NATRUE OPERATING MANUAL

INDEX

Errore. Il segnalibro non è definito.

1. PREFACE

Bioagricert (BAC) is among the leading organizations in certification and inspection services in the agri-food sector, with regards to sustainability and safety requirements.

BAC provides all necessary organic certifications for national and international markets, including Organic EU 848, NOP/USDA, JAS/Japan and LPO Mexico.

BAC also provides the additional inspection services necessary to access the main certifications in force in the Northern European markets (BioSuisse, Naturland, Krav, Soil Association, Demeter, etc.).

BAC offers other useful certifications for agri-food companies such as Geographical Indications, Integrated Pest Management, GLOBAL GAP and Supply Chain Traceability (ISO 22005), Vegan and Vegetable Product, Gluten free, etc.

Bioagricert also provides certification services in non-food sectors such as, for example, organic natural cosmetics and detergents, organic fabrics, etc.

Bioagricert is part of the Foodchain ID Group (www.foodchainid.com) and has a broad portfolio of certification, verification, testing and technical services.

The FoodChainID network provides all the necessary certifications to companies collaborating in international markets.

BAC's headquarters are in Bologna. In Italy BAC has other regional offices.

BAC works worldwide with inspectors and local offices, the main ones are in Mexico, Thailand, Romania and Turkey.

BAC guarantees the admission of Applicants to certification schemes without any discrimination. No undue economic or other conditions are applied, qualification for evaluation and certification is not conditioned by the size of the unit or membership of associations or groups.

BAC undertakes to apply current procedures and expense accounts based on its Schedule of Fees in force for each certification scheme, ensuring uniformity of application.

The request for inspection and certification does not imply any obligation for the Organization concerned to use other BAC services not covered in this Regulation and in the chosen standard.

NATRUE (ww.NATRUE.org), the International Association of Natural and Organic Cosmetics, is an international non-profit association (AISBL) based in Brussels. NATRUE was founded in 2007 by pioneers of the natural and organic cosmetics industry, including Weleda , WALA, Lavera , PRIMAVERA, LOGOCOS and CEP, to protect and promote natural and organic cosmetics for the benefit of consumers around the world.

In 2008, NATRUE members decided to create the internationally applicable NATRUE brand to support NATRUE's mission and to provide manufacturers and consumers with a one-stop shop for natural and organic cosmetics. After more than 10 years of commitment, NATRUE has a leading role in representing and defending the political, regulatory and scientific needs of the natural and organic cosmetics sector internationally.

The NATRUE brand continues today to be synonymous with high quality and transparency against greenwashing, thanks to its rigorous criteria for the formulation of natural and organic cosmetics. More details on certified products and raw materials carrying the NATRUE mark can be checked in real time in NATRUE's public online database.

2. PURPOSE AND FIELD OF APPLICATION

The purpose of this document is to describe the procedures followed by Bioagricert (BAC) to provide the control and certification service in compliance with the NATRUE standard (www.NATRUE.org)

The requirements and procedures described in this Operational Manual are applicable for the certification and approval of cosmetic products and raw materials and the approval of raw materials and formulas, obtained in accordance with the NATRUE standard "Requirements for natural and organic cosmetics" in version in force.

NATRUE standard, in fact, is applicable to raw materials and finished products intended for cosmetic use.

Following the positive outcome of a certification process completed by an independent certifying body approved by NATRUE, a Certificate of Conformity to the verifiable criteria established in the NATRUE standard is issued.

The Operational Manual (OM) is part of the BAC Quality System; it is connected to the Quality Manual and the related Procedures and refers to other documents: certification contract, operating instructions, technical standards and registration forms.

The certification and approval scheme for raw materials in accordance with the labeling criteria for NATRUE finished cosmetic products is part of a voluntary and accredited certification system, which first and foremost requires compliance with the NATRUE Standard and the "Requirements for Certification Bodies " proposed by NATRUE itself.

The certification is granted for the finished products (Natural Cosmetics, Natural Cosmetics with organic content, Organic Cosmetics) and for the raw materials with organic content.

Approval will be granted to natural or naturally derived raw materials as defined in the latest version of the NATRUE criteria and in section 7.2.1 Requirements for Certification Bodies. Specific programs, such as NATRUE Formula Approval, are also covered by these procedures unless otherwise indicated.

3. NORMATIVE REQUIREMENTS

- NATRUE Standard - The NATRUE Mark: requirements for natural and organic cosmetics
- Requirements for Certification Bodies NATRUE
- ISO/IEC 17065:2012 – Conformity assessment – Requirements for bodies certifying products, processes and services (formerly ISO/IEC GUIDE 65:1996);
- ISO/IEC GUIDE 68:2002(E). - Provisions for the recognition and acceptance of the results of the conformity assessment
- Regulation n. 1223/2009 on cosmetic products and subsequent amendments and additions .
- EU Reg. 848/2018 and other official standards recognized by Ifoam among the Family of Standards .

4. DEFINITIONS

ACRONYM	Description
BAC	Bioagricert srl, with headquarters in via Dei Macabraccia, 8/a Casalecchio di Reno (BO)
CC	Certification Committee
CRI	Appeals Committee
CSI	Committee for the Protection of Impartiality (CSI), separated from the management structure and structured in such a way as to guarantee the exclusion of preponderant interests
NC	Non-compliance
CB	Control and Certification Body
RS	Sector Manager (RS), member of the Bioagricert Certification Committee responsible for issuing the certification

"Accreditation" refers to the process of verifying the performance and adequacy of the activities of NATRUE approved certifiers carried out by an independent entity appointed by NATRUE for such activity, i.e. the accreditation body.

“Agreement” refers to the binding document between the interested parties.

“Applicant” refers to the body, individual or entity, applying to become a NATRUE Approved Certifier (NAC).

