ANNEX TO THE RESOLUTION No. 314-2013 (COMIECO-EX)

**CENTRAL AMERICA RTCA 65.05.54:09**

**TECHNICAL**

**REGULATION**

**FERTILISERS AND SOIL CONDITIONERS FOR AGRICULTURAL USE. REQUIREMENTS FOR REGISTRATION**

**CORRESPONDENCE**: This regulation does not correspond to any international standard.

ICS 65.080 RTCA 65.05.54:09

Central American Technical Regulation, edited by:

* Ministry of Economy of Guatemala, MINECO
* Salvadoran Agency for Technical Regulation of El Salvador, OSARTEC
* Ministry of Development, Industry and Commerce of Nicaragua, MIFIC
* Ministry of Industry and Trade of Honduras, SIC
* Ministry of Economy, Industry and Trade of Costa Rica, MEIC

**REPORT**

The respective Technical Committees for Standards and Technical Regulations across the Standardisation and Technical Regulation Entities of the Central American countries, are the bodies responsible for carrying out the study or the adoption of the technical regulations. They are composed of representatives of the Academic, Consumer, Private Enterprise and Government sectors.

This document was approved as Central American Technical Regulation RTCA 65.05.54:09 Requirements for Registration of Fertilisers and Soil Conditioners, of Agricultural Use, by the Subgroup on Standardisation Measures and Agricultural Inputs. The formalisation of this technical regulation entails the ratification by the Council of Ministers of Economic Integration (COMIECO).

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1. **OBJECTIVE**

To establish the requirements for granting the registration of fertilisers and soil conditioners for agricultural use.

1. **SCOPE**

Applies to the registration of fertilisers and soil conditioners for agricultural use, which are manufactured, formulated, extracted from natural sources, packaged, repacked or repackaged, imported, exported, distributed and sold in the States Parties of the Central American Region.

