

#### Annex to:

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# Annex A – Mapped fact-sheet used in the individual judgement on bovine genital campylobacteriosis

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# Article 5

#### Question A(i)

Question A(i) scientific evidence indicate that the disease is transmissible           Answer Y         N         na					
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet			
(a)(vi) the routes and speed of transmission of the disease between animals and, when relevant, between animals and humans	(a)(vi) 1 types of routes of transmission from animal to animal (horizontal, vertical)	The route of transmission from animal to animal of Cfv is venereal. Cows become infected through natural service or artificial insemination with contaminated semen. Bulls can become infected by serving an infected cow and transmission may occur between bulls during mounting. Vertical transmission has never been reported.			
	(a)(vi) 2 types of routes of transmission from animal to humans (direct, indirect)	Not applicable - humans are not susceptible for Cfv.			



# Question A(ii)

Question A(ii) animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union Interpretation: indicate if animal species susceptible to the disease or vector or reservoir are present in the Union Answer Y  N N n a					
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet			
(a)(i) animal species concerned by	(a)(i) 1 naturally susceptible wildlife species	The naturally susceptible wildlife species of <i>Campylobacter fetus</i> subspecies <i>venerealis</i> (Cfv) causing bovine genital campylobacteriosis (BGC) is cattle ( <i>Bos taurus</i> ) (OIE, 2012).			
the disease	(a)(i) 2 naturally susceptible domestic species	The naturally susceptible wildlife species of Cfv causing bovine genital campylobacteriosis is cattle ( <i>Bos taurus</i> ) (OIE, 2012).			
	(a)(i) 3 experimentally susceptible wildlife species	No experimentally susceptible wildlife species for Cfv causing BGC have been described. It is to be expected that wildlife cattle ( <i>Bos taurus</i> ) is the only wildlife species that is susceptible for BGC.			
	(a)(i) 4 experimentally susceptible domestic species	Experimentally susceptible domestic species for Cfv causing BGC are cattle ( <i>Bos taurus</i> ) (Corbeil et al., 1975; Cipolla et al., 1994) and guinea pigs ( <i>Cavia porcellus</i> ) (Plummer, 2017).			
	(a)(i) 5 wild reservoir species	The wild reservoir species for Cfv causing BGC is cattle ( <i>Bos taurus</i> ).			
	(a)(i) 6 domestic reservoir species	The domestic reservoir species for Cfv causing BGC is cattle ( <i>Bos taurus</i> ) (Blaser et al., 2008).			

# Question A(iii)

Question A(iii) disease causes negative effects on animal health OR poses a risk to public health due to its						
zoonotic character Answer Y	-					
Art. 7 criteria	Art. 7 parameters	Assessment	of the Art. 7 pa	rameters from the fact-s	heet	
(a)(ii) morbidity and mortality rates of the disease in animal populations	(a)(ii) 1 Prevalence/ incidence	Assessment of the Art. 7 parameters from the fact-sheet Although BGC is wide-spread in the world, the lack of monitoring programmes for this disease in many countries makes it difficult to estimate the prevalence rates of BGC world-wide. As shown in Table 1, the estimates are based on small studies with highly questionable representability. The prevalence of herds infected with <i>Campylobacter fetus</i> subspecies <i>venerealis</i> causing BCG is relatively high in low and middle-income countries (LMIC) compared to low prevalence or even eradication of BGC in developed countries (data available of the World Organisation for Animal Health (OIE) and published data (Mshelia et al., 2007; Mshelia et al., 2010)). <b>Table 1:</b> <i>C. fetus</i> prevalence world-wide				
		Country	Samples	Result	Reference	
		Argentina	Aborted bovine fetuses	26 of 354 tested fetuses (7%) were <i>C. fetus</i> positive	Campero et al. (2003)	
		Australia	Aborted bovine fetuses	11% of 265 tested fetuses were <i>C. fetus</i> positive	Jerrett et al. (1984)	
		Brazil	Preputial washings of bulls	170 of 327 tested bulls (52.3%) and 17 of 19 tested farms (89.5%) were <i>C. fetus</i> positive	Pellegrin et al. (2002)	
		Brazil (Goiás)	Vaginal mucus samples of cows	22.4% of 1685 cows were <i>C. fetus</i> positive	Andrade et al. (1986)	
		USA (California)	Blood samples of cows	189 of 400 (47%) tested cows were <i>C.</i> <i>fetus</i> positive	Akhtar et al. (1990)	
		USA (California)	Blood samples of dairy cows	22.2% of 790 tested cows were <i>C. fetus</i> positive	Akhtar et al. (1990)	
		Canada	Preputial washings of bulls	18 of 529 (3%) bulls tested were <i>C. fetus</i> positive	Devenish et al. (2005)	
		Colombia	Preputial washings of bulls	103 farms tested, 15% of the farms had <i>C. fetus</i> positive bulls	Griffiths et al. (1984)	
		Egypt		BGC prevalence of 10% in buffalo cows	Mshelia et al. (2010)	



India (Calcutta)	Fecal samples from cattle	No <i>C. fetus</i> found in 120 samples	Chattopadhay et al. (2001)
India (West Bengal)		Estimated BGC prevalence of 6% in cattle	Mshelia et al. (2010)
Japan	Fecal samples from cattle	26.5% of 94 tested samples were Cff positive. "A few" samples were Cfv positive.	Giacoboni et al. (1993)
Japan	Fecal samples from healthy cattle	13 of 338 (4%) samples were <i>C. fetus</i> positive	Ishihara et al. (2004)
New Zealand	Vaginal mucus samples from cows and preputial washings from bulls	1230 mucus samples from 125 beef cow herds were tested, 70% of herds had >1 <i>C. fetus</i> positive CVM sample. All 54 preputial washings from 9 herds were <i>C. fetus</i> negative	McFadden et al. (2005)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	15 of 585 (3%) tested bulls were <i>C. fetus</i> positive 5 of 104 (5%) tested cows were <i>C. fetus</i> positive	Bawa et al. (1991)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	3,7% of vaginal mucus samples of cows were <i>C. fetus</i> positive 11% of preputial washings of bulls were <i>C. fetus</i> positive	Mshelia et al. (2010)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	Total; 270 bovine samples tested, consisting of 170 preputial washings from bulls and 100 vaginal mucus samples of cows. Of these 270 samples, 2.2% were Cfv positive and 1.5% were Cff positive	Mshelia et al. (2012)
North America	Fecal samples from dairy cows cattle	5% of 720 cows were <i>Campylobacter</i> spp. positive	Harvey et al. (2004)
Malawi	Vaginal mucus samples from cows and preputial washings from bulls	1 bull was tested positive for vibriosis Vaginal mucus samples gave no clear result	Klastrup and Halliwell (1977)
Scotland	Preputial washings of bulls	0% of 109 tested bulls were <i>C. fetus</i> positive	McGowan and Murray (1999)
South Africa (Republic of Transkei)	Preputial washings of bulls	10 of 14 (71%) tested sites were <i>C. fetus</i> positive	Pefanis et al. (1988)
South Africa (Gauteng province)	Preputial washings of bulls	2.1% of 143 tested bulls were <i>C. fetus</i> positive	Njiro et al. (2011)
Tanzania	Preputial washings of bulls	3 of 58 (5.1%) tested bulls were Cfv positive	Swai et al. (2005)



