

MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY
SECRETARIAT OF AGRICULTURE AND LIVESTOCK DEVELOPMENT AND
COOPERATIVISM
BRAZILIAN INSTITUTE OF ENVIRONMENT AND NATURAL RESOURCES
NATIONAL HEALTH SURVEILLANCE AGENCY
JOINT NORMATIVE INSTRUCTION No. 1, OF MAY, 24 2011
D.O.U., May 25, 2011 - Section 1

THE SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION
FROM THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY -
MAPA, the SECRETARY OF AGRICULTURE AND LIVESTOCK
DEVELOPMENT AND COOPERATIVISM, THE PRESIDENT OF THE
BRAZILIAN INSTITUTE OF ENVIRONMENT AND NATURAL RESOURCES -
IBAMA and CHIEF EXECUTIVE OFFICER OF THE NATIONAL HEALTH
SURVEILLANCE AGENCY - ANVISA in the use of its statutory duties, in view of
the provisions of Law No. 10,831, of December 23, 2003, Decree No. 6,323, of
December 27, 2007, Law No. 7,802, of July 11, 1989, Decree No. 4,074, of January 4,
2002, and Decree 6,913, of July 23, 2009, and the provisions of Process No.
02001.002610/2010-43, resolve:

Art. 1 Establish the procedures for registering PHYTOSANITARY PRODUCTS
APPROVED FOR USE IN ORGANIC AGRICULTURE, in the form of Annexes I and
II of this Normative Instruction.

Art. 2 This Normative Instruction enters into force on the date of its publication.

FRANCISCO SÉRGIO FERREIRA JARDIM Secretary of Animal and Plant Health
and Inspection

ERIKSON CAMARGO CHANDOHA Secretary of Agriculture and Livestock
Development and Cooperativism

CURT TRENNEPOHL President of the Brazilian Institute of Environment and Natural
Resources

DIRCEU BRÁS APARECIDO BARBANO CEO of the National Health Surveillance
Agency

ANNEX I

PROCEDURES FOR REGISTERING PHYTOSANITARY PRODUCTS APPROVED
FOR USE IN ORGANIC AGRICULTURE

Art. 1 The current Joint Normative Instruction tries to establish procedures for
registering phytosanitary products approved for use in organic agriculture.

Sole paragraph. The procedures dealt by the main section only apply to products which
contain only substances permitted for use in organic agriculture established in own
regulation.

CHAPTER I

OF THE ESTABLISHMENT OF SPECIFICATIONS OF REFERENCE OF
PHYTOSANITARY PRODUCTS APPROVED FOR USE IN ORGANIC
AGRICULTURE

Art. 2 The Agroecology Coordination (COAGRE), from the MINISTRY OF
AGRICULTURE, LIVESTOCK AND FOOD SUPPLY (MAPA), is responsible for
identifying the priority phytosanitary products for the establishment of reference
specifications, based on the demand from the organic production network presented by
the Commissions of Organic Production in the Units of the Federation (COPs-UF).

§ 1 the interested part in establishing reference specification must present:

I - to the COP from its Unit of the Federation, the Application Form for Establishment of Reference Specification for PHYTOSANITARY PRODUCTS APPROVED FOR USE IN ORGANIC AGRICULTURE (Annex II) filled out and signed; and

II - to the COP coordinator from its Unit of the Federation, product information, containing characteristics and production process.

§ 2 The coordinator of each COP will carry out complete verification of the information foreseen in clause II of § 1 of this article and will forward to COAGRE:

I - the list of priority products approved in the meeting;

II - Minute or memory of the meeting, signed by all present, evidencing its approval; and

III - Application Forms foreseen in clause I of § 1 of this article.

Art. 3 The federal bodies of agriculture, health and environment may present proposal of reference specification due to the recognition of its agronomic efficiency, low toxicity and danger.

Art. 4 Once the priority products are identified, COAGRE will forward the proposal to the General Coordination of Pesticides, from MAPA, to the General Management of Toxicology, from ANVISA, and to the General Coordination of Evaluation and Control of Chemicals, from IBAMA which will define what information, tests and studies are necessary to establish the reference specifications.

§ 1 The tests and studies required for the establishment of specifications shall guide in reference to specific existing standards, considering the following product categories:

I - semiochemicals;

II - biological control agents;

III - microorganisms;

IV - compounds and derivatives of plant origin;

V - compounds and derivatives of mineral origin;

VI - compounds and derivatives of animal origin;

VII - mixtures and derivatives from the categories of clauses I to VI; and

VIII - similar.

§ 2 To establish the requirements foreseen in the main section of this article, it shall be considered the available knowledge about the safety and efficacy of the proposed product or substances that compose it.

§ 3 In the assessment of the agronomic efficiency, the principles of organic agriculture that seek to balance the system and increase the resistance of plants using products that do not necessarily aim at the elimination of certain pest will be considered.

Art. 5 COAGRE is responsible for coordinating the process of obtaining requested information, agronomic, toxicological and environmental testing and studies conducted by public or private education, technical assistance and research institutions.

Sole paragraph. The applicant companies, individually or collectively, can provide necessary exams and analysis.

