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SELF-DECLARATION OF CONTINENTAL ECUADOR AS A ZONE HISTORICALLY FREE OF INFECTION FROM THE HIGHLY PATHOGENIC AVIAN INFLUENZA VIRUS IN POULTRY

Declaration sent to the OIE on 10 October 2019 by Ing. Wilson Patricio Almeida Granja, Delegate of the Republic of Ecuador to the OIE and Executive Director of the Phytosanitary and Zoosanitary Regulation and Control Agency.

Continental Ecuador complies with chapter 1.4, article 1.4.6., Numerals 1 and 2a for the self – declaring as free of absence of a disease or infection, in accordance with the provisions of Chapter 1.6 of the Terrestrial Animal Health Code (the Terrestrial Code) and may be declared free of high pathogenic avian influenza in Continental Ecuador as a historically free zone, based on the application of the provisions of articles 10.4.2. and 10.4.4.

I. GENERAL INFORMATION ABOUT CONTINENTAL ECUADOR

Ecuador is located in north-western South America, and is bordered by Colombia to the north, by Peru on its southern and eastern flanks, and to the west by the Pacific Ocean. The Andes mountain range cuts through the country from north to south, dividing the continental territory into three geographic regions: *La Costa* (Coast); *La Sierra* (Highlands), and *El Oriente* (Eastern Region).

The coastal region is located between the Andes Mountains and the Pacific Ocean and consists of seven provinces: Esmeraldas, Santo Domingo de los Tsáchilas, Manabí, El Oro, Guayas, Santa Elena and Los Ríos. The territory is crossed by rivers that run down from the Andes until reaching the Pacific Ocean; it has an average temperature of 25°C, which ranges from 23°C to 36°C, depending on the topography and altitude.

La Sierra is a geographical region that is located within the Andes and is formed by two parallel mountain ranges that run from north to south, which are linked by transverse ridges. This region consists of ten provinces: Carchi, Imbabura, Pichincha, Cotopaxi, Chimborazo, Tungurahua, Bolívar,

Cañar, Azuay and Loja. The average temperature ranges between 7°C and 21°C, which is a characteristic of this region of Ecuador.

El Oriente or eastern region consists of six provinces: Sucumbíos, Orellana, Napo, Pastaza, Morona Santiago and Zamora Chinchipe. The region is demarcated by the Andes to the west, and Peru and Colombia on its southern and eastern flanks, respectively. The average temperature is 23°C.

Description of the Ecuadorian poultry industry

Ecuador contains an average of 1,900 small-, medium- and large-scale poultry farms. The country has an annual production of an estimated 230 to 250 million broiler chickens, with annual per capita consumption of meat between 30 to 32 kilograms. There are also an estimated 14 million laying hens: of this total, 12.5 million are in production with the remaining stock in the growing stage, an activity mainly concentrated in the centre of the country in La Sierra region. Per capita egg consumption is between 160 and 165 units per year. With respect to breeding birds, there are an estimated 2.5 million chickens ranging from light to heavy breeds.

The purpose of this document is to declare continental Ecuador as a zone free from the highly pathogenic avian influenza virus in poultry.

Wildlife

An investigation carried out in 2018 by Universidad Central del Ecuador, through an agreement with the Phytosanitary and Zoosanitary Regulation and Control Agency and the Ministry of the Environment, determined that there was no seropositive presence of certain avian viruses, including avian influenza, with respect to two species of water birds: *Phalacrocorax brasilianus* and *Fulica ardesiaca* (Rivera, 2018)¹, which did not show an immunological response and were found seronegative to Avian influenza (H5N1-H7N3) ([Annex 1](#)).

II. CONTROL MEASURES FOR THE SELF-DECLARATION OF ZONE FREE OF THE HIGHLY PATHOGENIC AVIAN INFLUENZA VIRUS IN POULTRY

The Phytosanitary and Zoosanitary Regulation and Control Agency represents the Official Veterinary Service of Ecuador. It has an organisational structure represented at the central level by governing processes (Executive Management), adjective processes (Support and Advice), and substantive processes, represented by the General Coordination Units (Animal Health, Plant Health, Register of Agricultural Inputs, Food Safety and Laboratories). The aforementioned agency carries out tasks throughout the continental territory in order to implement actions for the prevention, control and eradication of diseases for which official control is exercised. It also implements, monitors and assesses Sanitary Control Programmes in the field. It has 23 district offices distributed as follows: 7 Type A District and Territorial Articulation offices; 10 Type B district offices; and 6 management offices of the Agricultural Health Service. The Animal Health Coordination Unit of the Phytosanitary and Zoosanitary Regulation and Control Agency employs 312 technicians at the countrywide level, of which 27 are based in the central headquarters and 285 technicians in the type A and B district offices, as well as the management offices of the Agricultural Health Service, which are located throughout the country.

