Annex to:

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), More S, Bøtner A, Butterworth A, Calistri A, Depner K, Edwards S, Garin-Bastuji B, Good M, Gortázar Schmidt C, Michel V, Miranda MA, Nielsen SS, Raj M, Sihvonen L, Spoolder H, Thulke H-H, Velarde A, Willeberg P, Winckler P, Baldinelli F, Broglia A, Candiani D, Beltrán-Beck B, Kohnle L and Bicout D, 2017. Scientific Opinion on the assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): Bovine genital campylobacteriosis. EFSA Journal 2017;15(10):4990, 30 pp. doi:10.2903/j.efsa.2017.4990

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

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 ☐ na ☐

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 *Campylobacter fetus* subspecies *venerealis* (Cfv) causing bovine genital campylobacteriosis (BGC) is cattle (*Bos taurus*) (OIE, 2012).
	(a)(i) 2 naturally susceptible domestic species	The naturally susceptible wildlife species of Cfv causing bovine genital campylobacteriosis is cattle (*Bos taurus*) (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 (*Bos taurus*) 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 (*Bos taurus*) (Corbeil et al., 1975; Cipolla et al., 1994) and guinea pigs (*Cavia porcellus*) (Plummer, 2017).
	(a)(i) 5 wild reservoir species	The wild reservoir species for Cfv causing BGC is cattle (*Bos taurus*).
	(a)(i) 6 domestic reservoir species	The domestic reservoir species for Cfv causing BGC is cattle (*Bos taurus*) (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 ☐ N ☐ na ☐

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) 1 Prevalence/ 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 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 *Campylobacter fetus* subspecies *venerealis* 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)).

Table 1: *C. fetus* prevalence world-wide

Country	Samples	Result	Reference
Argentina	Aborted bovine fetuses	26 of 354 tested fetuses (7%) were *C. fetus* positive	Campero et al. (2003)
Australia	Aborted bovine fetuses	11% of 265 tested fetuses were *C. fetus* 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 *C. fetus* positive	Pellegrin et al. (2002)
Brazil (Goiás)	Vaginal mucus samples of cows	22.4% of 1685 cows were *C. fetus* positive	Andrade et al. (1986)
USA (California)	Blood samples of cows	189 of 400 (47%) tested cows were *C. fetus* positive	Akhtar et al. (1990)
USA (California)	Blood samples of dairy cows	22.2% of 790 tested cows were *C. fetus* positive	Akhtar et al. (1990)
Canada	Preputial washings of bulls	18 of 529 (3%) bulls tested were *C. fetus* positive	Devenish et al. (2005)
Colombia	Preputial washings of bulls	103 farms tested, 15% of the farms had *C. fetus* 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 *C. fetus* 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 *C. fetus* 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 *C. fetus* positive CVM sample. All 54 preputial washings from 9 herds were *C. fetus* negative	McFadden et al. (2005)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	15 of 585 (3%) tested bulls were *C. fetus* positive 5 of 104 (5%) tested cows were *C. fetus* 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 *C. fetus* positive 11% of preputial washings of bulls were *C. fetus* 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 *Campylobacter* 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 *C. fetus* positive	McGowan and Murray (1999)
South Africa (Republic of Transkei)	Preputial washings of bulls	10 of 14 (71%) tested sites were *C. fetus* positive	Pefanis et al. (1988)
South Africa (Gauteng province)	Preputial washings of bulls	2.1% of 143 tested bulls were *C. fetus* positive	Njiro et al. (2011)
Tanzania	Preputial washings of bulls	3 of 58 (5.1%) tested bulls were Cfv positive	Swai et al. (2005)

