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Towards a standardised surveillance for *Trichinella* in the European Union

L. Alban[a,*], E. Pozio[b], J. Boes[a], P. Boireau[c], F. Boué[c], M. Claes[d], A.J.C. Cook[e], P. Dorny[d], H.L. Enemark[f], J. van der Giessen[g], K.R. Hunt[e], M. Howell[h], M. Kirjusina[i], K. Nöckler[j], P. Rossi[b], G.C. Smith[k], L. Snow[e], M.A. Taylor[k], G. Theodoropoulos[l], I. Vallée[c], M.M. Viera-Pinto[m], I.A. Zimmer[k]

[a] *Danish Agriculture & Food Council (DAFC), Denmark*
[b] *Istituto Superiore di Sanità (ISS), Italy*
[c] *Agence Française de Sécurité Sanitaire des Aliments (AFSSA), France*
[d] *Institute of Tropical Medicine Antwerp (ITM), Belgium*
[e] *Veterinary Laboratories Agency (VLA), UK*
[f] *Technical University of Denmark, National Veterinary Institute (DTU), Denmark*
[g] *Rijksinstituut voor Volksgezondheid en Milieu (RIVM), The Netherlands*
[h] *The UK Food Standards Agency, UK*
[i] *Pārtikas drošības, dzīvnieku veselības un vides zinātniskais institūts "BIOR" (Institute of Food safety, Animal Health and Environment "BIOR"), Latvia*
[j] *Bundesinstitut für Risikobewertung (BfR), Germany*
[k] *The Food and Environment Research Agency (Fera), UK*
[l] *Agricultural University of Athens (AUA), Greece*
[m] *Universidade de Trás-os-Montes e Alto Douro (UTAD), Portugal*

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ABSTRACT

Each year, more than 167 million pigs in the European Union (EU) are tested for *Trichinella* spp. under the current meat hygiene regulations. This imposes large economic costs on countries, yet the vast majority of these pigs test negative and the public health risk in many countries is therefore considered very low. This work reviewed the current *Trichinella* status across the EU as well as the national level of monitoring and reporting. It also reviewed which animal species were affected by *Trichinella* and in which species it should be surveyed. This information was used to design a cost-effective surveillance programme that enables a standardised monitoring approach within the EU. The proposed surveillance programme relies on identifying sub-populations of animals with a distinct risk. Low-risk pigs are finisher pigs that originate from so-called controlled housing. All other pigs are considered high-risk pigs. Controlled housing is identified by the application of a specific list of management and husbandry practices. We suggest that member states (MS) be categorised into three classes based on the confidence that *Trichinella* can be considered absent, in the specified sub-population of pigs above a specified design prevalence which we set to 1 per million pigs. A simple and transparent method is proposed to estimate this confidence, based on the sensitivity of the surveillance system, taking into account the sensitivity of testing and the design prevalence. The probability of detecting a positive case, if present, must be high (>95 or >99%) to ensure that there is a low or negligible risk of transmission to humans through the food chain. In MS where the probability of a positive pig is demonstrated to be negligible, testing of fattening pigs from a sub-population consisting of pigs

* Corresponding author. Tel.: +45 3339 4973; fax: +45 8736 1013.
E-mail address: lia@lf.dk (L. Alban).

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from controlled housing can be considered unnecessary. Furthermore, reduced testing of finishers from the sub-population consisting of pigs from non-controlled housing might even be considered, if conducted in conjunction with a proportionate sampling scheme and a risk-based wildlife surveillance programme where applicable. The proposed surveillance programme specifies the required number of samples to be taken and found negative, in a MS. A MS with no data or positive findings will initially be allocated to class 1, in which all pigs should be tested. When a MS is able to demonstrate a 95% or 99% confidence that *Trichinella* is absent, the MS will be allocated to class 2 or 3, in which the testing requirement is lower than in class 1.

1. Introduction

Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents (known as the Zoonoses Directive) forms the basis for data on zoonoses being collected throughout the European Union (EU) Member States (MS) and reported to the EU on an annual basis. These data are collected and examined by the European Food Safety Authority (EFSA), which, in collaboration with the European Centre for Disease Control (ECDC) and assisted by the Zoonoses Collaboration Centre (ZCC), produce an annual report, the Community Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents, Antimicrobial Resistance and Foodborne Outbreaks in the European Union (available from EFSA's website http://www.efsa.europa.eu/). The report is aimed at detection of sources and trends for zoonotic and foodborne diseases within the EU MS and to pinpoint the long-term goal of protecting human health.