“Approval” refers to the process of verifying compliance with the NATRUE standard through documentation review by a NAC and on-site audits where applicable. The approval scheme can be applied to formulas or raw materials.

“Bottler” refers to any individual or entity 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 of verifying compliance with the NATRUE standard through documentation review and manufacturing site audit by a NAC.

"Certification body" third-party conformity assessment body that manages certification schemes.

“Chain of Custody (CoC) – identification within the supply chain” refers to the sequence of operators' responsibilities and control of inputs and outputs as they move through each stage of 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 the relevant EU law in force at the time. In non-EU countries/regions references to cosmetic products may need to be adapted according to the corresponding national regulations in the countries where the respective products will be marketed (e.g., regarding definition, composition, safety, efficacy and labeling requirements).

“Distributor” means any natural or legal person in the supply chain, other than the manufacturer or importer, who makes a cosmetic product available on the market; with reference to the distributor it’s meant all natural or legal persons who operate in the wholesale trade as well as retailers who sell directly to the consumer.

“End User” refers to a consumer or professional who uses the cosmetic product.

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

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

“Licensee” refers to the person undergoing certification or approval. This means that the licensee signs an agreement with the NAC of his choice, and is therefore subject to certification or approval requirements, including to ensure that other subcontractors also comply with the requirements. The licensee must also sign the label use agreement with NATRUE.

“For (providing access) to the market” means any supply of a cosmetic product for distribution, consumption or use in the course of a commercial activity.

"Manufacturer" as defined 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 certification body approved by the association that is responsible for carrying out certification and approval activities aimed at verifying compliance with the NATRUE standard. A certification body can become NAC only after successful accreditation by part of the accreditation body.

“NATRUE Label” or “the Label”, refers to the visual sign that identifies compliance with the NATRUE Label document: requirements that must be met by natural and organic cosmetics usually referred to as “the standard” and is granted to certified finished products, raw materials and 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 use on the label with the mandatory mention " NATRUE approved".

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

“Packaging operator” 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” means the document with which the licensee is granted temporary use of the

Trademark, in anticipation of receiving the Final Certificate.

"Standard" refers to the latest version of the NATRUE criteria document called: NATRUE Label: Requirements to be met by natural and organic cosmetics.

"Subcontractor" refers to the natural or legal person who is engaged by NAC to carry out the review/approval and inspection activity on its behalf which may be engaged by a licensee to carry out an activity defined within the CoC on its behalf (e.g. bottling, relabelling, etc.).

"Third Party Manufacturer" means the individual or entity to whom Licensee has entrusted the production of its finished products, raw materials or formulas. The Third Party Manufacturer is considered a Subcontractor.

5. GENERAL CONDITIONS

The purpose of certification of the products, processes and services of an organization (operator) is to provide, through initial assessment and subsequent surveillance, an independent and reliable guarantee that these products, processes and services comply with the rules and /or to the requirements specified and contained in the NATRUE standards

The certification system is based on the audit and approval of the production process and control system set up by the applicant followed by continuous surveillance through periodic checks of the conformity of the processes and quality systems, and through the testing of samples taken both from the market and from the production and/or processing sites.

In particular, the quality system established by the Licensee must take into consideration the management and application of the following requirements:

- Quality system relating to the product/process/service.
- Control of documents and data.
- Supplier procurement and qualification.
- Product identification and traceability.
- Process control.
- Testing and analysis.
- Non-compliant product control.
- Corrective and preventive actions.
- Handling, storage, packaging and delivery.
- Control of quality records.
- Internal quality-related audits.
- Training.
- Complaints
- Management review.

The certification application can be submitted by any operator capable of satisfying and/or committing to comply with the requirements of the NATRUE standards

To obtain certification, the Applicant Organization must demonstrate compliance with the NATRUE Standards and current legislation for the type of products and the activity involved.

The BAC certification authorizes the organization to use the NATRUE brand and references to the NATRUE certification on labels (of the raw material or final product) or on other promotional and informational material.

BAC is committed to ensuring fair and uniform application of certification costs.

BAC does not provide Organizations with any type of consultancy service that includes ways to overcome obstacles to certification, or promotional and information activities directed and aimed at the marketing of specific products of certified operators.

To facilitate access to information for interested parties in this certification scheme, BAC is committed to making all non-confidential documents and materials available upon request.

The correct implementation and management of the inspection and certification procedure and activities is constantly monitored by the Committee for the Protection of Impartiality (CSI), a body that guarantees the impartiality and correct execution of the certification activities and ensures fair representation of all subjects involved in the certification.

6. SPECIFIC REQUIREMENTS FOR NATRUE ACCREDITATION

6.1 Certification and Approval Agreement with Licensees

BAC provides its certification and approval services on the basis of a specific agreement called Certification Contract M_37 signed between BAC and the certification applicant/licensee.

This agreement must:

- Include a description of the rights and obligations of the NATRUE approved certifier and licensee.
- Specify requirements, restrictions or limitations on the use of the NATRUE logo.
- Contain confidentiality provisions to protect customer data. For raw material approval only, it allows BAC to transfer information previously agreed by BAC with the licensee to NATRUE for publication purposes.
- Contain provisions to enable BAC to exchange information with NATRUE, other certification bodies and designated accreditation bodies to verify the status and compliance of certified cosmetic products or raw materials or approved raw materials with the NATRUE standard.
- Grant both BAC and the designated accreditation body the right of access to all appropriate facilities as well as all relevant documentation and records. This point does not apply in the case of on-desk assessment for the approval of non-organic raw materials and already certified organic raw materials.

6.2 Responsibility for certification and approval decisions

BAC must ensure the updating on the NATRUE extranet platform of the lists of certified finished products and approved raw materials and formulas in order to make them available for NATRUE and other authorized certifiers.