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>Turkey</td><td>Preputial washings of bulls and aborted bovine fetuses</td><td>Cfv is isolated from both bulls and aborted fetuses</td><td>Mshelia et al. (2010)</td></tr>
<tr><td>United Kingdom</td><td>Aborted bovine fetuses</td><td>28 of 161 (17%) tested samples were C. fetus positive</td><td>Devenish et al. (2005)</td></tr>
<tr><td>Zimbabwe</td><td>Aborted bovine fetuses</td><td>9.5% of 21 tested fetuses were C. fetus positive
Estimated; BGC prevalence is 33% in cows in Zimbabwe</td><td>Mshelia et al. (2010)</td></tr>
</table>
Cff: Campylobacter fetus subspecies fetus;
Cfv: Campylobacter fetus subspecies venerealis.</td></tr>
<tr><td></td><td>(a)(ii) 2 Case-morbidity rate (% clinically diseased animals out of infected ones)</td><td>Bulls are asymptomatic carriers of Cfv, so by definition the case-morbidity rate is 0% in these. The case-morbidity rate in cows is unknown, since infection in naturally served animals is mainly detected through the BGC disease symptoms, such as abortion as most clear symptom, and there are no data of the total population of infected animals.</td></tr>
<tr><td></td><td>(a)(ii) 3 Case-fatality rate</td><td>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).</td></tr>
<tr><td>(a)(iii) zoonotic character of the disease</td><td>(a)(iii) 1 report of zoonotic human cases</td><td>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).</td></tr>
<tr><td>(a)(iv) resistance to treatments, including antimicrobial resistance</td><td>(a)(iv) 1 resistant strain to any treatment even at laboratory level</td><td>All C. fetus strains and most C. fetus subsp. venerealis strains are resistant to naladixic acid and all C. fetus strains are sensitive to cephalothin (On, 1996). In a field study, 1084 C. fetus strains were isolated from bovines in Alberta and 95% of the isolates showed to be resistant to naladixic acid, 60% of the isolates was resistant for doxycycline, 57% was resistant to tetracycline and 1% was resistant to ciprofloxacin and enrofloxacin (Inglis et al., 2006). The subspecies, however, was not reported and given that the isolates were obtained from feces, it 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, mostly to lincomycin and spectinomycin.</td></tr>
<tr><td rowspan="5">(b)(ii) Impact of the disease on human health</td><td>(b)(ii) 1 types of routes of transmission between animals and humans - see (a)(vi)2</td><td rowspan="5">Not applicable - humans are not susceptible to infection with BGC.</td></tr>
<tr><td>(b)(ii) 2 Incidence of zoonotic cases</td></tr>
<tr><td>(b)(ii) 3 Occasional or substantial?</td></tr>
<tr><td>(b)(ii) 4 Epidemic or pandemic?</td></tr>
<tr><td>(b)(ii) 5 DALY</td></tr>
<tr><td>(b)(iii) Impact of the disease on animal welfare</td><td>(b)(iii) 1 severity of clinical signs at case level and related level and duration of impairment</td><td>Infection of BGC in bulls is asymptomatic. Infection in cows can result in moderate endometritis and salpingitis and cows can become infertile for several months, but usually not life-long. Since infection is often not 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.</td></tr>
<tr><td rowspan="3">(c) potential to generate a crisis situation and its potential use in bioterrorism</td><td>(c) 1 listed in OIE/CFSPH classification of pathogens</td><td>BGC is an OIE-listed disease but not listed by the CFSPH.</td></tr>
<tr><td>(c) 2 listed in the Encyclopedia of Bioterrorism Defense of Australia Group</td><td>BGC is not listed in the Encyclopaedia of Bioterrorism Defence of Australia Group.</td></tr>
<tr><td>(c) 3 included in any other list of potential bio-agro-terrorism agents</td><td>BGC is not included in any other list of potential bio- agro-terrorism agents.</td></tr>
</table>

Question A(iv)