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		Turkey	Preputial washings of bulls and aborted bovine fetuses	Cfv is isolated from both bulls and aborted fetuses	Mshelia et al. (2010)
		United Kingdom	Aborted bovine fetuses	28 of 161 (17%) tested samples were <i>C. fetus</i> positive	Devenish et al. (2005)
		Zimbabwe	Aborted bovine fetuses	9.5% of 21 tested fetuses were <i>C. fetus</i> positive Estimated; BGC prevalence is 33% in	Mshelia et al. (2010)
		Cff: <i>Campvloba</i>	<i>cter fetus</i> subsp	cows in Zimbabwe	
				ecies <i>venerealis</i> .	
	(a)(ii) 2 Case- morbidity rate (% clinically diseased animals out of infected ones)	Bulls are asymp rate is 0% in th infection in natu disease sympto no data of the t	tomatic carriers ese. The case-m urally served ani ms, such as abo otal population o	of Cfv, so by definition the optication of Cfv, so by definition the optication of t	nown, since ugh the BGC n, and there are
	(a)(ii) 3 Case-fatality rate	can result in en through a herd annual weaning	hbryo mortality a and abortions and rate by 10% (M	e death of the infected bull a nd abortion. The disease ca nd/or infertility due to BGC o Ishelia et al., 2007).	n spread rapidly can reduce the
(a)(iii) zoonotic character of the disease	(a)(iii) 1 report of zoonotic human cases	reported, excep Sweden in 1987	t for one isolate 7 (Holst et al., 19		al vaginosis in
(a)(iv) resistance to treatments, including antimicrobial resistance	(a)(iv) 1 resistant strain to any treatment even at laboratory level	naladixic acid al In a field study, and 95% of the isolates was res 1% was resistal subspecies, how obtained from f study from Gen 2011). They rep In 14% of the s	nd all <i>C. fetus</i> st 1084 <i>C. fetus</i> s isolates showed istant for doxycy nt to ciprofloxaci vever, was not n eces, it might be many specifically port full susceptil strains there was	fetus subsp. venerealis strai rains are sensitive to cephal trains were isolated from bo d to be resistant to naladixic vcline, 57% was resistant to in and enrofloxacin (Inglis el eported and given that the i e. <i>C. fetus</i> subspecies <i>fetus</i> o reporting on susceptibility ( bility of 50 investigated strai is reduced susceptibility to or ycin and spectinomycin.	othin (On, 1996). vines in Alberta acid, 60% of the tetracycline and t al., 2006). The solates were nly. There is one (Hanel et al., ns to gentamicin.
(b)(ii) Impact of the disease on human health	<ul> <li>(b)(ii) 1 types of routes of transmission between animals and humans - see (a)(vi)2</li> <li>(b)(ii) 2 Incidence of zoonotic cases</li> <li>(b)(ii) 3 Occasional or substantial?</li> <li>(b)(ii) 4 Epidemic or pandemic?</li> <li>(b)(ii) 5 DALY</li> </ul>	Not applicable -	humans are no	t susceptible to infection wit	
(b)(iii) Impact of the disease on animal welfare	(b)(iii) 1 severity of clinical signs at case level and related level and duration of impairment	moderate endou several months, for a long time be very weak, it	metritis and salp but usually not or only when fer f any, suggesting	nptomatic. Infection in cows ingitis and cows can become life-long. Since infection is of tility rates drop, clinical sym g a rather minor impact on a	e infertile for often not detected optoms seem to
(c) potential to generate a crisis situation and its potential use in	(c) 1 listed in OIE/CFSPH classification of pathogens			t not listed by the CFSPH.	
bioterrorism	(c) 2 listed in the Encyclopedia of Bioterrorism Defense of Australia Group	Group.		baedia of Bioterrorism Defen	
	(c) 3 included in any other list of potential bio-agro-terrorism agents	BGC is not inclu	aed in any other	r list of potential bio- agro-te	errorism agents.



## Question A(iv)

Interpretation		c tools are available for the disease ols are available for the disease in the Union
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet
(a)(viii) existence of diagnostic and disease control tools	(a)(viii) 1 Existence of diagnostic tools	BGC is diagnosed by diagnostic tools prescribed by the OIE (OIE, 2012). The immunofluorescence antibody test (IFAT) is suitable to detect if a sample contains suspected <i>C. fetus</i> bacteria, but for definite diagnosis confirmation has to be done by isolating <i>C. fetus</i> from the sample. The isolation of the pathogen causing BGC can be challenging, since <i>C. fetus</i> is slow-growing and requires specific micro-aerobic conditions. It is critical that collected samples are sent immediately to the laboratory and cultured. If transport takes long, transport medium should be used. It is recommended to use selective Skirrow medium to isolate <i>C. fetus</i> . Alternatively, the filtration-technique can be used, where the sample is brought onto a 0.65 µm filter, allowing the <i>Campylobacter</i> bacteria to pass to a non-selective blood-based (5–7% blood) medium. Identification of <i>C. fetus</i> can be done with biochemical tests or molecular tests, as described in the OIE manual (OIE, 2012). Serological assays are not suitable for diagnosis due to cross-reaction between <i>C. fetus</i> subsp. <i>fetus</i> and <i>C. fetus</i> subsp. <i>venerealis</i> .
	(a)(viii) 2 Existence of disease control tools	BGC can be controlled by vaccination (Section 3.1.4.2), antimicrobials (Section 3.1.4.3), the separation of infected from non-infected animals and control measurements for the prevention of introduction to a herd by infected animals or their products (Section 3.1.1.7 Parameter 6), including quarantine measurements. Artificial insemination is considered to be the most effective for controlling BGC, as is evidenced by farms that have changed from natural breeding to controlled AI programs (Figueiredo et al., 2002).

## Question A(v)

Question A(v) the risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union Answer  $Y \square N \square$  na  $\square$ 

Answer Y 🗆 N 🗆 na 🗆				
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet		
(a)(viii) existence of diagnostic and disease control tools	(a)(viii) 1 Existence of diagnostic tools	BGC is diagnosed by diagnostic tools prescribed by the OIE (OIE, 2012). The immunofluorescence antibody test (IFAT) is suitable to detect if a sample contains suspected <i>C. fetus</i> bacteria, but for definite diagnosis confirmation has to be done by isolating <i>C. fetus</i> from the sample. The isolation of the pathogen causing BGC can be challenging, since <i>C. fetus</i> is slow-growing and requires specific micro-aerobic conditions. It is critical that collected samples are sent immediately to the laboratory and cultured. If transport takes long, transport medium should be used. It is recommended to use selective Skirrow medium to isolate <i>C. fetus</i> . Alternatively, the filtration-technique can be used, where the sample is brought onto a 0.65 µm filter, allowing the <i>Campylobacter</i> bacteria to pass to a non-selective blood-based (5–7% blood) medium. Identification of <i>C. fetus</i> can be done with biochemical tests or molecular tests, as described in the OIE manual (OIE, 2012). Serological assays are not suitable for diagnosis due to cross-reaction between <i>C. fetus</i> subsp. <i>fetus</i> and <i>C. fetus</i> subsp. <i>venerealis</i> .		
	(a)(viii) 2 Existence of disease control tools	BGC can be controlled by vaccination (Section 3.1.4.2), antimicrobials (Section 3.1.4.3), the separation of infected from non-infected animals and control measurements for the prevention of introduction to a herd by infected animals or their products (Section 3.1.1.7 Parameter 6), including quarantine measurements. Artificial insemination is considered to be the most effective for controlling BGC, as is evidenced by farms that have changed from natural breeding to controlled AI programs (Figueiredo et al., 2002).		
(b)(ii) Impact of the disease on human health	<ul> <li>(b)(ii) 6 Availability of medical treatment and their effectiveness</li> <li>(therapeutic effect and any resistance)</li> <li>(b)(ii) 7 Availability of vaccines and their effectiveness (reduced morbidity)</li> </ul>	Not applicable - humans are not susceptible to infection with BGC.		
(d)(i) feasibility, availability and	(d)(i) 1 officially/internationally recognised diagnostic tool, OIE certified	Diagnostic tests for BGC are prescribed by the OIE (OIE, 2012) and include immunofluorescence and an antigen-ELISA assay to detect <i>C. fetus</i> as well as isolation and identification methods of the agent.		
effectiveness of diagnostic tools and capacities	(d)(i) 2 Se and Sp of diagnostic test	IFAT to detect <i>Campylobacter fetus</i> subspecies <i>venerealis</i> has a reported sensitivity and specificity of 92.6% and 88.9% and the detection limit ranges between 102 – 104 cfu/ml (Figueiredo et al., 2002). The OIE recommended tests to diagnose BGC are the detection of the antigen (bacterium) by culture or the combination of an		



