SPECIAL REGULATION FOR CERTIFICATION OF AGRI-FOOD PRODUCTS

Revisions in this document

6	2012-12-21	• General review.
7	2015-10-12	• General review; • Cancels and replaces the Regulation "INN-STD-CE-PC-AGROALIM rev.6".
8	2016-04-11	• FOS standard feature insertion
9	2016-09-12	• Clarification of sampling methods
10	2019-11-02	• Updating references and clarified sampling modes for product certification

1 PURPOSE

This document constitutes the "Special Regulation" relating to the certification system of agri-food products, or defines and describes the conditions and procedures applied by DNV GL Business Assurance Italia S.r.l. (hence on DNV GL) for the certification, registration and award of the trademark for such products.
This Regulation shall lay down the additional conditions and procedures for this specific system in relation to what has already been defined in the documents:

"General regulation for the certification of products, processes and services";
"Regulation for the use of the DNV GL product/service certification mark";

these documents are therefore also fully applicable to this scheme unless the variants specified in this Regulation.

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2 REFERENCE DOCUMENTS

2.1 Qualityrequirements

The quality requirements of the certified product are specified in the certification reference documents.
These can be:

- national and/or international technical standards (including those in disciplinary form) recognised and adopted by DNV GL;
- "Technical Product Specifications"- STP, issued by DNV GL, possibly on the proposal of the organization. These STPs must clearly express significant and relevant characteristics and requirements of the specific product to be certified.
- "Specifications" (supply chain, good agricultural practices, etc.) issued by DNV GL, possibly on the proposal of the organization. In this context, those technical standards based essentially on identification and traceability requirements and/or production/processing methods not directly found on the product are classified as "Disciplinary".
- FoS Friend of the Sea Standard, broken down by type according to the species being verified. The Friend of the Sea certification scheme evaluates products from both fisheries and aquaculture according to criteria and sustainability indicators. Certification ensures that a product complies with sustainability requirements.

Regulatory documents issued by DNV GL are public, and made available to anyone interested in them upon simple request to DNV GL.

2.2 References to the certification system

The following documents, on the other hand, constitute references taken into account by DNV GL in the application of this system:

ISO/IEC DIS 17067	Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes
UNI ISO 2859 Part 2°	Sampling procedure in attribute testing. Sampling plans indexed according to limit quality (QL) for testing an isolated batch
Codex CAC/GL 33-1999	Recommended methods of sampling for the determination of pesticide residues for compliance with MRLS
Codex Stan 233-1969	Codex sampling plans for prepackaged foods
RT 11 rev 0	Minimum requirements for certification of non-GMO characteristic/requirement products
RT 17 rev 0	Requirements for the accreditation of certification bodies operating certifications in compliance with UNI EN ISO 22005 "Traceability in agri-food supply chains - General principles and basic requirements for design and implementation systems
ISO 22005:2008	Traceability in agri-food supply chains General principles and basic requirements for system design and implementation
FOS 0001	FoSaccreditation scheme- water, FoS-Wild, FOS- FF, FoS-FM, FoS-FO, FoS-

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3 SPECIAL RULES

The certification system of agri-food products is based on 2 different levels defined as follows:
LEVEL 1: is based on the type tests and/or inspection carried out on product samples taken from the organization having the characteristics defined in the relevant Technical Product Specifications.
LEVEL2: Certification is based both on the monitoring of production and quality system and on the testing or inspection of samples taken from the organization.
The level of the product certification system chosen by the organization must be indicated in the various registration documents of the verification activities.
Each certification scheme included in this system consists of the common procedures of the system and the particular regulatory document that specifies the characteristics of the product being certified.
In the case of Specifications, the certification scheme is supplemented by a special procedure for the management of the specific aspects related to each specification.