1. **DEFINITIONS**
   1. **Records update**: process by which the holders of the records of fertilisers and soil conditioners granted before the entry into force of this regulation and are in force and those covered by the transitional III, will bring to the ANC, the information required by this regulation.
   2. **Marginal annotation**: annotation that is done to the scope of the record, when it is modified.
   3. **Competent national authority (ANC)**: Ministry, Secretary of Agriculture or any other authority that is mandated by law to grant the registration of fertilisers and soil conditioners for agricultural use.
   4. **Available nutrient element**: an element is present in a fertiliser, in a particular chemical form in which it is used for plant nutrition.
   5. **Soil conditioner**: any organic, inorganic, natural or synthetic product that applied to the soil, is able to modify and improve the physical, chemical or biological properties of the soil and does not provide nutrients of an available form to the plant.
   6. **Container or package**: suitable container which is in direct contact with the fertiliser or soil conditioner for agricultural use, to conserve it, identify it and to facilitate its transport.
   7. **Label**: printed material or graphic inscription written in legible characters that identifies and declares its components, and describes the product contained in the container or accompanying packaging.
   8. **Extractor**: physical person (natural, individual) or legal entity who is engaged in the extraction and preparation of soil conditioners for agricultural use.
   9. **Manufacturer**: physical person (natural, individual) or legal entity who is engaged in the manufacture of products to be used as sources of nutritional elements or components, whether natural or synthetic origin for the formulation and production of fertilisers and soil conditioners, for agricultural use.
   10. **Fertiliser**: natural or synthetic product that is applied to the soil, substrate or foliage; it supplies one or more available nutrient elements to the plant, and it can be used as a component of other fertiliser formulation.
   11. **Low analysis fertiliser**: granular fertiliser, applied to the soil and consisting of physical mixture or chemical formula of two or three primary macronutrient elements, which are mixed in such proportions that the sum of the percentage of nitrogen (expressed as element N), phosphorus (expressed as element P2O5) and potassium (expressed as K2O) contained in said mixture is less than thirty percent (30%) of the product contained in the package. This definition does not apply to single products.
   12. **Slow-release fertiliser**: fertiliser whose characteristic is to guarantee that its nutrients are present as a chemical compound and in a physical state such that its availability for plants extends over a period of time or under controlled conditions.
   13. **Special formula**: those fertilisers that are prepared to meet the specific nutritional needs of a crop in a unit of production, which are not sold through retail chains.
   14. **Chemical formula**: homogeneous product that results from the chemical reaction that occurs between two or more compounds, involving physical and chemical changes of the starting compounds.
   15. **Formulator**: physical person (natural, individual) or legal entity who is engaged in the formulation of fertilisers and soil conditioners for agricultural use.
   16. **Formulate**: action of proportionally mixing elements or fertiliser products or components of soil conditioners, with or without the aid of formulation aids.
   17. **Confidential information**: information qualified as such in the present regulation and in the existing normative in this matter of each state party of the Central American Region.
   18. **Inert ingredient**: any substance without fertiliser or soil conditioner action for agricultural use which is used as a carrier, filler or as a conditioner in a formulation.
   19. **Brand**: any visible sign, suitable for distinguishing the products or services of a company, with respect to products or services of other companies.
   20. **Filler**: substance that is not a fertiliser material, which is added to a physical blend or chemical formula.
   21. **Physical mixture**: product that is obtained from the mixing or joint granulation of two more fertiliser materials or soil conditioners, without producing chemical reactions between the components thereof.
   22. **Modification to the record**: changes, additions or deletions in the registration of the record, requested by the holder of the same.
   23. **Single product**: fertiliser that contains a single type of chemical compound or that, in the product, there is no mixture.
   24. **Trade name**: name, denomination, designation or abbreviation that identifies or distinguishes a company or establishment in its commercial activity.
   25. **Pamphlet**: printed material that accompanies each commercial presentation of a fertiliser or soil conditioner, for agricultural use containing supplementary information to the label.
   26. **Natural product**: fertiliser or soil conditioner that comes from nature, of animal, vegetable or mineral origin that is used as such in simple form or by forming part of a more complex mixture.
   27. **Synthetic product**: fertiliser or soil conditioner that is generated from other materials in which chemical reactions occur by modifying the original components.
   28. **Repackaging or repacking**: action of transferring the product from its original packaging to other presentations.
   29. **Record**: administrative, technical and legal process by which any application for registration of a fertiliser or soil conditioner for agricultural use is evaluated by the competent national authority prior to the registration of a product.
   30. **Legal representative**: physical person (natural, individual), who represents the holder or owner of the record and is responsible to the competent national authority.
   31. **Applicant**: physical (natural, individual) or legal entity that requests of the competent national authority the registration, renewal, modification and updating of the record of fertiliser and soil conditioner, for agricultural use for commercial purposes.
   32. **Record holder**: Physical person (natural, individual) or legal entity, owner of the record of a fertiliser or soil conditioner for agricultural use, for the purposes of the competent national authority.
2. **GENERAL PROVISIONS**
   1. The physical person (natural, individual) or legal entity who intends to manufacture, formulate, extract, register, modify, renew, import, package, repackage, repack, export, store, or sell fertilisers and soil conditioners for agricultural use must be registered as such with the competent national authority in accordance with the legislation in force in each State Party in the Central American Region.
   2. For registration procedures, the legal representative of the holder of the record or applicant must be domiciled in the national territory.
   3. Fertilisers and soil conditioners for agricultural use must be registered with the competent national authority prior to importation, export, manufacture, formulation, packaging, repackaging, repacking and selling.
   4. The present regulation establishes the following types of records for commercial purposes:
3. Fertilisers
4. Soil conditioners
   1. The registration dossier of a fertiliser or an amendment for agricultural use must contain administrative and technical information in accordance with the requirements established in these regulations.
   2. The information contained in documents submitted to the competent national authority to support the registration and which are written in a language other than Spanish, shall be admissible by the competent national authority together with its translation into Spanish, the documents indicated in numerals 5.1.b or 6.1.b written in a language other than Spanish must be presented with their respective official translation into Spanish.
   3. If the certificate of qualitative-quantitative composition contains information that the applicant considers to be confidential, he can apply for status of confidentiality from the competent national authority, which will assess the request.
   4. Fertiliser containing one or more substances within its composition, which strengthen or modify its effect and without having a fertilising action, must be based on the tests of biological effectiveness (in controlled conditions or on the field) carried out in any State party of the Central American Region, or other trials carried out under similar agro-ecological conditions, which must be endorsed by the competent national authority of the registering country.
   5. The cost of the laboratory analysis that is derived from the registration process will be covered by the applicant or by the holder of the record.
   6. The validity of registrations for fertilisers and soil conditioners, for agricultural use, shall be ten years from the date that the registration was granted, in compliance with the provisions of these regulations; additionally, this article is applicable for renewals and those records of fertilisers and soil conditioners, for agricultural use, which comply with the provisions of transition I or II.
   7. The application for registration (Annex I) of a fertiliser or soil conditioner for agricultural use shall be valid for a single product, manufacturer, formulator or extractor.
   8. A record of a fertiliser or soil conditioner for agricultural use may have various trademarks.
   9. The fertiliser or soil conditioner for agricultural use that is imported, manufactured, formulated or extracted and sold must have adhered or lithographed on its container or packaging, the label(s) as it was/they were approved in support of the registration.

