COMMISSION IMPLEMENTING DECISION (EU) 2016/645
of 22 April 2016
concerning certain protective measures against lumpy skin disease in Bulgaria
(notified under document C(2016) 3261)
(Only the Bulgarian text is authentic)
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (1), and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (2), and in particular Article 10(4) thereof,

Having regard to Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease (3), and in particular Article 14(2) thereof,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (4), and in particular Article 4(3) thereof,

Whereas:

(1) Lumpy skin disease (LSD) is a primarily vector-transmitted viral disease of bovine animals characterised by severe losses in susceptible animals and with the potential for the disease to spread very quickly, notably through movements of and trade in susceptible live animals and products thereof. LSD is not a disease of public health importance, as the virus is not transmissible to humans.

(2) Directive 92/119/EEC lays down general measures for the control of certain animal diseases, including LSD. These include measures to be taken in the event of the suspicion and the confirmation of LSD in a holding. The measures to be taken include the establishment of protection and surveillance zones around outbreaks and other additional measures to control the spread of the disease. Those measures also provide for emergency vaccination in the event of an outbreak of LSD.

(3) Article 14(2) of Directive 92/119/EEC requires that where in a given region, the epizootic in question is exceptionally serious, all the additional measures to be taken by the Member States concerned shall be adopted under the comitology procedure.

(4) On 12 April 2016, Bulgaria informed the Commission of the suspicion of LSD in two bovine holdings situated respectively in the Voden and Chernogorovo villages in the municipality of Dimitrovgrad, in the region of Haskovo in the central-southern part of Bulgaria, about 80 km from the borders with neighbouring countries. On 13 April 2016, Bulgaria notified the confirmation of the two LSD outbreaks and a further suspicion of LSD.
in the neighbouring municipality of Vodenicharovo in the region of Stara Zagora. On 15 April 2016 Bulgaria confirmed further outbreaks in the village Bialo Pole, in the region of Stara Zagora, and the villages Radiwevo and Marijno in the region of Haskovo.

(5) Bulgaria has taken measures provided for by Directive 92/119/EEC, and in particular the establishment of protection and surveillance zones around the outbreaks as provided for by Article 10 of that Directive and it has in addition restricted the movement of susceptible animals within the two affected regions and, as a matter of precaution, in neighbouring regions Burgas, Yambol, Sliven, Kardzhali, Plovdiv, Pazardjik, Smolyan, Blagoevgrad, Kjustendil, Pernik, Sofia District and Sofia Town. Surveillance is intensified in the entire country.

(6) Due to the risk of the spread of the LSD virus to other areas of Bulgaria and to other Member States, particularly through trade in live bovine animals and their germinal products, the movement of certain wild ruminants and the placing on the market of certain products derived from bovine animals, should be controlled.

(7) This Decision should use definitions laid down in Article 2 of Directive 92/119/EEC, Article 2 of Council Directive 64/432/EEC (1) and Article 2 of Council Directive 92/65/EEC (2). However, it is also necessary to -lay down some specific definitions in this Decision.

(8) It is necessary to describe the part of the territory of Bulgaria which is considered to be free of LSD and not subject to the restrictions provided for in Directive 92/119/EEC and in this Decision. It is therefore necessary to describe the restricted zone in the Annex to this Decision, taking into account the level of risk for the spread of LSD. The geographical boundaries of that restricted zone should be based on the risk and the outcome of the tracing of possible contacts to the infected holding, the possible role of vectors and the possibility to implement sufficient controls on the movement of animals of susceptible species and products derived from those animals. The restricted zone should include any protection and surveillance zones established in accordance with Directive 92/119/EEC. Based on information provided by Bulgaria, the whole territory of the regions of Haskovo and Stara Zagora in Bulgaria should be the restricted zone described in the Annex to this Decision.

(9) It is also necessary to provide for certain restrictions on the dispatch of animals of susceptible species and their germinal products from the restricted zone to be set out in the Annex to this Decision, as well as restrictions for the placing on the market of certain products of animal origin and animal by-products from that restricted zone.

(10) In terms of the risk of the spread of LSD, different commodities pose different levels of risk. As indicated in the Scientific Opinion of the European Food Safety Authority (the EFSA) on lumpy skin disease (3) the movement of live bovine animals, bovine semen and raw hides and skins from infected bovine animals pose a higher risk in terms of exposure and consequences than other products, such as milk and dairy products, treated hides and skins or fresh meat, meat preparations and meat products originating from bovine animals, where scientific or experimental evidence is lacking on their role of transmission of the disease. Therefore, the measures to be laid down in this Decision should be balanced and proportionate to the risks.

