Guidelines for the establishment of the Control Plans of the 'Products of Quality' National Scheme (PQNS)

In accordance to L.N. 467 of 2014 for the purpose of Regulation (EU) No.1305/2013 on support for Rural Development by the European Agricultural Fund for Rural Development (EARFD)

MINISTRY FOR AGRICULTURE,
FISHERIES AND ANIMAL RIGHTS

Contents

1. Scope

The present document establishes the guidelines for the development of a Control System in line with SL 427.90. The guideline aims at setting up a control system that aims to ensure compliance with the product specifications approved within the PQNS and with the Rules for the Implementation of the PQNS and Rules for the Use of the Quality Mark with indication of origin "Products of Quality"

The Control system provides for three levels of control:

- Internal Control, made by operators included in the PQNS
- External Control, made by a Control Body
- Supervision made by Agriculture Directorate.

Furthermore the Operator shall adopt a traceability system.

2. Internal Control

2.1.Responsibility

The operator who adheres to the PQNS is responsible for the compliance with the approved technical specifications as well as S.L 427.9 and the rules for the Implementation of the PQNS and Rules for the Use of the Quality Mark with indication of origin "Products of Quality"

Each operator, whether as an individual or as a leading actor in the value chain, is responsible for the compliance with:

- the product specifications,
- the correct application of the control plan
- the adherence to the auto-control plan and
- other applicable rules such as those related to permits, licenses, labelling, hygiene, etc.

Any non compliance situation detected during the self-control procedure must be properly managed in compliance with the control plan.

2.2.Auto-control of the associated forms ofbusiness

Each year, the operator, whether as an individual or as a leading actor in the value chain, adhering to the PQNS has to provide for:

- The adoption of an internal management system
- internal controls on 100% of the associated operators;
- controls on 100% of the packaging/storage/ processing units belonging to the value chain;

The operator shall provide, implement and give evidence of the controls done in order to grant the compliance of the products with the requirements provided for the product specifications. The operator shall be able to provide at any point in time during the PQNS evidence of the compliance of the product/process with:

- rules for the Implementation of the PQNS and Rules for the Use of the Quality Mark with indication of origin "Products of Quality"
- the applicable product specification
- the control plan
- the traceability system

In view of the above, the operators are to register and record all the activities demonstrating the compliance of the product and of the processes. All the documents related to these activities must be prepared, stored and be available for control at the operator establishment.

Records must be kept for the whole cycle of the product and have to make reference to all the products adhering to the PQNS requirements and the regulations for the use of the mark.

Records are to be kept for a minimum of three years.

Third party inspection aim at verifying the compliance with the product specification and with the control plan, as well as the procedures put in place by the leading actor of the value chain to ensure compliance of the product over time.

2.3. Obligations of the operators adhering to the PQNS

The operator adhering to the PQNS is obliged to:

a) Comply with the rules of the use of the mark
b) Comply with the adopted product specifications
c) Comply with the laws concerning the labelling of the products;
d) Apply and document the auto-control activity, with particular reference to:
    i. the traceability of all raw materials, inputs and end products;
    ii. ensuring the compliance of the raw materials with the product specifications by means of control plans and relative application procedures;
    iii. ensuring compliance of the process;
e) Apply and document the auto-control activities related to the management of the labels bearing the mark, according to the rules for the implementation of the scheme;
f) Provide free access for the control activities provided for the present guidelines, even in the associated companies and for the supervision activity of the Director;
g) Communicate within 15 days to the Control Body and within 30 days to the Director any changes in the business organization, or the expanding or the decrease of the products identified by the Director;
h) Pay promptly any due fees related to the Scheme.

If the operator acts in an associated form of business, he must ensure the compliance of the associated business units with the product specification.
If the operator sub-contracts to external companies some productive phases he must ensure the compliance even of these phases with the product specification.
If the operator renounces his adhesion to the PQNS, is strictly forbidden to apply for a new one before three years from the date of the communication related to the withdrawal of the granting of the licence.
The costs related to the control activities of the authorized control bodies shall be borne by the operators adhering to the PQNS /optional requirements.

