

Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2020/692

of 30 January 2020

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin

(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 Articles 234(2), 237(4) and 239(2) thereof,

Whereas:

- (1) Union legislation in the area of animal health was recently updated by the adoption of the 'Animal Health Law'. That Regulation, which came into force on 20 April 2016, and which applies from 21 April 2021, repealed and replaced around 40 basic acts. It also requires the adoption of many Commission delegated and implementing regulations to repeal and replace around 400 Commission acts that existed in the area of animal health before the new legal framework established by the 'Animal Health Law'.
- (2) Trading conditions have evolved since the adoption of the first animal health rules at Union level, with the volume of trade in animals, germinal products and products of animal origin increasing significantly, both within the Union and with third countries. During the same period, as a result of Union animal health policies and rules, certain diseases have been eradicated in the Union and other diseases have been prevented or controlled in many Member States. However, on several occasions, emerging diseases have posed new challenges for the Union animal health status, trade and the local economy in the areas affected by those diseases.
- (3) The rules laid down in this act, supplement those already laid down in the 'Animal Health Law'. They should provide the necessary guarantees to ensure that consignments of animals, germinal products and products of animal origin entering the Union do not present an animal health risk for kept and wild animals that could jeopardise the Union

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health status as regards animal diseases and have a detrimental economic impact on the sectors involved.

- (4) Article 234 of the ‘Animal Health Law’ provides that pending the adoption of delegated acts laying down animal health requirements as regards a particular species and category of animal, germinal product or product of animal origin, Member States may, following evaluation of the risks involved, apply national rules if they comply with certain requirements laid down in that Regulation. Therefore, the entry into the Union of species and categories of animals, germinal products and products of animal origin not covered by this Regulation may be subject to such national rules applied by Member States.
- (5) The existing animal health rules, laid down in previous Commission acts concerning the entry into the Union of animals, germinal products and products of animal origin have proved to be effective, therefore the aim and substance of those existing rules should be maintained in this Regulation, but updated to take account of the rules on better regulation, of the new animal health framework laid down in the ‘Animal Health Law’ and of newly available scientific knowledge, international standards and experience in applying previous Union acts.
- (6) To avoid unnecessary trade disruptions, the animal health requirements for entry into the Union of consignments falling within the scope of this Regulation should ensure a smooth transition from the requirements laid down in pre-existing Union acts.
- (7) The ‘Animal Health Law’ lays down rules for the prevention and control of animal diseases transmissible to animals or to humans. In particular, Chapter 1 of Part V of that Regulation, which lays down the animal health requirements for entry into the Union of consignments of animals, germinal products and products of animal origin, provides for the Commission to adopt delegated acts to supplement the animal health requirements already laid down in it.
- (8) Article 229(1) of the ‘Animal Health Law’ lays down the requirements under which Member States are to permit the entry into the Union of consignments of animals, germinal products and products of animal origin. The requirements cover conditions concerning the third country or territory of origin, the establishment of origin, the animal health requirements that those consignments are required to comply with, as well as the animal health certificate, declarations or other document that should accompany such consignments.
- (9) In addition, Article 234(1) of the ‘Animal Health Law’ stipulates that the animal health requirements for entry into the Union of consignments of species and categories of animals, germinal products and products of animal origin from third countries or territories or zones thereof must be at least as stringent as those laid down in that Regulation, and in delegated acts adopted pursuant to it, applicable to movements within the Union of those species and categories of those commodities. If the requirements are not as stringent as those in the Regulation, they must offer equivalent guarantees to the animal health requirements provided for in Part IV of that Regulation.
- (10) Article 234(2) of the ‘Animal Health Law’ provides for delegated acts to be adopted to supplement the rules laid down in that Regulation, as regards the animal health

requirements for entry into the Union of species and categories of animals, germinal products and products of animal origin from third countries and territories, and for the movement within the Union and handling of those commodities after their entry into the Union, in order to mitigate the possible risks involved.

