THE REGISTRATION OF PESTICIDES IN THE UNITED STATES

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Descreve a forma adotada pelos Estados Unidos para regulamentar o registro de pesticidas, inclusive dos pesticidas aquáticos. Discute a eficácia da simples adoção pelo Brasil dos procedimentos norte-americanos. Salienta que o aproveitamento do trabalho já realizado naquele país pode ser vantajoso, desde que se inclua especificidades brasileiras no desenvolvimento de plano para licenciamento destes agentes químicos.

1 INTRODUCTION

On June 3 and 4, 1998, Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis (IBAMA - Brazilian Environmental Institute) hosted an Aquatic Plant Control Workshop, which was designed to create an atmosphere where the participants could learn about mutual problems and processes and begin to work together to address the diverse environmental, economic and political concerns affecting the management of aquatic vegetation in Brazil.

One of the advantages created by the workshop was the opportunity to learn from the successes and failures of other aquatic plant control efforts around the world and to, thus, fashion a successful program and process in Brazil. Of course there are strengths and weaknesses in each of the management options available: mechanical, biological, and chemical. The unique characteristics of each infested water body must be considered and the regulatory requirements should be flexible enough to encourage creativity while, at the same time, being protective of human health and the environment.

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It is intended to describe how pesticides, including aquatic pesticides, are regulated in the United States. This is not to suggest that a mirror image of the American procedures should be established in Brazil. Rather, an understanding of the American process might offer an opportunity to take advantage of much work already accomplished and to include Brazilian unique requirements into the development of a well-planned response and licensing process for Brazil.

Effective enforcement requires an understanding of the process that results in the labeling, sale and use of pesticides. The federal government in the United States has regulated pesticides since 1910. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was enacted in 1947 to establish a registration requirement. FIFRA was substantially amended in 1972 to modernize the registration process and to establish federal jurisdiction over the **use** of pesticides. FIFRA is now regularly updated on about a three-year cycle as technology improves and political trends shift between environmental, pesticide industry and public interests. The Environmental Protection Agency (EPA) is responsible for implementing and enforcing the provisions of FIFRA.

FIFRA is the most federal of all the U.S. environmental laws. Unlike the Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act and others, pesticide regulation rests on a national system of registration and labeling. States have little involvement. The heart of FIFRA is the pesticide registration program. Before a pesticide can be manufactured, distributed or even imported into the United States, the Environmental Protection Agency must approve it. Pesticide registration under FIFRA is complicated, time consuming and expensive. Various sources have indicated from the time chemical is synthesized to the time a pesticide is registered may take from ten to fourteen years and may cost between forty and sixty million dollars.

Prior to approval, a prospective registrant must prove four basic requirements to the satisfaction of EPA:

1 the composition of the pesticide warrants the proposed claims for it;
2 its labeling meets all the requirements of the Act;
3 it will perform its function without unreasonable adverse effects on the environment or human health; and
4 when used in common practice it will have no unreasonable adverse effects on human health and the environment.

A pesticide is defined as a substance intended for preventing, destroying, repelling, or mitigating any pest and substances intended for use as plant growth regulators defoliants, or desiccants.

Once a registrant decides to manufacture a pesticide, but **prior** to instituting production, he must apply to the EPA for pesticide registration

and approval. There are over 120 specified basic studies required to be submitted and, depending on the results of those studies, additional studies may be required. The studies can be grouped and characterized as described in the following list. What is hoped to be achieved by the studies is also provided.

A PRODUCT CHEMISTRY - data submitted must include information regarding:

1 starting chemicals;
2 production/formulation process;
3 possible formation of impurities;
4 analytic methods; and
5 certification of limits for ingredients.

B RESIDUE CHEMISTRY - to estimate the exposure of the general population to pesticide residues in food and feed for establishing tolerances.