3.1 Eligibility rites

Manufacturer: A legal party or person that is part or the entire production process being evaluated. A manufacturer could represent one or several sites. The manufacturer is legally responsible for the production process and the products marketed.
Individual Manufacturer: An individual manufacturer that requires certification. The individual manufacturer is the owner of the certificate.
Single site: An individual manufacturer or organization that owns a single production site.
Multiple Site: An individual manufacturer or organization that owns several production sites that do not operate as separate legal entities. An organization that has an identified central function, where some tasks are scheduled, controlled, or managed, and a network of local offices or locations (sites) where those tasks are fully or partially performed.
Producer Group: A group of producers, with different legal entities, who are bound by a contractual formula that defines the requirements of the group and that operate according to common procedures in accordance with the requirements defined by the reference standard. Once certified, the group, as a legal entity, or a company defined as the leader by the contractual formula in place among the members of the group is the owner of the certificate.
Group member: Group members, who can represent one or more sites. They are cited as certified, but do not own the certificate issued for the group. The members of the group adhere, by formal agreement, to the production according to FOS requirements, undertake, by formal agreement, to participate in the audit activity according to the frequencies and modalities defined by the standard owner and the certification body, make available site and documentation during the audit activity, in order to allow an effective performance of the activity itself.
Subcontractor: a service provider used by the manufacturer or producer group, which intervenes in the production chain, but which does not hold legal ownership of the product it is processing, which remains in the producer's head. The subcontractor intervenes in the production chain, but due to the nature of its activity carried out on behalf of third parties and given its non-adherence to the producer group, it does not own the certificate and is not mentioned on the same. Depending on the criticality of the process carried out by the subcontractor, the institution may request an on-site visit to the same (e.g. product handling company) or a documentary verification (e.g. trading companies: documentary verification only).
Production site: production area owned or rented by the producer, who has direct control from a production point of view.

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Eligibility criteria for sampling: The eligibility criteria for sampling are applicable to individual, multisite producers and are detailed in each specific standard. Producer groups are not sampled (all sites are audited, except if they are explained within each individual standard).

3.2 prices

DNV GL processes and transmits, to eachrequesting company, a specific offer for each product, complete with all the information related to the technical and cost aspects, based on the following aspects: unified certification process Quality-Product System, presence or not of Certified Quality System, number of productionunits; geographical location of the production unit(s). Sampling and analysis costs, which remain the responsibility of the applicant, are excluded from this quotation.

3.3 Non-compliance

The following are considered non-conformities (NC) or major anomalies:

- failure to meet product requirements related to certified characteristics, legal requirements, safety and/or healthiness of the product;
- failure to meet quality system requirements that would raise doubts about the system's ability to ensure the required level of quality;
- incorrect handling of complaints and/or disputes;
- incorrect use of the mark and the certificate.

The following are considered observations (SDOs) or minor anomalies:

- failure to meet product requirements that do not concern certified characteristics, legal requirements, safety and/or healthiness of the product;
- failure to meet quality system requirements that do not give rise to doubts about the system's ability to ensure the required level of quality.

In order to ensure the issue of the certificate or the maintenance of the validity of the certificate, any CN found (documentary and analytical) must be closed. The need to verify the closure of the NC on site or off site will be decided according to the type of NC. Then general CN line concerning documentary aspects can be evaluated and closed off site, all other types of CN must be verified and closed on site. When the test reports show that the requirements are not met, sampling is repeated up to 2 times (3 overall analyses), after which the product is declared un certifiable.

For any SDOs, the organisation shall define appropriate corrective actions and undertake to implement them within the next surveillance review.
Incorrect SDOs within the defined timelines can become NC.

For FoS, the classification of anomalies follows different rules depending on the type of requirement/indicator. These can be classified as essential, important or recommended.
Essential indicators must always be 100% met in order to be able to issue certification.
Non-compliance with essential indicators will be treated as larger NC and must be closed within 3 months of the audit date. Limited to certain requirements (mentioned in the specific standard) closing times of up to a maximum of 6 months are allowed.
Non-compliances detected with important indicators will be managed as minor NC, the organization will have a maximum time to send to the SB the proposal for corrective action with 3 weeks implementation times. Only after acceptance of the proposed corrective action can the certificate be issued. Non-conformities will be closed in the next audit.
The recommended indicators will be managed as the comments, the organization will have to evaluate the

possible need for corrective actions and, in terms of the subsequent inspection visit, it will have to inform the Certifying Body about the decisions taken and the corrective actions put in place

3.4 Evaluation of documentation

The documentation relating to the product, called as a whole "Technical Dossier", is made available to DNV GL for documentary verification (VQM), the activity includes a conformity assessment of the Technical Dossier in relation to the characteristics of the product defined in the relevant Technical or Disciplinary Specification.
In the Level **1 certification system,** such documentation must at least contain:

- control plans, analytical methods and related recordings;
- documents describing the identification and traceability of the product including labelling;
- the management of complaints relating to the certified product;
- management of non-compliant products.