Trichinella spp. are parasites with a world-wide distribution and aetiological agents of a (re-)emerging zoonosis in certain parts of the world (Murrell, 2001). *Trichinella* is included in list A of Annex I, Directive 2003/99/EC, which determines the agents that have to be monitored on a mandatory basis. Official testing is carried out according to Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat, which covers all finisher pigs, sows, boars, horses, wild boars and some other wild species (European Commission, 2005). These regulations require that all pig carcasses be tested for *Trichinella*, unless the pigs are derived from holdings or regions that meet stated criteria for being regarded as having negligible risk. The aim is to remove any contaminated meat from the food chain.

Pigs, horses, other mono-gastric mammals as well as birds and humans can act as a host for *Trichinella*. In the EU, transmission to humans primarily occurs through meat from infected pigs or horses (domestic cycle) or from infected wildlife, e.g., wild boar (sylvatic cycle) (Pozio, 2007). In general, the clinical symptoms of trichinellosis in humans are dose and species-dependent and show the same clinical characteristics irrespective of whether the infection is mild, moderate or severe, and the infections differ mostly in its strength/intensity (Capo and Despommier, 1996). The classical symptoms are gastrointestinal symptoms (diarrhoea, nausea, vomiting), fever, myalgia and periorbital oedema; complications are myocarditis, encephalitis and thromboembolic diseases (Dupouy-Camet and Bruschi, 2007). These conditions are more likely, but not exclusively, expected to occur in severe cases and are the main cause of fatalities. Chronic disease is under debate but the persistence of larvae in humans who did not receive treatment, or to whom treatment was given late, has been reported to cause symptoms such as impaired muscle strength and coordination, as well as conjunctivitis, for up to 10 years (Dupouy-Camet et al., 2002; Dupouy-Camet and Bruschi, 2007).

On 1 January 2008, Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, came into force. This implies that slaughterhouse operators request, receive, check and act upon food chain information for all pigs sent to the slaughterhouse. Within this framework it is mandatory to provide information about the production system. For pigs, information about outdoor production and whether production is conducted under controlled housing conditions or not is of particular interest not just because of *Trichinella* but also because of other hazards like toxoplasmosis and avian tuberculosis. The term controlled housing will be further described in Section 2.3.

The objective of this paper is to present a scheme for standardised surveillance and reporting of *Trichinella* in defined animal populations in the EU (EFSA, 2010a). This scheme was developed as part of an EFSA-funded project.

2. Materials and methods

2.1. Current status

First, we identified the current disease situation in EU MS and current national level of monitoring and reporting information. Next, we identified animal species and/or feedstuffs which could be affected and specified which should be monitored. Finally, we proposed a design for cost-effective standardised surveillance for *Trichinella* in all EU MS.

A spreadsheet for data and information collection was designed and circulated to the MS using established contacts to competent national authorities and networks within the project team (network of national reference laboratories for parasites). The spreadsheet asked for information on confirmed human cases and the current disease situation in relevant animal populations, as well as for supporting information on sampling and testing carried out in the MS, as a basis for the design of surveillance programmes. Where answers were not received, a literature search was carried out in order to fill the gaps.

A vast amount of literature on *Trichinella* has been published since its discovery in 1835. A comprehensive summary of the worldwide distribution of *Trichinella* (Pozio, 2007) and in Europe has been published recently (Pozio et al., 2009a). These sources of information, which are constantly being updated, were used to complete and/or complement data from spreadsheets.

2.2. Species to survey

The question about which species to survey was divided into the parasite and its host (livestock or wildlife), respectively. The literature (scientific publications, textbooks, official websites (OIE/WHO/ECDC)) on *Trichinella* was reviewed and the existing knowledge on zoonotic species summarised.

Regarding which host to survey, a table was compiled with animal species in which *Trichinella* has been reported. The animal species were then assessed as to their role in the life cycle of *Trichinella* and the human food chain. A summary of the results can be found in EFSA (2010a,b).

2.3. Design of standardised surveillance programme

The suggested framework operates with three classes: class 1 (endemic), class 2 (low risk), and class 3 (negligible risk), and the movement between these classes.

2.3.1. Identification of sub-populations with different risk

The proposed surveillance programme relies on identifying sub-populations of animals with a distinct risk. Low-risk pigs are finisher pigs that originate from so-called controlled housing. All other pigs are considered high-risk pigs. Controlled housing is identified by the application of a specific list of management and husbandry practices listed in Annex VIb in Regulation (EC) No 1244/2007 (Appendix A). This implies that the food business operator needs to comply with this set of criteria that includes these requirements among others to (1) no access to outdoor facilities, (2) rodent control in place, (3) proper bedding, feeding, and waste management. High-risk pigs are sows and boars as well as pigs not reared under controlled housing conditions. Hence, this category includes backyard and outdoor production as well as farmed wild boar.