C ECOLOGICAL TOXICITY

1 **Environmental Fate** - these studies are designed to assess toxicity to man by evaluating exposure to residues of pesticides after application. Exposure routes of concern include both directly by entering treated areas and indirectly through ingestion of food and water. The studies are also designed to evaluate persistence on land, surface water, ground water and in wildlife resources (potential to bioaccumulate). In addition, studies must be conducted to assess effects on habitats of endangered and threatened species;

2 **Degradation** - hydrolysis and photolysis studies to determine the rate of degradation in the environment;

3 **Metabolism** - aerobic and anaerobic metabolism studies to determine the nature and availability of pesticides to rotational crops and to evaluate persistence in the environment;

4 **Mobility** - pertains to leaching, adsorption/desorption and volatility of pesticides. This tells us the mode of transport and the eventual destination of the pesticide in the environment and can be used to assess the environmental hazards related to the contamination of food for man and animals, loss of land and water resources through pesticide contamination and potential habitat loss;

5 **Dissipation** - these studies are used to assess the potential environmental hazards under actual field conditions related to reentry into treated areas, hazards from residues in rotational crops, and loss of land and water resources;

6 **Accumulation** - indicates pesticide residue levels in food supplies that originate from crop rotation or from outside sources such as drift and irrigation water. These data:

a) allow the Agency to establish label restrictions regarding the application of pesticides;

b) establish tolerances on crops;

c) via accumulation studies in fish establish label restrictions to prevent applications in certain sites so that there will be minimal residues entering edible fish or shell fish; and

d) establish tolerances for residues in aquatic plants and animals eaten by humans.

7 **Endocrine Disrupters** - the following studies are required to support a continuing effort to detect the potential endocrine disrupting effects of pesticides:

a) reproduction tests on aquatic and terrestrial invertebrates;
b) chronic fish studies;
c) early and full life cycle tests in fish;
d) avian reproduction studies;
e) avian teratology studies;
f) developmental studies (rats & rabbits);
g) multi generational reproduction studies (rats);
h) subchronic studies (rats); and
I) chronic and oncogenic studies (mice and rats).

D TOXICOLOGY - determines hazards to humans and domestic animals using acute, subchronic, chronic and other tests to assess mutagenicity and pesticide metabolism.

1 **Acute studies** - oral, dermal, eye and inhalation toxicity studies provide information to assess toxic characteristics and enable the evaluation of health hazards likely to result from short-term exposure. Used as basis for the determination of pesticide

classification (Restricted Use or General Use) and precautionary labeling (worker protection standards, personal protection equipment requirements);

2 **Subchronic studies** - provide information regarding hazards that may arise from repeated exposure in a limited time -- looks at target organs and accumulation potential;

3 **Chronic studies** - determine the effects of a substance following prolonged and repeated exposure. Should identify latent and/or cumulative effects. In addition, oncogenicity studies, which cover most of the life span of the test organism, are to determine the likelihood of lesions under a variety of doses and routes of exposure;

4 **Teratogenicity and Reproduction Studies** - assess the potential of pesticides to induce structural abnormalities to the fetus as a result of exposure of the mother during pregnancy. Two generation studies provide information on gonadal function, estrus cycle, mating behavior, conception, lactation, weaning, and growth and development of the offspring. They also provide information on neonatal morbidity, mortality and teratogenesis;

5 **Mutagenicity studies** - a battery of tests to assess the potential of the pesticide to affect a mammalian cell's genetic components. The tests are to:

a) detect the capacity of a chemical to alter genetic material;
b) determine the relevance of mutagenic changes to mammals; and
c) indicate the potential of other problems.

6 **Metabolism studies** - absorption, distribution, excretion, and metabolism of pesticides in test organisms produce data to aid in understanding the behavior of the chemical in consideration of human exposure anticipated from the intended uses of the pesticides. It also helps to interpret the other data.

E RE-ENTRY PROTECTION - studies on toxicity, residue dissipation and human exposure help develop an understanding of the pesticide, which then helps to determine the need of a re-entry interval for workers.

