REGULATION FOR THE CERTIFICATION OF ORGANIC AND NATURAL COSMETICS

REG COSM 001

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INTRODUCTION

The Reg CE 1223/2009 establishes the standards for producing and commercializing cosmetics. ECOGRUPPO ITALIA S.r.l., hereinafter referred to as OCC, is a control and certification body that works according to the general standards of the rules UNI CEI EN ISO 17065. ECOGRUPPO ITALIA S.r.l. has written a private standard detailing the parameters that must be respected to certify Organic or Natural raw materials/cosmetics.

The Standard "Cosmesi Biologica e Naturale" was drawn up by the technical staff of ECOGRUPPO ITALIA's cosmetics department; an independent technical advice by competent external professionals is requested for each Standard revision.

This Regulation establishes the relationship between the OCC and the operators applying for the products certification in conformity with the "Standard for Organic and Natural Cosmetics" (REG COSM 002).

OBJECT

The object of this Regulation is disciplining the control and certification activity on the operators asking for the inclusion in the control system of the OCC, in order to obtain the relevant certification. This Regulation particularly describes the procedures the Operators must follow in order to obtain access to and remain in the control system.

Control system procedures adopted by the OCC will be explained in the following articles of this Regulation.

REFERENCE DOCUMENTS

- Standard for Organic and Natural Cosmetics (REG COSM 002);
- Reg CE 1223/2009;
- UNI CEI EN ISO 17065.

REFERENCE LANGUAGE

Italian is the official language used for the certification documents. If necessary the OCC will issue bilingual version (Italian-English) of the documents.

Art. 1 APPLICATION FIELD AND DEFINITIONS

The law describes cosmetics as "substances or preparations, different from medicines, designate for application on external surfaces of the human body (epidermis, piliferous system and hair, nails, lips, external genital organs), or on teeth and on the mouth mucosa with the sole or prevailing aim of cleaning, scenting, changing their appearance and/or correcting the body smells and/or protecting or maintaining them in good conditions".

Cosmetics don't have therapeutic aims and they can't claim therapeutic activities.

Specific legal provisions and good manufacturing practices regulate cosmetics production. The requirements for organic and natural certification come on top of these provisions, without replacing them. For this reason the full conformity to all these provisions is a necessary, preparatory and unavoidable condition for the producer.

According to the "Standard for Organic and Natural Cosmetics", the certification can be requested for the following products: Organic Cosmetic, Natural Cosmetic, Organic Raw Materials, Natural Raw Materials and Raw materials of Natural Origin.

Definitions

"Standard for Organic and Natural Cosmetics": a set of information the operator has to refer to in order to obtain the certification "Ecosmetica quality".

Operator: company, society, organization with its own functions and administration asking for certification.