	(d)(i) 3 type of sample matrix to be tested (blood, tissue, etc.)	antigen catching ELISA to detect the presence of <i>C. fetus</i> species cultured in transport medium followed by isolation. This ELISA has a specificity up to 98.5% ((Brooks et al., 2004; Devenish et al., 2005). The sensitivity of the culturing method is not determined but the number of <i>C. fetus</i> in preputial samples of infected bulls range from <102 to >2 x 105 organisms per milliliter (Clark, 1971), which can be below the detection limit of the recommended methods. Once the bacterium has been isolated, subspecies identification is very challenging and no molecular diagnostic test is available with 100% sensitivity and 100% specificity to identify <i>C. fetus</i> subsp. <i>venerealis</i> (OIE, 2012; van der Graaf-van Bloois et al., 2013). Whole genome sequencing can be used to identify <i>C. fetus</i> subspecies with 100% specificity. Alternatively, an ELISA can be used to detect antibodies. This technique, however, is not recommended for individual cases and this assay lacks the specificity in differentiating the two subspecies and can therefore not be used to diagnose BGC. In bulls, smegma samples may be obtained by scraping, suction or by preputial washing (OIE, 2012). The amount of <i>C. fetus</i> bacteria recovered from scraping samples will be greater than with the suction or preputial washing methods. Furthermore, less contamination from background microflora was observed in scraping samples compared with the samples collected using the other two methods (Tedesco et al., 1977). Cows or heifers should be sampled when the animals are close to oestrus or are in oestrus. Cervico-vaginal mucus samples may be obtained by swabbing, suction, or by washing the vaginal cavity (OIE, 2012). Aborted bovine foetuses, including the placenta, can be tested to detect an infection with <i>C. fetus</i> . The stomach contents (abomasal fluid), lungs and liver have been shown to be the best camples for the recovery of the bacterium (OIE 2012).
(d)(ii)	(d)(ii) 1 types of	shown to be the best samples for the recovery of the bacterium (OIE, 2012). Several commercial vaccines are available for BGC consisting of inactivated <i>C. fetus</i>
feasibility, availability and	vaccines available on the market	cells, including Vibrin® (Pfizer), Vibrio Leptoferm 5 (Pfizer) and BioAbortogen H (San Jorge Bago, Argentina). Both male and female cattle can be vaccinated against <i>C. fetus.</i>
effectiveness of vaccination	(d)(ii) 2 availability / production capacity (per year)	Unknown.
	(d)(ii) 3 Field protection as reduced morbidity (reduced susceptibility to infection and/or to disease)	According to information of the producer, the use of Vibrin can increase pregnancy rates in vaccinated heifers up to 44% compared to non-vaccinated control heifers . Both male and female cattle can be vaccinated against <i>C. fetus.</i> Vaccination of bulls might help to control the spread of infection but the effect is limited.
	(d)(ii) 4 Duration of protection	It is recommended to vaccinate against BGC by annual revaccination with a single dose between 30 days and 7 months before breeding (Pfizer, online).
	(d)(ii) 5 Way of administration	The way of vaccine administration is subcutaneously.
(d)(iii) feasibility, availability and	(d)(iii) 1 types of drugs available on the market and/or allowed by the EU regulatory system	Types of drugs against BGC available on the market are antibiotics, for example streptomycin or oxytetracycline.
effectiveness of medical treatments	(d)(iii) 2 availability / production capacity (per year)	The availability and production capacity of drugs against BGC are unknown.
	(d)(iii) 3 therapeutic effect in the field (effectiveness)	In bulls, antibiotic treatment can be successful if the bulls are less than 3 years old, while antibiotic treatment of older bulls is often not sufficient to clear the infection, and the older bulls remain life-long carriers of the bacterium (Blaser et al., 2008). The effectiveness of antibiotic treatment in cows and heifers is unknown, since female cattle are mainly not treated, because treatment results are poor and most females develop protective immunity enabling them to resist re-infection (Taylor, 2002; Mshelia et al., 2007).
	(d)(iii) 4 Way of administration	The way of administration of antibiotics against BGC is local in bulls.
(d)(iv) feasibility, availability and effectiveness of biosecurity measures	(d)(iv) 1 available biosecurity measures	Proper husbandry practices (e.g. careful selection of replacement cows and bulls) reduce the risk of introducing <i>Campylobacter fetus</i> into a herd. Only animals that are tested negative for <i>C. fetus</i> should be allowed to enter the herd. The risk of disease transmission can be substantially reduced or eliminated by applying sanitary protocols recommended by the International Embryo Transfer Society (IETS) and the World Organization of Animal Health (OIE). The basic principle to ensure such a high level of biosecurity for semen relies on the concept of pathogen-free semen collection centres. In the case of embryos, practical guidelines have been published in the manual of IETS in order to provide risk management procedures ensuring the safety of herds using embryo transfer.
	(d)(iv) 2 effectiveness of biosecurity measure (d)(iv) 3 feasibility of biosecurity measure	The major biosecurity measure against BGC is the use of BGC-free semen or embryos and this will ensure that no BGC is introduced into a herd. The diagnostic tests for BGC described in the OIE Manual to test if animals or materials are BGC-free are suitable to perform world-wide, even in low and middle-
L	stoceancy measure	materiale are been reclare balable to perform world wide, even in low and midule



		income countries.
(d)(v) feasibility, availability and effectiveness of restrictions en the	<ul> <li>(d)(v) 1 available</li> <li>restriction movement</li> <li>measures</li> <li>(d)(v) 2 effectiveness</li> <li>of restriction of animal</li> </ul>	According to Council Directive 88/407/EEC, if an animal of an AI station is tested positive for BGC, the AI station will be closed and production and trade or animals and their products are prohibited. The animals of the closed AI station are treated with antibiotics and must be tested negative for BGC for 3 times with 2 weeks interval, before the AI centre is allowed to continue the production and trade. The restriction of movement of BGC-infected animals to another farm will prevent the spread of BGC.
on the movement of animals and products, as control	movement in preventing the between farm spread (d)(v) 3 feasibility of restriction of animal movement	If artificial insemination is used, the restriction of movement of animals from one farm to another is suitable for BGC.
measure (d)(vi) feasibility, availability	(d)(vi) 1 available killing of animal measures	For BGC, killing of animal measures are available.
and effectiveness of killing of animals	(d)(vi) 2 effectiveness of killing animals (at farm level or within the farm) for reducing /stopping spread of the disease	If a BGC-infected animal is killed, the disease will not spread further from this animal.
	(d)(vi) 3 feasibility of killing animals	The economic loss by killing highly productive bulls can be very high. If the bull can be effectively treated with antibiotics, killing the infected bull is not necessary. If the antibiotic treatment is not effective and the bull remains BGC-positive, it cannot be used for production in AI stations, and killing will be an option. The economic loss of killing a cow will be much lower, but the feasibility of killing infected cows is questionable since recovery usually occurs spontaneously within 5 months and the acquired immunity protects the cows from re-infection. Culling infected animals in a herd has proven to be effective to control the disease (Truyers et al., 2014).
(d)(vii) feasibility,	(d)(vii) 1 disposal options available	Semen or embryos contaminated with BGC can be destroyed.
availability and effectiveness	(d)(vii) 2 effectiveness of disposal option (d)(vii) 3 feasibility of	Disposal of the semen or embryos will prevent BGC spread.
of disposal of carcasses and other relevant animal by— products	(d)(VII) 3 Teasibility of disposal option	Disposal of BGC contaminated semen or embryos can be expensive, but is feasible world-wide.