F PESTICIDE SPRAY DRIFT EVALUATION - data required to evaluate pesticide spray drift are derived from studies of droplet size spectra

and spray drift field evaluations. These data contribute to the development of the overall exposure estimates and are used in conjunction with other studies to help to assess the potential hazards of pesticides to human health, fish, wildlife, and plants. A purpose common to all these tests is to provide data, which will be used to determine the need and appropriate wording for precautionary labeling to minimize the potential adverse effects to non-target organisms.

G HAZARD TO NON-TARGET ORGANISMS - these studies are required to assess hazards to non-target organisms which are derived from tests to determine pesticide effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, subacute, reproductive, simulated field and full field studies arranged in a hierarchical or tier system, which progresses from the basic laboratory tests to the applied field tests. These tests are used to develop precautionary labeling and to minimize the potential adverse effects to non-target organisms.

H PRODUCT PERFORMANCE - these requirements are necessary to provide a mechanism to ensure the pesticide will control the pests listed on the label and that unnecessary pesticide exposure to the environment will not occur as a result of ineffective products. They are primarily used to validate efficacy data in the public health areas such as disinfectants and products use to control infections, micro-organisms, infections to man, and vertebrates that are vectors of disease.

The conclusion of the process is an analysis of the risks determined by these studies balanced by a biological and economic assessment of the benefits to society to be derived from the proposed use of the pesticide. It must be considered, for example, that many pests - especially aquatic pests -- in certain circumstances present a greater threat to human health and to the environment than the chemical proposed for use might present.

In the United States, most States have additional registration requirements before an EPA-registered pesticide may be sold or used in a specific State. In many States this additional requirement basically constitutes the imposition of a registration fee. Often the registration fee pays for much of the rest of their pesticide programs. In the few States that have an established pesticide review program, they verify that the federal (EPA) registration adequately addresses the specific human health and environmental concerns of that State. They may require additional specific studies or monitoring as a condition of State registration.

2 CONTROL OVER PESTICIDE USE

As part of the registration process, the registrant must submit a draft label indicating the proposed uses. As the results of the studies are reviewed, the label is modified accordingly. Restrictions will vary depending on the target site of application and the results of the studies. Restrictions will vary , for example, and will be specific for target sites such as ditch banks or shores; static water like ponds and lakes; quiescent water (slow moving) like bayous, sloughs, canals, etc.; or flowing water like streams and rivers. All labels must contain minimum basic information.

3 LABELING REQUIREMENTS

1 Name, brand or trademark under which product is sold;
2 name and address of the responsible company;
3 net contents;
4 product registration number;
5 producing establishment number;
6 ingredient statement;
7 precautionary statement (signal word and Keep Out of Reach of Children);
8 directions for use;
9 use classification - RUP (Restrict Use Pesticide) requires certification of applicators and record keeping; and a
10 disclaimer statement (While a disclaimer is not required, should a registrant choose to include one on the label, the language is regulated).

Other requirements may be required depending on the results of the studies, such as worker protection statements and child resistant packaging.

4 SECTION 6(a)(2)

Registrants are required to report any and all unanticipated adverse effects under Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As a result, the labels may be modified to correct the problem or the specific problematic uses can be canceled. Should a serious situation or imminent hazard be discovered, the EPA has the authority to suspend the production and use of the pesticide and to require its recall from the marketplace.

5 EXPERIMENTAL PERMITS

The EPA has the discretion to permit the use of pesticides pending registration for large-scale field trials under the terms of EUP. The purpose of the experiments are to conduct further necessary studies that can only be done in the field to fill any data gaps necessary to support the registration application.

6 EMERGENCY EXEMPTIONS

Section 18 of the FIFRA permits the use of unregistered pesticides under certain limited circumstances where emergency conditions exist. These are very limited applications involving a specified amount of pesticide, on specified areas and within a specific time frame to address an instance involving an unforeseen pest outbreak.

