



RDP in México today.

Despite assuming international obligations to protect regulatory data more than 30 years ago Mexico has, for the first time, incorporated provisions concerning regulatory data protection (RDP) in the domestic legislation.

Amendments to the Health Law Regulations now provide five years of protection for the safety and efficacy information of new molecules submitted in a marketing authorization application. During this period, the health authority may not allow third parties to rely on or use the protected information without the express consent of the owner, however it seems that the wording with respect to interchangeability tests (indirect use) could jeopardize the scope of the protection.

Additionally, amendments to the Regulations governing agricultural chemical products establish a 10-year exclusivity period for safety, efficacy, physicochemical, toxicological, ecotoxicological, and environmental data submitted for new agricultural chemical products.

These amendments, indeed, represent a significant step. However, it remains to be seen how effectively the protection will be implemented and enforced in practice.

IAM's Guide to Life Sciences



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