



## **Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429)**

### **Ebola virus disease**

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## Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): Ebola virus disease

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### Abstract

Ebola virus disease has been assessed according to the criteria of the Animal Health Law (AHL), in particular criteria of Article 7 on disease profile and impacts, Article 5 on the eligibility of Ebola virus disease to be listed, Article 9 for the categorisation of Ebola virus disease according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to Ebola virus disease. The assessment has been performed following a methodology composed of information collection and compilation, expert judgement on each criterion at individual and, if no consensus was reached before, also at collective level. The output is composed of the categorical answer, and for the questions where no consensus was reached, the different supporting views are reported. Details on the methodology used for this assessment are explained in a separate opinion. According to the assessment performed, Ebola virus disease can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL. The disease would comply with the criteria as in Sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1). The animal species to be listed for Ebola virus disease according to Article 8(3) criteria are some species of non-human primates, pigs and rodents as susceptible species and some species of fruit bats as reservoir, as indicated in the present opinion.

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## 1. Introduction

### 1.1. Background and Terms of Reference as provided by the requestor

The background and Terms of Reference (ToR) as provided by the European Commission for the present document are reported in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017).

### 1.2. Interpretation of the Terms of Reference

The interpretation of the ToR is as in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the AHL framework (EFSA AHAW Panel, 2017).

The present document reports the results of assessment on Ebola virus disease according to the criteria of the AHL articles as follows:

- Article 7: Ebola virus disease profile and impacts
- Article 5: eligibility of Ebola virus disease to be listed
- Article 9: categorisation of Ebola virus disease according to disease prevention and control rules as in Annex IV
- Article 8: list of animal species related to Ebola virus disease.

## 2. Data and methodologies

The methodology applied in this opinion is described in detail in a dedicated document about the ad hoc method developed for assessing any animal disease for the listing and categorisation of diseases within the AHL framework (EFSA AHAW Panel, 2017).

## 3. Assessment

### 3.1. Assessment according to Article 7 criteria

This section presents the assessment of Ebola virus disease according to the Article 7 criteria of the AHL and related parameters (see Table 2 of the opinion on methodology (EFSA AHAW Panel, 2017)), based on the information contained in the fact-sheet as drafted by the selected disease scientist (see section 2.1 of the scientific opinion on the ad hoc methodology) and amended by the AHAW Panel.

#### 3.1.1. Article 7(a) Disease Profile

Ebola virus (EV) disease (previously known as Ebola haemorrhagic fever) is a zoonotic disease of major concern for human health and certain African wildlife. The disease is caused by four of the five recognised species of the genus *Ebola*: *Ebolavirus* (formerly known as *Zaire ebolavirus*), *Sudan ebolavirus*, *Bundibugyo ebolavirus* and *Tai Forest ebolavirus* (Feldmann and Geisbert, 2011; Rougeron et al., 2015; CDC, online-e; WHO, online-f).

##### 3.1.1.1. Article 7(a)(i) Animal species concerned by the disease

*Susceptible animal species*

Parameter 1 – Naturally susceptible wildlife species (or family/orders)

Species that develop viral haemorrhagic fever, in which the virus has been isolated:

- Western gorilla (*Gorilla gorilla*) (Leroy et al., 2004a; Rouquet et al., 2005; Wittmann et al., 2007; Reed et al., 2014)
- Chimpanzee (*Pan troglodytes*) (Georges-Courbot et al., 1997a; Formenty et al., 1999; Georges et al., 1999; Leroy et al., 2004a; Rouquet et al., 2005; Wittmann et al., 2007)
- Bay duiker (*Cephalophus dorsalis*) (Rouquet et al., 2005)

Species with asymptomatic infection, in which viral nucleic acids have been detected:

- Franquet's epauletted fruit bat (*Epomops franqueti*) (Leroy et al., 2005; Pourrut et al., 2007, 2009; Hayman et al., 2012)
- Hammer-headed fruit bat (*Hypsignathus monstrosus*) (Leroy et al., 2005; Pourrut et al., 2007, 2009; Hayman et al., 2012)
- Little collared fruitbat (*Myonycteris torquata*) (Leroy et al., 2005; Pourrut et al., 2007, 2009)
- Peters' mouse (*Mus setulosus*) (Morvan et al., 1999)
- *Praomys* spp. (Morvan et al., 1999)
- Greater forest shrew (*Sylvisorex ollula*) (Morvan et al., 1999)

Species with asymptomatic infection, in which antibodies have been detected (WHO, online-f):

- Egyptian fruit bat (*Rousettus aegyptiacus*) (Pourrut et al., 2009)
- Leschenault's rousette (*Rousettus leschenaultii*) (Olival et al., 2013)
- Gambian epauletted fruit bat (*Epomophorus gambianus*) (Hayman et al., 2012)
- African straw-coloured fruit bat (*Eidolon helvum*) (Hayman et al., 2010; Ogawa et al., 2015)
- Peter's lesser epauletted fruit bat (*Micropteropus pusillus*) (Pourrut et al., 2009)
- Angolan free-tailed bat (*Mops condylura*) (Pourrut et al., 2009)

Species of captive, wild-born animals that have been exposed to the virus with unknown history of symptoms and in which antibodies have been detected:

- Mandrill (*Mandrillus sphinx*) (Leroy et al., 2004b)
- Drill (*Mandrillus leucophaeus*) (Leroy et al., 2004b)
- Olive baboon (*Papio Anubis*) (Leroy et al., 2004b)
- De Brazza's monkey (*Cercopithecus neglectus*) (Leroy et al., 2004b)

Full host range is not known. Observed mortality in other wildlife indicates that additional species might be susceptible to Ebola, e.g. among the mandrills (*Mandrillus* sp.), guenon (*Cercopithecus* sp.) and other nonhuman primates, as well as forest antelopes (*Cephalophus* sp.), bush pigs (*Potamochoerus porcus*), brush-tailed porcupines (*Atherurus africanus*) and other species (Lahm et al., 2007; Olson et al., 2012; Olivero et al., 2017).

#### Parameter 2 – Naturally susceptible domestic species (or family/orders)

Species that have been exposed to the virus with unknown history of symptoms and from which antibodies have been detected:

- Dogs (Allela et al., 2005; WHO, online-f)
- Guinea pigs (Stansfield et al., 1982)

#### Parameter 3 – Experimentally susceptible wildlife species (or family/orders)

Susceptible species that develop viral haemorrhagic fever:

- Rhesus macaques (*Macaca mulatta*) (Geisbert et al., 2015)
- Cynomolgus macaques (*Macaca fascicularis*) (Geisbert et al., 2015)
- Marmosets (*Callithrix jacchus*) (Smither et al., 2015)
- Baboon (*Papio* spp.) (Perry et al., 2012)
- African green monkeys (*Cercopithecus aethiops*) (Davis et al., 1997)
- Vervet monkey (*Chlorocebus pygerythrus*) (Bowen et al., 1978)

Susceptible species that develop asymptomatic infection, in which nucleic acids were detected and seroconverted (WHO, online-f):

- Egyptian rousette fruit bat (*Rousettus aegyptiacus*) (Jones et al., 2015; Paweska et al., 2016)
- Wahlberg's epauletted fruit bat (*Epomophorus wahlbergi*) (Swanepoel et al., 1996)
- Angolan free-tailed bat (*Mops condylurus*) (Swanepoel et al., 1996)
- Little free-tailed bat (*Tadarida pumila*, i.e. *Chaerephon pumilus*) (Swanepoel et al., 1996)

Species susceptible to species-adapted strains only (WHO, online-f):

- Mice (Banadyga et al., 2016; Cheresiz et al., 2016)
- Syrian hamster (*Mesocricetus auratus*) (Wahl-Jensen et al., 2012; Ebihara et al., 2013)

#### Parameter 4 – Experimentally susceptible domestic species (or family/orders)

Species that develop viral haemorrhagic fever:

- Domestic ferret (*Mustela putorius furo*) (Cross et al., 2016; Kozak et al., 2016)

Species that develop respiratory disease symptoms:

- Pigs (Kobinger et al., 2011; Weingartl et al., 2012)

Species susceptible to species-adapted strains only<sup>4</sup>:

- Guinea pigs (Banadyga et al., 2016; Cheresiz et al., 2016)

Species insensitive to infection, no detection of virus nucleic acid but seroconverted (animals purposely inoculated to produce hyperimmune serum):

- Goats (Dedkova, 1993; Kudoyarova-Zubavichene et al., 1999)
- Sheep (Dedkova, 1993; Kudoyarova-Zubavichene et al., 1999)
- Horses (Krasnianskii et al., 1995; Zheng et al., 2016)

#### Parameter 5 – Wild reservoir species (or family/orders)

This is not fully understood, but fruit bats have long been suspected to be reservoir species because: (1) studies have shown asymptomatic infections in the wild and in experimental studies, (2) 13 wild caught specimens have harboured viral nucleic acid, (3) antibodies have been detected in several species, and (4) contact to bats have been suspected to be the origin of human epidemics in West Africa, Democratic Republic of Congo and Sudan (WHO, 1978; Baron et al., 1983; Leroy et al., 2005; Pourrut et al., 2007; Leroy et al., 2009; Pourrut et al., 2009; Hayman et al., 2010, 2012; Olival et al., 2013; Marí Saéz et al., 2015; Ogawa et al., 2015).