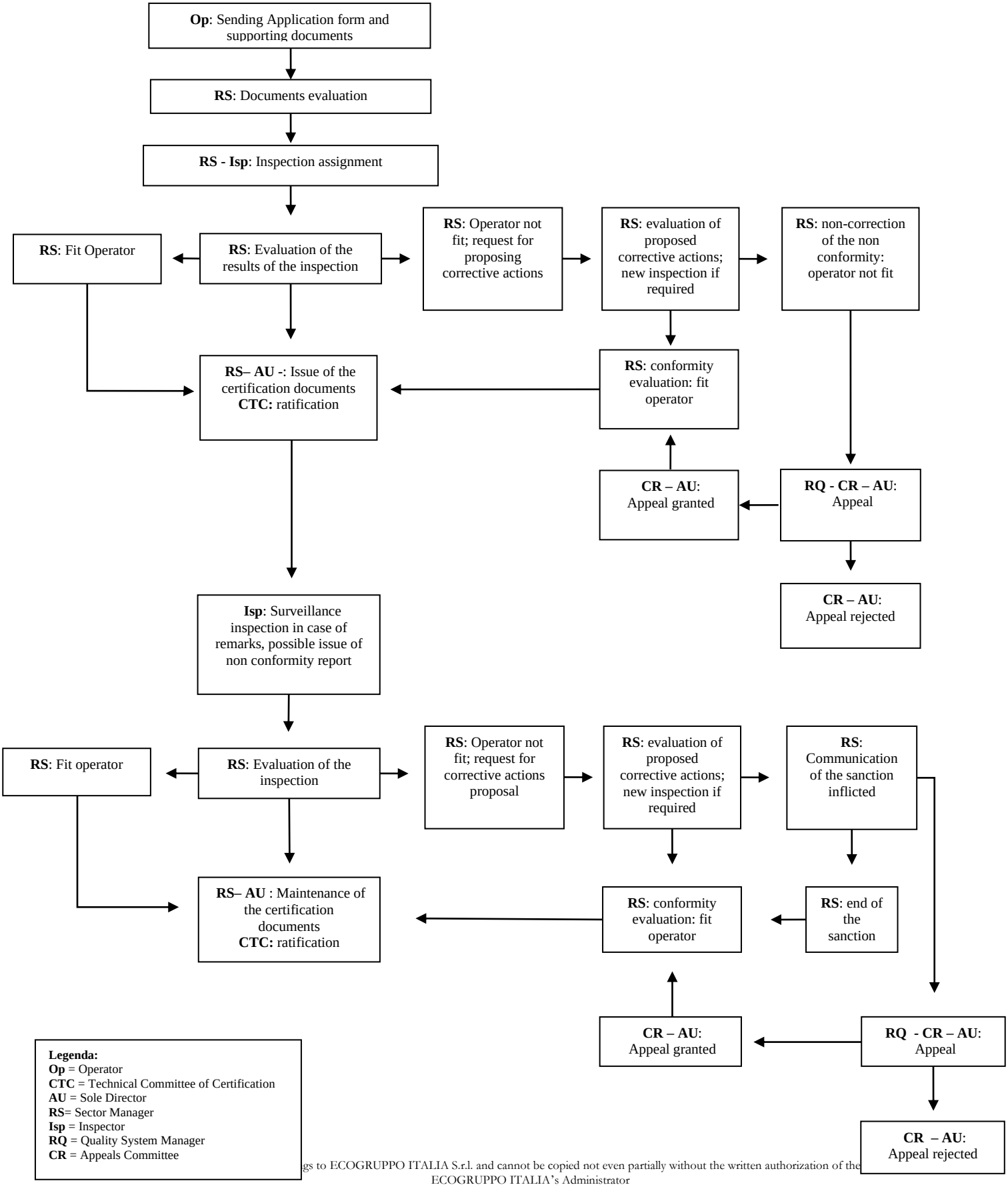
Certificate of Conformity: a document attesting the compliance of a product, process, service, to the particular requirements the "Standard for Organic and Natural Cosmetics" imposes.

Certificate of Product: a document attesting the compliance of a raw material of natural origin to the "Standard for Organic and Natural Cosmetics".

OCC: Control and Certification Body.

ACCREDIA: Italian Accreditation System.

CONTROL AND CERTIFICATION CHART



Art. 2 PROCEDURES TO OBTAIN ACCESS TO THE CONTROL AND CERTIFICATION SYSTEM

The operator willing to apply for certification submits to the OCC head office the Form Certification Documents Request (MD COSM 018). The form is published on the web site www.ecosmetica.it, or it can be requested at the head office.

The OCC receives the application of the Operator and sends him the "Standard for Organic and Natural Cosmetics" (REG COSM 002) and some preliminary documents, i.e. the Application form (MD COSM 001), the Confidentiality agreement (MD COSM 021), the Service contract (MD COSM 020) and the Economic offer (MD COSM 003).

The above preliminary documents have to be filled in, signed, stamped and then sent to the OCC in double copy, together with a copy of a valid identity card of the signatory.

A copy of these documents is registered in the file created for every Operator; the other copy is sent back countersigned by the Sole Manager or his authorized deputy.

