

TECHNICAL SPECIFICATION FOR THE CERTIFICATION OF AGRICULTURAL AND AGRI-FOOD VEGETABLE PRODUCTS WITH ZERO RESIDUE AND CONTROLLED RESIDUE

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CONTROLLED RESIDUE*

*Residues of plant protection products inferior or equal to XX% of the Maximum Residue Limit (LMR) required by law



ZERO RESIDUE*

*Residues of synthetic plant protection products inferior or equal to the limit of analytical quantification (0,01 mg/kg)

1. SCOPE AND FIELD OF APPLICATION

This product technical specification defines the requirements for the certification of vegetable agricultural and agri-food products that guarantee, at the time of placing them on the market, highly limited residues of plant protection products (min. <50% of the Maximum Residue Limit required by law) or in quantities not detectable by the analytical instruments of qualified and accredited testing laboratories (≤ 0.01 mg / kg).

The product is defined as “Zero Residue” when the residues of plant protection products of chemical synthesis are less than or equal to 0.01 mg / kg (10 ppb). This threshold is intended as the analytical quantification limit currently proposed by the most qualified test laboratories for most of the tests for the research of plant protection products.

The product technical specification applies to all agricultural and food products of plant origin and includes the phases of cultivation, transport, conditioning, processing, and packaging.

2. OBJECTIVES AND ADDED VALUE OF THE CERTIFICATION

The product technical specification edited by Bioagricert represents a useful tool for enhancing agricultural and agri-food productions obtained with production techniques that provide for important limitations in the use of pesticides, particularly attentive to the environmental impact and the health of consumers.

The significant reduction of residues and, when possible, the absence of pesticides residues in food products is one of the main requirements expected by the consumer and, consequently, required by the market, operators, and large retailers.

The objective of the certification is to encourage the diffusion of production systems that add, to the already restrictive principles of Integrated Production and good agricultural practices (*Standard prerequisite of reference*), the careful analysis and selection of plant protection products with low environmental impact characterized by a low residuality, up to obtaining products without pesticide residues in detectable quantities.

3. DEFINITIONS

TERMS	DEFINITIONS
Self - control	Documentation verification activity carried out by the applicant for the certification which allows to give objective evidence of compliance with the specified compliance requirements. Self-control is carried out both on raw materials and incoming inputs, both throughout the production process, and on the subsequent stages of production/processing understood in the strict sense, up to the sale; self-control activities are also considered to be those exercised by the requesting organization on other operators involved in the production process.
Farm/Producers	Individual or associated companies, which carry out agricultural production activities pursuant to art. 2135 of the Civil Code and that, in case of first processing, they carry out this activity on the products coming from the cultivation of their own land.
Food processing and conditioning companies	Single or associated companies in which the main activity is related to the production phase following the harvesting of the agricultural product. All intermediate factories/plants are included.
BAC	BioAgriCert S.r.l., located in via Dei Macabracchia, 8 - Casalecchio di Reno (BO), Italy.
Maximum residue limit (LMR)	The maximum allowed concentration of active substance residue present on agricultural foodstuffs, after treatment with a plant protection product, in accordance with Good Agricultural Practices (BPA), that is on the basis of compliance with the conditions of use (doses, number of treatments, interval of safety).
Limit of quantification (LOQ)	The lowest concentration of analyte in a sample that can be quantitatively determined with accuracy and precision.

