

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY

MINISTER'S OFFICE

NORMATIVE INSTRUCTION No. 19, OF MAY 28, 2009

D.O.U., May 29, 2009 - Section 1

THE STATE MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, exercising the power conferred upon him by art. 87, sole paragraph, clause II, from the Constitution, in view of what is disposed in Law no. 10,831, of December 23, 2003, in Decree no. 6,323, of December 27, 2007, and what is contained in Process no. 21000.001629/2008-11, resolves to:

.Art. 1 Approve the organic quality control and information mechanisms which are disposed in Annex I of the present Normative Instruction.

.Art. 2 Approve the official forms, from the Ministry of Agriculture, Livestock and Food Supply, which are dealt in Annexes II to XXIV of the present Normative Instruction.

.Art. 3 This Normative Instruction enters into force on the date of its publication.

REINHOLD STEPHANES

ANNEX I

ORGANIC QUALITY CONTROL AND INFORMATION MECHANISMS

Art. 1 Establish the organic quality control and information mechanisms to be followed by the individuals or legal entities, governed by public or private laws, which produce, transport, commercialize or store organic products, or which are responsible for the organic conformity assessment.

Art. 2 It is considered for effect of this Normative Instruction:

I - National Registry of Organic Producers: database with information related to the organic producers in compliance with the Brazilian regulation for organic production;

II - Organic Conformity Certificate: document issued by organic conformity assessment body, accredited by the Ministry of Agriculture, Livestock and Food Supply (MAPA) to operate in the Brazilian System of Organic Conformity Assessment, certifying that products or producing or commercial establishments fulfill to the provisions from the organic production regulation, being authorized to use the SisOrg seal;

III - social control: process for generating credibility organized from the interaction of people or organizations, sustained by the participation, commitment, transparency and trust of the people which are involved in the credibility generation process;

IV - Commercial Transaction Declaration: document issued by the Organic Conformity Assessment Bodies or by the production units, based on the procedures defined by the Organic Conformity Assessment Bodies (CABs), with qualitative and quantitative information about the commercialized products, in order to allow the control and the traceability of the products;

V - group: it is a set of people organized formally or informally which executes collective actions for mutual monitoring and conformity assessment of the production units of the suppliers; a group can include different social stakeholders which exercise the power and responsibility shared by the decisions related to the conformity of products in relation to the organic production regulations;

VI - inspection: visit of representatives from organic conformity assessment bodies, to verify if the production system is being operated in conformity with the current organic production standards, possibly being part of an audit process;

VII - Organic Conformity Assessment Body (CAB): institution which assesses, verifies and certifies that products or producing or commercial establishments comply with the provisions of the organic production regulation, possibly being a Certifier or Participative Conformity Assessment Body;

VIII - Participative Conformity Assessment Body (PCAB): it is an institution which takes the formal responsibility over the set of activities developed in a Participative Organic Quality Guarantee System (PGS), constituting in its organizational structure an Assessment Commission and an Appeal Council, both composed by representatives from the members of each PGS;

IX - shared power: horizontal process of organic conformity assessment, in which the decision making is shared among all participants from a participative guarantee system, which have the same level of responsibility and power in the determination of a product's organic quality;

X - Brazilian Organic Conformity Assessment System seal: a seal visually noticeable which identifies and differentiates controlled products in the Brazilian Organic Conformity Assessment System, as well as guaranteeing the conformity of these products with the organic production technical regulations;

XI - controlled production unit: production unit where the organic conformity assessment is performed by an Organic Conformity Assessment Body accredited by MAPA;

XII - internal control visit: process through which the members from an organizational structure, or technicians hired by them, perform the verification of the compliance with the technical regulations and other procedures established by the internal control system; and

XIII - peers visit: when people who integrate the same PGS assess, through visits, the compliance with production criteria and practices.

TITLE I

OF THE CONTROL MECHANISMS FOR THE ORGANIC QUALITY GUARANTEE

CHAPTER I

OF THE GENERAL PROVISIONS

Section I

Of the Control Mechanisms

Art. 3 The control mechanisms for the organic quality guarantee imply on the compliance with the requirements established for the family farmers in the direct sales without certification and, on the other cases, to the requirements established by the Brazilian Organic Conformity Assessment System.

Section II

Of the Administrative Processes Judgment Instances

Art. 4 The responsible for the judgment, in first instance, of the processes generated from the drafting of an Infraction Notice by an inspecting authority is the Federal Superintendent of Agriculture from the SFA in the unit of the federation where the inspecting action took place.

Art. 5 The responsible for the judgment of the appeals to the penalties imposed by the competent authority, foreseen in art. 4 of this Normative Instruction, is the Director of the Department of Production Systems and Sustainability - DEPROS/SDC/MAPA.

CHAPTER II

OF THE BRAZILIAN ORGANIC CONFORMITY ASSESSMENT SYSTEM

Art. 6 The Brazilian Organic Conformity Assessment System is integrated by bodies and entities from federal public administration and by the conformity assessment bodies accredited by the Ministry of Agriculture, Livestock and Food Supply.

Sole paragraph. The conformity assessment bodies are legal entities, governed by public or private law, responsible for the conformity verification of the assessed productive processes, in relation to the organic production technical regulations, in the Certification through Audit as well as in the Participative Guarantee Systems.

Section I

Of the Accreditation for Organic Conformity Assessment Bodies

Art. 7 The Organic Conformity Assessment Bodies (CABs) must be accredited by the Ministry of Agriculture, Livestock and Food Supply (MAPA).

§ 1 The accreditation of the certifiers will be preceded by accreditation from the Brazilian National Institute of Metrology, Quality and Technology - Inmetro.

§ 2 The accreditation of certifiers by MAPA will happen in 2 (two) phases: Phase 1 (one) with the request for joint audit with Inmetro according to what is foreseen in art. 23 of this annex, and Phase 2 (two), with the accreditation request, according to foreseen in art. 24 of this annex.

§ 3 The accreditation of the Participative Conformity Assessment Bodies (PCAB) must be preceded by audit under responsibility of the Agroecology Coordination COAGRE.