- (11) Article 237(1) of the ‘Animal Health Law’ provides that Member States are only to permit the entry into the Union of consignments of animals, germinal products and products of animal origin if such consignments are accompanied by the animal health certificates and the declarations or other documents required under that Regulation. Article 237(2) of that Regulation stipulates that the animal health certificate must have been verified and signed by an official veterinarian in the third country or territory of origin. In this context, Article 237(4) of the ‘Animal Health Law’ provides for the Commission to adopt delegated acts concerning derogations from the animal health certificate requirements laid down in Article 237(1) and Article 237(2) of that Regulation, and to lay down rules requiring such consignments to be accompanied by declarations or other documents.
- (12) Article 239(2) of the ‘Animal Health Law’ provides for the Commission to adopt delegated acts concerning special rules and additional requirements for certain specific types of entry into the Union of consignments of animals, germinal products and products of animal origin, and provides for derogations from the general animal health requirements laid down in Articles 229(1) and 237(1) of that Regulation, and in the supplementing rules laid down in delegated acts adopted pursuant to Articles 234(2) and 237(4) thereof.
- (13) The supplementing rules to be laid down in this Regulation pursuant to Articles 234(2) and 239(2) of the ‘Animal Health Law’ are interrelated. Article 234(2) provides for the Commission to lay down the general requirements for entry into the Union of consignments of animals, germinal products and products of animal origin, while Article 239(2) provides for the Commission to lay down the special rules and additional requirements for derogations from those general requirements.
- (14) The animal health certificate requirements provided for in Article 237 of the ‘Animal Health Law’ are part of the framework of rules relating to the entry into the Union of consignments of animals, germinal products and products of animal origin. The empowerment granted to the Commission under Article 237(4) of that Regulation to grant derogations from the animal health requirements is part of that general framework of rules.
- (15) The ‘Animal Health Law’ already provides a number of definitions. In addition, this Regulation should also have regard to the definitions laid down in other Union acts in the related areas of food hygiene and official controls, such as the definitions laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council⁽²⁾. However, for the purpose of laying down the animal health requirements for entry into the Union of animals, germinal products and products of animal origin it is appropriate to include particular definitions, including definitions for certain categories of animals, germinal products and products of animal origin. These definitions are needed to clarify which categories of animals, germinal products and products of animal origin represent

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an animal health risk and are therefore subject to the animal health requirements for entry into the Union.

- (16) In the interests of consistency of Union legislation, and based on the animal health risk they represent, the definition for ‘fresh meat’ for the purpose of this Regulation should incorporate the definitions for ‘fresh meat’, ‘minced meat’ and ‘meat preparations’ laid down in Annex I to Regulation (EC) No 853/2004.
- (17) In addition, the definition for ‘meat products’ for the purpose of this Regulation should incorporate the definitions for ‘meat products’, ‘treated stomachs’, ‘bladders’, ‘intestines’, ‘rendered animal fats’ and ‘meat extracts’ laid down in Regulation (EC) No 853/2004. This is because from an animal health point of view, all of those commodities represent the same animal health risk and should be subjected to the same risk-mitigating measures.
- (18) The definition for ‘carcase’ laid down in Regulation (EC) No 853/2004 should be adapted to define ‘carcase of an ungulate’ in order to differentiate it from ‘offal’. This is because those two commodities represent different animal health risks, with ‘offal’ representing a higher risk.
- (19) ‘Casings’ should be defined in this Regulation and that definition should take into account the definition included in the glossary of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE). The definition should clarify which products of animal origin must be considered as casings and therefore undergo the specific risk-mitigating treatments provided for in this Regulation.
- (20) Article 229(1) of the ‘Animal Health Law’ provides that consignments of animals, germinal products and products of animal origin are only to be permitted to enter into the Union if they come from third countries or territories listed for entry into the Union of the particular species and category of animals, germinal products or products of animal origin, in accordance with the criteria laid down in Article 230(1), and if the consignments comply with the animal health requirements provided for in Article 234 and subsequent delegated acts. This Regulation should make it the responsibility of the competent authority to verify that such consignments entering the Union comply with those requirements.
- (21) Article 237(1) the ‘Animal Health Law’ provides that the entry into the Union of consignments of species and categories of animals, germinal products and products of animal origin from third countries or territories is only to be permitted where those consignments are accompanied either by an animal health certificate, issued by the competent authority of the third country or territory, or by declarations or other documents, or by all of those documents. This Regulation should, therefore, clarify which documents are required in each case and should make it the responsibility of the competent authority to verify that such consignments entering the Union comply with that general requirement.
- (22) The information to be contained in the animal health certificates, declarations and other documents accompanying consignments of animals, germinal products and products of animal origin must accurately reflect whether or not those consignments comply with

the general requirements provided for in the ‘Animal Health Law’ and the relevant requirements laid down in this Regulation. This Regulation should, therefore, lay down the obligations for operators responsible for entry into the Union of such consignments and for the competent authorities of the Member State of entry into the Union, as regards the validity of the documents accompanying the consignments and the eligibility of such consignments to enter the Union.

