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Game meat: health assessment of human-pathogenic parasites

BfR Opinion No. 045/2018, 21 December 2018

Meat of game living in the wild, such as deer, roe deer and boar, is rich in nutrients, low in fat and commonly sustainably sourced. It may, however, contain parasites that can make people ill if the meat has not been prepared in a hygienically flawless manner. There are often uncertainties in the hygienic assessment of meat from hunted game – for example in case of parasite infestation, regarding localization of parasite infestation sites within the animal carcass. These uncertainties are also due to the limited amount of data on these specific pathogens in game. The German Federal Institute for Risk Assessment (BfR) has therefore conducted an evaluation of own and existing data in order to determine the game species and specific organs respectively in which the parasites listed below have been detected and on the frequency of infestation occurrence. The BfR has used this information to assess the risk of contracting a parasitic disease from consumption of game meat and has put together recommendations on how consumers can avoid such illnesses.

In its health assessment, the BfR has considered game species only, whose meat and products made from their meat are typically consumed, namely boar, deer, roe deer and fallow deer. Acquired data sets on consumption of game meat show that both adults and children in Germany consume game meat only rarely and only in small quantities. On average, people enjoy one to two meals containing 200 to 400 grams of game meat each year. The BfR therefore assesses a low risk of infection with these pathogens through consumption of game. Intensive consumers of game, however, such as families of hunters and their acquaintances eat up to 60 and more meals containing game each year. In general, there is a higher risk of infection if game meat is not prepared properly.

Following parasites and where indicated also their infectious development stages were considered and included in the assessment: toxoplasma (disease: toxoplasmosis), trichinella (disease: trichinellosis), sarcosporidia (disease: sarcosporidiosis), pork tapeworm (diseases: cysticercosis, taeniosis), fox tapeworm (disease: echinococcosis) and „Duncker's muscle fluke"– *Alaria alata* (possible disease: larval alariosis). These parasites possess the ability to embed themselves into other organisms and subsequently utilize these organism's resources to survive and breed. As in humans this behaviour can also cause clinical disease in infected animals.

Consumption of game meat and game meat products has increased in Germany in recent years. There is also a trend towards consumption of medium or rarely cooked game meat which is still pink at the core; moreover, higher amounts of different raw sausage products from game are being produced. In order to counter any health risk resulting from consumption of game meat, the BfR recommends that game meat, raw game sausages and raw meat products should be thoroughly cooked before consumption.

	BfR Risk Profile: Infection with parasites due to consumption of game meat/game meat products that have not been thoroughly cooked (Opinion No. 045/2018)				
A Affected groups	**Pregnant women, chronically ill people, general population**				
B Probability of a health impairment [1]	Practically excluded	**Unlikely**	**Possible**	Probable	Certain
C Severity of the possible health impairment [2]	**The severity of the impairment may vary [2].**				
D Reliability of available data	High: The most important data are available and are free of contradiction	**Moderate: Some important data are missing or contradictory**	Low: Numerous important data are missing		
E Controllability by the consumer [3]	Control not necessary	**Controllable through precautionary measures**	Controllable through avoidance	Not controllable	

Squares highlighted in dark blue indicate the properties of the risk assessed in this Opinion
(more detailed information on this is contained in BfR Opinion No. 045/2018 of 21 December 2018).

Explanations

The risk profile is intended to visualise the risk outlined in the BfR Opinion. It is not intended for the purpose of comparing risks. The risk profile should only be read in conjunction with the Opinion.

[1] Line B – Probability of a health impairment
The probability of a health impairment depends on the frequency with which inadequately cooked meals containing game meat are consumed, the type and amount of potential ingested disease pathogens, and the sensitivity of the person in question to the ingested disease pathogens. In the case of some of the disease pathogens, impairment is quite unlikely but may nevertheless occur in healthy people. A health impairment due to Toxoplasma gondii is more likely, particularly in pregnant women and people with compromised immune systems.

[2] Line C – Severity of the health impairment
The severity of the impairment may vary depending on the type and amount of potential ingested disease pathogens and the sensitivity of the person in question to the ingested disease pathogens.

[3] Line E – Controllability by the consumer
The BfR has provided recommendations for action in its Opinion. These recommendations can be found on page 1 towards the bottom of the grey box.

BUNDESINSTITUT FÜR RISIKOBEWERTUNG (BfR)

1 Subject of the assessment

Game intended for human consumption may be infected with parasites. Therefore, meat as defined in Regulation (EC) No 853/2004 (https://eur-lex.europa.eu) from infected game can become a health risk for humans when consumed. In order to reduce the risk of parasite infectivity in humans through consumption of game, meat hygiene assessment of the animal carcass is carried out in accordance with Regulation (EC) No. 854/2004. Based on Regulation (EC) No. 854/2004, Annex I, Section IV, Chapter VIII, meat must be declared unfit for human consumption if parasite infestation is found.

According to the Animal Food Hygiene Ordinance (Tier-LMHV), game is generally subject to meat inspection unless the meat is marketed in small quantities either directly to the consumer or to local retail establishments for direct marketing to the consumer (Tier-LMHV). In this case, an official inspection may be omitted if no characteristics of concern have been found before or after killing. The term “small quantity” by legislature is defined as animals shot during the course of one hunting day on one officially recognized hunting ground and when marketing takes place no further than a maximum distance of 100 km from the hunting ground or the hunter's residence.

However, during meat hygiene assessment of game potentially infested with parasites, there are always uncertainties regarding the distribution of the parasites within the carcasses and the resulting risk for consumers. Therefore, the German Ministry of Food and Agriculture (BMEL) commissioned the German Federal Institute for Risk Assessment (BfR) to conduct a risk assessment of parasitoses in game, with particular focus on echinococcosis, cysticercosis and *Alaria alata* and other parasites, which should be considered during official meat inspection of game.

With particular attention to preventive consumer protection, the BfR has limited its assessment to meat from roe deer, red deer, fallow deer and wild boar, as these species are the most prevalent game in Germany. Furthermore, examples of rarely consumed wild animals such as badgers and swamp beavers were included in this risk assessment with emphasis on Trichinella infection.

Due to the large number of parasites that can occur in hunted wild animals, the focus was placed on those pathogens that are of zoonotic relevance and that can cause disease in humans through the consumption of infected organs, game meat or game meat products, respectively. Therefore, other parasites whose infectious developmental stages can also be detected during official meat inspection (Sarcosporidia and Trichinella) were included in addition to the requested pathogens by the ministry. Infestation with Toxoplasma gondii cannot be diagnosed during official post-mortem inspection. However, since the pathogen has a significant zoonotic relevance and may cause serious human disease, it was included in the risk assessment as well.

2 Results

Based on the German consumption data available to the BfR, game is only consumed rarely and in small quantities by adults and children alike (Volkert *et al*., 2004; Banasiak *et al*., 2005; MRI, 2008). On average, a person in Germany consumes 200 - 400 g of game meat per year (BfR, 2011a; b). The risk of infection with parasites in Germany after eating game is estimated to be very low in accordance with these consumption levels. However, the risk may be higher for certain population groups, so-called extreme consumers (e.g. hunters), since they have been described to consume 50 to 90 times more game than the average population (Krostitz, 1996; Haldimann *et al*., 2002; Hoffmann, 2013).

Furthermore, the BfR concludes that for particularly sensitive population groups, such as pregnant women and immunosuppressed patients, the health consequences of an infection with certain parasites can be more serious. Therefore, these sensitive population groups should only consume foods containing raw game, such as raw sausages and raw meat products, fully cooked (at least 72 °C inside for 2 minutes).

Considering the fact that game meat may also contain other harmful parasites as well as bacterial and viral pathogens, the BfR recommends that foods containing raw game or raw game meat, should be heated sufficiently before consumption (at least 72 °C inside for 2 minutes).

3 Rationale

3.1 Risk assessment

The risk assessment was prepared on the basis of the current BfR guidelines for health assessments. As this risk assessment covers a large number of pathogens, the hazard identification and hazard characterization for each pathogen were combined to provide the reader with better cadence and ultimately reading experience. The exposure assessment chapter relates to game and its consumption. Therefore, in this section of the assessment all parasites involved are discussed together. In the subsequent risk characterization chapter, again individual parasites are discussed, followed by a final list of possible and advisable courses of action.

3.1.1 Hazard identification and Hazard characterization

In the context of hazard identification, relevant parasites that can be detected during the official post-mortem inspection of hunted wild animals are shown in the following table (Table 1).

Table 1: Relevant parasites, which can be detected during official meat inspection of hunted wild boar, roe deer, red deer and fallow deer (according to Deutscher Jagdverband and Gräfner, 1979).

animal body / organs	parasites	affected game	zoonotic potential of the pathogen
muscles / skin	*Sarcocystis* spp.	hoofed game	yes (certain species)
	Cysticercus cellulosae	wild boar	yes
	Cysticercus cervi	ruminant hoofed game	no
	Trichinella spp.*	wild boar, birds of prey, exceptional game	yes
	Hypoderma spp.	ruminant hoofed game	no
fat and connective tissue	*Cysticercus cellulosae*	wild boar	yes
joints	-	-	-
diaphragm	*Alaria alata**	wild boar	unknown
	Trichinella spp.*	wild boar, birds of prey, exceptional game	yes
	Cysticercus cervi	ruminant hoofed game	no
	Cysticercus cellulosae	wild boar	yes
pleura, peritoneum	*Cysticercus tenuicollis*	ruminant hoofed game	no
kidney	-	-	-
kidney-fat	-	-	-
head	*Cephenemyia* spp., *Pharyngomyia* spp., *Coenurus cerebralis, Cysticercus pisiformis,*	ruminant hoofed game	yes (certain species)
tongue	*Alaria alata**	wild boar	unknown
	Cysticercus cervi	ruminant hoofed game	no
	Cysticercus cervi	ruminant hoofed game	no
	Trichinella spp.*	wild boar, birds of prey, ruminant hoofed game	yes
oesophagus	-	-	-
trachea with larynx	*Cysticercus cervi*	ruminant hoofed game	no
tongue	*Metastrongylus* spp.	wild boar	no
	Dictiocaulus viviparus/ filaria	ruminant hoofed game	no

	Echinococcus granulosus	hoofed game [1,2]	yes
	Echinococcus multilocularis	hoofed game [2]	
	Ascaris suum	wild boar	no
pericardium	-	-	yes
heart	*Cysticercus cervi*	ruminant hoofed game	no
	Cysticercus cellulosae	wild boar	yes
liver	*Cysticercus tenuicollis*	ruminant hoofed game	no
	Echinococcus granulosus	hoofed game	yes
	Echinococcus multilocularis	hoofed game [3,4]	yes
	Fasciola hepatica	hoofed game	yes
	Dicrocoelium hepaticum	hoofed game	no
	Ascaris suum	hoofed game	yes
spleen	-	-	-
stomache/ intestine/ mesentery	In the gastrointestinal tract, numerous parasites such as protozoa (e.g. cryptosporidia, Giardia), roundworms, hookworms, whipworms and hairworms occur in the four most common species of cloven-hoofed game. Since the gastrointestinal tract is usually removed when breaking open, these are not discussed further.		
genitals	-	-	-
bladder	-	-	-

* pathogen not detectable via visual inspection, only during routine trichinella testing

In the following, selected pathogens are described in more detail; namely: *Alaria alata*, *Echinococcus* spp., *Sarcocystis* spp., *Taenia* spp. *Trichinella* spp. and *Toxoplasma gondii*.

[1] Morar and Feldman, 2003
[2] Mao et al., 2017
[3] LGL_Bayern
[4] Moro and Schantz, 2009

3.1.1.1 *Alaria alata*

3.1.1.1.1 Possible source of hazard

Taxonomy
Alaria alata (*A. alata*) is a parasitic trematode and belongs within the order *Strigeatidae* to the family *Diplostomatidae* and the genus *Alaria*. In addition to *A. alata*, further 18 *Alaria* spp. have been described so far. The different species of the genus *Alaria* are widespread worldwide (Manke, 1997; Rommel *et al*., 2000). In Europe and also in Germany only *A. alata* is autochthonous (Thiess, 2006; Dolle, 2016). Of possible zoonotic relevance may be the mesocercarial stage (larval developmental stage) of *A. alata*.

