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BRAZILIAN PESTICIDES REGISTRATION

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Since last year, Brazilian pesticides regulatory agency (Ministry of Agriculture) approved 3 registrations of technical products based on equivalency: Glyphosate, Paraquat and Carbendazin. According to AllierBrasil evaluation, at this moment, there are 15 to 20 registrations submissions under analysis and more than 20 in the list for future analysis. For registration based on equivalency there are products such as 2,4-D, Acephate, Diflubenzuron, Difenconazole, Diuron, Glyphosate, Imazetapyr, Lactofen, Methamidophos, Picloram, Tebuconazole. This number shall increase in the next months.

Presidential Decree 4074 from 2002 regulates pesticide registration and defines rules for registration based on equivalency. It was regulated by the Normative Instruction 49, which determines the criteria for registration of technical products based on 5 batches analyses. This allows cost reduction, since many of the physical-chemical and eco-toxicological tests, including long-term studies, have ceased to be mandatory. The same Decree has also broadened the mandatory condition of the Experimental Use Permit (EUP) for every sample importation, whether it's for laboratory or field testing and may take 6 to 12 months for approval. It is regulated by a specific Normative Instruction 25.

A complete dossier of the technical product is evaluated as regular procedure and it is required for those active ingredients that are not registered in the country yet. There shall not have any equivalency for new submissions which the already registered product of reference - that the equivalency would be based on, in case its registration was not granted based on complete dossier. It is explained by the fact that up to the Decree 4074, regulatory registration accepted some literature data for specific information.

At Federal level, registration is evaluated by three Agencies: MAPA (Ministry of Agriculture), responsible for the registration issuing; ANVISA (Ministry of Health) and IBAMA (Ministry of the Environment), each one is responsible for aspects related to agriculture, health and the environment. After this approval it is necessary to apply for registration in the respective States of interest.

For equivalency registration, besides 5 batches, additional studies are required, such as physical-chemical and 6 acute toxicological tests. For formulated product registration complete physical-chemical, eco-toxicological, residue and efficacy studies are mandatory as there is no registration based on equivalency. Laboratory studies must be conducted under

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good laboratory practices (GLP). Foreign laboratory must have international accreditation to have its reports accepted by Brazilian with international authorities. Nevertheless, some specific of these laboratory tests must be conducted locally, thus is obliged to have EUP to import/test the product. In Brazil there are laboratories accreditation which studies reports are also accepted in the United States as well as in Europe. Efficacy trials per crop/per biological target should be conducted locally. After registration at Federal level, it is required States registration. In some cases, States' regulations may be more restrictive than the Federal registration.

This is the case of Parana State that is very important as cereals producer. But in most of the other States, registration takes 2 to 3 months.

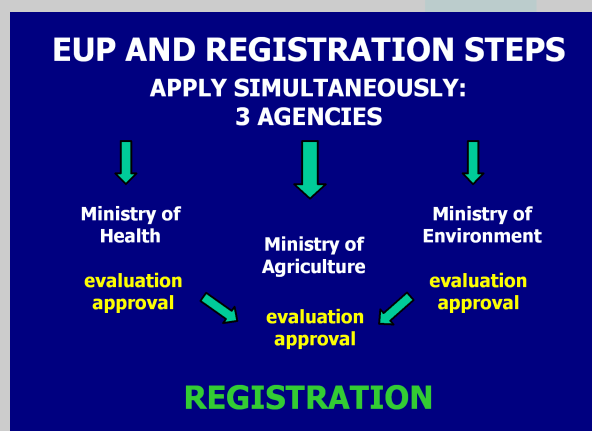
Registration costs for a regular equivalent product and its formulation are from US\$

170,000 to US\$ 200,000 (laboratory and field studies, and agencies fees) depending on the number of crops, type of molecule, etc. From the EUP submission up to the Federal registration approval, including field and laboratory testing it takes approximately 3 years. There are also specific regulations for biological and aquatic products, biochemicals (aminoacids, enzymes, feromones) and for

products that are considered atypical such as copper, sulphur, mineral and vegetal oils. For biological and atypical products, registrations requirements are less complex than a regular chemical pesticide. Nevertheless, different from regulations in several countries, according to the

Brazilian regulations there is no exempt of registration for any type of product.

Long time to obtain EUPs and the complex registration system that demands time and high costs are the main concerns of those who are pursuing a product registration in Brazil.



Publications and studies performed by AllierBrasil.

"Brazilian Pesticides Market", 2004; "Brazilian Soybean Asian Rust", 2004; "Brazilian Pesticides Regulations", 2005; "Impact of GMOs in the Brazilian Agriculture", 2005; "Brazilian Agribusiness Report", 2005.

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