6.2. Personnel

### 6.2.1. General

The certification body shall employ sufficient personnel competent to perform certification functions and operate its system

The certification body shall ensure that personnel have knowledge relevant to the scope of certification issued. Knowledge in the following areas is necessary to perform the NATRUE Certification:

- Chemistry and/or Cosmetics
- Raw materials expertise
- EU Cosmetics legislation (Regulation (EC) 1223/2009) and EU Organic Regulation (EC) 834/2007 and accompany documentation
- Manufacturing processes
- Audit experience related to DIN ISO 9001:2000 or a similar quality management (QM) system
- Good Manufacturing Practices (GMP) expertise
- The certification body shall maintain up-to-date records on personnel.

### 6.2.2. Qualification criteria and documentation

a. The certification body shall define minimum criteria for the competence of personnel. Criteria should specify minimum education, training, technical knowledge and work experience relevant to the scope of certification issued in particular:

   - a university degree in the field of cosmetics, chemistry or related subject plus expertise in QM system;
   - or, at least 3 years in professional experience in the cosmetic industry or similar field plus expertise in QM system;
   - or, at least 2 years professional experience in inspection and certification of cosmetic or organic products.

b. The certification body shall maintain up-to-date documents describing the respective responsibilities of assigned personnel.

### 6.2.3. Capacity-building

The certification body shall ensure that personnel involved in certification or approval (i.e. inspectors and other certification personnel, including members of technical committees) have and continue to have up-to-date technical knowledge in their respective fields of activity to enable them to conduct approval and certification effectively and uniformly. In particular, the certification body shall:

a. Review the competence of its personnel in light of their performance in order to identify training needs

b. Ensure that new personnel have sufficient competence and take contact with NATRUE to participate in a NATRUE Criteria Explanatory Session.

### 6.2.4. Assignment of personnel

The certification body shall require personnel, including committee members, involved in the certification or approval process to:

a. Commit themselves to observing the policies and procedures of the certification body

b. Declare any prior or present association on their own part, or on the part of their employer, with a licensee seeking certification or approval to which they are to be assigned to perform review, inspection, certification or approval activities.

### 6.2.5. Assignment of committees

The certification body shall have formal rules and structures for the appointment and operation of any committees that are involved in the certification process, reflecting requirements of 6.2.1 and 6.2.2.

### 6.2.6. Subcontracting (outsourcing)

When a certification body decides to subcontract work (outsourcing) related to certification or approval (e.g. formulation review/approval, inspection) to an external body or person, an agreement covering the arrangements, including confidentiality and conflict of interest, must be drawn up. The certification body must:

a. Take responsibility for such subcontracted work

b. Keep final responsibility for the granting, maintaining, renewing, extending, suspending or withdrawing of certification or approval. Delegation of certification decisions may only take place based on the requirements in accordance with the provisions of the ISO/IEC GUIDE 68:2002(E).

c. Ensure that the subcontractor is:

   - Competent to perform the subcontracted work,
   - Not involved, either directly or through the body/person's employer, with the operation, process or product that is subject to certification or approval in any way that may compromise impartiality, and
   - Committed to the policies and procedures as defined by the certification body.

d. Monitor the performance of the persons or bodies subcontracted for the work.

## 6.3. Impartiality and objectivity

### 6.3.1. Organisational structure and stakeholder involvement

The certification body must be impartial; it must not be financially dependent on single operations that are subject to its certification or approval in any way that compromises its impartiality. Specifically, the certification body must have a documented structure which safeguards impartiality by:

a. Including provisions to ensure the impartiality of the operations of the certification body;

b. Providing for the participation of all parties concerned in a way that balances interests and prevents commercial or other interests from unduly influencing decisions. *

c. not belonging to another company which develops, manufactures and/or sells natural and organic cosmetic products or raw materials either itself or for third-parties and not developing, manufacturing and/or selling natural cosmetic products or raw materials himself/herself or for third parties.