Art. 8 The CAB, when protocoling the accreditation request in the Federal Superintendence of Agriculture from the unit of the federation where it is based, must define the scope(s) in which it will act.

Sole paragraph. The scopes which the main section of this article refers to are:

- I - primary animal production;
- II - primary plant production;
- III - organic sustainable extractivism;
- IV - processing of plant origin products;
- V - processing of animal origin products;
- I - processing of agricultural inputs;
- VII - processing of livestock inputs;
- VIII - processing of phytotherapeutics;
- IX - processing of cosmetics;
- X - processing of textile products;
- XI - commercialization, transport and storage; and
- XII - restaurants, snack bars and similar.

Art. 9 the Agriculture and Livestock Politics and Development Service (Sepdag) from the Federal Superintendence of Agriculture will perform complete verification of the documentation foreseen in art. 18 (PCAB) and arts. 23 and 24 (Certifier), of this Annex, and will send process to the Agroecology Coordination - COAGRE, from the Ministry of Agriculture, Livestock and Food Supply, within a period not exceeding 10 (ten) days.

Art. 10. COAGRE, within 10 (ten) days, will consult the Commissions of Organic Production - COPs from the units of the federation where the Conformity Assessment Body already acts, in order to obtain expert opinion about its accreditation request.

Art. 11. The Agroecology Coordination will have up to 20 (twenty) days to deliberate about the accreditation request.

§ 1 In the case of PCABs accreditation, the period in the provisions of the main section of this article will only start to be counted after conclusion of the audit which must be

performed within a maximum period of 120 (one hundred and twenty) days counted from the moment COAGRE receives the documentation.

§ 2 The accreditation request can be rejected, through reasoned opinion of the Agroecology Coordination from MAPA.

§ 3 From COAGRE's decision there is admission of appeal to the Directory Board of the Department of Production Systems and Sustainability, of the Secretariat of Agriculture and Livestock Development and Cooperativism of MAPA, within the period of 30 (thirty) days counted from the knowledge or official publication of the decision.

§ 4 The Department of Production Systems and Sustainability will have the period of 30 (thirty) days to deliberate about the appeal which is dealt in § 3 of this article.

Art. 12. At the act of accreditation, the CAB will receive Declaration of Accreditation issued by COAGRE proving its situation and authorizing it to use the SisOrg seal, becoming part of the list for accredited CABs, which is available at MAPA's website.

Art. 13. For later scope of action alteration or expansion, the CAB will request COAGRE the extension of the accreditation for the intended scope, forwarding the complement for the manual of operational procedures and of the organic production standards related to this new scope.

§ 1 In the case of the certifiers, the resume of the indicated inspectors must also be presented, which must be regularly registered at the pertinent professional councils.

§ 2 After consultation to the COPs and analysis of the complementary documentation, COAGRE will decide if it will be necessary a new audit to authorize the expansion of the scope.

Subsection I

Of the Experts Database for the Accreditation Audits

Art. 14. COAGRE will have a list of experts trained to act in the audits necessary for the accreditation process of the CABs.

§ 1 The list which is dealt in the main section of this article will be formed by technicians, indicated by the COPs from the Units of the Federation, which must have experience proved and professional formation compatible to the scope in which they will act.

§ 2 The indication of the expert must refer to which scopes he is being indicated to and be accompanied by his Curriculum Vitae.

§ 3 COAGRE must keep the list updated and available to the public at MAPA's website.

Subsection II

Of the Data Launching on the Registries

Art. 15. After its accreditation, the CABs star to be responsible for launching and keeping updated the data referent to all production units under its control in the National Registry of Organic Producers, within the maximum period of 45 (forty-five) days.

Sole paragraph. The updates must occur within a maximum period of 30 (thirty) days counted from the approval by the CAB of new producers or of alterations in production units which are already controlled.

Art. 16. In case of canceling the Producer's Certificate of Organic Conformity, the CAB must exclude him from the national Registry of Organic Producers, within a maximum period of 7 (seven) days.

Art. 17. COAGRE will be responsible for updating and making available the National Registry of Organic Conformity Assessment Bodies and the National Registry of Organic Producers.

Subsection III

Of the Procedures for Accreditation of Participative Organic Conformity Assessment Bodies

Art. 18. The PCAB must request accreditation to the Service of Politics and Agriculture and Livestock Development (Sepdag) from the Federal Superintendence of Agriculture in the Unit of the Federation where the headquarter is located, presenting the following documents:

- I - form for Request of PCAB Accreditation (Annex IV) filled out and signed;
- II - list of the production units with producer's name, CPF/CNPJ, address, scope, area and productive activity, where already operates as Participative Conformity Assessment Body, or declaration of inexistence of projects under its control;
- III - proof of registration in CNPJ;
- IV - constitutive acts from the PCAB (statute, regiment and articles of incorporation);
- V - manual of operational procedures from the PCAB; and
- VI - used standards of the organic production.

Art. 19. The accreditation of Participative Organic Conformity Assessment Bodies must be preceded by audit under responsibility of the Agroecology Coordination - COAGRE.

Art. 20. The PCAB which declares it does not have controlled production units in the national territory will have accreditation conditioned to the execution of inspection audits, within a maximum period of 6 (six) months, which will confirm or not the accreditation.

Art. 21. If an accredited PCAB remains without controlling any production unit for a period greater than one year, it will be considered inactive and its accreditation will be canceled.

Subsection IV

Of the Procedures for the Accreditation of Certifiers

Art. 22. The accreditation process of certifiers is linked to the request of the accreditation to Inmetro, following the procedures established by it.

Art. 23. When requesting the accreditation, to Inmetro, the certifier must also start Phase 1 of the accreditation, filling out the form for Certifier Accreditation Request - Phase 1 disposed in Annex II of this Normative Instruction, protocoling it at Sepdag from the Federal Superintendence of Agriculture in the Unit of the Federation, where it is situated, forwarding the documents described below to subsidize the joint audit of accreditation, to be carried out by Inmetro and MAPA:

- I - resumes of the indicated inspectors, who must be regularly registered in the pertinent professional councils, with educational background according to the scope of action;
- II - list of the controlled production units with the producer's name, CPF/CNPJ, address, scope, productive activity and area, if already acting in the organic production certification, or declaration of controlled production unit inexistence;
- III - proof of registration in CNPJ;
- IV - constitutive acts from the certifier (statute, regiment, articles of incorporation);
- V - manual of operational procedures from the certifier; and
- VI - applicable standards of organic production.

