Administrative Decree No. 84 of 15 October 1996(*)

The Chairman of the Brazilian Institute for the Environment and Natural Resources (IBAMA), by virtue of the authority vested therein by Art. 24 of Annex I of Decree No. 78 1 of 5 April 1991, as well as IBAMA Internal Regulation approved by Administrative Decree No. 445 of 16 August 1989 by the Ministry of the Interior, and in accordance with the provisions contained in Law No. 6.938 2 of 31 August 1981 and Law No. 7.802 3 of 11 July 1989, regulated by Decree No. 98.816 4 of 11 January 1990, as amended by Decree No. 991 5 of 24 November 1993, as well as Administrative Decree No. 333 of 11 October 1996 by the Ministry of the Environment, Natural Resources and the Legal Amazon, as published in the Official Federal Daily Gazette of 14 October 1996,

In consideration that the environmental evaluation of agricultural toxins, their components and similar items is not limited to analysis of the results of laboratory testing;

In consideration that the environmental evaluation of these substances takes place through a continuous and dynamic process that also includes monitoring and analysis of their behavior and effects vis--vis different edafoclimatic conditions and forms of application which may generate information supporting their safe use so long as the registration remains in effect;

In consideration that one of the assumptions of the reorganization and modernization of the State is the sharing between the Government and the productive sector of the preservation, improvement and restoration of environmental quality propitious to life, with a view to ensuring sustainable development; and

In consideration that the costs of maintaining environmental quality are not solely the responsibility of the Government, hereby resolves as follows:

Preliminary Provisions

Art. 1. To establish procedures to be adopted vis--vis the Brazilian Institute for the Environment and Renewable Natural Resources (IBAMA), for purposes of the registration and evaluation of the Environmental Hazard Potential (EHP) of agricultural toxins, their components and similar items, in accordance with the definitions provided in sections XX, XXI and XXII of Article 2 of Decree No. 98.816/90.

Art. 2. To establish the Permanent System for the Evaluation and Control of Agricultural Toxins, their components and similar items, which shall include the following sub-systems:

a) classification of potential environmental hazards;

b) compliance study;

c) evaluation of environmental risk;

d) disclosure of information;

e) environmental monitoring;

f) inspections.

Sole paragraph. The Permanent System for the Evaluation and Control of Agricultural Toxins, their components and similar items shall be applied to all products submitted to IBAMA under current legislation.

Classification

Art. 3. Classification by potential environmental hazard shall be based on the following parameters: bioaccumulation, persistence, transport, toxicity to various organisms, and mutagenic, teratogenic and carcinogenic potential, in accordance with the following structure:

Class I -- Highly Hazardous Product;

Class II -- Very Hazardous Product;

Class III -- Hazardous Product;

Class IV -- Slightly Hazardous Product.

Sole paragraph. Agricultural toxins, their components and similar items falling within at least one of the following cases shall be categorized under the heading of Products Subject to Hazard Preventing Registration:

a) there are no methods available in this country for deactivation of the substance and its components, as provided for in section "a," Paragraph 6, Article 3 of Law No. 7.802/89 and section I, Article 22 of Decree No. 98.816/90;

b) it has the mutagenic, teratogenic or carcinogenic features mentioned in section "c," Paragraph 6, Article 3 of Law No. 7.802/89 and sections III, IV and V of Article 22 of Decree No. 98.816/90;

c) the EHP classification and/or environmental risk classification indicate unacceptable levels of hazard and/or risk, in view of the proposed uses.

Art. 4. For purposes of classification with respect to the EHP of agricultural toxins, their components and similar items, the interested party must submit the complete documentation as set forth in Annexes I, III, IV, V and X.

Paragraph 1. The tests conditionally required as set forth in the aforementioned annexes, as well as any other additional documents or information that may be relevant, may be requested of the applicant company, in the form and within the schedule established under current law.

Paragraph 2. Failure to comply or partial compliance by the interested party, without written technical justification within 30 days of the date of receipt of the notice to provide additional data, shall result in termination of the case by well-founded decision, followed by a notice to the registering body to adopt the applicable measures.

Paragraph 3. Failure to present the test or information required for EHP classification must be technically justified and evaluated by IBAMA.

Paragraph 4. The company shall be officially notified of non-acceptance of the technical justification it presented, and shall be given 10 (ten) business days to respond, as of the date of receipt of the notice.

