Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2020/689

of 17 December 2019

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law[(1)]'), and in particular Article 29, Article 31(5), 32(2), 37(5), Article 39, Article 41(3), Article 42(6) and Article 280(4) thereof,

Whereas:

(1) The Animal Health Law lays down rules for the prevention and control of animal diseases transmissible to animals or to humans. The rules laid down in this Regulation are required to supplement those laid down in Chapters 2, 3 and 4 of Part II of the Animal Health Law on surveillance, eradication programmes and disease-free status, as well as those in Part IX on transitional arrangements concerning existing surveillance or eradication programmes and existing disease-free status.

(2) These rules are substantially linked with many intended to be applied together. In the interest of simplicity and transparency, as well as to facilitate their application and avoid a multiplication of rules, they should therefore be laid down in a single act rather than in a number of separate acts with many cross-references and the risk of duplication.

(3) Indeed, surveillance represents an intrinsic part of any eradication programme and disease-free status is in most cases an outcome of a successful surveillance and eradication process. Moreover, surveillance is needed, besides other measures, as a key tool for maintaining the disease-free status after its achievement. The rules on surveillance, eradication programmes and disease-free status, including transitional rules, often serve common purposes and refer to complementary activities of operators, veterinarians and competent authorities. Therefore it is appropriate to group together these rules in a single delegated regulation.

(4) Surveillance is a key element of an efficient and effective disease prevention and control policy. It should be implemented jointly by operators and the competent authority. It

should also be designed to meet the objectives of early detection of outbreaks of any listed and emerging disease and to demonstrate compliance with the criteria for the granting, maintaining, suspension or withdrawal of disease-free status.

(5) The competent authority should put in place a basic general surveillance system for listed and emerging diseases of terrestrial animals based on notification and investigations of disease events in targeted animal population.

(6) These general surveillance requirements for terrestrial animals should be complemented by more specific requirements depending on the expected output of surveillance. They should be designed to serve different specific purposes such as Union surveillance programmes, compulsory and optional eradication programmes, demonstration of disease-free status, disease control measures, in the context of the approval of certain establishments and the movements of animals and animal products.

(7) The approach to designing general surveillance requirements for aquatic animals is similar to that for terrestrial animals, although not identical. All aquaculture establishments need to implement a basic surveillance system based on notification and investigation of disease events in a targeted animal population. In addition, surveillance for listed and emerging diseases of aquatic animal needs to incorporate certain disease control measures, when it is necessary to take such measures in aquaculture establishments.

(8) In addition to the general surveillance requirements, which apply to all aquaculture establishments, specific surveillance requirements apply to certain approved aquaculture establishments. These specific measures include implementing a risk-based surveillance scheme based on assessment of the risk that an establishment has of contracting and spreading an aquatic disease, be it listed or non-listed.

(9) The specific surveillance requirements also relate to the implementation of eradication programmes for certain listed diseases in order to obtain disease-free status from that disease and to maintain that status once achieved.

(10) In addition, Member States should be given the possibility to implement surveillance, in the form of ‘surveillance programmes’ for Category C diseases of aquatic animals at establishment level, without opting for a disease eradication programme. Surveillance programmes differ from eradication programmes in that they are based on a system of targeted surveillance which is comprehensive but which does not encompass all the elements of an eradication programme. Unlike eradication programmes, surveillance programmes do not offer the possibility to achieve official disease-free status.

(11) The specific eradication and surveillance programmes set out in this Regulation serve to substantiate health requirements for certain movements of animals and products of animal origin within the Union and in certain cases, of animals and products of animal origin entering the Union.

(12) The Animal Health Law requires rules for listed diseases to apply to listed species. Surveillance may not be relevant for all categories of animals of listed species, in particular as regards wild animals or certain categories of kept animals. Therefore this Regulation should provide rules to specify the relevant targeted animal population for

the purpose of surveillance. It should also be possible to expand the targeted animal population to non-listed kept species to ensure early detection of emerging diseases.

(13) Derogations should also make possible to further limit targeted terrestrial animal populations to specific surveillance purposes, namely: (i) Union surveillance programmes; (ii) compulsory or optional eradication programmes; and (iii) surveillance-based animal health requirements for movements within the Union or for entry into the Union.

(14) Diagnostic methods, together with the subsequent collection of samples to perform them, techniques, validation and interpretation are of a very technical nature and are subject to frequent modifications due to developments in scientific standards. Therefore to ensure that they are up to date, the rules on diagnostic methods should indicate in a flexible manner which methods should be used and how. In the area of animal diseases, there are different possible sources of scientific standards for diagnostic methods. It is therefore important to indicate the hierarchical order in which the methods should be considered, taking into account the general principles of sampling, analyses, tests and diagnoses laid down in Regulation (EU) 2017/625 of the European Parliament and of the Council[(2)].

(15) To ensure optimal use of all resources and to avoid unnecessary administrative burdens and costs for operators and the competent authorities, the detection of listed and emerging diseases should draw on sources of information gathered during official controls and other official activities not primarily intended for the surveillance of those diseases.

(16) The confirmation of a disease according to its case definition is the responsibility of the competent authority; it should be supported by appropriate investigations to confirm or rule out the presence of a suspected disease. Such investigations are relevant where the confirmation of the disease triggers disease control measures, as well as in certain other circumstances depending on the consequences of the confirmation of the disease. It is therefore important that this Regulation should lay down the additional circumstances where the confirmation of the disease is necessary.