**NOTE 1**: The foregoing does not apply to bulk presentations, which must be accompanied by a safety data sheet or technical data sheet.

* 1. Certificates or documentary proof/written evidence that support the registration of a product must have been issued within one year, on the date of its submission to the competent national authority. These documents that are presented must be duly legalised.
  2. The applicant must justify to the competent national authority, based on technical and scientific criteria, the non-submission of a requirement of the information stipulated that constitutes the technical requirements of the product, when demonstrated that it does not apply. For this purpose, the competent national authority will evaluate the arguments based on technical and scientific criteria, depending on the nature of the requirement and must notify the applicant.
  3. An already registered brand can be used to identify a fertiliser or soil conditioner for agricultural use, of a different chemical composition when followed by the same indicating the percentage or the name of the nutrient elements or components containing that product, provided that the mark does not correspond to the chemical or common name of the components of the product.
  4. An already registered brand can be used for registration purposes by a third party if and when authorised by the owner of the same.
  5. The ANC will not grant registration of a fertiliser or soil conditioner for agricultural use when:

1. Does not comply with what is established in these regulations.
2. It is proven, or verified, that the recommended use of the product causes damage to human health, animal health, plant health, or the environment.
3. The brand includes part or all of the composition of the product and is not consistent with the statement in the certificate of composition.
4. It uses a mark or terms that causes confusion or does not correspond to the characteristics or identification of the fertiliser or soil conditioner of agricultural use when registering.
   1. The ANC may request, in specific cases of health, environmental and agricultural risk, additional information to that provided by the applicant or holder of the registration, as appropriate, when it is essential for granting the registration, renewal, updating or modification of the registration, the same remains empowered to require opinions from other entities, all of the foregoing prior technical and scientific justification.
   2. The ANC will not grant the registration of soil conditioners as fertilisers, or fertilisers as soil conditioners.
5. **REGISTRATION OF FERTILISERS**
   1. The following administrative requirements are established:
6. Application, in accordance with Annex 1
7. Certificates of registration or free sale, in original, issued by the ANC of the country of origin of formulation or manufacture of the fertiliser or any other entity that demonstrates that it is legally entitled to issue the same. In the event that the product is not registered or is not sold in the country of origin of formulation or manufacture of the fertiliser, a certificate of origin or proof issued by the ANC or any other entity proving that it is legally entitled to issue the same should be presented, where it is indicated the reasons that the product is not registered or is not freely sold in the country of origin of formulation or manufacture of the fertiliser or proof of the ANC that indicates that the manufacturer or formulator is authorised to manufacture or formulate fertilisers for agricultural use. Exception to the compliance with this regulation: when the fertiliser is manufactured or formulated in the country of the Central American region where it is intended to register.

**NOTE 2**:When these certificates are issued only once by the ANC of the country of origin, the applicant may submit a photocopy duly legalised and at the same time attach the document proving said provision.

**NOTE 3**: If the original certificate of registration or free sale includes two or more products, photocopies of the original certificate can be submitted, which must be authenticated or certified copy of the original in the country where it will be registered.

1. Certificate of qualitative-quantitative composition of the fertiliser, in original, issued and signed by the manufacturer or formulator, indicating the nutrient elements, identifying the sources or compounds where they come from, with their chemical formula, as well as the inert ingredients, filler materials and additives for formulation, with their corresponding mass/mass percentages for solids and mass/volume percentages for liquids.
2. Certificate of analysis of the fertiliser, in original, provided by the manufacturer or formulator, of a sample of a particular batch that indicates the nutrient elements with their corresponding mass/mass percentages for solids and mass/volume percentages for liquids, signed by the chemical professional in charge.

For both (c) and (d), the content of the nutrients present must be declared in the following order and form:

1. Primary macronutrients:
   1. Nitrogen: Total Nitrogen, expressed as N(%), also indicate the determinable forms of nitrogen: Ammoniacal, Ureical and nitrates and their percentages and to identify the percentage of Biuret, when the Nitrogen comes from urea.
   2. Phosphorus: Total available phosphorus, expressed as P2O5 (%) (soluble in water and in ammonium citrate and its %).
   3. Potassium: Potassium available, expressed as K2O (%)
2. Secondary macronutrients:
   1. Magnesium: Magnesium available, expressed in oxide MgO (%) (soluble in water)
   2. Calcium: Calcium available, expressed in oxide CaO (%) (soluble in water)
   3. Sulphur: Sulphur available, expressed as S (%) (soluble in water)
3. Micronutrients:
   1. Boron: Boron available, expressed as B (%)
   2. Copper: Copper available, expressed as Cu (%)
   3. Cobalt: Cobalt available, expressed as Co (%)
   4. Manganese: Manganese available, expressed as Mn (%)
   5. Molybdenum: Molybdenum available, expressed as Mo (%)
   6. Zinc: Zinc available, expressed as Zn (%)
   7. Declaration of the presence of other elements considered as nutrients.