Paragraph 5. Tests E.1.2, E.2 and E.3 as described in Annex IV of this Administrative Decree must be carried out with soils of the following classes: Dark Red Latosoil, dystrophic or alic, A moderate, medium texture; Dystrophic or alic Red Latosoil, A moderate, clayey texture; Humic Glei, Tb, A proeminent, medium texture.

Compliance Study

Art. 5. The compliance study is aimed at confirming information submitted by the company, for purposes of

registration or classification of the environmental hazard potential, when deemed necessary by IBAMA.

Paragraph 1. The tests described in the main body of this article shall be carried out in a laboratory selected by IBAMA.

Paragraph 2. Upon request of a classification of the environmental hazard potential, the company shall provide a sample of the agricultural toxin or the component or similar item, along with a certification of validity period, which shall be sealed by IBAMA in the presence of the interested party, the company to remain as faithful depositary.

Environmental Risk Evaluation

Art. 6. The environmental risk evaluation shall be carried out upon classification of the environmental hazard, taking into consideration the proposed uses to determine the need to generate field information, or when, in IBAMA's judgment, such need is confirmed.

Paragraph 1. An environmental risk evaluation shall be required of substances already registered or to be registered, which may result in the change, suspension or cancellation of their registrations, if the evaluation indicates a maximization or minimization of the environmental risks provided for in the environmental hazard potential classification.

Paragraph 2. The registration shall be maintained in accordance with the specifications established for them provided that the assumptions of the preceding paragraph do not apply.

Paragraph 3. The need for an environmental risk evaluation of the substances, when identified, shall require that the registering party submit a commitment document, pursuant to section I of Annex VI, within the 90 (ninety)-day period established for the classification of environmental hazard, with non-compliance therewith to result in termination of the case by well-founded decision.

Paragraph 4. For substances already registered, the commitment document for execution of the field study must be submitted within 60 (sixty) days of the date of receipt of the notification.

Paragraph 5. The non-execution or interruption of the

commitment document mentioned in the preceding paragraphs, without a justification acceptable to IBAMA, shall result in the immediate application of the corresponding penalties.

Paragraph 6. The information needed to prepare the environmental risk plan is as set forth in section II, Annex VI, and may be increased and/or eliminated, depending upon each situation to be studied.

Disclosure

Art. 7. The disclosure of information relating to environmental evaluation and control is aimed at promoting environmental education, which stimulates safe and efficient use with a view to reducing the harmful effects on the environment and preventing accidents resulting from improper use.

Sole Paragraph. The information to be disclosed relative to the environmental hazard potential classification or the registration must be sent within a maximum of 30 (thirty) days after issuance of the registration and the registering company shall be responsible for its preparation, pursuant to Annex VII.

Monitoring

Art. 8. Environmental monitoring is aimed at observing the regional or national environmental impacts, with a view to providing a basis for making decisions in the establishment of public policies relating to agricultural toxins and similar items, with respect to improving environmental quality.

Sole Paragraph. IBAMA shall undertake the environmental monitoring discussed in the main body of this article, independently of the registration situation, for products forming part of the study in question and may request cooperation from the companies in the provision of technical information.

Registration

Art. 9. IBAMA shall provide for publication in the Official Federal Daily Gazette, within a period of 15 business days, of the following information relating to the registration request:

a) name of the applicant;

b) commercial name of the product;

c) chemical name and common name of the active ingredient;

d) scientific name of the active ingredient if it is a biological agent;

e) reason for the request: import, export, production or sale;

f) indication of intended use;

g) product class.

Art. 10. For purposes of registering agricultural toxins, components and similar items, the interested party must submit the complete documentation listed in Annexes I, II, III, IV, V and X.

Art. 11. Whensoever the specifications provided for in this Administrative Decree and its annexes are not met, or at the well-founded request of the Ministry of Health, the registration shall be denied and the applicant officially notified.

Art. 12. After receiving the toxicological evaluation issued by the Ministry of Health, IBAMA shall complete its analysis of the process within a period not to exceed 30 (thirty) days.

Art. 13. The company must forward a sample of the label and instructions for use, in accordance with IBAMA recommendations, for purposes of their approval.

Art. 14. The name and initials NA (Non-Agricultural) must be added to the commercial brand name of the formulated product.

Inspections

Art. 15. Inspections as described in Decree No. 98.816/90 shall be executed by IBAMA on an ongoing basis, with a view to environmental protection.