- (23) Taking into account animal health risks such as incubation periods for diseases, and in order to avoid the misuse of animal health certificates, it is necessary to establish a time limit for the validity of those certificates only in the case of animals and hatching eggs. This is because these pose a higher animal health risk than products of animal origin, which may have undergone risk-mitigating measures, and germinal products which are transported frozen in closed and sealed containers. However, as the transport by sea of live animals and hatching eggs may take long time, the validity period of the certificate in this case should be extended provided that certain risk-mitigating measures have been taken.
- (24) The animal health requirements that need to be complied with, and the guarantees to be provided by third countries and territories, for entry into the Union of consignments of animals, germinal products and products of animal origin depend on the diseases listed in Article 5 and in Annex II to the ‘Animal Health Law’ and their categorisation as provided for in Article 9(1) of that Regulation and in the Annex to Commission Implementing Regulation (EU) 2018/1882⁽³⁾. That Regulation lays down the definitions of category A, B, C, D and E diseases and states that the disease prevention and control rules for the listed diseases referred to in Article 9(1) of Regulation (EU) 2016/429 are to be applied to listed species and groups of listed species referred to in its Annex.
- (25) Chapter 1 of Part II of the ‘Animal Health Law’ lays down the rules on disease notification and reporting to ensure early detection and effective disease control in the Union. This Regulation should specify the details on the notification and reporting systems to be in place in the third countries or territories to guarantee equivalent systems to those implemented in the Union, including the diseases that should be notifiable and reportable. In this sense, while live animals can transmit the diseases for which they are a listed species in Implementing Regulation (EU) 2018/1882, not all products of animal origin and germinal products obtained from those animals can transmit all those diseases. This Regulation should clarify which are the animal diseases of concern and therefore notifiable and reportable for each particular species and category of animals, germinal products and products of animal origin intended for entry into the Union.
- (26) The animal health requirements laid down in this Regulation should be based on different levels of protection from the animal health risks. The different requirements vary depending on whether they relate to a third country of origin, to a territory of origin, to a zone within that third country or territory, to a compartment within that third country or territory in the case of aquaculture animals, to the establishment of origin of the animals or the products of animal origin, or to the establishment or centre for collection of germinal products.

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- (27) Disease surveillance and traceability in the establishments are key elements of the disease control policy in the Union. This Regulation should include certain basic requirements on traceability and animal health visits in the establishments of origin of the animals intended for entry into the Union, and in the establishment of origin of the animals from which the germinal products and products of animal origin intended for entry into the Union were obtained. These requirements should be equivalent to those laid down in Regulation (EU) 2016/429, and in delegated and implementing acts adopted pursuant to that Regulation.
- (28) Furthermore, where a certain type of establishment keeping animals or germinal products in a third country or territory poses a particular animal health risk, it should obtain specific approval by the competent authority in the third country or territory in order to export to the Union, providing equivalent guarantees as those provided in Articles 92 to 100 of Regulation (EU) 2016/429 for certain establishments in the Union.
- (29) Consignments of animals, germinal products and products of animal origin intended for entry into the Union should not be considered as representing an animal health risk in their country or territory of origin and should not be subject to national eradication programmes or any other national restrictions based on animal health concerns.
- (30) The animal health requirements for entry into the Union of consignments of animals, germinal products and products of animal origin must provide effective protection against the introduction and spread of transmissible animal diseases in the Union. The entry into the Union of those consignments should not be permitted from third countries or territories or zones or in the case of aquaculture animals, compartments thereof, infected with certain listed diseases for which the Union has disease-free status, and which consequently present a serious risk for the health of animals within the Union.
- (31) It is for the Union to assess whether a third country, territory or zone or, in the case of aquaculture animals, compartment of origin is free from a specific disease. The Union's assessment should be based on information related to disease surveillance provided by the competent authority of the third country or territory, and taking into account Union animal health rules as provided for in Part II of the 'Animal Health Law' and Commission Delegated Regulation (EU) 2020/689⁽⁴⁾. Specific conditions for certain diseases and circumstances may be required as additional risk-mitigating measures.
- (32) The freedom from a particular disease of a third country or territory or zone thereof must be based on internationally recognised diagnostic tests and methods performed under the same standards and procedures as those applied within the Union.
- (33) It is necessary to ensure that the health status of animals, germinal products and products of animal origin intended for entry into the Union complies with the guarantees provided by the third country, territory or zone of origin. This Regulation should therefore provide for a minimum residency period for animals in the third country, territory, zone or establishment of origin, and a minimum period without contact with commodities of a lower health status, before being dispatched to the Union. The length of the minimum period of residency should take into account the incubation period of relevant diseases,

and the intended destination and use of the animals, germinal products and products of animal origin.