The level **2** certification system documentation will contain at least:

- general information on the company organization and production chain (if applicable);
- documents describing raw materials and/or semi-finished products and related procurement requirements (purchase specifications) and supplier qualification criteria;
- documents describing the product, in accordance with the reference documents, specifying sizes, packages, etc.;
- documents describing the production process and its controls;
- documents describing the production quality assurance system;
- documents describing the HACCP plan in accordance with applicable legal requirements;
- documents describing the system of identification and traceability of the product (including labelling);
- documents describing how the non-compliant product is treated and corrective and preventive actions are operating.
- documents describing the system of internal inspections

The documentation relating to the FoS certification system will contain at least:

- general information on the company organization and the production chain;
- documents describing raw materials and/or semi-finished products and related procurement requirements (purchasing specifications) and supplier qualification criteria limited to GMO-related aspects;
- assessment of the impact on environmentalsustainability;
- documents describing the system of identification and traceability of the product (including labelling);
- training on the FOSstandard.
- documentation describing the key requirements defined in the FoS standard with particular reference to legal and regulated aspects (e.g. quality, environment, sustainability, etc.)

DNV GL evaluates the documentation and communicates its results to the organization as defined in the "General Regulation for the certification of products, processes and services".
The documentary verification related to the certification of traceability systems is carried out at the same time as the initial verification and the results recorded in the initial verification report.
FoS documentary verification will be carried out at the organization's headquarters. In special cases it will be acceptable to carry it out consecutively to the initial verification. The latter can only be carried out if the

documentary verification is passed.

3.5 Initial inspection

The initial inspection involves all the production units identified in the certification request (possibly sampled), and will take into account the product certification system chosen by the company, the activity will evaluate the compliance of the Technical Dossier in its application.
In the case of the level 1 product certification system, the verification provides only for the verification of application of what is defined in the Technical Dossier; for the level 2 product certificationsystem, traceability and FoS will also evaluate the compliance of the process and production quality assurance system according to the requirements of the ISO 9001 standards of the following topics:

- Supplier evaluation and purchase data management;
- Identification and traceability of the product;
- Control of the process and production chain (if applicable);
- Tests, checks and tests (on receipt, in production, final and related registrations)
- Control of test, measurement and testing equipment;
- Non-compliant product control;
- Corrective and preventive actions (including complaint and litigation management);
- Handling, storage, packaging, storage and delivery;
- Internal inspections;
- training.

In the case of fos verifications it will be necessary to fill in a specific check list to give evidence of the degree of satisfaction of each requirement. The check list will be specific depending on the scope and downloadable from the Friend of the Sea(http://www.friendofthesea.org/IT/download.asp?ID=31) website.

If the organisation already operates under a quality system certified by a certification body accredited under IAF mutual recognition, after evaluation of the certification body's verification reports, the initial inspection check could be carried out in a reduced form, including a documentation assessment and verification of the production quality assurance system.
In the case of joint quality and product system checks, the results of the two certifications are independent and possibly divergent (e.g. The final controls on the product systematically performed only on the certified product prevent system certification but not product certification).
In the case of level 1 product certification systems verifications, the initial inspection can take place after the documentary verification (therefore within the same day) only if the documentary verification does not present NC.

In the case of verification:

- the sampling criteria provided for in RT 17 (n=√N: n=number ofhomogeneous supply chain actors to be verified, N=total number of homogeneous supply chain players) apply on supply chain traceability systems;
- on the FoS standard, the samples must comply with what is defined in each standard for which the activity will be delivered (square root of homogeneous actors, multiplied by a correction factor according to the number of actors) and as defined in the cap. 3.1 (eligibility criteria);

on product certifications against STP (product technical specifications) which is expected sampling the criteria are defined within the same document

