>> Matrix of Compatibility

CERTIFICATION PROCEDURE

To doc: information flow
To doc: flow chart

Application[1]

For the application, EcoControl obtains all the necessary information to complete the certification process in accordance with the relevant certification scheme.

- the product(s) to be certified;
- the standards and/or other normative documents for which the client is seeking certification;
- the general features of the client, including its name and the address(es) of its physical location(s), significant aspects of its process and operations (if required by the relevant certification scheme), and any relevant legal obligations;
- general information concerning the client, relevant to the field of certification for which the application is made, such as the client's activities, its human and technical re-

[1] NATRUE specific requirements are marked in yellow

sources, including laboratories and/or inspection facilities, and its functions and relationship in a larger corporation, if any;

- information concerning all outsourced processes used by the client that will affect conformity to requirements; if the client has identified a legal entity/entities for producing the certified product(s) that is different from the client, then EcoControl establishes appropriate contractual controls over the legal entity/entities concerned, if necessary for effective surveillance; if such contractual controls are needed, they can be established prior to providing formal certification documentation;
- all other information needed in accordance with the relevant certification requirements, such as information for initial evaluation and surveillance activities, e.g. the locations where the certified product(s) are produced and contact personnel at these locations.

NATRUE specific Remark:
Licences without own licence contract (contract is signed between the contracted processor and NATRUE) has 2 options for the issuing of the certificate:

1) The applicant / licence is signing a certification contract for licensees and gets the certificate (in addition the contracted operator must sign the operator contract with all obligations of ISO 17065)

2) The certificate is issued in the name of the contracted processor and a reference to the licensee and his brand(s) is made.

As the NATRUE certification lasts 24 months, the timeline to have changed all relevant certificates, is the 31.05.2019 under the condition that there is no other timeline defined by NATRUE. All pure licensee clients shall be informed from now on (2017-05-29)

To doc: application form
To doc: registration forms
To doc: description of measures

Application Review

EcoControl conducts a review of the information obtained to ensure that:

- the information about the client and the product is sufficient for the conduct of the certification process;
- any known difference in understanding between EcoControl and the client is resolved, including agreement regarding standards or other normative documents;
- the scope of certification (see 3.10) sought is defined;
- the means are available to perform all evaluation activities;
- EcoControl has the competence and capability to perform the certification activity.

➔ If EcoControl has neither the competence, nor the resources to conduct the assessment EcoControl will not accept the application

Preparation for Evaluation

EcoControl prepares a plan for the evaluation activities to allow for the necessary arrangements to be managed. The plan is done an annual basis respecting:

- Deadlines for evaluation, re-evaluation

- Availability of the operator and competent auditors (the change / rotation of auditors is done according to individual situations and requirements). Competence includes also language skills for the geographical area.

NATRUE specific Remark:
To carry out the on-site audit 3-6 months after issuing a preliminary certificate is a should requirement of NATRUE EcoControl considers while planning the on-site audit the time of first production and the possibility to combine the audits with others in the area. As the final certificate may not be issued later than 6 months after the assessment of the recipes, the onsite audit of first applicants and their first product shall take place no longer than 6 months after this registration.

The explanations for the carrying out of brand specific audits the rule given by NTRUE to audit any new brand even if the recipe has been audited already is on hold and shall only be implemented if published in the rules for NATRUE certification.

EcoControl ensures that all necessary information and/or documentation is made available for performing the evaluation tasks. All information of the previous evaluation is handed over to the auditor prior to the planned audit:

- Measures of the operator to comply with the standard
- Audit report
- Products registration form

➔ All these docs are copies just in time into the auditors' intranet folder.

The audit steps and required preparation for the audit is brought forward to the operators with the official announcement of the audit. A written audit plan is prepared on request.

Evaluation

The basis for the evaluation are the control points and compliance criteria as outlined in the respective standard, as well as interpretations and explanations given by the standard owner and EcoControl. All explanations are recorded here

→ To doc: explanation of the NATRUE standard 

There could be individual exceptions e.g. if a raw material is not available for short period in a certain quality. These exceptions have to be granted by NATRUE and are documented individually.

Evaluation of the Registration
After the applicant has provided all necessary information including:

- List of Products
- Recipes
- Indication of product qualities
- Quality documents if required

The products are assessed for conformity against the relevant standard

➔ EcoControl only relies on evaluation results related to certification completed prior to the application for certification, if there is enough evidence that the body that performed the evaluation fulfils the requirements contained in 6.2.2 and those specified by the certification scheme. This means for NATRUE that it is a NAC.