¹ Rivera, G.X. (2018). Estimation of the virus seropositivity from: Newcastle, Influenza, Bronquitis y avian inf. Laryngotracheitis in two aquatic species from Yaguarcocha lagoon, 5, 31-37-39

Map 1. Map showing locations of the type A and B district offices, territorial articulation offices, management offices of the agricultural service and agencies.



Source: Type A and B district offices, territorial articulation offices, and agricultural health service management offices.

Prepared by: Animal Health Surveillance Directorate

The Phytosanitary and Zoosanitary Regulation and Control Agency (Agrocalidad), an entity attached to the National Agrarian Authority, is responsible for the regulation and control of animal health and welfare, in order to maintain and improve the phytosanitary and zoosanitary status of agricultural production. ORGANIC LAW OF AGRICULTURAL HEALTH (*LEY ORGANICA DE SANIDAD AGROPECUARIA - LOSA*) Official Gazette 27 of 3 July 2017; In force ([Annex 2](#)).

On 13 July 2011 and through resolution 031, Ecuador adopted the National Avian Influenza Prevention Programme, the general objective of which is to prevent the disease from entering the country. This is carried out through the training given to the Agency's technicians, the taking and processing of serological samples and tracheal and cloacal swabs; serological monitoring and the publication of results. Resolution DAJ-201338E-0201.0071 issued on 10 September 2013 led to the adoption of the National Poultry Health Programme, which identifies health risks and implements the control of diseases that have a high economic impact on the country's poultry sector. This is done by strengthening public and private institutional capacity, institutional organization, sanitary measures to control poultry farms, awareness, promotion and dissemination of the programme, and an information system (the Ecuadorian Animal Health Information System or SIZSE in its Spanish acronym). The programme also includes epidemiological surveillance, disease control, the Best Practices for Poultry Programme, and the registration and control of veterinary products, which is overseen by the Agricultural Input Registry Coordination Unit ([Annex 3](#)).

In 2016, the Agency issued Resolution 0040 of March 24, 2016, which adopted the Contingency Plan for Avian Influenza in Ecuador ([Annex 4](#)), which are the guidelines to be applied by local veterinarians of the *Agency for Regulation and Control of Phyto and Zoosanitary*, and sanitary actions to be established in the stages of emergency, such as: alert phase, suspicion phase, and emergency or confirmation phase which includes control measures to be performed. In order to face a sanitary emergency, a structure must be established that responds to three levels: political-strategic level, strategic level and technical-operational level. The intervention of one or another level in the different activities of the sanitary emergency in any of its stages will depend on the development of each event and there will be mechanisms for the determination. In addition, with the levels of confrontation of the emergency that counts on the strategic political level, strategic level and the operative technical level same that supported the sanitary strategy and delivered the necessary

guidelines. The use of vaccines for the control of Avian Influenza is prohibited in Ecuadorian territory. In addition, Resolution No. 0159, issued on 16 August 2019, which in Article 9 states that vaccination against avian influenza is prohibited in domestic and wild birds in Ecuador ([Annex 5](#)).

Resolution 038 of the Phytosanitary and Zoosanitary Regulation and Control Agency also provides for the monitoring of registered wildlife holdings and management centres, given the importance of information regarding the health status of wild animals and any domestic animals that may interact with them, with the purpose of establishing adequate plans for the control of diseases that can affect the health of the animals contained in such establishments, as well as those animals located in their surroundings: this is carried out through a registry of these types of establishments ([Annex 6](#)).

III. SURVEILLANCE OF HIGHLY PATHOGENIC AVIAN INFLUENZA TO CONFIRM THE STATUS OF ABSENCE OF THE DISEASE

Early warning system

In Ecuador, low pathogenic avian influenza (LPAI), and highly pathogenic avian influenza (HPAI) viruses are subject to permanent surveillance, and notification of disease outbreaks is mandatory, as set down in Resolution 0214², Article 31 of the Organic Law of Agricultural Health (LOSA in its Spanish acronym). Thus, all natural or legal persons must inform the Phytosanitary and Zoosanitary Regulation and Control Agency so that the complete response protocol can be deployed ([Annex 2](#)).

