APPROVES THE TECHNICAL STANDARDS OF ACT No. 20089, WHICH CREATES THE NATIONAL CERTIFICATION SYSTEM OF AGRICULTURAL ORGANIC PRODUCTS

SANTIAGO JAN. 29 2016

DECREE No.__ 03__/With regard to: Pursuant to Article 32 No. 6, of the Constitution of the Republic of Chile; the Decree with the force of law No. 294, of 1960, of the Agriculture Ministry; the Act No. 18,755, that establishes the Organization and the Powers of the Agriculture and Livestock Service; Act No. 20,089, that creates the National Certification System of Organic Agricultural Products; the Decree with the force of law No. 1/19,653 of 2000, of the Secretary General of the President, which approved the revised, coordinated and systemized text of Act No.18,575, Organic Constitutional Law No.18,575 of the General Bases of the Public Administration; Decree No. 36 of 2006, of the Agriculture and Livestock Service and Resolution No. 1,600 of 2008, of the Comptroller General of the Republic.

WHEREAS:

Act No. 20,089, that creates the National Certification System of Organic Agricultural Products, sets forth in Article 5 that: “The requirements and protocols for registration into the system by the various participants and for the implementation of the different phases of operation thereof will be established by a set of regulations to that end and, where appropriate, through technical standards. The aforementioned regulations and technical standards shall be approved and made official, respectively, by decrees from the Ministry of Agriculture and as such, shall be mandatory.”

By Decree No. 36 of 2006, the Ministry of Agriculture approved the Regulations of Act No. 20,089, that created the National Certification System of Organic Agricultural Products, which was modified by Decree No. 86 of 2011, of the Ministry of Agriculture.

Organic farming constitutes a dynamic activity, whose procedures change over time in such a way as to require constant updating of the standards governing said activity.

It has been decided to enact a new Regulation of Act No. 20089, that created the National Certification System for Organic Products that requires updating to include new requirements on the subject, Decree No. 36 of 2006, of the Ministry of Agriculture.
DECREE

The Regulations of Act No. 20089, which creates the National Certification System of Organic Agricultural Products, are hereby approved, and which read as follows:

TITLE I

General rules

Article 1. These Regulations have as their purpose to establish the requirements and protocols for subscribing to the National Certification System for Organic Agricultural Products and to regulate the additional aspects that are necessary for the adequate operation of said system, in accordance with Act No. 20089. The provisions of these Regulations will be applied to the certifying entities, be it the certification organizations or the organic farmers organizations and the operators that work in the area of organic farming.

Article 2. Notwithstanding the definitions established by the Law, for the effects of these Regulations, it shall be understood by:

a) Organic, ecological or biological agriculture: holistic agroforestry production system based on ecological management practices, whose main objective is to achieve sustained productivity based on the conservation and/or restoration of natural resources in accordance with the Technical Standard in force.

b) Inspection: assessment of conformity with this organic-production standard, through observation and ruling, accompanied as appropriate by measurements, essays/tests or pattern gauging.

c) Certification or certifying agent: body responsible for verifying that agroforestry production is carried out in accordance with applicable technical standards for the production of organic products or in-transition organic products; it includes certification bodies as well as organic farmers organizations.

d) Act: Act No. 20089, which created the National Certification System for Organic Agricultural Products.

e) Technical Standards, International Standards, or equivalent Chilean technical standards: Those that are officialized by decrees from the Ministry of Agriculture, for the effects of Articles 5 and 6 of the Act.

f) Operator: Natural or legal person who has signed an agreement for certification of organic products with a certification agent or an organization of organic farmers registered by the Agriculture and Livestock Service, and which can produce, process and/or market organic products and is responsible for ensuring that these comply with the certification requirements. Furthermore, national marketers who do not perform production or processing tasks and which are controlled directly by the Service and that must similarly comply with current regulations shall also be considered operators.
Article 3. The Service will be the competent authority in charge of supervising compliance with the Law, these Regulations, the technical standards and its supplementary standards.

TITLE II

National Certification System of Organic Agricultural Products

Paragraph 1 The System

Article 4. The National Certification System of Organic Agricultural Products aims to guarantee and certify that organic products are produced, elaborated, packaged and handled according to the standards regulating them.