- (34) In the case of dogs, cats and ferrets, the residency period is unnecessary as vaccination against rabies, the disease of greatest concern for those species, is required in all cases. Registered horses intended for competitions, races and equestrian cultural events should also be exempted from certain requirements as regards the residency period, if they comply with additional guarantees. This exemption is based on the expectation that such horses will have a high level of health.
- (35) The health status of animals, germinal products and products of animal origin intended for entry into the Union may be jeopardised during transport from the place of origin to the place of entry into the Union if they enter into contact with animals or products not complying with the same requirements or if they transit through third countries, territories or zones with a lower health status than the country or territory of origin or zone thereof. Therefore certain preventive measures should be applied in order to preserve their health status.
- (36) To ensure that only healthy animals are dispatched to the Union, animals in consignments should undergo an clinical inspection carried out by an official veterinarian before they are dispatched. The time frame for performing this inspection should be adapted for certain species and their inherent risk.
- (37) Terrestrial animals, hatching eggs and aquatic animals intended for entry into the Union should only be transported through, or unloaded in, third countries, territories or zones also listed for entry into the Union of the same species and categories of animals and hatching eggs. Those countries, territories or zones' inclusion on the list indicates that they provide equivalent animal health guarantees as the third country or territory of origin or zone thereof.
- (38) The transport of terrestrial animals and hatching eggs by means of aircraft or vessel could encounter unforeseen events such as mechanical problems in the means of transport, strikes in airports and seaports or unforeseen delays. It is therefore appropriate to provide for derogations in those cases where guarantees can be given. This will allow the transport of the terrestrial animals and hatching eggs to the Union to continue, while ensuring the health status of those commodities and preventing additional animal health risks.
- (39) In the case of equine animals, as transshipments and stopovers in non-listed countries are part of the usual transport operations, they should be allowed under certain preventive measures.
- (40) Cleaning and disinfection of means of transport is a key activity to prevent the risk of spreading animal diseases. When transporting consignments of live animals destined for the Union, cleaning and disinfection of means of transport should be carried out immediately before the loading of the animals for their dispatch to the Union.
- (41) Assembly operations of animals in third countries or territories of origin may pose an additional risk to the health status of animals intended for entry into the Union, as a result of the animals mixing with and coming into contact with animals of different

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origins. Therefore, the number, duration of such operations and species allowed to undergo them should be limited to a minimum and to those species with reliable traceability systems.

- (42) In addition to general animal health requirements, it is necessary to provide specific requirements taking into account the animal health risks linked to the different species and categories of terrestrial animals falling within the scope of this Regulation.
- (43) Different species of ungulates, as defined in the ‘Animal Health Law’, are listed as susceptible species for different listed diseases in Implementing Regulation (EU) 2018/1882. Listed diseases are also set out in different categories for different species of ungulates in the same Regulation. Therefore this Regulation should clearly establish the specific requirements and guarantees in relation to listed diseases for the different species and categories of ungulates.
- (44) To prevent the occurrence of category A diseases, from which the Union is considered free, the general requirement for the third country or territory of origin or zone thereof of ungulates should be an equivalent freedom from disease for a period of time that guarantees that the entry of animals from the third country, territory or zone does not jeopardise the Union’s disease freedom. For category B diseases, for which the Union has compulsory eradication programmes, this Regulation should provide for risk-mitigating measures where the third country or territory of origin is not completely free of such diseases.
- (45) Where consignments of ungulates are intended for entry into Member States which are officially disease-free, or which have an approved eradication programme for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, bovine viral diarrhoea or infection with Aujeszky’s disease virus, those consignments should comply with additional requirements to ensure that the animals do not jeopardise the health status of those specific Member States as regards those diseases.
- (46) Special rules as regards the third country or territory of origin and additional animal health requirements should apply where ungulates originate from a confined establishment and are intended for entry into a confined establishment in the Union. The special rules should take into account the specificity of those confined establishments and the specific conditions they comply with in order to be approved by the competent authority of the third country or territory of origin and by the competent authority of the Member States of destination.
- (47) The confined establishment of origin could be located in a third country or territory which is not listed for entry into the Union of the specific species of ungulates. However, the national legislation and the veterinary services of the third country or territory will need to have been assessed. In addition, the establishment of origin should comply with additional requirements as regards disease surveillance, veterinary supervision, record keeping and operations. To ensure that those guarantees can be provided, this Regulation should lay down specific conditions for the approval of those confined establishments by the competent authority in the third country or territory. A list of such confined establishments should be drawn up by the Member State of destination, following the favourable outcome of a risk assessment by the competent authority in

that Member State of all relevant information provided by the establishment as regards the animal health risks involved.

