Review of agrochemical regulations in Brazil

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Introduction

Brazil is one of the most efficient countries in agriculture production, considering productivity, crop protection market is estimated US$10 billion, the country is one of the largest producers and exporters of agricultural crops in the world, planting various tropical and temperate fruits, vegetables and grains. Regulatory changes in Brazil for Crop Protection products has been discussed in the last few years and the main purpose is to bring predictability, transparency and incorporation of scientific rigor to the regulatory framework.

The current Brazilian pesticide registration process follows the Law 7,802 from 1989 and Decree 4074 from 2002 and Decree 5,981, from 2006. The registration process involves three regulatory authorities: MAPA (Agriculture Ministry), ANVISA (National Agency of Sanitary Vigilance) and IBAMA (Brazilian Institute of Environment and Renewable Natural Resources). The registration of a new active ingredient can take 8 to 10 years for approval, considering time in the queue and dossier evaluation. This makes it difficult for new molecules to enter the Brazilian market.

The main discussion has been given to proposed law 6299/02 which deals with the registration, inspection and control of pesticides. This has already been approved by the Deputy Chamber however the regulatory agencies have failed to reach a consensus between themselves.

Other new regulations have been under discussion and published in the last 2 years. In general, most of the new regulations that have been discussed show a tendency towards new requirements in relation to agrochemical registrations.

Pesticide regulation history in Brazil and regulation changes

- Pesticides in Brazil has been regulated since 1934 and since then the Agriculture Ministry and the Health Ministry were responsible for the evaluation for registration process in the country.
- Decree no. 24.114, 1934 – registration granted for 5 years based on efficacy studies
- Law no. 7,802, 1989: Includes IBAMA into evaluation process and the registration of active ingredient for undetermined time. The law also establishes “the registration pesticides, their components and the like shall be prohibited”
- With the publication of Decree 991 in 1993, it was established that there is no longer any need to renew the registration of pesticide in the country.
- In 1999, by the Law no. 9.782 the National Agency of Health Surveillance (ANVISA) was created.
- Decree no. 4.074, 2002: introduces technical equivalence process, and risk assessment. Simultaneous submission on regulatory authorities – MAPA / ANVISA / IBAMA.
- Decree no. 5.981, 2006: establishes changes in Decree 4074 with respect to equivalence and components registration.

Brazilian pesticide registration process

Pesticide registration process is evaluated by independent registration authorities - MAPA, ANVISA and IBAMA in the following aspects:

- MAPA – Responsible for the agronomic / effectiveness evaluation of pesticides
- ANVISA – Responsible for the pesticide toxicological classification and evaluation (food consumer health risk)
- IBAMA – Responsible for the environmental assessment.

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Registration process by equivalence can take 5 years for approval.

The regulation requests the registration of the active substance and the registration of the plant production product. If in case of a new a.i. a complete dossier package should be submitted to authorities MAPA / ANVISA / IBAMA.

On the other hand the registration process of a registered pesticide, requires less information in the dossier compared to a new active substance.

Requirements in the pesticide registration process, considering a new active ingredient:

- MAPA – Ministry of Agriculture
  - Efficacy studies (3 new a.i and new use)
  - Residues studies 4 / crops (representative areas)
  - Phytoxicity
  - Physical chemical studies, including five-batches analysis
- ANVISA – National Agency of Surveillance Vigilance
  - Acute toxicity / sub-chronic toxicity / chronic toxicity / reproduction and development studies / ADME
  - Genotoxicity studies (also developed for Plant Protection Product)
  - Residue studies: 4 studies in representative areas / crop
  - Physical chemical studies, including five-batches analysis
  - Beach (acute adult, larvae acute, larvae chronic), acute contact aged foliage
  - Physical chemical studies, including five-batches analysis
- IBAMA – Brazilian Institute of Environment and Renewable
  - E-fate studies: 3 Brazilian soil types (read biodegradability, biodegradability, mobility and adsorption / desorption)
  - Ecotoxicological studies in microorganisms, soil microorganisms, algae (acute), earthworm (acute), daphnia (acute and chronic), fish (acute, chronic, BCF if required), microcrustaceans (acute and chronic), birds (acute, dietary and reproduction).
  - Physical chemical studies, including five-batches analysis
- Decree 4.074, 2002 establishes registrations prohibitions
  - A new product can be registered if the hazard classification, considering toxic action on the human being and the environment is proven.
  - Prohibitions for registration of pesticides, components and related products:
    - Absence of deactivation methods for the components
    - Absence of antidote or treatment with efficacy
    - Teratogenicity
    - Carcinogenicity
    - Mutagenicity
    - Hormonal disturbances, damage to the reproductive system:
    - More dangerous to man than lab tests with animals have been able to prove, according to updated technical and scientific criteria.
    - Pesticides with characteristics to cause damage to the environmental

Trends and recent changes in pesticide registration process in Brazil

- More dangerous to man than lab tests with animals have been able to prove, according to updated technical and scientific criteria.
- Pesticides with characteristics to cause damage to the environmental.

Conclusion

Brazilian regulation has been changing in last few years and in general, most of the trends and new regulations that have been discussed show a tendency towards new requirements in relation to agrochemical registrations.

References

Ministry of Agriculture website available in http://www.agricultura.gov.br

National Health Agency of Surveillance website available in http://www.anvisa.gov.br.