Article 5. Pursuant to the provisions of the Act, only agroforestry products, that during their production, manufacture, conservation and marketing have complied with the requirements and protocols established in these Regulations and the technical standards in force and have been certified according to the provisions of Article 6 of the present regulations may use the denomination “organic products” or their equivalents, such as “ecologic products,” “biologic products,” “bio,” “eco,” or a combination of them. Any term used on their labels, identification, marketing or denomination that misleads the consumer, will constitute an infraction of the Law and these Regulations.

Article 6. Any agroforestry product deriving form an organic production process, in order to be recognized as such, must be certified by a certifying agent, be it a certifying organization or an organization of organic farmers duly registered in the Service, according to the rules of these Regulations.

Article 7. For the effects of subscribing to the System, according to the Articles 3 and 5 of the Act, the Service may establish and administer lists of the various intervening parties that wish to participate in the System.

Article 8. The Service will administer a registry of all of the certifying entities, be they certifying organizations organic farmers organizations.

In addition, it will manage a registry of all of the technical standards of organic production.

Article 9. It will be the responsibility of the Service to manage and control the use of the official distinctive seal for organic agricultural products, being entitled to apply the same to certifying entities enrolled in their Registry, according to the rules of these Regulations.
Paragraph 2 Operators

Article 10. Operators shall comply with the following control provisions and obligations:

a) carry out production and/or commercialization operations in conformance with the technical standards in force;

b) maintain the registers that permit production traceability in conformance with the technical standards in force;

c) permit access to the establishments and their documentation, facilitating the delivery of their information when they are subject to inspection by the Service;

d) permit access to the establishments and their documentation, facilitating the delivery of their information when they are subject to announced or unannounced inspections by the certifying entities;

e) report to the pertinent certifying agent within a period not exceeding 10 business days, when it decides to leave the control system, the starting date in which it will no longer belong to the National Certifying System of Organic Agricultural Products;

f) maintain their certification valid and undergo at least one inspection within a period not exceeding 12 months;

g) inform the Service and the pertinent certifying agent of any irregularity or breach that may affect the organic character of its products or of those that have been received from other operators or subcontractors;

h) authorize the Service to publish the following information: Area of certification: Name or corporate name: Region: Community: Establishments (Properties or processing plants): Certification Organization: Certification Term: Category/type: and Quality (Organic or in transition).

The publication may include contact information, if expressly authorized by the operator.

Paragraph 3: General Conditions of the National Certification System for Organic Agricultural Products

Article 11. Enrollment in this Registry is obligatory for all certifying organizations, whether national or foreign, public or private.

Article 12.- The Service will establish and maintain current a Registry of certifying organizations, that will indicate the number or code granted to each entity, its name, the date of enrollment in the Registry and the expiration date, when required. The publication of the contact information will be carried out after receiving express authorization from the entity.

Article 13. Certifying organizations that have among their members, directors, administrators, managers, shareholders or employees, persons that are officials, employees or are contracted for professional fees, in the Service, may not be registered as legal entities.

Article 14. Procedure for enrolling in the Registry. The interested entity must file an enrollment request application in the Service Registry. Additionally, prior to the filing of the application, payment of the corresponding fee in force is required. This fee will not be reimbursed to the interested entity in the event that the application is rejected.
Once the application has been filed with all of the necessary background information and fulfillment of the requirements set forth in these Regulations, the Service will proceed to evaluate said information, and as such may carry out an on-site inspection. If the result of this evaluation is favorable, the candidate will be informed and enrolled in the Registry, as indicated in Article 12 of these Regulations.

In the event that the application submitted does not meet all of the requirements, the Service will return the documents to the certifying organization, so that it may correct the errors or add the missing information, as applicable, so that said entity may resubmit its application, within a period not exceeding thirty business days.

Should the aforementioned period expire before the application has been resubmitted, it shall be considered rejected, and as such the certifying agent must submit a new application and pay the corresponding fee.

Article 15. The certifying entities should regularly submit the results of the activities carried out during the period in the Organic Agriculture Information System or through the means as determined by the Service, with a view to the timeframes and formats established by such.

Notwithstanding the foregoing, the certifying organizations and the OFO must permanently keep the list that includes their operators up-to-date, according to the information contained in the formats mandated by the Service. This list will be published on the Service’s website, in accordance with the legislation in force.