- (48) Specific animal health requirements should apply for entry into the Union of poultry and captive birds to address the particular risks posed by the relevant listed diseases for those animals. These requirements should take account of the category, species and intended use of poultry and captive birds, and provide effective protection against the spread into the Union of diseases of concern from third countries or territories.
- (49) To facilitate the trade of consignments of small amounts of poultry, specific requirements and derogations should be established for consignments with less than 20 heads of poultry other than ratites.
- (50) Taking into account the activities and animal health risks associated with captive birds, consignments of those animals should only be permitted to enter the Union if they come from establishments approved by the competent authorities in the third country or territory of origin of the captive birds or zone thereof. The captive birds should be quarantined upon their arrival in the Union in order to confirm the absence of any disease of concern.
- (51) In addition, where consignments of birds and hatching eggs are intended for Member States with status free from infection with Newcastle disease virus without vaccination, such consignments should comply with additional requirements to ensure that those consignments do not jeopardise the health status for that disease of those specific Member States.
- (52) The infestation with the small hive beetle (*Aethina tumida*) is one of the diseases of most concern for bees. It is largely exotic to the Union but has spread globally in recent decades, creating serious problems for the apiculture industry and potentially also affecting bumble bees. *Tropilaelaps* mites (*Tropilaelaps* spp.) are potentially devastating pathogens of honeybees. They are also exotic to the Union. Effective and safe treatments against these diseases are at present not available. If these diseases entered the Union by entering consignments, they would pose a risk to the sustainability of the apiculture sector and beyond, potentially affecting agriculture and the environment which benefits from pollination services by kept and wild bees.
- (53) American foulbrood occasionally occurs in the Union but is controlled with regard to trade of honeybees, while certain areas in the Union have been recognised as free of *Varroa* mites and protected by additional trade guarantees to keep places of destination in the Union safe. Rules at Union level have been and remain essential to mitigate the risk of entry into the Union of the above pathogens as associated with consignments of honeybees and bumble bees. Therefore such rules should be laid down in this Regulation.
- (54) Only queen honeybees without a brood and accompanied by a small number of attendants in single queen cages can be easily checked for infestation with small hive beetle or with *Tropilaelaps* mites, therefore the entry into the Union of honeybees should be limited to such consignments.

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- (55) Colonies of bumble bees bred and reared in environmentally isolated establishments are often traded for the horticultural industry. Given the commonly used facilities, procedures and closed containers used for the shipped colonies, the entry into the Union of bumble bees (*Bombus* spp.) should be permitted only for colonies that are bred, reared and packaged solely under environmentally controlled conditions in establishments and which can be checked to ensure that they are free of the small hive beetle.
- (56) Because of its potential effects on humans and animals, rabies is the listed disease of most concern in the Union affecting dogs, cats and ferrets. Member States are therefore required to carry out a compulsory eradication programme against rabies infection in accordance with Delegated Regulation (EU) 2020/689. To prevent any possibility of rabies being introduced into the Union, vaccination should be required for all consignments of dogs, cats and ferrets entering it, taking into account the availability and effectiveness of existing vaccines against the disease.
- (57) Dogs intended for entry into a Member State with disease-free status or with an approved eradication programme for *Echinococcus multilocularis* should comply with additional requirements to ensure the protection of that status in those Member States. In this regard, a preventive treatment should be applied to such dogs before they enter the Union. However, where dogs, cats and ferrets are intended for a confined establishment in the Union, special rules as regards rabies and infestation with *Echinococcus multilocularis* and additional animal health requirements should apply, taking into account the specificity of such establishments' activities and the specific conditions under which animals are kept in them.
- (58) Germinal products may pose a significant risk for the spread of animal diseases. This is particularly true for semen, but also to a less extent to oocytes and embryos. As germinal products are collected or produced from a limited number of donors but used widely in the general animal population they can, if not handled properly or not classified with the correct health status, be a source of diseases for many animals. Such cases have occurred in the past and have caused substantial economic losses. Therefore, animal health requirements need to be put in place for entry into the Union of germinal products of certain kept terrestrial animals.
- (59) The requirements for entry into the Union of germinal products of ungulates should be based on the requirements for entry into the Union of live animals.
- (60) Specific requirements for germinal product establishments where germinal products of ungulates eligible for entry into the Union are collected, produced, processed and stored should reflect those established for the movements within the Union. The same approach applies to the traceability and animal health requirements for germinal products.
- (61) Due to the need to move germinal products from confined establishments located in third countries to confined establishments located in the Union, this Regulation should lay down special traceability and animal health requirements for such entry.
- (62) Animal health requirements for entry into the Union of hatching eggs should address the risks as regards listed diseases that the different categories of hatching eggs could

introduce into the Union. Therefore such requirements should correspond to those for entry into the Union of the respective species or categories of birds.