2.4.Management of the documentation

The operator adhering to the PQNS must communicate to the Director and to the Control Body:

- The amount of end product identified by the PQNS
- The amount of raw materials delivered and processed
- The suppliers of raw materials;
- The production capacity;

as well as all the other information necessary for verify the origin and the quality of the used materials according to the provisions of the control plan and the compliance of quantities of products with the production capacity.
All this information is communicated through the traceability system established by the Director.

Single Operator/ Leading actor is responsible for the correct update of the traceability system both for the information related to his own business and for the one related to a business belonging to the value chain agreement, or to delivering agreement or to the supply agreement.

2.5.Reviewing of the information included in the request for adhering to the PQNS and for the granting of the permission for the use of the mark.

The operator adhering to the PQNS must communicate to the Director and to the Control Body every change with respect to the information included in the request of granting of the certificate of adherence, in the procedures and time provided for the control plan.

If the communication concerns changes in the organization, in structural modifications relevant for the productive process, the Minister, with the advice of the Control body, may accept the changes proposed by the operator and may order further control visits and/or documentary checks in order to confirm or not the adhesion to the PQNS.

3. Control plan

The control plan is the document in which the procedures for the assessment of the compliance with the product specifications are identified as well as the frequency of the controls.

The control plan includes also the minimum elements of self-control considered binding for the assessment of the compliance with the PQNS.

The inspections concern:

a) the product compliance with the applicable product technical specification
b) the modes of use of the logo, which have to be in adherence to the provisions indicated in the rules of the use of the mark;
c) the compliance of product quantities compared to the production capacity;
d) the origin of the raw materials deriving from farms included in the value chain agreement and in the control system;
e) the origin of products, in case of value chains, which have to derive from members marked in the adherence sheet;
f) the traceability procedure used by the firm.

Analytical controls aim at ensuring compliance with the chemical-physical-microbiological parameters provided for by the referring product specifications.

The Control Body is responsible for establishing the control plan, which has to be prepared on the basis of the referring value chain product specification and of the Rules for the implementation of the PQNS and Rules for the Use of the Quality Mark with indication of origin "Products of Quality". The control plan has to be sent for approval to the Director, together with its tariffs. The control Body may start with the inspection visits only after formal approval of the control plans by the Director. The results of the inspections and the non-compliances will be notified by the Control Body to the interested operator and to the Director.

On the basis of the results of the inspection visit, the Director takes its decision on the granting, suspending or withdrawal of the certification of adherence and the use of the quality mark or.

In case of minor infringements, the operator adhering to the PQNS may be requested by the Director or Control Body to answer to the findings 30 days from the day of the inspection or may go on with the management of the non-compliances found during the inspections, in respect of the provisions of the control plan as approved by the Director.

The Director may apply sanctions according to the provisions laid down in the regulation.

Appeals may be provided for as per provisions in S.L. 427.90. Participants to the PQNS are subject to un-announced inspections on the basis of a risk analysis.

4. External Control

The external control is conducted by an approved Control Body

The controls consist of:

a) Inspection visits
b) Analytical controls

The inspection visits aim at verifying the respect of all the requirements provided for by the product specifications.

The analytical controls aim at ensuring compliance with the chemical-physical-microbiological parameters, record keeping, labelling, and other aspects provided by the approved product specifications.

The control authority may use certifications of segments of the value chain already issued by other notified Certification bodies (mutual recognition).
The director is responsible of the supervision on the Control Body.