Article 16. The registered agent must inform the Service immediately in the event of any variation in the information that was submitted for its enrollment in the Registry.

Article 17. The certifying entities must make at least one annual inspection of each production unit of its operators. The Service may require that the certifying agent, in justifiable cases, increase the amount of inspections, depending on the characteristics of the operator.

Article 18. The Service may directly require that any registered certifying agent, within the timeframe as determined by it and at any time, demonstrate the upholding of the conditions that permitted its registration.

Article 19. The suspension or cancelation of an agent’s enrollment in the Registry will be based on the information obtained during the inspection/audit, as well as any other information that the Service may consider relevant to this decision.

**Paragraph 4: Requirements and obligations of the Certifying Organizations**

Article 20. To enroll in the Registry, it will be the responsiblity of the certification organizations to comply with the formalities, requirements and technical and professional protocols necessary for the execution of the certification tasks provided for under the Law, the present regulation, technical standard and their supplementary standards.

Article 21. The certification organizations must comply with the following requirements:

a) be a current legal entity incorporated in conformance with the national or foreign legislation, as applicable;

b) be accredited in the certification of products within the scope of the National Certification System for Organic Agricultural Products, in accordance with ISO/IEC 17065 or international or official Chilean standards that replace or supplement the aforementioned regulations, provided that they are not in opposition to the provisions
of this decree. Notwithstanding the foregoing, the Service may request documents or additional information to verify the compliance of this requirement;

c) inform the Service, at the time of its registration, of the procedures to be used in the control of the different operators;

d) have the certification forms available, adapted to the conditions as determined by the Service;

e) have a plan of measures and corrective actions to be implemented in the event of non-compliance or breaches by the different operators, in accordance with the control of the Service;

f) publish the fees that are charged to the public for their services through the appropriate medium, in addition to including a seal or symbol that identifies the entity;

g) have an organization, whose technical operating inspection teams in the areas to be certified, are comprised of professionals or technicians from the agroforestry field with proven experience in the certification of organic products and mastery in the areas to be certified, in accordance with the guidelines as determined by the Service. To become authorized inspectors, the latter must undergo tests with the Service, in accordance with the requested scope. The frequency and content of said tests will be established by the Service and will grant official recognition to act as an inspector for 5 years, upon successful completion of the respective tests;

h) have at least one technical manager that will be the counterparty of the Service, with a degree in the agroforestry field of at least 8 semesters, and who also has at least 3 years of organic product certification experience; in the case of foreign entities, their personnel must have an educational background equivalent to those previously indicated;

i) have technical and administrative facilities that are adequate for the purpose of the certification;

j) present a guarantee of loyal compliance regarding their activities, in the amount of two hundred UF, through a promissory note, endorsable term deposit, insurance policy or bank guarantee in the name of the Agricultural and Livestock Service.

Article 22. The certifying organizations must present together with their application, the following background information:

a) photocopy of the Tax Identification Number of the applicant;

b) photocopy of the identification document of the legal representative or the official identification document in the case of foreigners;

c) notarized copy of the documents of the legal incorporation of the entity, with their respective modifications, if any;

d) photocopy of the respective statement publication, as applicable;

e) certificate of good standing of the legal entity, not exceeding 90 days, issued by the competent authority and certification of enrollment in the Commercial Registry;

f) document that demonstrates the legal capacity of the legal representative of the organization;

g) certificate of accreditation in the certification of products within the scope of the National Certification System for Organic Agricultural Products, according to ISO/IEC 17065 or international or Chilean official standards that replace or supplement the aforementioned regulations, which will be demonstrated through one of the following items:

i. certificate issued by the National Standards Institute (INN, Spanish acronym); or

ii. certificate issued by another accredited organization that is a member of the International Accreditation Forum (IAF) or the Inter-American Accreditation
Cooperation (IAAC); or

iii. a certificate issued by another accreditation organization, certifying its accreditation in ISO/IEC 17011:2004 or COPANT/ISO/IEC 17011:2004 and its respective amendments;

h) identification form for the technical manager(s) and for the personnel comprising the technical operating team, completed and signed by the legal representative and the applicant;

i) identification form of the responsible party in charge of the control system of the certifying agent;

j) certification of the degree, with an original or legalized photocopy of the technical manager and of the individuals of the technical team;