§ 1 The accreditation audit must be carried out by a staff composed by professionals chosen jointly by Inmetro and COAGRE and must generate report which will also be used for the accreditation process.

§ 2 The certifier which declares not to have controlled production units in the national territory will have accreditation conditioned to the execution of inspection audit, within the maximum period of 6 (six) months, which will confirm or not the accreditation.

Art. 24. To start Phase 2 of the accreditation, the certifier must fill out the form of Certifier Accreditation Request - Phase 2 (Annex III), protocoling it at the Service of Politics and Agriculture and Livestock Development (Sepdag) from the Federal Superintendence of Agriculture - SFA in the Unit of the Federation where its headquarter is located, presenting the evidential document of accreditation by Inmetro.

Art. 25. If an accredited certifier remains without certifying any production unit from a period greater than one year, it will be considered inactive and its accreditation will be canceled.

Art. 26. In case a certifier loses its accreditation by Inmetro, it must inform the fact to MAPA, which will provide disaccreditation of the certifier.

Art. 27. In case MAPA cancels the accreditation of a certifier, Inmetro must be informed.

Section II

Of the Procedures for Conformity Assessment through Certification

Subsection I

Of the Certification Process through Audit

Art. 28. The certification comprises the procedures executed, by accredited CABs, in the production and commercialization units in order to assess and guarantee its conformity in relation to the organic production standards.

Art. 29. The certifiers must have manual of procedures which mandatorily contains:

I - all phases of the certification process, since the initial request analysis until the final certification;

II - situation registration mechanisms of all certified production and commercialization units and their products, throughout the certification process; and

III - procedures for certification of new products in the certified production and commercialization units.

Art. 30. The certified production units must inform any inclusion or substitution of products and areas to the certifiers.

§ 1 In the cases foreseen in the main section of this article, the certified production and commercialization units can only commercialize the new products after approval of the certifiers.

§ 2 When dealing with products of different scope, the certifiers shall conduct additional audits; in this case the certified production and commercialization units can only commercialize the new products after approval by the certifiers.

Art. 31. The certifiers must have procedures for registration and tracking information on changing production processes, enlargement or reduction in the area used for certified products.

§ 1 The certifiers will assess the need for additional investigations due to the informed.

§ 2 When there is no consent of the certifiers, the production and commercialization units cannot commercialize as organic the products coming from the processed changes.

Art. 32. The certifiers must have acceptance mechanisms of the production and commercialization units, previously controlled by other certifiers or PCABs.

Sole paragraph. The certifiers must establish ways to forward, to the other certifier, the pertinent records, when requested by the production and commercialization units.

Art. 33. The certifiers must establish periods and frequency to elaborate inspection and audit reports and decisions of certification.

Art. 34. The decisions related to the certification process, which cover the initial approval of the certified production and commercialization units and also the subsequent, approval of products, changes in production, adoption of disciplinary measures and others, must be taken by people not involved with the audit activities of the production and commercialization units in question.

Art. 35. The certifiers must have procedures defined for the cases in which adopted exceptions foreseen in the technical regulations; these special concessions must be limited to a defined period of time, justified and registered.

Art. 36. The certifiers must have procedures for analysis of appeals presented against decisions of certification, being necessary to keep registration of all appeals and document the originated actions; the authorities responsible for the questioned decisions must not be involved in the analysis of the appeals.

Subsection II

Of the Organic Conformity Certificate

Art. 37. The product or producing or commercializing establishment which its conformity is approved will receive Organic Conformity Certificate issued by certifier accredited by MAPA.

§ 1 The Organic Conformity Certificate is valid for one year counted from the date of its issuance.

§ 2 To renew the validity of the Organic Conformity Certificate, it is necessary new process of conformity assessment, to be initiated prior to the ending of the undergoing process.

Subsection III

Of the System Integrity

Art. 38. The certification system must be based in formal agreements established by the involved parts with clearly defined responsibilities, being responsibility of the producers:

- I - to follow the technical regulations established for obtaining organic products;
- II - consent with execution of inspections and audits, including the ones executed by the bodies responsible for accreditation and licensing of the certifiers;
- III - provide the information necessary for the certification process, with accuracy and within the periods established by the certifier;
- IV - provide information on its participation in other activities referent to the scope, which are not included in the certification process; and
- V - inform the certifier about any changes in its production and commercialization system.

Subsection IV

Of the Commercial Transaction Declaration

Art. 39. The certifiers must have procedures defined for the issuance of Commercial Transaction Declarations, issued by it or by the certified production units.

§ 1 When issuing declarations through the production units, these must inform to the certifiers about each declaration issued in order to ensure that they can keep the control over the total of the commercialized certified product.

§ 2 The declarations foreseen in the main section of this article must contain:

I - salesperson's name;

II - buyer's name;

III - date of sales;

IV - date of its issuance;

V - clear description of the products, its quantity and, when relevant in order to the specific characteristic of the product or of special control required by the market, the quality and the period of production or harvest;

VI - lot numbers and other existing identifications of the products;

VII - reference to the fiscal document of sales;

VIII - indication of the certifier responsible for the certification;

IX - declaration from the certified production and commercialization unit that the product was produced according to the applicable technical regulations; and

X - information about the certification of raw materials.

Subsection V

Of the Information for the Certified Units

Art. 40. The certifiers will ensure that each production and commercialization unit will have throughout the whole time they are under their control:

I - updated versions of the technical regulations and procedures applicable in the certification process;

II - full description of the processes of audit, certification and appeals, in a clear and objective way to the interested ones;

III - current certificates referent to the situation of the certification; and

IV - copies of the inspection and audit reports and other documents related to the certification of the production, provided, at least, annually.