# Question B(i)

Answer Y 🗆 N 🗆	🗆 na 🗆						
Art. 7 criteria	Art. 7	Assessment o	of the Art. 7 paran	neters from the fact-sheet			
(a)(ii) morbidity	(a)(ii) 1	Although BGC i	s wide-spread in th	e world, the lack of monitoring p	rogrammes for thi		
and mortality	Prevalence/			it difficult to estimate the preval			
rates of the	Incidence			the estimates are based on small			
disease in		questionable re	epresentability. The	prevalence of herds infected w	ith Campylobacte		
animal				ng BCG is relatively high in low a			
populations				prevalence or even eradication of			
				World Organisation for Animal	Health (OIE) and		
			(Mishelia et al., 200 <i>tus</i> prevalence world	7; Mshelia et al., 2010)). I-wide			
		Country	Samples	Result	Reference		
		Argentina	Aborted bovine	26 of 354 tested fetuses (7%)	Campero et al.		
		<b>J</b>	fetuses	were <i>C. fetus</i> positive	(2003)		
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		fetuses were <i>C. fetus</i> positive (1984)					
		Brazil	Preputial	170 of 327 tested bulls	Pellegrin et al.		
			washings of	(52.3%) and 17 of 19 tested	(2002)		
			bulls	torme (VU EU/-) word (' totue			
			Dulis	farms (89.5%) were <i>C. fetus</i> positive			



	samples of	<i>fetus</i> positive	(1986)
	cows		
USA (California)	Blood samples of cows	189 of 400 (47%) tested cows were <i>C. fetus</i> positive	Akhtar et al. (1990)
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	washings of bulls	were <i>C. fetus</i> positive	(2005)
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Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	3,7% of vaginal mucus samples of cows were <i>C. fetus</i> positive 11% of preputial washings of bulls were <i>C. fetus</i> positive	Mshelia et al. (2010)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	Total; 270 bovine samples tested, consisting of 170 preputial washings from bulls and 100 vaginal mucus samples of cows. Of these 270 samples, 2.2% were Cfv positive and 1.5% were Cff positive	Mshelia et al. (2012)
North America	Fecal samples from dairy cows cattle	5% of 720 cows were <i>Campylobacter</i> spp. positive	Harvey et al. (2004)
Malawi	Vaginal mucus samples from cows and preputial washings from bulls	1 bull was tested positive for vibriosis Vaginal mucus samples gave no clear result	Klastrup and Halliwell (1977)
Scotland	Preputial washings of bulls	0% of 109 tested bulls were <i>C. fetus</i> positive	McGowan and Murray (1999)
South Africa (Republic of Transkei)	Preputial washings of bulls	10 of 14 (71%) tested sites were <i>C. fetus</i> positive	Pefanis et al. (1988)
South Africa (Gauteng province)	Preputial washings of bulls	2.1% of 143 tested bulls were <i>C. fetus</i> positive	Njiro et al. (2011)
Tanzania	Preputial washings of	3 of 58 (5.1%) tested bulls were Cfv positive	Swai et al. (2005)



			bulls		
		Turkey	Preputial washings of bulls and aborted bovine fetuses	Cfv is isolated from both bulls and aborted fetuses	Mshelia et al. (2010)
		United Kingdom	Aborted bovine fetuses	28 of 161 (17%) tested samples were <i>C. fetus</i> positive	Devenish et al. (2005)
		Zimbabwe	Aborted bovine fetuses	9.5% of 21 tested fetuses were <i>C. fetus</i> positive Estimated; BGC prevalence is 33% in cows in Zimbabwe	Mshelia et al. (2010)
			<i>ter fetus</i> subspecie <i>cter fetus</i> subspecie		
	(a)(ii) 2 Case- morbidity rate (% clinically diseased animals out of infected ones)	Bulls are asympt these. The case- animals is mainly	omatic carriers of ( morbidity rate in c / detected through	Cfv, so by definition the case-morl ows is unknown, since infection in the BGC disease symptoms, such no data of the total population of	naturally served as abortion as
	(a)(ii) 3 Case- fatality rate	embryo mortality abortions and/or (Mshelia et al., 2	v and abortion. The infertility due to B 007).	ath of the infected bull and/or cove disease can spread rapidly throu GC can reduce the annual weanin	gh a herd and g rate by 10%
(a)(iii) zoonotic character of the disease	(a)(iii) 1 report of zoonotic human cases			of cattle and no human cases are bacterial vaginosis in Sweden in 1	
(a)(iv) resistance to treatments, including antimicrobial resistance	(a)(iv) 1 resistant strain to any treatment even at laboratory level	acid and all <i>C. fet</i> 1084 <i>C. fetus</i> str showed to be re- doxycycline, 57% and enrofloxacin given that the iso only. There is on al., 2011). They 14% of the strain mostly to lincom	etus strains are sen rains were isolated sistant to naladixic 6 was resistant to (Inglis et al., 2006 plates were obtaine restudy from Germ report full susceptions there was reduc ycin and spectinon		n a field study, of the isolates istant for to ciprofloxacin not reported and subspecies <i>fetus</i> eptibility (Hanel et gentamicin. In
(b)(ii) Impact of the disease on human health	<ul> <li>(b)(ii) 1 types of routes of transmission between animals and humans - <i>see (a)(vi)2</i></li> <li>(b)(ii) 2 Incidence of zoonotic cases</li> <li>(b)(ii) 3 Occasional or substantial?</li> <li>(b)(ii) 4 Epidemic or pandemic?</li> <li>(b)(ii) 5 DALY</li> </ul>			sceptible to infection with BGC.	

# Question B(ii)

and/or anim Interpretation: animal health.	Question B(ii) disease agent has developed resistance to treatments WHICH poses a significant danger to public and/or animal health in the Union? Interpretation: disease agent has developed resistance to treatments AND therefore poses a significant danger to public and/or animal health. If no treatment exists the answer should be na Answer Y $\square$ N $\square$ na $\square$						
Art. 7	Art. 7	Assessment of the Art. 7 parameters from the fact-sheet					
criteria	parameters						
(a)(iv)	(a)(iv)1 list of	All C. fetus strains and most C. fetus subsp. venerealis strains are resistant to naladixic acid					
resistance to	any resistant	and all C. fetus strains are sensitive to cephalothin (On, 1996). In a field study, 1084 C. fetus					
treatments,	strain to any	strains were isolated from bovines in Alberta and 95% of the isolates showed to be resistant to					
including	treatment	naladixic acid, 60% of the isolates was resistant for doxycycline, 57% was resistant to					
antimicrobial	······································						
resistance	laboratory	atory subspecies, however, was not reported and given that the isolates were obtained from feces, it					
	level	might be C. fetus subspecies fetus only. There is one study from Germany specifically reporting					
		on susceptibility (Hanel et al., 2011). They report full susceptibility of 50 investigated strains to					
		gentamicin. In 14% of the strains there was reduced susceptibility to one or more					



	antimicrobials, mostl	y to lincom	ycin and s	pectinom	ycin.	

# Question B(iii)

aquaculture pro Interpretation: dis aquaculture produ	Question B(iii) disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union?         Interpretation: disease and/or infection causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union if no intervention is in place         Answer Y       N       n						
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet					
(a)(ii) morbidity and mortality rates of the disease in animal populations	(a)(ii) 3 Case-fatality rate	Infection with Cfv will not cause death of the infected bull and/or cow, but can result in embryo mortality and abortion. The disease can spread rapidly through a herd and abortions and/or infertility due to BGC can reduce the annual weaning rate by 10% (Mshelia et al., 2007).					
(b)(i) the impact of the disease on agricultural and aquaculture production and	(b)(i) 1 Number of MSs where the disease is present	See Section 3.1.1.7, BGC is sporadic in several MSs. In 2016, sporadic cases of BGC were reported in four MSs; United Kingdom, Ireland, France and Spain. The presence of the disease in EU countries from 2005-2016 is presented in Appendix A (see "Tables" section at the end of the document).					
other parts of the economy	(b)(i) 2 Proportion of production losses (%) by epidemic/endemic situation (milk, growth, semen, meat, etc.)	Control measures prevent the spread of BGC within the EU. Data about production losses in the EU are not available, however it was estimated that during the first year of infection, the gross profit margins may be reduced by 66% and when the disease becomes established within a herd, gross profit margins are 36% lower than those of uninfected herds (Hum et al., 1994).					

## Question B(iv)

Question B(iv) disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism Answer Y  N N n a						
Art. 7 criteria Art. 7 parameters Assessment of the Art. 7 parameters from the fact-sheet						
(c) potential to generate a crisis situation and its	(c) 1 listed in OIE/CFSPH classification of pathogens	BGC is an OIE-listed disease but not listed by the CFSPH.				
potential use in bioterrorism	(c) 2 listed in the Encyclopaedia of Bioterrorism Defense of Australia Group	BGC is not listed in the Encyclopaedia of Bioterrorism Defence of Australia Group.				
	(c) 3 included in any other list of potential bio-agro-terrorism agents	BGC is not included in any other list of potential bio- agro-terrorism agents.				