k) curriculum vitae of the technical manager;

l) curriculum vitae of the person performing the certification duties, along with the documents that demonstrate their experience in the certification of organic products and their expertise in the areas to be certified;

m) the description of the process to be used to carry out the certification and the control of the different operators according to the technical standards in force;

n) organizational chart of the entity, identifying the name, position and responsibilities of each member;

o) quality assurance manual and its procedures;

p) fee system;

q) examples of certificates issued by the entity;

r) design of the official stamp that will be used;

s) description of the technical and administrative facilities;

t) copy of the receipt of payment of the fee;

u) certificate of having past the test for the inspectors;

v) sworn declaration in which the applicant declares to not be affected by the established ineligibilities in Article 13 of these Regulations.

Article 23. The Certifying Organizations and their personnel responsible for the certification task, must permanently maintain the conditions that permit their registry and comply with all of the obligations that this implies.

Article 24. The certifying organizations must fulfill the following obligations:

a) allow the inspections, deliver the information and comply with the requirements as determined by the Service, within the framework of carrying out their control and supervisory functions;

b) submit the performance bond, as provided for by the resolution approving its enrollment in the Registry, which must remain valid for as long as it is enrolled;

c) deliver to the Service, by June 30 of each year, an annual report of its activities, which must include at least the following:

i. summary of the Activities of the certification organization, detailing the following aspects: Introduction; Executive Summary for the year; structure; and organizational changes.

ii. Results of the audits, evaluations and training provided to its personnel and inspectors;
iii. updated list of the certified operators for the period under evaluation, only including the identification of the operator and its risk classification;
iv. operator Inspection Program; and
v. conclusions regarding the results of the activities during the period.

d) maintain the confidentiality of the information obtained from its operators, with regard to its certification activities;
e) inform the Service of the existence of pests or diseases for mandatory control;
f) adopt the corresponding measures when the Service communicates the results of a sanction process affecting one of its operators;
g) adapt their procedures to the directives of the Service.
h) carry out annual sampling of pesticide residue, on at least 5% of the operators that it certifies, rounding to the nearest whole number. Samples may include the collection and analysis of soil, water, waste, vegetable tissue; and samples of processed vegetable and animal products;
i) make unannounced visits to at least 10% of its operators during the respective period;
j) carry out at least one inspection visit to each operator in a period not exceeding 12 months;
k) in the case of a voluntary withdrawal from the Registry, it must inform all of its operators with the necessary prior notice, so as to allow for the continuity of their certification;
l) the certifying organization must transfer its control files when an operator requests a change of certifying organization;
m) in the event of the suspension of the certification of an operator, the buyers of the product must be informed in writing, with the purpose of guaranteeing that the labels or packaging related to the organic quality of the product are removed from said production;
n) when an operator withdraws from the System, the certifying agent must store its control files for a period of no less than five years;
o) it must maintain up-to-date the information of its operators in the organic farming Information System or the medium determined by the Service for this purpose.

Article 25. Regarding foreign certification organizations, to carry out their certification tasks in Chile, they must comply with all of the requirements established in these Regulations, enroll in the Registry, and have a legal representative and domicile in Chile, where all of the required documentation required to carry out its supervisory and control activities shall be stored.

Article 26. The certifying organizations will delivery to their inspectors, for their identification while carrying out their functions, a credential that identifies the inspector, the characteristics and information that are determined by the Service for this purpose.

Article 27. The certifying organizations may not intervene in the certification processes in which they may have interest in the partners or the personnel of the organization or who are spouses, children or family members to the third degree of consanguinity and the second degree of affinity, with respect to said partners or personnel. In addition, the certifying organizations may not intervene in those certification processes with circumstances impeding their impartiality.
Paragraph 5: Requirements and obligations of the Organic Farmers Organizations.

Article 28. To enroll in the Registry, it will be the responsibility of the OFO to demonstrate that they comply with the formalities, requirements and technical protocols to execute the certification tasks contemplated under the Law, these Regulations, the technical standards and their supplementary standards.