Subsection VI

Of the Registrations and Documentation of the Certified Production Units

Art. 41. The certifiers must require that each controlled production unit has a registration system adapted to the type of production which allows the traceability and obtainment of information to execute the necessary verifications about production, storage, processing, acquisitions and sales.

Subsection VII

Of the Hiring of Outsourced Services by the Production Units

Art. 42. The certifiers must have regulations for the hiring of outsourced services for storage, processing, handling, transport, packaging, labeling and commercialization.

Sole paragraph. The certifiers must determine that the executed hiring for the services foreseen in the main section of this article include clauses related to the compliance with the technical regulations, with the obligation to provide information and granting free access to the certifiers and inspecting bodies.

Subsection VIII

Of the Certification in Group of Producers

Art. 43. Only the small producers, family farmers, settlement projects, former slave communities, riverside communities, indigenous and extractivist communities which comply with the following requirements will be able to be contemplated through the certification process in group:

I - have organization and structure enough to ensure an Internal Control System (ICS) based on a risk assessment which guarantees the adoption, by the individual production units, of the regulated procedures;

II - internal control visits must be made in every production unit at least once a year;

III - guarantee that the inclusion of new production units to the group can only be executed after the approval by the certifiers;

IV - have internal registrations correspondent to the items determined by the certifier;

V - guarantee to the production units of the group proper comprehension of the technical regulations; and

VI - is firm, by every responsible for the production units which are part of the group, a formal agreement to define the responsibility of the group and of its internal control system; it should contain the request for the commitment from all individual production units to comply with the current technical regulations and to allow the execution of internal control visits and audit by the certifier and by the inspecting bodies.

Art. 44. The certifiers which adopt the certification in group must have specific procedures for the inspections and audits.

§ 1 The sampling system and the main points to be audited will take into consideration the risk assessment of the internal control system based on shared process between the auditor and the group which seeks certification, considering social, economical, cultural and technological aspects which lead to elements of the group to noncompliance of the technical regulations.

§ 2 In case of adopting systematic of inspections through sampling, these must comply with the provisions of Chapter II, Subsection XIV, of this annex.

Art. 45. All the production units which compose the group must be object of initial visit by the certifier or from internal control, being ensured to each producer the right to individual certificate, as well as the access to and use of the documents of certification, background of the tracts and description of the production process.

Art. 46. The internal control system must be audited annually by the certifier, where it will verify, among others:

I - that 100% of the producers are being inspected by the ICS;

II - that the inspections are following the specific procedures previously approved;

III - that the Brazilian regulation for organic production is being complied with;

IV - that the internal inspection reports are being kept and correspond to the information obtained by the inspector from the certifier due to the visit; and

V - that the nonconformities detected in the internal inspection visits are being registered and the corresponding corrective measures are being adopted and equally registered.

Art. 47. The certifiers must keep basic information about all the production units which compose the group, being necessary to contain the identification, name, year of ingress to the group, location map of the area, production unit area, and the registration of production and commercialization.

Art. 48. The certifiers must have procedures for the suspension of the group certification in the cases of problems in the internal control system, until the responsibilities are assessed.

Subsection IX

Of the Acceptance of Certification from Other Countries

Art. 49. In the case of countries with recognition of equivalence for the certification system or agreements of mutual recognition, the official body responsible for the

certification system of organic products from the exporting country must provide formal registrations of the certifiers which are accredited by it.

Art. 50. In the case of countries without the recognition of equivalence of the certification system, the certifiers from these countries must be accredited at MAPA complying with the criteria for accreditation of certifiers of organic products defined by this regulation.

Subsection X

Of the Inspections and Audits for the Certifiers

Art. 51. The procedures necessary for the inspections and audits must be established by the certifiers, in compliance with the organic production regulation.

Art. 52. The inspections and audits have as objective the assessment of the conformity for granting the certification or maintaining it, being possible in this last case to be executed without previous notice.

Art. 53. The auditors must have specific educational background in audit of management system, as well as proved knowledge in organic production, being responsible for the supervision and accompanying of the inspectors' work, not being mandatory their presence in the inspections.

Art. 54. The inspectors must have experience according to the scope of the requested certification, being responsible for the execution of the inspections on the spot at the production units.

§ 1 The indication of inspectors in responsibility of the certifier, not being possible for the production units to choose or recommend inspectors.

§ 2 The production units must be informed of the identity of the inspectors prior to the audit visits for granting the certification, being possible to present objections related to eventual impartiality or suspicion.

§ 3 In the case of inspections not informed previously, any objection in relation to the inspectors can only be presented after the execution of the inspection.

Art. 55. The audits and inspections performed during the conversion period must verify the compliance with the foreseen organic management plan.

Subsection XI

Of the Inspections at the Production Units

Art. 56. The inspections at the production units must observe the following requirements:

I - the certifiers must have access to all the facilities, registrations and documents of the production units;

II - the inspections must be previously prepared, so the inspectors have enough information about them;

III - the inspections, their checklists and reports must cover the requirements contained in the organic production technical regulations pertinent to the scope of the activity which is being assessed;

IV - the certifiers must have access to any area of non organic production in the production unit, or other units which, through property or administrative links, are related to the certified activity; and

V - the inspections must follow objective and non-discriminatory procedures.

Art. 57. In the case of projects which involve several production units from organizations or groups of producers which have internal control system, this could be used as part of the inspection process by the certifiers.

Sole paragraph. For cases foreseen in the main section of this article, the certifiers must follow the determinations established in arts. 61 and 62 of this annex.

Subsection XII

Of the Inspections and Audits in the Organic Sustainable Extractivist Production

Art. 58. The inspection and audit procedures, besides the visits to the certified production units and their facilities, must also include:

- I - interviews with local collectors and intermediates;
- II - visit to a representative fraction, qualitative and quantitative to the certified area, considering the established management plan; and
- III - interviews with people and institutions linked to environmental and social issues which might provide information about the production units.

Subsection XIII

Of the Scope and Frequency of the Inspections and Controls

Art. 59. The inspections at the production units must be performed, at least, once a year being that, in the interval between the inspections, the certifiers are obliged to use control procedures which allow assessing the organic quality of the certified products.