Then the OCC requests the following documents:

a) Operators producing organic and natural raw materials/cosmetics

- Product's technical form (MD COSM 002)
- Material safety data sheet and Technical sheet of all raw materials (if the OCC requests it, even the Raw material form MD COSM 014)
- Documents about packaging (eg. Designs and technical sheet)
- Planimetry of the company installations and a copy of their sanitary authorization and of their suitability/safety certificates
- Detailed description of the used equipments
- Company organization chart.

b) Operators producing raw materials of natural origin

- Product's technical form (MD COSM 002)
- Raw material form (MD COSM 014)
- Material safety data sheet and Technical sheet of the raw material to certify
- Material safety data sheet and Technical sheet of all components of the raw material to certify (supported, if necessary and if the OCC requests it, with the Raw material form MD COSM 014)

The staff of the Cosmetics Office records the fitness of these documents filling the Form for documentary control (MD COSM 019).

For Raw Materials not certified under the Standard "Cosmesi Biologica e Naturale", the Cosmetics office may assess their conformity based on the information provided by the operator with the Raw Material form (MD COSM 014).

Art. 3 CONTROL ACTIVITY

The control activity of the OCC implies inspections at the production units the Operator has notified and documentary controls carried out at the offices. For the inspection activity the OCC employs qualified inspectors ensuring the principles of competence, professionalism, impartiality and independence.

Any noticed anomaly can determine a non conformity that the operator shall manage according to established steps and times (PRQ COSM 005).

The number of annual controls is based on the company type, and is determined by the sum of factor "A" (number of references certified) and factor "B" (number of sites to be controlled), as reported in the following table:

	A			B			
TYPE OF COMPANY	Number of products			Number of sites			
	From 1 to 25	From 26 to 50	More than 50	1 site	2 site	3-5 site	> 5 site
Trading Company	0	0	1	1	2	3	4
Manufacturing unit	0	0	0	1	2	3	4
Production Company	0	1	1	1	2	3	4

Number of annual controls = A + B

The number of planned controls is specified within the offer form (MD COSM 003) sent to the operator together with the preliminary documents. In case of changes in the initial operator' set up (i.e. number of manufacturing sites, number of certified references, the OCC will send a new offer.

For companies producing raw materials of natural origin the control is documentation-based. If the outcome is positive, the OCC issues the relevant certification.

In order to obtain the renewal of the certification, the raw material producer will send each year:

- A declaration stating that suppliers, products and processes concerning the above mentioned raw materials of natural origin have not changed;
- The purchasing invoices of the various components of the raw material

For all controlled operators, in addition to the regular on site inspections, Ecogruppo Italia S.r.l., may deem appropriate asking for analytical testing on product samples.
The sampling plan is based on the following criteria:

- No sampling for businesses dealing with product marketing only, without making any product manipulation;
- One sampling during the certification validity time (3 years) for all the other business types. If the sample analysis finds not allowed substances in the product, sampling and testing will be repeated in the next inspection.

The inspector, however, has the power to decide and take product samples in case of doubts raised during the on-site inspection.

First inspection – Starting stage:

The starting stage is the preliminary act for the evaluation of the Operator's eligibility to access the control and certification system of the OCC. The aims of the starting stage are: acknowledge the existence of a company organization, check conformity between real operations and submitted documents and check overall conformity to the "Standard of Natural and Organic Cosmetics".

The first inspection takes place within 60 days from the receipt of the Application form. This term is respected if the documents received by the OCC are correct and complete.

The operator or his/her delegated deputy accompanies the inspector during the on-site inspection. A written delegation is not requested if the responsible for the company management is an employee of the controlled Operator. In this case copying the personal data of the responsible on the inspection report, specifying his position inside the company, is sufficient.

The following aspects will be controlled:

- The processing installations and the storage rooms for raw materials, semi-finished products and finished products;

In case of Operators producing both "organic" and "conventional" products, the inspector checks:

- If the separation of the production cycles (physical or time-wise) is possible;
- The equipment cleaning procedure before any processing of organic product;
- The physical separation of the storage rooms for raw materials, semi-finished products and finished products.

The inspector has the power to take samples for analysis.

At the end of the inspection the inspector prepares a report (MD COSM 010), writing down findings and observations relevant to the respect of the Standard. The applicant or the responsible for the company management with a specific delegation must sign the inspection report. The inspector consigns a copy of the inspection report.

If the inspector notices some non conformities, he shall classify them according to the Procedure of infliction and application of the sanctions (PRQ COSM 005), and he shall write them in the Non conformity Report (MD COSM 012).

Observations and recommendations, if any, shall be written on the control outcome letter.