Article 29. For the OFO to be registered in the Service, it must meet the following requirements:

a) be a current legal entity, incorporated in conformance with the national legislation;
b) meet the production requirements established under the Law, these Regulations, the technical standards in force and their supplementary standards;
c) maintain records of their production activities that allow establishment of a traceability system;
d) present an internal control system with at least the following elements:
  d1.- list of personnel comprising the internal control system;
  d2.- method and control activity records that permit the establishment of the supervisory level of the members of the group;
  d3.- current information of the members of the group (name, Tax Identification Number, name or identification of the property, geographic location, total surface of the property specifying the organic cultivating surface, type of crops, production destination, management plans, subcontracts if any, among others);
  d4.- internal procedures manual. This manual should include a diagram of the structure of the group, the process used to control its members and the confidentiality policy to follow. Said manual must specify the rights and obligations of the members; technical standards to be utilized; inspection procedures; procedures for the designation of internal inspectors; procedures for decision making and risk evaluation; regularity of the visits; the procedure for in the even of breaches and the application of sanctions for non-compliance with the technical standards or other obligation, among others; all of which must be in accordance with the standards of the Service;
  d5: guarantee the fulfillment of the technical standards of Chilean organic production;
  d6.- sworn statement or letter of commitment from each of its members to undergo the group internal control procedures;
  d7.- designate a person responsible for the internal control system, who will be the counterparty before the Service for the purposes of the corresponding controls;
  d8.- flowchart of the marketing process of the products with their respective registers and their control.

e) Other requirements established by the Service to this effect.

Article 30. Organic farmers organizations must fulfill the following obligations:

a) give free access to their production and marketing units to the Service controllers;
b) allow the inspections, deliver the information and comply with the requirements as determined by the Service, within the framework of their control and supervisory functions;
b1. deliver to the Service, by June 30 of each year, an annual report of its activities, which must include at least the following:
i. - summary of the Activities of the Organization that includes at least the following aspects: Introduction; Executive Summary for the year; structure; and organizational
changes.
ii. - Current number of certified operators for the period under evaluation.
iii. - Operator Inspection Program.
iv. - Conclusions of the results of the activities during the period;
b2. adopt the corresponding measures when the Service communicates the results of a sanctioning process affecting one of its operators;
b3. adapt their procedures to the directives of the Service;
b4. it must maintain up-to-date the information of its operators in the organic farming Information System or the medium determined by the Service for this purpose.

Article 31. For all effects of the National Certification System of Organic Agricultural Products, organizations considered OFOs shall be those legal entities with annual sales not exceeding the equivalent of 25,000 UF.

The aforementioned organizations must enroll in the Registry referred to in Article 8 of these Regulations, presenting an application accompanied by the information mentioned in the prior items a), b), c), d), e), f), q), r), s), t) and v) of Article 22 of these Regulations, along with the following information that demonstrates the implementation of the internal control system and procedures:

a) list of products that pertain to the applying organization, according to the form;
b) form that identifies the person/people in charge of the control system and the work team, completed and signed by the legal representative of the applicant;
c) method and control activity records that permit the establishment of the supervisory level of the members of the group;
d) internal procedures manual that includes at a minimum:
   d1. diagram of the group structure and the specification of their responsibilities.
   d2. Method for performing inspections of members. d3. Obligations, rights and sanctions of the members of the organization. d4. Technical standards to be used;
   d5. criteria to exclude members from the group due to non-compliance with the technical standards or for other reasons;
   d6. confidentiality policy;
   d7. policy and procedures for decision making, risk assessment, regularity of visits and designation of “internal inspectors”;
   d8. identification of responsibilities and the decision making processes;
e) flowchart of the marketing process of the products with their respective registers and their control at each stage;
f) certification issued by the Internal Tax Service that demonstrates the annual sales.
Paragraph 6. Certification Standard Register

Article 32. The Service will maintain a Register of Standards, which will be comprised of the technical standards in force and of the international standards with their equivalency or recognition agreement.

Paragraph 7. Equivalency and Recognition Procedures.

Article 33. In accordance with the provisions of Article 6 of the Act, the official technical standards of other countries may be recognized or established as equivalents when the control systems and their standards have been validated, provided that the differences between the standards are identified with the measures necessary to correct them. These actions may include an in-situ visit to the country with which the recognition or equivalency has been established.

The area of application of this recognition or equivalency will only grant reciprocity to the scopes established within the corresponding Chilean technical standards.