** Explanatory note: a committee representing key interests such as those of clients, other industry representatives, representatives of government services, or representatives of non-governmental organizations, including consumer organizations could be established to consider whether the certification body management acts impartially.*

### 6.3.2. Management of impartiality

The certification body shall identify, analyse and document the possibilities for conflicts of interest arising from its provision of certification, including any conflicts arising from its relationships. Rules and procedures shall be established to prevent or minimize threat of conflicts of interest. In particular, the certification body must:

a. Require personnel, committee and board members to declare existing or prior association with an operation subject to certification. Where such an association threatens impartiality, the certification body shall exclude the person concerned from work, discussion and decisions at all stages of the certification process related to the potential conflict of interest;

b. Ensure that personnel do not assess their own work by following defined rules for appointing and operating committees involved in certification or approval activities to ensure that decisions taken are not influenced by any commercial, financial and/or other interest.

c. If a conflict of interest between certification personnel and an operator is found after assessment has occurred, assign another unbiased person to assess if it has affected the certification or approval process as well as complete the remainder of the process if possible

### 6.3.3. Division of functions

The certification body shall not provide any other products or services which could compromise the confidentiality, objectivity or impartiality of its certification or approval processes and decisions. In case the certification body also performs other activities in addition to certification or approval, it shall apply additional measures to

ensure that the confidentiality, objectivity and impartiality of its certifications are not affected by these other activities.

In particular the certification body must not give advice or provide consultancy services to the licensee as to methods of dealing with matters which are barriers to the certification or approval requested. Barriers can be, for example, non-conformities identified in the course of the certification or approval process. Giving explanations regarding the standard are not considered to be advice or consultancy.

General information or training may be given as long as this service is offered to all licensees in a non-discriminatory manner. Any training or services may be provided as long as they are clearly separated at any stage (offer, application, costs) from the certification or approval services.

### 6.3.4. Accessibility

The certification body shall make its services equally accessible to all licensees whose activities fall within its declared field of operation. It must work according to non-discriminatory policies and procedures, ensuring that no undue financial (e.g. with regard to the fee structure) or other conditions (size of the supplier, or membership to any association, or number of certificates already issued) are applied.

## 6.4. Access to Information

### 6.4.1. Publicly accessible information

The certification body shall provide access to information to ensure confidence in the integrity and credibility of its certification or approval.

The certification body must make available (through publications, electronic media or other means) on request:

a. The NATRUE Criteria to be met by licensees in order to obtain/maintain certification or approval

b. Information about procedures applied for evaluating whether licensees meet the applicable standard principally

c. Information about procedures applied to cases where certification or approval is extended

d. Information about procedures and sanctions applied where non-conformities with standards are detected

e. The fee structure for its services

f. A description of rights and duties of licensees, including requirements, restrictions or limitations on the use of any certification or approval logos and on ways of referring to the certification or approval granted principally via a link to the NATRUE Label Usage Guidelines (Annex C) and by timely provision of the latest version of the Agreement on the Usage of the NATRUE Label and its other Annexes (A to E).

g. Information about procedures for handling general complaints and appeals against its certification or approval decisions.

### 6.4.2. Confidentiality

In order to gain privileged access to information, the certification body shall make adequate arrangements to safeguard the confidentiality of the information obtained in the course of its certification or approval activities at all levels of its organisation, including committees and external bodies or individuals acting on its behalf. Arrangements shall:

a. Protect proprietary information of a client against misuse and unauthorised disclosure

b. Ensure that the certification body has the right to exchange information with other approved certification bodies and/or with nominated Accreditation Bodies and NATRUE, to verify the authenticity of the information.

### 6.4.3. Reference to certification or approval and use of NATRUE logo

The certification body shall:

a. Exercise control over ownership, use and display of licenses, certificates and logos that it can authorise certified or approved licensees to use

b. Be able to request a licensee to discontinue use of certificates and NATRUE logos

c. Apply suitable actions to deal with incorrect references to the certification or approval system or misleading use of licenses, certificates or NATRUE logos

## 6.5. Quality management (QM) system

### 6.5.1. General

a. The certification body shall define, document and implement a QM system in accordance with the relevant elements of these requirements so as to impart

confidence in its ability to perform organic certification. The QM system must be effective and appropriate for the type, range and volume of work performed

b. The management shall ensure that the QM system is understood, implemented and maintained at all levels of the organisation.