Awareness Programme

The Phytosanitary and Zoosanitary Regulation and Control Agency runs a programme that encourages the notification and reporting of suspected cases of avian influenza throughout the country. This consists in strengthening the capacity of farm owners to detect health problems, for which purpose they receive permanent training on how to detect clinical symptoms and also the mortality and morbidity of poultry when avian influenza is suspected. Once training is completed, the owner of the farm is referred to as a *sensor sanitario* (health sentinel) and is registered for this purpose in the Ecuadorian Animal Health Information System (SIZSE).

Diagnosis of highly pathogenic avian influenza

The Agency's Animal Diagnostic Laboratory is the only one in charge of carrying out the diagnostic tests, which is formed by the laboratories of Virology, Microbiology, Serology, Pathology, Animal Molecular Biology, Vaccine Quality Control Laboratory, Parasitology, Biotherium, Cell Culture, and Reproductive Material Laboratory; whose diagnostic work is framed in the national health programs, epidemiological surveillance and control activities, quarantine and attention to users in general.

The laboratory performs competitive ELISA test as screening, the positive samples to this test are analyzed for subtyping of Influenza A (H5 and H7) using the Hemagglutination Inhibition (HI) technique. In the event that the samples are positive for HI, they are tested by real-time (RT-PCR) as a confirmatory test.

² [Resolution No. 0214](#)

Passive Surveillance

The Animal Health Epidemiological Surveillance System provides information at the national, regional and local level regarding the presence and evolution of diseases that require obligatory notification, such as avian influenza. The latter is an exotic disease to the country, and the purpose is to implement immediate preventive and control measures in the case of a first occurrence. The strategies and actions to be carried out during the response to a sanitary emergency are defined in three phases: alert phase, suspicion phase and confirmation phase.

Passive surveillance consists in notification by the farm owner of sick poultry that show clinical signs compatible with Avian Influenza and also when mortality exceeds 0.5% for two consecutive days. All notifications are processed at any office of the Phytosanitary and Zoosanitary Regulation and Control Agency, which are distributed throughout continental Ecuador in all of the country's provinces (see Map 1), and whose personnel include veterinary professionals along with animal husbandry and agricultural engineers.

Once a health alert has been received, a veterinarian will visit the farm within 24 hours and undertake an examination and clinical observation of the suspected sick birds; and will also gather epidemiological information regarding the incident. For the latter purpose, a poultry health incident reporting form is used to record all information concerning geographical location, a description of the animal population, sampling and a geographical coordination chronology, etc. The incident is thus registered from the initial notification until it is considered concluded. If the suspected case requires serological or swab samples to be taken, this is carried out according to existing protocols for the extraction of such samples. These are then sent as rapidly as possible to the Agency's laboratory, in accordance with the maintenance standards established in the manual for transporting samples.

Once the laboratory results have been received, both the veterinarian in the affected territory and his or her counterpart at the central level, will undertake an epidemiological analysis of the information recorded in the Animal Health Information System (SIZSE) for poultry health incidents, which also includes the results of laboratory tests to determine the definitive diagnosis. In the case of the sample results being positive, a contingency plan immediately enters into force, and if they are negative the incident is concluded with further laboratory tests for other prevalent diseases. Quarantine measures continue until the incident is considered over.

The epidemiological surveillance system received 18 suspected notifications of avian diseases during the period July 2018 to July 2019, the details of which can be found in ([Annex 7](#)).

Active surveillance of Avian Influenza in poultry

The Animal Health Regulation and Control Agency - AGROCALIDAD, dated December 3, 2013 issues resolution DAJ-20134B3-0201.0242 in which Article 1 states "Adopt the "Instruction for Animal Health Inspection in Livestock Fairs", which aims to establish the control of the health status of animals, products and by-products of animal origin, in order to prevent the occurrence and spread of exotic diseases and maintain the health status, protecting the national livestock heritage.

In section "C" "CLINICAL INSPECTION OF ANIMALS", mentions the clinical signs that must be considered in the poultry species compatible with visible diseases such as: nasal secretion, diarrhoea, nervous problems, swollen head, cough, purple crest, chin or leg and animal in poor condition.

Since 2012, the Animal and Plant Health Regulation and Control Agency has implemented an active surveillance program to carry out serological monitoring of avian influenza virus in the susceptible poultry population at the national level. Serological surveillance is carried out in industrial poultry farms (more than 100 birds) for broilers, layer birds and breeding birds. Monitoring is carried out prior to the elaboration of an epidemiological design; in all cases the studies are cross-sectional with probabilistic sampling design; in 2012 4725 birds were sampled in 189 industrial poultry farms; in 2014 there were 3250 birds in 130 farms; in 2016 there were 4000 birds in 160 farms. In 2017, active surveillance was carried out in backyard premises (less than 100 animals) close to industrial farms. A total of 1595 birds were sampled in 319 backyard premises. In the 4 serological monitoring carried out in the country, a total of 13570 birds were sampled in 798 farms, of which 142 birds were positive for competitive ELISA, but negative to HI (H5 and H7) as can be seen in Table No. 1.