Paragraph 1. When so requested by IBAMA, companies shall provide the information or undertake to submit the documents within the established deadlines, in order to not impede the inspection activities and other measures that may be necessary.

Paragraph 2. The penalties corresponding to the inspection activities shall be as provided for in Articles 14 and 15 of Law No. 6.938/81, 15 and 17 of Law No. 7.802/89 and 74 to 77 of Decree No. 98.816/90.

General Provisions

Art. 16. The procedures set forth in resolutions deriving from International Agreements or Treaties of which Brazil is a signatory shall conform to the specifications listed therein.

Art. 17. The procedures to be adopted vis--vis IBAMA for purposes of the environmental evaluation of household cleaning products, the registration of components, the registration and environmental evaluation of biotechnology products, the registration and evaluation of products intended for use in water environments, special temporary registration, and preliminary environmental evaluation shall be defined in a specific decree within a period not to exceed 90 (ninety) days after the date of publication of this Regulatory Administrative Decree.

Art. 18. For purposes of including or substituting a manufacturer/supplier of a technical product or formulated product, proof of current registration will be required to be supplied, in accordance with current law.

Sole Paragraph. The change to which this article refers shall be authorized provided that it does not result in changes to the ecotoxicological properties of the registered product.

Art. 19. When carrying out IBAMA processes, the tests, information and technical supporting documentation must conform to the following specifications:

a) each section of the file (C, D, E, F and G) must consist of separate volumes, and one section may also have more than one volume, but not the contrary;

b) the tests shall be required to be in the same order as the codes listed in Annexes IV and V, with their respective cover pages (pursuant to Annex X);

c) each volume must be mounted in file folders with separators and identification tabs for each test;

d) each volume must be presented at least on each front

and back cover in the color corresponding to the section, as described below: (Part C -- White, Part D -- Pink, Part E -- Yellow, Part F -- Blue and Parte G -- Green).

Art. 20. IBAMA shall only promote classification of the environmental hazard potential and/or registration of a formulated product produced in Brazil, for which the respective technical product is registered or the registration process is being carried out simultaneously with that of the formulated product.

Paragraph 1. The data relating to the active ingredient or technical product shall not be required to be re-presented.

Paragraph 2. For the case of imported substances the presentation of data corresponding to the technical product and the active ingredient deemed necessary shall be required.

Art. 21. The tests to be carried out for the environmental hazard evaluation as listed in Annexes IV and V must conform to the methodologies contained in the Test Manual for the Ecotoxicity Evaluation of Chemical Agents (IBAMA).

Paragraph 1. Any change of methodology shall be communicated to the interested parties. IBAMA shall set a period for completing them, consistent with the needs for adjustment.

Paragraph 2. At the discretion of IBAMA, methodologies other than those set forth in the aforementioned Manual may be accepted, described in detail, in Portuguese and accompanied by information as to their scientific recognition.

Paragraph 3. All documentation referring to the tests (methodology and conclusion) set forth in Annexes IV and V must be summarized in Portuguese.

Paragraph 4. The test reports must be signed by the executor and certified by the applicant.

Art. 22. For purposes of acceptance by IBAMA of a publication in substitution of a test, in the cases set forth in Annexes IV and V, in addition to the scientific nature of the publication, the nature of the information presented vis--vis the needs for evaluation of the parameter will also be noted.

Art. 23. The samples of the technical product or substance sent to the laboratories must be accompanied by a statement of the concentration of the active ingredient, issued by the contracting company. The executing laboratory must provide for determination of the concentration of the active ingredient in the sample to be tested, which shall form an integral part of each test report.

Art. 24. The samples of the technical product or substance accompanying the environmental hazard potential evaluation shall be sealed by IBAMA in the presence of the company representative, for which it shall remain as faithful depositary.

Art. 25. The tests for the evaluation of agricultural toxins, components and similar items shall be accepted when originating from laboratories accredited and/or recognized by the Institute for Industrial Measurement, Standardization and Quality (INMETRO).

Art. 26. Payments of the amounts set forth in item 8 of Annex IX, relating to Maintenance of the Registration and/or Classification of the EHP may be made in up to 4 (four) consecutive monthly installments.

Paragraph 1. Lump-sum payment or collection of the first installment must take place by 28 (twenty-eight) February of each year, after the date of publication of this Regulatory Administrative Decree.

Paragraph 2. On an exceptional basis, during fiscal year 1996 the deadline for payment of the lump sum or collection of the first installment shall be 15 (fifteen) November.