Sole paragraph. For the activities whose assessments are more complex, as crops or breeding of several annual cycles and production or processing in establishments with parallel production, the certifier must establish a systematic of more frequent control, with at least one inspection per semester, alternating programmed inspections with the ones without previous notice.

Art. 60. The certifiers must perform visits without previous notice in at least 5% (five percent) of the certified units, each year.

Sole paragraph. In the case of visits in groups of producers, the number of unit to be inspected will be defined due to the risk assessment of the group.

Subsection XIV

Of the Inspection through Sampling System

Art. 61. The inspections through sampling system can be performed in organizations or groups of producers which involve several production units, and these must:

- I - have an Internal Control System - ICS approved previously by the certifier;
- II - have an administrative body (internal inspectors trained on the system) able to accompany, with inspection visits, 100% (one hundred percent) of the producers;
- III - establish contract with producers linked to them according to the model provided by the certifier;
- IV - make available for producers the applicable updated legislation, in a clear way and proper to the level of understanding of the group;
- V - have the following documents:
 - a) manual of procedures for internal control;
 - b) identification of the organization;
 - c) the project summary to certify with list of producers;
 - d) sketch of the production units;
 - e) record with the background of the parcels, at least, in the last 3 (three) years;
 - f) term of commitment from each producer;
 - g) inspection and internal control report from each producer, production or processing establishment;
 - h) documents related to the recognition of the production unit as organic, highlighting those referent to the conversion period reduction; and
 - i) certification table specifying status per tract per producer.

Art. 62. The certifier, starting from the risk assessment from the internal control system of the organization or group, will determine the sample percentage or number of producers who will receive external inspection visits.

Sole paragraph. The number of external inspections will be of at least the square root of the total number of producers.

Subsection XV

Of the Information Contained in the Inspection and Audit Reports

Art. 63. The inspection and audit reports must contain, mandatorily, the following information:

I - date and time of beginning and end of the inspection or audit;

II - names and personal data of the interviewed people;

III - crops, breeding or products which certification has been requested;

IV - visited areas, places and facilities;

V - documents examined;

VI - observations of inspectors or auditors;

VII - assessment of the compliance with the specific regulation and non-conformity report;

VIII - assessment of application of the corrective measures for non-conformities found in previous audits; and

IX - manifestation from the inspected or audited about the non-conformities found.

Sole paragraph. Besides the mandatory information foreseen in the main section of this article, complementary information might be necessary due to particularities related to the certified production unit, to specificities of the product or to the specific requirements established by the market.

Subsection XVI

Of the Laboratory Analysis

Art. 64. The laboratory analysis might need to subsidize the inspection or audit procedures or to comply with additional declarations required in specific certifications.

Sole paragraph. The analysis must be executed by official laboratories or the ones accredited by federal official bodies.

Art. 65. The certifiers must have procedures defined to execute analysis, foreseeing at least:

I - indication of the cases where samples must be collected;

II - obligatoriness of sampling where there are suspicions for the use of prohibited substances;

III - procedures for the decision in relation to the execution of analysis on the collected samples;

IV - procedures to be adopted to guarantee the compliance with the contaminants and residues limits established by the technical regulations.

Art. 66. The certifiers must have in their manuals of procedures the criteria and routines used for the collection of samples destined to analysis and exams needed to guarantee the organic quality.

Subsection XVII

Of the Certification Costs

Art. 67. In case the certifier establishes certification cost based on a percentage over the certified production, it must, mandatorily, offer another modality of charging.

Section III

Of the Procedures for Conformity Assessment through Participative Guarantee Systems

Art. 68. The PGSs must use credibility generation methods, proper to the social, cultural, political, territorial, institutional, organizational and economical realities.

Art. 69. The PGSs characterize themselves for the social control, the participation and responsibility of all members for the compliance with the organic production regulations.

§ 1 The social control is established through the direct participation of the PGS members; these actors establish and dynamize collective actions of conformity assessment from the suppliers to the organic production regulation.

§ 2 The participation refers to the effective action of the members in the PGS actions, to the shared power in the decisions and to the responsibility for guaranteeing the organic quality resulting from the process.

Subsection I

Of the Structure of the Participative Organic Quality Guarantee Systems

Art. 70. A PGS is composed by the members of the System and by a Participative Conformity Assessment Body PCAB.

§ 1 The System members can be individuals or legal entities which are part of a group, classified into two categories defined as follows:

I - the suppliers, constituted by the producers, distributors, traders, transporters and storers, with the following roles:

- a) request the conformity assessment of their products;
- b) provide the needed information, with the details and frequency stipulated by the PGS and requested by the PCAB;
- c) contribute for the credibility generation through their participation in the PGS;
- d) comply with the preventive orientations and arrange the correction of the non-conformities according to the recommendations from the Assessment Commission; and
- e) guarantee the conformity of the products assessed individually and in a participative way in the guarantee of the products from the group;

II - the collaborators, constituted by the consumers and their organizations, technicians, public or private organizations, NGOs and organizations of class representation, with the role to contribute with the credibility generation through their active participation in the PGS.

§ 2 The PCAB: is the legal entity which takes the formal responsibility over the set of activities developed in a PGS, with the following characteristics:

I - be the legal representative for from the PGS (s) at the competent bodies;

II - take the legal responsibility over the conformity assessment;

III - have in its structure, at least, an Assessment Commission and an Appeal Council, both constituted by representatives of the PGS members;

IV - issue documents related to the PGS operation;

V - organize and keep the records and documents related to the conformity assessment;

VI - point the non-conformities and propose the necessary preventive and corrective actions to the suppliers; and

VII - have social statue which characterizes their attributions, containing at least:

- a) criteria for composition or choice of the members from the Assessment Commission and Appeal Council from the PCAB;
- b) minimum requirements of participation, rights and duties of the members;
- c) periodicity of the meetings and assemblies of the members;
- d) administrative penalties;

- e) minimum composition of members to characterize a PGS and minimum requirements of operation; and
- f) minimum quorum for deliberation in the assemblies.

VIII - have internal regulation.