TERMS	DEFINITIONS
Homogeneous phytosanitary lot	Quantity of product, of the same species, on which equal phytosanitary treatments have been carried out in terms of formulations and doses.
Homogeneous semi-finished/finished product lot	Minimum unit, having homogeneous characteristics, which has been produced and/or processed and/or packaged in identical or in any case equivalent conditions for the purposes of the species. It is the responsibility of the organizations requesting certification to define the lot according to their objectives and needs. The lot must be uniquely identified. Lot definition example: homogeneous quantity of product from which it is possible to take statistically significant samples for the evaluation of the characteristics and compliance with the defined eligibility criteria.
Technical product specification	Document implemented and approved by a recognized and competent body, which collects the rules and requirements or characteristics relating to certain activities (processes) and/or their results (products, services). This technical document is added to the reference prerequisite Standards (GlobalG.A.P.- IFA - Fruit & Vegetable, SQNPI - "National Quality System of Integrated Production", Regional Quality Regulations and UNI 11233: 09 Standard).
Organization	Entity requesting Bioagricert access to the control system for certification of conformity, for an agri-food product or process, both individually and in associated form.
OdC	Control and Certification Body
Commercial operators	Recognized subjects authorized to sell certified products
Agri-food product	Product of agricultural origin, vegetal, processed and unprocessed, intended for human consumption.
Pesticides (Plant Protection Products) Phytosanitary products	Active substances and preparations, that is commercial products formulated by industry, in the form in which they are supplied to users, containing one or more active substances, agronomic antidotes, synergists, co-formulants, adjuvants, intended for: <ul style="list-style-type: none"> • Protect plants or plant products from all harmful organisms or prevent their effects (insecticides, acaricides, fungicides) etc; • Promote or regulate the vital processes of plants (plant growth regulators), with the exception of fertilizers; • Preserve plant products, with the exception of specifically regulated preservatives; • Control the weeds, unwanted or harmful plants present within the crop (herbicides); • Eliminate parts of plants, stop or prevent their unwanted growth (except algae).
Traceability	The ability to reconstruct the history and to follow the use or location of a product through recorded identifications, in particular: the origin of materials and components, the "history" of processes related to the product, distribution and location of the product after delivery and up to the first buyer.
SAU	Agricultural Area Used: company production area intended for agriculture, to be identified in plots, meaning by plot the homogeneous surface for productive use, identifiable with one, more or part of the cadastral parcel.
Target Threshold	Maximum limit of residues of phytosanitary substances and active ingredients that the organization undertakes to guarantee and systematically control in the agri-food product intended for placing on the market.
Significant changes	These are all those variations regarding the production process, conditioning, processing, the management system and structural requirements that require an additional inspection in order to assess if the variations comply with the compliance requirements set out in this document.
Certificate of Conformity	Document that lists the products for which the Licensee is authorized by BAC to issue declarations of conformity; such declarations are represented by the packaging labels. The certificate issued by Bioagricert is valid for one year.
Standard prerequisite of reference	<ul style="list-style-type: none"> • GlobalG.A.P.- IFA - Fruit & Vegetable; • SQNPI - "National Quality System for Integrated Production"; • UNI 11233: 09 "Integrated production systems in agro-food chains; • Regional quality schemes • Sustainability standards (example Biodiversity friend, Proterra etc.) • Companies in conversion subject to the organic farming regime pursuant to EU Reg. 834/2007 and subsequent amendments.

4. REGULATORY REFERENCES

Reg. (CE) n. 178 28 January 2002	It establishes the general principles and requirements of food law, establishes the European Food Safety Authority and establishes procedures in the field of food safety
Reg. (CE) N.852 29 April 2004	Hygiene of food products
UNI EN ISO 19011 (2012)	Guidelines for the audits of management systems for quality and/or environmental management
UNI CEI EN ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
GlobalG.A.P. IFA Fruit & Vegetable	Good agricultural practices for integrated safety in agriculture and chain of custody
UNI 11233:2009	Concerning Integrated Production Systems in the agri-food supply chains - General principles for the planning and implementation in the vegetable supply chains.
SQNPI	National quality system for integrated production.
Law n. 4 of 3 February 2011	Provisions on labelling and quality of food products "in art. 2, paragraphs 3 - 9 establishes the national quality system for integrated production.
Regional technical standards/ Regional quality schemes	Quality Regional Specification for Integrated Production (e.g. QC, Agriquality, Puglia Quality Products, etc.)
Reg. CEE 1257/99 of 17 May 1999	On support for rural development by the European Agricultural Guidance and Guarantee Fund (EAGGF)
DIRECTIVE 2009/128/CE	It establishes a framework for EC action for the sustainable use of pesticides
Reg. (CE) N. 1107/2009	Relating to the placing on the market of plant protection products and repealing Council Directives 79/117 / EEC and 91/414 / EEC
Legislative Decree 150/2012	Relating to the implementation of Directive 2009/128/EC which establishes a framework for EC action for the purpose of the sustainable use of pesticides.
Ministerial Decree of 22 January 2014	Concerning the adoption of the PAN (National Action Plan for the sustainable use of plant protection products)
SANTE/11813/2017	Guidance document on analytical quality control and method validation procedures for pesticides residues analysis in food and feed.
Ministerial Decree 23/07/2003	Implementation of Directive 2002/63/EC of 11 July 2002 relating to sampling methods for the official control of pesticide residues in food products of vegetal and animal origin. (GU General Series n.221 of 09-23-2003)
Reg. (EC) N. 889/08	Rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control

5. CERTIFICATION REQUIREMENTS

5.1 PREREQUISITE STANDARD OF REFERENCE

The Organization requesting certification **must have** obtained or it must have requested, at the same time of application, at least one of the following certifications. The Organization also undertakes **to maintain for the entire certification cycle and for the same products** the chosen certification/s:

- GlobalG.A.P.- IFA - Fruit & Vegetable;
- SQNPI - "National Quality System for Integrated Production";
- UNI 11233: 09 "Integrated production systems in agri-food chains";
- Regional quality schemes
- Sustainability standards (example: Biodiversity friend, Proterra etc.)
- Companies in conversion pursuant to EU Reg. 834/2007 and subsequent amendments

Companies that have notified pursuant to EU Reg. 834/2007 and subsequent amendments and who request the zero-residue certification, must not make any reference to the ORGANIC certification. The certificate will be withdrawn at the end of the conversion period. For the other reference prerequisite standards, the certificate will not be issued or will be revoked if the Organization does not obtain such certification or does not meet the requirements that allowed the certification to be granted and maintained.

6. CERTIFICATION REQUIREMENTS

6.1 “CONTROLLED RESIDUE” PRODUCT

Maximum residue level of plant protection products according to the following table:

	Lot	Residue
Plant protection products	Homogeneous phytosanitary lot	Minimum target threshold ≤ 50% of the legal MRL * (*) EC Reg. No. 395/2005 and subsequent amendments and integrations
	Homogeneous semi-finished lot	
	Homogeneous finished product lot	

(*) The target threshold is declared in advance to BAC, with the certification application, explicitly communicated to the customer and clearly reported on the label and in the remaining communication material.

6.1.1 “ZERO RESIDUE” PRODUCT

Maximum residue level of active substances of plant protection products according to the following table:

	Lot	Residue
Plant protection products	Homogeneous phytosanitary lot	≤ 0,01 mg/kg
	Homogeneous semi-finished lot	
	Homogeneous finished product lot	

6.1.2 EVALUATION OF THE ANALYTICAL DATA

The results of the analyses will be evaluated according to the extended uncertainty criterion, as per the SANTE/11813/2017 guidelines. Therefore, the analytical data detected following the laboratory analyses must be considered compliant with this product technical specification, if it falls within the measurement uncertainty range, that means within the range of values indicated in the test report.

6.1.3 ADDITIONAL REQUIREMENTS

The organization may request additional certification requirements.

These requirements must:

- Be verifiable and/or measurable;
- Give the product real "added value" compared to similar non-certified products on the market;
- Be defined and described by voluntary technical documents and not required by mandatory legislation.

In the event that the operator provides for certification requirements to be verified analytically, the sampling of raw materials/semi-finished/finished products, in order to carry out analytical tests, is defined according to standardized sampling criteria. Depending on the case, BAC will implement the sampling plan, in addition to that provided for in this technical specification.

- *Example of additional requirements: zero/controlled residue with compostable packaging*
- *Example of additional requirements: zero residue/controlled with "plastic free" packaging*
- *Example of additional requirements: zero/controlled residue "without the use of glyphosate, neonicotinoids, herbicides (terbuthylazine, S-metolachlor, bentazone, etc.)"*

6.2 ACCESS TO CERTIFICATION

The organizations that can join the certification in single or associated form are:

- Agricultural producers;
- Food processing and conditioning companies;
- Agricultural cooperatives, producers' organizations (POs) and consortia;
- Intermediate factories/plants;
- Distributors/operators/traders.

6.3 PLAN OF THE ORGANIZATION FOR THE SELF-CONTROL OF THE RESIDUES OF PLANT PROTECTION PRODUCTS

6.3.1 General requirements

Organizations certified in accordance with this technical product specification must:

- Define and periodically review the "target threshold" that they intend to guarantee for each individual type of product in relation to the protection programs and the cultivation techniques adopted, the risk analysis and the evaluation of the historical analytical data available.
- Provide evidence on the validation of the activities/procedures implemented to ensure the absence of any cross-contamination on raw materials, semi-finished and finished products;
- Evaluate the need to train the personnel who carry out activities having an influence on the quality of the product and prepare a training plan in order to provide adequate training;
- Implement and maintain a quality management system updated and continuously improve the effectiveness and efficiency of its performance in accordance with the requirements defined in this technical product specification and in the reference prerequisite standards;
- Provide an accurate risk analysis, an adequate control plan and a periodic review;
- Ensure that non-compliant products or products awaiting compliance outcome are identified, segregated and kept under control in order to avoid their involuntary use or delivery.