Question A(iv) diagnostic tools are available for the disease Interpretation: diagnostic tools are available for the disease in the Union 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 *C. fetus* bacteria, but for definite diagnosis confirmation has to be done by isolating *C. fetus* from the sample. The isolation of the pathogen causing BGC can be challenging, since *C. fetus* 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 *C. fetus*. Alternatively, the filtration-technique can be used, where the sample is brought onto a 0.65 µm filter, allowing the *Campylobacter* bacteria to pass to a non-selective blood-based (5–7% blood) medium. Identification of *C. fetus* 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 *C. fetus* subsp. *fetus* and *C. fetus* subsp. *venerealis*.
	(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 ☐ 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 *C. fetus* bacteria, but for definite diagnosis confirmation has to be done by isolating *C. fetus* from the sample. The isolation of the pathogen causing BGC can be challenging, since *C. fetus* 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 *C. fetus*. Alternatively, the filtration-technique can be used, where the sample is brought onto a 0.65 µm filter, allowing the *Campylobacter* bacteria to pass to a non-selective blood-based (5–7% blood) medium. Identification of *C. fetus* 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 *C. fetus* subsp. *fetus* and *C. fetus* subsp. *venerealis*.
	(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	(b)(ii) 6 Availability of medical treatment and their effectiveness (therapeutic effect and any resistance)	Not applicable - humans are not susceptible to infection with BGC.
	(b)(ii) 7 Availability of vaccines and their effectiveness (reduced morbidity)	
(d)(i) feasibility, availability and effectiveness of diagnostic tools and capacities	(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 *C. fetus* as well as isolation and identification methods of the agent.
	(d)(i) 2 Se and Sp of diagnostic test	IFAT to detect *Campylobacter fetus* subspecies *venerealis* 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

		antigen catching ELISA to detect the presence of *C. fetus* 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 *C. fetus* 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 *C. fetus* subsp. *venerealis* (OIE, 2012; van der Graaf-van Bloois et al., 2013). Whole genome sequencing can be used to identify *C. fetus* 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.
	(d)(i) 3 type of sample matrix to be tested (blood, tissue, etc.)	In bulls, smegma samples may be obtained by scraping, suction or by preputial washing (OIE, 2012). The amount of *C. fetus* 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 *C. fetus*. The stomach contents (abomasal fluid), lungs and liver have been shown to be the best samples for the recovery of the bacterium (OIE, 2012).
(d)(ii) feasibility, availability and effectiveness of vaccination	(d)(ii) 1 types of vaccines available on the market	Several commercial vaccines are available for BGC consisting of inactivated *C. fetus* cells, including Vibrin® (Pfizer), Vibrio Leptoferm 5 (Pfizer) and BioAbortogen H (San Jorge Bago, Argentina). Both male and female cattle can be vaccinated against *C. fetus*.
	(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 *C. fetus*. 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 effectiveness of medical treatments	(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.
	(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 *Campylobacter fetus* into a herd. Only animals that are tested negative for *C. fetus* 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	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.
	(d)(iv) 3 feasibility of biosecurity measure	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-

		income countries.
(d)(v) feasibility, availability and effectiveness of restrictions on the movement of animals and products, as control measure	(d)(v) 1 available restriction movement measures	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.
	(d)(v) 2 effectiveness of restriction of animal movement in preventing the between farm spread	The restriction of movement of BGC-infected animals to another farm will prevent the spread of BGC.
	(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.
(d)(vi) feasibility, availability and effectiveness of killing of animals	(d)(vi) 1 available killing of animal measures	For BGC, killing of animal measures are available.
	(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, availability and effectiveness of disposal of carcasses and other relevant animal by—products	(d)(vii) 1 disposal options available	Semen or embryos contaminated with BGC can be destroyed.
	(d)(vii) 2 effectiveness of disposal option	Disposal of the semen or embryos will prevent BGC spread.
	(d)(vii) 3 feasibility of disposal option	Disposal of BGC contaminated semen or embryos can be expensive, but is feasible world-wide.

Question B(i)

Question B(i) 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?
Answer Y ☐ N ☐ na ☐

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) 1 Prevalence/ 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 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 *Campylobacter fetus* subspecies *venerealis* 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)).