However, natural shedding of the virus has not been reported and the virus has not been isolated from wild bats. The suspected links between bats and human outbreaks have not been confirmed and further research is necessary to confirm or identify reservoir species. Great apes (family Hominidae, e.g. chimpanzees and gorillas) are not considered reservoirs given the disease's rapid spread and high case fatality in these species, i.e. they do not fulfil important criteria for a reservoir host (Huijbregts et al., 2003; Olival and Hayman, 2014; Leendertz et al., 2016).

The susceptibility of Barbary macaque, bat and monkey species present in the European Union (EU) overseas territory is not known.

#### Parameter 6 – Domestic reservoir species (or family/orders)

There are no species recognised so far.

### **3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations**

#### *Morbidity*

##### Parameter 1 – Prevalence/Incidence

See Table 1.

##### Parameter 2 – Case-morbidity rate (% clinically diseased animals out of infected ones)

The case-morbidity rate is unknown.

## Mortality

## Parameter 3 – Case-fatality rate

**Table 1:** Seroprevalence and mortality in Ebola-infected animal populations. There are no data on the case-morbidity rate (% clinically diseased animals out of infected ones)

Species (references)	Seroprevalence % (n samples)	Mortality	Country	Time period
Bats (Leroy et al., 2005; Pourrut et al., 2007, 2009; Hayman et al., 2010, 2012; Olival et al., 2013; Ogawa et al., 2015)				
Franquet's epauletted fruit bat ( <i>Epomops franqueti</i> )	7 (117)	None	Gabon	2004
	3.9 (355)	None	Gabon/ROC	2003–2005
	1.4 (370)	None	Gabon/ROC	2006
	4 (805)	None	Gabon/ROC	2003–2008
	11 (27)	None	Ghana	2008
Hammer-headed fruit bat ( <i>Hypsignathus monstrosus</i> )	24 (17)	None	Gabon	2001–2003
	5.6 (67)	None	Gabon/ROC	2003–2005
	2.2 (44)	None	Gabon/ROC	2006
	7 (125)	None	Gabon/ROC	2003–2008
	12.5 (16)	None	Ghana	2008
Little collared fruit bat ( <i>Myonycteris torquata</i> )	7 (54)	None	Gabon	2001–2003
	3.9 (231)	None	Gabon/ROC	2003–2005
	0.3 (323)	None	Gabon/ROC	2006
	3 (573)	None	Gabon/ROC	2003–2008
Egyptian rousette ( <i>Rousettus aegyptiacus</i> )	8 (307)	None	Gabon/ROC	2003–2008
Leschenault's rousette ( <i>Rousettus leschenaultii</i> )	3.5 (37)	None	Bangladesh	2010–2011
Gambian epauletted fruit bat ( <i>Epomophorus gambianus</i> )	11 (37)	None	Ghana	2008
African straw-coloured fruit bat ( <i>Eidolon helvum</i> )	1 positive specimen (262)	None	Ghana	2008–2009
	9.5 (748)	None	Gambia	2006–2013
Peter's lesser epauletted fruit bat ( <i>Micropteropus pusillus</i> )	2 (197)	None	Gabon/ROC	2003–2008
Insectivorous bats incl. Angolan free-tailed bat ( <i>Mops condylurus</i> ) and Giant Leaf-nosed Bat ( <i>Hipposideros gigas</i> )	12 (24)	None	Gabon/ROC	2003–2008
Rodents/Shrew (Morvan et al., 1999)				
Peters mouse ( <i>Mus setulosus</i> )	4 PCR positive	None	CAR	Not reported
<i>Praomys spp.</i>	2 PCR positive	None	CAR	Not reported
Greater forest shrew ( <i>Sylvisorex ollula</i> )	1 PCR positive	None	CAR	not reported
Primates (Formenty et al., 1999; Leroy et al., 2004a; Rouquet et al., 2005; Wittmann et al., 2007; Reed et al., 2014)				
Western gorilla ( <i>Gorilla gorilla</i> )	Not estimated	Population declines up to 98%	Gabon/ROC	1994–1996
	Not estimated	Population declines up to 98%	Gabon/ROC	2000–2006
	10 (80)	(no outbreak)	ROC	2005–2007



Species (references)	Seroprevalence % (n samples)	Mortality	Country	Time period
Chimpanzee ( <i>Pan troglodytes</i> )	Not estimated	Population declines up to 98%	Gabon/ROC	1994–1966
	Not estimated	Ca. 25%	Côte d'Ivoire	1994
	Not estimated	Population declines up to 98%	Gabon/ROC	2000–2006
Ungulates (Leroy et al., 2004a; Rouquet et al., 2005)				
Bay duiker ( <i>Cephalophus dorsalis</i> )	1 PCR positive	Not investigated	Gabon/ROC	2000–2006
Other animals (Stansfield et al., 1982; Allela et al., 2005)				
Dogs	31.8 (439)	None	Gabon	2001–2002
Guinea pigs	26 (138)	None	DRC	1979

DRC: Democratic Republic of Congo; CAR: Central African Republic; ROC: Republic of Congo.

### 3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease

#### Presence

##### Parameter 1– Report of zoonotic human cases (anywhere)

Zoonotic human infections have been reported in several African countries (Pigott et al., 2014; CDC, online-f). In most cases, the zoonotic origin of infection is still unknown.

Infections have been reported in Democratic Republic of Congo in 1972, 1976, 1977, 1995, 2007, 2008, 2012 and 2014. In 2007, the index case was a child who had presumably been infected through the sweat of her asymptomatic father who had bought fruit bat meat at the local market (Leroy et al., 2009); however, none of the numerous hunters who took part in the large annual mass hunting of the bats were among the first to succumb to the disease and it has been questioned if fruit bats were indeed the origin of the outbreak (Leendertz et al., 2016). In 2014, the index case was a woman who had been in contact with a non-human primates (NHP) carcass (unidentified species); however, no samples were obtained for confirmation of Ebola virus infection in the carcass (Maganga et al., 2014). No source of infection was suspected in the other outbreaks.

All outbreaks in Gabon (1994, January and July 1996, 2001) and Republic of Congo (2001, 2002, 2003, 2005) were epidemiologically linked with infected gorillas, chimpanzees and duikers through hunting or scavenging; the source of three of these outbreaks were also laboratory confirmed (Georges-Courbot et al., 1997b; Georges et al., 1999; Rouquet et al., 2005).

In Côte d'Ivoire in 1994, one researcher was infected when performing a necropsy on an infected chimpanzee carcass (Formenty et al., 1999).

In Sudan in 1976 and 1979, the outbreaks were epidemiologically linked to a cotton factory where insectivorous bats were roosting; in the outbreak in 2004 no such link was suspected (WHO, 1978; Baron et al., 1983).

In Guinea in 2013, the index case was a 2-year-old child who had likely been in direct or indirect contact with a large colony of insectivorous bat (*Mops condylurus*) roosting in a hollow tree, however, this link was not confirmed (Marí Saéz et al., 2015).

No infectious source could be identified in the outbreaks in Uganda in 2000, 2007, 2011 and May and November 2012.

Serological surveys indicate that contacts with the virus outside outbreak times have occurred (Heymann et al., 1980; Mathiot et al., 1989; Becquart et al., 2010; Schoepp et al., 2014; Mulangu et al., 2016).

### 3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

##### Parameter 1 – Resistant strain to any treatment even at laboratory level

No treatment is licensed for human or animal use (please see section below).

### 3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment

#### Animal population

##### Parameter 1 – Duration of infectious period in animals

Bats: Not known. Viral nucleic acid has been detected but the virus has not been isolated from wild bats (Leroy et al., 2005; Pourrut et al., 2007, 2009; Hayman et al., 2010, 2012; Olival et al., 2013; Ogawa et al., 2015). In one experimental study of the insectivorous bats species *Mops condylurus* and *Chaerephon pumilus* and the fruit bat species *Epomophorus wahlbergi*, the virus was isolated in blood and tissue up to 3 weeks post infection and in one of the infected fruit bats the virus was also isolated once from faeces (Swanepoel et al., 1996) indicating that the infectious period in susceptible bat species may be more than 3 weeks, although no natural shedding of Ebola has been detected (Kuhn, 2008; Olival and Hayman, 2014; Schoepp et al., 2014).

