Ref. Ares(2024)3088359 - 26/04/2024

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/1113/2023 ANNEX
(POOL(G2/2023/1113/1113-EN
ANNEX.docx)
[…](2024) XXX draft

ANNEXES 1 to 2

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for approval and recognition of disease-free status of compartments keeping terrestrial animals

ANNEX I

REQUIREMENTS FOR THE APPROVAL OF DISEASE-FREE STATUS FOR CATEGORY A DISEASES OF COMPARTMENTS KEEPING TERRESTRIAL ANIMALS

Part I
Compartment manager

The compartment manager referred to in Article 3(2) shall:

(a) supervise and monitor the activities of the compartment in relation to its health status;

(b) compile the necessary documentation for the application by the operator for approval of the disease-free status of the compartment as referred to in Article 4;

(c) ensure that the compartment complies with the following requirements:

  (i) the common biosecurity management system is in place, which includes each biosecurity plan of the establishments forming part of the compartment;

  (ii) movements of animal and animal products into, within and out of the compartment can be traced;

  (iii) surveillance (including a surveillance plan, an early warning system, sampling schemes, and adaptation of the surveillance plan to the risk of introduction of disease and to the analysis of laboratory results) demonstrates the continuous absence of the category A disease(s) for which an application for approval of the disease-free status of the compartment has been made;

  (iv) training maintains the necessary competences of the personnel of the compartment for the implementation of the biosecurity measures;

  (v) communication is carried out for the awareness of all involved parties to the risk of introduction of the category A disease(s) for which an application for approval of the disease-free status of the compartment has been made;

(d) ensure regular internal audits by trained personnel, and at least once a year external audits by a contracted third party, to verify compliance with the requirements listed in point (c);

(e) be responsible for validating or refusing the reports of the audits referred to in point (d);

(f) keep the reports of the audits referred to in point (e) available to the competent authority;

(g) ensure that immediate action is taken to correct any non-compliance with the requirements listed in point (c) revealed by the audits referred to in point (d) or by official controls, and keep records of the corrective actions and the verification of their implementation and effectiveness;

(h) keep disease surveillance and biosecurity information and documentation up-to-date, and make them available to the competent authority on request;

(i) inform the competent authority of animal health events, functioning problems, biosecurity breaches, modifications of establishments or of biosecurity or surveillance plans, or any other matter that might affect the approval of the compartment.

Part II
Common biosecurity management system of a compartment

The common biosecurity management system of a compartment as referred to in Article 3(2), point (b), shall include at least the following elements:

(a) a description of the general animal health and biosecurity measures applied as provided for in Article 10 of Regulation 2016/429, which shall include at least the following:

  (i) written procedures for good animal husbandry;

  (ii) physical protection measures of all establishments forming part of the compartment and other compartment components, adapted to their situation and their relations with one another;

  (iii) general measures applied to minimise the risk of the introduction and spread of diseases, adapted to the species and categories of kept terrestrial animals, to the products and to the type of production;

  (iv) specific management measures to avoid the entry, establishment and spread into, within and from the compartment, of the category A disease(s) for which an application for approval of disease-free status of the compartment has been made;

(b) a training plan for the animal professionals and other personnel of the compartment to have the necessary knowledge of animal health, especially in relation with the category A disease(s) for which an application for approval of the disease-free status of the compartment has been made;

(c) awareness activities, which shall include all involved parties;

(d) a documented implementation system of a plan for staff hygiene, including general and specific hygienic practices, general and specific training for permanent and temporary staff and the procedure for control of that hygiene plan;

(e) a risk analysis for each of the category A diseases for which an application for approval of the disease-free status of the compartment has been made, and the related terrestrial animal species and categories, which shall be documented and available to the competent authority, and shall:

  (i) include the identification of the agents of those category A diseases, the assessment of the risk of their entry, establishment and spread in the compartment, the measures to reduce the risk, and the risk communication among all involved parties;

  (ii) consider internal and external risks; the risks shall be regularly re-assessed, especially external risks when outbreaks of one or more of those category A diseases occur in the Member State where compartment components are located;