Art. 27. The amounts corresponding to the services set forth in Annex IX must be paid via Sole Payment Document (DUA).

Paragraph 1. Payment of the amount corresponding to the "Check List" service must be made prior to forwarding the request for registration or evaluation/classification of the EHP.

Paragraph 2. Payment of the services corresponding to items 2 to 7 of Annex IX must be made when the interested company is notified to that end by IBAMA, with proof of payment being a prerequisite for issuance of the respective certification or for inclusion of the product within Class

II, as provided for in Article 29 of this Regulatory Administrative Decree.

Art. 28. Companies must send a semi-annual report containing information on production, exports and imports pursuant to Annex VIII.

Art. 29. After the applicant has satisfied the provisions set forth in this Regulatory Administrative Decree and its annexes, failure by IBAMA to issue a decision within the period stipulated by law shall result in immediate issuance of the environmental hazard potential evaluation, with the product to fall under Class II -- Very Hazardous.

Art. 30. The financial resources relating to the services specified in Annex IX of this Regulatory Administrative Decree shall be allocated to evaluation, monitoring and inspection activities promoting the protection of environmental quality.

Art. 31. This Regulatory Administrative Decree shall enter into force on the date of its publication, with Regulatory Administrative Decrees No. 139 of 21 December 1994 and 149 of 30 December 1994 to be revoked.

Eduardo de Souza Martins, President.

(*) Editor's Note: Published in accordance with the republication issued in "Official Federal Daily Gazette" No. 206 of 23 October 1996.
1 Federal Laws, 1991, page 210.
2 1981, page 381.
3 1989, page 541.
4 1990, page 46.
5 1993, page 970.

Annexes Comprising Regulatory Administrative Decree No. 84 of 15 October 1996

Annex I

I -- For the Registration of Agricultural Toxins, Components and Similar Items

A -- Application in 3 (three) copies, in accordance with the provisions contained in section I, Article 8 of Decree No. 98.816/90, as amended by Decree No. 991/93;

B -- Technical Report I, containing the documents corresponding to the commercial product efficiency evaluation, as set forth in Annex II of this Regulatory Administrative Decree;

C -- Technical Report II and other documents required by the Ministry of Health;

D -- Technical Report III, as provided for in section IV, article 8 of Decree No. 98.816/90, as amended by Decree No. 991/93, containing the data and information set forth in Annex III of this Administrative Decree;

E -- Label Model, pursuant to the provisions of Articles 37, 38 and 39 and Annex IV of Decree No. 98.816/90;

F -- Usage Instructions Model, as provided for in Article 41 of Decree No. 98.816/90, which must contain the following, with respect to section III:

a) first aid measures and detailed information regarding emergency actions to be taken in the event of environmental accidents involving the product;

b) methods and procedures for soil and water decontamination;

c) company emergency telephone number;

d) technical instructions on the final disposal of residue and packaging;

e) description of the method of deactivating agricultural toxins, their components and similar items.

G -- Description of the packaging: type, material, volumetric capacity and type of labeling;

H -- Proof of payment of the sum corresponding to the Check List set forth in Annex IX, through the Sole Tax Payment Document (DUA);

I -- Declaration specifying the list of experimental field tests carried out, or where relevant, a copy of the Special Temporary Registration (RET) certificate issued by IBAMA.

II -- For Evaluation of Environmental Potential and Hazard

A -- One copy of the application, as provided for in section I, Article 8 of Decree No. 98.816/90; amended by Decree No. 991/93;

B -- Technical Report III, as provided for in section IV, Article 8 of Decree No. 98.816/90, as amended by Decree No. 991/93, containing the data and information set forth in Annex III of this Regulatory Administrative Decree;

C -- Label model, as provided for in section II, Article 38 of Decree No. 98.816/90;

D -- Usage instructions model, as provided for in sections III and IV of Article 41 of Decree No. 98.816/90, including the following:

a) first aid measures and detailed information regarding emergency actions to be taken in the event of environmental accidents involving the product;

b) methods and procedures for soil and water decontamination;

c) company emergency telephone number;

d) technical instructions on the final disposal of residue and packaging;

e) description of the method of deactivating agricultural toxins, their components and similar items.

E -- Description of the packaging: type, material, volumetric capacity and type of labeling;

F -- Proof of payment of the sum corresponding to the Check List set forth in Annex IX, through the Sole Tax Payment Document (DUA);

G -- Declaration specifying the list of experimental field tests carried out, or where relevant, a copy of the Special Temporary Registration (RET) certificate issued by IBAMA.