- (63) Where hatching eggs of poultry are intended for entry into Member States with status-free from infection with Newcastle disease virus without vaccination, the eggs should comply with additional requirements to ensure that they do not jeopardise the status of those specific Member States.
- (64) Products of animal origin can transmit disease agents to animals and products. The animal health risk linked to fresh and raw products of animal origin is obviously higher than those that have been processed and treated. Therefore the animal health requirements for the third country or territory of origin of fresh meat, raw milk, colostrum and colostrum-based products should be stricter than those for meat products and dairy products. However, the treatment applied to those treated products needs to be effective in order to mitigate the risk they pose depending on the species of origin of the product and the country or territory of origin.
- (65) The risk-mitigating treatments applicable for products of animal origin originating in restricted zones established in the event of confirmation of category A diseases in the Union are laid down in Commission Delegated Regulation (EU) 2020/687⁽⁵⁾, based on the available scientific knowledge and experience gained in the application of previous legislation. Therefore, the same risk-mitigating treatments should apply to those products originating in third countries, territories or zones thereof posing an equivalent animal health risk.
- (66) The risks linked to fresh meat entering the Union should be mitigated by requirements on the freedom from diseases of the third country or territory of origin and by requirements on animal diseases for the live animals from which the meat is obtained, on the dispatch of the kept animals to slaughter, on slaughter and killing operations, and on handling and preparation operations.
- (67) Fresh meat of terrestrial animals can be obtained from kept animals, including farmed game as defined in Regulation (EC) No 853/2004, and from wild animals. However, in the Union, meat obtained from animals kept as production animals, particularly, animals belonging to the species *Bos taurus*, *Capra hircus*, *Ovis aries* and *Sus scrofa*, must be obtained in a slaughterhouse. To provide adequate and equivalent guarantees, it is therefore appropriate to exclude those species from the possibility to be categorised as farmed game or wild animals when fresh meat intended for entry into the Union originates from them.
- (68) When an outbreak of a relevant animal disease occurs in a third country or territory, the date and location of slaughter of kept animals or the date of killing of wild animals or farmed game are key to establishing the possible animal health risks associated with those animals and products of animal origin obtained from them. Therefore, the date of slaughter or killing needs to be established, in order to verify that the animals have been slaughtered or killed in a period of time without outbreaks of disease and when the third country or territory was listed as being authorised to enter fresh meat into the Union.

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- (69) The type of treatment to be applied to products of animal origin should be in line with the risk posed by the third country or territory or zone thereof manufacturing the product. Entry into the Union of processed products of animal origin which have undergone treatments whose effectiveness in eliminating the risks linked to the listed diseases of concern for the particular category of product of animal origin has not been proven, should only be authorised from third countries or territories or zones thereof that provide all guarantees of freedom from the relevant diseases. For third countries or territories or zones thereof that do not provide all those guarantees, the entry into the Union of products of animal origin should be permitted only if those products have undergone a specific treatment.
- (70) In some cases, a third country or territory or zone thereof will source raw meat to produce meat products from a third country or territory or zone thereof listed for entry into the Union of meat products of the relevant species subject to a specific treatment. In such cases, the meat product should always undergo the most severe specific treatment in order to mitigate all possible animal health risks.
- (71) Meat products containing poultry meat from a third country or territory or zone thereof where there has been an outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus should undergo a treatment that is effective at mitigating the risk in the third country or territory or zone thereof listed for entry into the Union. In this way, trade can be allowed to continue before measures for control such as regionalisation are implemented. The immediate application of a risk-mitigating treatment after an outbreak decreases the animal health risks and at the same time reduces the impact on trade.
- (72) When meat products are manufactured from fresh meat from different species the treatment applied should eliminate any possible animal health risks. Therefore, if the treatment is applied before mixing, the different types of fresh meat should receive the relevant treatment assigned to the species of origin of the fresh meat. However, if the treatment is applied after mixing, the final meat product should undergo the treatment assigned to the fresh meat ingredient with the highest animal health risk.
- (73) Treatments to mitigate specific animal health risks linked to the entry of casings should be reviewed and updated taking into account the conclusions and recommendations of the latest scientific evidence assessed by the European Food Safety Authority (EFSA) Panel on Animal Health and Welfare⁽⁶⁾.
- (74) The conditions for entry into the Union of raw milk, dairy products, colostrum and colostrum-based products are based on the animal health risks represented by these products. Such risks are linked to the country or territory of origin or zone thereof and to the species of animals from which they were obtained. Foot and mouth disease and infection with rinderpest virus are the two diseases of concern in the case of milk and colostrum, therefore raw milk and colostrum should only enter from third countries or territories or zones thereof which are free from those diseases. Colostrum-based products should also only originate from those third countries, territories or zones as there are no scientific-based risk-mitigating treatments to ensure the destruction of the disease agent in that category of products.