Life cycle / transmission to humans
The adult parasite *A. alata* grows to 2.5-6.0 x 0.5-2.0 mm and lives in the intestines of dogs, cats, foxes, mink and other carnivores (final hosts). The eggs of this trematode are excreted with the faeces by these definite hosts. In an aqueous environment, mirazidia (larvae) hatch after 2 weeks, which either actively penetrate the first intermediate host (freshwater snail of the *Planorbidae* family) or are taken up orally. Here they develop via two sporocyst generations into the so-called cercaria, which represent a further larval stage. These leave the snail and penetrate the second intermediate host (anurans: frogs and their tadpoles), where they develop into mesocercariae. The development cycle closes when a definite host ingests the infected second intermediate host e.g. as prey or accidental. In the final host, the mesocercariae migrate via the gastrointestinal tract through the abdominal cavity into the lungs, where development of metacercariae takes place. Subsequently the developed mesacercariae migrate via the trachea into the mouth cavity and return via the oesophagus to the gastro-intestinal tract, where they develop into adult, reproductive trematodes in the intestine (Rommel *et al*., 2000).

Mesocercariae can also be ingested by other, not exclusively carnivorous animals and by humans (paratenic hosts). In the paratenic host, they migrate through the intestinal wall and settle in various organs or muscles, preferring the adjacent fatty tissue (Odening, 1963; Hiepe *et al*., 1985). The paratenic hosts do not develop into sexually mature trematodes. These paratenic hosts also include wild boar (Boch and Supperer, 1992).

Geographical and seasonal characteristics
There are regional differences in the occurrence of *A. alata* in wild boar. The detection rate is higher, especially in water-rich regions, which offer optimal living conditions for intermediate hosts (Wójcik *et al*., 2001; Lücker, 2010). There are also reports of seasonal fluctuations. Mesocercariae are most frequently found in late spring (April/May/June) (Dolle, 2016).

Diagnostics
In most cases, *A. alata* in feral pigs is detected by chance during the official meat inspection for *Trichinella* using the digestion method. However, there exists also a validated method for the detection of *A. alata* in wild boar meat, the so-called AMT (*Alaria* spp. *mesocercariae* migration technique) (Riehn *et al*., 2010). This method is more sensitive and was specifically developed and validated for the detection of *A. alata* mesocercariae.

The mesocercariae are predominantly found in body regions with high fat and connective tissue as well as in cartilage and glandular tissue (Riehn *et al*., 2010). The following predilection sites were identified in wild boar (descending order) (Riehn *et al*., 2010):

1. peritoneum

2. larynx (larynx)

3. diaphragm

4. tongue

5. abdominal muscles

6. jaw and masticatory muscles

Food technology processes for inactivation

The number of studies on the tenacity of *A. alata* mesocercaria in meat and meat products has so far been very limited. Therefore, further studies on the tenacity in relation to different production processes and storage conditions of wild boar meat products should be carried out in future. The data available so far do not allow a reliable statement about inactivation of *A. alata* through freezing (Lücker *et al*., 2015).

According to current knowledge, heat treatment is an effective method for inactivating *A. alata* in wild boar meat. After sufficient heating (at least 72 °C core temperature for 2 minutes), meat contaminated with *A. alata* can be regarded as harmless to humans, since the mesocarcariae are efficiently killed by the heating process.

3.1.1.1.2 Hazard Characterization

Description of disease in humans

Disease in humans caused by mesocercariae of different *Alaria* spp. is called larval alariosis, which is a non-communicable disease and the infection is not notifiable in Germany. The larval alariosis can manifest itself in different organs and can be of varying severity. Clinically it manifests itself through respiratory symptoms, neuroretinitis, subcutaneous granulomas or as a systemic disease that can be fatal. The infection occurs orally through consumption of raw or insufficiently heated meat from infested game. Smear infections during preparation of food have also been described (Shea *et al*., 1973; Fernandes *et al*., 1976; McDonald *et al*., 1994; Kramer *et al*., 1996).

There is no detailed information on the infectious dose. Based on descriptions of known cases of larval alariosis, however, it can be assumed that the severity of the disease correlates with the number of pathogens ingested (Shea *et al*., 1973; Fernandes *et al*., 1976; McDonald *et al*., 1994; Kramer *et al*., 1996).

To date, there is no documented case of larval alariosis caused by mesocariae of the species *Alaria alata.* However, the following facts point out that human disease caused by *Alaria alata* is unlikely but cannot be completely excluded: Already in 1961 Odening reported that primates (rhesus monkeys) can be orally infected with mesocercariae of *A. alata* (Odening, 1961). In Switzerland, the species *Alaria alata* is considered a zoonotic parasite. In 2003, the Swiss Federal Office for the Environment (FOEN) and the Swiss Federal Office of Public Health (FOPH) classified *Alaria alata* in risk group 2 (Gottstein, 2013).

3.1.1.2 *Echinococcus* spp.

3.1.1.2.1 Possible source of hazard

Taxonomy

Echinococcus, which belongs to the class of cestodes (tapeworms) and to the family of *Taeniidae*, is a 2 - 7 mm long endoparasite. The genus *Echinococcus (E.)* has a worldwide distribution (exception: Antarctica) and is composed of ten species, seven of which can cause infections in humans. (*E. granulosus, E. ortleppi, E. canadensis, E. intermedius, E. multilocularis, E. vogeli* and *E. oligarthra*) (Thompson, 2017).

Life cycle / transmission to humans

Echinococcosis is caused by an infection with the larval stage (metacestodes) of the parasite *Echinococcus* in an intermediate or accidental host. As with all taenidia, an obligatory change of host is characteristic for the life cycle. Live adult cestodes can only develop in final hosts (carnivorous mammals). A clinical picture does not develop here or only when there is very strong infestation. Infections of the intermediate or accidental host (human, wild boar) with the larval stage, on the other hand, often show a pronounced pathogenicity (Thomas *et al*., 2017).

Since the scope of this risk assessment is limited to wild animals, the development cycle is described using the example of the small fox tapeworm (*E. multilocularis*), the only *Echinococcus* species for which reliable data on the occurrence in wild animals exist in Germany. The habitat of adult tapeworms is in the villi of the small intestine of the fox and more rarely in the villi of other canids or felines. For example, wolves, raccoon dogs and cats can be final hosts of the fox tapeworm. However, this depends on whether intermediate hosts (especially small mammals) serve as food source. After oral intake of infectious parasite stages from the intermediate host, it takes 5 to 7 weeks until eggs are released with the faeces from the final host. Infection of the intermediate host occurs through oral ingestion of excreted eggs. Here, a hook-bearing larva, known as the oncosphere, hatches after stomach passage. The oncosphere passes through the intestinal wall and reaches the liver via the bloodstream. Other organs, such as the lungs, can also be affected. In these target organs fins develop, which are called metacestodes and are small bubbles of a few mm to 2 cm in size. The so-called budding process leads to infiltration of surrounding tissue, which results in tumor-like growth. After a few months, head structures (protoscolices) develop which are located inside the fins. These protoscolices develop into adult sexually mature parasites (Thompson, 2017) after per-oral absorption by the final host (e.g. consumption of the intermediate host as prey).

Transmission of *Echinococcus* to humans occurs through - oral uptake of tapeworm - eggs, which can be found in the faeces (faecal-oral infection) but also in the fur of infected animals. In addition, for the small dog tapeworm (*E. granulosus*), soil contaminated with eggs and food (berries, mushrooms) are relevant sources of infection (RKI, 2005; WHO, 2018a). For *E. multilocularis*, transmissions through contaminated soil, food or water are also conceivable, but so far have not been described (RKI, 2005). Human-to-human transmissions are not known to occur. Furthermore, the BfR is not aware of any studies devoted to the question of whether *Echinococcus* eggs can also accumulate in the fur of non-infected animals and transmitted from there (via accidental smear contamination from faeces of infected animals). This seems to be possible when considering the known routes of transmission. Alimentary transmission via meat of infected intermediate or other accidental hosts (e.g. wild boars, hares) to humans is not possible, since only the eggs are infectious for humans as final hosts (WHO, 2018a).

Geographical features

In high-endemic areas in Bavaria and Baden-Württemberg, such as the Swabian Alb, the Alb-Danube region, Upper Swabia and the Allgäu, a high level of foxes infected with *E. multilocularis* must be expected (> 50%) (König *et al.*, 2005; Moro and Schantz, 2009).

Diagnostics
Wild boar is one of the most probable intermediate hosts (LGL_Bayern; Remde, 2008) to consider. Visually perceptible pathological changes are observed mainly in the liver and, depending on the extent of the infestation, also in adjacent tissue and other organs (e.g. lungs) (LGL_Bayern; Morar and Feldman, 2003; Remde, 2008; Oksanen *et al*., 2016). White lesions of 1 - 15 mm in size (in exceptional cases also larger) can be observed either occurring sporadically or in larger numbers. Furthermore, all lesions show inflammation with calcification and thick acellular lamellar structures typical for *Echinococcus* (LGL_Bayern; Remde, 2008). However, macroscopic species differentiation is difficult and can only be estimated by using prevalence data. In order to make such a distinction, laboratory diagnostic methods must be used. In serology, ELISAs are often applied, but they do not always produce reliable results due to the possibility of cross-reactions. Therefore, use of molecular-biological methods, such as PCR, which allow species differentiation by amplification of specific gene sequences areis recommended (Zhang and McManus, 2006).

Food technology processes for inactivation
Echinococcus eggs excreted by infected animals are highly resistant to environmental influences and disinfectants. Temperatures of 60 - 80 °C kill the eggs within 5 minutes (Eckert and Deplazes, 2004). Boiling (100 °C) directly kills the eggs (Eckert and Deplazes, 2004). The eggs are also sensitive to dehydration. Temperatures from -70 to -80 °C for 96 or 48 hours also lead to the safe inactivation of the eggs (Eckert and Deplazes, 2004).

3.1.1.2.2 Hazard Characterization

Description of the disease in humans
Echinococcosis: Most common representatives of the genus *Echinococus* with clinical relevance are *E. granulosus* and *E. multilocularis*. They cause echinococcosis in humans, which is divided into cystic echinococcosis (pathogen: *E. granulosus*) and alveolar echinococcosis (pathogen: *E. multilocularis*) respectively.

Cystic echinococcosis (CE): Humans as final hosts become infected by close contact with the principle host (e.g. dog) (RKI, 2005; Brehm 2017). The incubation period of cystic echinococcosis varies between several months and many years (WHO, 2018a). Communicated data from previous years suggest that an autochthonous infection in Germany is now considered highly unlikely, suggesting that the pathogen is not circulating in Germany anymore or at least not momentarily. This is also supported by the fact that CE reported in Germany mostly affects people who were already infected in their countries of origin (RKI, 2005; Richter *et al*., 2009; Brehm 2017; Thomas *et al*., 2017). Infections through imported dogs from endemic areas are also possible (RKI, 2005; Richter *et al*., 2009; Brehm 2017; Thomas *et al*., 2017). Typical for an infection with the small dog tapeworm is the formation of a host-side connective tissue capsule around the developing cyst. In 70 % of cases the liver is affected, in 20 % the lung, rarely the heart, bones, muscles or the nervous system (Thomas *et al*., 2017). All age groups can be affected. Symptoms appear late and are unspecific (nausea, vomiting, stomach pain). These develop through secondary bacterial infections of the cysts, once they have reached considerable size (Kammerer and Schantz, 1993; Thomas *et al*., 2017). Rupture of cysts (spontaneous or traumatic) can lead to anaphylactic shock (de Wispelaere *et al*., 2011). There is a particular risk of infection in high-endemic areas (Balkans, Mediterranean region). The BfR has no reliable data on the infectious dose. In endemic areas, intermediate hosts are mostly sheep or cattle, through which dogs can become infected when fed with intestines after slaughter (Moro and Schantz, 2009). Mouflon and wild boar can also be considered as intermediate or accidental hosts. Immigration of infected carnivorous final hosts from endemic areas, such as the wolf, pose a potential for the pathogen to re-establish itself within the wild animal population in Germany. However, such an event has not been described so far.