6.3.2 Implementation of the self-control plan

The Organization must establish and implement a self-control plan for residues of plant protection products to be carried out on homogeneous plant protection lots and on homogeneous semi-finished/finished product lots at laboratories accredited according to UNI CEI EN ISO/IEC 17025: 2005. In particular, the product conformity tests must be 100% accredited with reference to the active substances used by the organization and for at least 70% of the other molecules permitted on plant matrices. Test reports must be available and assessable upon request and during the audit. In implementing the plan, the organization must take into account the experience, knowledge about the degradation over time of the active substances (deficiency times) and the degradation curve, also depending on the season in which the treatments are carried out.

The self-control plan must indicate:

- Which raw materials, semi-finished or finished products must be analysed (homogeneous phytosanitary lots);
- The minimum number or frequency of controls;
- In which stages of the production process the sampling is carried out (pre-harvest, during harvest, post-harvest, during storage on the semi-finished and/or finished product);
- The sampling methods and procedure;
- The type of multiresidue analysis to be carried out;
- The functions responsible for carrying out sampling and authorizing the collection of the product.

The organization must send the self-control plan implemented to Bioagricert before the inspection and at each change for a documentary evaluation. Based on the self-control plan sent by the organization, Bioagricert prepares its own product compliance plan.

6.3.3 Control of homogeneous lots of primary production

a) No-covered production

The number of compliance tests must cover **all plant protection lots** that are homogeneous by crop and by product specification produced by the farm.

b) Covered production

The number of compliance tests must cover, for each species, the first cut to validate the self-control plan implemented by the organization. Given the type of production in covered crops, the organization can only analytically search for the active substances used on the crop and recorded in the field book. In the event of further treatments, use of new active substances, following an assessment of the degradation curve according to the season in which the treatments are carried out, the Organization is required to carry out further validation analyses of the self-control plan.

6.3.4 Control of homogeneous lots of semi-finished product

The homogeneous lots of semi-finished products are classified according to the number of lots that were used to obtain them.

The self-control plan implemented based on risk assessment, **in addition** to those provided for by the reference prerequisite standard, must be prepared by the organization and BAC will verify its effectiveness in the start-up phase and in surveillance.

6.3.5 Control of homogeneous lots of finished products

The homogeneous lots of finished products are classified according to the number of lots that were used to obtain them.

The self-control plan implemented based on risk assessment, **in addition** to those provided for by the reference prerequisite standards, must be prepared by the organization and BAC will verify its effectiveness in the start-up phase and in surveillance.

6.3.6 Internal controls plan

The organization must provide for internal audits in accordance with the provisions of the reference prerequisite standard.

Based on the results of internal audits, self-control, any complaints and non-conformities, the organization is required to carry out a review of the system aimed at maintaining and improving its effectiveness.

6.4 IDENTIFICATION AND TRACEABILITY

The organization requesting certification must implement an identification and traceability system at every stage of the production process up to the final packaging.

The organization must identify fresh agricultural products, semi-finished products, finished products and document the methods of identification and traceability along all stages of the supply chain, also to prevent possible mixing and/or contamination with products that do not comply with this document.

During the conditioning and/or processing phases of the products, the organization must manage the processes used and the processed products giving evidence through a spatial and/or temporal separation of the processes in each individual processing phase and a storage of fresh agricultural products, semi-finished products and/or finished products covered by this standard.

7. BIOAGRICERT CONTROL METHOD

7.1 CONTROL PLAN

7.1.1 Inspections plan

The inspections referred to in this paragraph are to be understood as those provided for by the reference prerequisite standard with which the organization has obtained the certification.

7.1.2 Additional inspections

If, following the inspections and analytical controls, non-compliant situations emerge, additional inspections may be arranged, to be carried out by the operator itself, aimed at ascertaining the resolution of the non-conformities found.

7.2 PRODUCT CONFORMITY TEST PLAN

Considering that BAC has the task of assessing the compliance of the certified organization and therefore of assessing its reliability, it is advisable to report that the number of tests conducted cannot have statistical significance as the main objective is to validate the activities prepared by the operator subject to certification in its own self-control regime.

BAC prepares a product conformity test plan for each organization requesting certification, which includes at least the following indications:

- Number of samples to be taken and tested;
- Place of collection;
- Matrix to be picked up;
- In which phases of the production process the sampling is carried out (pre-harvest, during harvest, post-harvest, during storage on the semi-finished and/or finished product);
- Technician responsible for carrying out the sampling;
- The type of multi-residual analysis to be carried out;
- Test laboratory for the execution of the same.

The compliance test plan is prepared taking into consideration:

- The criticality of the product;
- How the product is obtained;
- The peculiar characteristics of the production area;
- The self-control plan planned and executed by the Organization;
- The quantity and type of product;
- The number of suppliers.

7.2.1 Initial compliance tests

If the prerequisite Standard of *reference* (for example SQNPI) provides for mandatory analyses, the latter can be merged into the product compliance test plan prepared by Bioagricert for the zero-residue standard.