**NOTE 4**: The micronutrients should be expressed in percentage and the dimensional ppm in parentheses can be added next to the name of the element.

1. Declaration of the presence or absence of heavy metals (Cadmium, Chromium, Arsenic, Mercury and Lead) expressing the maximum concentration in ppm, or other substances that can become harmful metabolites in the soil.
2. Draft labels apply to:
   1. Solid and liquid fertilisers, see Annexes 2 and 3

**NOTE 5**: Labelling does not apply to bulk products, they must be accompanied by their corresponding safety sheet or data sheet only.

* 1. The size of the label must be proportional to the size of the container and in text of legible form in Spanish and authorised by the ANC.
  2. In the case that the package size does not allow the inclusion of all of the information on the label required under Annex 3, it must include at least the information of the numerals described in Annex 3: 1, 2, 3, 4, 5, 7, 8, 19, 20, 21 and 22, report the percentage of the filling material and attach to the package a leaflet with the following information: 1, 2, 3, 5, (indicate the names of the nutrients) 6, 8 to 20, which must be authorised by the ANC.

**NOTE 6**: The composition of the fertiliser indicated on the label must be in accordance with what is stated in paragraph 5.1.d

* 1. The following technical requirements are established:

1. Physical and chemical properties of the fertiliser
   1. Physical state
   2. Colour
   3. Specific weight or density expressed g/ml at a given temperature in degrees Celsius, depending on the physical state of the product.
   4. pH only for liquids
   5. Solubility in water, only for solids (% or g/L) indicating the temperature.
   6. Granulometry (average diameter of particles in mesh or millimeters for granulated formulations).
   7. Corrosiveness
   8. If the product contains chelated nutrients, chemically identify the chelating agent and its % by weight / volume.
   9. If it is a slow-release fertiliser, chemically indicate its composition.
   10. Indicate if it is a physical mixture or chemical formula.
2. Details on fertiliser application
   1. Scope of application: controlled environment, open field, fertigation, other
   2. Recommended crops form of application.
   3. Conditions in which the product can be applied, the optimum pH of the application mixture indicated.
   4. Compatibility
   5. Phyto-toxicity
3. Safety data
   1. Information on personal protective equipment
   2. Cleaning procedure of the application equipment
   3. Present the respective studies that support the conditions of storage for the maintenance of the stability of the product, in order to ensure the quality of the same and the time in which the physico-chemical properties will be maintained.
   4. Data on the effect on the environment
4. Methods of analysis
   1. Indicate the physical and chemicals methods of analysis, duly referenced (ASTM, AOAC, or other internationally recognised methods), if they prove to be valid.
5. Details on the container of the product to be sold
   1. Type of container
   2. Material of container
   3. Capacity of container
6. **REGISTRATION OF SOIL CONDITIONERS**
   1. **The following administrative requirements are established:**
7. Application, in accordance with Annex 1
8. Certificates of registration or free sale, in original, issued by the ANC of the country of origin of formulation, manufacture or extraction of the soil conditioner or any other entity that demonstrates that it is legally entitled to issue the same. In the event that the product is not registered or is not sold in the country of origin of formulation, manufacture or extraction of the soil conditioner, a certificate of origin or proof issued by the ANC or any other entity proving that it is legally entitled to issue the same should be presented, where it is indicated the reasons that the product is not registered or is not freely sold in the country of origin of formulation, manufacture or extraction of the soil conditioner or proof of the ANC that indicates that the manufacturer, formulator or extractor is authorised to manufacture, to formulate or to extract soil conditioners for agricultural use. Exception to the compliance with this regulation: when the soil conditioner is manufactured, formulated or extracted in the country of the Central American region where it is intended to register.

**NOTE 7**: When these certificates are issued only once by the ANC of the country of origin, the applicant may submit a photocopy duly legalised and at the same time attach the document proving said provision.

**NOTE 8**: If the original certificate of registration or free sale includes two or more products, photocopies of the original certificate can be submitted, which must be authenticated or certified copy of the original in the country where it will be registered.

1. Certificate of qualitative-quantitative composition of the amendment, in original, issued and signed by the manufacturer or formulator, indicating its composition, and inert ingredients, with their corresponding mass/mass percentages for solids and mass/volume percentages for liquids.
2. Certificate of analysis of the soil conditioner, in original, provided by the manufacturer, formulator or extractor, of a sample of a particular batch that indicates the components with their corresponding mass/mass percentages for solids and mass/volume percentages for liquids, signed by the chemical professional in charge.