Raw materials or (a) compound substance(s) of the raw material, which have been approved on a confidential basis, shall not be disclosed to other NACs (or to the public NATRUE database). The only information that must be disclosed is the commercial name and the name of the manufacturer.

In the event of conflicting compliance decisions and assessments between NATRUE-approved certifiers, BAC will ensure that it shares its assessment evidence with the aim of reaching a consensus decision. Otherwise, the NATRUE Scientific Committee will consider all evaluation evidence and decide whether the specific raw material or substance is acceptable or not.

6.3 Acceptance of prior certification

Where finished products, raw materials or formulas have been certified or approved by another NATRUE approved certifier to NATRUE criteria, BAC accepts prior certification and approval to ensure consistent application of the NATRUE standard.

6.4 Personnel

BAC ensures that the personnel involved in certification and approval are sufficient and competent and have up-to-date knowledge in their respective fields of activity relevant to the scope of the certification issued.

New staff should contact NATRUE to attend a session explaining the NATRUE criteria.

6.5 Accessibility

BAC makes its services equally accessible to all licensees whose activities fall within its declared field of activity. BAC applies non-discriminatory policies and procedures and guarantees that unexpected financial conditions or conditions conditioned by non-objective and unjustified factors are not imposed.

6.6 Confidentiality

BAC has the right to exchange information with other approved certification bodies and/or nominated accreditation bodies and NATRUE, to verify the authenticity of the information.

BAC ensures adequate arrangements to protect and safeguard proprietary and confidential customer information obtained in the course of its certification or approval activities at all levels of its organization, including external committees and bodies or persons acting on its behalf.

6.7 Reference to certification or approval and use of the NATRUE logo

BAC exercises control over the ownership, use and display of licenses, certificates and logos to ensure correct use in accordance with the NATRUE Label Use Guidelines and the NATRUE Label Use Agreement and its attachments.

In the event of incorrect references to the certification or approval system or misleading use of NATRUE licenses, certificates or logos, BAC is able to require a licensee to stop using NATRUE certificates and logos and take appropriate legal action.

6.8 Record keeping and management

The electronic registration system adopted by BAC (BAG software) supports staff for the purposes of the effective and systematical fulfillment of the certification and approval procedures.

In particular, it must allow you to manage and archive application forms, evaluation or reevaluation reports and other documents relating to the granting, maintenance, renewal, extension, suspension or revocation of certification. The same applies to raw material and formula approval procedures.

The software must also allow the management and archiving of inspection reports, certification or approval history, exceptions granted, complaints, high-risk situations, appeals and subsequent actions.

Records should also be kept of exceptions granted, complaints, high risk situations, appeals and subsequent actions.

BAC maintains a public list of certified or approved operators and the scope of their certification/approval at www.bioagricert.org.

6.9 Internal audit and management review

To ensure quality improvement and implementation of procedures, BAC periodically organizes internal staff training and review of procedures based on the type, range and volume of certification and approval granted.

6.10 Management of appeals and complaints

BAC policies and procedures are intended to ensure constructive and timely resolution of appeals and complaints received from licensees or other parties.

Depending on the nature of the complaint and the progress of the investigation, it may be necessary to conduct additional activities such as additional inspections, sampling and document review.

7. CERTIFICATION AND APPROVAL PROCESS

7.1 Certification of finished products or raw materials

The certification process is intended for manufacturers, contract manufacturers and brand owners who wish to certify finished products or raw materials with certification references and the NATRUE mark.

The certification path includes the following steps:

A. Preliminary evaluation

It consists of the initial assessment of conformity with NATRUE requirements of the composition of the products for which certification is requested and the conformity of the raw materials used, through an in-depth documentary analysis.

For organic ingredients, certification issued by authorized control and certification bodies is required, while for non-organic ingredients the compliance requirements with the NATRUE specifications are verified through the technical sheets and/or other documents and declarations issued by the supplier or seller.

Other preliminary information requested is:

- Information on the percentage of NATRUE certified products within the product range in case of certification of finished products.
- Expected marketing date
- Information on the production site(s) involved
- Quantitative formulation with INCI designation and evidence regarding the biological origin or otherwise of the raw materials
- Expected export countries

Following the positive outcome of the documentary verification, BAC can, if explicitly requested by the Licensee, issue a preliminary certificate which allows the Licensee to present itself on the market as an entity authorized to produce formulations in compliance with the NATRUE standard.

The certificate contains the list of approved formulations based on their classification (Organic or Natural) and the commercial name of the future product. Within six months of issuing the Preliminary Certificate, BAC will still have to carry out the on-site certification audit.

Alternatively, we proceed with the normal certification start-up inspection.

In order to assess the possible need to extend the geographical scope of accreditation, the Evaluator will inform the quality office within 5 working days at qualita@bioagricert.org upon receipt of the certification request signed by new operators.

The quality office will check the countries authorized for Natrue on the IOAS website and will proceed within 10 days to the request for extension of scope for the countries/activities not already included in the accreditation.

B. Audit check

The audit at the production site, both at the start of the certification and in the subsequent surveillance phase - involves ascertaining the actual conformity of the products and production processes to the requirements required by the NATRUE specifications, the control of the actual adoption of the measures declared by the Licensee in the Technical Report for the purposes of complying with the requirements set by the NATRUE standard

In case of previous issue of the preliminary certificate, the Licensee is required to communicate the start of work in order to allow BAC to plan the certification audit as soon as possible.

3. Issuance of the Certificate or attestation of conformity

Based on the information and data collected as part of the document evaluation process and during the inspection, BAC issues the certificate of conformity which contains the list of products judged to comply with the relevant Organic or Natural classification.