# Question B(v)

Question B(v) disease has or could have a significant negative impact on the environment, including biodiversity, of the Union Answer Y  Question N  Question B(v) A  Question B						
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact- sheet				
(b)(iv) impact of the disease on biodiversity and the environment	(b)(iv) 1 endangered wild species affected: listed species as in CITES and/or IUCN list	Only cattle ( <i>Bos taurus</i> ) are reported to be infected with BGC, however it cannot be excluded that rare bovine species on the CITES and/or IUCN list can also be infected with BGC; studies are, however, not available.				
	(b)(iv) 2 mortality in wild species	BGC can cause embryonic death in wild bovines.				
	(b)(iv) 3 capacity of the pathogen to persist in the environment and cause mortality in wildlife	Soil and water can be contaminated with <i>C. fetus</i> , however data about the length of survival of <i>C. fetus</i> in the environment is lacking.				
(e)(iv) the impact of disease prevention and control measures, as regards the environment and biodiversity	(e)(iv) 2 Mortality in wild species	BGC can possible cause embryonic death in wild cattle, but this disease is primarily a problem in domestic animals.				



# Article 9

#### **Questions 1**

<u>Instruction</u> to answer: The answer to the question 1CAq can be Y only for diseases affecting aquatic animal species, therefore do not assess this question for diseases affecting terrestrial animal species **Question 1A the disease is not present in the territory of the Union OR present only in exceptional cases** 

**Question 1CAq several Member States or zones of the Union are free of the disease Answer** Y D N D na D

	1	
Art. 7	Art. 7	Assessment of the Art. 7 parameters from the fact-sheet
criteria	parameters	
(b)(i) the impact of the disease on agricultural and aquaculture production and other parts of the	(b)(i) 1 Number of MSs where the disease is present	See Section 3.1.1.7, BGC is sporadic in several MSs. In 2016, sporadic cases of BGC were reported in four MSs; United Kingdom, Ireland, France and Spain. The presence of the disease in EU countries from 2005-2016 is presented in Appendix A (see "Tables" section at the end of the document).
economy		
(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	(a)(vii) 1 Map where the disease is present in EU	WANHOOKE 2:012 Teleand Faer oe-Isl ands Permittik Denmark Den
		The map where BGC is present in EU is depending on the self-reporting of the country and this will certainly not show a full picture. The BGC distribution in the EU in 2016 is presented in Figure 1.
	(a)(vii) 2 Type of epidemiological occurrence	The use of artificial insemination in Europe has greatly reduced the incidence of BGC. In countries from which BGC is reported, the type of epidemiological occurrence is only sporadic cases. For the sporadic cases, to our knowledge, there are no studies on risk factors. It is in addition questionable whether all cases of BGC in Europe are reported to the WAHIS system of the OIE (OIE, online).
	(a)(vii) 3, 4, 5, 6, 7, 8, Risk of introduction (all related parameters)	Parameter 3 - Routes of possible introduction As some countries report on a more regular basis cases (e.g. UK), the pathogen is frequently detected in some European countries but the disease is sporadic (few outbreaks). In countries that do not report cases and are supposed to be free of BGC, there is a risk for introduction of BCG. The routes of possible introduction of BGC are import of infected cattle or contaminated bovine products, like semen and embryos. Parameter 4 - Number of animal moving and/or shipment size In 2014, the EU has imported around 9.7 million doses of bovine semen (Eurostat; The European Platform of Exporters of Bovine Genetics (ExPla)). Parameter 5 - Duration of infectious period in animal and/or commodity The duration of the infectious period in animals is mentioned in Section 3.1.1.5 of this fact-sheet.



Parameter 6 - List of control measures at border (testing, quarantine, etc.) The general animal health requirements governing the intra-EU trade and import of bovine semen are laid down in Council Directive 88/407/EEC <sup>1</sup> and for bovine embryos in Council Directive 89/556/EEC <sup>2</sup> . These directives harmonize the animal health conditions for the trade within the EU and import to the EU from third countries, as well as the conditions of collection and storage. According to Council Directive 88/407/EEC, bulls whose semen is used for intra-community trade must be kept in quarantine before being admitted to an AI station. During the quarantine, bulls younger than 6 months are tested once for BGC and bulls older than 6 months are tested 3 times with one week interval. Bulls that are in production must be tested annually. Bulls that are on hold are excluded with the proviso that when they are longer than 6 months on hold, they should be tested at the earliest 30 days prior to the resumption of the semen production. Bulls in non-EU countries are mainly tested 2x twice per year. Bulls are screened for BGC as described in the Terrestrial Animal Health Code by the OIE (OIE, 2013). If an animal is tested positive for BGC in an AI station, the AI station is closed and all semen obtained in the period from the latest negative test will be destroyed, according to Council Directive 88/407/EEC. All bulls will be treated with antibiotics and must be tested negative for BGC for 3 times with 2 weeks interval, before the AI centre is allowed to continue their production. Parameter 7 - Presence and duration of latent infection and/or carrier status The presence and duration of the latent infection and/or carrier status of BGC are mentioned in Section 3.1.1.5 of this fact-sheet. Parameter 8 - Risk of introduction

#### Questions 2.1

Question 2.1A the disease is highly transmissible         Answer: Y          N         na          Question 2.1BC the disease is moderately to highly transmissible         Answer Y         N         na					
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet			
(a)(vi) the routes and speed of transmission of the disease between animals and,	(a)(vi) 3 Incidence between animals and, when relevant, between animals and humans	The transmission of Cfv between animals within a herd depends on the presence of a "vector"; an infected bull that spreads the infection between animals, because BGC is a venereally transmitted infection. However, no quantitative estimates are available in bibliography.			
when relevant, between animals and humans	(a)(vi) 4 Transmission rate (beta) (from R₀ and infectious period) between animals and, when relevant, between animals and humans	No data available about the transmission rate of BGC between animals.			

#### **Question 2.2**

**Question 2.2AB** there be possibilities of airborne or waterborne or vector-borne spread Interpretation: the disease or the infection can be transmitted via airborne or waterborne or vector-borne (mechanical or biological vector) spread Answer Y 🗆 N 🗆 na 🗆 Art. 7 criteria Assessment of the Art. 7 parameters from the fact-sheet Art. 7 parameters (a)(vi) the routes and speed of (a)(vi) 1 types of routes The route of transmission from animal to animal of Cfv is transmission of the disease of transmission from venereal. Cows become infected through natural service or between animals and, when animal to animal artificial insemination with contaminated semen. Bulls can (horizontal, vertical) relevant, between animals and become infected by serving an infected cow and transmission humans may occur between bulls during mounting. Vertical transmission has never been reported.

<sup>&</sup>lt;sup>1</sup> Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species. OJ L 194, 22.7.1988, p. 10–23.

<sup>&</sup>lt;sup>2</sup> Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species. OJ L 302, 19.10.1989, p. 1–11.



#### **Question 2.3**

Question: 2.3A the disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance Answer Y  Question: N  Question: 2.3A the disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance					
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet			
(a)(i) animal species concerned by the disease	(a)(i) 1 naturally susceptible wildlife species	The naturally susceptible wildlife species of <i>Campylobacter fetus</i> subspecies <i>venerealis</i> (Cfv) causing bovine genital campylobacteriosis (BGC) is cattle ( <i>Bos taurus</i> ) (OIE, 2012).			
	(a)(i) 2 naturally susceptible domestic species	The naturally susceptible wildlife species of Cfv causing bovine genital campylobacteriosis is cattle ( <i>Bos taurus</i> ) (OIE, 2012).			
	(a)(i) 3 experimentally susceptible wildlife species	No experimentally susceptible wildlife species for Cfv causing BGC have been described. It is to be expected that wildlife cattle ( <i>Bos taurus</i> ) is the only wildlife species that is susceptible for BGC.			
	(a)(i) 4 experimentally susceptible domestic species	Experimentally susceptible domestic species for Cfv causing BGC are cattle ( <i>Bos taurus</i> ) (Corbeil et al. 1975; Cipolla et al. 1994) and guinea pigs ( <i>Cavia porcellus</i> ) (Plummer, 2017).			
	(a)(i) 5 wild reservoir species	The wild reservoir species for Cfv causing BGC is cattle ( <i>Bos taurus</i> ).			
	(a)(i) 6 domestic reservoir species	The domestic reservoir species for Cfv causing BGC is cattle ( <i>Bos taurus</i> ) (Blaser et al., 2008).			