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3.5.1 Initial type tests

DNV GL shall take the product samples to be subjected to the initial type tests if the initial inspection is successful. The samples shall be taken in such a way that they are representative of the production system and in sufficient numbers to ensure the results of the tests with the confidence level established in the reference documents referred to in § 2.1; samples are taken from the production and/or warehouse of the organization.
In special cases, and specifically those where the methods of storage and transport of the product do not alter its characteristics, the sample may be taken from the market, without prejudice, in the interpretation of the data, to the rules of statistical significance of the sample itself.
The costs of sampling and carrying out laboratory analyses shall be borne by the organization.
The laboratory where the tests are carried out is chosen by DNV GL in agreement with its customer; in general, laboratories with the eligibility and competence requirements are defined as specified in uni cei en iso/iec 17025 (accredited and/or qualified by DNV GL). In any case, DNV GL will ensure the absence of any kind of discrimination in the access of its customers to the analytical services of the designated laboratories.
In special cases, the use of the organization's laboratories or laboratories of its trust may be evaluated; in this case the tests are attended by DNV GL evaluators if they are not accredited. The latter activity, if requested, will be the responsibility of the organization.
For traceability systems, sampling is aimed at carrying out traceability tests and mass balances.

3.5.2 Evaluation reports

DNV GL communicates the outcome of the activities (inspection verification and type tests) with reports describing the results and any non-conformities to be resolved before obtaining certification. The certificate of conformity shall not be issued until any CN found during the initial inspection and initial testing activities has been adequately resolved (as defined in paragraph 3.2).

3.6 Issue of the certificate of conformity and authorisation for the use of the certification mark

Upon successful completion of verification activities, DNV GL issues and transmits to the organization the certificate of conformity and authorization to use the brand and certificate as specified in the "General Regulation for the certification of products, processes and services".
Certificates are valid for three years. For the use of the FoS logo, the organization will be required to comply with what the owners of the standard have defined.

3.7 Surveillance Verification

3.7.1 Generality

As regards quality requirements and reference documents, the same applies as for the initial checks.
Surveillance activities on certified products include, for level 1 product certification, product controls and any controls on the application of sampling plans and related documentation, while for level 2 product certification, the activity provides for quality system control and product testing as specified below. In case of non-compliance DNV GL may decide (giving prior written notice to the organization) to increase the frequency of surveillance activities or carry out additional visits to verify the resolution of the non-conformities found.
In case of complaints or special events, DNV GL reserves the right (giving prior written notice to the organization) of:

- perform additional verification and/or testing activities (even without prior notice) to verify the maintenance of compliance conditions;

- change the frequency of surveillance checks.

The costs of additional and/or additional surveillance activities are borne by the organization.

In the case of verification:

- the sampling criteria laid down in RT 17 (n=√N *0.6:n=number of homogeneous supply chain actors to beverified, N=total number ofhomogeneous supply chain players) apply on supply chain traceabilitysystems;
- on the FoS standard, the samples must comply with what is defined in each standard for which the activity will be delivered (square root of homogeneous actors, multiplied by a correction factor according to the number of actors) and as defined in the cap. 3.1 (eligibility criteria);
- on product certifications against STP (technical product specifications) which is expected sampling the criteria are defined within the same document.

3.7.2 Surveillance inspections

The inspection of the applied system is carried out on an annual basis or on the basis of the frequency already established (for organizations with quality system certified by DNV GL); for fos the first surveillance check must necessarily be carried out within 12 months of the initial verification, the next must be paid within 18 months at the latest. Only one surveillance check will be carried out to the FOS standard. The audit planning will be carried out taking into account the fishing period that has a particular seasonality.
the verification covers all production units included in thecertificate, for 22005 and FoS sampling will be applied as defined in RT 17 and fos standard.
The verification generally (but not exclusively and if applicable according to the level of product certification system applied) the following aspects:

- process control;
- examination of test records and controls in production;
- tests, checks and tests on receipt of raw materials and semi-finished products;
- supplier evaluation;
- equipment control (calibration);
- non-compliant product control and related corrective actions (including complaints and litigation);
- Internal inspections
- training;
- use of the brand and certificate.

In the case of specifications, technical inspections may be carried out, in addition to the annual checks, with a higher frequency, defined in the appropriate procedure

3.7.3 Surveillance tests

For surveillance tests, an annual sampling shall be carried out, without any specific prior notice to the organization; samples shall be taken in such a way that they are representative of the production system and in sufficient numbers to ensure the results of the tests with an adequate level of confidence; samples are taken from your organization's production and/or warehouse (the choice of these options will also depend on the

characteristics defined in the relevant Product Technical Specifications).
In the case of specifications, surveillance tests may be carried out with a higher frequency, defined in the appropriate procedure.
The costs of sampling and carrying out analyses shall be borne by the organization.
The tests shall be carried out in accordance with the criteria defined in § 3.4.1 above.