Subsection II

Of the Adhesion

Art. 71. To become a PGS member, the interested part must present to the group a signed request, which will forward to the PCAB, containing:

- I - a manifestation of interest to adhere to the PGS;
- II - registration data requested by the PCAB and, in the case of suppliers, also the data and information from the controlled production unit;
- III - declaration for knowing and complying with the PGS operation regulation.

Art. 72. The system members must register in proper document the acceptance of the interested part as PGS member, signing with the interested part a contract of adhesion.

Subsection III

Of the Conformity Assessment Process

Art. 73. The PCAB must have manual of procedures where it is established:

- I - information, registrations and documents which the producer must keep in the controlled production unit;
- II - minimum items of the verification visit and peers visit itinerary;
- III - definition of the minimum periodicity for the peers visit;
- IV - minimum items of the visit report;
- V - control mechanisms used in the intervals between the verification visits;
- VI - control systematic for more complex assessment activities;
- VII - minimum items of the organic management plan;
- VIII - instruments for traceability to be used by the suppliers;
- IX - procedures related to the laboratory analysis;
- X - administrative penalties; and
- XI - procedures for analysis of appeals and complaints.

Art. 74. In the PGSs, the conformity assessments aim:

- I - to promote actions of preventive nature which guarantee the compliance with the organic production regulations;
- II - to identify the non-conformities;
- III - to assist the suppliers for the resolution of the non-conformities and for the enhancement of the productive systems; and
- IV - to promote the experience exchange among the participants.

Art. 75. The group must request to the PCAB, in written, the conformity assessment of the production units from the members assessed by it, specifying the pertinent scope (s).

Sole paragraph. The request will be accompanied by the organic management plan and the document from the supplier certifying knowledge and compliance with the organic production regulation.

Art. 76. The verifications of conformity in the PGSs are carried out by the assessment commissions and by the peer visits.

Art. 77. The conformity verification visits must be executed, at least, once a year, in the group or individual supplier.

Sole paragraph. In the interval between visits, other social control mechanisms must necessarily be used, such as the peer visits, participation of suppliers in the PGS activities and in the PCAB meetings.

Art. 78. For the activities whose assessments are more complex, as crops or breeding of several productive cycles throughout the year, processing in establishments with parallel production and organic sustainable extractivism, must be established, by the PCAB, a systematic to execute a greater number of verification visits, during the production period.

Art. 79. The ones responsible for the conformity verification must, during the visits, have access to all facilities, registrations and documents from the production units and to any non-organic production area, being of the unit itself or of the others which, through property or other links, are related to the verified activity.

§ 1 The visits which are dealt by the main section of this article must be previously prepared, so the involved ones have enough information to carry out the visits, being also necessary to:

I - follow an itinerary which identifies the items to be verified;

II - follow objective and non-discriminatory procedures; and

III - issue visit reports which cover the requirements pertinent to the organic production technical regulation and to the PGS criteria.

§ 2 The verification visits can be executed through sampling and, in this case, the number of visits should not be less than the square root of the number of suppliers of the group.

§ 3 The PCAB must establish a period so that all production units from each group are visited due to the identified risks.

§ 4 The PCAB will be able to execute verification visits, without previous notice, as complementation to the scheduled visits.

Art. 80. In the peer visits, it will be possible to have participation of others parts which represent different interests, such as consumers and technicians.

Art. 81. The peer visit must be registered and signed in document containing information regarding the compliance with the organic production regulation and it will be contained in the minute from the meeting of members.

Art. 82. In the case of peer visit in production unit, which has Conformity Certificate, where the non-compliance of the organic production regulation is found, the group requests the Assessment Commission a verification visit.

Art. 83. The Assessment Commission can decide for the need of laboratory analysis to subsidize the decision on the conformity.

Sole paragraph. The analysis must be executed by official laboratories or accredited by federal bodes and, in the case of inexistence of accreditation, the approval of the laboratory must be submitted to MAPA.

Subsection IV

Of the Decisions on the Conformity

Art. 84. The decision on the conformity will be made after verification visit, by the Assessment Commission from the PCAB, by the visited supplier and by the group it integrates, in specific meeting, respecting the minimum quorum defined in the PCAB Internal Regulation, being necessary to:

I - be registered in the minute of the meeting;

II - be signed by all present members of the group; and

III - be registered in Organic Conformity Approval or Renewal Document from the producer, signed by all members of the group.

Art. 85. In case the verification visit certifies any non-conformity, the decision about the corrective measures and the penalties will be made, in joint meeting, by the PCAB Assessment Commission, by the visited producer and by the group which it integrates respecting the minimum quorum defined in the PCAB Internal Regulation.

Sole paragraph. The decision foreseen in the main section of this article will be registered in proper document or in the minute of the meeting and will be endorsed and signed by the Assessment Commission and by the present members of the group.

Art. 86. The Producer will have period of 30 (thirty) days counted from the date of the meeting which defined the administrative penalties to appeal of the decision at the PCAB.

Art. 87. The Assessment Commission must perform visits to accompany the compliance with the penalties and correction of the non-conformities and register the findings in proper document.

Sole paragraph. In the case of non-compliance with the corrective measures and penalties, the Assessment Commission will apply the penalties foreseen in the PCAB Manual of Procedures and will register its decision.

Art. 88. Eventual complaints about non-conformities coming from suppliers will be forwarded to the Assessment Commission for verification of the facts and adoption of procedures foreseen in the PCAB Manual of Procedures.

Subsection V

Of the Appeal Council

Art. 89. The PCAB will have Appeal Council, which will be responsible for the analysis and deliberation of the appeals.

§ 1 The PCAB will establish procedures for analysis of appeals and complaints, will keep records of all legal proceedings brought and will document the originated actions.

§ 2 The ones responsible for the questioned assessments will not be able to participate in the decisions in relation to the analysis of appeals.

§ 3 The Appeal Council will have period of thirty days for the assessment of the appeal petitioned by the producer.

§ 4 In the case when the Appeal Council ratifies the decision of the Assessment Commission, the producer must adopt the corrective measures and comply with penalties when they exist.