(11) The movements of live bovine animals from the restricted zone in Bulgaria to be set out in the Annex to this Decision should be prohibited in order to prevent the spread of LSD. According to the Scientific Opinion of the EFSA on lumpy skin disease and the Word Organisation for Animal Health (OIE) wild fauna, that is to say, certain exotic wild ruminants may play a potential role in the transmission of LSD, in particular in Africa where that disease is endemic. Therefore some preventive measures should also apply to wild ruminants. In the absence of more precise rules in the Union legislation, the appropriate international standards for such movements provided for in the Terrestrial Animal Health Code of the OIE (OIE Terrestrial Animal Health Code) (4) should be used for this purpose.

(12) As Bulgaria has requested for an exemption from the prohibition on the dispatch of bovine animals for direct slaughter from holdings situated in the restricted zone outside protection and surveillance zones and such an exemption is provided for in Article 11.11.5 of the OIE Terrestrial Animal Health Code, it is appropriate to allow the dispatch of such consignments under certain conditions.

(3) EFSA journal 2015;13(1):3986 [73 pp.].
Similarly, the transmission of LSD through semen and embryos of animals of the bovine species cannot be excluded. Therefore, certain protective measures should be provided for in relation to those commodities. In the absence of Union standards, the Scientific Opinion of the EFSA on LSD and the appropriate OIE Animal Health Terrestrial Code recommendations should be used for this purpose.

According to the Scientific Opinion of the EFSA on lumpy skin disease, the transmission of the LSD virus through semen, natural mating or artificial insemination, has been experimentally demonstrated, and the LSD virus has been isolated from semen of experimentally infected bulls. The collection and use of semen of animals of the bovine species originating in the restricted zone should therefore be prohibited.

In accordance with Article 4.7.14 of the OIE Terrestrial Animal Health Code, LSD is assigned in accordance with the Manual of the International Embryo Transfer Society to Category 4 diseases or pathogenic agents, which are those ‘for which studies have been done, or are in progress, that indicate that no conclusions are yet possible with regard to the level of transmission risk or that the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled in accordance with that Manual between collection and transfer’. The collection and use of embryos of animals of the bovine species originating in the restricted zone should therefore be prohibited.

There is no scientific or experimental evidence suggesting that there is transmission of the LSD virus to animals of susceptible species through fresh meat, meat preparations or meat products. Although the Scientific Opinion of the EFSA on LSD indicates that the LSD virus may survive in meat for a non-indicated period of time, the existing Union ban on the feeding of ruminant proteins to ruminants would exclude the possibility of an unlikely oral transmission of the LSD virus. To avoid any risk of the spread of LSD, the placing on the market of fresh meat, meat preparations and meat products produced from bovine animals originating in the restricted zone to be set out in the Annex to this Decision should only be allowed where the fresh meat was produced from bovine animals kept on disease-free holdings situated in the restricted zone outside established protection and surveillance zones. Such meat should only be placed on the market in the territory of Bulgaria.

In addition, the dispatch of consignments of fresh meat obtained from animals kept and slaughtered outside the restricted zone, as well as meat preparations and meat products, as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council (1) and treated stomachs, bladders and intestines, as defined in point 7.9 of Annex I to Regulation (EC) No 853/2004, which have undergone one of the treatments laid down in Part 4 of Annex II to Commission Decision 2007/777/EC (2) produced from such fresh meat and processed in establishments situated in the restricted zone, outside protection and surveillance zones, should be permitted under certain conditions.

Colostrum, milk and dairy products used as animal feed may play an important role in the spread of LSD, in particular, where the colostrum, milk and dairy products have not been sufficiently heat-treated or acidified to inactivate the LSD virus.

In its Scientific Opinion on the animal health risks of feeding animals with ready-to-use dairy products without further treatment (3) the EFSA specifies more precisely some methods that can mitigate the risks of the spread of LSD through milk and dairy products. Therefore, the placing on the market and the dispatch of consignments of milk and dairy products for human consumption produced from animals kept in the restricted zone, should be permitted under certain conditions.

Commission Regulation (EU) No 142/2011 (4), lays down implementing rules for Regulation (EC) No 1069/2009 of the European Parliament and of the Council (5), including requirements for the safe processing of animal by-products and derived products. In order to prevent the spread of LSD, the placing on the market of products and derived products. In order to prevent the spread of LSD, the placing on the market of

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unprocessed animal by-products should be prohibited. A reference to processed animal by-products in this Decision should be considered as a reference to the animal health standards set out in Regulation (EU) No 142/2011.