### 6.5.2. Management system manual

a. The certification body shall address and document all applicable procedures, either in a manual or in associated documents, in order to ensure uniform and consistent application

b. The manual and associated documents, as appropriate for the type, range and volume of work performed, and considering the number of personnel involved in the process, shall contain:

- An organisational chart showing lines of authority, responsibilities and allocation of functions
- A description of procedures applied by the certification body in the course of performing certification or approval, including granting, maintaining, renewing, extending, suspending and withdrawing of certification or approval
- A collection of procedures including the following documents: Minutes of the NATRUE Approved Certifiers Meetings/Conference Call with relevant annexes and any relevant communication forwarded by NATRUE
- Procedures for the recruitment, selection, training and assignment of the certification body's personnel (as outlined under 6.2.)
- Policy and procedures for appeal against certification or approval decisions and other complaints
- Policy and procedures for reviewing quality (e.g. internal audits, management review)

c. The certification body shall ensure that the manual and relevant associated documents are accessible to all relevant personnel.

### 6.5.3. Document control

The certification body shall establish and maintain procedures to control its documents that relate to its certification and approval functions. In particular, the certification body shall:

a. Through authorised and competent personnel, review and approve documents for adequacy prior to their original issue or any subsequent amendment

b. Maintain a list of all appropriate documents with the respective issue dates and duly identify their amendment status

c. Control the distribution of all such documents to ensure that the appropriate documentation is provided to personnel of the certification body or its subcontractors when they are required to perform any function relating to the certification body’s activities, and prevent the unintended use of obsolete documents.

### 6.5.4. Maintaining and managing records

a. The certification body must maintain a system of records (either electronic or paper documents) to demonstrate that the certification and approval procedures have been effectively fulfilled, particularly with respect to application forms, evaluation or re-evaluation reports, and other documents relating to granting, maintaining, renewing, extending, suspending or withdrawing certification or approval

b. The records must be identified, managed and disposed of in such a way as to ensure the integrity of the process and the confidentiality of the information

c. Licensees records must be up-to-date and contain all relevant information, including inspection reports and certification or approval history

d. Records shall also be kept on exceptions granted, complaints, high risk situations, appeals and subsequent actions

e. Records must be kept for at least five years, or as required by law, in order to be able to demonstrate how certification and approval procedures have been applied

f. Maintain a public list of certified or approval operations and the scope of their certification/approval.

### 6.5.5. Internal audit and management review

The certification body shall demonstrate that it seeks and achieves continuous quality improvement. It shall perform management reviews and internal audits according to the type, range and volume of certification and approval performed. In particular, it shall:

a. Periodically (biennial basis) review all procedures in a planned and systematic manner, to verify that the quality system and its procedures are implemented and effective. Performance reviews conducted periodically shall be part of the review

b. Review intervals shall be sufficiently short to ensure that the objective of quality improvement is fulfilled. Records of quality reviews shall be maintained.

### 6.5.6. Appeals and complaints

The certification body shall have in place policies and procedures for the resolution of complaints and appeals received from licensees or other parties about the

handling of certification and approval or any other related matters. In particular, the certification body must:

a. Take appropriate subsequent action to resolve complaints and appeals

b. Document the action taken and its effectiveness

c. Inform NATRUE about complaints and appeals by providing at the end of every calendar year a resume of complaints and/or appeals and actions taken to address them.

# 7. Process requirements for conducting certification or approval

## 7.1. Application procedures

### 7.1.1. Information for licensees

The certification body shall provide to licensees an up-to-date description of the procedures to be applied for conducting certification or approval. The certification body shall inform licensees about:

a. Contractual conditions, including fees and possible contractual penalties

b. Licensees' rights and duties, including the appeal procedure

c. The applicable Standard (latest version of the NATRUE Criteria)

d. Program changes, including regular updates of procedures and standards

e. The evaluation and inspection procedures applied by the certification body in the course of certification or approval

f. Documentation to be maintained by the licensee to enable verification of compliance with applicable standards by the certification body.