It is important to distinguish between two different purposes of surveillance among EU MS. Both relates to the overall aim of ensuring trade. Firstly, in those MS where *Trichinella* is either known to be present or where the status is unknown, the aim remains to detect all contaminated carcasses to enable these to be removed from the food chain to protect public health. Secondly, where the risk of *Trichinella* is believed to be negligible, then testing is conducted to confirm or refute that presumption.

2.3.2. Estimation of sample size

If a surveillance process tests a representative group of animals, all with negative results, and these animals are assumed to be independent of each other with regard to the probability of infection, the over all sensitivity of the surveillance system (SSe) is the probability that one or more positive pigs will be detected, given that the MS is infected (Martin et al., 2007). The method proposed by Martin et al. (2007) is simple and transparent and can be used to demonstrate confidence in the absence of infection in a given population or sub-population. It requires that a design prevalence P^* is chosen. This is a fixed value at the unit or group level, which is used as the basis for declaring a country free from the disease in question. The estimation of confidence on absence is based on the sensitivity of the surveillance system (SSe), taking into account the sensitivity of testing and the design prevalence:

$$\begin{aligned} \mathrm{SSe} &= \text{probability(identifying infection)} \\ &= 1 - \text{probability(overlooking infection)} \\ &= 1 - (1 - \mathrm{Se})^{n\_pos} \end{aligned} \quad (1)$$

$$n\_pos = N \times P*$$

where Se = test sensitivity, n_pos = expected number of positive animals in the population given the design prevalence, N = population size, P^* = design prevalence.

A sensitivity of 0.4 was used as recommended by Alban et al. (2008). According to a recent risk assessment for *Trichinella* carried out by EFSA, a negligible risk corresponds to less than one case per million individuals (EFSA, 2005). This choice of design prevalence (P^*) is also used in the OIE surveillance guidelines for BSE (OIE, 2007). In accordance, 1 per million pigs was chosen for the basic scenarios.

Example: If 15 million fattening pigs are tested in a MS and the design prevalence is one per million, there are an estimated 15 positive pigs among those tested. Thus, assuming the sensitivity of detection is 0.4, the system surveillance sensitivity is: $1 - (1 - 0.4)^{15} = 0.999$. This means that, if the disease is present in the MS at a level of the design prevalence or higher, the probability that one or more positive pigs will be detected is 99.9%.

Therefore, if only one million pigs are tested and found negative, a confidence of 40% of absence of infection is obtained ($1 - (1 - 0.4)^1 = 0.40$). And if two million pigs are tested, a confidence of 64% is obtained. Hence, the formula can be used to estimate the number of pigs to sample in a population of a given size to be able to demonstrate confidence in the absence of infection at, e.g., 95% or 99%.

A design prevalence P^* of 1 per 100,000 pigs was also used to investigate the effect on sampling (results can be found in EFSA, 2010a). In epidemiological terms, the sensitivity (Se) of an individual test is defined as the probability that a true positive sample tests positive in a test. The artificial digestion test by means of magnetic stirrer method was used. The Se of this method depends among others on the level of infestation and the amount of tissue examined. Here, it is assumed that at least we have a 40% chance of detecting an infection level of 1 larva per g and 1 g of tissue is digested (Forbes and Gajadhar, 1999). This is a conservative estimate according to data from proficiency testing in Denmark (H.L. Enemark, pers. comm.) and France (Vallée et al., 2007). It is anticipated that the sensitivity will vary between different laboratories throughout European MS. A minimum sensitivity of 40% should be seen as a requirement that a laboratory should be able to fulfil.

2.3.3. Correction of sample size for finite populations

For populations smaller than 10 million, this approach has its limitations; either several years of data are added, or a correction for the size of the finite population is used as suggested by Canon and Roe (1982):

$$\frac{1}{n} = \frac{1}{N} + \frac{1}{n^*} \quad (2)$$

where N = population size; n^* = initially calculated sample size; n = resulting sample size.

Based on formula (1) it was found that six million or 10 million pigs would need to be tested and found negative to demonstrate a 95% or 99% confidence in absence, respectively. However, if the entire population in a MS consisted of one million pigs only, then a resulting samples size was found to be:

$$\frac{1}{n} = \frac{1}{1 \text{ million}} + \frac{1}{6 \text{ million}} \Rightarrow n = 857,143$$

This approach was used for different population sizes.