The certificate of conformity contains the following information:

A. The name and address of the licensee whose products, formulas or raw materials are subject to 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 names of certified/approved products, formulas or raw materials which can be listed by type or range of products/formulas/raw materials.
- The manufacturing standard that forms the basis for certification/approval, e
- The date of issue (= entry into force) and the expiry date of the certification/approval.

4. Surveillance

The annual surveillance aims to verify the maintenance of the conditions of conformity and includes periodic inspections at the production units considered critical for the purposes of compliance with the requirements of the Natrue standard.

7.2 Approval or certification of raw materials

In relation to the type of raw material, two different scenarios and procedures could be applied.

A. **Approval:** for natural and naturally derived raw materials without biological content (e.g. natural, naturally derived substances).
The approval system normally provides only for documentary control and not on-site inspection.

B. **Certification:** for natural and naturally derived raw materials that also have (and intend to boast) an organic content.

Raw materials already certified according to a regulation or standard of the IFOAM family of standards without any further processing (including also re-packaging and re-labeling) are automatically accepted. **No control and no audit is provided in these cases.**

Raw materials that are already certified according to a regulation or standard in the IFOAM family of standards but are then repackaged and/or re-labeled outside the scope of these regulations or standards **require the NATRUE approval procedure with documental review + an initial audit**.

Raw **materials that are not certified according to a regulation or standard of the IFOAM family of standards** (e.g. when preservatives not allowed by EU Reg. 848/2018 or NOP are used) require **documental review and on-site inspection at least every two years.**
In these cases, therefore, the **normal NATRUE certification procedure** (documental review + udit) is applied, as is the case for finished products.

“Customized” raw materials, used exclusively by a manufacturer of finished products, including but not limited to customized fragrance blends, are excluded from the obligation and, therefore, from the approval and certification procedures. When these conditions are proven, the conformity of the raw material is verified by BAC during the certification process of the finished product containing these components.

To facilitate the determination of the process to be undertaken for the evaluation of the raw material, NATRUE has published specific instructions for the approval of raw materials available on www.natrue.org.

The "Raw material approval" process is divided into the following phases:

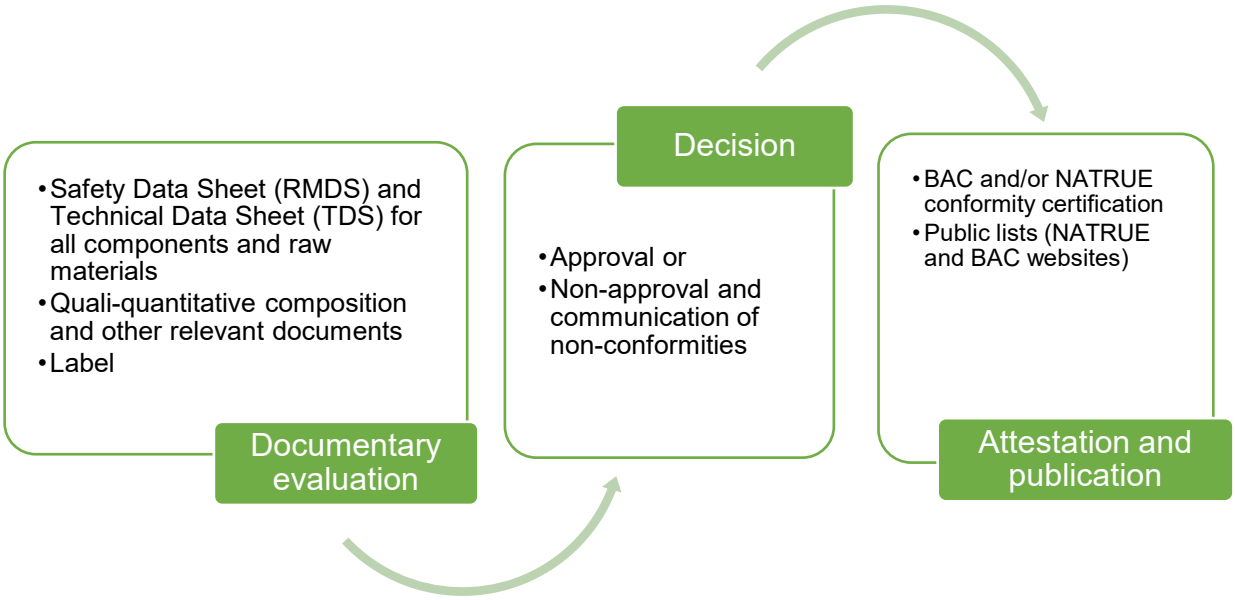
1) Evaluation of the conformity of the raw material and its production process.

It includes the conformity assessment of all component substances through the technical data sheets and all other relevant and necessary documents to examine the information necessary to evaluate compliance with the requirements of the applicable standard (e.g. NATRUE criteria).

2) Sending to the Licensee the outcome of the evaluation with a judgment of approval or non-approval with the related non-conformities.

Following the positive outcome of the approval, a specific declaration is issued (BAC Conformity Certificate).

In case of BAC approval, it inserts the raw material into the specific list of approved raw materials available on the NATRUE website.



For operators who require the evaluation and approval of NATRUE raw materials, the M_37 certification contract in addition to allowing BIOAGRICERT to exchange information relating to product approvals with other certification bodies to verify the status or conformity of the approved raw materials with the NATRUE standards.

You must confirm that BIOAGRICERT is the authorized and chosen control body for the approval of NATRUE raw materials.

a) ***(in case of approval of NATRUE raw materials)*** allow BIOAGRICERT to transfer to NATRUE, for publication purposes, the following information:
   - the trade or business name
   - the producer/manufacturer
   - the Chemical Name or INCI name of the constituents
   - the purpose/function of the approved raw material
   - the percentage composition of the raw material according to NATRUE
   - classification and labeling criteria

If such exchanges concern confidential information, the Certification Body and the licensee must jointly and in advance identify the information that can be transmitted in this context (at least the commercial name and the name of the manufacturer should be shared).