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Brazil (Goiás)	Vaginal mucus	22.4% of 1685 cows were *C.*	Andrade et al.

	samples of cows	*fetus* positive	(1986)
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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 *C. fetus* positive	Devenish et al. (2005)
Zimbabwe	Aborted bovine fetuses	9.5% of 21 tested fetuses were *C. fetus* positive Estimated; BGC prevalence is 33% in cows in Zimbabwe	Mshelia et al. (2010)

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	(a)(ii) 2 Case-morbidity rate (% clinically diseased animals out of infected ones)	Bulls are asymptomatic carriers of Cfv, so by definition the case-morbidity rate is 0% in these. The case-morbidity rate in cows is unknown, since infection in naturally served animals is mainly detected through the BGC disease symptoms, such as abortion as most clear symptom, and there are no data of the total population of infected animals.
	(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).
(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)(iv) resistance to treatments, including antimicrobial resistance	(a)(iv) 1 resistant strain to any treatment even at laboratory level	All *C. fetus* strains and most *C. fetus* subsp. *venerealis* strains are resistant to naladixic acid and all *C. fetus* strains are sensitive to cephalothin (On, 1996). In a field study, 1084 *C. fetus* strains were isolated from bovines in Alberta and 95% of the isolates showed to be resistant to naladixic acid, 60% of the isolates was resistant for doxycycline, 57% was resistant to tetracycline and 1% was resistant to ciprofloxacin and enrofloxacin (Inglis et al., 2006). The subspecies, however, was not reported and given that the isolates were obtained from feces, it 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, mostly to lincomycin and spectinomycin.
(b)(ii) Impact of the disease on human health	(b)(ii) 1 types of routes of transmission between animals and humans - *see (a)(vi)2*	Not applicable - humans are not susceptible to infection with BGC.
	(b)(ii) 2 Incidence of zoonotic cases	
	(b)(ii) 3 Occasional or substantial?	
	(b)(ii) 4 Epidemic or pandemic?	
	(b)(ii) 5 DALY	

Question B(ii)

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 ☐ N ☐ na ☐		
Art. 7 criteria	**Art. 7 parameters**	**Assessment of the Art. 7 parameters from the fact-sheet**
(a)(iv) resistance to treatments, including antimicrobial resistance	(a)(iv)1 list of any resistant strain to any treatment even at laboratory level	All *C. fetus* strains and most *C. fetus* subsp. *venerealis* strains are resistant to naladixic acid and all *C. fetus* strains are sensitive to cephalothin (On, 1996). In a field study, 1084 *C. fetus* strains were isolated from bovines in Alberta and 95% of the isolates showed to be resistant to naladixic acid, 60% of the isolates was resistant for doxycycline, 57% was resistant to tetracycline and 1% was resistant to ciprofloxacin and enrofloxacin (Inglis et al., 2006). The subspecies, however, was not reported and given that the isolates were obtained from feces, it 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, mostly to lincomycin and spectinomycin.

Question B(iii)

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 ☐ na ☐

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 other parts of the economy	(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).
	(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 ☐ na ☐

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 potential use in bioterrorism	(c) 1 listed in OIE/CFSPH classification of pathogens	BGC is an OIE-listed disease but not listed by the CFSPH.
	(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)

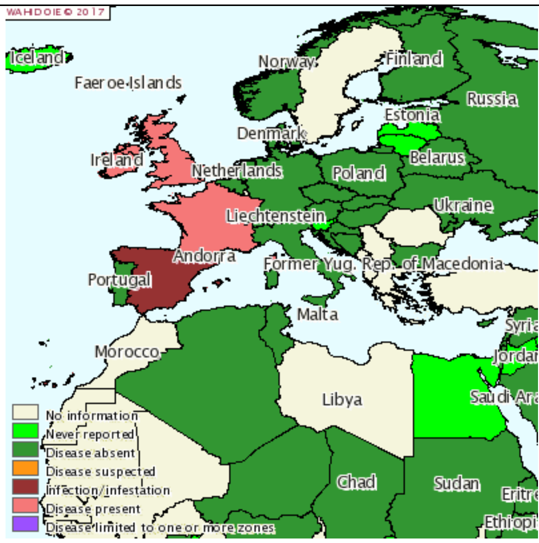
Question B(v) disease has or could have a significant negative impact on the environment, including biodiversity, of the Union
Answer Y ☐ N ☐ na ☐