Art. 6 The competent bodies are responsible for reviewing the information, exams and studies submitted by COAGRE and preparing the reference specifications of the phytosanitary products subject to registration for use in organic agriculture.

Sole paragraph. The presentation of the information and studies requested does not guarantee the establishment of the reference specification of the product.

Art. 7 The Secretary of Animal and Plant Health and Inspection and the Secretary of Agriculture and Livestock Development and Cooperativism from the Ministry of

Agriculture, Livestock and Food Supply are components to establish the reference specifications in proper regulation, after its approval by the Technical Advisory Committee for Pesticides - CTA, to be published in the Daily Journal of the Union (D.O.U.) and made available on MAPA's website on the internet.

CHAPTER II

OF THE REGISTRATION OF PHYTOSANITARY PRODUCTS APPROVED FOR USE IN ORGANIC AGRICULTURE

Art. 8 The registered products based on the reference specifications will have the denomination of PHYTOSANITARY PRODUCTS APPROVED FOR USE IN ORGANIC AGRICULTURE.

Art. 9 For the registration of a PHYTOSANITARY PRODUCT APPROVED FOR USE IN ORGANIC AGRICULTURE, the applicant must protocol the request, in MAPA, ANVISA and IBAMA, within a period not exceeding five working days counted from the date of the first protocolling of the application, according to provisions of Annex II, items 1 to 11 and 24 of Decree No. 4,074, 2002.

Sole paragraph. The procedure for protocolling set forth in the main section of this article will be gradually replaced by a digital system integrated among the competent bodies.

Art. 10. Once the product to be registered meets what was established in the published reference specifications, shall not be required to submit further agronomic, toxicological and environmental studies, except for situations where the assessing bodies deem necessary to send additional information and testing.

Art. 11. Each commercial product approved for use in organic agriculture will have its own registration.

Art. 12. Products that meet the reference specifications are exempted from Special Temporary Registry (STR) and from registration of components.

Sole paragraph. The exemption from STR which is dealt in the main section of this article shall not apply to imported products and active ingredients that have not yet established their reference specifications and which will be used for research in the Country.

Art. 13. The PHYTOSANITARY PRODUCTS APPROVED FOR USE IN ORGANIC AGRICULTURE are exempted from agronomic prescription.

Sole paragraph. The exemption from the prescription will be indicated on the label and package leaflet of the product and may be groundedly added eventual recommendations deemed necessary by the bodies mentioned in art. 3 of this Annex.

Art. 14. The label and leaflet of the phytosanitary products referred to in this Annex shall contain in its bottom, with a height equivalent to fifteen percent of the packaging printing height, white stripe, with the following sayings in black: "PHYTOSANITARY PRODUCT APPROVED FOR USE IN ORGANIC AGRICULTURE"

§ 1 The letters of the sayings contained in the stripe must occupy fifty percent of its height.

§ 2 On the label and leaflet of the products dealt in the main section of this article shall not include the symbols of the skull with the crossbones.

Art. 15. The importers, exporters, producers and formulators of PHYTOSANITARY PRODUCTS APPROVED FOR USE IN ORGANIC AGRICULTURE will provide to the competent federal and state bodies, until January 31 and July 31 of each year, data referent to quantities of products which were imported, exported, produced, formulated and commercialized, in accordance with the biannual report model provided in Annex VII of Decree No. 4,074, of 2002.

Art. 16. The PHYTOSANITARY PRODUCTS APPROVED FOR USE IN ORGANIC AGRICULTURE produced exclusively for their own use will be exempted from registration.

Art. 17. The registration process of PHYTOSANITARY PRODUCTS APPROVED FOR USE IN ORGANIC AGRICULTURE will have its own processing and with priority.

ANNEX II

I - APPLICATION FORM MODEL FOR ESTABLISHING REFERENCE SPECIFICATION OF PHYTOSANITARY PRODUCT APPROVED FOR USE IN ORGANIC AGRICULTURE

01	NAME OF APPLICANT			02	CNPJ / CPF
03	COMPLETE ADDRESS	04	NEIGHBORHOOD	05	MUNICIPALITY
06	Zip Code	07	UF	08	COUNTRY
				09	PHONE
10.	FAX	11.	E-MAIL		
12.	CONTACT NAME	13.	POSITION	14.	PHONE
15.	PRODUCT NAME				
16.	PRODUCT COMPOSITION				
17.	TYPE OF FORMULATION				
18.	INDICATIONS FOR USING THE PRODUCT				
	<ul style="list-style-type: none"> - Biological Targets; - Cultures; - Dose; - Number and method of application. 				
19.	DECLARATION				
	<p>I, the applicant / legal representative, declare that I have full knowledge of the possibility of publication of the composition of the product to establish the reference specification (identification and percentage of each component) in joint regulation of the bodies responsible for registration and that such publication will serve as a basis for the registration of other commercial products.</p>				
20.	NAME OF APPLICANT / LEGAL REPRESENTATIVE			21.	CPF
22	SIGNATURE OF APPLICANT / LEGAL REPRESENTATIVE			23	DATE