#### **Questions 2.4**

<u>Instruction</u> to answer: The answer to the question 2.4CAq can be Y only for diseases affecting aquatic animal species, therefore do not assess this question for diseases affecting terrestrial animal species

	question for diseases affe			•				
	he disease may result i	n nign morbidit	y and significan	t mortality rates				
Answer Y I N		n high markidit	u and in a second	Lieur es este liter				
	he disease may result i	n nign morbidit	y and in general	low mortality				
		a mat vagult in hi	ale menuleiditer en	d has nogligible or no most				
	red effect of the disease			nd has negligible or no mort	anty AND often			
			1055					
		lt in high morhi	dity and youally	low mortality AND often th	o most			
	of the disease is produ		uity and usually	low mortality and often th				
Answer Y 🗆 N 🛛		100011033						
Art. 7 criteria	Art. 7 parameters	Assessment	f the Art. 7 nara	meters from the fact-sheet				
(a)(ii) morbidity	(a)(ii) 1 Prevalence/			he world, the lack of monitorin				
and mortality	Incidence			akes it difficult to estimate the				
rates of the				Table 1, the estimates are base				
disease in		with highly que	estionable represe	ntability. The prevalence of h	erds infected with			
animal				venerealis causing BCG is rela				
populations				LMIC) compared to low pre				
				ped countries (data availab				
				(OIE) and published data (Ms	helia et al., 2007;			
		Mshelia et al., 2		dd wido				
		Country	tus prevalence wor Samples	Result	Reference			
		Argentina	Aborted	26 of 354 tested fetuses	Campero et al.			
		Argentina	bovine	(7%) were <i>C. fetus</i>	(2003)			
			fetuses	positive	(2000)			
		Australia	Aborted	11% of 265 tested fetuses	Jerrett et al.			
			bovine	were C. fetus positive	(1984)			
			fetuses					
		Brazil	Preputial	170 of 327 tested bulls	Pellegrin et al.			
			washings of	(52.3%) and 17 of 19	(2002)			
			bulls	tested farms (89.5%) were				
		Duranil	Ma aire al	C. fetus positive	Andreada			
		Brazil	Vaginal	22.4% of 1685 cows were	Andrade et al.			
		(Goiás)	mucus	C. fetus positive	(1986)			
			samples of cows					
		USA	Blood samples	189 of 400 (47%) tested	Akhtar et al.			
	(California) of cows cows were <i>C. fetus</i> positive (1990)							
		USA	Blood samples	22.2% of 790 tested cows	Akhtar et al.			
		(California)	of dairy cows	were <i>C. fetus</i> positive	(1990)			
	1	Canada	Preputial	18 of 529 (3%) bulls tested	Devenish et al.			



	washings of bulls	were C. fetus positive	(2005)
Colombia	Preputial washings of bulls	103 farms tested, 15% of the farms had <i>C. fetus</i> positive bulls	Griffiths et al. (1984)
Egypt		BGC prevalence of 10% in buffalo cows	Mshelia et al. (2010)
India (Calcutta)	Fecal samples from cattle	No <i>C. fetus</i> found in 120 samples	Chattopadhay et al. (2001)
India (West Bengal)		Estimated BGC prevalence of 6% in cattle	Mshelia et al. (2010)
Japan	Fecal samples from cattle	26.5% of 94 tested samples were Cff positive. "A few" samples were Cfv positive.	Giacoboni et al. (1993)
Japan	Fecal samples from healthy cattle	13 of 338 (4%) samples were <i>C. fetus</i> positive	Ishihara et al. (2004)
New Zealand	Vaginal mucus samples from cows and preputial washings from bulls	1230 mucus samples from 125 beef cow herds were tested, 70% of herds had >1 <i>C. fetus</i> positive CVM sample. All 54 preputial washings from 9 herds were <i>C. fetus</i> negative	McFadden et al. (2005)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	15 of 585 (3%) tested bulls were <i>C. fetus</i> positive 5 of 104 (5%) tested cows were <i>C. fetus</i> positive	Bawa et al. (1991)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	3,7% of vaginal mucus samples of cows were <i>C.</i> <i>fetus</i> positive 11% of preputial washings of bulls were <i>C. fetus</i> positive	Mshelia et al. (2010)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	Total; 270 bovine samples tested, consisting of 170 preputial washings from bulls and 100 vaginal mucus samples of cows. Of these 270 samples, 2.2% were Cfv positive and 1.5% were Cff positive	Mshelia et al. (2012)
North America	Fecal samples from dairy cows cattle	5% of 720 cows were <i>Campylobacter</i> spp. positive	Harvey et al. (2004)
Malawi	Vaginal mucus samples from cows and preputial washings from bulls	1 bull was tested positive for vibriosis Vaginal mucus samples gave no clear result	Klastrup and Halliwell (1977)
Scotland	Preputial washings of bulls	0% of 109 tested bulls were <i>C. fetus</i> positive	McGowan and Murray (1999)
South Africa (Republic of Transkei)	Preputial washings of bulls	10 of 14 (71%) tested sites were <i>C. fetus</i> positive	Pefanis et al. (1988)
South Africa (Gauteng province)	Preputial washings of bulls	2.1% of 143 tested bulls were <i>C. fetus</i> positive	Njiro et al. (2011)
Tanzania	Preputial washings of	3 of 58 (5.1%) tested bulls were Cfv positive	Swai et al. (2005)



		Turkey	Preputial	Cfv is isolated from both	Mshelia et al.							
		TUIKEy	washings of	bulls and aborted fetuses	(2010)							
			bulls and		(2010)							
			aborted									
			bovine									
			fetuses									
		United	Aborted	28 of 161 (17%) tested	Devenish et al.							
		Kingdom	bovine	samples were C. fetus	(2005)							
			fetuses	positive								
		Zimbabwe	Aborted	9.5% of 21 tested fetuses	Mshelia et al.							
			bovine	were <i>C. fetus</i> positive	(2010)							
			fetuses	Estimated; BGC prevalence								
				is 33% in cows in								
		Cff: Campulaha	ctar fatus subspor	Zimbabwe								
		Cff: <i>Campylobacter fetus</i> subspecies <i>fetus</i> ; Cfv: <i>Campylobacter fetus</i> subspecies <i>venerealis</i> .										
	(a)(ii) 2 Case-	Bulls are asymptomatic carriers of Cfv, so by definition the case-morbidity rate is										
	morbidity rate			rate in cows is unknown, since								
	,	naturally served	l animals is mainly	y detected through the BGC dis	ease symptoms,							
				mptom, and there are no data								
		population of in	fected animals.									
	(a)(ii) 3 Case-fatality			death of the infected bull and/o	'							
	rate			ortion. The disease can spread								
				ity due to BGC can reduce the	annual weaning							
(b)(i) impact of	(b)(i) 1 Number of		shelia et al., 2007	'). Idic in several MSs. In 2016, sp	oradic cases of							
(b)(i) impact of the disease on	MSs where the disease			Jnited Kingdom, Ireland, France								
agricultural and	is present			untries from 2005-2016 is prese								
aquaculture	is present			d of the document).								
production and	(b)(i) 2 Proportion of			read of BGC within the EU. Data	a about							
other parts of	production losses (%)			ot available, however it was es								
the economy	by epidemic/endemic	during the first	year of infection,	the gross profit margins may b	e reduced by 66%							
	situation (milk,			stablished within a herd, gross	profit margins are							
	growth, semen, meat,	36% lower than	those of uninfect	ted herds (Hum et al., 1994).								
	etc.)											