### 7.1.2. Application form and the licensee's obligations

The certification body shall require completion of an application form, signed by a duly authorised representative of the licensee. To enable evaluation and assignment of qualified personnel, the certification body shall require licensees to provide information about the scope of the desired certification or approval, including a description, as specified by the certification body, of the production, products, raw materials or formulas and area to be certified or approved.

## 7.2. Evaluation

### 7.2.1. Scope

a. The certification body shall evaluate licensees against all certification or approval requirements, respectively, as specified. The evaluation shall consist of:

   - a review of documents and an on-site inspection for certification of finish products and organic raw materials falling outside the scope of the IFOAM family of standards as outlined in *Annex 3.2 – RM Approval decision tree*

   - a documentation review for approval of product formula, non-organic raw materials and organic raw materials falling under the scope of the IFOAM family of standards as outlined in *Annex 3.2 – RM Approval decision tree.*

b. When a licensee decides to subcontract work related to certification or approval to an external company or person, an agreement covering the arrangements, including scope of the subcontract work and liability must be drawn up. The licensee must:

   - Take responsibility for such subcontracted work

   - Take final responsibility for ensuring that the characteristics of the products remain compliant to the NATRUE requirements across the CoC

   - Ensure that the subcontracted entity is competent to perform the subcontracted work, committed to the policies and procedures as defined in the NATRUE requirements, CBs procedures and to accept the visit by NAC and if necessary by the Accreditation Body.

   - Monitor the performance of the company or person subcontracted for the work

### 7.2.2. Review of application and preparation of inspection

a. Prior to the inspection, the certification body shall review the application documents to ensure that certification or approval can be carried out and that application of certification or approval procedures is possible. In particular, the certification body shall review whether:

   - Documents submitted by the licensee are complete

   - The licensee appears to be able to comply with all certification or approval requirements (applicable procedures and standards)

   - The scope of the certification or approval sought is within the scope of the certification or approval services provided

- The certification body shall assign qualified personnel to the evaluation in line with the requirements of 6.2 and 6.3 above, and provide them with appropriate work-related documents

b. The certification body in order to issue the Preliminary Certificate must verify the product/raw material formulation's compliance with the NATRUE criteria on the basis of the documentation provided including:

   - Information on the percentage of NATRUE certified products within the product range in case of certification of finish products.
   - Intended marketing date
   - Information about the production site
   - Quantitative formulation + INCI designation
   - Raw materials proof of origin
   - Envisaged export countries

c. The certification body shall inform inspectors about any non-conformities and the associated requests for corrective action issued previously, to enable the inspectors to verify whether the non-conformities have been resolved.

### 7.2.3. Inspection protocol

On-site inspection should be performed within 6 months after issue of Preliminary Certificate.

Inspection is carried out in order to verify information and compliance with certification requirements applicable to the licensee. It shall follow a set protocol to facilitate non-discriminatory and objective inspection.

The inspection protocol as part of the identification of areas of risk to the integrity of the product characteristics must at the very minimum undertake the following:

a. Quality Control and Management: assessment of the production or processing system by means of visits to facilities and storage units (which may also include visits to non-organic areas if there is reason for doing so)

b. Chain of Custody: review of records and accounts in order to verify flow of goods (production/sales reconciliation, input/output reconciliation and the tracing back of audits in processing and handling facilities)

c. Verification that changes to the standards and to requirements of the certification body have been effectively implemented

d. Verification that corrective actions have been taken.

e. Parallel production. In order to prevent co-mingling or contamination of NATRUE standard and non-NATRUE standard products including organic products with other products that do not meet the standards, the certification body must verify whether handling and documentation regarding production or processing, storage and sales is well managed and makes clear distinctions between certified and non-certified products. In cases where products are not visibly distinguishable, specified measures must be applied to manage the risk.

Successful inspection leads to the issue of the Final Certificate.