➔ Information about the outcome of the assessment is brought forward to the applicant and, after all non-conformities and open questions are corrected and solved to the Reviewer / Certifier for certification decision.

Evaluation on-site
After the production has started an on-site audit is scheduled. For the NATRUE standard these are 6 months later at the most (according to the latest Version of the standard). During the on-site audit the following areas are audited and assessed:

- Completeness of registration
- Correctness of recipes (100% sample during first assessment, all new products during follow up audits as well as the square root sample of all certified recipes).
- Availability of all required quality proofs (natural, organic, non-GMO …) (100% sample during first assessment, all new ingredients during follow up audits as well as the square root sample of all ingredients that require specific qualities).
- Assessment of basic GMP requirements
- Traceability check of the operators' production records from the label of the final product (or of bulk lots at subcontractors) to the single ingredient on the basis of production protocols and delivery notes / invoices.
- Check of the use of labels and marks a well as any conformity statement including internet advertising.

➔ All results will be recorded in an Audit report which is a given Format and shows all required information. The final report with all findings, non-conformities, agreed corrective actions and conditions is signed and counter signed by the operator (it is enough if the last page of the report is printed for signature).

➔ If an operator shows hazardous processes causing higher risk to contamination or commingling the operator is required to place operational prerequisite programs in order to control the hazard below an acceptable risk level. This has to be documented in the description of measures the operator undertakes in order to control hazards identified.

➔ The assessment of the production or processing system by means of visits to facilities and storage units may also include visits to non-organic areas if there is reason for doing so. Reasons could be parallel production, missing quality proofs for ingredients, unclear mass balances or unclear traceability results, etc.

➔ To doc: risk assessment 

Evaluation of operators with multisite processing facilities
"Each production unit should be audited as outlined in 7.2.3 However, under its own responsibility; the Certification/control body 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 Company or owned by a subcontractor of the company. If Unit A has already been successfully audited and if the quality management 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 checked by the Certification/control 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.

"Evaluation of subcontractors

Subcontracted processors who are subcontracted by another processor (not only by a licencee without own production) shall be evaluated / audited completely during a 3 years cycle minimum.

Evaluation by a desk top audit of documents
(for NATRUE only in addition to the regular on-site audits)
In situations that one applicant has:

- Many units/one product or
- Many units/different products product or
- Many units/different production steps or

And If one of the Units has already been successfully audited and if the Certification/control body is provided with the information/confirmation from the quality management 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.

EcoControl then pre-views a document desk top assessment in order to verify this situation.

Evaluation and Certification / Approval of NATRUE raw materials
Reference: Meeting minutes (15th July 2019) under Point 6 – Timeline & transition period (and taking into account adapted transitional period of 24+24 months, instead of 18+18):

- Already compliant RMs can be approved – January 2020 until latest January 2022 (24 months)
- Starting from January 2020, there will 24 months for all already compliant RMs to obtain the approval and be entered in the IT platform. Starting from this point NACs can start issuing **RM approval certificates**.
- Important – For already compliant RMs (assessed compliant by multiple NACs during different FP certifications), after the release of the RM approval scheme, NACs will need to contact all RM producers for the existing compliant RMs for them to decide which NAC (only one) they want to have for their RM approval and sign contracts with them.
- New RMs will be automatically dealt according to the new approval scheme.

Evaluation (onsite audits exemptions) in specific crises situation
Mark Smith posted a comment about this message on Basecamp. 18.3.2020

Re: COVID-19 and (re)certifications

- To conclude during this time first certifications, as well as regular audits / re-certifications, off-site (desktop) audits are accepted.
- On-site (physical) audits are to be carried out to cover the missing aspects not possible from a desktop audit when possible once restrictions lift.
- The NATRUE scheme already provides a timeline (cf. 6 months) after the pre-certificate for on-site auditing.
- If the company has to produce a product covered by pre-certificate asks the certification for this product, then an off-site desktop audit is permitted (as indicated above) for completion with on-site audit within 6 months starting from the off-site audit date.

Evaluation of Processes of the ISO 22716 Scheme as Product certification

Aktuell ist die Sprachregelung in der ISO 22716 als Leitlinie formuliert und spricht im Konjunktiv. EcoControl übersetzt diesen in ***Muss-Vorgaben***.