Alveolar echinococcosis (AE): AE is one of the most dangerous zoonoses in Europe. Humans pose as accidental intermediate hosts. Wild boars are also an intermediate or more likely an accidental host. The asymptomatic incubation period of AE is 5 to 15 years due to the slow growth of larvae (WHO, 2018a), which is the main reason why retrospective description of the case-specific transmission route is often difficult or no longer possible. Mean age of onset of disease in humans is between 50 and 60 years of age. Immunocompromised patients have a higher risk of contracting the disease. The disease is rather rare in children and adolescents (RKI, 2005; Brehm, 2017). The BfR is not aware of any data regarding infectious dose.

One third of patients become symptomatic due to icterus, another third due to unspecific upper abdominal pain (WHO, 1996). In the remaining patients, AE is diagnosed as a coincidental finding after clarification of further symptoms such as chronic fatigue, unwanted weight loss, hepatomegaly (abnormal enlargement of the liver), or through routine laboratory testing and/or ultrasound examinations (Bresson-Hadni *et al*., 1994; WHO, 1996). In 98 % of cases, the liver is primarily affected. Larval growth is infiltrative, which is why neighbouring organs can also be affected. In 34% of all patients metastases (mostly in the lungs, brain, bones or spleen) are already present at the time of diagnosis (Khuroo *et al*., 1997). The disease is fatal if left untreated.

Depending on the type of *Echinococcus*, diagnostic options differ insignificantly. Imaging procedures and the detection of pathogen-specific antigens are always at the centre of clinical findings. Imaging methods used here include ultrasound (US), computed tomography (CT) and magnetic resonance (MR) (Brunetti *et al*., 2010). If a liver carcinoma or liver cirrhosis is suspected, alveolar echinococcosis can also be considered as a differential diagnosis given corresponding anamnesis.

Occurrence in humans in Germany

E. granulosus and *E. multilocularis* have the greatest clinical relevance in humans in Europe (Thomas *et al*., 2017), with autochthonous infections of humans with *E. granulosus* hardly occurring in Germany (RKI, 2005, Richter *et al*., 2009; Brehm 2017; Thomas *et al*., 2017). Both human diseases are notifiable in Germany according to legislature IfSG §7.

E. multilocularis is only found in the northern hemisphere. Clusters have been described in Bavaria, Baden-Württemberg and North Rhine-Westphalia (Fig. 1) in particular, but also in northern Switzerland, West Austria and eastern France (RKI, 2005; Brehm 2017). An average of 117 human echinococcosis cases per year is reported (Fig. 1, Robert Koch Institute: SurvStat@RKI 2.0, https://survstat.rki.de, query date: 14.09.2018).

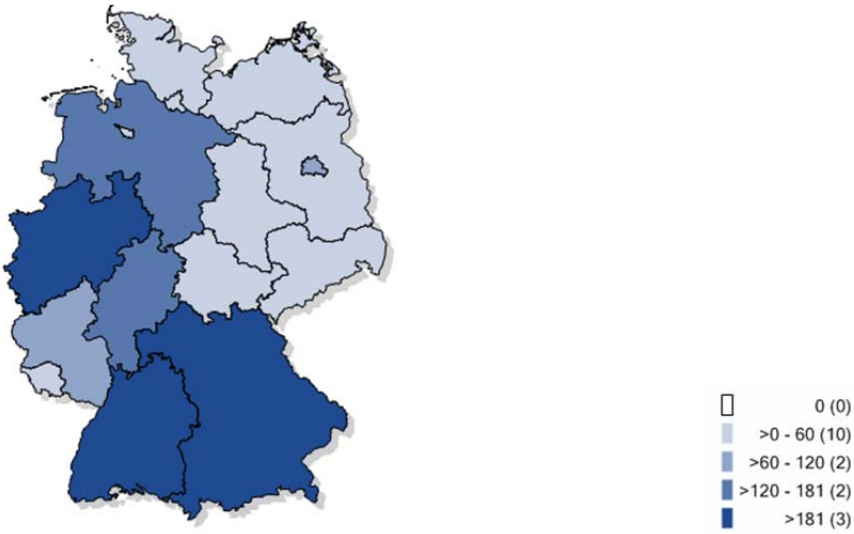

Figure 1:
Echinococcosis cases not reported by name by the public health services and distribution per federal state since 2001 (2054 reported cases in total); Source: Robert Koch Institute: SurvStat@RKI 2.0, https://survstat.rki.de, query date: 14.09.2018.

3.1.1.3 Sarcocystis spp.

3.1.1.3.1 Possible source of hazard

Pathogen/ Taxonomy
Sarcosporidia are microscopically small unicellular parasites which infect the muscle tissue of a host. They belong to the cyst-forming coccidia whose development cycle includes a definite host (sexual cycle) and an intermediate host (asexual cycle). Currently, more than 150 different species are described worldwide. Currently only 3 humanpathogenic *Sarcocystis* species are characterized. For *Sarcocystis nesbitti* humans serve as intermediate hosts; putative definite hosts are reptiles (Matuschka, 1987). *Sarcocystis hominis* (intermediate host cattle) and *Sarcocystis suihominis* (intermediate host pig) are also considered human pathogens; here humans serve as definite hosts (Fayer *et al*., 2015). It is assumed that other *Sarcocystis* species can also infect humans as definite hosts and cause clinical symptoms; these are not yet described in detail (Fayer *et al*., 2015).

Transmission/ Development cycle
The genus *Sarcocystis* has an obligatory two-host cycle. Humans can be either intermediate hosts or definite hosts. Infection occurs through consumption of insufficiently heated or raw meat containing infectious sarcocysts of the species *S. hominis* or *S. suihominis*. Possible sources of infection are meat from farm animals or from furred game, feathered game and reptiles (Fayer, 2004).

Infection occurs when sporocysts are ingested from a competentintermediate host (e.g. shellfish) by consumption of contaminated plant based foods or water. They reach the stomach, where infectious sporozoites are released. These sporozoites penetrate into the intestinal wall and from there are distributed via blood and lymphatic channels first into the vascular endothelium and later into target organs; where they reside mainly in the striated muscles. There the parasite multiplies asexually by division. Long-lived tissue cysts (the so-called Miescher tubes) are formed, which contain millions of cystozoites. If the meat of an intermediate host is consumed raw or insufficiently heated, the cystozoites remain infectious.

If competent definite hosts take up these cystozoites, cystozoites emerge from the tissue cysts and settle in the intestinal wall of the end host after digestion of the meat. Genital cells are formed and sexual reproduction takes place. The fertilized female cell surrounds itself with a shell and becomes an oocyte. This oocyte develops into permanent forms, which are excreted with the faeces of the host over a longer period of time. These permanent forms are also called sporocysts and the development cycle has thus been completed once (BfR, 2008).

Infections in animals can be accompanied by fever, lethargy, emaciation, lameness and abortus depending on the infecting Sarcocystis species and the infection dose. The majority of infections in animals remain asymptomatic (Fayer, 2004).

<u>Geographical Distribution</u>
There is no known geographical accumulation in Germany.

<u>Diagnostic</u>
Neither EU nor national law requires specific testing to detect these protozoa. Only when there are clear visual recognizable alterations in the tissue caused by numerous cysts can the meat be declared as unfit after meat inspection. Macroscopically, the affected musculature has a slightly glassy appearance. If the infestation is severe, a white speckling of the musculature can be detected (Miescher's tubes) (Böhmler, 2008).

In meat, cysts with infected cystozoites can be detected by microscopic imaging in haematoxylin-eosin (HE) stained muscle sections. For larger sample quantities, the pathogen can be detected from meat using a digestion method (Fayer, 2004). A species determination via cysts in the musculature is not possible on the basis of the morphological properties alone (BfR, 2008). However, differentiation at species level can be carried out using various molecular biological techniques (e.g. PCR, sequencing) (Tenter, 1995; Gonzalez *et al*., 2006). Infection in animals can be detected through presence of specific serum antibodies. There is a high cross-immunity between the sarcosporidia species, so that a positive serological result cannot be used to draw conclusions about the respective infecting species (Damriyasa *et al*., 2004).

<u>Food technology processes</u>
Sarcosporidia in meat may be inactivated by appropriate methods. When the meat is heated, a temperature of at least 71 °C must be reached inside the meat for two minutes in order to safely kill the pathogen (Honda et al., 2018). Deep freezing at -20 °C for at least 2 days also provides effective protection against sarcosporidia infection. (Saleque et al., 1990; Honda et al., 2018).

3.1.1.3.2 Characterization of the Hazard

<u>Description of the Disease in Humans</u>
Sarcosporidiosis (human as final host) is characterized by nausea, vomiting and acute to chronic enteritis. Based on data from voluntary infection trials, an incubation period of a few hours has been described. Clinical symptoms were observed until 48 h post infection (p.i.) and sporocysts were detected between 17 days to > 21 months p. i. in stools of infected persons (Laarman, 1962; Rommel, 1970). Sarcosporidiosis is considered self-limiting. Long elimination times are associated with possible reinfection and/or impaired immunity (Fayer *et al*., 2015).

The muscular form (human as intermediate host) is a very rare disease; about 100 clinical cases have been reported worldwide so far. In the majority of these cases, the infecting *Sar-*

cocystis species was not identified. Only two outbreaks in Malaysia have been associated with *S. nesbitti* (Fayer *et al*., 2015). Described symptoms included fever, muscle and joint pain, headache, weakness and cough (Fayer *et al.*, 2015).

Occurrence in humans in Germany
According to the EU zoonoses report for the reference year 2016, no Member State reported human sarcosporidiosis cases (EFSA, 2017). The disease is a non-communicable under the German Infection Protection Act.

From the literature, there are hardly any reports of intestinal sarcocystosis outbreaks after eating pork, cattle or other animal species that were infected with *Sarcocystis* species pathogenic to humans. In 2007, an accumulation of sarcosporidiosis cases in Lower Saxony after eating ground pork meat was reported (Böhmler, 2008).

In human stool samples, *Sarcocystis* sporozysts are found in about 7% of cases in Central Europe. In non-European countries (e.g. Thailand) the prevalence is significantly higher,(up to 23 %). Whether the detected sarcocysts were pathogenic species *S. suihominis* of pigs or *S. hominis* of cattle was not investigated (Daugschies, 2006). In a German study by Janitschke et al. (1974), *Sarcocystis hominis* was found in 12 out of 150 persons who had eaten raw meat or raw meat products. 50% of the infected persons reported gastrointestinal symptoms (Janitschke, 1974).

The BfR is currently not aware of any reports of sarcosporidiosis cases in humans in Germany that may be associated with consumption of game. In association to outbreaks of muscular sarcocystosis reported in Malaysia, cases have also been described in German travellers (Tappe *et al.*, 2014).

3.1.1.4 *Taenia* / *Cysticercus* spp*.*

3.1.1.4.1 Possible source of danger

Taxonomy
Cysticercus (*C.*) represents a larval developmental form, the so-called fin stage, of cestodes (tapeworms) of the genus *Taenia (T*.), which can be found in the intermediate hosts of the parasites. A total of 40 species of the genus *Taenia* are known, which are endemic on all continents except Australia and Antarctica (Hoberg, 2002). Only the species *T. saginata, T. solium* and *T. asiatica* with the associated fin stages *C. bovis* or *inermis*, *C. cellulosae* and *C. viscerotropica* have zoonotic potential (Ale *et al*., 2014; WHO, 2018b).

Development cycle / Transmission to Humans
The sexually mature cestodes are host-specific and live in the intestines of their final hosts. Tapeworms of the genus *Taenia* consist of a head (Scolex), a neck (Proliferation zone) and a link chain (Strobila). The head part has suction cups for attachment to the intestine of the final host. Starting from the neck, new tapeworm links (proglottids) are formed, which make up the following link chain. The sexual organs are located in the proglottids. The representatives of the genus *Taenia* are hermaphroditic. After fertilization, which takes place within the proglottids, the individual, egg-containing tapeworm members are tied off from the rest of the body and leave the final host either actively via the anus or are excreted by the final host with the faeces. The proglottids excreted into the environment dry out, break open and the tapeworm eggs are released. If an egg is taken orally by a suitable intermediate host (e.g. pig in *T. solium*), the so-called oncosphere (hook larvae, 1st larval stage) slips into its intestinal tract. The oncosphere migrates through the intestinal mucosa into the bloodstream and thus reaches the muscles and organs of the intermediate host (Janitschke, 2002). The on-

cosphere adheres to the target organ and forms a liquid-filled bladder around it, a so-called fin. Finns can develop in a wide variety of tissues.