Non-human primates (NHP): The biological aspects of the disease process are similar in humans and NHP and individuals are currently presumed infectious when clinical symptoms occur (Kuhn, 2008; Olival and Hayman, 2014; Schoepp et al., 2014). Experimental infections show that death in NHPs usually occur ca. 5–8 days post-infection but can occur up to 14 days after infection depending on dose and species of virus (Geisbert et al., 2009; Nakayama and Saijo, 2013). Filoviruses could be isolated up to 20 days after onset of infection from surviving NHPs (Fisher-Hoch et al., 1992).

One study reported ape carcasses remaining infectious in the rainforest for 3–4 days; another determined the virus to remain viable up to 7 days in macaque carcasses (Leroy et al., 2004a; Prescott et al., 2015).

The virus is not inactivated by freezing or refrigeration (Chepurinov et al., 1995; Piercy et al., 2010). It is uncertain how long EV survives in carcasses and meat under different environmental conditions, e.g. salting and drying (EFSA, 2014, 2015b).

##### Parameter 2 – Presence and duration of latent infection period

The occurrence of latent infection is not known in bats nor in chimpanzees and gorillas.

##### Parameter 3 – Presence and duration of the pathogen in healthy carriers

The infection is asymptomatic in bats. Studies of wild bats caught 5 months apart in a human outbreak area showed rapid clearance of the infection (Leroy et al., 2005). The virus could be recovered up to 3 weeks in experimentally infected, asymptomatic bats (Swanepoel et al., 1996).

Semen from men who survived the infection may remain infectious for 179 days or more after onset of symptoms (Mate et al., 2015); such viral persistence may also occur in healthy great apes (Leendertz et al., 2017). In one case, EV genetic material could be detected after 565 days but the test could not tell if live virus was present and capable of spreading disease (Soka et al., 2016).

#### Environment

##### Parameter 4 – Length of survival (dpi) of the agent and/or detection of DNA in selected matrices (soil, water, air) from the environment (scenarios: high and low T)

Data exist only from experiments which are usually mimicking hospital settings and are not based on observations in nature.

**Table 2:** Ebola-virus survival in the environment

Environment	Survival	Temp. (°C)	Rel. humidity (%)	Additional conditions	Ref.
Blood	Up to 14 days	21 or 27	40 or 80	–	(Fischer et al., 2015)
Drying blood	Up to 5 days	21	40	–	(Fischer et al., 2015)
Drying blood	Up to 5 days	27	80	–	(Fischer et al., 2015)
Serum	Up to 46 days	4 or 24	50–55	–	(Wittmann et al., 2007)
Semen	At least 8 days	27	80	–	(Fischer et al., 2016b)
Dried semen	Up to 4 days	27	80	–	(Fischer et al., 2016b)
<b>On solid surface</b>	Up to 6 days	21	40	In darkness	(Sagripanti et al., 2010)

Environment	Survival	Temp. (°C)	Rel. humidity (%)	Additional conditions	Ref.
Dried on solid surface	Up to 14 days	21	40	–	(Fischer et al., 2015)
In tissue culture media, dried on solid surface	Up to 50 days	4	50–55	On glass, in darkness	(Wittmann et al., 2007)
In tissue culture media, dried on solid surface	At least 26 days	4	50–55	On plastic, in darkness	(Wittmann et al., 2007)
Water	Up to 6 days	21	–	–	(Fischer et al., 2015)
Water	Up to 3 days	27	–	–	(Fischer et al., 2015)
Domestic wastewater	At least 8 days	–	–	–	(Bibby et al., 2015)
<b>Air (laboratory generated aerosol)</b>	180 minutes	18–22	80	–	(Fischer et al., 2016a)
<b>Air (laboratory generated aerosol)</b>	90 minutes	19–25	50–55	–	(Piercy et al., 2010; Smither et al., 2011)

Viruses with structural lipids (e.g. Ebola) survive best in dry air with a relative humidity less than 50–70% (Cox, 1995).

### 3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans

#### Routes of transmission

#### Parameter 1 – Types of routes of transmission from animal to animal (horizontal, vertical)

Transmission chains and routes are not known for most animals.

NHP-to-NHP transmission: Horizontal transmission. Direct contact, conjunctival and oral contact with infected individuals, carcasses and body fluids (Feldmann and Geisbert, 2011; Mire et al., 2016). Transmission via sexual contact with surviving males is theoretically possible as this route has been identified in humans (Mate et al., 2015). It is not known how the infection enters into the NHP population (Leendertz et al., 2017).

Bat-to-bat transmission: Such transmission is not confirmed. Virus has not been isolated from wild bats and virus shedding in wild bats has not been detected (Leroy et al., 2005; Pourrut et al., 2007, 2009; Hayman et al., 2010, 2012; Olival et al., 2013; Olival and Hayman, 2014; Ogawa et al., 2015). Experimentally infected bats (*Rousettus aegyptiacus*) did not infect other in-contact bats of the same species (Paweska et al., 2016).

Aerosol transmission in laboratory settings:

Experimental aerosol infection documented in NHP, pigs, mice, and guinea pigs (Johnson et al., 1995; Kobinger et al., 2011; Reed et al., 2011; Weingartl et al., 2012; Zumbrun et al., 2012a,b; Twenhafel et al., 2013, 2015; Smither et al., 2015).

Aerosol transmission reported from guinea pigs to guinea pigs, pigs to pigs, pigs to NHP and from NHP to NHP (Dedkova, 1993; Jaax et al., 1995; Kobinger et al., 2011; Weingartl et al., 2012; Wong et al., 2015).

In these experiments, the animals were housed close together and droplet infection cannot be excluded. Filoviruses have very little or no capacity to be airborne, i.e. no inhalation of infectious particles takes place at a distance from the source. Transmission by air is not similar to influenza or other airborne infection and the virus does not transmit from an infected person to a susceptible person that is located at a distance (Mekibib and Ariën, 2016).

#### Parameter 2 – Types of routes of transmission between animals and humans (direct, indirect, including food-borne)

Direct contact via hunting, scavenging or butchering of infected NHP or other infected wildlife. There is epidemiological evidence of such transmission in the human outbreaks in Gabon and Republic of Congo in 1994 and 1996 and 2000–2005; three outbreaks were also laboratory confirmed by isolation of virus in carcasses from gorillas, chimpanzees and duiker (Georges et al., 1999; Rouquet et al., 2005; Nkoghe et al., 2011). The risk factor for infection was related to the activities of hunting and handling the carcasses, not to the consumption of meat. Virus is killed by heating for 60 min at 60°C or boiling for 5 min (CDC, online-d).

Direct contact with bats or bat meat have been suspected, but not confirmed, to be the source of infection see Section 3.1.1.3.

#### *Speed of transmission*

##### Parameter 3 – Incidence between animals and, when relevant, between animals and humans

Measures of speed of transmission between animals or between animals and humans are not known.

##### Parameter 4 – Transmission rate (beta) (from $R_0$ and infectious period) between animals and, when relevant, between animals and humans

The transmission rate is not known. Due to the physiological and sociable similarities between great apes and humans, the transmission rate could be comparable to what has been observed in humans: In the human outbreak in West Africa in 2013–2016, the range of estimated mean value of the basic  $R_0$  and transmission rate (for the outbreak in general and for the three main countries individually) were 1.55–2.73 and 0.20–0.45 per day, respectively (Althaus, 2014; Ahmad et al., 2016). Previous estimates of  $R_0$  in other outbreaks have ranged between 1.33 and 2.7 (Chowell and Nishiura, 2014). Great apes are highly sociable and larger outbreaks have been observed in these species (Caillaud et al., 2006; Leendertz et al., 2017).

### **3.1.1.7 Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union**

#### *Presence and distribution*

##### Parameter 1 – Map where the disease is present in EU

The disease is not present in the EU; limited to the tropical belt of Africa (Pigott et al., 2014; WHO, online-f).

##### Parameter 2 – Type of epidemiological occurrence (sporadic, epidemic, endemic) at MS level

Sporadic cases are reported in humans who have travelled, or who have been medically rescued, from West Africa during the 2013–2016 outbreaks (ECDC, online-e).

