



## **NATIONAL AGRICULTURAL HEALTH AND QUALITY**

### **SERVICE Resolution 22/2019**

#### **RESOL-2019-22-APN-PRES # SENASA - Veterinary products: prohibition of processing, distribution, import, use and possession.**

City of Buenos Aires, 11/01/2019

SEEN the File No. EX-2018-54429573- -APN-DNTYA # SENASA, Laws Nr. 13,636 and 27,233; Joint Resolution No. 834 and No. 391 of June 22, 2015 of the then MINISTRY OF HEALTH and of the then MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, Resolutions Nr. 345 of April 6, 1994 of the former NATIONAL SERVICE OF ANIMAL HEALTH, 681 of August 12, 2002 and 591 of November 24, 2015, both of the NATIONAL SERVICE OF HEALTH AND AGRI-FOOD QUALITY, and

#### CONSIDERING:

That the resistance to antimicrobials generates every year huge human, animal and economic losses throughout the world.

That the WORLD HEALTH ORGANIZATION (WHO) urges all countries to take measures to combat antimicrobial resistance.

That the WORLD ORGANIZATION OF ANIMAL HEALTH (OIE) promotes the rational and prudent use of antimicrobial agents through its strategy approved in 2015 and supports the World Plan prepared by WHO.

That by Joint Resolution No. 834 and No. 391 of June 22, 2015 of the then MINISTRY OF HEALTH and of the then MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, the Argentine strategy for the control of antimicrobial resistance is established.

That by means of Resolution No. 345 of April 6, 1994 of the former NATIONAL ANIMAL HEALTH SERVICE, the "REGULATORY FRAMEWORK FOR VETERINARY PRODUCTS" was adopted and put into effect, the "CONVALIDATION SYSTEM OF THE VETERINARY PRODUCTS REGISTRY CERTIFICATE WITH HARMONIZED STANDARDS IN MERCOSUR "and" MERCOSUR REGISTRATION APPLICATIONS "for veterinary products.

That Resolution N ° 681 of August 12, 2002 of the NATIONAL AGRICULTURAL HEALTH AND QUALITY SERVICE approves the "Regulatory Update of the Legal Framework in Force in the Registry of Veterinary Products," the "Guidance for Procedures in the Registry and the" Application for Registration of Cosmetic Veterinary Products ".

That by Resolution No. 591 of November 24, 2015 of the NATIONAL SERVICE OF HEALTH AND AGRI-FOOD QUALITY, the National Antimicrobial Resistance Surveillance Program was created in animals destined for human consumption.

That the WHO has prepared a list of antimicrobial agents of critical use in human health.

That the antimicrobial agent Colistin and its salts, is classified by the WHO as "RESERVE" due to its importance as a therapeutic tool of last choice in intensive care units.

That, therefore, it is important to preserve the aforementioned antimicrobial as a therapeutic tool for human health.

That the results obtained by the National Antimicrobial Resistance Surveillance Program in animals destined for human consumption have demonstrated significant levels of resistance to Colistin.

That, consequently, it is necessary not to administer Colistin and any of its salts to animals, in order to preserve its effectiveness in the treatment of infections caused by multiresistant bacteria in humans.

That the Directorate of Legal Affairs has taken the intervention that is its responsibility.

That this measure is issued in the exercise of the powers conferred by Article 8, paragraphs e) and f) of Decree No. 1,585 of December 19, 1996, replaced by its similar No. 825 of June 10, 2010.

Therefore,

THE PRESIDENT OF THE NATIONAL AGRICULTURAL HEALTH AND QUALITY SERVICE

RESOLVES:

ARTICLE 1.- Prohibition. The elaboration, distribution, importation, use and possession of veterinary products that contain the active ingredient Colistin and its salts are prohibited in the entire National Territory.

ARTICLE 2.- Term. The prohibition established in the preceding article shall take effect from ONE HUNDRED EIGHTY (180) calendar days counted from the effective date of this resolution.

ARTICLE 3.- Cancellation. Once the period established in the preceding article has been met, all the Certificates of Use and Marketing of veterinary products that contain Colistina and its salts in its formulation will be canceled.

ARTICLE 4.- Incorporation. The present resolution is incorporated into Book Three, Part Four, Title II, Chapter I, Section 4, Subsection 4 of the Thematic Index of the Normative Digest of the NATIONAL SERVICE OF HEALTH AND AGRI-FOOD QUALITY, approved by Resolution No. 401 of June 14, 2010 and its complementary N ° 913 of December 22, 2010, both of the aforementioned National Service.

ARTICLE 5.- Validity. This resolution is effective as of the day following its publication in the Official Gazette.

ARTICLE 6. - Communicate, publish, give to the NATIONAL DIRECTORATE OF THE OFFICIAL RECORD and file. Ricardo Luis Negri

and. 01/15/2019 N ° 2100/19 v. 01/15/2019