Inspections following the starting stage - Surveillance:

The aim of the surveillance inspections is to verify the correct and continuous application of the "Standard for Organic and Natural Cosmetics".

The inspections, planned by the OCC according to an annual control plan, will be executed periodically and at least once a year, with or without advanced notice.

The operator or his/her delegated deputy accompanies the inspector during the on-site inspection. A written delegation is not requested if the responsible for the company management is an employee of the controlled Operator. In this case copying the personal data of the responsible on the inspection report, specifying his position inside the company, is sufficient.

Besides what is checked during the first inspection, the following aspects will be controlled:

- The tax documents of the raw materials suppliers and their certifications, as well as the correctness of the records on the In-Out register (MD COSM 006);

- The records on the Production Form (MD COSM 005), in order to control the quantity of products obtained in the different processing cycles;
- The tax documents concerning the products sold, as well as the correctness of the records on the In-Out register (MD COSM 006);;
- The compliance of the labels and the correct management of their account;
- The correct use of the ECOGRUPPO ITALIA marks.

The inspector can take samples for analysis.

The quota of samples that has to be analyzed is consigned to the chosen laboratory, together with the "Form of sample delivery" (MD COSM 016) where the type of the requested analysis requested is specified (according to the nomenclatures the laboratory adopts).

At the end of the inspection the inspector prepares a report (MD COSM 010), writing down findings and observations relevant to the respect of the Standard. The applicant or the responsible for the company management with a specific delegation must sign the inspection report. The inspector consigns a copy of the inspection report.

If the inspector notices some non conformities, he shall classify them according to the Procedure of infliction and application of the sanctions (PRQ COSM 005), and he shall write them in the Non conformity Report (MD COSM 012).

The inspectors sends the dossier back to the Cosmetics Office.

Observations and recommendations, if any, shall be written on the control outcome letter.

Documentary control:

The OCC can request, for its activity, documentary evidence concerning:

- Products, raw materials and all other used means of production (delivery documents, invoices, certifications, etc.);
- Management of the records concerning executed production processes (registers and other documents of the quality system);
- Finished products sales (delivery documents, invoices, etc).

The documentary control is part of the control activity of the OCC. For this reason, a spotted anomaly may trigger a non conformity. This non conformity must be managed within the sanctions system.

Art. 4 OPERATOR'S DUTIES

The Operator engages himself in giving the OCC full assistance to carry out a valid control of his own activity. He particularly engages himself in:

- Communicating to the OCC any change in the information concerning his production activity (including phone and post address) within 30 days from the starting day of the change;
- Permitting the free access of the inspectors to the production units, to the company registers and to the supporting documents;
- Accepting controls without any advance notice;
- Accepting the presence of other people (inspectors of Accreditation bodies or representatives of associations) supporting the inspectors of the OCC;

- Informing the OCC, by registered letter, of every formal or informal complaint concerning the certified product, within 15 days from its acknowledgement;
- Maintaining always updated a list of complaints/non conformities received from external parties. For every complaint/non conformity the Operator shall establish and carry out suitable corrective actions, always informing the OCC;
- Preventing commingling between certified and conventional products and minimizing non conformities. The operator prepares a "Risk management plan" and handle it to the OCC
- Respecting the economic duties reported in this regulation, in time and according to the ways reported in the Article 10 of this regulation;
- Safekeeping the control and certification documents issued and/or received by the OCC or other bodies.
- Respecting the Community and National rules in force, as well as the particular provisions of ECOGRUPPO ITALIA S.r.l.;
- Accepting the sanctions imposed by the OCC, without prejudice to the right to lodge an appeal;

as well as to comply with of the legislation and explicitly indicated in the contracts stipulated beetween the Operator and the OCC.

Art. 5 CERTIFICATION BODY'S DUTIES

The OCC engages itself in enforcing the following regulation, and particularly it:

- Provides for training and updating the certification dossier of the Operator;
- Carries out the ordinary supervision activity.

In the performance of its duties the OCC must respect the professional secrecy and it engages itself in not revealing the confidential information it has received during the inspections and the controls.