  (iii) take into consideration identified pathways and risk factors related to those category A diseases;

  (iv) propose risk management options that are adaptable to the level of risk and describe actions to be taken in the case of increased risk, such as an enhanced level of confinement or a higher frequency of sampling;

(f) a traceability system able to follow the movements of the animals of the compartment during all stages of their life within the compartment, and document all the movements of these animals and their products between the establishments forming part of the compartment, as well as their place of origin when entering the compartment and their destination when leaving the compartment;

(g) a documentation system for all inputs and outputs of goods and services from and to each compartment component;

(h) the specific biosecurity plans of the establishments forming part of the compartment, with an evaluation of their implementation and effectiveness against the category A disease(s) for which the application for approval of the disease-free status has been made; the biosecurity plans shall be updated taking account of the assessed risks referred to in point (e), and shall indicate whether vaccination against the category A disease(s) for which the application for approval of the disease-free status has been made is carried out or not, with a description of the related vaccination schemes;

(i) a plan regulating and recording the movements of any person entering or leaving the establishments forming part of the compartment, distinguishing authorised and non-authorised persons or visitors, including a description of the physical barriers that clearly define the perimeters of the premises of those establishments, signs, locked gates and entrances to buildings; external visitors, including auditors or inspectors, must not have had any contact with animals susceptible to the category A disease(s) for which an application for approval of the disease-free status has been made, for a defined period of time before entering one of those establishments;

(j) a plan regulating and recording the movements of any vehicles into, out of or between the establishments forming part of the compartment, including private and delivery vehicles for animals, feed, equipment or other supplies;

(k) a description of all critical points and possible breaches in biosecurity, and whether a particular breach is to be considered as a minor or major breach;

(l) a description of the corrective actions to be taken, and the measures to assess the implementation of the corrective actions;

(m) the procedures to inform the competent authority of animal health events, functioning problems, biosecurity breaches, modifications of compartment components or plans, or any other matter that might affect the approval of the disease-free status of the compartment.

Part III
Description of a compartment

In addition to the information required by Article 96(1) of Regulation (EU) 2016/429 for establishments, applications for approval of disease-free status as referred to in Article 4 of this Regulation shall include the following information:

(a) the name of the compartment manager, the compartment manager's qualifications and position, contact details and the address of the compartment;

(b) a detailed description of the compartment including all its components, including the following:

  (i) site map(s) showing the compartment demarcations and the precise location of all the establishments forming part or the compartment and other compartment components;

  (ii) a flow chart clearly indicating in detail all activities carried out in the compartment, and the responsibilities, roles and interrelations of all involved parties;

  (iii) the functional interactions between the establishments forming part of the compartment, and between those establishments and other compartment components, including a diagram of all premises showing their links to one another;

  (iv) the means of transport for terrestrial animals and products belonging to the compartment, their usual routes, and cleaning and parking places;

(c) a description of the common biosecurity management system;

(d) the biosecurity plans of all the establishments forming part of the compartment;

(e) the category A disease(s) for which an application for approval of the disease-free status of the compartment has been made, and detailed information on the specific measures, criteria and requirements for risk-based disease surveillance intended to demonstrate the disease-free status of the compartment;

(f) results of the surveillance demonstrating the absence of the category A disease(s) referred to in point (e) for a period of at least the preceding six months prior to the date of the application for approval of the disease-free status.

ANNEX II

SPECIFIC REQUIREMENTS FOR THE APPROVAL OF DISEASE-FREE STATUS FOR HPAI OR NDV OF POULTRY COMPARTMENTS

Part I

SECTION 1

DETAILED DESCRIPTION OF THE POULTRY COMPARTMENT TO BE INCLUDED IN THE APPLICATION

1. The description of the compartment as provided for in Part III of Annex I shall contain details of the types of poultry establishments forming part of the compartment, as well as of the feed processing or storage facilities, other material storage facilities, slaughterhouses and processing plants and any other plants that may contain poultry, poultry products and poultry by-products.