§ 5 In the case when the Appeal Council does not ratify the decision from the Assessment Commission, the producer must comply with the corrective measures and penalties determined by this Council.

§ 6 In case the producer does not appeal within the period of thirty days, the Assessment Commission will apply the foreseen penalties.

Subsection VI

Of the Organic Conformity Certificate

Art. 90. The supplier which has the conformity of its production unit approved, will receive an Organic Conformity Certificate issued by the PCAB.

§ 1 The Organic Conformity Certificate is valid for one year counted from the date of its issuance.

§ 2 For renewal of the validity of the Organic Conformity Certificate, it is necessary a new conformity assessment process, to be executed prior to its expiration.

Art. 91. In case a supplier which has Organic Conformity Certificate does not participate in the PGS activities, the Organized Group will be able to deliberate for its exclusion.

Sole paragraph. In the cases of exclusion foreseen in the main section of this article, the group must communicate to the PCAB, forwarding copy of the minute from the meeting where the decision was made, within the maximum period of seven days.

Art. 92. In the case foreseen in art. 91, the PCAB must provide the cancelling of the Organic Conformity Certificate from the excluded supplier.

Subsection VII

Of the Commercial Transaction Declaration

Art. 93. The PCAB must have procedures defined for the issuance of commercial transaction declarations, issued by itself or by the suppliers under its control, if containing the following items:

I - name of salesperson;

II - name of buyer;

III - date of sales;

IV - date of its issuance;

V - clear description of the products, its quantity and, when relevant, the quality and the period of production or harvest;

VI - lot numbers and other types of identification (brands) of the products;

VII - reference to the fiscal document of sales;

VIII - the indication of the PCAB responsible for guaranteeing the product conformity;

IX - the declaration from the production and commercialization unit that the product was produced according to the applicable technical regulations; and

X - information about control of raw materials.

Sole paragraph. The production units must report accountability to the PCAB about the issued declarations.

Subsection VIII

Of the Information

Art. 94. During all the phases of the Conformity Assessment process, the PCAB will ensure through regular meetings that each supplier member of the group in the PGS will have:

I - access to the updated versions of the applicable technical regulations;

II - full description of the conformity and appeal assessment processes, in accessible language;

III - updated documents which prove, in written, the conformity situation of the controlled production unit; and

IV - right to copies of the conformity verification reports and of any other documentation related to the conformity assessment, provided, at least, annually.

Subsection IX

Of the Acceptance for the Conformity Assessment of PGSs from Other Countries

Art. 95. In the case of countries with the PGS recognition of equivalence, the official body responsible for the organic conformity assessment system from the exporting country must provide formal registration to the PCABs which are accredited by it.

Sole paragraph. In the case where the recognition of equivalence does not exist, the bodies responsible for the conformity assessment of the PGSs, from these countries, must be accredited by MAPA.

CHAPTER III

OF THE SOCIAL CONTROL IN THE DIRECT SALES OF ORGANIC PRODUCTS WITHOUT CERTIFICATION

Art. 96. The commercialization through direct sales must be performed by family farmers linked to social control organizations, registered at MAPA or at another associated inspecting body, of federal, state or district level.

§ 1 At the commercialization moment, the family farmer can be represented by a producer or family member included in the production process and who is part of its own organizational structure.

§ 2 Complaints about the irregularities referent to the commercialization process through direct sales, without certification, must be forwarded to the inspecting bodies.

Art. 97. The Social Control Organization must have its own control process, be active and guarantee the right of visit by the consumers as well as the free access of the inspecting body to the production units which are linked to it.

Art. 98. The Social Control Organization will be able, when necessary, to consult the COP from the unit of the federation where it is situated about technical decisions charged from it by the regulations.

Section I

Of the Social Control Organization Registration

Art. 99. To register the Social Control Organization at the inspecting body, the interested part must present the following documents:

I - Registration Request form of Social Control Organization in the terms of Annex V of this Normative Instruction;

II - registration data form from each producer (Annex VI);

III - Term of Commitment form with the Organic Quality Guarantee, in the terms of Annex VII, of this Normative Instruction, filled out and signed by all members, agreeing to comply with the technical regulations;

IV - description about the social control procedure on the production and commercialization of the products in order to guarantee that all parts are complying with the technical regulations and ensure the traceability of the products; and

V - official declaration which proves the condition of family farmer of its members.

Section II

Of the Social Control Organization Obligations

Art. 100. The SCO must communicate to the inspecting body the inclusions, within a maximum period of 30 (thirty) days, and the exclusions, within a maximum period of 7 (seven) days, of family farmers in the Social Control Organization.

Art. 101. The SCO must collect the Declaration of Linked Producer Registration from the SCO of the family farmer who is excluded from the organizational structure, notifying to the inspecting body when not possible to do so.

Art. 102. The SCO must update at the inspecting body, at least once a year, the lists of the main products and estimated production quantities, per family production unit.

Section III

Of the Inspecting Bodies

Art. 103. The inspecting body must issue Declaration of Linked Producer Registration for each member of the Social Control Organization, according to model established in Annex IX of this Normative Instruction.

Art. 104. The inspecting body will feed and maintain updated the National Registry of Organic Producers.

Art. 105. The inspecting bodies responsible for the registration and compliance by the SCOs are the Federal Superintendence of Agriculture in the units of the federation or, through agreement, other bodies of federal, state and district level.

Sole paragraph. For the celebration of the agreement foreseen in the main section of this article, the interested body must:

I - have enough structure for complying with the requests for registration of family farmers linked to social control organizations in its area of action;

II - have technical body which complies with the following specifications:

a) have legal licensing for the inspection activity; and

b) prove training for organic conformity assessment, according to the guidelines to be established by normative act to be edited by the Secretariat of Agriculture and Livestock Development and Cooperativism - SDC/MAPA;

III - register the technicians who are licensed at MAPA; and

IV - present the Work Plan and schedule of activities.

Art. 106. The associated body will adopt the legal measures in case of irregularities and forward the corresponding documentation to the Federal Superintendence of Agriculture from its unit of the federation, for application of the pertinent penalties.

