

Environmental Regulations of BRAZIL FEDERAL

SUBJECT: chemical substance control, agriculture, pesticide, environmental effects testing, health effects testing, registration, reporting, compliance, enforcement, laboratory, reference, administrative, certification, sampling, analysis, financial, application

Ministry of the Environment and the Legal Amazon

Brazilian Institute of the Environment and Renewable Natural Resources

Administrative Order No. 139 of 21 December 1994

The President of the Brazilian Institute of the Environment and Renewable Natural Resources -- IBAMA, the President of the Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA), by virtue of the legal responsibilities attributed thereto by Article 83 of the Internal IBAMA Regulations, approved by Administrative Ruling No. 445 of 16 Aug 1989 of the Interior Ministry, and in consideration of the provisions contained in Law No. 7.802 of 11 July 1989, regulated by Decree No. 98.816 of 11 January 1990, as amended by Decree No. 991 of 24 November 1993, resolves the following:

Article 1. To establish procedures to be adopted by the Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA), for purposes of evaluating the potential environmental hazards of chemical products deemed agro-toxic, their components and similar products, pursuant to definitions established in sections XX, XXI and XXII of Article 2, Decree No. 98.816.

Article 2. Classification according to the potential for environmental hazard is based on the parameters of bioaccumulation, persistence, transport, toxicity to various organisms, and the mutagenic, carcinogenic and teratogenic potential of the product, according to the following scale:

- Class I -- Highly Hazardous Product
- Class II -- Very Hazardous Product
- Class III -- Hazardous Product
- Class IV -- Slightly Hazardous Product

Sole paragraph. The classification "Product Involving Hazard Levels that Prevent Registration" shall be assigned to agro-toxic products, their components and similar products, the characteristics of which are harmful to the environment, as provided for in item f, 6, Article 3 of Law 7.802 and section VIII, Article 22 of Decree 98.816, in the event that the product is subject to one or more of the following conditions:

- a) there are no methods available to deactivate its components, as provided for in item a, paragraph 6, Article 3 of Law 7.802 and section I, Article 22, of Decree 98.816;

b) there is evidence of the mutagenic, carcinogenic or teratogenic characteristics mentioned in item c, 6, Article 3 of Law 7.802 and sections III, IV and V, Article 22, Decree 98.816;

c) when its bioaccumulation, persistence, transport and toxicity parameters are categorized as class 1;

d) when its parameters involving bioaccumulation, persistence and toxicity to mammals are categorized as class 1;

e) when its parameters of bioaccumulation, persistence and 50% of the acute toxicity tests are categorized as class 1.

Article 3. For purposes of evaluating the potential environmental hazards of agro-toxic products, their components and similar products, the interested party must submit the documentation listed in Annexes I and II to the Monitoring and Auditing Office.

1. The documentation to which the main body of this article refers must be submitted for each specific evaluation. It shall only be used for analyzing the procedures of the company that submitted it, or when its use by third parties is formally authorized.

2. IBAMA shall only use the documentation submitted by one company for purposes of evaluating the product of a second company by formal authorization of the holder of the data.

3. The Technical Report III must be an accurate summary of the information contained in the tests or information submitted as an annex.

4. In the event it is not possible to submit a test or information, a written technical explanation must be provided, which shall be evaluated by IBAMA.

5. The information, tests and explanations shall be identified one by one and placed in the order called for in Annexes I and II of this Administrative Order.

6. Failure by the company to submit a written technical explanation, or the non-acceptance thereof by IBAMA, shall result in the filing of the process by a legal decision, followed by notification to the company.

Article 4. The tests established in Annex II must be carried out in laboratories approved or recognized by the National Institute for Industrial Measurement, Standardization and Quality (INMETRO). For domestic laboratories, official or private, approval shall be required, while foreign laboratories shall require recognition.

Sole paragraph. Until such time as the aforementioned approval or recognition by INMETRO is obtained, domestic laboratories must be registered with IBAMA. Foreign laboratories must provide evidence of recognition by an

official entity in their respective countries.

Article 5. The tests to be carried out for evaluation of environmental hazards, as listed in Annex II, must conform to the methodologies contained in the Testing Manual for the Evaluation of the Ecotoxicity of Chemical Agents, published by IBAMA, as well as those that may be approved by a specific order of this Institute.

1. Any change in methodology shall be communicated to the interested parties. IBAMA shall establish a period for compliance by the interested parties, which shall be compatible with the adaptation needs.

2. Methodologies other than those contained in the aforementioned Manual, described in detail in Portuguese and accompanied by information on their scientific recognition, may be accepted at the discretion of IBAMA.