7 USE CLASSIFICATION

When considering the proposed registration of a pesticide, if the EPA finds that the pesticide when used as directed may generally cause, without additional regulatory restrictions, unreasonable adverse effects on man or the environment, the EPA may classify the pesticide for restricted use. This means, prior to the purchase or use of a restricted use pesticide (RUP), a person must be certified as competent by a State. A certified applicator may then buy, use and supervise the use of RUP. There are two types of certification:

1 **Private** - persons in this categories are private citizens, like farmers, who need to use RUP for the production of an agricultural commodity;

2 **Commercial** - persons in this category are governmental employees, employees of commercial businesses or individuals who operate commercial businesses who charge a fee for the application of RUP. Commercial categories may include: aerial, industrial, household, forestry, aquatic, right-of-way, public health, agricultural plant, agricultural animal, regulatory and research.

Every State desiring to have the authority to certify applicators must submit a plan to EPA that describes how applicators under their jurisdiction

will certified. Each State Plan must, at least, describe how certain minimum standards will be addressed and how applicators will demonstrate:

1 practical knowledge of principles and practice of pest control and the safe use of pesticides;
2 label and labeling comprehension - understanding instructions and directions for use;
3 safety - toxicity of pesticides, causes of accidents, precautionary measures to take to minimize accidents, personal protective equipment, symptoms of pesticide poisonings, first aid, storage, handling and mixing procedures;
4 environment - effects of weather and soil types on pesticide applications and performance, effects of pesticides on non target organisms, and drainage/runoff problems;
5 pest identification;
6 pesticides - types, importance of proper selection and modes of action;
7 equipment - calibration, maintenance and use;
8 application technology; and
9 laws and regulations.

8 ENFORCEMENT

Based on the labeled uses of registered pesticides and the other controls in place, the EPA has a very good understanding within a reasonable certainty, and **provided** all label directions are followed, of what will happen to man and the environment when a registered pesticide is used. In order to assure pesticides are applied within the scope of the labels, FIFRA provides for and EPA has developed a very vigorous enforcement program in cooperation with the States. It is a violation of both federal and State laws to use any EPA registered pesticide in a manner inconsistent with its label.

Use inconsistent with the label does not include some uses:

1 mixes of pesticides, fertilizers, and other additives are authorized unless prohibited by the label. All application rates must be followed closely;
2 one may use less than the labeled application rate, but one may not use a concentration greater than that authorized by the label. Also, the specific diluent must be used as described on the label. If the label is silent, the presumption is that the diluent is to be water;

3 an applicator may use a registered pesticide to control any unnamed target pest **provided** the site is on the label, maximum application rates are not exceeded and all other directions for use are followed;

4 any method of application may be used **provided** the method is consistent with other directions and rates on the label and is not specifically prohibited by the label.

9 CONCLUSION

So what are the practical applications of the EPA registration process for IBAMA and for those concerned with implementing effective aquatic plant management programs? Depending on one's perspective, EPA could serve either as a model to emulate or a curse to avoid. The best route to take is probably somewhere in between. Definitive decisions should only be made after a careful consideration of what information has already been collected and reviewed by EPA and what additional information is necessary to address the unique ecosystems and needs of Brazil. Before IBAMA can depend on the reliability of EPA's review process and avoid the duplication of effort, a level of trust must be developed between the two Agencies. How that process can take place is well beyond the scope of this paper.

Abstract

This paper describes how pesticides, including aquatic pesticides, are regulated in the United States. It is discussed the effectiveness of a supposed Brazilian simple adoption of the North American procedures, reminding that the use of the work already accomplished in the United States can be advantageous, since the Brazilian specific requirements are included into the development of a well-planned response and licensing process for these chemical agents.

REFERENCES

1 USA. **Federal insecticide, fungicide and rodenticide act, as amended**. [S.n.t.].

2 USA. **Code of federal regulations**. [S.n.t.]. Parts 152, 156, 158, 160 and 171.