(21) In the event of an outbreak of LSD, Article 19 of Directive 92/119/EEC provides for the possibility to carry out vaccination against that disease. Bulgaria has not excluded a recourse to emergency vaccination against LSD. The risk of the spread of that disease from vaccinated animals and their products is different from the risks arising from non-vaccinated and possibly incubating animals. Therefore, it is necessary to lay down conditions for the movement of vaccinated bovine animals and for the placing on the market of products derived from such animals.

(22) Scientific knowledge about LSD is incomplete. Vaccinated bovine animals are protected from clinical signs of that disease but are not necessarily protected from infection and not all vaccinated animals respond with a protective immunity. Therefore, such animals after the period of at least 28 days following the vaccination should be allowed to be sent directly for immediate slaughter to slaughterhouses situated on the territory of Bulgaria.

(23) Consequently, fresh meat and meat preparations thereof, as well as meat products subjected to a non-specific treatment may constitute a non-negligible risk for the spread of LSD. Therefore, it is justified to limit the placing on the market of the fresh meat of bovine animals and susceptible wild ungulates, and meat preparations and meat products thereof to the territory of Bulgaria, provided that such commodities are subjected to special marking which is not oval and cannot be confused with the health mark for fresh meat as set out in Chapter III of Section I of Annex I to Regulation (EC) No 854/2004 of the European Parliament and of the Council (1) and the identification mark for meat preparations and meat products consisting of or containing meat of bovine animals, as set out in Section I of Annex II to Regulation (EC) No 853/2004.

(24) A specific treatment of meat products in hermetically sealed containers to a $F_0$ value of three or more and a treatment described in points 1.1 to 1.5 of Part A of Annex IX to Council Directive 2003/85/EC (2) of milk and dairy products sufficiently inactivate LSD virus in such products destined for human consumption and therefore such meat products and such milk and dairy products should be allowed to be placed on the market on the whole of the territory of Bulgaria and in other Member States and to be dispatched to third countries.

(25) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

This Decision lays down protective measures in relation to the outbreak of lumpy skin disease in Bulgaria and the additional measures to be taken by the Member States concerned in accordance with Directive 92/119/EEC.

Article 2

Definitions

For the purposes of this Directive, the definitions laid down in Article 2 of Directives 64/432/EEC, 92/65/EEC and 92/119/EEC respectively apply.


In addition, the following definitions shall apply:

(a) ‘bovine animal’ means ungulates of the species *Bos taurus*, *Bos indicus*, *Bison bison* and *Bubalus bubalis*;

(b) ‘restricted zone’ means the part of the territory of a Member State listed in the Annex to this Decision which includes the area where lumpy skin disease was confirmed and any protection and surveillance zones established in accordance with Article 10 of Directive 92/119/EEC;

(c) ‘captive wild ruminant’ means an animal of the suborder Ruminantia within the order Artiodactyla that has a phenotype not significantly affected by human selection but that lives under direct human supervision or control, including zoo animals;

(d) ‘wild ruminant’ means an animal of the suborder Ruminantia within the order Artiodactyla that has a phenotype unaffected by human selection and lives independent of direct human supervision or control;

(e) ‘meat products’ means meat products, as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004, and treated stomachs, bladders and intestines, as defined in point 7.9 of that Annex, which have undergone one of the treatments laid down in Part 4 of Annex II to Decision 2007/777/EC.

**Article 3**

Prohibition on the movement and dispatch of certain animals and semen and embryos thereof, and placing on the market of certain products of animal origin and animal by-products

1. Bulgaria shall prohibit the dispatch of the following commodities from the restricted zone to other parts of Bulgaria, to other Member States and to third countries:

(a) bovine animals and captive wild ruminants;

(b) semen, ova and embryos of bovine animals.

2. Bulgaria shall prohibit the placing on the market outside the restricted zone and the dispatch to other Member States and to third countries of the following commodities produced from bovine animals and wild ruminants kept in or hunted in the restricted zone:

(a) fresh meat and meat preparations and meat products produced from such fresh meat;

(b) colostrum, milk and dairy products of bovine animals;

(c) fresh hides and skins other than those falling within the definitions in points 28 and 29 of Annex I to Regulation (EU) No 142/2011;

(d) unprocessed animal by-products, unless destined and channelled under official supervision of the competent authority for disposal or processing in an approved plant in accordance with Regulation (EC) No 1069/2009 within the territory of Bulgaria.