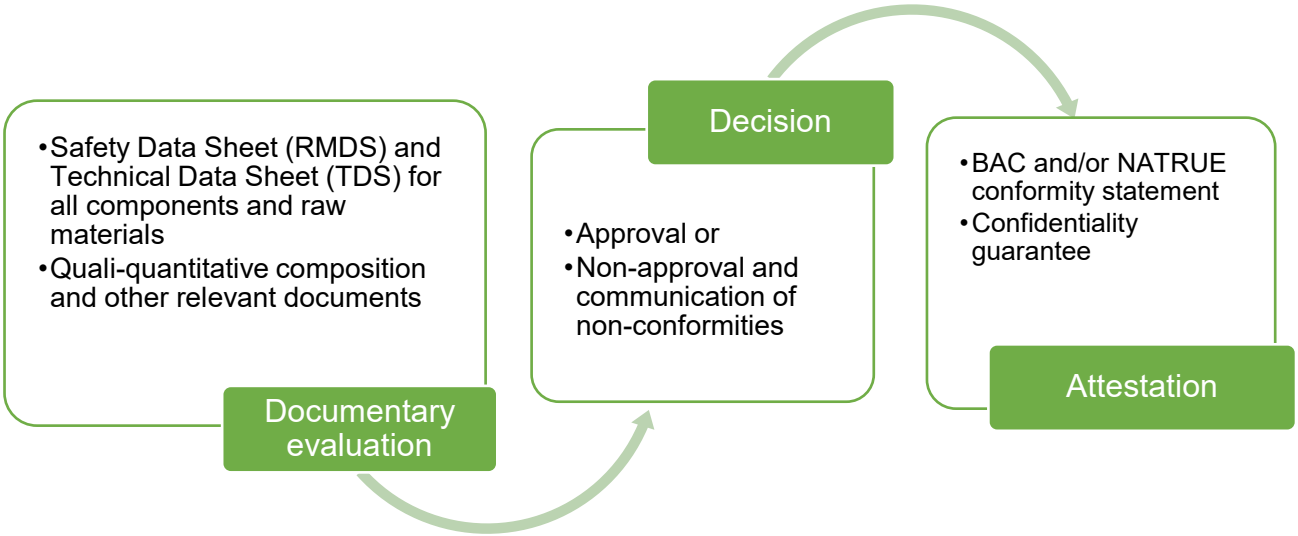
7.3 Approval of the formula

Formula approval is intended for third-party manufacturers who want to sell their formulas to brand owners so they can use them under their own branding. The process follows the same steps and criteria as the approval of raw materials and includes the conformity assessment of the qualitative-quantitative formulas.

The “Formula Approval” process follows the same steps and criteria as the evaluation of raw materials, applied in this case to all components, and includes the control and judgment of conformity of the qualitative and quantitative formula.

Following the positive outcome of the approval, a specific declaration is issued (BAC and NATRUE CERTIFICATE OF CONFORMITY).

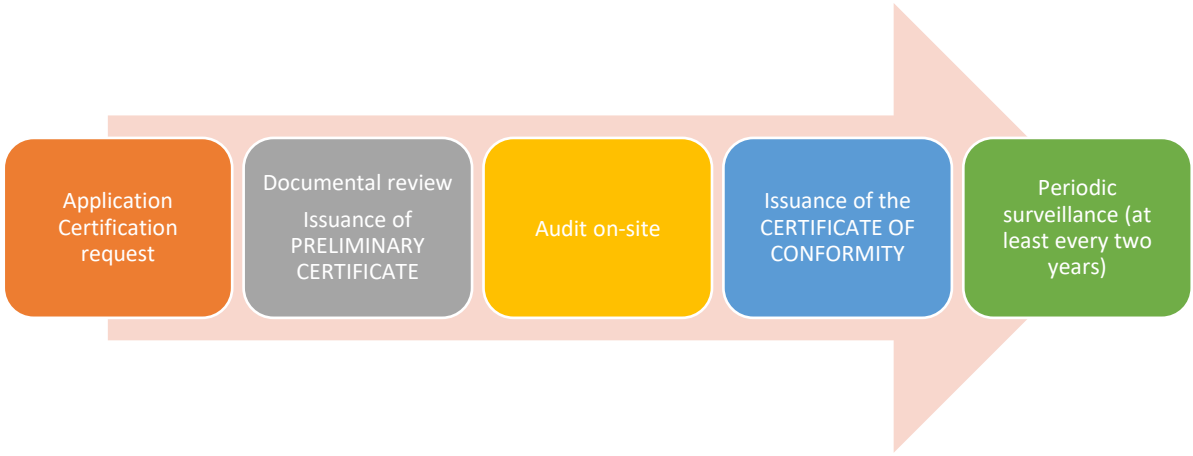
The approved formula remains absolutely confidential. Information on approved formulas will be disclosed to third parties only with the explicit authorization of the owner organization.



7.4 Certification of the finished product or raw material (with organic content)

The certification process is divided into the following phases:

- **Initial documentary assessment of the conformity of the products/raw materials** for which certification is required**,** the conformity of the **proposed production process** and the management system. The following documents are evaluated: certification application, recipe and list of suppliers, technical report, technical data sheets, etc**.**
- **Issuance of the preliminary certificate (if required).**
- **On-site inspection** aimed at ascertaining i) the effective **compliance of the products** with the requirements of the Natrue criteria; ii) the **correct organization and management** of the manufacturing processes and internal procedures that may compromise the conformity of the product itself; iii) compliance **with the requirements** of the Natrue criteria applicable to the specific reality.
- **Issuance of the Certificate of Conformity** on the basis of the information and data collected as part of the assessment and verification process. The certificate contains the list of certified products and their category.
- **Surveillance activities** that include **periodic inspections (at least every two years)** at the production units, storage and distribution centers of the products in order to verify the maintenance of compliance conditions.