Cysticercus is a thin-walled capsule (fin) into which the head of the future tapeworm is inserted from the wall into the interior. The fin appears as a light blister in which the whitish scolex of the larva can be easily seen. The temporal development to an infectious fin (Metazestode) is different depending on the species (*C. cellulosae*: 70-90 days; *C. tenuicollis*: 42-56 days; (Boch and Supperer, 1992) and lasts on average about 2-3 months (Janitschke, 2002). An intermediate host can also contain Finns of different ages at the same time. Depending on the species, fins may remain infectious for several years (CFSPH, 2005) (Iowa State University, 2005). If infectious fin-containing tissue is consumed by the final host, the capsule dissolves due to gastric acid, the head turns over and the pathogen attaches itself to the wall of the small intestine, where it develops into an adult tapeworm. *C. cellulosae* is the only representative that can occur in humans both in the larval stage (*C. cellulosae*) and in the adult form (*T. solium*). As a result, humans can act both as final and intermediate hosts (Janitschke, 2002). The infection takes place orally through the consumption of raw or insufficiently treated meat (food-technological procedures for inactivation), meat containing fins or through the ingestion of taenia eggs in a faecal-oral way.

<u>Geographical Distribution</u>
There is no known geographical accumulation in Germany.

<u>Diagnostic</u>
In animals infected with *Cysticercus* spp. no symptoms of disease are generally observed. Occasionally there are respiratory problems, movement disorders, difficulty eating and nervous disorders (Boch and Supperer, 1992). The infestation can therefore usually only be detected visually when the animal is broken open and dismantled or during a meat inspection. The Finns are recognizable as whitish blisters on the affected tissues. In addition, an infection can be detected serologically by ELISA or enzyme-linked immunoelectrotransfer-blot (EILT) (Ito *et al*., 1999; Ohsaki *et al*., 1999; Dorny *et al*., 2003; Gupta *et al*., 2018). Species differencing can often only be performed with difficulty macroscopically on the basis of the fin morphology. Therefore molecular biological methods (e.g. blotting methods, PCR) should be used for species differentiation (González *et al.*, 2000).

<u>Food technology processes for Inactivation</u>
Tapeworm fins of the species *C. cellulosae* die after a few minutes at an internal temperature of 60 °C. Furthermore, they are inactivated at a temperature of -15 °C (inside temperature) after 75 minutes and at -18 °C (inside temperature) after 30 minutes (ANSES, 2012).

3.1.1.4.2 Characterization of the Hazard

<u>Description of Disease in Humans</u>
Depending on the stage of development in which the pathogen is absorbed, two different forms of disease can occur in humans (taeniosis and cysticercosis).
Taeniosis: The disease caused by adult cestodes of the genus *Taenia* is called taeniosis. In the human host, taeniosis is caused by the species *T. asiatica*, *T. saginata* and *T. solium* (Nguyen *et al*., 2016).

Humans become infected by oral ingestion of meat containing fins. Initially, the disease is characterized by mild, non-specific symptoms such as abdominal pain, nausea and vomiting. Later, when the tapeworm has reached the adult stage (about 8 weeks p.i.), diarrhoea or constipation may occur. The symptoms persist as long as the pathogen lives in the intestine of the final host. If there is no drug treatment with anthelminthics (e.g. praziquantel or niclosamide), the adult tapeworm can parasite for 2-3 years before it dies (WHO, 2018b).

Cysticercosis: The infection is caused by oral ingestion of taenian eggs (autoinfection of *T. solium* carriers, smear infection or consumption of contaminated food) from which the oncospheres hatch in the human intestine. The incubation period varies greatly and can be up to several years (WHO, 2018b). Cysts containing larvae can form in the musculature, in the eye, under the skin and in the central nervous system (CNS). After a longer period, which varies from case to case, the cysts calcify (ANSES, 2012). If cysts develop in the brain, this leads to what is known as neurocysticercosis. The symptoms of neurocyticercosis vary depending on the immune status of the host and the number, size and location of cysts in the brain. The following symptoms are described in neurocyticercosis: chronic headaches, impaired vision until blindness, epileptic seizures, hydrocephalus, meningitis, dementia and other symptoms caused by lesions in the CNS. Deaths are also reported. Between 1990 and 2002, a total of 221 fatal cases related to cysticercosis were registered in the USA (Sorvillo *et al*., 2007). In 2015, the disease was identified internationally as one of the leading causes of death associated with food-borne infections (WHO, 2018b). Worldwide, the number of patients (with and without symptoms) is estimated at a total of 2.56 - 8.30 million (WHO, 2018b). For both diseases, there are no particular vulnerable groups in the population. Data on the minimum infectious dose in humans are not yet available (ANSES, 2012).

Occurrence in Humans in Germany
Both taeniosis and cysticercosis of humans are non-communicable in Germany.
The diseases are rare in Europe. The occurrence of neurocyticercosis in Europe is associated with increased travel activity and migration of tapeworm carriers from rural regions of Africa, Asia and Latin America, where the disease mainly occurs (WHO, 2018b). In Europe, a total of 846 cases of cysticercosis were described between 1990 and 2011, of which 522 were autochthonous and mostly identified in Portugal. The remaining 324 were imported cases, diagnosed predominantly in Spain, France and Italy (Zammarchi *et al*., 2013). In Germany, a total of 6 clinically confirmed human cysticercosis cases were reported between 1990 and 2015. (Laranjo-González *et al.*, 2017).

3.1.1.5 Toxoplasma gondii

3.1.1.5.1 Possible Source of Danger

Taxonomy
Toxoplasma (T.) gondii is an unicellular obligate intracellular parasite which is classified within the *Apicomplexa* strain into the subclass of coccidia and the *Sarcocystidae* family. *T. gondii* is the only species of the genus *Toxoplasma* (http://taxonomicon.taxonomy.nl/TaxonTree.aspx?id=1309&src=0).
In Europe and North America the majority of *T. gondii* isolates can be assigned to three genotypes (Type I, II, III), all of which are infectious to humans. The majority of human infections are attributed to genotype II, which is also the predominant genotype in Europe (Howe and Sibley, 1995; Schlüter *et al.*, 2014).

Development cycle/Transmission
Due to its wide distribution and low host specificity, T. gondii is considered one of the most important parasitic zoonotic pathogens worldwide. The parasite is able to infect almost all warm-blooded vertebrates, including birds, with only cats and other felids serving as final hosts (Tenter et al., 2000).

The development cycle of T. gondii is divided into sexual and an asexual reproduction phases. Three different stages of development can be distinguished (oocysts, tachyzoites, bradyzoites), which are all infectious for both the intermediate and final host. Transmission of the parasite is not only possible between intermediate and final hosts, but can also occur between two different intermediate or final hosts (Tenter et al., 2000).

Only in the intestinal epithelium of the final host does the parasite multiply sexually, resulting in several million oocysts which are excreted with the faeces (Dubey and Frenkel, 1972). In the environment, the oocysts sporulate within 1 - 5 days and become infectious through this maturation process (Dubey, 1998a; Dubey et al., 1998). Oocysts are a resistant permanent form that can withstand frost and remain viable and infectious in soil for up to 18 months (Frenkel et al., 1975). By oral uptake of sporulated oocysts from the environment, new hosts can become infected. The oocyst wall is lysed during the gastrointestinal passage and the sporozoites are released. After infection of the intestinal epithelium, a strong asexual multiplication and spread of the pathogen occurs in the body in the form of rapidly dividing tachyzoites. With the onset of the immune response, this acute stage passes into a chronic phase of infection. The division rate of the tachyzoites slows down and they differentiate into bradyzoites, hundreds of which persist protected within tissue cysts in various organs and muscles for years or even life in the host (Robert-Gangneux and Darde, 2012). The consumption of raw meat containing tissue cysts eventually leads to infection of the host or other intermediate hosts. Bradyzoites are released during the gastrointestinal passage, infect the intestinal epithelium and a new asexual (intermediate host) or sexual reproduction phase (final host) is initiated. Due to the large distribution and wide host spectrum, all infected warm-blooded farm animals, slaughtered animals and wild animals can generally be regarded as reservoirs (RKI, 2007). The most important horizontal transmission pathways for humans are oral uptake of infectious tissue cysts by consumption of raw or insufficiently heated meat or unheated meat products and oral uptake of sporulated oocysts from the environment via smear infection (e.g. through gardening, direct contact with cat droppings) or by consumption of contaminated plant food and water. In the case of an initial infection during pregnancy, the pathogen can also be transmitted vertically to the unborn child (Tenter *et al.*, 2000).

With regard to an infection by tissue cysts, cases of acute toxoplasmosis, for example, have also been associated with the consumption of raw venison (Sacks *et al*., 1983; Choi *et al*., 1997; Ross *et al*., 2001) and smear infections when cutting up wild animal bodies and processing raw meat are also conceivable (McDonald *et al.*, 1990; Dubey, 1991).

<u>Geographical Features</u>
Data on geographical accumulations of *T. gondii* infections in game in Germany are not available to the BfR at this point.

<u>Diagnostic</u>
There is no meat hygiene regulation for the examination of carcasses or wild game meat for *T. gondii* tissue cysts. Contamination of meat with *T. gondii* tissue cysts is not detectable with the naked eye. In hares, for example, an enlarged spleen and liver and millet grain-sized reddish-yellow inclusions in the liver can indicate an acute and mostly lethal toxoplasmosis disease (Gräfner, 1979; Kujawski and Heintges, 1984).

No standardised or official methods are available for detection of *T. gondii* tissue cysts in meat. However, numerous molecular biological or serological methods are described in the literature, which allow additional investigations. It should be considered that the recovery rate by direct detection is significantly influenced by the sample size investigated due to irregular distribution and often low concentration of cysts in tissue of infected animals (<1 tissue cyst/50g) (Dubey *et al*., 1996) (Robert-Gangneux and Darde, 2012). Therefore, concentration techniques, e.g. acid pepsin digestion, are often used to first digest larger amounts of meat and to concentrate the released pathogens. The pathogen can then be detected in the concentrate using molecular biological methods or bioassays (Dubey, 1998b).

For the meat inspection of farmed game (cervids and wild boars), EFSA has already proposed harmonised key epidemiological indicators according to which either every animal or every older animal (>1 year) could be tested at slaughter for the presence of *T. gondii*-specific antibodies in meat juice from musculature (European Food Safety Authority, 2013). However, since detection of *T. gondii* specific antibodies does not allow a reliable statement on the actual presence of tissue cysts in meat, animals can only be classified into a high or low risk category for *T. gondii* infection on this basis. Commercial ELISA kits for the detection of *T. gondii* specific antibodies are available.

<u>Food technology processes for Inactivation</u>
Dubey et al (1990) reported that tissue cysts in pork were killed by heating to an internal temperature of 67 °C for 3 min (Dubey *et al*., 1990). Due to inconsistent temperatures during microwave heating, microwave heating is not considered a safe method of killing (Lunden and Uggla, 1992).

In further studies, tissue cysts in meat were killed by freezing to -12 °C for 3 days (Dubey, 1988) and -20 °C for 4 hours (Neumayerova *et al*., 2014). Still, an infectious *T. gondii* isolate could be obtained from tissue of a squirrel monkey frozen at -20 °C for 16 days (Aldrin strain) (Dubey and Frenkel, 1973).

Curing and smoking can also inactivate tissue cysts in meat. However, this is strongly dependent on the conditions selected in the production process, such as salt concentrations, water activity and maturation time. As already stated in BfR Opinion No. 039/2005 of 05 September 2005, salted, salted or dried meat, such as raw ham or salami, is generally considered safe. However, raw or only briefly matured meat products such as sausages or Teewurst-sausages may contain infectious tissue cysts (BfR, 2005).