#### *Risk of introduction*

##### Parameter 3 – Routes of possible introduction

- Infected humans travelling from outbreak areas (ECDC, online-e).
- Import of contaminated bushmeat from Africa, although no cases have yet been reported out of the primary outbreaks locations due to the consumption of imported bushmeat (EFSA, 2014, 2015b). Bushmeat is meat from wild animals (endangered or not) native to Africa (Swamy and Pinedo-Vasquez, 2014; BCTF, online).
- Import of infected NHP (Rollin et al., 1999).
- Food other than bushmeat has never been identified as associated with human cases in any of the reported outbreaks. Other food products such as fruits and vegetables are unlikely routes of introduction (EFSA, 2014, 2015b).

##### Parameter 4 – Number of animal moving and/or shipment size

Illegal imports of bushmeat do exist: examples of bushmeat amounts reported in personal luggage at airports include (but not a complete list):

- France, Charles de Gaulle airport: 273 tonnes per year, mainly from Central Africa. Average consignments of bushmeat were over 20 kg (Chaber et al., 2010).
- Switzerland: 249 kg/year, mainly from West Africa. Medium weight of consignments was 4.5 kg (Falk et al., 2013).
- Austria: in 8 months bushmeat was confiscated six times (Schoder et al., 2015).

Nevertheless, the quantities mentioned above are just examples and they are not representative of the real imported amounts, which are likely to be much higher, though impossible to quantify with more accuracy. Furthermore, it should be considered that not all bushmeat is from animals susceptible to EV and contaminated by the virus.

#### Parameter 5 – Duration of infectious period in animal and/or commodity

Please see Section 3.1.1.5 Parameter 1. Carcasses of NHP have been documented to remain infectious up to 7 days after death (Prescott et al., 2015). Infectious period in wild bats is not known; in experimental infections, the virus could be recovered after 3 weeks (Swanepoel et al., 1996).

The virus viability is prolonged by freezing or refrigeration (Chepurnov et al., 1995; Piercy et al., 2010; Reed et al., 2011). Please, see also Section 3.1.1.5 Parameter 4. It is uncertain how long EV survives in carcasses and meat under different treatments, e.g. salting, smoking and drying which is commonly done with bushmeat (EFSA, 2014, 2015b).

#### Parameter 6 – List of control measures at border (testing, quarantine, etc.)

- Human travel and border health measures (ECDC, online-c);
- Personal luggage control for imported bushmeat (Commission Regulation (EC) No 206/2009<sup>1</sup>);
- Control of air and sea freight;
- Illegally imported live animals: quarantine and testing and/or euthanasia;
- Public information on risk of importing bushmeat (CDC, online-g).

#### Parameter 7 – Presence and duration of latent infection and/or carrier status

See Section 3.1.1.5.

#### Parameter 8 – Risk of introduction by possible entry routes (considering parameters from 3 to 7)

It is difficult to provide a figure or a range of values of the overall risk of introduction of Ebola through the different routes because a number of factors necessary for such estimation are not known and some parameters might not be possible to estimate. The risk and uncertainties in estimating such risk of introduction through the different routes are described in general terms below.

##### Humans travelling from outbreak areas

Such introduction has already been proven possible several times. A medically evacuated patient entering a well prepared health care setting carries less risk of introduction to the general public than a person who is unaware that he/she is infected when leaving the outbreak area. Clearly, the larger outbreak and the more travellers from the area the higher risk of introduction.

##### Import of bush meat

The outcome of the assessment is the probability for at least a single case of human infected by Ebola virus in Europe due to transmission via handling and preparation (carried out by consumers or staff handling the food in kitchens immediately prior to consumption) and consumption of bush meat illegally imported from infected areas. This probability is the result of a combination of several necessary steps: (1) the bush meat has to be contaminated with Ebola virus at the point of origin; (2) the bush meat has to be (illegally) introduced into the EU; (3) the imported bush meat needs to contain viable virus when it reaches the person; (4) the person has to be exposed to the virus; and (5) the person needs to get infected following exposure.

Due to lack of data and knowledge, which results in very high uncertainty, it is not possible to estimate that risk. However, considering all the elements in these steps, and based on: (i) the limited number of outbreaks that have been reported to date in spite of the routine consumption of bush meat in that continent, (ii) the handling of bush meat in Europe not involving high risk practices such as hunting and butchering, and (iii) the assumed low overall consumption of bush meat in Europe, it can be assumed that the potential for introduction and transmission of Ebola virus via bush meat in Europe is currently low. It should be noted that the public health consequences of such an event (a single human case of Ebola virus occurring in Europe) would be very serious given the high lethality and potential for secondary transmission. In addition, it should be noted that the information considered in this opinion is largely based on historic Ebola outbreaks and not specifically the recent wide outbreak in West Africa (EFSA, 2014).

<sup>1</sup> Commission Regulation (EC) No 206/2009 of 5 March 2009 on the introduction into the Community of personal consignments of products of animal origin and amending Regulation (EC) No 136/2004. OJ L 77, 24.3.2009, p. 1–19.

### Import of non-human primates

Export quarantine lasting longer than the virus incubation time should in theory ensure that infected animals are not exported, unless the animals could come in contact with the virus during the stay in the export quarantine. Imported primates are not exposed directly to the general public; avoidance of infection of personnel at import quarantine stations relies on training and infection prevention. The route of infection to animal care workers has been demonstrated when Ebola Reston virus was introduced into primate quarantine station in the USA from infected primates coming from Philippines.

### Food other than bush meat

In this assessment, 'top-down' (e.g. surveillance-based) and 'bottom-up' (e.g. using the standard microbial risk assessment paradigm, where the agent is followed through the food chain to produce a prediction of risk to human health relative to other agents and/or foods) approaches were combined. Using the 'top-down' approach, it was concluded that food other than bush meat has never been associated with human cases in any of the reported outbreaks. There is no evidence for food-borne transmission of Ebola virus to persons in the EU.

Using the 'bottom-up' approach, it was concluded that the necessary sequence of events in the risk pathway involves many hurdles: (1) the raw food to be exported has to be contaminated with Ebola virus at the point of origin; (2) the imported food needs to contain viable virus at sufficient load to cause human infection when it arrives in the EU; (3) the person has to be exposed to the virus through the handling and preparation (both carried out by consumers or staff handling the food in kitchens immediately prior to consumption) as well as consumption of contaminated food; and (4) the person needs to get infected following exposure. Each of these steps is necessary in order for a case of disease to occur and none have been documented to happen in practice. Due to lack of data and knowledge, which results in very high uncertainty, it is not possible to quantify the risk of food-borne transmission of Ebola virus derived from the consumption of these imported foods, or in fact whether or not this mode of transmission could occur at all.

The overall conclusions of both 'top-down' and 'bottom-up' approaches are consistent and suggest that the risk of food-borne transmission of Ebola virus via food other than bush meat imported into the EU remains a theoretical possibility only and has never been demonstrated in practice. However, the uncertainty in the combined assessment is considered high given the lack of data (EFSA, 2015b).

#### **3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools**

##### *Diagnostic tools*

##### Parameter 1 – Existence of diagnostic tools

- Direct detection of pathogen: polymerase chain reaction (PCR), antigen-capture enzyme-linked immunosorbent assay (ELISA), immunohistochemistry testing
- Virus isolation
- Detection of antibodies: ELISAs (IgM and IgG) (see Table 3 for test performance)

##### *Control tools*

##### Parameter 2 – Existence of control tools

In Europe:

- Isolation of human cases
- Contact tracing (ECDC, online-b)
- Disinfection of contaminated areas with 0.5% sodium hypochlorite as recommended by WHO (online-c).
- Incineration of imported bushmeat (CDC, online-a).
- Euthanasia of infected animals imported from Africa.

There are no licensed treatments or vaccines, however several are in human clinical trials (please see below).

In outbreak areas, safe burial practice (see Section 3.1.5.2) and avoidance of bushmeat are also recommended.

### 3.1.2. Article 7(b) The impact of diseases

#### 3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy

*The level of presence of the disease in the Union*

##### Parameter 1 – Number of MSs where the disease is present

The disease is not present.

*The loss of production due to the disease*

##### Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation

This is not applicable. The disease is of human health concern.

#### 3.1.2.2. Article 7(b)(ii) The impact of the disease on human health

*Transmissibility between animals and humans*

##### Parameter 1 – Types of routes of transmission between animals and humans

Contact with infected animals, carcasses, meat and body fluids from infected wildlife. So far, the virus has been isolated from carcasses of chimpanzees, gorillas and duikers however infection is likely to occur in additional species (Leroy et al., 2004a; Rouquet et al., 2005; Lahm et al., 2007; Olivero et al., 2017).

The risk of infection from bat meat is unknown.

The reservoir host is not determined hence additional infective sources and infection routes may exist.

##### Parameter 2 – Incidence of zoonotic cases

Since 1972, 26 cases of zoonotic transmission are known to have occurred in Sub-Saharan Africa (Pigott et al., 2014; WHO, online-f). The population of Sub-Saharan Africa is 856 million people (WB, online).