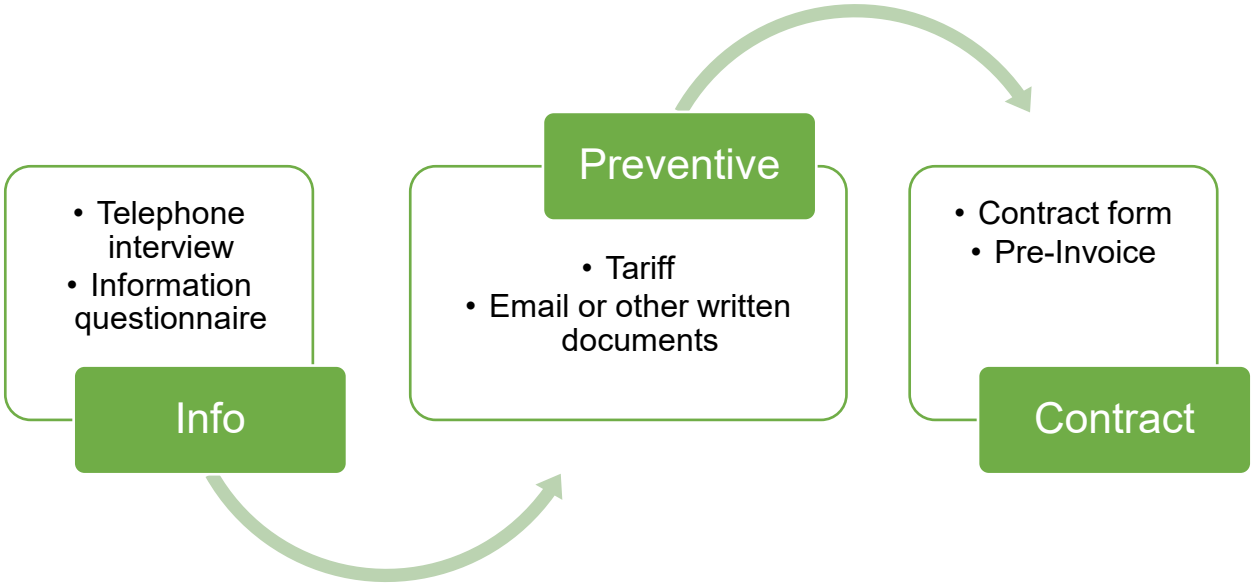
8. REQUEST FOR CERTIFICATION AND APPROVAL SERVICE

The Licensee interested in starting the certification or approval process can contact Bioagricert's sales office or the cosmetics office staff.

To collect the information necessary for the correct processing of the offer, the requesting Licensee fills out the BAC E NATRUE COSMETICI INFORMATION QUESTIONNAIRE M_305

The commercial process ends with sending the customer the quote/price list for the certification and evaluation of BAC and NATRUE raw materials (TF_C)

Once the estimate/price list accepted by the Licensee has been received, the administrative office will send the Contract with the M_37 certification.



9. NATRUE CERTIFICATION AND APPROVAL

The following table provides a summary of the mandatory and optional documentation based on the type of service requested.

- = mandatory

DOCUMENTS	CERTIFICATION OF THE FINISHED PRODUCT OR RAW MATERIAL	RAW MATERIAL APPROVAL	APPROVAL OF THE FORMULA	COMPILED BY	VERIFIED BY
M-305 BAC and NATRUE Cosmetics Information Questionnaire	Optional	Optional	Optional	Applicant	Commercial office
TF_C Price list/quote	•	•	•	Commercial office	Commercial office
M_308 Certification request	•	•	•	Applicant	BAC evaluator
M_37 Certification contract	•	•	•	Applicant	BAC evaluator
NATRUE Agreement*	•	•	•	Applicant	BAC evaluator
M_307 List of recipes and suppliers	•	•	•	Applicant	BAC evaluator
M_306 Technical Report	•	•	•	Applicant	BAC evaluator
Technical and Safety Data Sheet (raw materials)	•	•	•	Applicant	BAC evaluator
M_309 List of raw materials	•	•	•	Applicant	BAC evaluator
Animal Testing Statement	•	• (if requested)	•	Applicant	BAC evaluator
GMO Free Declaration	•	•	•	Supplier	BAC evaluator
RMDF (Raw Material Documentation File)	•	•	•	Supplier	BAC evaluator
Label (draft)	•	If labeled		Applicant	BAC evaluator

(*) BAC also provides the requesting Licensee with the NATRUE agreement model for the use of the NATRUE brand based on the type of certification requested (certification of finished products, certification or approval of raw materials, certification of formulas).

The agreement must be signed and sent to the NATRUE contact person, identified by BAC at the time of application, and must be returned to BAC once countersigned.

11. INITIAL ASSESSMENT

BAC evaluates applicant and licensee operators against all certification or approval requirements.

The NATRUE requirements for obtaining certification or approval are available in the NATRUE Criteria published on the website www.natrue.org

The evaluator is responsible for:

- Managing and updating company files related to assigned companies.
- Evaluating the documentation submitted by the applicant or licensee.
- Evaluating operators against all specified NATRUE certification requirements
- Evaluating the on-site inspection visit and related documents (inspection report, non-compliance, etc.)
- Presenting the proposal for certification or approval of raw materials to the Certification Committee

The evaluation includes:

- Examination of documents and on-site inspection for the purpose of certification of finished products and organic raw materials that do not fall within the scope of the IFOAM Family Standards, as required by the RM NATRUE approval decision tree (Annex 3.2).
- Review of documentation for approval of product formula, non-organic raw materials and unprocessed organic raw materials (including re - packaging and re-labelling) that fall within the scope of the IFOAM family of standards as per the Decision Tree for the approval of the RM (Annex 3.2).