3.1.1.5.2 Characterization of the Hazard

<u>Description of Disease in Humans</u>
With an estimated infection rate of 30%, toxoplasmosis is one of the most common parasitic zoonotic diseases in humans worldwide. In immunocompetent individuals, 80-90% of postnatally acquired infections are asymptomatic and therefore undetected. In 10-20% of cases, mild unspecific flu-like symptoms with fever, headache, muscle pain, sore throat, fatigue and lymph node swelling (predominantly in the head and neck area, more rarely generalized) may occur in the acute phase of infection (Hill and Dubey, 2002; RKI, 2007; Robert-Gangneux and Darde, 2012). First clinical symptoms usually occur 10-14 days after infection (EFSA, 2007). Inflammation of the retina and choroid of the eye (ocular toxoplasmosis) with visual disturbances up to blindness can also occur in immunocompetent children and adults. Severe diseases such as myocarditis, pneumonia, encephalitis and hepatitis have already been described in immunocompetent individuals, but occur very rarely (EFSA, 2007; Schlüter *et al*., 2014). There is evidence that particularly severe diseases are associated with highly virulent atypical genotypes (EFSA, 2007; Schlüter *et al*., 2014).

In immunosuppressed patients (e.g. HIV/AIDS patients, patients undergoing chemotherapy), severe clinical manifestations, which can sometimes be fatal, can often occur, mostly due to reactivation of latent infections. Encephalitis is most common, but pneumonia, ocular toxoplasmosis and the disseminated form of toxoplasmosis involving various organs can also occur (EFSA, 2007; RKI, 2007). Without prophylactic therapy, reactivation and development of encephalitis can occur in 47% of AIDS patients chronically infected with *T. gondii* (Zangerle *et al*., 1991).

If an initial infection occurs during pregnancy, the pathogen can be transmitted transplacentarly to the unborn child (prenatal or congenital infection) and lead to severe physical and neurological malformations, such as inflammation of the retina and choroid of the eye, hydrocephalus and cerebral calcifications up to miscarriages (Mylonas *et al*., 2013). In up to 20% of cases, the pathogen is transmitted to the fetus (Li *et al*., 2014). However, only 27% of infected newborns show specific symptoms (Dunn *et al*., 1999). However, late damages can manifest several years after birth, mainly affecting the eyes, central nervous system and hearing (Tenter and Fehlhaber, 2002).

The effectiveness of drug treatment is limited to tachyzoites but not to already established tissue cysts, which contains acute infection but the pathogen cannot be completely eliminated from the body.

Nothing is known about the minimum infection dose in humans (EFSA, 2007). In animal-experimental studies, a minimum infection dose of one bradyzoite in cats and 10-1000 bradyzoites in mice was determined when administered orally. (Dubey, 2006).

<u>Occurrence in Humans in Germany</u>
The direct or indirect detection of *T. gondii* in connatal infections of humans is required to be communicated under the German Infection Protection Act (RKI, 2007). Between 2002 and 2017, between 6 and 23 cases of connatal toxoplasmosis were reported directly to the RKI each year (Fig. 2) (Robert Koch Institute: SurvStat@RKI 2.0, https://survstat.rki.de, query date: 29.08.2018). However, strong underreporting is assumed, since in Germany no routine screening of pregnant women is carried out and only clinically or serologically conspicuous cases at the time of birth are reported (RKI, 2007). In the federal german state of Saxony, there is also an obligation to report postnatally acquired toxoplasmosis. Between 2002 and 2017, 51 - 127 cases of postnatal toxoplasmosis were reported directly to the RKI each year (Abb. 2) (Robert Koch-Institut: SurvStat@RKI 2.0, https://survstat.rki.de, Abfragedatum: 29.08.2018).

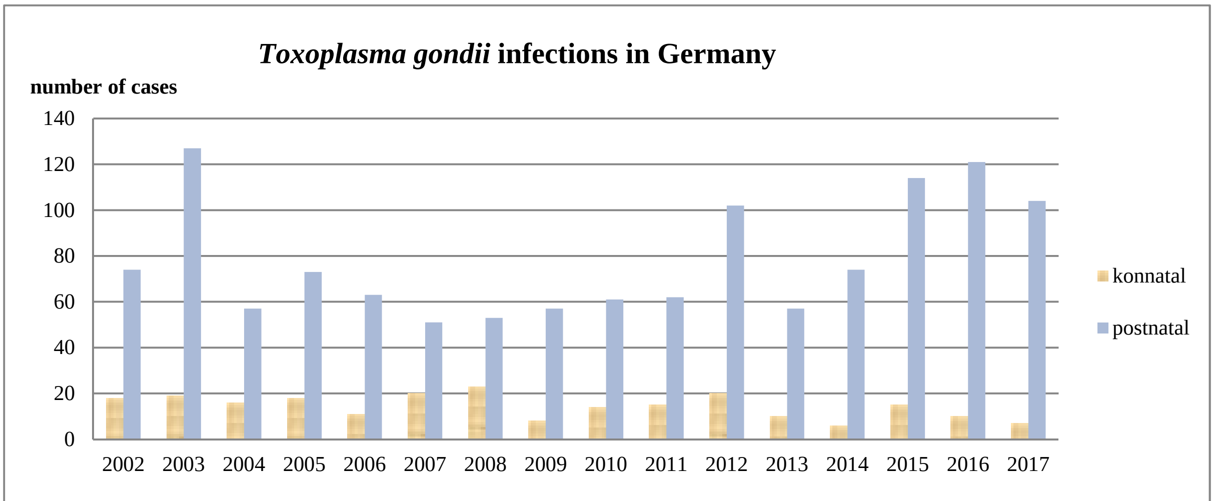

Figure 2*:*
Number of cases of connatal toxoplasmosis not reported by name to the RKI since 2002 in Germany and reported cases of postnatal toxoplasmosis in Saxony (source: Robert Koch-Institut: SurvStat@RKI 2.0, https://survstat.rki.de, query date: 29.08.2018).

In 2016, a first nationwide representative study by the RKI determined a seroprevalence of 55 % in the entire adult German population (Wilking *et al*., 2016). Seroprevalence rose from 20.0% in the age group of young adults (18 - 29 years) to 76.8% among seniors (70 - 79 years). In eastern Germany, higher seroprevalences were found in the population than in the west, which could be due to the increased consumption of raw minced pork in the east (Wilking *et al*., 2016). From the determined seroprevalences an incident rate of postnatally acquired infections of 1,099 per 100,000 inhabitants was estimated. Furthermore, these data were used to calculate that 74.1% of all pregnancies in Germany are at risk and that there are about 6,400 pregnancies per year with a primary infection. This could lead to approximately 1300 prenatal infections and 345 newborns with apparent clinical symptoms each year (Wilking *et al.*, 2016).

3.1.1.6 Trichinella spp.

3.1.1.6.1 Possible source of Danger

Taxonomy
From nematodes of the genus Trichinella, 3 *Trichinella* genotypes (T6, T8, T9) and 8 independent species (*T. spiralis, T. nativa, T. britovi, T. pseudospiralis, T. nelsoni, T. murrelli, T. papuae, T. zimbabwensis*) have been described so far worldwide. These have adapted to the respective climatic conditions (tropics, temperate climate zones, Arctic) and can infest a broad host spectrum (warm-blooded animals, birds, reptiles) (Pozio, 2001; Gottstein *et al*., 2009). In Germany *T. spiralis* (warmbloods), *T. pseudospiralis* (warmbloods and birds), *T. britovi* (warmbloods) and *T. nativa* (warmbloods) have been described so far (Mayer-Scholl *et al.*, 2011; Chmurzynska *et al.*, 2013).

Transmission/ Development cycle
Human trichinellosis is caused by consumption of meat from infected animals that have not been tested for trichinellae and are infected, or have not been properly tested, or have not been subjected to an appropriate inactivation procedure (Gamble *et a*l., 2000). Transmission to humans may occur through a sylvatic cycle (e.g. wild boar) and/or a domestic cycle (domestic pig). Transmission takes place without an exogenous phase exclusively orally-alimentary through meat containing the infectious muscle larvae. Typical hosts of the sylvatic cycle in Germany are fox, raccoon dog and wild boar. In the domestic cycle domestic pigs become infected through feeding of meat waste or through contact with infected (wild) carcasses. In Germany, the latter infection cycle is regarded as practically non-existent (Jansen *et al*., 2008).

After infection, development and sexual reproduction take place in the intestines of the new host (larvae 2 - 4). Newborn larvae then migrate via the blood and lymph vessel system to the well perfused striated musculature, where they can parasite as larva 1 over many years (Despommier *et al*., 1975). Infections in animals are usually asymptomatic.

Geographical Distribution
Trichinella spp. occurs throughout Germany in the sylvatic cycle. Since 2005, especially in the German federal state of Mecklenburg-Western Pomerania, more and more trichinae have been found in wild boar (Pannwitz *et al*., 2009). Six of the seven *Trichinella* infectious diseases reported in domestic pigs since 2005 also came from Mecklenburg-Western Pomerania (Federal Statistical Office). This increase can probably be attributed to increased prevalence of *Trichinella* in the bordering region Polish Voivodeship of West Pomerania and the spread of the raccoon dog in the region (Pannwitz *et al.,* 2010).

Diagnostics
According to the implementing regulation (EU) 2015/1375 of the European Commission, all wild animals in Germany which are susceptible to Trichinella and intended for human consumption are subjected to a systematic Trichinella examination. Sampling of wild game is regulated in Annex III of this regulation. Samples of at least 10 g of antebrachium, tongue or diaphragm shall be taken for examination of wild boar, at least 5 g of which shall be fat free meat and meat free from connective tissue. In the case of other wild animals intended for human consumption, 10 g of musculature must be taken at the predilection site or, if this is not available, in larger quantities at other sites.

The examination for trichinella is carried out according to the principle of artificial digestion ((EU) 2015/1375, Annex I), using the magnetic stirring method as the reference method. Other acceptable methods for the detection of Trichinella in wildlife samples according to (EU) 2015/1375, Annex II are the mechanically assisted method of artificial digestion, the on-filter isolation technique and the automatic digestion method (Trichomatic-35). In order to ensure the quality of Trichinella testing, all Trichinella testing sites must participate regularly and with satisfactory results in comparative laboratory tests (ring trials) in accordance with the Implementing Regulation (EU) 2017/625 of the Commission and carry out the tests under supervision of the competent authorities or an official accredited laboratory.

Processes for the Inactivation of *trichinellae* in Food technology
Temperature/time combinations for the inactivation of *Trichinella* in pork are described in the guidelines of the International *Trichinella* Commission (ICT; http://www.trichinellosis.org/Guidelines.html). At an internal temperature of > 62.2 °C, the *trichinellae* are killed within a few seconds (http://www.trichinellosis.org/Guidelines.html). It can be assumed that inactivation temperatures for game are comparable.

Further, parasites can be killed by freezing under certain conditions. Freezing treatment of pig meat is regulated in Annex II of the Commission's Implementing Regulation (EU) 2015/1375. However, certain *Trichinella* species (*T. nativa* and *T. britovi*) occurring in free-range pigs and wild animals are resistant to freezing treatment at the temperature/time combinations recommended in this implementing regulation (Davidson *et al*., 2008). Freezing is therefore not recognised by ICT as a safe method for killing trichinella in wild animals (ICT, http://www.trichinellosis.org/Guidelines.html).

So far, there are only inadequate studies which describe the influence of the a_w and pH values as well as salt content on the survival rate of the trichinella reliably. Curing and smoking for inactivation of Trichinella in meat is therefore not recommended by ICT (http://www.trichinellosis.org/Guidelines.html). If such methods are used regardless, the effectiveness of the method must be validated.

3.1.1.6.2 Characterization of the Hazard

Description of the Disease
A characteristic feature of trichinellosis is the sudden and unexpected occurrence of outbreaks involving large numbers of people. Humans are regarded as highly susceptible hosts for all *Trichinella* species occurring in Germany, whereby the severity of the infection depends on the number of larvae ingested and the host immune status (BfR, 2007). Incubation period is between 5 and 14 days; in individual cases up to 45 days. Indications of infection in the early stages are fatigue, intermittent high fever, insomnia, diarrhoea and vomiting (enteral phase). After about a week, high fever, chills, pronounced myalgia and edema appear on the face (migration phase). Later on, myocardial inflammation, encephalitis, pneumonia, sepsis, circulatory failure, adrenal insufficiency, coma and seizures may also occur. Exact figures on

the mortality rate are not available, but they are considered low (BfR, 2007). Data from worldwide clinical findings suggest that trichinellosis occurs mainly in adults aged 20-50 years (Murrell and Pozio, 2011). The authors assume that this is due to eating habits in the age group.