Table 1.- Registry of the number of farms and birds sampled through the avian influenza surveillance programme at the countrywide level.

Year	Farms sampled	Birds sampled	Positive birds ELISA	Percentage positive	HI Results
2012	189	4725	2	0.04	NEGATIVE
2014	130	3250	126	3.88	NEGATIVE
2016	160	4000	12	0.30	NEGATIVE
2017	319	1595	2	0.13	NEGATIVE
TOTAL	798	13570	142	1.05	

Source: Animal Health Surveillance Directorate
Prepared by: Animal Health Surveillance Directorate

Sampling design for 2012, 2014 and 2016.

A two-stage stratified sampling design was conducted. The first stage was to determine the number of farms to be sampled. The calculation of the sample size was done independently for the three productive strata: layers, breeders and broilers; in the three years the following was used as parameters for the calculation of the sample:

- Expected prevalence: 5%.
- Desired accuracy: 5%.
- Confidence interval: 95%.

POPULATION IN ECUADOR

System of production	Target population 2016 (establishments)
Breeders	58
Commercial layer hen	310
Broilers	1451
Total	1819

Source: Census 2015.

The second stage was to determine the number of birds to be sampled within the farm. The following parameters were used in the three samplings (2012, 2014 and 2016):

- - Expected prevalence: 5%.
- - Desired accuracy: 10%.
- - Confidence interval: 95%.
- - Sensitivity: 95%.
- - Specificity: 97.7%.

With an infinite population, it was necessary to sample 24 birds per farm, rounded to 25.

Sample design 2017

Two backyard premises (closer to the industrial farm sampled in 2016) were selected and 5 birds in each premise were sampled. There is no census of the total number of backyard birds in the country.

It is concluded that there is no evidence of circulation of avian influenza virus in poultry in continental Ecuador, under the premises from which it was based in the different studies.

IV. MEASURES TO MAINTAIN THE STATUS OF ABSENCE OF THE HIGHLY PATHOGENIC AVIAN INFLUENZA VIRUS

Authorisation permits to import animals, products and by-products of avian origin are issued taking into account the sanitary status of the country of origin. This process includes the mandatory application of Resolution 115 of the Phytosanitary and Zoosanitary Regulation and Control Agency, which establishes the procedure for *"Enabling companies and their foreign establishments that wish to export livestock goods to Ecuador"*. This information allows us to determine the sanitary situation of the country of origin according to animal species, through the information set down in Annex 1 of resolution 115. The process then continues with the revision of Annex 2 of resolution 115), where information is gathered concerning the export company.

After compliance with Resolution 115, the process continues with the ascertaining of the sanitary requirements of the Official Veterinary Service of the country of origin and, if necessary, the preparation of an inspection visit to said country. These established mitigation measures are based on the guidelines of the World Organisation for Animal Health - OIE ([Annex 8](#)).

Galapagos Islands are considered a biosphere reserve, whose productive characteristics do not make trade towards Continental Ecuador possible, but only for internal consumption between Galapagos' islands. However, AGROCALIDAD and the Agency for the Regulation and Control of Biosafety and Quarantine for Galapagos - ABG have established quarantine inspection and control systems, which implements procedures based on national and international regulations. If there is an interest from the islands to trade with Ecuador Continental, the process is done as if it were an independent country, i.e. establishing sanitary requirements.

The Galapagos Islands are under the regulation of the Agency for the Regulation and Control of Biosafety and Quarantine for Galapagos - ABG, which, through Resolution No. D-ABG-004-07-2013 (<http://bioseguridadgalapagos.gob.ec/lista-de-productos-2/>) establishes the general rules and specific requirements that must be met by the products, by-products and derivatives of animal and plant origin that are transported to the province of Galapagos. Live animals, which are highly dangerous and can transport diseases, are considered as "Not Allowed Products", except those that are transported by institutions with the authorisation of the Directory of the ABG because of the different animal health situation to that of Ecuador Continental; animal health requirements must be met, under the agreement between AGROCALIDAD and the ABG.