Art. 6 SAMPLES AND ANALYSIS

The inspectors shall always take samples in presence of the operator or the company manager and, in any case, of a person with a specific delegation. This person will sign the Form for Sampling (MD COSM 017); the written delegation is not requested if the responsible for the company management is an employee of the controlled Operator.
The sample is made of four quotas and every quota will be put inside a container that will be sealed and labelled with an identification code that the OCC issues (Procedure for labelling the product samples PRQ COSM 004). The inspector delivers three of the four quotas to the OCC; one quota will remain at the Operator and he must keep it in a suitable way so that the sample quota remains unchanged.
The three quotas at the OCC disposal will be used for the analysis; the Operator can use his quota for his own controls.
The sample quotas are submitted to accredited tests according to the rule ISO/IEC 17025.
1. If the result of the first analysis is negative, as far as the substances researched are concerned, the analytic control ends and the other sample quotas are disposed.
2. The OCC sends the Operator a copy of the Report of Analysis only if he requests it.

3. If the result of the first analysis is positive, for one or more non conform substances, the following procedure will be carried out:

- The OCC sends the Operator a written communication notifying him the ongoing control activity and the result of the analysis, prescribing the precautionary quarantine of the product (concerned lot) since the end of the control. The OCC requests to the Operator the analysis of the causes and any useful information;
- Within 10 days from the dispatch date of the above communication, the Operator has the right to request a revision analysis on the second quota that the OCC keeps. This second analysis will be executed at another laboratory, always in conformity with the above mentioned requirements. The OCC and the Operator choose this laboratory in agreement;
- If the Operator doesn't request the revision analysis, the OCC proceeds with the sanction;

4. If the result of the second analysis is positive, for one or more non conform substances, the OCC proceeds with the sanction;
5. If the result of the second analysis is negative, as far as the substances researched are concerned, (and it is different from the result of the first analysis), the OCC requests the third revision analysis on the third quota that the OCC keeps. The third analysis will be executed at another laboratory, different from the previous ones.
6. The result of the third analysis solves the case, confirming the result of the first or of the second analysis. On the result of this last analysis the OCC takes a final decision on the conformity.

The OCC reserves the right to subcontract the analysis activity to external laboratories, always accredited according to ISO/IEC 17025.

For the second and third analysis the Operator can appoint an expert and can decide to execute the analysis in laboratories different from those having an arrangement with the OCC, provided that they are accredited according to ISO/IEC 17025.

The list of the laboratories having an arrangement with the OCC is at disposal on the web site www.ecogruppoitalia.it, or it can be requested at the Head Office.

Art. 7 ISSUE, USE AND DURATION OF THE CERTIFICATION DOCUMENTS.

The OCC uses the following certification documents:

1. Conformity Certificate (MD COSM 008);

2. Product Certificate (MD COSM 013);

The Operators can use these documents only in order to indicate that their products are in conformity with the "Standard for Organic and Natural Cosmetics". The same documents must not be used to discredit the OCC and they must be given back to the OCC (on request) or they must be destroyed (the destruction must be documented) if the Operator withdraws or is excluded from the control system.

Conformity Certificate

The Conformity Certificate states both, the inclusion of the Operator in the control system of the OCC and for which products, processes or services the Operator can issue conformity statements.

The OCC issues the Conformity Certificate, which is renewed every 36 months.

The Cosmetics Office issues the Certificate just after the conformity of the Operator has been controlled. The evaluation is based on the most recent information acquired during the inspection at the production sites.

The document is made of two inseparable sections:

-The Section A reports the certificate number, the personal and identification data of the Operator and the version of the Standard according to which the certificate is issued.

-The Section B (Annex's Certificate) shows the certificate number it belongs to, and the products, processes and services for which the Operator is certified.

Any change to the Section A will involve the issue of a new document; any change to the Section B won't involve the issue of a new document, but only the updating of the same section.

The Cosmetics officer issues the Conformity Certificate, stamp it and put his/he initials; the certificate is then signed by the Sole Director or his delegated deputy.

The Operator keeps the original Conformity Certificate and he distributes the copies.

The Cosmetics Office can revoke the Conformity Certificate if some non conformities are noticed.

The OCC is not responsible for the inappropriate or wrong use of the Conformity Certificate. The Operator has the legal responsibility in case of non respect of the rules concerning the product marketing.