Outbreak data suggest a low infectious dose for Trichinella to cause disease in humans. During an outbreak of trichinellosis in Saxony in 2013, the intake of approximately 60 trichinellae was sufficient to develop trichinellosis. The attack rate quadrupled when twice the number of trichinellae was ingested, indicating a clear dose-response relationship (Faber *et al*., 2015). In a dose-response analysis (Teunis *et al*., 2012), a high risk of infection was described with the intake of > 10 larvae.

Occurrence in Humans in Germany
Human trichinellosis is a rare disease in Germany that must be communicated under the German Infection Protection Act. On average, six reported cases of Trichinellosis are reported to the RKI every year (Figure 3). No temporal or spatial trends are discernible. Often the source of infection remains undetected. However, it is not uncommon for cases of illness to be attributed to infections abroad (Jansen *et al*., 2008).

Small autochthonous outbreaks are reported at regular intervals, e.g. in 2006 in Mecklenburg-Western Pomerania as 16 persons fell ill after eating a privately kept and slaughtered domestic pig (Littmann and Nöckler, 2006). In 2013, 14 people in Saxony fell ill after eating raw sausages made from wild boar meat (Faber *et al.*, 2015).

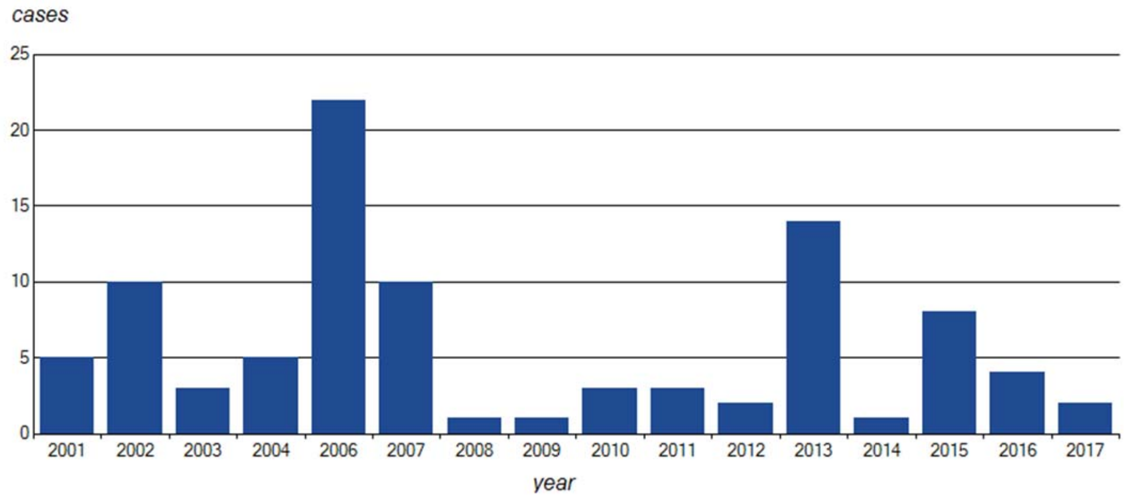

Figure 3:
Human trichinellosis cases recorded by the RKI from 2001-2017 (source: Robert Koch-Institut: SurvStat@RKI 2.0, https://survstat.rki.de, query date: 29.08.2018).

3.1.2 Exposition

3.1.2.1 Occurrence of Parasites in Wild animals in Germany

Alaria alata
So far, there is no legal requirement for examination of DME presence in wild boar. In a study from 2015 in Germany, the occurrence of DME in wild boar was monitored by applying AMT. In eight participating federal states a total of 949 animals were examined and an average prevalence rate of 4.7 % was determined (BVL, 2016).

In addition to the data on the occurrence of DME in hunted wild boars, initial studies on the infestation intensity in wild boars were also carried out. Von Riehn et al. (2011) found an average of 7.6 larvae/100 g tissue in 44 of 54 investigated wild boars in the German federal states of Saxony and Brandenburg (Riehn *et al.*, 2011).

Echinococcus spp.
E. granulosus is momentarily likely not endemic in Germany and therefore no prevalence data exist (RKI, 2005; Brehm 2017). *E. multilocularis*, on the other hand, is endemic in Germany and principal hosts are carnivorous mammals that feed on intermediate hosts, mainly rodents. Principal hosts include fox and raccoon dog (Romig *et al*., 2006; Schwarz *et al*., 2006), 2011; Brehm 2017) The prevalence of *E. multilocularis* in foxes in Germany is approximately 26.0-32.4 %, in raccoon dogs between 0.1 and 7.4 %, in cats between 0.3 and 1.0 % and in dogs between 0.2 and 0.3 %, in arvicolids between 0.4 and 1.0 % and in muskrats between 2.8 and 4.9 % (Oksanen *et al*., 2016; EFSA, 2017).

Due to the successes in rabies control, more foxes live in Germany today than in the past. In addition, these foxes are relocating their habitat ever closer to human settlements and frequently live within towns and cities, which may indicate an increased risk of infection (Brehm, 2017). Some findings have also been recorded in wild boar, hares and nutrias in Germany. However, the BfR is not aware of any prevalence data here.

There are a few case reports on the occurrence of infections in wild animals as intermediate, accidental or dead end hosts (LGL_Bayern; Remde, 2008). These cases show for example that no protoscolic liver lesions could be observed in fox tapeworm infections in wild boars. It is therefore expected at this time that the fox tapeworm fin in wild boars cannot develop completely and a parasite life cycle can therefore not be maintained, which is why wild boars are probably a dead end host. (LGL_Bayern; Remde, 2008).

Sarcocystis spp.
Sarcosporidia have been identified in wild boar (*Sarcocystis miescheriana*), roe deer, red deer and fallow deer (among others *Sarcocystis gracilis, Sarcocystis oviformis, Sarcocystis silva, Sarcocystis capreolicanis*) (Kolenda *et al.*, 2014) and mouflon (*Sarcocystis tenella*). Table 2 describes prevalences and predilection sites from studies in Germany.

Table 2: Occurance of sarcosporidia in wild animals in Germany

Species	Prevalence	Predilection side	References
Wild boar	67 %	stomache-, ham-, and neck-musculature, diaphragm	(Drost, 1974)
Roe deer	42-95 %	stomache- and neck-musculature, diaphragm, heart	(Erber, 1978; Spickschen and Pohlmeyer, 2002)
Red deer	82-86 %	stomache musculature, diaphragm	(Spickschen and Pohlmeyer, 2002)
Mouflon	90 %	stomache musculature, diaphragm	(Spickschen and Pohlmeyer, 2002)

With regard to the ability of the Sarcocystis species of red deer, roe deer and mouflon to cause pathogenicity in humans, only limited investigations have so far been carried out and in some cases the final proof of host is still pending (Spickschen and Pohlmeyer, 2002).

Taenia / Cysticercus spp.
In general, *C. tenuicollis, C. cervi*, *C. pisiformis* and *C. cellulosae* are described in game (Gräfner, 1979; Boch and Supperer, 1992). Overall, there are very few studies dealing with the prevalence of *Cysticercus* spp. in wild animals.

The Metacestode most frequently found in game is *C. tenuicollis*, the fin stage of the tape-worm *Taenia (T.) hydatigena.* (Gräfner, 1979; Boch and Supperer, 1992).

An overview of the fins of the genus *Taenia* occurring in wild game in Germany is shown in Table 3.

Table 3: Occurrences of *Cysticercus* in wild game - Overview after (Gräfner, 1979; Boch and Supperer, 1992; Zrenner and Haffner, 1999)

Tape worm fin	Intermediate host (wild animal)	Localization in intermediate host	definite host
C. tenuicollis (narrow neck, pedicu-lated fin)	roe,-red,-fallow deer, chamois, Elk, wild boar	peritoneum, pleura, Net, mes-entery, stomache, subserosa of liver	carnivores (*T. hydatigena*)
C. cervi (average size: 8x6 mm)	red-, roe, fallow deer	sceletal-, and heart-musculature	dog, fox (*T. cervi*)
C. cellulosae (average size: 6x6 mm)	wild boar	heart-, diaphragm-, tongue, masseter- and skeletal muscu-lature, liver, lung, kidney, brain, eye, fatty tissue	humans (*T. solium*)

Since *C. cellulosae* is the only zoonotic representative of the genus *Taenia* (Alpers *et al*., 2004), which occurs in game in Germany, this species is described in detail below. *C. cellu-losae* represents the fin stage of *T. solium* and has a size of 6 - 15 x 5 - 7.5 mm (Eckert *et al*., 2008). With regard to the occurrence of *C. cellulosae* in wild boars in Germany, the BfR is not aware of any reliable data.

Toxoplasma gondii

Wild animals in particular have an increased risk of exposure to sporulated *T. gondii* oocysts in nature compared to conventionally kept farm animals, and therefore generally show rela-tively high seroprevalence. In Europe, seroprevalences of up to 60 % are described in cer-vids and up to 40 % in wild boars, where the highest seroprevalences were observed in France (European Food Safety Authority, 2013). High seroprevalences of 37.6 % in wild boar, 24.1 % in red deer and 30.4 % in roe deer were also observed in Poland (Witkowski *et al*., 2015).

In Germany, no monitoring studies on the occurrence of *T. gondii* in game have been carried out to date. In individual studies, a seroprevalence of 15 - 33 % in German wild boars (Rom-mel *et al*., 1967; Lutz, 1997; Tackmann, 1999) and 46 % in hares (Frölich *et al*., 2003) was reported. High seroprevalence in foxes of 75 - 85 % in Brandenburg and Saxony-Anhalt sug-gest that *T. gondii* is widespread in these areas (Herrmann *et al*., 2012). Studies on red deer, fallow deer and roe deer as well as on the occurrence of tissue cysts in game meat are not yet available for Germany. The BfR's own initial studies on the occurrence of *T. gondii* in wild game in Brandenburg show seroprevalences of 3.7 % in red deer, 15.7 % in roe deer and 25 % in wild boars.

So far, tissue cysts of *T. gondii* have been detected in the hearts of white deer from Ala-bama, USA (Lindsay *et al*., 1991) and in the hearts of wild boars from France (Richomme *et al*., 2009). Detailed studies on the localization of the pathogen specifically in game are not known to the BfR at this point. In a systematic review, however, brain and heart were identi-fied as predilection sites for the successful detection of *T. gondii* tissue cysts in pigs, small ruminants, horses and poultry, while the liver was proposed for cattle (Opsteegh *et al*., 2016). As a representative sample to assess "safe meat for consumption" the sampling of dia-phragm muscles in the case of pigs, small ruminants, horses and cattle and thigh muscles in the case of poultry is proposed (Opsteegh *et al*., 2016).

Trichinella spp.
Trichinella finds in domestic wild boars are documented by the German Federal Statistical Office in the series 3, series 4.3. (table 4) (Statistisches_Bundesamt, 2018).

Table 4: Trichinella finds in wild boars of domestic origin in Germany

Year	Hunting plain	number of trichinella positive animals	Prevalence (%)	number of trichinella findings per federal state
2008	354.118	16	0,004	BW(1), BB(1), MV(12),TH(2)
2009	275.290	3	0,001	NRW(1), SN(1), TH(1)
2010	308.267	5	0,002	BB(2), MV(1), RP(1), TH(1)
2011	237.426	15	0,006	BB(1), MV(11), NRW(2), ST(1)
2012	195.685	4	0,002	BW(1), BY(1), MV(2)
2013	443.214	11	0,002	BB(4), BW(2), MV(5)
2014	398.446	5	0,001	BB (3), BW (1), MV (1)
2015	362.591	9	0,002	BB (4), MV (5)
2016	464.616	8	0,002	BB (1), BY (1), MV (4), NI (2)
2017	597.002	21	0,004	BW (1), BB (6), MV (14),

BY=Bavaria, BW=Baden-Wuerttemberg, BB=Brandenburg, NRW=North Rhine-Westphalia, NI=Lower Saxony, RP=Rhineland-Palatinate, SN=Saxony, TH=Thuringia

In the year 2005 / 2006, 758 muscle samples of birds of prey were examined in a retrospective study by the BfR in cooperation with the Institute for Zoo and Wildlife Research, whereby no trichinella was detected in any sample (BfR, 2007). So far only worldwide *T. pseudospiralis* finds have been documented in eight bird species (Pozio, 2016).