(17) The definitions of a suspected case and confirmed case of a listed disease and, where relevant, an emerging disease are of key importance. These enable operators, veterinarians and other stakeholders involved in surveillance to identify circumstances where it is necessary to notify the competent authority and for the competent authority to apply disease control measures. Therefore it is necessary to provide general criteria for the definitions of a suspected case and a confirmed case and to provide, where needed, disease-specific definitions, depending on the specific characteristics of certain diseases.

(18) A Union surveillance programme is a surveillance programme relevant for the Union as a whole. This is necessary in order to achieve greater harmonisation of surveillance of a specific disease across the Union due to its specific public or animal health concerns. Therefore it is necessary to lay down the criteria that diseases eligible for Union surveillance programme should meet.

(19) Commission Decision 2010/367/EU[3] lays down minimal requirements for surveillance programmes for avian influenza in poultry and in wild birds and sets out technical guidelines in its annexes. This Regulation should provide for similar technical guidelines in an annex. However, the level of detail in this Regulation is lower to ensure a good capacity to adapt to changes in the situation as regards surveillance of avian influenza. Therefore the technical requirements for the Union surveillance programme for avian influenza focus exclusively on the objectives, the scope and the methodological principles to follow.

(20) The Animal Health Law sets out rules for the application of compulsory and optional eradication programmes for category B and category C diseases in Member States. These diseases, or groups of them, have their own characteristics. Their eradication should be based on a disease control strategy specific for the disease in question. This should include at least: (i) the surveillance that needs to be performed in order to achieve disease-free status as the ultimate goal; (ii) the timeframe; (iii) a definition of the animal population that is subject to the eradication programme; (iv) the territory in which this eradication programme will apply; and (v) specific disease prevention and control measures that will apply to the disease during the eradication phase.

(21) If the territory in which an eradication programme will be implemented includes the external border of the Member State, the competent authority should make efforts to address the risk of introduction of the disease from outside its borders.

(22) The purpose of an eradication programme is to achieve disease-free status on the territory covered by the programme. Ideally, for terrestrial animals it should cover the whole territory of the Member State where the disease is present. If this is not possible, the minimum area that is acceptable should be defined. The minimum surface of the area should take into account the experience gained through previous eradication programmes and allow for flexibility depending on the specific characteristics of the disease.

(23) The programme's qualitative or quantitative targets should be set by the competent authority. Final targets should be based on the criteria for granting disease-free status, while intermediate targets may also comprise other activities or steps important for achieving the disease-free status, reflecting the evolution of the programme.

(24) The competent authority should determine the period of application of the eradication programmes. In the case of optional eradication programmes for category C diseases, a maximum period of application of the programme is laid down in order to prevent disproportionate and long lasting disruption of movements within the Union. Nevertheless, the competent authority may start the eradication programme before its approval by the Commission but should not implement restrictions to the movements within the Union at that stage. A possibility should also be provided for Member States to request that the Commission extend this period where justified circumstances exist.

(25) The eradication strategy of certain diseases might be based on granting disease-free status at establishment level. The disease-specific measures for such diseases should be grouped and spell out obligations for the operators and for the competent authorities.

(26) The targeted animal population to be included in the disease eradication programme should be set out on a disease-specific basis. The possibility for the competent authority to include in the programme certain additional animal populations should also be set out on a disease-specific basis.

(27) The primary responsibility for obtaining and maintaining the establishment's disease-free status lies with the operator as it is the primary recipient of the benefits linked to the disease-free status. Therefore the operator should comply with certain obligations in order to be granted and maintain disease-free status.

(28) Once the general and disease specific criteria for achieving disease-free status have been met by the operator, it is for the competent authority to grant that status. When these specific criteria are no longer met, it is also for the competent authority to either suspend or withdraw the status.

(29) Moreover, the obligations for operators and competent authorities in the context of eradication programmes should, where necessary, be detailed considering the specific disease profile. The disease-specific requirements are of a technical nature and are set out for each specific disease in annexes to this Regulation.

(30) Commission Implementing Regulation (EU) 2018/1882[(4)] lists infection with *Brucella abortus*, *B. melitensis* and *B. suis* and infection with *Mycobacterium tuberculosis* complex for compulsory eradication programmes and lists enzootic bovine leukosis, infection with Aujeszky's disease virus, infectious bovine rhinotracheitis/infectious pustular vulvovaginitis and bovine viral diarrhoea for optional eradication programmes. For these diseases, eradication programmes should be based on the granting of establishment disease-free status.

(31) Eradication programmes based on granting disease-free status at establishment level should include all establishments keeping animals from the targeted animal population. However, the competent authority should have the possibility to exclude certain specific types of establishments and slaughterhouses from the eradication programme provided appropriate risk mitigating measures are implemented.

(32) In the case of eradication programmes based on granting disease-free status at establishment level, the competent authority should have the possibility to attribute different health status to different epidemiological units.

(33) In the case of terrestrial animals, the requirements to demonstrate disease-free status at establishment level are based on the absence of infection supported by the testing and surveillance regime, by the conditions for introducing animals and germinal products into the establishments and, if necessary, by restrictions on the use of vaccination. When the conditions for maintaining the disease-free status are no longer satisfied, specific requirements apply to suspend, withdraw and restore this status. Due to their technical nature, the disease-specific detailed requirements and the list of diagnostic methods to be used for granting and maintenance of the status are laid down in annexes.

(34) Conditions for granting, maintaining, suspending and withdrawing disease-free status at establishment level were set out in the following Union rules in place before the date of