**Article 4**

Derogation from the prohibition on the dispatch of bovine animals and captive wild ruminants for direct slaughter and the dispatch of fresh meat, meat preparations and meat products obtained from such animals

1. By way of derogation from the prohibition provided for in Article 3(1)(a), the competent authority may authorise the dispatch of bovine animals and captive wild ruminants from holdings situated in the restricted zone to a slaughterhouse located in other parts of Bulgaria provided that:

(a) the animals have been resident since birth, or for the past 28 days, on a holding where no case of lumpy skin disease was officially reported during that period;
(b) the animals were clinically checked at loading and did not present any clinical signs of lumpy skin disease;
(c) the animals are transported for immediate slaughter directly, without stopping or unloading;
(d) the slaughterhouse is designated for this purpose by the competent authority;
(e) the competent authority of the slaughterhouse must be informed in advance by the dispatching competent authority of the intention to send animals and notifies the dispatching competent authority of their arrival;
(f) on arrival at the slaughterhouse, the animals are kept and slaughtered separately from other animals within a period of less than 36 hours;
(g) the animals intended to be moved:
   (i) were not vaccinated against lumpy skin disease and have been kept on holdings:
       — where vaccination was not carried out and which are situated outside protection and surveillance zones, or
       — where vaccination was carried out and which are situated outside protection and surveillance zones, and a waiting period of at least 7 days after vaccination in the herd has elapsed, or
       — which are situated in a surveillance zone maintained beyond 30 days because of the occurrence of further cases of the disease, as referred to in Article 13 of Directive 92/119/EEC; or
   (ii) were vaccinated against lumpy skin disease at least 28 days prior to the date of movement and come from a holding on which all susceptible animals had been vaccinated at least 28 days prior to date of the intended movement.

2. Any dispatch of bovine animals and captive wild ruminants in accordance with paragraph 1 shall only take place if the following conditions are fulfilled:
   (a) the means of transport has been properly cleansed and disinfected before and after the loading of such animals in accordance with Article 9;
   (b) before and during the transport, the animals are protected against the attacks of vector insects.

3. The competent authority shall ensure that fresh meat, meat preparations and meat products obtained from the animals referred to in paragraph 1 of this Article are placed on the market in accordance with the requirements provided for in Articles 5 and 6.

**Article 5**

**Derogation from the prohibition on the placing on the market of fresh meat and meat preparations of bovine animals and wild ruminants**

1. By way of derogation from the prohibitions provided for in Article 3(2)(a) and (c), the competent authority may authorise the placing on the market in Bulgaria outside the restricted zone of fresh meat, excluding offal other than liver, and meat preparations thereof, as well as fresh hides and skins obtained from bovine animals and wild ruminants:
   (a) kept on holdings in the restricted zone that were not under restrictions in accordance with Directive 92/119/EEC; or
   (b) slaughtered or hunted before 13 April 2016; or
   (c) referred to in Article 4(1).

2. The competent authority shall only authorise the dispatch to other Member States or third countries of consignments of fresh meat obtained from bovine animals kept and slaughtered outside the restricted zone, and meat preparations produced from such fresh meat, provided that such meat and meat preparations were produced, stored and
handled without coming into contact with meat and meat preparations not authorised for dispatch to other Member States in accordance with Article 3(2)(a), and the consignments to other Member States are accompanied by an official health certificate in accordance with the model set out in the Annex to Commission Regulation (EC) No 599/2004 (1), of which Part II has been completed with the following attestation:

‘Fresh meat or meat preparations complying with Commission Implementing Decision (EU) 2016/645 of 22 April 2016 concerning certain protective measures against lumpy skin disease in Bulgaria.’.

Article 6

Derogation from the prohibition on the placing on the market of meat products consisting of or containing meat of bovine animals or wild ruminants

1. By way of derogation from the prohibition provided for in Article 3(2)(a), the competent authority may authorise the placing on the market of meat products produced in the restricted zone from fresh meat of bovine animals and wild ruminants:

(a) kept on holdings in the restricted zone which are not subject to restrictions in accordance with Directive 92/119/EEC;
(b) slaughtered or hunted before 13 April 2016; or
(c) referred to in Article 4(1); or
(d) kept and slaughtered outside the restricted zone.

2. The competent authority shall authorise the placing on the market of meat products referred to in paragraph 1, that comply with the conditions of points (a), (b) or (c) of that paragraph, only on the territory of Bulgaria, provided that the meat products have been subjected to a non-specific treatment which ensures that the cut surface of the meat products shows no longer the characteristics of fresh meat.