3.7.4 Evaluation report on monitoring activities

DNV GL communicates the outcome of the surveillance activities (inspection verification and type tests) with reports describing the results. In surveillance activities, SDOs may be accepted, so that the certificate remains valid, the organisation is required to define appropriate corrective actions and undertake to implement them within the next verification.
If NC is found in the surveillance activities, the certificate and use of the certification mark will be suspended; In serious cases which may harm consumer safety, the product may be withdrawn from the market. If the CN concerns the analytical results of the sampled product, the provisions already described in paragraph 3.2 (non-conformity) will apply. In the event that the CN is not successfully resolved within the established timeframe, the certificate and the use of the certification mark shall be revoked.
For the FoS Standard in the event of greater non-compliance and in the event of failure to implement serious NC corrective actions, the certificate will be suspended, and the use of the trademark revoked.

3.8 Recertified Verification

3.8.1 generality

As regards quality requirements and reference documents, the same applies as for the initial checks.
The recertification of certified products includes, for level 1 product certification, product controls and any controls on the application of sampling plans and related documentation, while for the level 2 product certification, the activity provides for a quality system control and product testing as specified below.
In the case of verification:

- the following sampling criteria apply to supply chain traceabilitysystems: n=√N*0.8: n=number of homogeneous supply chain actors to be verified, N=total number of homogeneous supply chain actors;
- on the FoS standard, the samples must comply with what is defined in each standard for which the activity will be delivered (square root of homogeneous actors, multiplied by a correction factor according to the number of actors) and as defined in the cap. 3.1 (eligibility criteria);
- on product certifications against STP (technical product specifications) which is expected sampling the criteria are defined within the same document.

3.8.2 Recertification inspection check

The inspection verification of the recertification of the applied system is carried out on a three-year basis; the verification covers all production units included in the certificate.
The verification generally (but not exclusively and if applicable according to the level of product certification system applied) the following aspects:

- process control;
- examination of test records and controls in production;
- tests, checks and tests on receipt of raw materials and semi-finished products;
- supplier evaluation;
- equipment control (calibration);
- non-compliant product control and related corrective actions (including complaints and litigation);

- Internal inspections
- training;
- use of the brand and certificate.

In the case of specifications, technical inspections may be carried out, in addition to the annual checks, with a higher frequency, defined in the appropriate procedure

3.8.3 Recertification tests

For the recertification tests, 1 annual withdrawal is made, without any specific notice to the organization; samples shall be taken in such a way that they are representative of the production system and in sufficient numbers to ensure the results of the tests with an adequate level of confidence; samples are taken from your organization's production and/or warehouse (the choice of these options will also depend on the characteristics defined in the relevant Product Technical Specifications).
In the case of specifications, surveillance tests may be carried out with a higher frequency, defined in the appropriate procedure.
The costs of sampling and carrying out analyses shall be borne by the organization.
The tests shall be carried out in accordance with the criteria defined in § 3.4.1 above.

3.8.4 Evaluation report on the recertification activity

DNV GL communicates the outcome of the recertification activities (inspection verification and type tests) with reports describing the results. In recertification activities, SDOs may be accepted, in order for the certificate to be reissued the organization is required to define appropriate corrective actions and undertake to implement them within the next verification.
If nc is found in the recertification activities, the certificate and use of the trademark will be suspended; In serious cases which may harm consumer safety, the product may be withdrawn from the market. If the CN concerns the analytical results of the sampled product, the provisions already described in paragraph 3.2 (non-conformity) will apply. In the event that the CN is not successfully resolved within the established timeframe, the certificate and the use of the certification mark shall be revoked.
For the FoS Standard in the event of greater non-compliance and in the event of failure to implement serious NC corrective actions, the certificate will be suspended and the use of the trademark revoked.

3.9 Tasks of the manufacturer

The organization is required to carry out tests, checks within the production system of certified products on the basis of a control plan approved by DNV GL and based on the checks and tests specified in the reference documents for the certified product.
The organization is required to keep adequate records of such controls to be made available to DNV GL during surveillance checks and/or on request; the records must contain at least:

- date of control and identification of the operator;
- identification of the controlled product (product identification code, production batch);
- stage of the production process in which the sample was taken;
- controlled product characteristics and measured value for each;
- outcome of the check.