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 environment	(b)(iv) 1 endangered wild species affected: listed species as in CITES and/or IUCN list	Only cattle (*Bos taurus*) 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 *C. fetus*, however data about the length of survival of *C. fetus* 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

Instruction 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 (irregular introductions) OR present in only in a very limited part of the territory of the Union **Answer** Y ☐ N ☐ na ☐		
Question 1B 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 **Answer** Y ☐ N ☐ na ☐		
Question 1C the disease is present in the whole OR part of the Union territory with an endemic character **Answer** Y ☐ N ☐ na ☐		
Question 1CAq several Member States or zones of the Union are free of the disease **Answer** Y ☐ N ☐ na ☐		
Art. 7 criteria	**Art. 7 parameters**	**Assessment of the Art. 7 parameters from the fact-sheet**
(b)(i) the impact of the disease on agricultural and aquaculture production and other parts of the economy	(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).
(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	 **Figure 1:** BGC distribution in the EU in 2016 (obtained from OIE (online)) 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[1] and for bovine embryos in Council Directive 89/556/EEC[2]. 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 If animals are infected or products are contaminated, the risk of introduction of BGC to the EU is high, but spread can be prevented by the control measures of AI centres and treatment of animals.

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, 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_0 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	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.

[1] 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.

[2] 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 ☐ N ☐ na ☐		
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 *Campylobacter fetus* subspecies *venerealis* (Cfv) causing bovine genital campylobacteriosis (BGC) is cattle (*Bos taurus*) (OIE, 2012).
	(a)(i) 2 naturally susceptible domestic species	The naturally susceptible wildlife species of Cfv causing bovine genital campylobacteriosis is cattle (*Bos taurus*) (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 (*Bos taurus*) 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 (*Bos taurus*) (Corbeil et al. 1975; Cipolla et al. 1994) and guinea pigs (*Cavia porcellus*) (Plummer, 2017).
	(a)(i) 5 wild reservoir species	The wild reservoir species for Cfv causing BGC is cattle (*Bos taurus*).
	(a)(i) 6 domestic reservoir species	The domestic reservoir species for Cfv causing BGC is cattle (*Bos taurus*) (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 2.4A the disease may result in high morbidity and significant mortality rates **Answer** Y ☐ N ☐ na ☐		
Question 2.4B the disease may result in high morbidity and in general low mortality **Answer** Y ☐ N ☐ na ☐		
Question 2.4C 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 **Answer** Y ☐ N ☐ na ☐		
Question 2.4CAq the disease may result in high morbidity and usually low mortality AND often the most observed effect of the disease is production loss **Answer** Y ☐ N ☐ na ☐		
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) 1 Prevalence/ 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 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 *Campylobacter fetus* subspecies *venerealis* 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)).

Table 1: *C. fetus* prevalence world-wide

Country	**Samples**	**Result**	**Reference**
Argentina	Aborted bovine fetuses	26 of 354 tested fetuses (7%) were *C. fetus* positive	Campero et al. (2003)
Australia	Aborted bovine fetuses	11% of 265 tested fetuses were *C. fetus* 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 *C. fetus* positive	Pellegrin et al. (2002)
Brazil (Goiás)	Vaginal mucus samples of cows	22.4% of 1685 cows were *C. fetus* positive	Andrade et al. (1986)
USA (California)	Blood samples of cows	189 of 400 (47%) tested cows were *C. fetus* positive	Akhtar et al. (1990)
USA (California)	Blood samples of dairy cows	22.2% of 790 tested cows were *C. fetus* positive	Akhtar et al. (1990)
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 *C. fetus* 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 *C. fetus* 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 *C. fetus* 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 *C. fetus* positive CVM sample. All 54 preputial washings from 9 herds were *C. fetus* negative	McFadden et al. (2005)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	15 of 585 (3%) tested bulls were *C. fetus* positive 5 of 104 (5%) tested cows were *C. fetus* 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 *C. fetus* positive 11% of preputial washings of bulls were *C. fetus* 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 *Campylobacter* 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 *C. fetus* positive	McGowan and Murray (1999)
South Africa (Republic of Transkei)	Preputial washings of bulls	10 of 14 (71%) tested sites were *C. fetus* positive	Pefanis et al. (1988)
South Africa (Gauteng province)	Preputial washings of bulls	2.1% of 143 tested bulls were *C. fetus* positive	Njiro et al. (2011)
Tanzania	Preputial washings of bulls	3 of 58 (5.1%) tested bulls were Cfv positive	Swai et al. (2005)