In 2011, monitoring for the presence of *Trichinella* in foxes, which are regarded as indicator animals for the assessment of the epidemiological situation, was carried out in 9 federal states. Of 3154 investigated foxes, 10 were tested positive for *Trichinella*, which corresponds to a prevalence of 0.3 %. The regional prevalences were between 0 and 1,4 %. The eastern federal states of Saxony (1.4 %), Mecklenburg-Western Pomerania (0.94 %) and Brandenburg (0.42 %) showed the highest prevalences (investigations of the NRL *Trichinella*). The majority of foxes were infected with *T. spiralis*, followed by *T. britovi* and *T. pseudospiralis*.

In Mecklenburg-Western Pomerania 117 raccoon dogs were examined in the context of the monitoring mentioned above. 2.6 % of these animals were *Trichinella* positive. In a longitudinal study carried out between 2008 and 2014, 1.9% of the racoon dogs examined in Brandenburg were found to have *Trichinella* (Mayer-Scholl *et al*., 2016). More than 90 % of the infected raccoon dogs were infected with T. spiralis.

Swamp beavers (Nutrias) are generally susceptible to Trichinella infection, as has been demonstrated in infection experiments (Moretti *et al*., 2001). In Europe, there are isolated reports of trichinella findings in swamp beavers kept on fur farms (Rübli, 1936; Bessonov, 1980). In both cases, the authors suspected that the infection resulted from feeding of kitchen waste with meat components (pig or relevant game). The BfR is not aware of any trichinellaa findings in free-living swamp beavers.

The NRL for *Trichinella* has so far confirmed a *T. britovi* find on a badger in Germany. According to the database of the International *Trichinella* Reference Center in Rome (http://trichinella.iss.it), *Trichinella* spp. has been described in this species twenty times worldwide. The distribution of Trichinella in the body depends on the degree of perfusion of the muscle parts. Trichinellae migrate preferentially into strongly perfused musculature (Serrano *et al*., 1999), whereby the sites of predilection also depend on the infection dose and the *Trichinella* species (Kapel *et al*., 2005). Predilection sites detected in experimentally infected wild animals are shown in Table 5.

Table 5: Predilection sites of Trichinella in experimentally infected wild animals

animal - species (*Trichinella* Spezies)	reported predilection sides	References
fox (*T. spiralis, T. nativa, T. britovi)*	tongue, foreleg, hind leg, diaphragm	(Kapel *et al.*, 2005)
fox (*T. pseudospiralis*)	diaphragm	(Kapel *et al.*, 2005)
racoon dog (*T. spiralis, T. nativa)*	Foreleg, tongue, eye-musculature	(Mikkonen *et al.*, 2001)
wild boar (*T. spiralis, T. nativa, T. britovi, T. pseudospiralis)*	diaphragm, tongue	(Kapel, 2001)
swamp beaver (nutria) (*T. spiralis, T. pseudospiralis)*	diaphragm, masseter, tongue	(Moretti *et al.*, 2001)

Overview of prevalence data

Overall, a large number of wild animals are infected with parasites, and only a certain proportion of those are pathogenic in humans (Table 6). The data described in this table represent the current state of knowledge on the occurrence of the most important zoonotic parasites in the four most common species of cloven-hoofed game in Germany. All data on the occurrence of parasites in wild animals should be regarded as not representative for the occurrence of pathogens in the overall population, as the sample sizes are very small or regional studies are involved. The studies are described in more detail in the comment field of Table 6.

Table 6: Occurrence of the most important zoonotic parasites in the most common cloven-hoofed game species in Germany

	prevalence in wild animals							
	wild boar	**Comment**	**Roe deer**	**Comment**	**Red deer**	**Comment**	**Fallow deer**	**Comment**
Alaria alata	4,7 %[1,2]	direct detection, small sample size, Data from zoonosis-monitoring 2015 with 8 participating federal states	n.r.		n.r.		n.r.	
Echinococcus multilocularis	n.r.	visual detection, small sample size, regional stud-ies, direct detectin possible	n.r.	no studies known to BfR	n.r.	no studies known to BfR	n.r.	no studies known to BfR
***Sarcocystis* spp.**	67 %[3]	direct detection, small sample size, regional stud-ies	42-95 %[4,5]	direct detection, small sample size, regional stud-ies	82-86 %[5]	direct detection, small sample size, regional stud-ies	90 %[5]	direct detection, small sample size, regional stud-ies
Taenia solium	-	no studies known to BfR	n.r.		n.r.		n.r.	
Toxoplasma gondii	15-33 %[6]	detection by serology, small sample size, regional studies	15,7 %[7]	detection by serology, small sample size, re-gional studies	3,7 %[7]	detection by se-rology, small sam-ple size, regional studies	-	no studies known to BfR
***Trichinella* spp.**	0,003 %[8]	direct detection, sample size includes most hunted wild boars	n.r.		n.r.		n.r.	

n.r. nicht relevant

[1] Riehn et al., 2011
[2] BVL, 2016
[3] Drost, 1974
[4] Erber, 1978
[5] Spickschen and Pohlmeyer, 2002
[6] Lutz, 1997; Tackmann, 1999; Rommel, 1967
[7] Untersuchungen des BfR zum Vorkommen von *T. gondii* in Wild in Brandenburg
[8] Statistisches_Bundesamt, 2018

3.1.2.2 Yearly hunting routes

Over the past 20 years, there has been an increasing trend in hunting of the four most common species of cloven-hoofed game in Germany (roe deer, wild boar, red deer, fallow deer) (Figure 4). A sharp increase in the number of hunted animals can be observed in roe deer and wild boars in particular (Table 7).

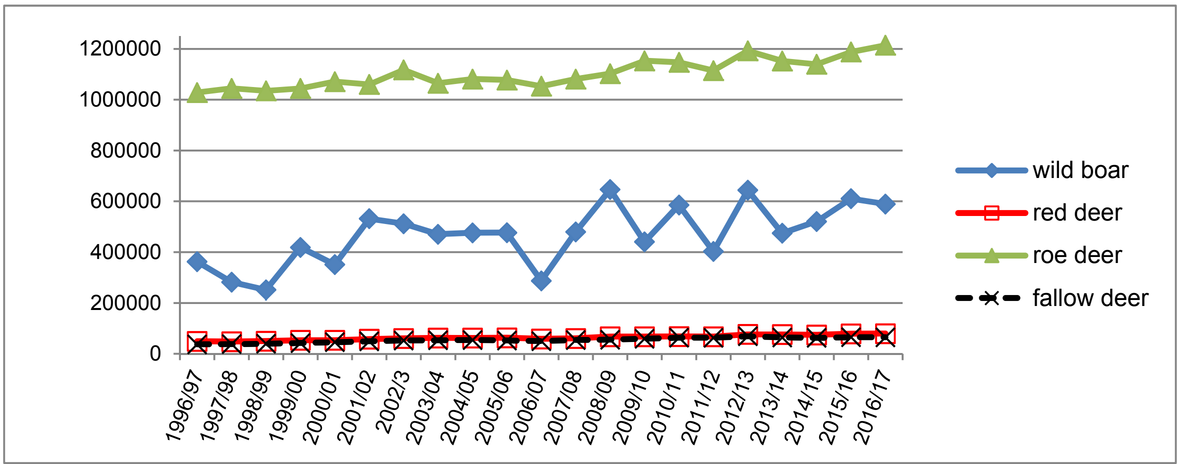

Figure 4:
Annual hunting route for the most common species of cloven-hoofed game in Germany in the hunting years 1996/1997 to 2016/2017. The numbers include fallow game (mostly accident game) (Source: German Hunting Association, www.jagdverband.de).

Table 7: Annual hunting route for the most common species of cloven-hoofed game in Germany from 1996/1997 to 2016/2017. The numbers include fallow deer (mostly accident game) (Source: German Hunting Association, www.jagdverband.de)

Hunting year	wild boar	deer	roe deer	fallow deer
1996/97	362214	49127	1028493	37094
1997/98	281916	47665	1044809	37835
1998/99	251431	49735	1034925	39243
1999/00	418667	53116	1044469	42140
2000/01	350976	53241	1071236	45609
2001/02	531887	57593	1060272	48951
2002/3	512050	60407	1117511	52240
2003/04	470283	62363	1064782	53255
2004/05	476042	62057	1081416	54055
2005/06	476645	62902	1077441	52186
2006/07	287080	58590	1053121	49742
2007/08	479907	60308	1081160	54055
2008/09	646790	67246	1102604	55407
2009/10	440354	67356	1153073	59052
2010/11	585244	67969	1147219	63266
2011/12	402507	67179	1114610	62955
2012/13	644239	76391	1192583	68980
2013/14	474363	75773	1152565	64113
2014/15	520623	74359	1139536	62521
2015/16	610631	78596	1188066	65176
2016/17	589417	79132	1214458	64895

According to Golze (2007), approximately 45 % of all farms with agricultural game husbandry within the EU are located in Germany. In approximately 6000 gateways, the number is estimated at about 15000 ha mainly fallow deer (90 % of the total game population) but also red deer (4-6 %), rarely wild boars and roe deer (Golze, 2007).

3.1.2.3 Game supply

Depending on the study, between 40% and 60% of the game consumed in Germany originates from Germany (Golze, 2007; BfR, 2011a). The German Hunting Association (DJV) calculates the volume of game in Germany per hunting year (01.04. - 31.03. of the following year). These are theoretically calculated values based on the hunting distance (excluding the fallow game) of a hunting year, whereby free-living hunted game is counted as part of the hunting distance. According to these figures, the highest numbers of wild game are found in Germany for wild boar, followed by roe deer, red deer and fallow deer. For the hunting year 2016 / 17, a total of 18,137 tons (t) of game (boneless) was recorded for frequent cloven-hoofed game, with 8544 tons for wild boar, 6242 tons for roe deer, 2286 tons for red deer and 1065 tons for fallow deer.

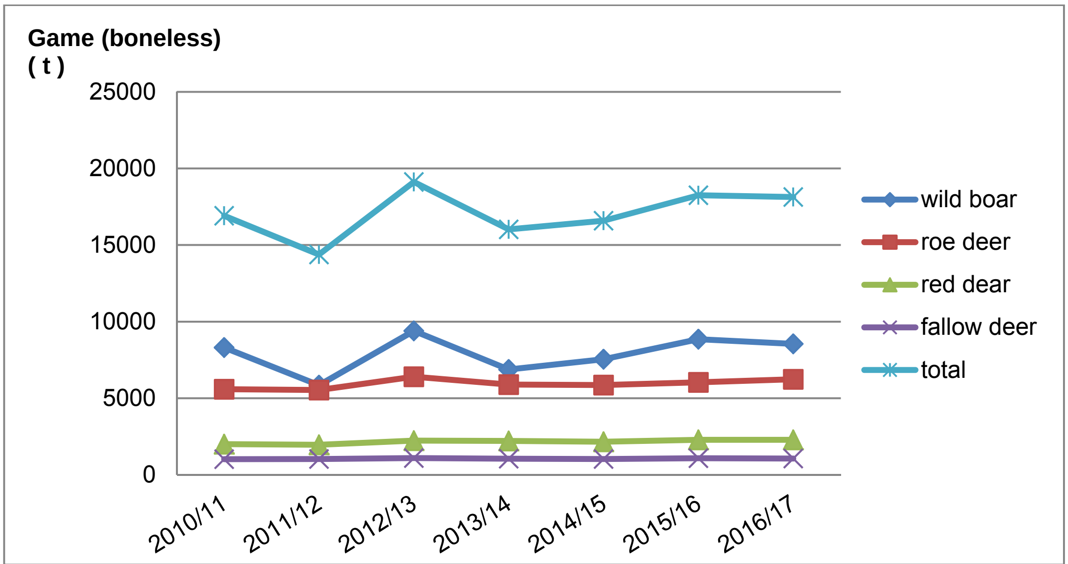

Figure 5:
Game (boneless) due to frequent cloven-hoofed game in the hunting years 2010/11-2016/17 (Source: German Hunting Association, www.jagdverband.de; https://www.jagdverband.de/daten-und-fakten/jagdstatistik/wildbretstatistik

3.1.2.4 Consumption of Game

3.1.2.4.1 Data basis

The National Consumption Study II (NVS II) of the Max Rubner Institute (MRI, 2008) serves as the data basis for the consumption of game meat for adults. The NVS II took place between 2005 and 2006 throughout Germany and is currently the most recent representative study on food consumption of the German population. For evaluation of the consumption of game, 15,371 persons between 14 and 80 years of age were interviewed and their usual consumption of the last four weeks recorded retrospectively. The consumption data evaluations were carried out as part of the "LExUKon" project financed by the BMU at the BfR (BfR, 2009).