3. Results

3.1. Summary of trichinellosis cases found in animals and humans in the EU

3.1.1. Human situation

In the last 30 years or more, no autochthonous infections in humans (meaning originating from food animals from the MS in which the infected humans reside) have been documented in 14 MS: Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, Ireland, Luxemburg, Malta, Netherlands, Portugal, Slovenia, Sweden and the United Kingdom (UK). In 13 MS (Bulgaria, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Poland, Romania, Slovakia and Spain) autochthonous trichinellosis in humans occurs, although the reported prevalence varies, and human cases are mainly attributed to consumption of undercooked or raw untested meat originating from wild boar and/or from backyard and free-ranging pigs (Pozio, 1998). In Romania, the prevalence of human trichinellosis is markedly higher due to the additional exposure to meat from infected pigs which acquire infection within the domestic cycle (Blaga et al., 2007). In addition, human infections also occur in some MS because of the consumption of meat from imported animals or products coming from other MS or from third countries. Outbreaks related to consumption of raw horse meat have also occurred, and several of these were due to a failure of horse meat controls (Boireau et al., 2000; Liciardi et al., 2009). Excluding Romania, where a large number of hospitalised human infections occur (350 cases reported to EFSA in 2006, 432 in 2007, 503 in 2008), 130–457 cases were reported annually in the EU between 2003 and 2008 (EFSA, 2010b). The data for 2008 is presented country-by-country in Table 1.

3.1.2. Situation in domestic animals and wildlife

Trichinella occurs in wild animals throughout EU MS with the exception of Malta, Cyprus and Great Britain, and the prevalence varies depending on the geographical region, animal host and agent species (Pozio, 2007; EFSA, 2010b). The range of prevalence varies, and estimates can be obtained from the data presented in Table 1. The occurrence of *Trichinella* in livestock is highly dependant on husbandry practices, i.e., the level of on-farm biosecurity measures and, therefore, a useful distinction can be made between "intensive farms" which generally operate under controlled housing conditions and backyard and free-range farms with non-controlled housing. In 14 MS (Bulgaria, Estonia, Finland, France, Germany, Hungary, Italy, Latvia, Lithuania, Poland, Romania, Slovakia, Spain and Sweden) *Trichinella* has been reported from backyard pigs or free-ranging wild boars in the last 10 years, although in some of those countries the occurrence is rare. This is also seen in the data from 2008 (Table 1). A graphical presentation of the distribution of *Trichinella* in wildlife can be found in http://www.efsa.europa.eu/en/scdocs/doc/1496.pdf.

3.2. Review of Trichinella species implicated in human and animal trichinellosis in the EU

3.2.1. The parasite

Humans are generally considered to be highly susceptible to infections with *Trichinella* spp., although it is important to differentiate between infection and clinical disease. Clinical symptoms range from asymptomatic to fatal and vary over the disease course. The severity of symptoms is directly correlated with the number of infective larvae ingested and is also influenced by the *Trichinella* species (Capo and Despommier, 1996). If and why different species seem to cause differences in severity of symptoms is not fully understood at this point. It is suspected that the number of newborn larvae produced by the female may be the main contributing factor. The published data on the reproductive capacity index of *Trichinella* spp. (RCI) are based on data derived from experimental animals rather than humans. It is believed that immunity and individual susceptibility in the human host also play an important role (Dupouy-Camet and Bruschi, 2007). Fatalities are rare and mostly associated with complications as mentioned above (Dupouy-Camet et al., 2002). Studies on dose response models are being carried out to gain new insights into the transmission risk for humans and the first results indicate that the infective dose may be lower than previously assumed (Takumi et al., 2009).

The following species are currently endemic in Europe: *Trichinella spiralis*, *Trichinella britovi*, *Trichinella nativa* and *Trichinella pseudospiralis*. However, since *T. nativa* is found only among carnivores living in arctic and subarctic regions (Estonia, Finland, Latvia and Sweden among EU MS), the importance of this species for humans is very limited and only relevant to people who consume game meat from bears and other carnivores from those regions. Hence, it is recommended that monitoring of this particular species can be limited to those particular areas. The other taxa *Trichinella murrelli*, *Trichinella nelsoni*, Trichinella T6, T8, T9, T12, *Trichinella papuae* and *Trichinella zimbabwensis* have not yet been found in Europe and the potential for establishment is considered low because of a lack of suitable host species. Meat of animal species imported from third countries could contain *Trichinella* species not present in Europe. These products fall under import regulations and

Table 1
Surveillance and monitoring data for *Trichinella* in European countries in humans, pigs, free-range wild boar, foxes and other wildlife reported to EFSA for 2008 (modified after EFSA, 2010b).