When a licensee decides to subcontract certification or approval work to an external company or individual, an agreement must be drawn up that clearly defines the type of subcontracted work and responsibility.

The Licensee must:

- Maintain responsibility for subcontracted work.
- Maintain final responsibility for the compliance of subcontracted products throughout the CoC to ensure they remain compliant with NATRUE requirements
- Ensure that the subcontracted entity is competent to carry out the required work, complies with the policies and procedures defined in the NATRUE requirements, the Bioagricert (BAC) procedures and accepts inspection by the BAC inspector and, if necessary, by the personnel of the accreditation body.
- Monitor the performance of the company or person to whom the work has been subcontracted.

Prior to the inspection, the BAC assessor will review the application documents to ensure that certification or approval can be carried out and that certification or approval procedures can be applied.

In case of inconsistency or deficiencies in the documentation, the evaluator informs the Licensee of the non-conformities detected by communicating the deadlines within which any additional documentation must be submitted.

When the documentation is complete and positively evaluated, the evaluator proposes to the Certification Committee (CC) the issuing of the NATRUE Preliminary Certificate (if requested). This certificate is valid for a maximum of 6 months within which the on-site inspection must still be carried out.

When the Preliminary Certificate is not expressly requested by the Licensee, the normal certification start-up audit is instead planned and executed.

12. STARTUP INSPECTION AND SURVEILLANCE

The inspection activity, both in the start-up and surveillance phases, is planned by the BAC evaluator who appoints the qualified inspector.

BAC will inform the inspectors of any non-conformities detected during the document evaluation phase and of the related requests for corrective actions to allow the inspectors to verify that such non-conformities have been resolved.

The inspection procedure includes the following phases and activities:

- Initial meeting (to confirm the scope of verification and best organize the specific activities, identifying the personnel involved).
- Evaluation of company documents (technical reports or other internal procedures presented by operators and related documents).
- Evaluation of NATRUE requirements applicable to products/processes.
- Verification of the effectiveness of the concrete measures adopted to comply with NATRUE requirements and application of good production practices.
- Evaluation of production processes through inspections of plants and storage units. *If deemed useful for the purposes of the investigations, the inspector can also request to view areas of the plant and warehouses not involved in the production subject to certification.*
- Examination of all relevant processing and accounting records in order to verify the traceability of all production batches through specific traceability tests which, starting from a batch of finished product, allow the batches of individual raw materials used to be identified.
- Examination of accounting (invoices, accompanying documents, accounting and warehouse loading/unloading records) for the purpose of verifying the congruence between the flows of incoming raw materials and outgoing NATRUE certified finished products (mass balances).
- Evaluation of the separation system and identification of raw materials and risk areas in order to avoid contamination that could compromise the conformity of organic raw materials.
- Assessment of compliance with all requirements set out in the NATRUE standard including those regarding packaging and labelling.
- Verification of the availability of the authorizations required by law for carrying out the activities subject to certification and of any measures or non-conformities detected in this regard by the public authorities.
- Verify that the changes to the standard and related requirements have actually been implemented.
- Verifies that previously issued non-conformities have been resolved and that the related corrective actions have been correctly adopted.
- Verification of complaints received and their treatment.
- Reporting of deviations from the standard and notification of any non-compliance.
- Final meeting to present the results of the inspection and NC (if any).

The inspector may also take samples for analysis in case of well-founded suspicion regarding the conformity of the raw materials and/or finished product.

During the visit, the inspector will use the BAC E NATRUE COSMETICS AUDIT REPORT M_300 FORM.

13. RISK ASSIGNMENT FOR INSPECTION ACTIVITY PLANNING

Based on the information provided in the Certification Request and subsequent changes, Bioagricert will assign the Licensee a risk category, low or high, which affects the frequency requirements of on-site inspections, according to the following criteria:

Risk category	Audit frequency criteria	Conditions
Low	Mandatory audit for the start-up phase and (at least) one audit every 24 months in the surveillance phase.	Brand distribution activities when the third-party manufacturers already have their own NATRUE certification for the same type of product. Manufacturers of up to 20 products with a single manufacturing plant. Operators who only carry out packaging and labeling

Risk category	Audit frequency criteria	Conditions
		activities for finished products. PLEASE NOTE! For operators who carry out packaging and/or relabelling of organic raw materials for the sole purpose of evaluating the raw materials, only one initial inspection is carried out.
High	Mandatory audit for the start-up phase and (at least) one audit every 12 months in the surveillance phase.	Manufacturers with more than 20 products or, in any case, with multiple production plants.
NOTE Audits of the most critical manufacturing processes must be prioritized to ensure product integrity. Any exceptions to the above criteria must be technically justified by the evaluator and approved by the Sector Manager.		

14. CERTIFICATION PROPOSAL AND CERTIFICATION RESOLUTION

When the outcome of the documentary evaluation and inspection (when applicable) is positive, the evaluator proposes certification to the Certification Committee which decides on the issue of the NATRUE Certificate of Conformity or, in the case of raw materials and formulations, the Certificate of Approval NATRUE.

Subsequently, the certificate of conformity and the certificate of approval are issued by the assessor and signed by the legal representative of BAC.

15. NON-CONFORMITY MANAGEMENT

In case of minor non-conformity that does not affect the conformity of the products with NATRUE requirements, the Certification Committee requires the correction of the non-conformity within a certain period of time.