No. of samples to be taken	Sampling locations	Matrices to be sampled	Analytical tests to be carried out
1 sample for each agricultural producer subject to inspection	Farm (on the plant or post-harvest)	Fresh product during harvest or post-harvest	Multiresidue (Specific tests if necessary)
1 sample for each food processing and conditioning company subject to inspection	Food factory Intermediate factory	Agricultural product or semi-finished product	Multiresidue (Specific tests if necessary)
1 sample for each distributor/operator/commercial company	At the distributor/operator/commercial company	Semi-finished or finished product	Multiresidue (Specific tests if necessary)
Associated operators: \sqrt{Ni} for the homogeneous sites making up the supply chain subject to inspection and 1 sample at the head company	At the headquarters of the head company and of the homogeneous sites subject to verification.	Fresh product during harvest or post-harvest Finished product	Multiresidue (Specific tests if necessary)

Ni is the number of sites attributable to the *i*-th group of homogeneous sites, by species and by standard (for example farms, conditioning plants, processing plants, etc.).

7.2.2 Compliance testing in surveillance

If the prerequisite Standard of *reference* (for example SQNPI, UNI 11233) provides for analyses, the latter can be included in the product compliance test plan prepared by Bioagricert for the zero-residue standard.

No. of samples to be taken	Sampling locations	Matrices to be sampled	Analytical tests to be carried out
1 sample for each agricultural producer subject to inspection	Farm (on the plant or post-harvest)	Fresh product during harvest or post-harvest	Multiresidue (Specific tests if necessary)
1 sample for each food processing and conditioning company subject to inspection	Food factory Intermediate factory	Agricultural product or semi-finished product	Multiresidue (Specific tests if necessary)
1 sample for each distributor/operator/commercial company	At the distributor/operator/commercial company	Semi-finished or finished product	Multiresidue (Specific tests if necessary)
Associated operators: 50% of the \sqrt{Ni} for the homogeneous sites making up the supply chain subject to inspection and 1 sample at the head company	At the headquarters of the head company and of the homogeneous sites subject to verification.	Fresh product during harvest or post-harvest Finished product	Multiresidue (Specific tests if necessary)

Ni is the number of sites attributable to the *i*-th group of homogeneous sites, by species and by standard (for example farms, conditioning plants, processing plants, etc.).

7.3 SAMPLING METHODS

As regards the methods of carrying out the sampling, official and/or regulated methods are used.

8. DECLARATION OF CONFORMITY AND USE OF THE CERTIFICATION

The Organization must communicate in advance to BAC the method of commercial presentation of the product (e.g., type of package, size, sales unit, weight, etc.), the labelling methods and what is indicated in the label, without prejudice to the provisions of the mandatory legislation.

The target threshold defined for each type of "CONTROLLED Residue" product, explicitly reported in the BAC certificate, must be clearly communicated to the customer both on the label and in the remaining communication material (technical data sheets, brochures and communication material, website, etc.).

The communication of the certification must always be referred to and clearly traceable to the products subject to certification. Once the licensee organizations have obtained the certificate of conformity, they will be able to use the certification mark provided for the specific category of products.

CONTROLLED RESIDUE



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*Residues of plant protection products
inferior or equal to XX% of the
Maximum Residue Limit (LMR)
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ZERO RESIDUE



ZERO RESIDUE*

*Residues of synthetic plant protection products
inferior or equal to the limit
of analytical quantification (0,01 mg/kg)



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The trademark shown on the label must be clearly visible and identifiable by the consumer, the note that specifies the target threshold and the guaranteed maximum limit of plant protection products must be indicated with fonts and sizes that are easily visible and clearly legible by the customer and consumer (ref. Art. 13 Reg. CE 1169/2011).

All communication, including the use of the logo, must be carried out in compliance with the BAC General Regulations for product certification and, it is specified that the indications on the label of the finished product and direct advertising to the consumer must be subjected to prior approval by BAC.

In addition to the obligation to provide a controlled copy of the Certificate of Conformity to the recipients of the products, the words "Zero residue - BAC NT XX Certificate" must be indicated in the tax documents and/or in the documents accompanying the product.

Misleading and/or incorrect advertising is considered a non-compliance and therefore sanctioned by BAC. Incorrect use of the logo and the Certificate of Conformity, such as printing or advertising errors, not followed by appropriate denial or corrective actions, is the cause of measures that can range from the suspension to the revocation of the certification.

False claims, as well as counterfeiting of conformity certificates and of the logo, are prosecuted legally.