Stage 1 and 2 Audits
(although accredited to ISO 17065 the first audit shall distinguish between the stage 1 and 2 audit logic, in order to have well prepared companies for certification)

The objectives of the stage 1 are to provide a focus for planning the stage 2 audit by gaining an understanding of the organization's GMP SYSTEM and the organization's state of preparedness for stage 2 by reviewing the extent to which:

a) the organization has identified PRP that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements),

b) the GMP SYSTEM includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations),

c) relevant food safety legislation is implemented,

d) the GMP SYSTEM is designed to achieve the organization's food safety policy,

e) the GMP SYSTEM implementation programme justifies proceeding to the audit (stage 2),

f) the validation of control measures, verification of activities and improvement programmes conform to the requirements of the GMP SYSTEM standard,

g) the GMP SYSTEM documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties, and

h) there is any additional documentation which needs to be reviewed and/or information which needs to be obtained in advance.

Where an organization has implemented an externally developed combination of control measures, the stage 1 shall review the documentation included in the GMP SYSTEM to determine if the combination of control measures

— is suitable for the organization,

— was developed in compliance with the requirements of ISO 22716, and

— is kept up to date.

The availability of relevant authorizations shall be checked when collecting the information regarding the compliance to regulatory aspects.

For GMP SYSTEM, the stage 1 shall be carried out at the client's premises in order to achieve the objectives stated above. In exceptional circumstances, part of stage 1 can take place off-site and shall be fully justified. The evidence demonstrating that stage 1 objectives are fully achieved shall be provided. Exceptional circumstances can include very remote location, short seasonal production

The client shall be informed that the results of the stage 1 may lead to postponement or cancellation of the stage 2.

Any part of the GMP SYSTEM that is audited during the stage 1 audit, and determined to be fully implemented, effective and in conformity with requirements, may not need to be re-audited during the stage 2 audit. However, EcoControl shall ensure that the already audited parts of the GMP SYSTEM continue to conform to the certification requirements. In this case, the audit report shall include these findings and shall clearly state that conformity has been established during the stage 1 audit.

The interval between stage 1 and stage 2 shall not be longer than 6 months. Stage 1 shall be repeated if a longer interval is needed.

Audit time
The audit time must be appropriate in relation to the company size, number of employees and processes.

In determining the audit time needed for each site, EcoControl shall consider the minimum on-site duration for initial certification given in Table B.1 below.

The minimum time includes stage 1 and stage 2 of the initial certification audit but does not include the time for preparation of the audit nor for writing the audit report.

The minimum time for on-site auditing of the product and/or service realization of the organization shall be 30 % of the total minimum audit time (applies to all type of audits).

The number of auditors per audit day shall take into consideration the effectiveness of the audit, the resources of the organization being audited as well as the resources of EcoControl.

Where additional meetings are necessary, e.g. review meetings, coordination, audit team briefing, an increase in audit time may be required.

The number of employees involved in any aspect of food safety shall be expressed as the number of fulltime equivalent employees (FTE). When an organization deploys workers in shifts and the products and/or processes are similar, the FTE number will be calculated based on employees on the main shift (including seasonal workers) plus office workers.

Calculation of minimum initial certification audit time

Allgemein: Die Auditierung von GMP Systemen im NON-Food Bereich benötigen weniger Auditzeit als im Food Bereich. Dies kommt daher, weil es prinzipiell weniger potentielle Gefahren für die Sicherheit von Kosmetikprodukten gibt und die Prozesse in der Regel geschlossen.

The minimum audit time for a single site, expressed in days, is calculated as follows (**table B1**):

Basic on-site audit time (in audit days)	**Number of employees** (in additional audit days)	**For each additional site visited**
1,25	1 to 199 = 0 200 to 499 = 0,5 > 500 = 1,0	50 % of minimum on-site audit time

Calculation of minimum recertification audit time

The minimum recertification audit time shall be two-thirds of the initial certification audit time, with a minimum of 0,75 audit days. When properly documented and justified, a re-

duction to the minimum can be made in a less complex organization measured by number of employees, size of the organization and/or product volume.

Review / Certification Decision

EcoControl has assigned one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process (see table of responsibilities).

The review and the certification decision are completed concurrently by the same person.

The certification decision will be taken based on all information related to the evaluation, its review, and any other relevant information.

A certificate based on the format of the scheme owner will be handed over to the operator who holds the license agreement with the scheme owner. The products will be registered in the scheme owners' data base if required.

Reasons for denial, withdrawal or suspension of certification will be stated with clear reference to the applicable standard or certification requirement violated. As the audit report (on-site audit report or report on the assessment of product registrations) is also used for the recording of the review results, including all information available for the certification decision. This document records also the reasons for denial, withdrawal or suspension of certification.

NATRUE specific:
In the NATRUE scheme a preliminary certificate is issued, with a validity of 6 month or shorter if the on-site audit has taken place earlier. After the successful onsite audit, the final certificate shall be issued. This rule is only valid for new customer and their first registered product. Info to NATRUE when Preliminary certificate runs out with telling the reasons why, e.g. the production did not start and therefore Audit could not take place yet.