Annex II Data and Information to be Included in Technical Report I

I -- Tests of the efficiency and feasibility of the substance for purposes of registration and technical reevaluation, for products intended for use in the

protection of forests, industrial environments and non-cultivated areas, must contain a minimum of the following:

1 -- Title, Author(s), Institution(s);

2 -- Introduction;

3 -- Materials and Methods:

3.1 -- place and date;

3.2 -- the type and variety used in the test must be indicated, as well as the phytotechnical procedures used in the experiment (soil preparation, spacing and crop treatments);

3.3 -- description of products used:

3.3.1 -- cite the commercial brand, type of substance, concentration and common name(s) of the active ingredient(s);

3.3.2 -- name of the chemical group(s), when defined.

3.4 -- treatment:

3.4.1 -- dosage(s) used;

3.4.2 -- size of the parcel of land, specifying spacing used, population density of the crop, and biological target (when relevant);

3.4.5 -- application interval;

3.4.6 -- application technology.

3.5 -- statistical delineation;

-- Use the appropriate methodology and experimental delineation, in order to achieve the proposed objectives;

-- Use a minimum of 6 (six) treatments and 4 (four) repetitions, including one treatment with a standard product for the region and a control treatment.

3.6 -- evaluation methods:

-- The appropriate method for each situation must be used, in addition to production data, where relevant.

4 -- Results and discussion:

4.1 -- include considerations relating to phytotoxicity.

5 -- Conclusions;

6 -- Bibliographies consulted;

7 -- Technical responsibility:

-- Signature of the professional responsible for conducting the work, with a typed name, council registration number for the category and region. The document must be typed on stamped paper of the official agency or private entity. The technical work must be approved or sent by the researcher's immediate supervisor:

a) tests will only be allowed when carried out under field conditions and established in representative regions of the crop, and those not conforming must be justified;

b) conclusive information on the tests must be reported in such a way as to leave no doubt as to the efficiency and feasibility of the tested product;

c) any change occurring in the instructions and methodologies described above must be duly justified by the researcher.

II -- The tests and information corresponding to product compatibility shall be provided by the requester when deemed necessary.

Annex III Data and Information to be Included in Technical Report III

I -- For Components

A -- Technical products (section XXV, Article 2 of Decree No. 98.816/90):

a) complete name(s) and address(es) of the manufacturer(s) and supplier(s) of the product to be evaluated;

b) code number(s) of the active ingredient(s) in the "Chemical Abstracts Service Registry" (CAS);

c) diagram of the product production process, including its synthesis stages, byproducts and impurities;

d) statement, with attached report, of the qualitative-quantitative composition of the technical product corresponding to each manufacturer, including impurities in toxicologically significant concentrations equal to or greater than 0.1%, as well as the minimum and maximum variation limits of the content of each component in the product;

e) statement, with attached report, identifying and quantifying byproducts or impurities present in the technical product in concentrations less than 0.1%, when significant from a toxicological and environmental standpoint. In the event that there is more than one manufacturer, provide specific reports;

f) description of the analytic methodology(ies) for the qualitative-quantitative description of the active ingredient and, where relevant, of toxicologically significant impurities;

g) tests and information listed in Annex IV.

II -- For Agricultural toxins and similar items:
(sections XX and XXII, Article 2 of Decree No. 98.816/90):

a) name(s) and address(es) of the manufacturer(s) and supplier(s) of the formulated product and technical product;

b) codes assigned during the experimental phase;

c) code number of the active ingredient(s) in the "Chemical Abstracts Service Registry" (CAS);

d) diagram of the major production stages of the product formulated on the basis of the technical product and other components, as well as those involving obtaining the formulated product directly from the raw materials;

e) statement, with attached report, of the qualitative-quantitative composition of the formulated product in all its components, indicating their specific functions in the formulation; if there is more than one manufacturer, provide specific reports;

f) statement of the maximum and minimum variation limits for the content of each component of the formulated product;

g) toxicological and environmental information on the principal products resulting from degradation of the technical product, accompanied by a copy of the bibliographic reference;

h) copy of the certificate or registry or protocol voucher of the request for registration of the technical product;

i) tests and information listed in Annex IV or Annex V.

Annex IV Tests and Information Needed for Ecotoxicological Evaluation

EFFECTIVE-DATE: 10/15/1996