Data from the VELS study (consumption study to determine the food intake of infants and young children for the assessment of an acute toxicity risk due to residues of plant protection products) served as the data basis for the consumption of game meat for children (Volkert *et al*., 2004; Banasiak *et al*., 2005). The study was carried out between 2001 and 2002 on 816 infants and young children aged between 6 months and under 5 years throughout Germany. Based on the assumption that the average population shows no preference for a particular game species, the consumption data were used for the whole game, i.e. without differentiating between individual game species (BfR, 2011b; a).

3.1.2.4.2 Consumption quantities

The evaluations were taken from BfR Opinions No. 048/2011 of 16 May 2011 and No. 040/2011 of 3 December 2010 (BfR, 2011a; b). Table 8 shows the average long-term consumption of wild game by different population groups.

Table 8: Mean long-term intake of wild game in grams per day based on NVS II study

Population group	Number of interviewed and evaluated persons	Percentage of people consuming game (%)	Mean consumption of game meat in g/day
Total	15371	11	0,6
Male	7613	13	0,9
Female	7758	8	0,4
Women capable of giving birth (15-45 years)	3820	6	0,3
*Children (2 - <5 years)	475	6	0,1

* Children's consumption data were taken from the VELS study and were not included in the total number.

Based on consumption data of the NVS II and VELS studies, it can be seen that game is rarely consumed in adults and children and only in small quantities. Game was eaten by about 11% of the adult population and by about 6% of the 2 - < 5 year old children. 13 % of the men and 8 % of the women ate game. All population groups ate on average less than 1 g of game per day. With a portion size of 200 g game meat, on average one to two game meals per year are consumed by the total population. For those who eat a lot (95th percentile of the total population), a daily consumption of 3.8 g game meat is assumed, which corresponds to six to seven meals of 200 g game meat. These figures include game hunted in Germany, farmed game (gated) and imported game.

Several studies have shown that hunter households and their environment consume more game than the average population. For example, (Krostitz, 1996) described that three quarters of the game killed in Germany is consumed directly by hunters and their relatives, or marketed directly by hunters and hunting cooperatives (Krostitz, 1996). In a non-representative survey conducted by the DJV, it was established that in Germany an average of 66 game meals of 200 g each are eaten in hunter households per year and capita (Hoffmann, 2013). Hunters in Switzerland were found to consume an average of fifty times more than normal consumers. This corresponds to 91 meals of 200 g game meat each (Haldimann *et al*., 2002).

3.1.3 Risk characterization

The risk of contracting a parasitosis in Germany through consumption of game meat and products derived thereof depends first and foremost on the parasite species, its occurrence in game, the production and treatment of the foodstuffs and the consumption habits and susceptibility of consumers.

In recent years, consumption of game meat in Germany has shown an upward trend. In some parts of the population, game is regarded as a popular regional, ethical and high-quality product. Existing consumption data make it clear that very little amount of game is normally eaten in Germany (one to two game meals of 200 g per year per person). Only so-called extreme consumers, such as hunter households and their environment, consume up to 50 to 90 times as much as normal consumers according to the literature (Haldimann *et al*., 2002).

In Germany, the ways in which game is prepared vary greatly. Traditionally, it is eaten completely cooked. However, there is a trend towards consumption of semi-raw game in particular venison (pink interior) and the production of various raw sausage products. However, the BfR does not have reliable data on the proportion of game that is not fully cooked.

In the following, the risk of infection of consumers by consuming game meat and products made from it in Germany is estimated for the individual parasites on the basis of prevalence data presented for pathogen behaviour and consumption data, if the game meat has not been sufficiently heated before consumption. Heating to at least 72 °C inside temperature for 2 minutes or more is sufficient to eliminate the risks described below.

3.1.3.1 Alaria alata

Alaria alata is autochthonous in Germany and other European countries. In the wildlife populations of raccoons and raccoon dogs are increasing also, increasing the number of potential hosts. In the past, the number of wild boars also increased and so did the number of possible paratenic hosts.

So far, no clinical case of larval alariosis in humans caused by mesozerkaria of the species *Alaria alata* has been documented worldwide. However, the cases of *Alaria alata* described by *Alaria americana* in North America indicate that there may be a risk of human infection or disease through mesocerciasis in wild pig meat. According to the initial monitoring results, the BfR believes that mesocercriae-infected wild boar meat may enter the market. The currently prescribed meat hygiene measures for the detection of worm larvae in wild boar meat serve exclusively to prevent an infection of humans with the pathogen *Trichinella* spp. and the previous findings of mesocercariae in wild boar meat are mostly accidental. Furthermore, only very few and not representative studies exist, which are afflicted with a high degree of uncertainty. Due to the insufficient data available on the occurrence of mesocercariae in wild boars and the lack of cases of disease caused by *Alaria alata*, the risk of disease cannot be accurately estimated. However, based on the low consumption quantities, it can be assumed that the disease risk to the average population is very low (see BfR statement no. 011/2017).

3.1.3.2 Echinococcus granulosus and *Echinococcus multilocularis*

Infection is not possible by eating contaminated meat from an intermediate host or a false host (e.g. wild boar), since only the eggs of *E. granulosus* and *E. multilocularis* are capable to cause infection. Contamination of meat with these eggs is unlikely, so that a very low risk of disease to the average population can be assumed, especially considering the low consumption quantities.

3.1.3.3 Sarcocystis spp.

In the studies on the occurrence of sarcosporidia in cloven-hoofed game, these pathogens were identified in the majority of the animals studied. So far, however, the studies from Germany have exclusively dealt with *Sarcocystis* species which, according to current knowledge, are harmless to humans. It is pointed out that in Spain and the USA individual finds of the human pathogenic species *Sarcocystis suihominis* in wild boar have been documented. Based on these data, the few reports on human diseases and the rare consumption of raw or not sufficiently heated game and products made from it, it is unlikely that consumers in Germany will become infected with sarcosporidia and contract sarcosporidiosis or the muscular form of disease due to their consumption. However, due to the small number of studies on the occurrence of sarcosporidia in wild boar in Germany, this risk assessment is associated with a high degree of uncertainty.

3.1.3.4 Taenia/ Cysticercus spp.

There are currently few confirmed data on the occurrence of *Cysticercus cellulosae*, the fin stage of Taenia solium, in wild boar. However, in Germany the probability that wild boars can become infected with *C. cellulosae* is very low. Due to the high standard of hygiene and the very low prevalence in humans in Germany, the development cycle of the parasite is largely interrupted (source of infection for wild pigs: Taenia eggs from stool of infected humans).

In summary, the BfR estimates the probability that wild boar meat contaminated with *C. cellulosae* will be placed on the market in Germany and that people will become ill after eating it to be very low.

3.1.3.5 Toxoplasma gondii

Data on the occurrence of *T. gondii* in various game species in Germany are still insufficient. However, isolated studies from Germany and other European countries to date and the BfR's own data currently collected indicate that *T. gondii* is also widespread in game in Germany.

Therefore it is basically possible that consumers may develop toxoplasmosis after eating raw or insufficiently heated game or raw meat products made from it. Due to the insufficient data available on the occurrence of *T. gondii* in game, however, the probability of occurrence cannot be accurately estimated. Further, based on the low consumption of T. gondii in the average population, the risk of disease from the consumption of game or game products made from game can be assumed to be very low. However, in view of a possible particular severity of disease for the case of connatal toxoplasmosis or toxoplasmosis among immunosuppressed patients, these population groups should be classified as particularly sensitive.

3.1.3.6 Trichinella spp.

On the basis of the epidemiological situation in Germany and the obligatory trichinella investigation in relevant wild animals, a very low probability of human infection with trichinella can be assumed for both normal and extreme eaters by consumption of game and products made from it. However, if the obligation to meat inspection is not fulfilled, food-borne outbreaks are possible, but the probability of their occurrence cannot be estimated due to lack of data.

Due to the divergent, incomplete lists of animal species which may be infected with Trichinella and which are intended for human consumption, the obligation to investigate is not always clear. The current example of such a so-called exceptional wild animal is the swamp beaver (nutria). Although the swamp beaver is named in the animal LMHV as subject to examination, the risk of infection of the swamp beaver is negligible due to its lifestyle as an almost pure herbivore.

3.2 Framework for action / measures

- For particularly sensitive population groups, such as pregnant women and immunosuppressed patients, the health consequences of infection with parasites can be more severe. For this reason, it is recommended, in particular for these sensitive population groups, that foods containing raw game, including raw sausages and raw meat products made from it, should only be consumed fully cooked (at least 72 °C inside temperature for 2 min). In view of the fact that game meat may also contain other harmful parasites as well as bacterial and viral pathogens, the BfR recommends that foods containing raw game meat, raw sausages made from it and raw meat products be heated sufficiently before consumption (at least 72 °C inside temperature for 2 minutes). With regard to the prevention of *Toxoplasma gondii* infections, we refer to the BfR leaflet of 1 October 2017 "Verbrauchertipps: Protection against toxoplasmosis" (https://www.bfr.bund.de/cm/350/verbrauchertipps_schutz_vor_toxoplasmose.pdf).
- Since, with regard to the pathogens *Alaria* spp., *Echinococcus* spp. and *Toxoplasma gondii* evaluated here, a smear infection and cross-contamination during cutting and gutting of the game body by the hunter as well as during processing of raw game meat by consumers cannot be excluded, reference should be made at this point to the BfR leaflets Information No. 01/2006 of 2 January 2006 "Tipps für Jäger zum Umgang mit Wildbret" (BfR, 2006) and "Protection from foodborne infections in the home." (https://www.bfr.bund.de/cm/350/verbrauchertipps_schutz_vor_lebensmittelinfektionen_im_privathaushalt.pdf).
- Due to their way of life as almost pure herbivores, the risk of trichinella infection can be neglected for free-living swamp-beavers. Therefore, the obligation to examine free-living swamp beavers in the Tier-LMHV should no longer be applied in the future.
- So far, there is no legal regulation requiring the testing of wild boars for presence of *Alaria alata* mesocercariae. However, it is considered advisable to additionally examine killed wild boars by AMT in known risk areas with a high prevalence, since the digestion method for trichinella detection is not a suitable method for the detection of *Alaria alata* mesocercariae. If these mesocercariae aredetected during trichinella testing (pool samples), individual animals of the pool sample should then be examined by AMT to precisely identify the infected animal body.
- If parasites are found during visual inspection, appropriate measures should be taken in accordance with regulation (EC) No 854/2004 Annex I, Section II, Chapter V (https://eur-lex.europa.eu).
- Data available on the actual occurrence of parasites in game in Germany is either missing or usually insufficient and there is a general need for more research in this field. Therefore, the BfR is planning its own studies to improve datadensity for risk assessment.

More information on this topic on the BfR website (in German):

https://www.bfr.bund.de/cm/350/verbrauchertipps_schutz_vor_lebensmittelinfektionen_im_privathaushalt.pdf

https://www.bfr.bund.de/cm/350/verbrauchertipps_schutz_vor_toxoplasmose.pdf

“Opinions app” of the BfR

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