### 7.2.4 Validity of the Certification or Approval

a. Certification of finish products and raw materials, and Approval of product formulas and raw materials, have a validity of 24 months

b. In case of certification of finish products, even if no new products are submitted for certification, each production site, to the extent that natural/organic cosmetics which are still certified are produced or filled there, must be audited at least every two calendar years.

c. The NATRUE label standard for finish products works per brand – it is not related to the licensee – which in case of third-party manufacturer could be dealing with products sold under different brand. A production audit, within 6 months after the issue of preliminary certificate, is always required for a new brand to achieve certification even if produced by an operator which is already under the NATRUE system. Adjustment of the issuing date for the preliminary certificate is permitted provided that manufacture of natural and organic cosmetics (i.e. not conventional products or in the case of non-production) is observed by ensuring that the production site audit within the 6 months following its release.

d. A second production audit is not required if the licensee submit additional products (regardless under which brand they are put on the market) within one year of the original production audit date. If additional products are certified when this period has elapsed, another audit is required*.

e. If necessary and depending on the importance and number of changes made to the formulation, costs can be charged for the re-examination of the product documentation

***Example of application**

Brand A (produced by Y) had their initial production audit in January 2019

Brand B ((produced by Y) had their initial production audit in October 2019

Brand A added several products in June 2020 - no need of audit (October keeps the 12 months validity – no matter of the brand).

Brand B added various products in Dec 2020 - audit is needed (after 12 months audit is always required.

A or B can add products with no production audit required until October 2020 – given the fact that both had their initial brand-related audit. If either A or B add products in December 2020 audit is required (and this would be the new starting date for both brands...)

If brand C is still produced by the same operator no matter when products are launched audit is required as this being the first brand related audit.

### 7.2.5 Reporting Variation

Variations to the formulas or composition of a raw material must be reported to the certifier by the licensee. The certifier evaluates whether a re-examination is required and to which degree. Minor changes are reported for documentation purposes while major changes can necessitate a complete re-certification/re-approval.

### 7.2.6 Particular requirements to address multiple production units

Each production unit should be audited as outlined in 7.2.3. However, under its own responsibility, the NAC may take the following scenarios into consideration:

#### a. Company with different production Units concerning one product P1

Product P1 can be produced in Unit A as well as in Unit B. Unit A and B can be owned by the licensee or owned by a third-party manufacturer.

If Unit A has already been successfully audited and if the QM system of the producing company is also able to present for Unit B tangible documents, proving that:

- the production process and the product quality are well controlled
- the production procedures have been successfully verified by the Certification body,

- Unit B does not necessarily have to undergo an additional audit. The final decision is to be made by and under the responsibility of the Certification body.

**b. Company with different production Units - concerning different products P1 and P2. Unit A and B can be owned by the licensee or owned by a third party manufacturer.**

If Unit A has already been successfully audited for a product P1 and if the QM system of the producing company is able to present tangible documents also for Unit B, proving that:

- the production process and the product quality are well controlled
- the production procedures have been successfully verified by the Certification body,
- Unit B does not necessarily have to undergo an additional audit. The final decision is to be made by and under the responsibility of the Certification body.

**c. Company with different Units for different production steps (US1 and US2) - concerning one product P1. Unit A and B can be owned by the licensee or owned by a third-party manufacturer.**

For Product P1, the first production step takes place in Unit A and the second production step in Unit B

If one of the Units has already been successfully audited and if the Certification body is provided with the information/confirmation from the QM system that the production processes are equivalently managed and controlled in both Units.

The second Unit concerned does not necessarily have to undergo an additional audit. The final decision is to be made by and under the responsibility of the Certification body.

### 7.2.7. Particular requirements to address high-risk situations

The certification body shall amend and adapt its certification procedures to address higher risks found in certain situations.

Depending on the risk identified, the certification body should decide whether it is appropriate to increase the frequency of inspections.

### 7.2.8. Reporting

The certification body shall report evaluation findings according to documented reporting procedures.

a. Inspection reports shall follow a format appropriate to the type of operation inspected, and facilitate a non-discriminatory, objective and comprehensive analysis of the respective production system.

b. The inspection report shall cover all relevant aspects of the standards, and adequately validate the information provided by the licensee. It shall include:

   - A statement of any observations relating to conformity with the certification requirements;
   - Date and duration of the inspection, persons interviewed, facilities visited;
   - Type of documents reviewed.

c. The certification body shall promptly notify the licensee of any non-conformity to be resolved in order to comply with applicable certification or approval requirements.

d. The certification body shall document and apply measures to verify effectiveness of corrective actions taken by licensees to meet the requirements.