*Transmissibility between humans*

##### Parameter 3 – Human-to-human transmission is sufficient to sustain sporadic cases or community-level outbreak

Human-to-human transmission occurred in all but four of the known zoonotic transmissions. Before the epidemic in West Africa in 2013–2016, where the number of recorded cases was 28.600, outbreaks included up to 425 people maximum (CDC, online-f).

##### Parameter 4 – Sporadic, endemic, epidemic, or pandemic potential

The disease occurs sporadically in Africa. The disease was, however, widespread in Guinea, Liberia and Sierra Leone in the 2013–2016 epidemics and the infection was imported into several countries (Mali, Senegal, Nigeria, the USA, Spain, Italy, France, Switzerland, Germany, the United Kingdom, Norway) through infected medical personnel and international travels. In Nigeria, the infection spread to 19 people (WHO, online-a). The WHO declared the Ebola epidemic to be a Public Health Emergency of International Concern in August 2014 (WHO, online-b).

*The severity of human forms of the disease*

##### Parameter 5 – Disability-adjusted life year (DALY)

DALY has not been calculated. Ebola virus disease first entered the Global Disease Burden list in 2015 in the group of 'Neglected tropical diseases and Malaria' (Global Burden of Disease 2015 Mortality and Causes of Death Collaborators, online). The years of lives lost (YLL) due to Ebola for that year was estimated to be 5.500. In total, 11,300 people were recorded to have died between December 2013–April 2016, mainly in Guinea, Sierra Leone and Liberia (CDC, online-f). The population of these three countries combined is 22.5 million people (WB, online).

Up until 2013, the overall number of recorded deaths in Sub-Saharan African countries since the disease was detected in 1976 was ca. 1,500 (CDC, online-f). The population of sub-Saharan Africa is 856 million people (WB, online).

*The availability of effective prevention or medical treatment in humans*

Parameter 6 – Availability of medical treatment and their effectiveness (therapeutic effect and any resistance)

No Ebola specific medical treatment is licensed. Experimental treatments are in clinical trials (see below). Treatment relies on supportive care. WHO recommends use of convalescent blood products (WHO, online-d).

Parameter 7 – Availability of vaccines and their effectiveness (reduced morbidity)

So far, no vaccine is licensed. Several vaccine candidates are in clinical trials (see below). Only one has been tested for efficacy in humans; the rVSV-EBOV vaccine candidate protected 100% of the 4,123 vaccinated in-contact people in a ring-vaccination trial during the 2013–2016 epidemic (Henao-Restrepo et al., 2017).

### **3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare**

Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

NHP develop haemorrhagic fever with severe clinical signs similar to humans (Kuhn, 2008; Leendertz et al., 2017). Experimental infections show that deaths in NHPs usually occur ca. 5–8 days post-infection but up to 14 days have been recorded depending on dose and species of virus (Geisbert et al., 2009; Nakayama and Saijo, 2013).

### **3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment**

*Biodiversity*

Parameter 1 – Endangered wild species affected: listed species as in CITES and/or IUCN list

CITES (online)

- Chimpanzees (*Pan troglodytes*); Appendix I
- Western gorilla (*Gorilla gorilla*); Appendix I

IUCN list (IUCN, online)

- Chimpanzees (*Pan troglodytes*) - Endangered
- Western gorilla (*Gorilla gorilla*) - Critically endangered (upgraded to critically endangered in 2007 due to EV disease)

Parameter 2 – Mortality in wild species

Ebola infection is not detected in wildlife in EU.

In Africa, large outbreaks in great apes (e.g. chimpanzees and gorillas) have led to population declines of 98% in some places and the disease is of concern for the survival of these endangered species (Leendertz et al., 2017). Observed mortality in other wildlife during human outbreaks indicate that additional species might be susceptible, e.g. mandrills (*Mandrillus sp.*), guenon (*Cercopithecus sp.*) and other NHP, as well as forest antelopes (*Cephalophus sp.*), bush pigs (*Potamochoerus porcus*), brush-tailed porcupines (*Atherurus africanus*) and other animals (Lahm et al., 2007; Olson et al., 2012). The infection is asymptomatic in bats (Swanepoel et al., 1996; Leroy et al., 2005).

*Environment*

Parameter 3 – Capacity of the pathogen to persist in the environment and cause mortality in wildlife

The reservoir and/or environment maintaining the virus between recorded outbreaks is not known; central drivers involved in virus spillover are wildlife hunting, deforestation/forest fragmentation, and demographic changes of wildlife (Feldmann and Geisbert, 2011; EFSA, 2015a; Leendertz, 2016).

For stability of the virus outside hosts, please see Section 3.1.1.5 Parameter 4.



### 3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism

#### Parameter 1 – Listed in OIE/CFSPH classification of pathogens

It is not listed (OIE, online-b).

#### Parameter 2 – Listed in the Encyclopaedia of Bioterrorism Defence of Australia Group

It is listed (Berger, 2005).

#### Parameter 3 – Included in any other list of potential bio- agro-terrorism agents

It is listed, including:

- WHO: Category A priority agent (WHO, online-i)
- CDC: Category A Bioterrorism Agent (CDC, online-c)
- US Department of Health and Human Services: Select Agent, Tier 1 agent (HHS, online)
- National Institute of Allergy and Infectious Diseases: Priority pathogen, Category A (NIAID, online)

### 3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures

#### 3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities

Diagnostic tests that have been approved for Emergency Use Assessment and Listing procedure by WHO are shown in Table 3, with an indication of the test performance and the matrix sample to be used. The positive and negative predictive values can only be estimated using data from a cross-sectional study or other population-based study in which valid prevalence estimated can be obtained. No OIE certified diagnostic tool exists (OIE, online-a).

**Table 3:** Diagnostic tests for Ebola approved for Emergency Use Assessment and Listing procedure by WHO (WHO, online-g)

Name	Type of test	Matrix	Sensitivity* (95% CI)	Specificity* (95% CI)
OraQuick® Ebola Rapid Antigen Test Kit	Immunoassay for detection of Ebola (EBOV) antigen	Cadaveric oral fluid, blood	94.1% (83.8–98.8)	100% (98.1–100.0)
SD Q Line Ebola Zaire Ag	Immunoassay for detection of Ebola (EBOV) antigen	Blood, plasma, serum	84.9% (78.6–91.2)	99.7% (99.1–100.0)
Antigen Rapid Test Kit, ReEBOV™	Immunoassay for detection of Ebola (EBOV) antigen	Blood, plasma, serum	91.8% (84.5–96.8)	99.7% (99.1–100.0)
RealStar® Filovirus Screen RT-PCR Kit 1.0	RT-PCR for detection of Ebola RNA (EBOV, SUDV, TAFV, BDBV)	Plasma	Performance acceptable**	–
Liferiver™ Ebola Virus (EBOV) Real Time RT-PCR Kit	RT-PCR for detection of Ebola RNA (EBOV, SUDV, TAFV, BDBV)	Blood, serum, plasma	Performance acceptable**	–
Xpert® Ebola Test	RT-PCR for detection of Ebola RNA (EBOV)	Blood	Performance acceptable***	–
FilmArray™ Biothreat-E	RT-PCR for detection of Ebola RNA (EBOV)	Blood, urine	Performance acceptable***	–

EBOV: Ebola virus (Zaire); SUDV: Sudan ebolavirus; TAFV: Tai Forest ebolavirus; BDBV: Bundibugyo ebolavirus; RT-PCR: reverse transcriptase polymerase chain reaction; RNA: ribonucleic acid.

\*: Sensitivity and specificity as reported by WHO public reports (WHO (online-g)).

\*\* : Safety and performance documentation was reviewed by WHO and external experts.

\*\*\*: The analytical evaluation of the tests was conducted at the Bernhard Nocht Institute for Tropical Medicine in Hamburg, Germany, which is a WHO Collaborating Centre for Arbovirus and Haemorrhagic Fever Reference and Research.

### 3.1.4.2. Article 7(d)(ii) Vaccination

No vaccine is licensed. Table 4 shows vaccine candidates that are in the most advanced stages of clinical trials, and their effectiveness tested so far. Additional candidates are under development and evaluation (Martins et al., 2016; ECDC, online-d).

Only one vaccine candidate has been tested for efficacy in humans; the rVSV-EBOV vaccine candidate protected 100% of the 4,123 vaccinated people in a ring-vaccination trial during the 2013–2016 epidemic (WHO, online-d). Duration of protection in humans not known for any candidate. Limited data on duration of protection in animal models; up to 18 months in rodent model (rVSV-ZEBOV) has been documented (Wong et al., 2015).