<table>
<tr><td rowspan="3"></td><td></td><td>
<table>
<tr><td>Turkey</td><td>Preputial washings of bulls and aborted bovine fetuses</td><td>Cfv is isolated from both bulls and aborted fetuses</td><td>Mshelia et al. (2010)</td></tr>
<tr><td>United Kingdom</td><td>Aborted bovine fetuses</td><td>28 of 161 (17%) tested samples were C. fetus positive</td><td>Devenish et al. (2005)</td></tr>
<tr><td>Zimbabwe</td><td>Aborted bovine fetuses</td><td>9.5% of 21 tested fetuses were C. fetus positive Estimated; BGC prevalence is 33% in cows in Zimbabwe</td><td>Mshelia et al. (2010)</td></tr>
</table>
Cff: Campylobacter fetus subspecies fetus;
Cfv: Campylobacter fetus subspecies venerealis.
</td></tr>
<tr><td>(a)(ii) 2 Case-morbidity rate</td><td>Bulls are asymptomatic carriers of Cfv, so by definition the case-morbidity rate is 0% in these. The case-morbidity rate in cows is unknown, since infection in naturally served animals is mainly detected through the BGC disease symptoms, such as abortion as most clear symptom, and there are no data of the total population of infected animals.</td></tr>
<tr><td>(a)(ii) 3 Case-fatality rate</td><td>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).</td></tr>
<tr><td rowspan="2">(b)(i) impact of the disease on agricultural and aquaculture production and other parts of the economy</td><td>(b)(i) 1 Number of MSs where the disease is present</td><td>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).</td></tr>
<tr><td>(b)(i) 2 Proportion of production losses (%) by epidemic/endemic situation (milk, growth, semen, meat, etc.)</td><td>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).</td></tr>
</table>

Questions 3

Question 3C the disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety
Answer Y ☐ N ☐ na ☐

Question 3B the disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety
Answer Y ☐ N ☐ na ☐

Question 3A the disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety
Answer Y ☐ N ☐ na ☐

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 between animals and, when relevant, between animals and humans	(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.
	(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_0 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)	Not applicable - humans are not susceptible to infection with BGC.
	(b)(ii) 6 Availability of medical 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 situation and its potential use in bioterrorism	(c) 1 listed in OIE/CFSPH classification of pathogens	BGC is an OIE-listed disease but not listed by the CFSPH.
	(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

Question 4AB the disease in question 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
Interpretation: due to the substantial costs related to the disease's direct impact on the health and productivity of animals, the disease has a significant impact on the economy
Answer current impact Y ☐ N ☐ na ☐
Answer potential impact Y ☐ N ☐ na ☐

Question 4C the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems
Interpretation: due to its direct impact on certain types of animal production systems, the disease has a significant impact on the economy
Answer current impact Y ☐ N ☐ na ☐
Answer potential impact Y ☐ N ☐ na ☐

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) 1 Prevalence/ 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 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 *Campylobacter fetus* subspecies *venerealis* 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)).