## **Questions 3**

Question 3C the or significant threat		significant consequences for public health or possible										
Answer Y 🗆 N 🗆												
		significant consequences on public health, including										
	al OR possible significant threats to f	food safety										
Answer Y 🗆 N 🗆		sincificant concerns on weblic backto including										
		significant consequences on public health, including										
epidemic or pandemic potential OR possible significant threats to food safety Answer Y  N N n a												
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet										
(a)(iii) zoonotic character of the disease	(a)(iii) 1 report of zoonotic human cases	Cfv is restricted to the genital tract of cattle and no human cases are reported, except for one isolate from a woman with bacterial vaginosis in Sweden in 1987 (Holst et al., 1987).										
(a)(vi) the routes and speed of transmission of the disease	(a)(vi) 2 types of routes of transmission between animals and humans (direct and indirect including foodborne)	Not applicable - humans are not susceptible for Cfv.										
between animals and, when relevant, between animals and humans	(a)(vi) 3 Incidence between animals and, when relevant , between animals and humans	The transmission of Cfv between animals within a herd depends on the presence of a "vector"; an infected bull that spreads the infection between animals, because BGC is a venereally transmitted infection. However, no quantitative estimates are available in bibliography.										
	(a)(vi) 4 Transmission rate (beta) (from R <sub>0</sub> and infectious period) between animals and, when relevant ,between animals and humans	No data available about the transmission rate of BGC between animals.										
(b)(ii) Impact of the disease on human health	(b)(ii) 5 Disability-adjusted life year (DALY) (b)(ii) 6 Availability of medical	Not applicable - humans are not susceptible to infection with BGC.										
	treatment and their effectiveness (therapeutical effect and any resistance) (b)(ii) 7 Availability of vaccines and											



	their effectiveness (reduced morbidity)	
(c) potential to generate a crisis	(c) 1 listed in OIE/CFSPH classification of pathogens	BGC is an OIE-listed disease but not listed by the CFSPH.
situation and its potential use in bioterrorism	(c) 2 listed in the Encyclopaedia of Bioterrorism Defense of Australia Group	BGC is not listed in the Encyclopaedia of Bioterrorism Defence of Australia Group.
	(c) 3 included in any other list of potential bio- agro-terrorism agents	BGC is not included in any other list of potential bio- agro- terrorism agents.

## **Questions 4**

costs, mainly re	elated to its direct impa	ct on the health	n and productivi		_										
			ease's direct impa	ct on the health and productivi	ty of animals, the										
	nificant impact on the ecor	nomy													
	<b>: impact</b> Y 🗆 N 🗆 na 🗆														
	al impact Y 🗆 N 🗆 na 🗆														
<b>Question 4C the</b>	e disease has a significa	ant impact on th	he economy of t	he Union, mainly related to	its direct impact										
on certain type	s of animal production	systems													
			animal production	systems, the disease has a sig	gnificant impact on										
the economy			·	· · ·											
Answer current	<b>impact</b> Y 🗆 N 🗆 na 🗆														
	al impact Y 🗆 N 🗆 na 🗆	1													
Art. 7 criteria	Art. 7 parameters	1	f the Art 7 nara	meters from the fact-sheet											
(a)(ii) morbidity	(a)(ii) 1 Prevalence/														
and mortality	Incidence	Although BGC is wide-spread in the world, the lack of monitoring programmes for this disease in many countries makes it difficult to estimate the prevalence rates of													
rates of the	Incidence														
disease in	BGC world-wide. As shown in Table 1, the estimates are based on small stud with highly questionable representability. The prevalence of herds infected w														
animal	<i>Campylobacter fetus</i> subspecies <i>venerealis</i> causing BCG is relatively high in lo														
populations	and middle-income countries (LMIC) compared to low prevalence or even														
populations	eradication of BGC in developed countries (data available of the World														
	Organisation for Animal Health (OIE) and published data (Mshelia et al., 2007														
	Organisation for Animal Health (OIE) and published data (Mshelia et al., 2007 Mshelia et al., 2010)).														
			<i>tus</i> prevalence wor	ld wido											
				Deference											
		Country	Samples Aborted	Result           26 of 354 tested fetuses	Reference										
		Argentina		(7%) were <i>C. fetus</i>	Campero et al. (2003)										
			bovine fetuses		(2003)										
		Australia	Aborted	positive 11% of 265 tested fetuses	loweth at al										
		Australia			Jerrett et al. (1984)										
		Brozil	bovine fetuses	were <i>C. fetus</i> positive 170 of 327 tested bulls	Pellegrin et al.										
		Brazil	Preputial												
			washings of bulls	(52.3%) and 17 of 19 tested farms (89.5%) were	(2002)										
			Dulis	<i>C. fetus</i> positive											
		Brazil	Vaginal mucus	22.4% of 1685 cows were	Andrade et al.										
		(Goiás)	samples of	<i>C. fetus</i> positive	(1986)										
		(00/03)	cows	e. <i>retus</i> positive	(1900)										
		USA	Blood samples	189 of 400 (47%) tested	Akhtar et al.										
		(California)	of cows	cows were <i>C. fetus</i> positive	(1990)										
		USA	Blood samples	22.2% of 790 tested cows	Akhtar et al.										
		(California)	of dairy cows	were <i>C. fetus</i> positive	(1990)										
		Canada	Preputial	18 of 529 (3%) bulls tested	Devenish et al.										
		Cunduu	washings of	were <i>C. fetus</i> positive	(2005)										
			bulls	were el retus positive	(2003)										
		Colombia	Preputial	103 farms tested, 15% of	Griffiths et al.										
		Colorribid	washings of	the farms had <i>C. fetus</i>	(1984)										
			bulls	positive bulls	(1901)										
		Egypt	build	BGC prevalence of 10% in	Mshelia et al.										
		-9790		buffalo cows	(2010)										
		India	Fecal samples	No <i>C. fetus</i> found in 120	Chattopadhay										
		(Calcutta)	from cattle	samples	et al. (2001)										
		India (West		Estimated BGC prevalence	Mshelia et al.										
		Bengal)		of 6% in cattle	(2010)										
		Japan	Fecal samples	26.5% of 94 tested	Giacoboni et										
			from cattle	samples were Cff positive.	al. (1993)										
				"A few" samples were Cfv											
				positive.											
		Japan	Fecal samples	13 of 338 (4%) samples	Ishihara et al.										
			from healthy	were <i>C. fetus</i> positive	(2004)										
	1	1 1	nonnicalary		(2001)										



		New Zealand	cattle Vaginal mucus samples from cows and preputial washings from bulls	1230 mucus samples from 125 beef cow herds were tested, 70% of herds had >1 <i>C. fetus</i> positive CVM sample. All 54 preputial washings from 9 herds were <i>C. fetus</i> negative	McFadden et al. (2005)
		Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	15 of 585 (3%) tested bulls were <i>C. fetus</i> positive 5 of 104 (5%) tested cows were <i>C. fetus</i> positive	Bawa et al. (1991)
		Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	3,7% of vaginal mucus samples of cows were <i>C.</i> <i>fetus</i> positive 11% of preputial washings of bulls were <i>C. fetus</i> positive	Mshelia et al. (2010)
		Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	Total; 270 bovine samples tested, consisting of 170 preputial washings from bulls and 100 vaginal mucus samples of cows. Of these 270 samples, 2.2% were Cfv positive and 1.5% were Cff positive	Mshelia et al. (2012)
		North America	Fecal samples from dairy cows cattle	5% of 720 cows were <i>Campylobacter</i> spp. positive	Harvey et al. (2004)
		Malawi	Vaginal mucus samples from cows and preputial washings from bulls	1 bull was tested positive for vibriosis Vaginal mucus samples gave no clear result	Klastrup and Halliwell (1977)
		Scotland	Preputial washings of bulls	0% of 109 tested bulls were <i>C. fetus</i> positive	McGowan and Murray (1999)
		South Africa (Republic of Transkei)	Preputial washings of bulls	10 of 14 (71%) tested sites were <i>C. fetus</i> positive	Pefanis et al. (1988)
		South Africa (Gauteng province)	Preputial washings of bulls	2.1% of 143 tested bulls were <i>C. fetus</i> positive	Njiro et al. (2011)
		Tanzania	Preputial washings of bulls	3 of 58 (5.1%) tested bulls were Cfv positive	Swai et al. (2005)
		Turkey	Preputial washings of bulls and aborted bovine fetuses	Cfv is isolated from both bulls and aborted fetuses	Mshelia et al. (2010)
		United Kingdom	Aborted bovine fetuses	28 of 161 (17%) tested samples were <i>C. fetus</i> positive	Devenish et al. (2005)
		Zimbabwe	Aborted bovine fetuses	9.5% of 21 tested fetuses were <i>C. fetus</i> positive Estimated; BGC prevalence is 33% in cows in Zimbabwe	Mshelia et al. (2010)
			<i>cter fetus</i> subspec <i>cter fetus</i> subspec		
F	(a)(ii) 2 Case-			f Cfv, so by definition the case-	morbidity rate is
	morbidity rate (% clinically diseased	0% in these. Th naturally served	e case-morbidity i animals is mainly	rate in cows is unknown, since detected through the BGC dise	infection in ase symptoms,
	animals out of infected ones)	such as abortion population of inf		mptom, and there are no data o	of the total