**Table 4:** Most advanced vaccine candidates against EV disease (ECDC, online-d; OIE, online-a)

Vaccine candidate	Clinical trial status	Type of vaccine	Administration route	Booster/pairing required	Effectiveness*
rVSV-ZEBOV (Geisbert and Feldmann, 2011; Wong et al., 2014; Huttner et al., 2015; Agnandji et al., 2016; Marzi et al., 2016; Henao-Restrepo et al., 2017; Regules et al., 2017)	Phase III	Virus-vectored, live, replicating	IM**	No	100%***
Ad26.ZEBOV (Milligan et al., 2016)	Phase III	Virus-vectored, live, non-replicating	IM	Yes	–
ChAd3-Ebo (Stanley et al., 2014; De Santis et al., 2016; Ewer et al., 2016; Tapia et al., 2016)	Phase II	Virus-vectored, live, non-replicating	IM	Yes	–
Ad5-EBOV (Zhu et al., 2017)	Phase II	Virus-vectored, live, non-replicating	IM	Yes	–
MVA-BN-Filo(Ewer et al., 2016; Tapia et al., 2016)	Phase III	Virus-vectored, live, non-replicating	IM	Yes	–

IM: Intramuscular injection.

\*: One human study only. All candidates in clinical trials are protective in NHP studies.

\*\* : Mucosal (oral or intranasal) in mouse and macaque model (Qiu et al., 2009).

\*\*\*: 4123 contact people in outbreak vaccinated.

### 3.1.4.3. Article 7(d)(iii) Medical treatments

#### Availability

#### Parameter 1 – Types of drugs available on the market

No Ebola specific treatment is licensed. Table 5 shows experimental treatment candidates that are in the most advanced stages of clinical trials. Additional treatment candidates are under development and evaluation (ECDC, online-d; WHO, online-e). The antiviral drug favipiravir in Table 5 is licensed for human use against influenza in Japan (Furuta et al., 2013). Convalescent blood/plasma is currently the priority treatment option of WHO based on empirical evidence (WHO, online-d). The use of whole blood or plasma from survivors does not require an EU authorisation and is the responsibility of National Competent Authorities for Blood and Blood Components (ECDC, online-a).

**Table 5:** Most advanced treatment candidates (Mendoza et al., 2016; ECDC, online-d); NIH, online; WHO, online-e)

Name	Clinical trial status	Type of treatment	Administration route	Notes
CP/CBP (WHO, online-d)	Phase II/III	Convalescent plasma/blood	IV	
Favipiravir (Bai et al., 2016)	Phase II	Antiviral drug	PO	Licensed for human use against Influenza in Japan.
Zmapp (McCarthy, 2014; Qiu et al., 2014)	Phase II	Monoclonal antibodies	IV	MIL-77 is a similar product
rVSV-EBOV (Marzi et al., 2011, 2016)	Phase III	Virus-vectored vaccine	IM*	Vaccine has potential for post-exposure treatment
BCX4430 (Taylor et al., 2016)	Phase I	Antiviral drug	IM	

\*: Mucosal (oral or intranasal) in mouse and macaque model (Qiu et al., 2009).

#### Parameter 2 – Availability/production capacity (per year)

Existing supplies of most experimental medicines are limited.

European Blood Alliance coordinates the European stocks convalescence blood products from survivors in the EU/EEA (EBA, online).

Ca. 10,000 treatment doses of favipiravir are available (WHO, online-e).

Ca. 150 treatment doses of ZMapp are available (WHO, online-e).

#### *Effectiveness*

#### Parameter 3 – Therapeutic effects on the field (effectiveness)

See Table 5.

Efficacy in humans is not determined for any treatment. Despite perceived success in the few treated on compassionate grounds, their efficacy determination remains elusive due to other interventions (WHO, online-e).

Preliminary studies of favipiravir showed that this drug may increase survival rate and reduce viral load in EVD patients (Bai et al., 2016; Sissoko et al., 2016). In a retrospective clinical case series that was performed for PCR-confirmed EVD-patients in a hospital in Sierra Leone, 56.4% (22/39) of EVD-patients treated with WHO-recommended therapy plus favipiravir recovered in comparison with 35.3% (30/85) of the control EVD-patients that were treated with WHO-recommended therapy only, 52.9% of patients who received favipiravir had a > 100-fold viral load reduction, compared with only 16.7% of patients in the control group (Bai et al., 2016).

#### *Feasibility*

#### Parameter 4 – Way of administration

See Table 5.

### **3.1.4.4. Article 7(d)(iv) Biosecurity measures**

#### Parameter 1 – Available biosecurity measures

- Regular updates on the availability of licensed vaccines and treatments: this is likely to change rapidly (see section on vaccines and treatments) (Borio et al., 2002; Bray, 2003; Sprenger and Coulombier, 2014; Cenciarelli et al., 2015);
- Prevention of access to virus stocks: Reduce possibilities for theft of virus from laboratories or during outbreaks;
- Security at airports and other high risk places for bioterrorism attacks;
- Quarantine and biosafety routines at centres and veterinary inspection posts for non-human primates imported;
- Improved means of detection of deliberately induced disease outbreaks: recognition of an unusually large number of similar cases of severe illness over a short period of time, rapid medical recognition and rapid laboratory confirmation;

- Prevention of person-to-person transmission: isolation and health care facilities, personal protection and reliable decontamination procedures;
- Contact-tracing: rapid identification and follow-up of possibly infected people.

#### *Effectiveness*

##### Parameter 2 – Effectiveness of biosecurity measures in preventing the pathogen introduction

Vaccination: Should efficient vaccines become available, they could prevent introduction of the pathogen in high-risk populations such as airport security personnel, veterinarians and animal handlers at primate importation centres, and health care employees. However, the unpredictable introduction routes of terrorist attacks make it difficult to identify all possible target populations for vaccination programmes.

Virus theft prevention: High level security and personnel control in laboratories reduce the likelihood of theft. Virus could however have been acquired by terrorist groups in the past. Acquisition of virus from infected patients or animals during outbreaks is possible.

Airport security: Unsuspicious material and possibly small volume of virus containing substance could be difficult to detect. Non-travellers can also enter airports.

Quarantine and biosafety routines at non-human primates import centres: Provided high-quality standards and routines this should be efficient to prevent virus introduction.

Other measures are not likely to be effective in preventing pathogen introduction (Borio et al., 2002; Bray, 2003; Sprenger and Coulombier, 2014; Cenciarelli et al., 2015).

#### *Feasibility*

##### Parameter 3 – Feasibility of biosecurity measure

- Vaccination and treatments: Should vaccines and/or treatments become available, vaccination is feasible.
- Prevention of access to virus stocks is unfeasible due to the possible existence of unregistered virus stocks and access to infectious material in outbreaks.
- Security: broadening security measures to include screening of travellers for potentially infectious biological material is theoretically feasible; however, it is unfeasible to control all airport visitors.
- Prevention of virus introduction at NHP import centres is feasible provided high-quality quarantine and biosafety standards.
- Improved means of detection of deliberately induced disease outbreaks: Feasible. It requires preparedness plans and available material.
- Prevention of person-to-person transmission: Feasible. It requires preparedness plans and available material.
- Contact tracing: Feasible. It requires preparedness and available material. A SMS system for follow up persons can be used (Tracey et al., 2015).

### **3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products**

#### *Availability*

##### Parameter 1 – Available movement restriction measures

Avoid import of NHP from Africa.

#### *Effectiveness*

##### Parameter 2 – Effectiveness of restriction of animal movement in preventing the between-farm spread

This is not applicable. Restriction of farm animal movement in the EU is not indicated.

#### *Feasibility*

##### Parameter 3 – Feasibility of restriction of animal movement

Avoidance of import of non-human primates from Africa is feasible; several other supplying countries exist (Hunsmann, 2003).

### 3.1.4.6. Article 7(d)(vi) Killing of animals

#### *Availability*

##### Parameter 1 – Available methods for killing animals

Euthanasia of animals imported from Africa is available. There is no indication for killing EU animals.

#### *Effectiveness*

##### Parameter 2 – Effectiveness of killing animals (at farm level or within the farm) for reducing/stopping spread of the disease

This is not applicable. There is no indication for killing EU animals.

#### *Feasibility*

##### Parameter 3 – Feasibility of killing animals

It is feasible to euthanise animals imported from Africa. There is no indication for killing EU animals.

### 3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products

#### *Availability*

##### Parameter 1 – Available disposal option

Incineration of confiscated bushmeat (CDC, online-a,b).

#### *Effectiveness*

##### Parameter 2 – Effectiveness of disposal option

Appropriately incinerated material does not pose a health risk (CDC, online-a).

#### *Feasibility*

##### Parameter 3 – Feasibility of disposal option

It is feasible.