For both (c) and (d), the content of the components present must be declared in the following order and form:

* 1. For organic soil conditioners, the following shall be declared:
     1. The components should be expressed in percentage (%), weight/weight or weight/volume, according to their physical state, in their elemental form.
     2. Total organic matter
     3. Carbon/nitrogen ratio (C/N)
     4. Percentage of moisture
     5. In the case of humic substances identification and percentage of same.
     6. Declaration of the presence or absence of heavy metals (Cadmium, Chromium, Arsenic, Mercury and Lead) and their maximum concentration in parts per million (ppm), or other substances that can become harmful metabolites in the soil.
  2. For mineral soil conditioners, express the minimum guaranteed concentration as follows:
     1. Calcium carbonate CaCO3 %w/w
     2. Calcium oxide CaO %w/w
     3. Magnesium carbonate MgCO3 %w/w
     4. Magnesium oxide MgO %w/w
     5. Calcium sulphate CaSO4 %w/w
     6. Percentage of moisture %w/w
     7. Declaration of the presence or absence of heavy metals (Cadmium, Chromium, Arsenic, Mercury and Lead) and their maximum concentration in parts per million (ppm), or other substances that can become harmful metabolites in the soil.

1. Draft labels apply to:
   1. Soil conditioners for agricultural use, see Annexes 2 and 3

**NOTE 9**: Labelling does not apply to bulk products, they must be accompanied by their corresponding safety sheet or data sheet.

**NOTE 10**: The size of the label must be proportional to the size of the container, its text must be of legible form in Spanish and authorised by the ANC.

**NOTE 11**: When the package size does not allow the inclusion of all of the information on the label required under Annex 3, the label must include at least the information of the numerals described in Annex 3: 1, 2, 3, 4, 5, 7, 8, 19, 20, 21 and 22, and attach to the package a leaflet with the following information: 1, 2, 3, 5, (indicate the names of the nutrients) 6, 8 to 20, which must be authorised by the ANC.

**NOTE 12**: The composition of the soil conditioner indicated on the label must be in accordance with what is stated in numeral 6.1.d

* 1. **The following technical requirements are established:**
     1. Physical and chemical properties of the soil conditioner

1. Neutralising capacity (PRNT) for the case of minerals, expressed as percentage of neutralisation comparable with 100kg of pure Calcium Carbonate.
2. Specific weight or density expressed g/ml at a given temperature in degrees Celsius, depending on the physical state of the product.
3. Granulometry (average diameter of particles 20, 60 and 100 mesh for granulated products).
   * 1. Indicate the methods of analysis, duly referenced, to determine the composition of the soil conditioner, if they prove to be valid.
     2. Process of preparation of the product in the case of soil conditioners of organic origin.
     3. Details on application and management of the amendment: scope of application, dosage, number and frequency of application, instructions for use, methods of application, phyto-toxicity, compatibility, handling of leftovers, personal protective equipment, cleaning procedures of application equipment, storage conditions and effects on the environment.
     4. Indicate the following about the container of the product to be sold
4. Type of container
5. Material of container
6. Capacity of container
7. **REASONS AND REQUIREMENTS FOR MODIFICATION OF RECORDS**
   1. The registration of a fertiliser or soil conditioner, for agricultural use can be modified for the following reasons:
8. Change of ownership.
9. Change of name or business name of the holder, manufacturer or formulator.
10. Change or addition of brand (product name).
11. Addition and removal of presentations of containers or packaging.
12. Change or extension of origin of the manufacturer or formulator.
13. Inclusion or exclusion of use.
    1. For purposes of amendment to the registration, the holder must submit the request indicating the reasons for it, as well as indicate that the composition and physical-chemical properties of the product are not modified. Depending on the case, the following requirements must be met:
14. Change of ownership.
    1. Legal document evidencing the assignment or transfer of such registration.
    2. Draft labels addressing the capacity of the container.
15. Change of name or business name of the holder, manufacturer or formulator.
    1. Legal document evidencing the change of name or business name of the holder, manufacturer or formulator.
    2. Draft labels addressing the capacity of the container.
16. Change or addition of brand (product name).
    1. Draft labels addressing the capacity of the container, with the new brand.
    2. Certificate of trademark when there is one
17. Addition and removal of presentations of containers or packaging.
    1. Type of container, material of container, and capacity of container
    2. Draft labels addressing the capacity of the container.
18. Inclusion or exclusion of use.
    1. Draft labels addressing the capacity of the container, with the requested amendment.
    2. Any modification to the registry that implies a change in the product's label, the ANC will grant a maximum term of six (6) months to deplete the stock of the labelled product or label.
    3. The modification to the registration of certain fertilisers or soil conditioners, for agricultural use, will be made by Administrative Resolution by the ANC; a new certificate of registration will be issued in the cases that are necessary, keeping the number, registration date and expiry date.
19. **SUSPENSION OF REGISTRATION**
    1. The registration of a product will be subject to suspension when:
20. The holder of the registration or legal representative sells the product with a label not authorised by the ANC.
21. The judicial authority orders it.
22. The registration of the holder or the legal representative is expired.
23. The physical person (natural, individual) or legal entity, engaged in the manufacture, formulation or extraction of fertilisers or soil conditioners for agricultural use, within any State Party of the Central American Region, has an expired operating permit or license.
24. The registration holder does not provide, within the deadline granted by the ANC, the information required in numeral 4.19.
25. The registration holder does not comply with the deadline established in number 7.3 of this regulation.
26. When a second sample shows that the breach of the official standard in the formulation of the product of each State Party of the Central American Region persists.
27. When the registration holder does not present by the deadline what is indicated in Transitional Provisions V and VI.