2. In addition, the application for approval of the disease-free status of a poultry compartment shall include at least the following:

   (a) information on the infrastructural and functional factors and their contribution to an epidemiological separation between the poultry in the compartment and animal populations with a different health status, which must include a description of the type of activity and the products or other commodities produced in the compartment, including the total capacities of the compartment;

   (b) information on the epidemiological aspects and the risk factors regarding HPAI or NDV, including at least the following elements:

      (i) the health status of the establishments forming part of the poultry compartment for the preceding 12 months, and in particular any information in relation to HPAI or NDV;

      (ii) the allowed movements into, out of, or within the poultry compartment (inputs and outputs), of persons, products or other commodities, birds or bird products or other animals, products of animal origin or other products in contact with animals, transport vehicles, equipment, animal feed, water supply and drainage;

      (iii) poultry or captive birds establishments outside the poultry compartment that may affect the health status of the poultry compartment because of their proximity to one or more of the compartment components; the risk factors shall also be evaluated in relation with the type of those establishments, non-commercial establishments, markets, assembly centres, slaughterhouses, zoos or other premises containing captive birds;

      (iv) the environmental risk factors such as waterways, wildlife resting and mixing places, including migratory routes of wild birds, the presence of rodents or other pests, and the occurrence in the preceding 12 months of HPAI or NDV in the vicinity of any of the poultry compartment components;

      (v) the specific risk factors and pathways for the entry and spread of HPAI or NDV in the poultry compartment;

   (c) information on the early warning system in place to detect HPAI or NDV and to inform the competent authority of findings of risk factors and pathways as referred to in point (b).

SECTION 2

COMMON BIOSECURITY MANAGEMENT SYSTEM OF A POULTRY COMPARTMENT

1. In addition to the elements set out in Part II of Annex I, under the common biosecurity management system, the specific biosecurity plans of each of the poultry establishments forming part of a poultry compartment shall include at least the following:

   (a) a rule that the personnel of the poultry compartment shall:

      (i) not personally keep poultry or captive birds;

      (ii) not have close contact with birds other than those of the poultry compartment for a period of at least 72 hours before entering an establishment; however, a shorter period may be required in the case of the urgent need of specific staff, but it shall in no event be less than 24 hours and the procedure mitigating the risk shall be described in the biosecurity plan;

   (b) a rule that external visitors, including auditors or inspectors, must not have had any contact with birds for a period of at least 48 hours before entering the establishment; however, a longer period may be required depending on risk factors, especially for visitors coming from a restricted zone; and a shorter period may be required for official veterinarians or in the case of urgent need of external specific intervention, such as a consultant or veterinarian, in which case the procedure mitigating the risk shall be described in the biosecurity plan;

   (c) the flows of products and personnel, described on a diagram of all the premises of the establishment with colour-coded levels of biosecurity; there shall be hygiene barriers with changing zones, including where appropriate showers, with separated clean and dirty areas at all entry points to the premises;

   (d) a specific procedure to prevent contamination of poultry, including contamination through the supply, transportation, storage, delivery and disposal of:

      (i) packing materials, including at least the use of new or disinfected packing materials;

      (ii) bedding materials, including at least an appropriate storage quarantine time or a disinfection of bedding materials;

      (iii) feed, including the use of enclosed systems of feed;

      (iv) water, including an internal water treatment system;

      (v) animal by-products, including carcases, eggs containing dead embryos and manure;

   (e) a cleaning and disinfection plan of the establishment, including equipment and materials used; a specific protocol for vehicle cleaning and disinfection shall be available;

   (f) a pest control plan, including rodents and other wild animals, providing for physical barriers and measures in the case of findings of their activity;

   (g) a critical control points plan, relating to HPAI or NDV, which shall include at least the following elements, ongoing and for the preceding six months:

(i) data on the production, data on morbidity and mortality, details of medications used, and data relating to animal feed and water consumption;

(ii) information relating to the clinical checks and sampling plans for active and passive surveillance and screening analyses, including frequencies, methods and results;

(iii) a register of visitors to the establishment, in sufficient detail to be able to trace and contact any visitor;

(iv) information concerning any vaccination programmes applied, including the type of vaccine used and the frequency and dates of administration;

(v) detailed information records on the related critical control points not complied with, and the corrective actions performed.