- (75) For milk obtained from *Bos taurus*, *Ovis aries*, *Capra hircus*, *Bubalus bubalis* and *Camelus dromedarius*, the risk related to foot and mouth disease can be mitigated with the application of well-known specific risk-mitigating treatments. However, as the effectiveness of certain of those treatments for dairy products from animal species other than *Bos taurus*, *Ovis aries*, *Capra hircus*, *Bubalus bubalis* and *Camelus dromedarius* cannot be ensured, they should undergo the most severe risk-mitigating treatment.
- (76) Treatments for products of animal origin should always be carried out in the third country or territory of origin or zone thereof listed for entry of those products into the Union.
- (77) Aquatic animals of listed species are sometimes transported by sea in vessels, including well-boats which may exchange water during the journey. In such cases, in addition to a health certificate, the animals should also be accompanied by a declaration signed by the master of the vessel outlining details of the ports of origin and destination and of any other ports visited during the journey. This declaration should confirm that the animals of listed species on board the vessel have not been exposed to any conditions that could have altered their health status during the journey to their final destination.
- (78) Aquatic animals may enter the Union for many different purposes. Given the disease risk associated with the movement of live animals, such animals entering the Union for human consumption should be treated in the same way as if they were entering the Union for other purposes such as farming or release into the wild. Products of animal origin from aquatic animals other than live aquatic animals represent a lower risk than aquatic animals, and the measures to be taken in relation to such products entering the Union for further processing, are therefore, less rigorous than those which apply to live animals.
- (79) Releasing aquatic animals into the wild in natural waters is a high-risk activity if those animals are infected with a listed disease. For that reason, for category A and B diseases specifically, the third country or territory of origin or zone or compartment thereof should be free of those diseases when aquatic animals are intended for release into the wild in natural waters of the Union. In addition, aquatic animals brought into the Union to be released into the wild in natural waters should in all cases, originate from a third country or territory or zone or compartment declared free of a category C disease even when the Member State or zone or compartment of destination is not free from that disease.
- (80) In the case of aquatic diseases, Member States may take national measures under Article 226 of the ‘Animal Health Law’ designed to limit the impact of diseases other than listed diseases, within their own territory. In such cases, consignments of species susceptible to the diseases to which those national measures apply will also need to originate from third countries, territories, zones or compartments thereof, which are free of those diseases.
- (81) Article 226 of the ‘Animal Health Law’ reflects the same intent as Article 43 of Council Directive 2006/88/EC⁽⁷⁾ as it allows Member States to take national measures against diseases which are not listed. It is therefore appropriate, to continue to recognise the list

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of diseases and the relevant species for which those measures have been put in place. These details should be set out in this Regulation.

- (82) Certain rules apply within the Union in relation to the registration and approval of aquaculture establishments. The differentiation between whether an establishment can be registered or whether it should be approved depends upon the risk it presents of contracting or spreading disease. It is important therefore, that aquaculture animals which enter the Union from aquaculture establishments in a third country, territory, zone or compartment thereof, should originate from aquaculture establishments which are assessed in a similar way. In that context, such establishments should comply with registration or approval requirements which are at least as stringent as those laid down for such establishments within the Union.
- (83) It is not mandatory in all situations to apply the requirement that aquatic animals of listed species and products of animal origin from those animals originate from a third country or territory or zone or compartment thereof free from disease. Certain risk-mitigation measures can be taken to facilitate the entry into the Union of aquatic animals and certain products of animal origin thereof which do not have such an origin. Certain risk-mitigation measures are acceptable for aquatic animals of listed species and given the lower level of risk associated with such movements, different, less stringent risk-mitigation measures are acceptable for products of animal origin from aquatic animals other than live aquatic animals.
- (84) The mitigation measures that apply to aquatic animals include their being consigned to a disease control aquatic food establishment, a confined establishment or an approved quarantine establishment after entry into the Union. A number of other risk-mitigating measures apply to molluscs and crustaceans of listed species which enter the Union alive and in compliance with Regulation (EU) No 853/2004 but which represent an acceptable risk because of how they were treated or packaged before dispatch or because they are not intended for storage in the Union, prior to processing.
- (85) It is possible to derogate from the requirements that certain products of animal origin from aquatic animals other than live aquatic animals, have to originate in a third country or territory or zone or compartment thereof which is free from the relevant listed diseases. The risk-mitigation measures allowing such trade to occur may consist of consigning the products of animal origin to a disease control aquatic food establishment in the Union for further processing, or of ensuring that the products of animal origin consist of fish which were slaughtered and eviscerated before being dispatch to the Union. In either case, the risk posed by the products of animal origin is assessed as negligible.
- (86) Implementing Regulation (EU) 2018/1882 establishes a list of aquatic species and groups of species that pose a considerable risk for the spread of the diseases listed in Article 5 and Annex II to the ‘Animal Health Law’. The list also includes a list of vector species, which is set out in column 4 of the table in the Annex to that Regulation. Many of those species do not, however, act as vectors in all circumstances. In relation to movements, details of the circumstances in which those species are considered to be vectors of the listed diseases are set out in Annex XXX to this Regulation. In

circumstances where aquatic animals of listed species do not fulfil the conditions to be vectors, they are not covered by the rules set out in this Regulation. In addition, given the lower level of risk posed by products of animal origin from aquatic animals other than live aquatic animals, the measures set out in this Regulation in relation to these products do not apply to the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882.