## 7.3. Decision on certification or approval

### 7.3.1. Division of functions

The certification body shall ensure that each decision on certification or approval is taken by a person(s) or committee different from the one(s) that carried out the on-site inspection.

### 7.3.2. Basis for the decision

The decision shall be based solely on the conformity of the operation with the certification or approval requirements specified, using information gathered during the evaluation process.

### 7.3.3. Documentation

Documentation of certification or approval decisions shall include the basis for the decisions.

### 7.3.4. Dealing with non-conformities

a. Certification or approval decisions may include requests for the correction of minor non-conformities within a specified time period. In case of major non-conformities, a certificate shall be withheld or suspended until implementation of corrective actions can be demonstrated. In serious cases, certification or approval shall be denied or withdrawn.

b. Reasons for denial, withdrawal or suspension of certification or approval shall be stated with clear reference to the applicable standard or certification/approval requirement violated.

### 7.3.5. Exceptions to certification or approval requirements

a. Criteria and procedures for granting exceptions are outlined by NATRUE upon decision by the Scientific Committee Criteria and Label

b. Exceptions shall be of limited duration, and not be granted permanently

c. The documentation of any exception shall include the basis on which the exception is granted.

### 7.3.6. Issuing of certificates and approval documents

The certification body shall issue official certificates or approval documents as applicable to each licensee. Certificates and approval documents must contain the following information:

a. The name and address of the licensee whose products, formulas or raw materials are the subject of certification or approval

b. Name and address of the certification body that issued the certificates or approval documents

c. The scope of the certification/approval granted, including

   - The products, formulas or raw materials names which are certified/approved and which may be listed by type or range of products/formulas/raw materials

   - The production standard that is the basis for the certification/approval, and

- The effective date and term of certification/approval.

## 7.4. Extension and renewal of certification/approval

### 7.4.1. Re-certification/approval

a. The certification body shall regularly re-evaluate licensees in order to verify whether they continue to comply with the applicable standard. Re-certification/re-approval should be anticipated by written agreement with the licensee at least 3 months (when possible) before the first 24 months validity period has elapsed. Mechanisms shall be in place to effectively monitor whether corrective actions have been implemented.

b. The certification body shall report and document its re-evaluation activities, and shall keep licensees informed about their certification/approval status.

c. Re-certification or re-approval generally follows procedures outlined in Section 7.2. (i.e. Evaluation).

However, evaluation for the purpose of renewal may focus on certain measures related to risk, and might not repeat all procedures listed in Section 7.2.

### 7.4.2. Frequency of inspection

a. The certification body shall decide on the frequency for regular inspections as outlined in Section 7.2.4.

b. In addition to the regular inspection audit, the certification body may conduct follow-up or unannounced on-site inspections of certified licensees, chosen randomly and/or chosen taking into account the risk or threat to the organic integrity of the production or products.

### 7.4.3. Notification of changes made by the licensee

a. The certification body must require licensees to inform the certification body about changes cited in Section 7.1.2.

b. The certification body shall determine whether the announced changes require further investigations according to their procedures on changes to the certification or approval scope. If such is the case, the licensee shall not be allowed to release certified finished products and raw material or approved product formulas and raw materials produced under the changed conditions until the certification body has notified the licensee accordingly.

### 7.4.4 Changes in the certification/approval requirements

a. NATRUE and its Scientific Committee “Criteria and Label” shall reserve the right to update the NATRUE standard’s criteria regularly corresponding particularly to the current state of research and technology. If during the validity period of the certificate/approval declaration an update of the NATRUE criteria results in a product, formula or raw material already certified/approved no longer complying with the amended requirements, the changes required to the product composition or the manufacturing process must have been implemented at the end of the certification or approval period following the current certification or approval period at the latest.

b. In the instance of said proposed change to the NATRUE standard’s criteria, NATRUE may request certifiers to provide data applicable to assist an impact assessment.

c. When a change is implemented the certification body shall ensure that each licensee is notified of any changes in the certification/approval requirements without unnecessary delay.

d. The certification body shall verify the licensee’s implementation of such changes in a timely manner, within the given implementation periods.