**NOTE 13**: Suspension of registration of a fertiliser or amendment for agricultural use: the product cannot be processed, manufactured, formulated, imported, exported, extracted, packaged, repackaged, repacked or sold accordingly. In cases where the suspension is due to the quality of the product, the registrant must submit to the ANC the corrective measure and the deadline by which to comply, which will be assessed by the ANC.

* 1. The suspension will have a maximum term of three (3) months to correct the causes that originated it, with the exception of those suspensions ordered by the court.

1. **CANCELLATION OF REGISTRATION**
   1. The registration of a product may be canceled when:
2. The registration holder requests it.
3. The causes that gave rise to the suspension of registration are not remedied within the period established in clause 8.2 of this regulation.
4. When a third sample shows that the breach of the official standard in the formulation of the product of each State Party of the Central American Region persists.
5. The registration has been granted with errors of absolute nullity.
6. It is technically and scientifically proven that the product while being used under approved recommendations for use poses an unacceptable risk to health and the environment, or that the product is proven to be ineffective for the uses that were authorised in the corresponding registration.
7. The fertiliser or soil conditioner is manufactured or formulated by a company other than the one stated in the registration.
8. The registration holder that does not submit the application for renewal of registration of a fertiliser or soil conditioner for agricultural use, as established in numeral 10.1.
9. When the registration holder does not present by the deadline what is indicated in Transitional Provisions I, II.
10. **RENEWAL OF THE REGISTRATION**
    1. The holder of the registration of a fertiliser or soil conditioner, for agricultural use, must request the renewal of the registration with the ANC prior to its expiry date.
    2. For the renewal of registration of a product registered with requirements established by this regulation, the request in number 5.1 for fertilisers and 6.1 for soil conditioners in this regulation must be submitted, depending on whether it is a fertiliser or soil conditioner.
11. **FINAL PROVISIONS**
    1. The application of this regulation corresponds to the ANC of each State party of the Central American Region.
12. **REFERENCES**
13. Phytosanitary Protection Law No. 7664, Costa Rica
14. Executive Decree No. 28429-MAG-MEIC, Costa Rica
15. Executive Decree No. 26503-MAG, Costa Rica
16. Executive Decree No. 26503-MAG, Costa Rica
17. Legislative Decree 315 Law on control of pesticides, fertilisers and products for agricultural use and its regulations, El Salvador
18. Legislative Decree 524 Plant and Animal Health Law, El Salvador
19. Phyto-zoosanitary Law, Decree No. 157-94 and Decree No. 344-2005, Honduras
20. Regulation on the registration, use and control of fertilisers and raw materials, Decree 002-94, Honduras.
21. Law 274 Basic Law for the regulation and control of pest-control substances, toxic, dangerous and similar substances and its regulation, Nicaragua
22. MAGFOR Ministerial Agreement No. 21-2001, Register of simple materials of edaphic and granular fertilisers, Nicaragua
23. Law on Plant and Animal Health, Decree 36-98 and its regulations Governmental Agreement 745-99, Guatemala