	(a)(ii) 3 Case-fatality rate	Infection with Cfv will not cause death of the infected bull and/or cow, but can result in embryo mortality and abortion. The disease can spread rapidly through a herd and abortions and/or infertility due to BGC can reduce the annual weaning rate by 10% (Mshelia et al., 2007).
(b)(i) impact on agricultural and aquaculture production and	(b)(i) 1 Number of MSs where the disease is present	See Section 3.1.1.7, BGC is sporadic in several MSs. In 2016, sporadic cases of BGC were reported in four MSs; United Kingdom, Ireland, France and Spain. The presence of the disease in EU countries from 2005-2016 is presented in Appendix A (see "Tables" section at the end of the document).
other parts of the economy	(b)(i) 2 Proportion of production losses (%) by epidemic/endemic situation (milk, growth, semen, meat, etc.)	Control measures prevent the spread of BGC within the EU. Data about production losses in the EU are not available, however it was estimated that during the first year of infection, the gross profit margins may be reduced by 66% and when the disease becomes established within a herd, gross profit margins are 36% lower than those of uninfected herds (Hum et al., 1994).

#### Question 5a

Interpretation: labour markets Answer curre	Question 5a the disease has a significant impact on society, with in particular an impact on labour markets Interpretation: the disease has a significant impact on society with (as the most important but not the only one) an impact on labour markets Answer current impact Y  N n a Answer potential impact Y  N n a										
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet									
(b)(i) impact on agricultural and	(b)(i) 1 Number of MSs where the disease is present	See Section 3.1.1.7, BGC is sporadic in several MSs. In 2016, sporadic cases of BGC were reported in four MSs; United Kingdom, Ireland, France and Spain. The presence of the disease in EU countries from 2005-2016 is presented in Appendix A (see "Tables" section at the end of the document).									
aquaculture production and other parts of the economy	(b)(i) 2 Proportion of production losses (%) by epidemic/endemic situation (milk, growth, semen, meat, etc.)	Control measures prevent the spread of BGC within the EU. Data about production losses in the EU are not available, however it was estimated that during the first year of infection, the gross profit margins may be reduced by 66% and when the disease becomes established within a herd, gross profit margins are 36% lower than those of uninfected herds (Hum et al., 1994).									

#### Question 5b

Question 5b the disease has a significant impact on animal welfare, by causing suffering to large numbers of animals Interpretation: due to the suffering of large numbers of animals caused by the disease, the disease has a significant impact on animal welfare Answer current impact Y 
N 
N 
na 
N Answer potential impact Y 
N
N
na Art. 7 criteria Art. 7 parameters Assessment of the Art. 7 parameters from the fact-sheet (b)(iii) impact of the (b)(iii) 1 severity of Infection of BGC in bulls is asymptomatic. Infection in cows can result in disease on animal clinical signs at case level moderate endometritis and salpingitis and cows can become infertile for welfare and related level and several months, but usually not life-long. Since infection is often not duration of impairment detected for a long time or only when fertility rates drop, clinical symptoms seem to be very weak, if any, suggesting a rather minor impact on animal welfare. (a)(ii) morbidity and (a)(ii) 2 Case-morbidity Bulls are asymptomatic carriers of Cfv, so by definition the case-morbidity rate (% clinically diseased rate is 0% in these. The case-morbidity rate in cows is unknown, since mortality rates of the infection in naturally served animals is mainly detected through the BGC animals out of infected disease in animal populations disease symptoms, such as abortion as most clear symptom, and there ones) are no data of the total population of infected animals.

#### **Question 5c**

Question 5c 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         Interpretation: due to the direct impact of the disease OR to the impact of the measures taken to control it, the disease has a significant impact on the environment         Answer current impact Y									
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet							
(b)(iv) impact of the disease on biodiversity and the environment	(b)(iv) 1 endangered wild species affected: listed species as in CITES and/or IUCN list	Only cattle ( <i>Bos taurus</i> ) are reported to be infected with BGC, however it cannot be excluded that rare bovine species on the CITES and/or IUCN list can also be infected with BGC; studies are, however, not available.							



	(b)(iv) 2 Mortality in wild species	BGC can cause embryonic death in wild bovines.
(e)(iv) the impact of disease prevention and	(e)(iv) 2 Mortality in wild species	BGC can possible cause embryonic death in wild cattle, but this disease is primarily a problem in domestic animals.
control measures	•	

#### Question 5d

Question 5d The disease has a significant impact on the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds Interpretation: the consequences of the impact of the disease can even lead to the possible disappearance or long-term

<u>Interpretation</u>: the consequences of the impact of the disease can even lead to the possible disappearance or long-term damage of endangered species or breeds

Answer poten	tial impact Y 🗆 N 🗆 na 🗆	
Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet
(b)(iv) impact of the disease on biodiversity and the	(b)(iv) 1 endangered wild species affected: listed species as in CITES and/or IUCN list	Only cattle ( <i>Bos taurus</i> ) are reported to be infected with BGC, however it cannot be excluded that rare bovine species on the CITES and/or IUCN list can also be infected with BGC; studies are, however, not available.
environment	(b)(iv) 2 Mortality in wild species	BGC can cause embryonic death in wild bovines.
	(b)(iv) 3 Capacity of the pathogen to persist in the environment and cause mortality in wildlife	Soil and water can be contaminated with <i>C. fetus</i> , however data about the length of survival of <i>C. fetus</i> in the environment is lacking.

#### **Question D**

Question 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 Answer Y 🗆 N 🗆 na 🗖 Art. 7 criteria Art. 7 parameters Assessment of the Art. 7 parameters from the fact-sheet (d)(v) (d)(v) 1 available According to Council Directive 88/407/EEC, if an animal of an AI station is feasibility, restriction movement tested positive for BGC, the AI station will be closed and production and trade availability and measures or animals and their products are prohibited. The animals of the closed AI effectiveness of station are treated with antibiotics and must be tested negative for BGC for 3 restrictions on times with 2 weeks interval, before the AI centre is allowed to continue the the movement production and trade. of animals and (d)(v) 2 effectiveness of The restriction of movement of BGC-infected animals to another farm will products, as restriction of animal prevent the spread of BGC. control measure movement in preventing the between farm spread If artificial insemination is used, the restriction of movement of animals from (d)(v) 3 feasibility of restriction of animal one farm to another is suitable for BGC. movement

# Tables

Table 2: Presence/Absence of BGC in EU countries from 2005-2016, obtained from OIE WAHIS (OIE, online)

	Status	for six	month j	periods																				
	2005		2006		2007		2008		2009		2010		2011		2012		2013		2014		2015		2016	
Country	Jan- Jun	Jul- Dec																						
Austria																								
Belgium																								
Bulgaria																								
Cyprus																								
Czech Republic																								
Denmark																								
Estonia																								
Finland																								
France																								
Germany																								
Greece																								
Greenland																								
Croatia																								
Hungary																								<u> </u>
Ireland																								
Italy																								
Latvia																								
Liechtenstein																								

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Lithuania												
Luxembourg												
Malta												
Netherlands												
Poland												
Portugal												
Romania												
Slovenia												
Spain												
Sweden												
United Kingdom												

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Key to colours

There is no information available on this disease

Never reported

Disease absent

Disease suspected but not confirmed

Infection/infestation

Disease present

Disease limited to one or more zones

Infection/infestation limited to one or more zones

Disease suspected but not confirmed and limited to one or more zones