CHAPTER IV

OF THE ORGANIC QUALITY IN THE STORAGE, TRANSPORT AND COMMERCIALIZATION

Section I

Of the Integrity of Organic Products and Ingredients

Art. 107. In all phases of the production process, in the storage, transport and commercialization operations, must be kept the integrity of the organic products and ingredients, applying the following measures:

I - at every moment, the organic products must be protected not to get mixed with the products which were not obtained from organic systems and not to have contact with materials and substances whose use are not authorized in the cultivation and post-harvest of organic products; and

II - the organic products likely of contamination through contact or the ones which cannot be differentiated visually must be identified and kept at a separate place from the other products which were not obtained from organic systems.

Art. 108. The compliance with the provisions of this regulation does not exempt the compliance with other requirements on commercialization, internal and external, disposed in the specific legislations.

Art. 109. At the retail market, the organic products likely to contamination through contact or the ones which cannot be differentiated visually from the similar ones not obtained from organic systems must be kept in a delimited and identified space, exclusively occupied by organic products.

Sole paragraph. All the products commercialized in bulk must identify their supplier in the respective exposure space.

Art. 110. The restaurants, hotels, snack bars and similar places which announce in their menus meals prepared with organic ingredients must:

I - keep available for the consumers updated list of the organic items offered or which contain organic ingredients, as well as their suppliers; and

II - inform, when requested by the inspecting bodies, the suppliers of organic products and the acquired quantities.

Art. 111. At the moment of the direct sales of organic products to the consumers, the family farmers must keep available the Declaration of Registration for Producer Linked to the SCO issued by the inspecting body.

Section II

Of the Imports

Art. 112. It will only be allowed to be commercialized in the country the imported organic products which comply with the Brazilian regulation for organic production.

Art. 113. The entrance into the country, of imported organic products, will only be authorized if the product guarantee is executed by the CAB accredited at MAPA or if the country of origin already has an agreement of equivalence for its conformity assessment system with the Brazilian Organic Conformity Assessment System.

Art. 114. The imported products which were submitted to quarantine treatment not compatible to the Brazilian organic production regulation will lose the condition of organic.

TITLE II

OF THE ORGANIC QUALITY INFORMATION

CHAPTER I

OF THE GENERAL PROVISIONS

Art. 115. The organic quality information can happen through the Commercial Transaction Declaration, through the labeling of products, through publicity and advertisement material and through sayings exposed in the commercialization places.

CHAPTER II

OF THE LABELING OF ORGANIC PRODUCTS IN THE BRAZILIAN ORGANIC CONFORMITY ASSESSMENT SYSTEM

Art. 116. The compliance with the provisions from this regulation does not exempt to the compliance with other requirements about labeling contained in the specific legislations for the different products.

Section I

Of the Labeling for the Internal Market

Art. 117. The label of organic products for the internal market must contain information about the productions unit including, at least, the name or corporate name, address and CNPJ or CPF number.

Art. 118. The organic products and the products with organic ingredients, which comply with the established in clause II, of art.120, of this annex, will be identified by the Brazilian Organic Conformity Assessment System seal.

§ 1 The seal, which is dealt by the main section of this article, must be in the frontal part of the product and right below it there must be the identification of the used organic conformity assessment system.

§ 2 The seal from the Organic Conformity Assessment Body can be used simultaneously with the one from the Brazilian Organic Conformity Assessment System.

Art. 119. The organic quality information in the labels must be in the frontal part of the product and it will be identified by the use of the terms: "ORGANIC", "ORGANIC PRODUCT", "PRODUCT WITH ORGANIC INGREDIENTS" or their variations of grammatical gender (masculine or feminine) and number (singular or plural).

Sole paragraph. The terms foreseen in the main section of this article can be complemented by the terms ECOLOGICAL, BIODYNAMIC, OF NATURAL AGRICULTURE, REGENERATIVE, BIOLOGICAL, AGROECOLOGICAL, PERMACULTURE and ORGANIC SUSTAINABLE EXTRACTIVISM and others which comply with the principles established by the organic production regulation.

Art. 120. For products which contain ingredients, including additives, which are not organic, the following rules are applied:

I - for products with 95% or more of organic ingredients, the non-organic ingredients must be identified and they can use the term "ORGANIC" or "ORGANIC PRODUCT";

II - for products with 70% to 95% of organic ingredients, the labels must identify these organic ingredients and present the sayings: "PRODUCT WITH ORGANIC INGREDIENTS"; and

III - the products with less than 70% of organic ingredients must not contain any expression related to organic quality.

Sole paragraph. Added water and salt must not be included in the calculation of the percentage for organic ingredients.

ANNEX II

Section II

Of the Labeling for Products Exclusive for Exports

Art. 121. In the cases of products destined exclusively to exports, where the compliance with requirements from the importing country implies on the use of prohibited products or processes in the Brazilian legislation, their labels must contain the sayings: "PRODUCT EXCLUSIVE FOR EXPORTS".

Sole paragraph. In the case referred in the main section of this article, the product will not be able to receive the Brazilian Organic Conformity Assessment System seal.

Section III

Of the Labeling of Imported Products

Art. 122. In the cases of import of products controlled by bodies accredited in Brazil or through agreement of equivalence, the labels of the products must contain the Brazilian Organic Conformity Assessment System seal (SisOrg).

CHAPTER III

OF THE ORGANIC QUALITY IDENTIFICATION FOR DIRECT SALES WITHOUT CERTIFICATION

Art. 123. The non-certified organic products commercialized directly among family farmers and final consumers must be identified in a way to allow the association of the product to the farmer responsible for its production and this to the Social Control Organization to which it is linked.

Art. 124. The products referred by art. 123 will not be able to use the Brazilian Organic Conformity Assessment System seal; however, the producer will be able to include in the labeling, when existing, or in the commercialization place the expression: "Organic product for direct sales by organized family farmers not subject to certification according to Law no. 10,831, of December 23, 2003".

Art. 125. The producers and commercialization places can contain or use ways of identification referent to the organization responsible for the social control of the organic quality.

ANNEX II

[ANNEXES](#)