The standards for the evaluation of the control system and the ability to achieve recognition or equivalency include the following:

a) Description of the certification system for organic products.

b) Explanatory documents of the control system and the control procedures utilized. Identification of the competent authorities that will act as a counterparty to the Service.

c) Comparative analysis that considers the mechanisms to identity the differences between the standards.

d) Current list of the authorized certification agents in the foreign country.

Article 34. Products imported for final consumption may use the official stamp according to the technical descriptions established by the Service, as long as they originate from a country with which Chile has a recognition or equivalency agreement in force.

Article 35. The certifications of the products imported for final consumption that originate from countries with which Chile has signed a Recognition or Equivalency Agreement, must comply with the technical provisions indicated in said Agreement.

Paragraph 8 Use of the official seal

Article 36. The terms organic, biological, ecological or their equivalents indicated in Article 5 of these Regulations, and the use of the Official Seal, may only be utilized on the label or packaging of agroforestry products that meet this quality requirement and which are duly certified, including ingredients that have been produced, handled and sold according to the specifications established in these Regulations and in the technical standards in force and their supplementary standards.

Article 37. The Official Seal must be legible and indelible and its graphic characteristics will be established through a resolution of the Service.

Article 38. The Official Seal must be utilized on those products that are certified by a certifying organization or organic farmers organization and which are duly registered according to the provisions of these Regulations.
Article 39. The use and administration of the Official Seal may be entrusted to the duly registered certifying agents. To this effect, the Service may authorize the agents to use the official seal, and the numbering will be assigned annually along with the registry enrollment code, which information must be included in the certification. The certifying agents must renew their authorization for use and administration of the official seal on an annual basis, paying the corresponding fee and reporting the quantity of certificates issued. This procedure must be carried out in the first ten days of the month of January every year. The official seal will be utilized on the respective certificates accrediting the organic quality of a product, through the formats as determined for this purpose by the Service. In the case of processed products, the seal will be placed on its label. This obligation will be controlled by the Service, with the certifying agents being responsible for compliance with said obligation.

TITLE III
Importations

Article 40.- Imported organic products may be sold when they originate from a country whose competent authority certifies that they have been obtained through an organic production method equivalent to the present regulation and the technical standards in force.

Article 41. The Service may recognize, with respect to imported products, the certification granted in accordance with the national certification systems of organic products of foreign countries, in the event that the importer of said products demonstrates the following to the Service:

a) that the organic production system is valid and meets the technical and administrative requirements established in the country of origin; and

b) that the certification of the imported product is recognized by the competent authority in the country of origin and is accompanied by a certificate of the transaction. The format of this document will be established by the Service.

Article 42. The Service may require all of the information necessary to collect the information mentioned in the previous article. In addition, experts may be hired to prepare the necessary reports on the production standards and the control measures applied in the products’ country of origin.

The importer must allow the Service to have access to its facilities and records, for their control, particularly the importation transaction, phytosanitary, existence records and product sales certifications.

The imported products must comply with the same legislation applicable to national products, without prejudice to the special standards established under the Act, in these Regulations and in the official technical standards in force.

Article 43. The imported products must be labeled in accordance with the legislation in force.
Article 44. In the event the imported products are in bulk and/or are to be used as raw material for the manufacture of organic products, they must be certified by one of the certifying agents registered with the Service, who must verify compliance with the national standards.

Notwithstanding the aforementioned clause, with respect to organic products or raw materials from countries with which Chile has a recognition or equivalency agreement, this condition will not apply.

TITLE IV
Sanctions

Article 45. The Service shall be the competent authority to sanction the breaches mentioned in Articles 9 and 10 of the Act, in accordance with the procedure set forth in Paragraph IV of Title I of Act No. 18755.

PROVISIONAL ARTICLES

Article One. These Regulations will enter into effect 180 days after the date of its publication in the Official Gazette.

Second Article. With respect to item h) of Article 21 of these Regulations, the inspectors that are authorized when these standards enter into effect must take and pass the respective test within a term not to exceed 12 months.

2. Repeal of Decree No. 36 of 2006, of the Ministry of Agriculture.

LET IT BE COMMUNICATED AND DULY PUBLISHED.

MICHELLE BACHELET JERIA
PRESIDENT OF THE REPUBLIC

SIGNATURE
CLAUDIO TERNICIER GONZALEZ
MINISTER OF AGRICULTURE (S)