Contingency Plan

In 2016, the Agency issued Resolution 0040, which provides for the adoption of a Contingency Plan for avian influenza in continental Ecuador, and the guidelines to be applied by veterinarians at the local offices of the Phytosanitary and Zoosanitary Regulation and Control Agency, which also include the health interventions based on the emergency care phases as follows: alert phase, suspicion phase and emergency or confirmation phase, which also includes the control measures to be implemented ([Annex 4](#)).

V. CONTROL MEASURES FOR THE IMPORT OF LIVESTOCK GOODS

Ecuador, as a member of the countries that are part of the World Organization for Animal Health - OIE, for imports, requires compliance with the three conditions mentioned in Article 10.4.5 of the *Terrestrial Code*; for by-products derived from meat, it requires compliance with a temperature and time procedure contemplated in the procedures for the inactivation of avian influenza viruses in meat according to Chapter 10.4.26 of the *Terrestrial Code*.

All imports of livestock goods must be inspected at quarantine control points when entering the country (seaports, airports and border crossings) in accordance with the procedures established in the *“Manual of procedures for the inspection of live animals, products and by-products of origin animal in quarantine checkpoints (seaports, airports and border posts) and at internal checkpoints”*. This procedure allows us to implement quarantine measures for the protection of the country's animal health status.

Imported birds, as well as genetic material of avian origin, enter a quarantine monitoring process, which is regulated in the *“Manual of procedures for quarantine monitoring of animals of the species: bovine, equine, caprine, sheep, swine, adult birds, day old chicks, live lagomorphs, exotic birds and genetic material (semen, embryos and fertile eggs) imported into the country”*; on a farm enabled for this purpose, which meets the requirements of the "Procedure manual for the registration and certification of land used for quarantine purposes", during which time there are technical visits to observe animals or imported genetic material, as well as for taking and sending samples for diagnosis in the official laboratory ([Annexes 9, 10](#)).

When outbreaks of highly pathogenic avian influenza occur in the country of origin of the livestock goods that are to be imported into continental Ecuador, the Phytosanitary and Zoosanitary Regulation and Control Agency applies sanitary measures that can range from the suspension of imports from the affected country or zone, to the suspension of imports, for example as in the following:

Resolution 013 dated 11 March 2013, suspending the importation of live animals, genetic material of avian origin and other products of risk that may transmit the H7N3 virus causing highly pathogenic avian influenza, from the United States of Mexico. In force ([Annex 11](#)).

Resolution 0104 of 16 May 2016, for the United States of America, whereby it is determined that in order to proceed with the commercial exchange, the certificate of origin of the merchandise must be attached to the supporting documents, which must indicate the county and state of location of the exporting farm. In force ([Annex 12](#)).

Resolution 004 of 27 January 2017, which temporarily prohibits the entry into Ecuador of live birds, adults, genetic material of avian origin (day old chicks and fertile eggs) and products that originate from the Republic of Chile, which are susceptible to transmitting the avian influenza virus. Not in

force ([Annex 13](#)). Resolution 0107 dated 14 August 2017, which repeals Resolution 004 for Chile, but indicates that to proceed with the commercial exchange, the application of Resolution 217 issued by Agrocalidad on 15 September 2016 must continue to be applied, which establishes the procedure for “Enabling companies and their foreign establishments that wish to export livestock goods to Ecuador”. In force ([Annex 14](#)).

The Phytosanitary and Zoosanitary Regulation and Control Agency permanently monitors the notification and conclusion of outbreaks of low and highly pathogenic avian influenza according to OIE updates and the Official Veterinary Services of the affected countries, until such outbreaks of avian influenza have ended.

VI. CONCLUSION

Taking into account that:

- After performing laboratory studies, the causative agent of highly pathogenic avian influenza in poultry in continental Ecuador has not been diagnosed.
- Ecuador Continental can be declared as a highly pathogenic avian influenza free zone, according Chapters 1.6 and 10.4. of the *Terrestrial Code*.
- The national epidemiological surveillance and diagnostic systems have the capacity to detect in a timely manner any suspected cases of the disease by means of mandatory notification, its confirmation through laboratory diagnosis, allowing for the timely application of animal health control measures.
- The Phytosanitary and Zoosanitary Regulation and Control Agency has implemented the necessary measures so that animals and products imported into the country do not represent a significant risk for the introduction of highly pathogenic avian influenza.

The OIE Delegate of Ecuador declares that the continental part of the country, fulfills the requirements for a free zone from highly pathogenic avian influenza in poultry as of 01 August 2019, in compliance with Chapter 1.6 and 10.4 and Article 1.4.6. (point 2a and 2b) of the OIE *Terrestrial Code* (2019) and in accordance with the information provided in WAHIS.”