2. The specific biosecurity plans of the establishments forming part of a poultry compartment shall be updated in accordance with Part II, point (h), of Annex I, in particular where an outbreak of HPAI or NDV is officially suspected or confirmed in the Member State or in the area where one or more of the compartment components are situated.

Part II

SECTION 1
SPECIFIC PROTECTION AND SURVEILLANCE MEASURES FOR HPAI

1. All the establishments forming part of the poultry compartment shall be approved in accordance with Article 3(1), point (c)(i), of this Regulation, and comply with the requirements for granting approval of hatcheries laid down in Article 7 of Commission Delegated Regulation EU 2019/2035[1] or the requirements for granting approval of establishments keeping poultry laid down in Article 8 thereof. In addition, the following requirements shall be complied with:

   (a) the diagram referred to in Part III, point (b)(iii), of Annex I to this Regulation shall indicate the location of the establishments keeping all types of poultry, as well as hatcheries, rearing sites, laying sites, trial sites, egg stores and all places where eggs or poultry are kept; it shall indicate the flows of products and other commodities between those locations;

   (b) a detailed procedure shall regulate the movements of poultry, their eggs and other related products; poultry, their eggs and other related products entering any establishment forming part of the poultry compartment shall come from an establishment having a disease-free status as regards HPAI and be checked to ensure that they present no risk of introduction of HPAI;

   (c) poultry and hatching eggs moved into or within the poultry compartment shall be identified in such a way that they can be traced, and be accompanied with the proper documented identification;

   (d) in the case of a multi-age site or in other cases where poultry are added at different times of the life span of poultry, a written procedure shall describe the addition and removal of poultry, including the cleaning and disinfection of catching crates and reusable transport boxes.

2. The surveillance referred to in Part I, point (c)(iii), of Annex I, shall be established under the responsibility of the compartment manager, and shall include continuous passive and active surveillance to demonstrate the absence of infection in all establishments forming part of the poultry compartment. In addition, the following requirements shall be complied with:

   (a) the passive surveillance shall contain clinical indicators and describe related follow-up investigations, including sampling for laboratory testing;

   (b) the active surveillance shall contain testing carried out on a defined number of samples taken from birds of each establishment, or epidemiological unit if more than one per establishment, providing at least a 95% level of confidence to detect the infection at a target prevalence rate of 5%:

[1] Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115, ELI: https://eur-lex.europa.eu/eli/reg_del/2019/2035/oj/eng).

(i) at least every six months during the production period, where no outbreaks of HPAI in poultry or other captive birds, have been confirmed during the preceding six months in the territory of the Member State;

(ii) at least every three months where an outbreak of HPAI in poultry or other captive birds, has been confirmed during the preceding six months in the territory of the Member State;

(iii) when any component of the poultry compartment is located within a restricted zone due to an outbreak of HPAI, within one week following the date of the outbreak and at least every 28 days thereafter; in addition, the surveillance shall be updated to include daily clinical examination as well as samples taken weekly on a representative number of birds sick or found dead, for molecular virological testing.

(c) The samples shall be sent to a laboratory designated in accordance with Article 37 of Regulation (EU) 2017/625 of the European Parliament and of the Council[2] by the competent authority to carry out the tests, taking into account the vaccination status of the birds and the types of vaccines used.

3. The early warning system referred to in Section 1, point 2(c), of Part I, shall be based upon a written protocol that specifies the reporting procedures. It shall be adapted to the species of poultry present in the compartment and their susceptibility to HPAI, and it shall:

(a) prescribe action levels based on results and defined thresholds of the passive and active surveillance described in point 2;

(b) describe the actions to be taken;

(c) include a list of the responsible personnel to be notified.