4.1. Inspection visits made by the Control Body

The control activities are made by the Control Body. Each year, the Control Body makes inspection visits and analytical controls on the operators adhering to the PQNS according to timing and procedures defined in the control plans approved by the Director. The inspections, however, must be done respecting the following minimum criteria:

Type of actor	N. registered farms	Initial inspection visit	Inspection visit of maintenance
Single operator/ Leading actor		100%	100%
Other operators in the group/ value chain	Up to 100	5%	5%
	From 101 to 200	4%	4%
	> 200	3%	3%

In the starting phase, 100 % of Single operator/ Leading actor are checked, later at least once a year, without prejudice to any additional checks.

If provided in the control plans, the Control Body may take samples for analytical controls in order to verify chemical-physical and microbiological requirements.

In case the Single operator/ Leading actor has different production, processing and storage facilities in the value chain agreement, the control activities shall be on 100% of the facilities.

All exceptions to the procedures established above must be expressly authorised in advance by the Director and applied only after formal authorization.

The Control Body defines the sample of operators to be checked on the basis of a risk analysis, which analysis must be presented to the director.

4.2. Outsourcing

If the operator Sub-contracts some productive phases to external operators, not included in the value chain agreement, all the entities involved in the production have to be checked along with the documentation (quantity in and out and related records), related to the quantity of product managed by the licensee adhering to the PQNS.

4.3. Analytical controls made by the Control Body

The analytical controls, if provided for in the control plans, aim at ensuring compliance with the chemical-physical-microbiological parameters provided for by the referring product specifications.

Normally these controls are done each year (or according the productive cycle) on the product in the field and on the end product, according to the following minimum criteria:

a) If the operator acts as an individual it has to do:
- An analysis on the each product batch (packaged) for every operator adhering to the PQNS and/or for every plant of production, processing, storage;
- An analysis on the product ready to be harvested.

b) For different products, sampling and analysis activities must be done for each product, identified according to the following criteria:

Operator with n. farms involved for each type of product	Sampling point	N. samples for analysis for each type of product and for each product specification
Up to 30 farms	For each site of production, processing, storage	1 sample of end product 1 sample taken in the farm
From 31 to 60 farms	For each site of production, processing, storage	1 sample of end product 3 samples taken in the farm
From 61 to 90 farms	For each site of production, processing, storage	2 sample of end product

		4 samples taken in the farm
From 91 to 120 farms	For each site of production, processing, storage	2 sample of end product 5 samples taken in the farm
Over 120 farms	For each site of production, processing, storage	3 sample of end product 6 samples taken in the farm

In order to verify the parameters defined in the product specifications, the Control Body has to make analytical controls on samples belonging to different batches already defined compliant by the operator. The sampling frequency, specific for each product, will be defined in the related control plans approved by the Director.

For crop production the analytical tests may be taken in order to assess auto-control ensuring that operators do not use non-authorized substances and that the finished product does bit exceed the MRLs.

4.4.Sampling methods and laboratories

The sampling procedure must meet the criteria of representativeness in relation to the mass of material from which the sample is extracted. In particular, samples of fruit and vegetables must follow the requirements of Directive 2002/63 / EC of 11 July 2002 relating to methods of sampling for the official control of pesticide residues in food of plant and animal origin.

Each sample to be allocated to the laboratory is identified, by affixing a label giving references to the relevant methods of sampling, the abbreviations of the pick and the representative company, and is closed by a secure uniquely identifiable seal.

Records of each sample must at leave have the following information:

- type of the material sampled
- details of the sampled lot and related quantities
- date and place of sampling
- unique identification of the sample and the corresponding label
- identification of the personnel carrying out the sampling
- details of the corporate representative attending the sampling laboratory in charge of the analysis

Other information that could be useful to the analyst may be provided.

The laboratory samples shall be placed in containers impermeable to air and moisture, so as to protect them adequately from any contamination. Laboratory analysis shall commence within

60 hours of collection (excluding non-business days). Appropriate conservation shall be ensured according to the nature of the sample, such as keeping it in a cool place away from light and heat sources.