**ANNEX 1**

**(Normative)**

**Application for Fertilisers and Amendments**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **General information** | | | | | | |
| About the application | | | | | | |
| Reason for the request: | | ( ) Registration  ( ) Update of registration | | | ( ) Renewal of registration  ( ) Change to registration | |
| About the applicant | | | | | | |
| ID card or ID document: | | | Name or business name of the owner (physical person (natural, individual) or legal entity): | | | |
| Full address: | | | | | | |
| Registration number of physical person (natural, individual) or legal entity: | | | |  | | |
| Telephone: | Fax: | | | Email address: | | Postal address: |
| About the Legal Representative | | | | | | |
| Complete name: | | | | ID number: | | Telephone: |
| Fax: | | Email address: | | | Postal address: | |
| Address: | | | | | | |
| About the manager | | | | | | |
| Complete name: | | ID number: | | | Telephone: | |
| Fax: | | Email address: | | | Postal address: | |
| Address: | | | | | | |
| Product data | | | | | | |
| Brand | | | | Class (Indicate if the product is a fertiliser or soil conditioner) | | |
| Composition and percentage: (Indicate the nutrient(s) for fertiliser or component(s) for soil conditioners) | | | | | | |
| Name of the Manufacturer – Formulator – Extractor: | | | | | | |
| Address: | | | | Country of origin: | | |
| Place or environment where to receive notifications within the national territory: | | | | | | |
| Signature of legal representative | | | | | | |
| Signature of manager | | | | | | |
| This application has the character of an **affidavit** and must be presented along with the requirements requested in the present technical regulations. | | | | | | |

**ANNEX 2**

**(Normative)**

**LABELLING INFORMATION**

**FOR FERTILISERS AND SOLID SOIL CONDITIONERS**

**PART I**

**LABELLING INFORMATION FOR FERTILISERS**

For packages greater than or equal to 20 kilograms

1. Logo or brand name.
2. Include clearly legible the text “FERTILISER”.
3. Brand (product name).
4. Caption: physical mixture or chemical formula.
5. Composition and concentration expressed as % w/w.
   1. In the case of fertilisers indicate the nutrient(s) and its % as indicated in 5.1.d and its sources.
   2. The smaller elements must be expressed in percentage, and the dimensional ppm can be added in parentheses next to the element name.
6. Net content.
7. Manufacturer or formulator (indicate the name) and country of origin of the fertiliser.
8. Importer or Distributor (indicate the name).
9. Batch Number.
10. Expiry date.
11. Country of registration of the State Party of the Central American Region where it is registered.
12. Registration number
13. If it is a fertiliser of low concentration of nutrients (sum of the content of NPK), an information strip must be included in the central part and in both faces of the packaging. This information strip must comply with the following characteristics:
    1. Width of the strip must be 30% of the total height of the package (bag). Low concentration fertilisers should place the strip in the middle of the sack (around the entire sack).
    2. The strip must be colour **PURPLE (Pantone 2602 C)**
    3. Within the information strip, the following information should be included:
       1. The text “(percentage) of filling material” should be included on the front side of the packaging, and at the bottom of this caption, the fertiliser grade, as a percentage of the nutrients: N-P2O5-K2O. For the purposes of this regulation, the front side of the packaging is considered as the one where the name, formula and brand of the product are declared more prominently.
       2. Within the information strip on the back side of the package the following text should be included:  
          FERTILISER OF LOW NUTRIENT CONCENTRATION. Within the information strip on the back side of the package (sack) should include the text HIGH CONTENT OF FILLING MATERIAL, and to the bottom of this caption, the content (percentage) of filling material.
       3. The text indicated in m.3.1 should be placed in highly legible form (print) and the size of its characters must be 25% of the width of the strip, and the text indicated in m.3.2 should be placed in highly legible form (print) and the size of its characters must be 20% of the width of the strip. The texts will be placed in uppercase, white colour, centred to the top and width of the strip.
       4. The information strip should not interfere with the technical information that is detailed on the label.

**NOTE 14**: The information listed above does not prevent a registrant from including more information prior to the assessment of the ANC.

**PART II**

**LABELLING INFORMATION FOR SOIL CONDITIONERS**

1. Logo or brand name.
2. Brand (product name).
3. Name of the component(s)
4. Type of use
5. Granulometry (for granulated products)
6. Neutralising capacity PRNT, expressed as percentage of neutralisation (in case of minerals)
7. Composition and concentration expressed as %w/w. Indicate the components and their percentages.
8. Net content.
9. Manufacturer, formulator or extractor (indicate the name) and country of origin of the soil conditioner.
10. Distributor (indicate the name).
11. Batch number.
12. Expiry date.
13. Country of registration of the State Party of the Central American Region where it is registered.
14. Registration number.
15. Include an information strip on the top of the package. This information strip must comply with the following characteristics:
    1. Width of the strip must be 30% of the total height of the package
    2. The strip must be colour **BROWN (Pantone 1545 C)**
       1. Within the information strip, the following information must be included:
          1. The text “**SOIL CONDITIONER**” must be included on the front and back sides of the packaging. For the purposes of this regulation, the front side of the packaging is considered as the one where the name, formula and brand of the product are declared more prominently.
          2. The text indicated in o.2.1.1 should be placed in highly legible form (print) and the size of its characters must be 25% of the width of the strip. The texts will be placed in uppercase, white colour, centred to the top and width of the strip.
          3. The information strip should not interfere with the technical information that is detailed on the label.