- (87) All derogations and handling requirements provided for in this Regulation in relation to aquatic animals of listed species and to products of animal origin from those listed species other than live aquatic animals, should also apply to the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882 for which Member States have taken national measures under Article 226 of the ‘Animal Health Law’. Likewise, these derogations and handling requirements should also apply to certain susceptible species.
- (88) It is important that aquatic animals of listed species, and the water in which they are transported, are handled appropriately after entry into the Union to ensure that they do not pose a disease risk. Appropriate handling includes ensuring that the animals are transported directly to the place of destination and are not released or otherwise immersed in natural waters of the Union, where they could cause a potential disease risk.
- (89) In certain cases, however, the competent authority at the place of destination may allow authorisation for such animals to be released into natural waters. In all such cases, it should be for the competent authority to ensure that the release or immersion does not jeopardise the health status at the place of release. Furthermore, even if the receiving waters are not free of a specific category C disease, the animals to be released should be disease-free, in order to ensure the best overall health status is achieved for wild populations in natural waters of the Union.
- (90) In relation to the animal health risk involved, all transit movements through the Union should be considered as movements for entry into the Union as they imply the same level of risk. Transit movements should therefore comply with all the relevant requirements for entry into the Union. However, derogations and special rules for transit should be established under specific risk-mitigating conditions linked to the place of origin. Such derogations and special rules are intended to cover situations where the Union is not the final destination for the animals and products thereof and to take into account geographical constraints and geopolitical factors.
- (91) Derogations and special rules should also be established for the transit of consignments of animals and products thereof via a third country or territory between Member States. This is to cover situations where such type of entry into the Union is required by a Member State.
- (92) In some cases commodities originating in the Union are refused by the competent authorities of a third country or territory following controls carried out at their border. Special rules should be adopted under Article 239 of the ‘Animal Health Law’ to allow the return of those commodities on the grounds that they have been produced under the Union’s animal health legislation.

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- (93) Special rules are also necessary for the return to the Union of registered horses after temporary export to third countries in order to participate in races, competitions and equestrian cultural events.
- (94) With a view to the uniform application of Union legislation on entry into the Union of animals, germinal products and products of animal origin and to ensure that the legislation is clear and transparent, this Regulation should repeal Commission Regulation (EU) No 206/2010⁽⁸⁾, Commission Implementing Regulation (EU) No 139/2013⁽⁹⁾, Commission Regulation (EU) No 605/2010⁽¹⁰⁾, Commission Regulation (EC) No 798/2008⁽¹¹⁾, Commission Decision 2007/777/EC⁽¹²⁾, Commission Regulation (EC) No 119/2009⁽¹³⁾, Commission Regulation (EU) No 28/2012⁽¹⁴⁾ and Commission Implementing Regulation (EU) 2016/759⁽¹⁵⁾.
- (95) The rules contained in this regulation are linked and complement those of the ‘Animal Health Law’ that applies from 21 April 2021. For this reason and to facilitate the application of the new animal health legal framework this Regulation should also apply from 21 April 2021,

HAS ADOPTED THIS REGULATION:

- (1) [OJ L 84, 31.3.2016, p. 1.](#)
- (2) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ([OJ L 139, 30.4.2004, p. 55](#)).
- (3) Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases ([OJ L 308, 4.12.2018, p. 21](#)).
- (4) 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 (see page 211 of this Official Journal).
- (5) Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (see page 64 of this Official Journal).
- (6) EFSA Panel on Animal Health and Welfare (AHAW); Scientific Opinion on animal health risk mitigation treatments as regards imports of animal casings. *EFSA Journal* 2012; 10(7):2820. [32pp.] doi:10.2903/j.efsa.2012.2820. Available online: www.efsa.europa.eu/efsajournal
- (7) Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals ([OJ L 328, 24.11.2006, p. 14](#)).
- (8) Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements ([OJ L 73, 20.3.2010, p. 1](#)).
- (9) Commission Implementing Regulation (EU) No 139/2013 of 7 January 2013 laying down animal health conditions for imports of certain birds into the Union and the quarantine conditions thereof ([OJ L 47, 20.2.2013, p. 1](#)).
- (10) Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption ([OJ L 175, 10.7.2010, p. 1](#)).
- (11) Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements ([OJ L 226, 23.8.2008, p. 1](#)).
- (12) Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC ([OJ L 312, 30.11.2007, p. 49](#)).
- (13) Commission Regulation (EC) No 119/2009 of 9 February 2009 laying down a list of third countries or parts thereof, for imports into, or transit through, the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements ([OJ L 39, 10.2.2009, p. 12](#)).
- (14) Commission Regulation (EU) No 28/2012 of 11 January 2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009 ([OJ L 12, 14.1.2012, p. 1](#)).
- (15) Commission Implementing Regulation (EU) 2016/759 of 28 April 2016 drawing up lists of third countries, parts of third countries and territories from which Member States are to authorise the introduction into the Union of certain products of animal origin intended for human consumption, laying down certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC ([OJ L 126, 14.5.2016, p. 13](#)).

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