Three samples must be collected:

- one is intended for the laboratory test
- the second is to be retained by the control body as against any eventual contestation of the test report
- the third is kept by the 'intermediary participating in the PQNS or company from which the sample was taken.

The analysis of pesticide residues are carried out by performing analysis of multi residual according to official methodology of analysis, ISO 17025 accredited laboratories, chosen in agreement with the operator participating to PQNS.

The controls on the samples may be carried out by the Control Body who has the equipment suitable for the purpose, or through the use of qualified analytical laboratories.

4.5.Supplementary Inspection Visits

If non-compliance situations emerge after the inspection visits and the analytical controls, additional inspections may be carried out on the operator.

4.6.Non compliance classification

Non-compliances to the rules of the Scheme shall be classified as followed.

Major non compliance(Maj): the infringements of the obligations provided for the scheme PQNS within the meaning of the Reg. EU n. 1305/2013; they are of two different types:

a) Infringements of the rules, of the acting procedures or of the current law that make traceability not applied or badly applied, causing the inclusion of wrong information on the label;
b) Situations with an impact on the end product in such a manner to make it non compliant with the product specifications' provisions and with the labelling of the product;

Minor (Min): the infringements of the obligations provided for the scheme QPNS in the meaning of the Reg. EU n. 1305/2013; they are of three different types:

a) Irregularities concerning the traceability and/or the requirements defined in the technical sheets and in the referring documents only formally;
b) Irregularities that, even if they do not immediately cause a non compliance with the product specifications, they could compromise it along time;
c) Formal errors not causing the insertion of wrong information on the label (such as misleading information).

Observations(O): irregularities that, even causing deficiency in a requirement provided for by the PQNS, in the meaning of the Reg. EU n. 1305/2013, they do not :

a) Cause negative effects on the product,
b) Have effects on the conditions leading to the granting of the licence,
c) Have effects on the identification of the product interested by the collective mark and the label.

4.7.Non compliance procedure

All information related to the non compliance management and found during the self-control activities, must be stored and available to Control Body controls. In case of the non compliance doesn't permit to bring back the compliance conditions provided for by the product specification, the operators involved in the value chain have to prove that the non compliant product has not been involved in the commercial distribution of the marked product or, in case of, it has been removed.

The non compliant situations revealed during the Control Body controls are notified to the interested operators who have to identify the actions to solve the situation, according to the modalities provided for by the control plan.

The Ministry has to be informed with all major non compliances at the same time of the communication of the verification report.

If the non compliance leads to the exclusion of the product from the commercial distribution and from the use of the mark, the Control Body may do an additional inspection visit. The non compliance situation leading to the suspension of the operator from the control system leads also to the exclusion of the related product from the use of the mark.

The effects of the suspending measure end when the compliance conditions provided for by the product specification, by the referring documents, by the acting law and by the control plan are restored and notified to the Director and to the Control Body who will verify the adjustment through another inspection visit.

All the measures related to the exclusion of the product from the commercial distribution, to the suspension and withdrawing from the control and certification system will be communicated by the Minister to the involved operators.

4.8.Communication of the results to Director of Agriculture

When the inspection is completed, the Control Body sends the inspection report to the Agriculture Directorate, as well as the results of the analytical controls and the evaluation of the proposed corrective actions able to redress the non compliance situations emerged during the

inspection visit. On the basis of the evaluation of this report, the Minister may accept the adhesion to the PQNS and at the same time grants the licence for the use of the mark.

5. Supervision

The supervision activity is made also by the Director, according to rules and procedures adopted and approved. This activity aims at:

a) Verifying the compliance with the requirements provided for the present guidelines in the point of sales and in the distribution network;
b) Ensure the correspondence between the amount of product identified by the mark and the quantity put on the market;
c) The right functioning of the adhesion procedures to the PQNS and to the control plan;
d) Assess the activities of the control bodies in their inspection visits and analytical controls.