The competent authority shall ensure that the meat products referred to in the first subparagraph are not dispatched to other Member States or to third countries.

3. The competent authority shall only authorise the dispatch of consignments of meat products produced from fresh meat obtained from the animals referred to in paragraph 1(a), (b) and (c) to other Member States or to third countries, provided that the meat products have been subjected to a specific treatment, as set out in point B of Part 4 of Annex II to Decision 2007/777/EC, in hermetically sealed containers to an F0 value of three or more, and the consignments to other Member States are accompanied by an official health certificate in accordance with the model set out in the Annex to Regulation (EC) No 599/2004, of which Part II has been completed with the following attestation:

‘Meat products complying with Commission Implementing Decision (EU) 2016/645 of 22 April 2016 concerning certain protective measures against lumpy skin disease in Bulgaria.’.

4. The competent authority shall only authorise the dispatch to other Member States or third countries of consignments of meat products produced from fresh meat obtained from the animals referred to in paragraph 1(d), provided that the meat products have been subjected at least to a non-specific treatment, as set out in point A of Part 4 of Annex II to Decision 2007/777/EC, which ensures that the cut surface of the meat products shows no longer the characteristics of fresh meat and the consignments to other Member States are accompanied by an official health certificate in accordance with the model set out in the Annex to Regulation (EC) No 599/2004, of which Part II has been completed with the following attestation:

‘Meat products complying with Commission Implementing Decision (EU) 2016/645 of 22 April 2016 concerning certain protective measures against lumpy skin disease in Bulgaria.’.

Article 7

**Derogation from the prohibition on the dispatch and placing on the market of milk and dairy products**

1. By way of derogation from the prohibition provided for in Article 3(2)(b), the competent authority may authorise the placing on the market of milk for human consumption obtained from bovine animals kept on holdings situated in the restricted zone, and dairy products thereof, provided that the milk and dairy products have been subjected to a treatment described in points 1.1 to 1.5 of Part A of Annex IX to Directive 2003/85/EC.

2. The competent authority shall only authorise the dispatch to other Member States or to third countries of consignments of milk obtained from bovine animals kept on holdings situated in the restricted zone, and dairy products thereof, provided that the milk and dairy products are intended for human consumption, have undergone the treatment referred to in paragraph 1 of this Article and the consignments to other Member States are accompanied by an official health certificate in accordance with the model set out in the Annex to Regulation (EC) No 599/2004, of which Part II has been completed with the following attestation:

'Milk or dairy products complying with Commission Implementing Decision (EU) 2016/645 of 22 April 2016 concerning certain protective measures against lumpy skin disease in Bulgaria.'

Article 8

**Special marking of fresh meat, meat preparations and meat products referred to in Articles 5(1) and 6(2) respectively**

Bulgaria shall ensure that the fresh meat, meat preparations and meat products referred to in Article 5(1) and Article 6(2) are marked with a special health mark or identification mark that is not oval and cannot be confused with:

(a) the health mark for fresh meat as set out in Chapter III of Section I of Annex I to Regulation (EC) No 854/2004;

(b) the identification mark for meat preparations and meat products consisting of, or containing meat of bovine animals, as set out in Section I of Annex II to Regulation (EC) No 853/2004.

Article 9

**Requirements concerning transport vehicles, cleansing and disinfection**

1. The competent authority shall ensure that, for any vehicle which has been in contact with animals of susceptible species in the restricted zone and intends to leave this same zone, the operator or driver of this vehicle provides evidence showing that, since the last contact with those animals, the vehicle has been cleansed and disinfected in a manner to inactivate the lumpy skin disease virus.

2. The competent authority shall specify the information to be submitted by the operator or driver of the livestock vehicle in order to demonstrate the required cleansing and disinfection has taken place.

Article 10

**Information requirements**

Bulgaria shall inform the Commission and the other Member States, within the framework of the Standing Committee on Plants, Animals, Food and Feed, of the results of the surveillance for lumpy skin disease carried out in the restricted zone.
Article 11

Application

This Decision shall apply until 31 December 2016.

Article 12

This Decision is addressed to the Republic of Bulgaria.

Done at Brussels, 22 April 2016.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

ANNEX

RESTRICTED ZONE REFERRED TO IN POINT (b) OF THE SECOND SUBPARAGRAPH OF ARTICLE 2

The following regions in Bulgaria:

— Haskovo Region
— Stara Zagora Region