The Conformity Certificate cannot be used as a batch certificate or transaction document.

The OCC reserves the right to go to court if it notices an inappropriate use of the Conformity Certificate.

If the Operator has a valid Conformity Certificate and he is excluded or he decides to exit the control system of the OCC, he must give the document back, if the OCC requests it.

Product Certificate

The Product Certificate (MD COSM 013) is issued when a "raw material of natural origin" is certified following the requirements of the "Standard for Organic and Natural Cosmetics" of the OCC.

This kind of certificate reports the references to the Operator and to the certified product, specifying the classification.

The certificate is valid for 12 months and it reports the date of issue.

The Cosmetics officer issues the Conformity Certificate, stamp it and put his/he initials; the certificate is then signed by the Sole Director or his delegated deputy.

The Operator keeps the original Product Certificate and he distributes the copies.

The Cosmetics Office can revoke the Product Certificate if some non conformities are noticed.

The OCC is not responsible for the inappropriate or wrong use of the Product Certificate. The Operator has the legal responsibility in case of non respect of the rules concerning the product marketing.

The OCC reserves the right to go to court if it notices an inappropriate use of the Product Certificate

If the Operator has a valid Product Certificate and he is excluded or he decides to exit the control system of the OCC, he must give the document back, if the OCC requests it.

Art. 8 AUTHORIZATION FOR PRINTING LABELS: ISSUE, DURATION AND WITHDRAWAL

The Operator must refer to the production method, for the products obtained respecting the "Standard for Organic and Natural Cosmetics", directly on the labels or on the packages.

The OCC issues the authorization for printing labels. The Operator must submit a written application (MD COSM 011), together with a proof of the label, to the Cosmetics Office. The Cosmetics Office decides if other controls are necessary or if it can issue the authorization (MD COSM 004). The validity of the authorization is linked to the certification of the product itself and the lack of variation of the label.
In case of change both in the layout and in the subject of the label, authorization must be requested again.

The Authorization for Printing Labels is given for particular kind of products, by assigning a code that will be inserted in the label of the certified product.

The OCC can revoke the authorization for printing labels if some non conformities are noticed and if the labels don't correspond exactly to the approved version.

The OCC is not responsible for the inappropriate or wrong use of the authorizations for printing labels. The Operator has the legal responsibility in case of non respect of the rules concerning the product marketing.

The OCC reserves the right to go to court if it notices an inappropriate use of the authorizations issued. The Operator shall pay damages.

The Operator has to notify in writing the OCC if he, after leaving or being excluded from the control system, has still got a stock of authorized labels referring to the certification "ECOSMETICA quality". The OCC can request their destruction (it must be documented) or it can decide to withdraw them.

Art. 9 USE OF THE MARK

The Conformity Certificate and the certification mark "ECOSMETICA quality" always belong to the OCC. All labels, packages, marks and advertisement which include a reference to our mark or our certification, must be expressly and in writing authorized. The use of the marks is specified in the following documents:

- Regulation for using the mark ECOSMETICA quality- Organic Certification (REG COSM 003).
- Regulation for using the mark ECOSMETICA quality- Natural Certification (REG COSM 004).

Art. 10 COSTS

The cost of the control and certification process is based on the Tariff sheet (MD COSM 022). The Economic offer (MD COSM 003) for every Operator is based on the price list in force and on the information reported in the Form Request of certification documents (MD COSM 018).

The tariff is annual and is to be paid within thirty days from the date of the invoice, apart from any extension of payment that the administrative office may allow.
The economic offer (MD COSM 003) is tacitly renewed on a yearly basis if the initial set up (company, processes, products) persists, otherwise the OCC will submit a new offer.

Any laboratory analysis on product samples taken at the Operator represents an additional cost. The payment of such costs shall respect the terms reported in the request of payment sent by the Administrative Office of the OCC. The non payment of the requested tarif, including the analysis costs, can cause the withdrawal of the certification and the annulment of all licences already issued.