### 3.1.5. Article 7(e) The impact of disease prevention and control measures

#### 3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole

##### Parameter 1 – Cost of control (e.g. treatment/vaccine, biosecurity)

Vaccines or treatments are under development; there is no data on the cost of disease prevention and control measures.

##### Parameter 2 – Cost of eradication (culling, compensation)

Not applicable. Culling of farm animals in the EU is not indicated.

##### Parameter 3 – Cost of surveillance and monitoring

There is no data on the cost of surveillance and monitoring.

##### Parameter 4 – Trade loss (bans, embargoes, sanctions) by animal product

There are no costs because no restriction of EU animals or animal products is indicated.

##### Parameter 5 – Importance of the disease for the affected sector (% loss or € lost compared to business amount of the sector)

Not applicable for farm animals. Losses and costs are associated with the prevention and effect of human disease and deaths.

#### 3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures

Due to cultural issues, there were social resistance to Ebola control measures (for example, safe burial including avoiding washing and touching the dead body (WHO, online-h) in West Africa (Fairhead, online). Such resistance is unlikely to occur in the EU.

For imported great apes, quarantine and biosafety measures are suggested. Euthanasia should be considered, if the animal is positive. Considering the severity of the symptoms it might be the most action to take in line with animal welfare, although considering these are endangered species of great apes, this may be a sensitive issue.

### 3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals

#### Parameter 1 – Welfare impact of control measures on domestic animals

No control measures in domestic animals are indicated.

#### Parameter 2 – Wildlife depopulation as control measure

No control measures in European wildlife are indicated.

### 3.1.5.4. Article 7(e)(iv) The environment and biodiversity

#### *Environment*

#### Parameter 1 – Use and potential residuals of biocides or medical drugs in environmental compartments (soil, water, feed, manure)

Sodium chlorite, recommended disinfection agent by WHO (Cook et al., 2015; WHO, online-c) is widely used in industrial cleaning and in private households. Due to its high reactivity and instability, it rapidly disappears in the environment. Sodium hydrochlorite is toxic to aquatic animals; it is however rapidly inactivated in organic matter such as in wastewater and sewage. The role of hypochlorite pollution is assumed as negligible. No secondary poisoning has been considered, hypochlorite not being transferred in the trophic chain (ECHA, online).

#### *Biodiversity*

#### Parameter 2 – Mortality in wild species

No control measures in European wildlife are indicated.

## 3.2. Assessment according to Article 5 criteria

This section presents the results of the expert judgement on the criteria of Article 5 of the AHL about Ebola virus disease (Table 6). The expert judgement was based on Individual and Collective Behavioural Aggregation (ICBA) approach described in detail in the opinion on the methodology (EFSA AHAW Panel, 2017). Experts have been provided with information of the disease fact-sheet mapped into Article 5 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 5, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was ten. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

**Table 6:** Outcome of the expert judgement on the Article 5 criteria for Ebola virus disease

<b>Criteria to be met by the disease:</b>		<b>Final outcome</b>
According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease, are effective and proportionate to the risks posed by the disease in the Union	Y

**At least one criterion to be met by the disease:**

In addition to the criteria set out above at point A(i)–A(v), the disease needs to fulfil at least one of the following criteria

B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	Y
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	na
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	N
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	Y
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	N

Colour code: green = consensus (Yes/No), red = not applicable (na), i.e. insufficient evidence or irrelevant to judge.

### 3.2.1. Outcome of the assessment of Ebola virus disease according to criteria of Article 5(3) of the AHL on its eligibility to be listed

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. According to the results shown in Table 6, Ebola virus disease complies with all criteria of the first set and with two criteria of the second set, therefore it is considered eligible to be listed as laid down in Article 5 of the AHL.

### 3.3. Assessment according to Article 9 criteria

This section presents the results of the expert judgement on the criteria of Annex IV referring to categories as in Article 9 of the AHL about Ebola virus disease (Tables 7, 8, 9, 10 and 11). The expert judgement was based on ICBA approach described in detail in the opinion on the methodology. Experts have been provided with information of the disease fact-sheet mapped into Article 9 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 9, and the reasoning supporting their judgement. The minimum number of judges in the judgement was 10. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

**Table 7:** Outcome of the expert judgement related to the criteria of section 1 of Annex IV (category A of Article 9) for Ebola virus disease

<b>Criteria to be met by the disease:</b> The disease needs to fulfil all of the following criteria		<b>Final outcome</b>
1	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	Y
2.1	The disease is highly transmissible	NC
2.2	There be possibilities of airborne or waterborne or vector-borne spread	NC
2.3	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	NC
2.4	The disease may result in high morbidity and significant mortality rates	Y

**At least one criterion to be met by the disease:**

In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria

3	The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	NC
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	NC
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

**Table 8:** Outcome of the expert judgement related to the criteria of section 2 of Annex IV (category B of Article 9) for Ebola virus disease

<b>Criteria to be met by the disease:</b>		<b>Final outcome</b>
The disease needs to fulfil all of the following criteria		
1	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	N
2.1	The disease is moderately to highly transmissible	NC
2.2	There be possibilities of airborne or waterborne or vector-borne spread	NC
2.3	The disease affects single or multiple species	Y
2.4	The disease may result in high morbidity with in general low mortality	N

**At least one criterion to be met by the disease:**

In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria

3	The disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety	Y
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	NC
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).



**Table 9:** Outcome of the expert judgement related to the criteria of section 3 of Annex IV (category C of Article 9) for Ebola virus disease

<b>Criteria to be met by the disease:</b> The disease needs to fulfil all of the following criteria		<b>Final outcome</b>
1	The disease is present in the whole OR part of the Union territory with an endemic character	N
2.1	The disease is moderately to highly transmissible	NC
2.2	The disease is transmitted mainly by direct or indirect transmission	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss	N
<b>At least one criterion to be met by the disease:</b> In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	Y
4	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	N
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	NC
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

**Table 10:** Outcome of the expert judgement related to the criteria of section 4 of Annex IV (category D of Article 9) for Ebola virus disease

<b>Criteria to be met by the disease:</b> The disease needs to fulfil all of the following criteria		<b>Final outcome</b>
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	Y
The disease fulfils criteria of section 1, 2, 3 or 5 of Annex IV of AHL		Y

Colour code: green = consensus (Yes/No).

**Table 11:** Outcome of the expert judgement related to the criteria of section 5 of Annex IV (category E of Article 9) for Ebola virus disease

<b>Diseases in category E need to fulfil criteria of Sections 1, 2 or 3 of Annex IV of AHL and/or the following:</b>		<b>Final outcome</b>
E	Surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently category E would apply.)	Y

Colour code: green = consensus (Yes/No).

### 3.3.1. Non-consensus questions

This section displays the assessment related to each criterion of Annex IV referring to the categories of Article 9 of the AHL where no consensus was achieved in form of tables (Tables 13, 14, 15, 16 and 17). The proportion of Y, N or 'na' answers are reported, followed by the list of different supporting views for each answer.

**Table 12:** Outcome of the expert judgement related to criterion 2.1 of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
2.1 (cat.A)	The disease is highly transmissible	NC	70	30	0
2.1 (cat.B,C)	The disease is moderately to highly transmissible	NC	30	70	0

NC: no consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes for 2.1 (cat.A):

- The disease is highly transmissible in humans and thus potentially also in great apes.

Supporting Yes for 2.1 (cat.B,C):

- Based on  $R_0$  values reported in humans, the transmission is not high.
- Not all Ebola strains are highly transmissible.

**Table 13:** Outcome of the expert judgement related to criterion 2.2 of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
2.2 (cat.A,B)	There be possibilities of airborne or waterborne or vector-borne spread	NC	30	20	50

NC: no consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes:

- Experimental aerosol infection documented in NHP, pigs, mice, and guinea pigs.
- EV survival in water at 21 or 27°C can be for days, so the disease might be potentially waterborne.

Supporting No:

- Direct contact with body fluid is the main route of spread.
- According to ECDC, Ebola virus disease is not an airborne disease.
- Aerosol transmission has been demonstrated only in experimental conditions, while the major route is direct transmission.
- Survival in water does not necessarily imply waterborne transmission of infection.
- Flaviviruses have very little or no capacity to be transmitted by the airborne route.

Supporting na:

- Transmission chains and routes are not known for most animals.

**Table 14:** Outcome of the expert judgement related to criterion 2.3 of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
2.3 (cat.A)	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	NC	80	20	0

NC: no consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes:

- Animals (NHPs) can be experimentally affected.
- Naturally susceptible species in the EU are present in zoos.
- Pigs can be experimentally infected and they may develop a respiratory form of the disease.

