

Agrochemical Compliance in South America:

Brazil, Argentina, Colombia and Paraguay



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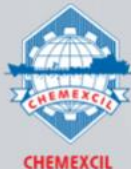




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MERCOSUR and the Andean Community

- **MERCOSUR:**
Argentina, Brazil, Paraguay, and Uruguay;
- **Andean Community:**
Bolivia, Colombia, Ecuador, and Peru;
- Similar in concept to the European Union
- These trade blocs may develop regulations applicable only to their Member States;
- Member States must then pass them into their National law (can be >3 year process);
- Keep in mind that a MERCOSUR or Andean Community member state may:
 - Choose to only implement some portion(s) of the regulation;
 - May also have their own separate National law on the same topic

Brazil (1)



- World-leader in agricultural pesticide consumption (>\$10 billion USD annually);
 - Largest purchaser of Highly Hazardous Pesticides (HHP):
 - **Agrochemicals with Active Ingredients (A.I.) with extremely acute toxicity;**
 - **Highly persistent in the environment; and**
 - **Chronic negative effects on human health and the environment.**
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- Brazil began accelerating pesticide approvals in September 2016 – caused controversy;
 - **1,270 pesticides approved (double the number in previous four years) 2016-2019;**
 - **Of these, 193 contained A.I.s banned in the EU;**
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Brazil (2)



- 3 entities have roles in pesticide regulation:
- Agência Nacional de Vigilância Sanitária (Brazilian Health Regulatory Agency; **ANVISA**);
- **Example: Monitors pesticide residue in products of plant origin**

- Instituto de Medio Ambiente y Recursos Naturales Renovables (Ministry of Environment and Renewable Natural Resources; IBAMA);

- Ministerio de Agricultura, Ganadería y Abastecimiento (Ministry of Agriculture, Livestock and Supply; MAPA);
- Example: Monitors pesticide residue in products of plant origin

Brazil (3)



- Some Key Legislation:
 - Decree 4074 (04 January 2002)
 - Requires phys/chem, tox, ecotox and related studies to be performed at GLP facilities;
- ANVISA Ordinance 3 (16 January 1992):
 - **Procedures for registration of an equivalent Technical product (required test ítems, criteria for equivalence determination, etc.)**
- Order IDIARIN No. 30:
 - **Addresses the registration of pesticides and their components to be used in the agricultural production sectors IN RIO GRADE DE NORTE.**

Brazil (4)



- Time required for registration may be up to six years;

- Information on pesticides for plant protection pre-market approval procedures fall under Decree 4074/2002, and Manual of Procedures for Registration of Pesticides;
- Decrees implement Laws: Law 7802 **“On research, production, labelling, packaging, exploitation, classification, use, etc. of pesticides”**;

- Pre-market approvals do not expire, but they might be cancelled in cases of toxicological reassessment, when “irregularities” cannot be adequately addressed, or when fraud is detected.

Argentina (1)



- “Phytosanitary products” (PP) – relating to or being measures for control of plant diseases, especially in agricultural crops;
- Servicio Nacional de Sanidad y Calidad Agroalimentaria (The National Service of Health and Food Quality; SENASA) is Competent Authority;

- For a PP to be marketed or applied – either experimentally or commercially – it must be registered in the National Register of Plant Therapeutics, as per Decree No. 3489/58 and Decree No. 5769/59;
- The requirements of Resolution No. 350/99 must additionally be followed;

- The above Decrees adopt the fifth edition of the “Manual on the Development and Use of FAO Specifications for Products Intended for the Protection of Plants”;
- **This is a procedure for evaluating data to determine if the product is effective for its intended purpose, and not unduly risky for health and environment.**

Argentina (2)



- **Law 27262: Argentina bans the application of pesticides to crops while they are being loaded or transported;**

- **Form must be completed that this has not occurred;**
- **Fine is equal to the sale amount of the material being transported**

- The Comisión Nacional de Trabajo Agrario (National Agricultural Labor Commission; CNTA) established the hygiene and safety conditions that must be met by workplaces, machinery, tools and other work items;

- There are substantial safety and hygiene regulations for the agriculture sector. The key regulation is:

- **Decree 617/1997: Hygiene and Safety Regulations for Agricultural Activity. (B.O. 11/07/1997) of Law 19.587 on Occupational Health and Safety;**
- **There is no enforceable data exclusivity protection for agricultural chemical products;**

Argentina (3)



- Specific tests – physical, chemical, toxicological, ecotoxicological and waste properties – must be done per internationally-recognized protocols (e.g., OECD methods);
- All data must be submitted to SENASA ;
- If approval is granted, applicant will receive a Certificate of Use and Marketing that allows it to be used throughout the National Territory;
- Keep in mind:
 - **Atrazine is not permitted for use in soybean cultivation;**
 - **Paraquat is permitted for soybean cultivation, as long as the requirements of Codex Alimentarius are followed.**

Colombia (1)



- Competent Authority is the Instituto Colombiano Agropecuario (Colombian Agricultural Institute; ICA);
- To begin the process of pesticide registration in Colombia, manufacturers, formulators, importers, exporters, packers, and distributors must be registered with ICA;

- The ICA is responsible for establishing the technical registration requirements, including information on both the technical active ingredient (A.I.) and the formulated product;
- This derives from Decision 436 of the Andean Community;

- A technical manual, issued by the Andean Community, harmonizes the rules for pesticide registration and control in Bolivia, Colombia, Ecuador, and Peru;
- Potential for special permits in case of research or health emergencies exists (A.I. or product).

Colombia (2)



- Information to be provided (specific to the A.I.) includes: mammalian toxicology effects, toxicology effects on certain other species; degradation and activity metabolites, and environmental effects;

- **Registration must include efficacy tests performed by technical departments registered with the ICA;**
- **These tests provide information on the pesticide's ability to meet the label claims;**
- **Tests must be carried out under local conditions (that is, in country);**

- The evaluation of the test data must consider the risk of resistance to the pesticide;
- Strategies for the detection and management of resistance must be presented;
- Registration is granted when the evaluation results show the benefits outweigh the risks.

Paraguay (1)



- **Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas (National Service of Quality and Plant and Seed Health; SENAVE) is the competent Authority;**
- The National Institute of Technology, Standardization and Measurement (INTN) is the governmental organization in charge of developing Paraguay's standards;
- Law 3742 (2009) – “Control of Phytosanitary Products for Agricultural Use” is overarching regulation;
- In 2010, Paraguay passed Law 3.519 that establishes 5 years of CBI protection for agrochemical products, but only if the first global registration is sought in Paraguay;

Paraguay (2)



- SENAVE Resolution No. 660 requires users must be explicitly authorized before aerial spraying of plant protection products;
- Tanks used for mixing pesticides for aerial OR ground spraying must have sealing devices to prevent direct contact or inhalation by applicators;

- Enterprises employed in pesticide application must provide personnel with protective equipment such as waterproof overalls, masks with filters, gloves, and rubber boots;
- Related entities must receive approval from SENAVE, and have valid liability insurance against 3rd parties;

- All agrochemical products approved for marketing in Paraguay have to undergo re-evaluation, including submission of CBI;
- In the absence of confidentiality safeguards, registrants have the choice of either revealing their CBI or losing their licenses to market.

Thank you for your attention!



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