3. For tests required in this Administrative Order, the methodologies of which are not contained in the Manual, or which have not been approved by a specific order for purposes of evaluation of the parameter, copies of publications in internationally recognized scientific magazines or tests carried out using internationally used methodologies, accompanied by information on the corresponding scientific recognition, shall be acceptable.

4. Test results must be submitted in Portuguese, Spanish or English.

5. Test results must be signed by the executor and certified by the requester. It is mandatory that the summary and conclusions be in Portuguese.

Article 6. Samples of technical or formulated products sent to laboratories must be accompanied by a declaration of the concentration of the active ingredient issued by the contracting company. The executing laboratory shall provide a calculation of the concentration of the active ingredient in the sample to be tested, which shall form an integral part of the report for each test.

Sole paragraph. Acceptable variances between the composition of the formulated product and the results of the chemical evaluation shall be as shown in the following table:

Declared quantity of a.i. [active ingredient] per g/kg or g/l of the product	Acceptable levels of difference
500 or more	25 units
250 to < 500	5%
100 to < 250	6%
25 to < 100	10%
< 25	15%

Article 7. IBAMA may, at any time, request that a verification test be performed, which shall be performed at the expense of the company registering the product, at a laboratory specified by this Institute.

Article 8. Requests filed with the registering agency prior to the date of publication of this Administrative Order, pursuant to the requirements of IBAMA Administrative Order No. 349 of 14 March 1990, shall be carried out pursuant to prevailing law on the date of the protocol.

Sole paragraph. For requests filed with the registering agency after the date of publication of this Administrative Order, laboratory findings shall be acceptable, pursuant to the requirements of IBAMA Administrative Ruling No. 349 of 14 March 1990, for cases in which initiation of the test is verified within 30 days of publication of this Administrative Order.

Article 9. Cases not addressed in this Administrative Order shall be resolved by the President of IBAMA.

Article 10. This administrative order shall enter into force on the date of its publication, and IBAMA Regulatory Order No. 349, of 14 March 1990 shall be annulled.

Nilde Lago Pinheiro

#### Appendix I

I -- request, pursuant to the provisions contained in section I, Article 8, Decree No. 98.816;

II -- technical report III, as provided for in section IV, Article 8, Decree No. 98.816, containing the data and information established in Annex II of this administrative order;

III -- labeling format, as provided for in section II, Article 38, Decree No. 98.816.

IV -- printed instructions sample, as provided for in sections III and IV, Article 41, Decree No. 98.816, including the following:

a) first-aid measures and detailed information relating to emergency actions to be taken in the event of an environmental accident involving the product;

b) methods and procedures for soil and water decontamination;

c) company emergency telephone;

d) technical guidelines on the final destination of waste and packaging;

e) description of the method of deactivating agro-toxic products, their components and similar products.

V -- description of the packaging: type, material, volumetric capacity and type of labeling.

VI -- evidence of collection of the Single Tax Collection Document (DUA), in any authorized bank branch, in accordance with the revenue and value codes defined by the IBAMA price table.

VII -- declaration listing the experimental field tests carried out, or when relevant, a copy of the results of the Preliminary Environmental Evaluation issued by IBAMA and the Temporary Special Registration (RET) issued by MAARA for the phase that generated the final results for determining efficiency.

## Annex II

I -- For Components: active ingredients, technical products, raw materials, inert ingredients and additives (section XXI, Article 2, Decree No. 98.816).

- a) complete name(s) and address(es) of the manufacturer(s) and supplier(s) of the component to be evaluated;
- b) code(s) assigned to the product during the testing phase;
- c) production process structure for the component to be analyzed, including its summary stages, by-products and impurities;
- d) declaration of the qualitative-quantitative composition of the technical product, including impurities at concentrations equal to or greater than 0,1%, and those which are present and toxicologically significant;
- e) identification of by-products or impurities present in the technical product in concentrations of less than 0,1%, when significant from a toxicological and environmental standpoint;
- f) description of the analytical methodology(ies) used in the qualitative-quantitative description of the active ingredient and, when relevant, of toxicologically significant impurities.

II -- For Agro-Toxic and Similar Products (sections XX and XXII, Article 2, Decree No. 98.816).

- a) complete name(s) and address(es) of the manufacturer(s) and supplier(s) of the manufactured product and technical product;
- b) code(s) assigned to the product during the testing phase;
- c) structure of the principal stages of production of the formulated product based on the technical product and other components, with regard to the process of obtaining the formulated product directly from the raw materials;
- d) declaration of the qualitative-quantitative composition of the formulated product in all its

components, specifying their specific functions in the manufacturing process;

e) statement of the maximum and minimum contents of the components present in the formulated product.

f) information on toxicological and environmental aspects of the components listed in letter "c", along with copies of bibliographic references;

g) toxicological and environmental information on the principal degradation products of the technical product, accompanied by copies of bibliographic references.

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