

Resolution No. 559/2011

Residue limits on food of animal origin are hereby approved.

HAVING REGARD to Docket file No. S01:0469502/2010 of the Register of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, Resolution No. 58 of January 24, 2001 of the ex SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD, Resolution No. 934 of December 29, 2010, of the NATIONAL SERVICE FOR AGRI-FOOD HEALTH AND QUALITY, and considering:

That Resolution No. 58 of January 24, 2001, of the ex Secretariat of Agriculture, Livestock, Fisheries and Food, adopts MERCOSUR TECHNICAL REGULATION on "ANALYTICAL METHODS, ACCEPTABLE DAILY INTAKE AND MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS ON FOOD OF ANIMAL ORIGIN."

That the aforementioned Resolution establishes a limited number of Maximum Residue Limits.

That the Argentine Republic does not have any specific rule establishing Maximum Residue Limits (MRL), for food of animal origin, of the several drugs used in the production of veterinary products, except for those belonging to certain external antiparasitics laid down in Resolution No. 934 of December 29, 2010 of the National Service for Agri-Food Health and Quality.

That the list of active ingredients covered in Resolution SENASA No. 934/2010 and Resolution SAGPyA No. 58/2001 is insufficient to provide for all the reference toxicological values that ensure the safety of food, in view of the amount of substances used in the production of veterinary products.

That, from the veterinary drug residues point of view, the notable role of our country as an exporter of products and by-products of animal origin, requires the existence of measures that assure the quality and safety of food.

That the Maximum Residue Limits are necessary to establish restriction periods for veterinary products, which must be respected for the purpose that food originating from treated animals be safe and to avoid Public Health issues.

That to this day, the Maximum Residue Limits established by competent international bodies were used as reference.

That it is appropriate to establish which Maximum Residue Limits shall be considered as valid so that laboratories clearly understand which MRL's they should take into account when carrying out residue depletion trials.

That the Directorate for Legal Affairs has duly intervened.

That the undersigned is empowered to issue this Resolution, pursuant to the provisions in Article 8 (f) of Decree No. 1585 of December 19, 1996, replaced by Decree No. 825 of June 10, 2010.

Therefore, the President of the National Service for Agri-Food Health and Quality resolves:

ONE— Maximum Residue Limits on food of animal origin: The Maximum Residue Limits (MRL's) for food of animal origin are hereby approved for the active ingredients used in the development of veterinary products and which are reflected in the Annex of this Resolution.

TWO— Active Ingredients with non-established MRL's: For those active ingredients that do not have a Maximum Residue Limit value (MRL) established in the Annex of this Resolution, the company interested in registering veterinary products formulated on the basis of such active ingredient and prescribed for those species which products or by-products are intended for human consumption, shall suggest and sustain a/the Maximum Residue Limit(s) (MRL's) for said ingredient. The values proposed shall be evaluated to be or not to be accepted by the National Directorate for Agrochemicals, Veterinary Products and Food.

THREE— Registered Active Ingredients with non-established MRL's: In the case of already registered veterinary products formulated on the basis of an active ingredient for which there is no Maximum Residue Limit (MRL) established in the Annex this Resolution and which have been prescribed for species which products or by-products are intended for human consumption, the procedure for the companies owing said registrations is the following:

- a) Within three hundred and sixty (360) calendar days as from the issuance of this Resolution, the provisions of the preceding Article must be complied with.
- b) If there is a breach of the obligations established in said period or if the presented basis is not accepted, the improperly sustained indications for use must be withdrawn. If applicable, registration in the National Registry for the product involved shall be cancelled.

FOUR— Lack of data on Maximum Residues Limits: In case of lack of data on Maximum Residues Limits (MRL's) for a certain active ingredient, in the tissues of a certain animal species that produces food intended for human consumption, the indication to use veterinary products containing said active ingredient in the species involved must not be authorized.

FIVE— Glossary: For the purposes of this Resolution, the following terms shall apply:

Edible offal: Edible tissues that are not specifically mentioned, except for muscle. They could be kidney, liver, intestine, or any other edible tissue in conformity with the customs of each country.

Muscle (according to Codex): Muscle is the skeletal tissue of an animal carcass or cuts of those tissues from an animal carcass that contain interstitial and intramuscular fat.

The muscular tissue may also include bone, connective tissue, tendons as well as nerves and lymph nodes in natural portions. It does not include edible offal or trimmable fat.

Portion of the product to which the MRL's apply: The whole product, no bones.

Edible tissue: edible offal and muscle.

SIX— Update: The National Director for Agrochemicals, Veterinary Products and Food may modify the Annex of this Resolution every time that the scientific information indicates so.

SEVEN— Exemptions: Veterinary products that have been registered, exclusively for their exportation, in the registry established in Article 1 of Disposition No. 391 of July 6, 1990 of the ex-National Animal Health Service are exempted from the scope of this Resolution.

EIGHT— Annex: Approval. The Annex of this Resolution, by which the Maximum Residue Limits (MRL's) of active ingredients used in the production of veterinary products on food of animal origin are laid down, is hereby approved.

NINE— Incorporation: This Resolution is included in Third Book, Part Four, Title II, Chapter I, Section 4, Subsection 5, of the Legal Digest Index of the National Service for Agri-Food Health and Quality approved by Resolution No. 401 of June 14, 2010, of the National Service for Agri-Food Health and Quality.

TEN— Validity: This Resolution shall be valid as from the day after the date of its publication in the Official Bulletin.

ELEVEN— Form: Have it notified, published, transferred to the National Official Registry and filed. — Jorge N. Amaya.