Supporting No:

- No susceptible domestic or free-range wild animals are present in the EU.

**Table 15:** Outcome of the expert judgement related to criterion 3 of Article 9

Question	Final outcome	Response		
		Y (%)	N (%)	na (%)
3 (cat.A) The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	NC	70	30	0

NC: no consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes:

- There may be pandemic potential in humans. It is not certain that biosecurity measures are able to prevent a pandemic spread, e.g. if a large-scale epidemic is present among humans in a country with a lot of exchanges with the rest of the world (aircraft travelling).
- There have been cases of widespread disease deeming the Ebola epidemic a Public Health Emergency of International Concern in August 2014 (see Section 3.1.2.2).

Supporting No:

- The EV disease leads to potential significant consequences to public health with epidemic potential although without pandemic potential. According to the definition of a pandemic by ECDC, 'an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people', the introduction of EV into EU would not lead to such a big scale spread, but it would be rather contained due to implementation of control and hygienic measures.

**Table 16:** Outcome of the expert judgement related to criterion 5(a) of Article 9

Question	Final outcome	Response		
		Y (%)	N (%)	na (%)
5(a) The disease has a significant impact on society, with in particular an impact on labour markets	NC	30	70	0

NC: no consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes:

- In the 2013–2016 epidemic in Africa, the impact on labour markets was catastrophic.
- EV disease could have an impact on labour markets in the EU, but not related specifically to agricultural production.
- The impact on society and labour markets would depend on the extent of epidemics in humans. It may have potentially an impact on domestic species in the EU, but not currently.

Supporting No:

- No domestic species were affected during the outbreaks in Africa, further the possible role of pigs (which are experimentally susceptible to Ebola) remains mostly unclear. Therefore, the impact on labour market is not significant due to its effect purely on domestic species.

### 3.3.2. Outcome of the assessment of criteria in Annex IV for Ebola virus disease for the purpose of categorisation as in Article 9 of the AHL

As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E corresponding to point (a) to point (e) of Article 9(1) of the AHL) if it is eligible to be listed for Union intervention as laid down in Article 5(3) and fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d) as shown in Tables 7–11. According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is ‘Yes’.

A description of the outcome of the assessment of criteria in Annex IV for Ebola for the purpose of categorisation as in Article 9 of the AHL is presented in Table 17.

**Table 17:** Outcome of the assessment of criteria in Annex IV for Ebola virus disease for the purpose of categorisation as in Article 9 of the AHL

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	Y	NC	NC	NC	Y	NC	N	NC	N	N	N
B	N	NC	NC	Y	N	Y	N	NC	N	N	N
C	N	NC	Y	Y	N	Y	N	NC	N	N	N
D						Y					
E						Y					

According to the assessment here performed, Ebola complies with the following criteria of the sections 1–5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a) to (e) of Article 9(1):

- 1) To be assigned to category A, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment Ebola complies with criteria 1 and 2.4 and the assessment was inconclusive on compliance with criteria 2.1, 2.2 and 2.3. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and Ebola disease does not comply with criteria 4, 5b, 5c and 5d and the assessment is inconclusive on compliance with criteria 3 and 5a.
- 2) To be assigned to category B, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment Ebola disease complies with criterion 2.3, does not comply with criteria 1 and 2.4 and the assessment is inconclusive on compliance with criteria 2.1 and 2.2. To be eligible for category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and Ebola disease complies with criterion 3 and does not comply with criteria 4, 5b, 5c and 5d, and the assessment is inconclusive on compliance with criterion 5a.
- 3) To be assigned to category C, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment Ebola disease complies with criteria 2.2 and 2.3, does not comply with criteria 1 and 2.4 and the assessment is inconclusive on compliance with criterion 2.1. To be eligible for category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and Ebola complies with criterion 3, does not comply with criteria 4, 5b, 5c and 5d the assessment is inconclusive on compliance with criterion 5a.
- 4) To be assigned to category D, a disease needs to comply with criteria of section 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of section 4, which Ebola disease complies with.
- 5) To be assigned to category E, a disease needs to comply with criteria of section 1, 2 or 3 of Annex IV of the AHL and/or the surveillance of the disease is necessary for reasons relating

to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, which Ebola disease complies with.

### 3.4. Assessment of Article 8

This section presents the results of the assessment on the criteria of Article 8(3) of the AHL about Ebola virus disease. The Article 8(3) criteria are about animal species to be listed, as it reads below:

'3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

- a) they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
- b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely'.

For this reason, the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible and reservoir species or routes of transmission, which cover also possible role of biological or mechanical vectors.<sup>2</sup> According to the mapping, as presented in Table 5, Section 3.2 of the scientific opinion on the ad hoc methodology (EFSA AHAW Panel, 2017), the main animal species to be listed for Ebola virus disease according to the criteria of Article 8(3) of the AHL are as displayed in Table 18.

**Table 18:** Main animal species to be listed for Ebola virus disease according to criteria of Article 8 (source: data reported in Section 3.1.1.1)

	Class	Order	Family	Genus/Species	
Susceptible <sup>+</sup>	Mammalia	Primates	Hominidae	<i>Gorilla gorilla</i>	
				<i>Pan troglodytes</i>	
			Cercopithecidae	<i>Macaca mulatta</i>	
				<i>Macaca fascicularis</i>	
				<i>Papio spp.</i>	
				<i>Chlorocebus pygerythrus</i>	
				<i>Cercopithecus aethiops</i>	
			Callitrichidae	<i>Callithrix jacchus</i>	
			Chiroptera	Pteropodidae	<i>Epomops franqueti</i>
					<i>Hypsignathus monstrosus</i>
		<i>Myonycteris torquata</i>			
		<i>Rousettus aegyptiacus</i>			
		<i>Epomophorus wahlbergi</i>			
		Molossidae		<i>Mops condylurus</i>	
				<i>Tadarida pumila</i>	
				<i>Chaerephon pumilus</i>	
		Rodentia		Muridae	<i>Mus setulosus</i>
					<i>Praomys spp</i>
			<i>Mus spp.*</i>		
			<i>Mesocricetus auratus*</i>		
	Cricetidae	<i>Mesocricetus auratus*</i>			
	Caviidae	<i>Cavia porcellus*</i>			
Eulipotyphla	Soricidae	<i>Sylvisorex ollula</i>			
Carnivora	Mustelidae	<i>Mustela putorius furo</i>			
Artiodactyla	Bovidae	<i>Cephalophus dorsalis</i>			
	Suidae	<i>Sus scrofa</i>			

<sup>2</sup> A vector is a living organism that transmits an infectious agent from an infected animal to a human or another animal. Vectors are frequently arthropods. Biological vectors may carry pathogens that can multiply within their bodies and be delivered to new hosts, usually by biting. In mechanical vectors, the pathogens do not multiply within the vector, which usually remains infected for shorter time than in biological vectors.

	Class	Order	Family	Genus/Species
Reservoir	Mammalia	Chiroptera	Pteropodidae**	not specified
Vectors	None			

+: Animal species in which only antibodies have been detected are not included in the table.

\*: Susceptible to species-adapted strains only.

\*\* : Fruit bats have long been suspected to be reservoir species not confirmed; further research is necessary to confirm or identify reservoir species confirmed.

## 4. Conclusions

**TOR 1:** for each of those diseases an assessment, following the criteria laid down in Article 7 of the AHL, on its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;

- According to the assessment here performed, Ebola complies with all criteria of the first set and with two criteria of the second set and therefore can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

**TOR 2a:** for each of the diseases which was found eligible to be listed for Union intervention, an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;

- According to the assessment here performed, Ebola meets the criteria as in sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1) of the AHL.

**TOR 2b:** for each of the diseases which was found eligible to be listed for Union intervention, a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL;

- According to the assessment here performed, the animal species that can be considered to be listed for Ebola according to Article 8(3) of the AHL are some species of non-human primates, pigs and rodents as susceptible species and some species of fruit bats as reservoir, as reported in Table 18 in Section 3.4 of the present document.

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## Abbreviations

AHAW	EFSA Panel on Animal Health and Welfare
AHL	Animal Health Law
CDC	Centers for Disease Control and Prevention
CFSPH	Center for Food Security and Public Health
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
DALY	disability-adjusted life year
ECDC	European Centre for Disease Control and Prevention
ELISA	enzyme-linked immunosorbent assay
EV	Ebola virus
EVD	Ebola virus disease
Ig	immunoglobulin
ICBA	Individual and Collective Behavioural Aggregation
IUCN	International Union for the Conservation of Nature
MS	Member State
NHP	non-human primates
OIE	World Organization for Animal Health
PCR	polymerase chain reaction
ToR	Terms of Reference
WHO	World Health Organization
YLL	years of lives lost