The Licensee must submit to BAC, within the established deadlines, complete documentation demonstrating that the preventive and corrective actions have been adopted.

In case of major non-conformity which also threatens the integrity and conformity of the product, the assessor submits the file to the Certification Committee, which immediately issues a precautionary measure that temporarily suspends the validity of the certification and prevents the placing the product itself on the market, until the investigations are completed and the non-conformity detected is resolved.

If the investigations confirm the non-compliance or infringement of the specifications committed by the Licensee, the suspension of the certificate will be confirmed with the application of the consequent sanctioning measures, which may lead to the withdrawal of the product from the market.

16. MAINTENANCE OF CERTIFICATION

Once the certificate or declaration of approval for the raw materials and formulas has been issued, the Licensee must guarantee the regular maintenance of the conformity requirements established by the NATRUE standard.

The maintenance of these requirements is verified by BAC through periodic documentary checks and inspections (when required).

The certificate of conformity and the certificate of approval of the raw materials or formulations is valid for 24 months from the date of issue and allows the Licensee to legitimately use the references to the certification and the applicable NATRUE logo.

The Licensee undertakes to use the NATRUE logo and references to certification only for products and formulations found to be compliant, indicated in the certificate or certificate of approval. Such references cannot concern products not indicated on the certificate, even if they are being evaluated, or be extended to the activity carried out by the entire company.

Licensee agrees that for the duration of certification and approval, relevant information regarding certified or approved products will be uploaded to the NATRUE online database by BAC.
BAC ensures that no confidential information will be made available through the NATRUE database or any other means.
To maintain compliance, you must:

- Continuously comply with the NATRUE standard.
- Continuously comply with the BAC Certification Agreement for NATRUE certification (M_37).
- Make certification statements only for the purposes for which the certification was issued.
- Notify BAC of any changes in product or raw material formulation, process or management system that may change compliance.
- Inform BAC of any fortuitous event that may change compliance and if it is for any reason involved in legal proceedings relating to product compliance.
- Record complaints and retain all documents relating to corrective actions taken.
- Correctly and systematically manage the records related to NATRUE certified processes and products.

17. EXTENSION AND RENEWAL OF CERTIFICATION AND APPROVAL

The Licensee may request the extension of the certification or evaluation at any time by sending the appropriate certification request (M_308) in which the new products or raw materials for which certification or evaluation is requested must be indicated. The documents necessary for the evaluation must also be attached.

BAC will evaluate the need to plan any further inspections (e.g. introduction of new factories and very different production processes) after a complete evaluation of the request it will proceed to issue the updated certificate.

By the expiry of the certificate of approval or approval, the licensee must inform BAC of his desire to renew the certification or evaluation service.

If the licensee does not wish to re-approve his products, he will immediately inform BAC of this decision and the right to use the NATRUE logo on the label will cease.

18. SURVEILLANCE

The surveillance activity carried out by BAC aims to ensure that operators maintain the compliance requirements established by the specifications and the contract for BAC certification.

During the period in which the Licensee is within the control and certification system, BAC monitors the maintenance of the requirements through periodic inspections planned based on the assigned risk.

The annual inspection plan is defined following the criteria indicated in the previous point 13 (Risk assignment for the purposes of planning the inspection activity).

Depending on the risk identified, BAC may decide whether it is appropriate to increase the frequency of inspections.

In addition to the normal surveillance inspection, BAC can conduct additional or unannounced inspections of certified operators, chosen randomly or taking into account the level of risk attributed to the Licensee or the criticality of the processes and products and previous non-conformities.

In the case of raw material approval where on-site inspection is required within the first year of approval, subsequent audits are only necessary based on the risk assessment by DI BAC or if the composition of the raw materials needs to be changed.

19. MODIFICATIONS MADE BY THE LICENSEE

The Licensee must inform BAC of any changes to the product, production system or management system (e.g. Technical Report, Product Sheet/Supplier List, etc.) that may impact compliance with NATRUE requirements.

BAC will determine whether the announced changes require further investigation by following normal certification and approval procedures. In such case, the Licensee will not be permitted to market certified finished products and raw materials, or approved formulas and raw materials produced under the new conditions until BAC has completed the evaluation process and informed the Licensee accordingly.

20. CHANGES TO CERTIFICATION/APPROVAL REQUIREMENTS

NATRUE and its scientific committee "Criteria and label" reserve the right to regularly update the criteria of the NATRUE standard in order to accommodate developments in research and technology.

In the event of a change to the standard and to the certification and approval criteria, BAC must ensure that each operator is promptly informed of such changes and the timing of their entry into force.

BAC will promptly verify the implementation of such changes by the Licensee, within the indicated implementation periods.

If updating the NATRUE criteria means that an already certified/approved product is no longer compliant due to the new requirements, the Licensee may continue to market the product (as previously approved) and the required changes to the composition of the product or to the manufacturing process must be implemented within the validity period of the certificate.

21. GENERAL CONDITIONS

For anything not provided for in this document, the conditions and obligations established in the following documents apply:

1) Standard - NATRUE Criteria The NATRUE Mark: requirements for natural and organic cosmetics
2) Requirements for Certification Bodies NATRUE
3) NATRUE Agreement and other official documents available on the web
4) Other complementary documents of the Bioagricert Quality Management System (QMS).
   a) IO_01 Accreditation and Authorization Requirements for Certification Processes
   b) EPRA_00 List of staff with roles and activities
   c) Pro_002 Activities of the Committee for the Protection of Impartiality
   d) Pro_003 Activities of the Complaints-Appeals Committee.
   e) Pro_004 Education, Training and Performance Evaluation.
   f) Pro_005 Control of Documentation and Records
   g) Pro_007 Administrative management