**NOTE 15**: The use of terms different to the characteristics of soil conditioner, that leads to confusing the farmer is prohibited.

**NOTE 16**: The information listed above does not prevent a registrant from including more information prior to the assessment of the ANC.

**ANNEX 3**

**(Normative)**

**LABELLING INFORMATION**

**FOR FERTILISERS AND SOIL CONDITIONERS**

For all liquid packaging and solid packaging less than 20 kilogrammes.

1. Caption in uppercase and bold: STOP! READ THIS LABEL BEFORE HANDLING THE PRODUCT.
2. Brand (product name).
3. Class (Indicate if the product is a fertiliser or soil conditioner)
4. Legend: In the case of fertilisers indicate: Physical mixture or Chemical formula
5. Composition, concentration expressed as % w/v or w/w, as applicable.
   1. In the case of fertilisers indicate the nutrients and their % as indicated in 5.1.d and their sources.
   2. The smaller elements must be expressed in percentage, and the dimensional ppm can be added in parentheses next to the element name.
   3. In the case of soil conditioners, indicate the component(s) and their % as indicated in 6.1.d and their sources.
6. Density expressed in g/ml in the case of liquids.
7. Net content.
8. Manufacturer, formulator or extractor (indicate the name) and country of origin of the fertiliser or soil conditioner.
9. Importer and distributor.
10. Indicate (the) first aid measures in case of poisoning.
11. Measures of mitigation (protection) of the environment.
12. Storage and transport.
13. Instructions for use.
14. Crop or families.
15. Preparation of the mixture.
16. Form of application.
17. Incompatibility.
18. Phyto-toxicity.
19. Country of registration of the State Party of the Central American Region where it is registered.
20. Registration number.
21. Batch number.
22. Expiry date.
23. In the case of fertilisers of low concentration of nutrient elements, they must comply with what is indicated in Part I, “m” of Annex II.
24. In the case of soil conditioners, what is indicated in Part II, “o” of Annex II must be included.

**NOTE 17**: The information listed above does not prevent a registrant from including more information prior to the assessment of the ANC.

**TRANSITIONAL PROVISIONS**

**TRANSITIONAL PROVISION I**

For the updating of fertiliser and soil conditioner records for agricultural use, that do not have an expiry date and which were registered before the entry into force of this regulation, the registration holders will have a maximum period of three years to present the documentation and information requested in 5.1 and 5.2 for fertilisers, and 6.1 and 6.2 for soil conditioners of this regulation.

**TRANSTIONAL PROVISION II**

For products registered prior to the entry into force of this regulation that have a deadline, they must request their renewal, before the expiry date and submit the requested in numbers 5.1 and 5.2 for fertilisers, and 6.1 and 6.2 for soil conditioners of agricultural use, of this regulation.

**TRANSTIONAL PROVISION III**

Registration holders who wish to update their records before the expiry date may do so by submitting the information in 5.1 and 5.2 for fertilisers, and 6.1 and 6.2 for soil conditioners for agricultural use, of this regulation, maintaining the validity of the original registration.

**TRANSTIONAL PROVISION IV**

Applications for the registration of fertilisers and soil conditioners for agricultural use, which began the process prior to the entry into force of these regulations, will complete the registration process, complying with the requirements and procedures established in the respective regulations at the time of application. Fertilisers and amendments to agricultural use, thus registered and in which the legislation of the country does not provide the term of expiration, must comply with what is established in Transitional Provision I, in those cases where, if the term of expiration is provided, they must comply with what is established in Transitional Provision II of this regulation.

**TRANSTIONAL PROVISION V**

Those products that are “soil conditioners” that have been registered as fertilisers, before the entry into force of this regulation, the draft labels must be presented in accordance with the requirements indicated in paragraph 6.1.e) of this regulation, to the ANC, for evaluation and approval, within a maximum period of 3 months. Once the new label has been approved, the registration holder will have a period of 6 months to re-label the product that is in the trade.

**TRANSTIONAL PROVISION VI**

Those products considered as low concentration fertilisers according to the definition of this regulation, before the entry into force of this regulation, the draft labels must be presented in accordance with the requirements indicated in paragraph 5.1.e) of this regulation, to the ANC, for evaluation and approval, within a maximum period of 3 months. Once the new label has been approved, the registration holder will have a period of 6 months to re-label the product that is in the trade.

**--END OF THE TECHNICAL REGULATION--**