Art. 11 NON CONFORMITIES AND FOLLOWING SANCTIONS

In case of remarks, the staff of the Cosmetics Office communicates the results to the Operator, requesting his proposal of corrective action.
The Operator must propose suitable corrective actions, indicating a deadline for their implementation. The Cosmetics Office assesses the proposed corrective actions and if they are accepted, the same office evaluates the conformity and judges the operator as fit. If necessary, the implementation of corrective actions might be checked through an "ad hoc" inspection.
The Cosmetics Office establishes then if inflicting or not the sanction reported in the Sanctions Book (ISL COSM 001) and it informs the Operator with a communication signed by the proposer and the AU.
The sanction must be inflicted from an employee of the Cosmetics Office different from the one who has issued the NC.

There are three levels of non-conformity: non-observance, irregularity and infraction. The corresponding sanctions are tuned according to the capacity of the non-conformity to compromise the solidity of the control system.

Non-observance

It is a slight non compliance not undermining the conformity of the production process, the self-checking system on the production method, the management of the firm documentation, not having long-lasting effects, not implying substancial changes of the certification status of the products or the operator, or his/her reliability.

Non-observances can be minor or major, depending on their effect on the conformity to the standard.

Irregolarity

It is a non-compliance undermining the products certification, but not the self-checking system on the production method and the management of the firm documentation. It does not have long-lasting effects and does, not imply substantial changes of the certification status of the products or the operator, or his/her reliability.

Infringement

It is a severe non-compliance undermining the conformity of the production process, or the self-checking system on the production method, or the management of the firm documentation, or the compliance of the contractual obligations with the control body.

Infringements cause long-lasting effects on the certification status of the products or the operator, or his/her reliability.

Based on the level of gravity and on the graduality principle, the following sanctions are inflicted: Reprimand or Warning (for non-observances), Withdrawal of organic labelling (for irregularities), Suspension of the certification and Exclusion of the Operator from the control and certification system (for Infringements).

Reprimand

It is a sanction that doesn't have any effect on the certification. The control of the corrective action takes place during the next inspection or at the CB offices. The non-respect of a reprimand causes the infliction of a more important sanction, usually a warning.

Warning

It is a sanction that doesn't have any effect on the certification, provided that the non-conformity is positively closed within the reported terms. The control of the corrective action takes place during the next inspection or at the CB offices. The non-respect of a warning causes the infliction of a more important sanction, usually the suppression of the organic information.

Withdrawal of organic labeling

The Operator can't report, on the labels and on the documents of the irregular products, the information concerning the certification of the relevant batch. The control of the implementation of the corrective actions and of their effectiveness takes place during the next inspection. The non-respect of a withdrawal of organic labelling causes the infliction of a more important sanction, usually the suspension of the certification.

Suspension of the certification

It is the temporary suspension of the certification of conformity to the standard NATRUE. It is inflicted when the reliability of the controlled operator is compromised. During the suspension period the operator cannot commercialize the products referencing information on the certification NATRUE. The suspension can be referred to on or more processing areas or to the whole company. It can be also applied to singular processing lines. The control of the corrective action takes place in the respect of the sanction provisions. Usually the non-respect of a suspension causes the exclusion of the Operator.

Exclusion of the Operator

It takes place in case on infractions compromising the reliability of the Operator's company management and so his permanence in the control system, or when the same infraction is reiterated or when the Operator doesn't respect the commitments towards the competent authorities and/or the CB.

The CB Technical Committee of Certification has to confirm all sanctions.

The Operator is informed about applied sanctions through a registered delivery letter or equivalent means. The communication can be anticipated by fax.

Art. 12 APPEALS

Within 15 days from the sanction letter receipt, the Operators can appeal against the OCC decisions and/or sanctions.

The RQ manages the appeal according to the PRQ 006 (Procedure of Appeal), available at www.ecogruppoitalia.it.

If the two parties cannot solve the case, they can go to court and the competent court is that of Catania.

Art. 13 COMPLAINTS

All Operators in the control system of the OCC have to keep records of the complaints related to the activities and products under certification. While performing the control activity, the OCC can check the management of the complaints as far as the implemented corrective actions are concerned.

All Operators in the control system of the OCC can raise complaints on inefficiencies or other anomalies in the OCC activity. The RQ manages the complaints according to the PRQ 009 (Procedure for the treatment of the complaints).