NATRUE Raw Material Approval System
Raw material certificates for "approved" RMs would be the same as for the approval of the Formulas just referring to the RMs i.e. the same as for the certification for RMs just referring to their approval now. (Mail from NATRUE 20.11.19)

To doc: certification cycle

Surveillance

There are no surveillance activities defined in the schemes applied by EcoControl. The NATRUE scheme previews a 2-year cycle of onsite audits if no new products are added meanwhile or no recipes have been changing. However in-between the 2 yearly audits no surveillance is planned.

EcoControl informs all operators in due time if their product certification status runs out and asks if re-certification is wanted.

According to 7.4.2. of the NATRUE requirements for certification bodies, the certification body shall decide on the frequency for regular inspections as outlined in 7.2.4.

Despite the rule for minimum 2 yearly audits, EcoControl carries out yearly audits if after the last audit

- New products are certified
- Formulas of certified products are changed

- Products are re-certified

Rules for the process to take over products from another Certification Body (CB)

In case an operator changes the Certification, body coming to EcoControl there are the following scenarios:

1. All or parts of the products run out of certification or are close to: Then EcoControl considers these products as newly registered formulas and evaluates those before re-certification. EcoControl accepts the previous audit of the former CB in order to calculate the next audit date.

2. An operator changes to EcoControl with formulas certified by a NAC which have a valid certificate. EcoControl assesses the products for plausibility (INCI are compliant and percentages for the label level are correct) and takes them over to the EcoControl certificate. These formulas are re-evaluated when they are re-certified.

➔ In all cases EcoControl asks the previous CB all existing documentation for formulas, raw materials and audit documentation. Scenario 2 may only be implemented if the formula that has been assessed by the previous NAC is available.

CHANGES AFFECTING CERTIFICATION

When the certification scheme introduces new or revised requirements that affect the client, EcoControl ensures these changes are communicated to all clients considering the implementation deadlines defined by the standard owner of the changes, however a.s.a.p. EcoControl verifies the implementation of the changes by its clients and takes actions required by the scheme.

It there are any changes in the EcoControl certification procedures affecting the customers, they are informed immediately.

To doc: INFORMATION template
Changes from NATRUE Scientific Committee

EcoControl considers also all other changes affecting certification, including changes initiated by the client, and shall decide upon the appropriate action. Changes affecting certification can include new information related to the fulfillment of certification requirements obtained by EcoControl after certification has been established.

The actions to implement changes affecting certification shall include, if required (and agreed by the client), the following:

- evaluation
- review
- decision
- issuance of revised formal certification documentation to extend or reduce the scope of certification;
- issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme).

Transition period

NATRUE and its Scientific Committee “Criteria and Label” shall reserve the right to update the NATRUE criteria regularly corresponding particularly to the current state of research and technology. If during the validity period of the certificate/conformity declaration

an update of the NATRUE criteria results in a product already certified/controlled 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/ conformity control period following the current certification/conformity control period at the latest.

Changes at operator side

The operator needs to provide information about all changes regarding the scope of the desired certification, including all changes of the provided description, as specified by EcoControl, of the production, products and area to be certified.

EcoControl will determine whether the announced changes require further investigations. If such is the case, the operator is not being allowed to release certified products produced under the changed conditions until EcoControl has notified the operator accordingly. Any changes of the recipe and the ingredients (quality) will lead to a renewal of the assessment process.

If organic qualities of raw materials are not available for a certain period, the NATRUE approved exception process will be applied. Please refer for details to doc 

TERMINATION, REDUCTION, SUSPENSION OR WITHDRAWAL OF CERTIFICATION

When a non-conformity with certification requirements is substantiated, either as a result of the audit, surveillance or otherwise, EcoControl considers and decides upon the appropriate action.

Appropriate action can include the following:

a) Continuation of certification under conditions specified by EcoControl (e.g. surveillance);

b) Reduction in the scope of certification to remove nonconforming product (variants);

c) Suspension of the certification pending remedial action by the client;

d) Withdrawal of the certification.

When the appropriate action includes evaluation, review or a certification decision, the requirements mentioned above shall be fulfilled.

If certification is terminated (by request of the client), suspended or withdrawn, EcoControl take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information (incl. the NATRUE data base), authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified. If a scope of certification is reduced, EcoControl takes actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

If certification is suspended, the GM of EcoControl formulates and communicates the following to the client:

➔ actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme;

➔ any other actions required by the certification scheme.

If certification is reinstaled after suspension, EcoControl make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications, exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, the EcoControl make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.