

National Agrifood Health and Quality Service

BIOLOGICAL AND CHEMICAL TESTING Resolution 274/2010

This resolution establishes the conditions that Laboratories performing biological and chemical assays for the production of toxicological, ecotoxicological and pesticides residues data must meet.

Buenos Aires, 11/5/2010

HAVING SEEN file No. N° S01:0443263/2009 of the Register issued by the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, Resolution No. 617 issued on July 18, 2002 by the NATIONAL AGRIFOOD HEALTH AND QUALITY SERVICE and No. 736 issued on November 14, 2006 by the ex-SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD, and

CONSIDERING:

That Resolution No. 617 issued on July 18, 2002 by the NATIONAL AGRIFOOD HEALTH AND QUALITY SERVICE establishes the requirements, conditions and procedures that must be met by the laboratories that have production animal facilities, maintenance and animal experimentation site in order to obtain a technical operating licence.

That likewise, the cited resolution specifies the conditions that the Laboratories that carry out biological and chemical tests for the production of toxicological, ecotoxicological data and of residues of pesticides, both in plant and environmental matrices, whether for registration, renewal, reassessment and / or monitoring of phytosanitary products, must meet.

That, according to Articles 3rd, 4th, and 9th of Resolution No. 617/02, the Laboratories that carry out the tests and final reports mentioned therein, must meet the Good Laboratory Practices Principles (GLP), developed by the Organization for Economic Co-operation and Development (OECD).

That the Argentine Accreditation Body (OAA) is the Body responsible for monitoring the Good Laboratory Practices (GLP) developed by the Organization for Economic Co-operation and Development (OECD) in ARGENTINA.

That the Directorate of Laboratories and Technical Control, the Directorate of Agrichemicals, Pharmacological and Veterinary Products and the Directorate of Legal Affairs have taken the intervention incumbent to them.

That the undersigned is competent to dictate the present act in virtue of the provisions given en Article 8th, bullet f) of Decree No. 1585 issued on December 19, 1996 and replaced by its similar No. 237 issued on March 26, 2009.

Therefore,

THE PRESIDENT OF THE NATIONAL AGRIFOOD HEALTH AND QUALITY SERVICE

RESOLVES:

Article 1st — The companies that request recognition of the requirements set down in Articles 3rd, 4th and 9th of Resolution No. 617 issued on July 18, 2002 by the NATIONAL AGRIFOOD HEALTH AND QUALITY SERVICE or other non-clinical safety studies of products, physicochemical properties, analytical chemistry or other studies, for registration purposes, by a National or Foreign Laboratory, must provide the supporting documentation relevant to Good Laboratory Practices (GLP) developed by the Organization for Economic Co-operation and Development (OECD) issued by the Argentine Accreditation Body (OAA).

Art. 2nd — A period of THREE (3) years from the date this Resolution comes into force is established in order that Laboratories belonging to the National Network of Testing and Diagnosis Laboratories comply with the prescriptions specified in article 1st of this resolution.

Art. 3rd — The Directorate of Laboratories and Technical Control will be entitled to carry out additional audits, according to the current legislation of this National Service, which are not required by the Good Laboratory Practices (GLP) developed by the Organization for Economic Co-operation and Development (OECD).

Art. 4th — This resolution will come into force the date of its publication in the Official Bulletin.

Art. 5th — Be it thus notified, published, forwarded to the National Directorate of the Official Register and filed — Jorge N. Amaya.