4. Documentation referred to in Part I, point (h), of Annex I shall:

(a) be retained for a minimum period of three years;

(b) contain the results of the disease surveillance, which shall be reported to the competent authority:

(i) every three months when an outbreak of HPAI in poultry or captive birds has been confirmed during the preceding six months in the territory of the Member State;

(ii) every 28 days when any compartment component is located within a restricted zone due to an outbreak of HPAI.

SECTION 2

SPECIFIC PROTECTION AND SURVEILLANCE MEASURES FOR NDV

1. All the establishments forming part of the poultry compartment shall be approved in accordance with Article 3(1), point (c), of this Regulation and comply with the requirements for granting approval of hatcheries laid down in Article 7 of Delegated

[2] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (OJ L 95, 7.4.2017, p. 1–142, ELI: https://eur-lex.europa.eu/eli/reg/2017/625/oj).

Regulation EU 2019/2035 or the requirements for granting approval of establishments keeping poultry laid down in Article 8, thereof. In addition:

(a) the diagram referred to in Part III, point (b)(iii), of Annex I to this Regulation, shall indicate the location of the establishments keeping all types of poultry, as well as hatcheries, rearing sites, laying sites, trial sites, egg stores and all places where eggs or poultry are kept; it shall indicate the flows of products and other commodities between those locations;

(b) a detailed procedure shall regulate the movements of poultry, their eggs and other related products; poultry, their eggs and other related products entering any establishment forming part of the poultry compartment shall come from an establishment where there are no outbreaks or restrictions due to outbreaks of NDV and be checked to ensure that they present no risk of introduction of NDV;

(c) poultry and hatching eggs moved into or within the poultry compartment shall be identified in such a way that they can be traced, and be accompanied with the proper documented identification;

(d) in the case of a multi-age site or in other cases where poultry are added at different times of the life span of poultry, a written procedure shall describe the addition and removal of poultry, including the cleaning and disinfection of catching crates and reusable transport boxes.

2. The surveillance referred to in Part I, point (c)(iii), of Annex I shall be established under the responsibility of the compartment manager and shall include continuous passive and active surveillance to demonstrate absence of infection in all establishments forming part of the poultry compartment:

(a) the passive surveillance shall contain clinical indicators and describe related follow-up investigation, including sampling for laboratory testing;

(b) the active surveillance shall contain testing carried out on a defined number of samples taken from birds of each establishment, or epidemiological unit if more than one per establishment, providing at least a 95% level of confidence to detect the infection at a target prevalence rate of 5%:

(i) at least every six months during the production period, where no outbreaks of NDV in poultry or other captive birds, have been confirmed during the preceding six months in the territory of the Member State;

(ii) at least every three months where an outbreak of NDV in poultry or other captive birds, has been confirmed during the preceding six months in the territory of the Member State;

(iii) when any component of the poultry compartment is located within a restricted zone due to an outbreak of NDV within one week following the date of the outbreak and at least every 28 days thereafter; in addition, the surveillance shall be updated to include daily clinical examination as well as samples taken weekly on a representative number of birds sick or found dead for molecular virological testing;

(c) The samples shall be sent to a laboratory designated in accordance with Article 37 of Regulation (EU) 2017/625 by the competent authority to carry out the tests, taking into account the vaccination status of the birds and the types of vaccines used.

3. The early warning system referred to in Section 1, point 2(c), of Part I, shall be based upon a written protocol that specifies the reporting procedures. It shall be adapted to the species of poultry present in the poultry compartment and their susceptibility to NDV, and it shall:

   (a) prescribe action levels, based on results and defined thresholds of the passive and active surveillance described in point 2;

   (b) describe the actions to be taken;

   (c) include a list of the responsible personnel to be notified.

4. Documentation referred to in Part I, point (h), of Annex I shall:

   (a) be retained for a minimum period of three years;

   (b) contain the results of the disease surveillance, which shall be reported to the competent authority:

      (i) every three months when an outbreak of NDV in poultry or captive birds, has been confirmed during the preceding six months in the territory of the Member State;

      (ii) every 28 days when any compartment component is located within a restricted zone due to an outbreak of NDV.