Table 1: *C. fetus* prevalence world-wide

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Brazil (Goiás)	Vaginal mucus samples of cows	22.4% of 1685 cows were *C. fetus* positive	Andrade et al. (1986)
USA (California)	Blood samples of cows	189 of 400 (47%) tested cows were *C. fetus* positive	Akhtar et al. (1990)
USA (California)	Blood samples of dairy cows	22.2% of 790 tested cows were *C. fetus* positive	Akhtar et al. (1990)
Canada	Preputial washings of bulls	18 of 529 (3%) bulls tested were *C. fetus* positive	Devenish et al. (2005)
Colombia	Preputial washings of bulls	103 farms tested, 15% of the farms had *C. fetus* 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 *C. fetus* 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	13 of 338 (4%) samples were *C. fetus* positive	Ishihara et al. (2004)

	cattle		
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 *C. fetus* positive CVM sample. All 54 preputial washings from 9 herds were *C. fetus* negative	McFadden et al. (2005)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	15 of 585 (3%) tested bulls were *C. fetus* positive 5 of 104 (5%) tested cows were *C. fetus* 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 *C. fetus* positive 11% of preputial washings of bulls were *C. fetus* 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 *Campylobacter* 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 *C. fetus* positive	McGowan and Murray (1999)
South Africa (Republic of Transkei)	Preputial washings of bulls	10 of 14 (71%) tested sites were *C. fetus* positive	Pefanis et al. (1988)
South Africa (Gauteng province)	Preputial washings of bulls	2.1% of 143 tested bulls were *C. fetus* 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 *C. fetus* positive	Devenish et al. (2005)
Zimbabwe	Aborted bovine fetuses	9.5% of 21 tested fetuses were *C. fetus* positive Estimated; BGC prevalence is 33% in cows in Zimbabwe	Mshelia et al. (2010)

Cff: *Campylobacter fetus* subspecies *fetus*;
Cfv: *Campylobacter fetus* subspecies *venerealis*.

	(a)(ii) 2 Case-morbidity rate (% clinically diseased animals out of infected ones)	Bulls are asymptomatic carriers of Cfv, so by definition the case-morbidity rate is 0% in these. The case-morbidity rate in cows is unknown, since infection in naturally served animals is mainly detected through the BGC disease symptoms, such as abortion as most clear symptom, and there are no data of the total population of infected animals.

	(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 other parts of the economy	(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).
	(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

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 ☐ na ☐
Answer potential impact Y ☐ N ☐ na ☐

Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet
(b)(i) impact on agricultural and aquaculture production and other parts of the economy	(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).
	(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 ☐ na ☐
Answer potential impact Y ☐ N ☐ na ☐

Art. 7 criteria	Art. 7 parameters	Assessment of the Art. 7 parameters from the fact-sheet
(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	Infection of BGC in bulls is asymptomatic. Infection in cows can result in moderate endometritis and salpingitis and cows can become infertile for several months, but usually not life-long. Since infection is often not 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 mortality rates of the disease in animal populations	(a)(ii) 2 Case-morbidity rate (% clinically diseased animals out of infected ones)	Bulls are asymptomatic carriers of Cfv, so by definition the case-morbidity rate is 0% in these. The case-morbidity rate in cows is unknown, since infection in naturally served animals is mainly detected through the BGC disease symptoms, such as abortion as most clear symptom, and there 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 ☐ N ☐ na ☐
Answer potential 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 environment	(b)(iv) 1 endangered wild species affected: listed species as in CITES and/or IUCN list	Only cattle (*Bos taurus*) 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 control measures	(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.

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 damage of endangered species or breeds

Answer current impact Y ☐ N ☐ na ☐

Answer potential 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 environment	(b)(iv) 1 endangered wild species affected: listed species as in CITES and/or IUCN list	Only cattle (*Bos taurus*) 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 *C. fetus*, however data about the length of survival of *C. fetus* 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) feasibility, availability and effectiveness of restrictions on the movement of animals and products, as control measure	(d)(v) 1 available restriction movement measures	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.
	(d)(v) 2 effectiveness of restriction of animal movement in preventing the between farm spread	The restriction of movement of BGC-infected animals to another farm will prevent the spread of BGC.
	(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.

Tables

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

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

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

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