Country	Total no. of confirmed human cases (imported)	Pigs tested		Free-range wild boar		Foxes		Other wildlife	
		No.	No. pos.	No.	No. pos	No.	No. pos	No.	No. pos
Austria	0	5,491,872	0	11,555	0	–	–	–	–
Belgium	5[a]	11,547,720	0	15,177	0	61	0	–	–
Bulgaria	67	342,942	12	4307	34	94	3	–	–
Cyprus	0	–	–	–	–	–	–	–	–
Czech Republic	0	3,401,215	0	78,911	0	–	–	–	–
Denmark	–	18,935,880	0	–	–	122	0	193	2
Estonia	0	474,859	0	4255	12	–	–	50	5
Finland	0	4,872,522	0	–	–	455	100	511	173
France	3	16,548,576	2	44,708	0	40	3	–	–
Germany	1 (1)	9,358,968[b]	3	–	–	4221	2	–	–
Greece	0	848,620	0	–	–	–	–	–	–
Hungary	5 (3)	–	–	–	–	1046	25	–	–
Ireland	0	2,561,293	0	–	–	452	2	445	0
Italy	0	9,786,611	0	7978	29	551	2	934	0
Latvia	4	405,460	0	2040	17	45	35	56	40
Lithuania	31	688,603	9	18,150	62	–	–	–	–
Luxembourg	0	2305	0	877	0	–	–	–	–
Malta	0	–	–	–	–	–	–	–	–
Netherlands	1 (1)	13,999,301	0	3585	0	–	–	338	7
Poland	4	20,027,092	69	103,612	524	–	–	–	–
Portugal	0	78,369	0	2152	0	–	–	–	–
Romania	503	3,030,926	1005	7313	27	–	–	164	22
Slovakia	18	1,124,256	2	12,960	2	–	–	–	–
Slovenia	1 (1)	385,195	0	1496	1	–	–	49	0
Spain	27	38,897,604	77	81,248	182	–	–	121,655	8
Sweden	0	3,015,835	0	27,131	1	348	1	316	7
United Kingdom	0	1,673,775	0	31	0	600	0	44	0
EU Total	670 (6)	167,499,799	1179	427,486	891	8025	173	123,944	101
Iceland	–	–	–	–	–	–	–	–	–
Liechtenstein	–	–	–	–	–	–	–	–	–
Norway	0	1,470,100	0	–	–	–	–	–	–
Switzerland	–	2,418,732	0	1458	3	–	–	–	–

No surveillance system in place or no reporting to EFSA in that year.

[a] The five cases were detected only by serology using a commercial serological kit with cross reactions and they were most likely false-positive cases (M. Claes, pers. comm.).

[b] All pigs are tested in Germany, however, due to a time lack between testing and reporting, only a fraction of the tested pigs are listed here (K. Nöckler, pers. comm.).

are required to be tested before entering the EU (Regulation (EC) No 2075/2005, Article 13).

In conclusion, *T. spiralis*, *T. britovi*, and *T. pseudospiralis* are the appropriate and necessary species to include in any survey.

3.2.2. Livestock

Determination of livestock species and production systems to survey for *Trichinella* infection must be related to their risk of exposure and the purpose of testing. Where sampled animals are intended to represent a subpopulation with demonstrated negligible risk, then it is also necessary for their origin to be known. Where all animals are to be tested in order to remove infected carcasses from the food chain, then traceback information is less important.

In the last 25 years, no *Trichinella* infections have been documented in pigs reared indoors on EU farms, where animals are reared according to modern standards regarding biosecurity. Most *Trichinella* infections in domestic animals occur in backyard and outdoor husbandry systems, in which livestock has direct or indirect contact to wildlife (via vectors, e.g., rodents) and/or are caused by illegal swill feeding (feeding of untreated or improperly treated scraps).

Transmission risk from wildlife to farms depends mostly on farm practices, the contact between pigs and wildlife (directly and indirectly through feed) and the prevalence of *Trichinella* in wildlife (Pozio, 1998; Pozio and Murrell, 2006). Therefore, the significance of testing for protection of public health varies from area to area. Backyard and free-ranging pigs have a higher likelihood of coming in contact with wildlife and, thus, of being infected with *Trichinella*. Sows and boars in intensive systems are also more likely to be infected than fattening pigs (Pozio et al., 2009b) because of their greater longevity and because they generally hold a higher social status in the group, which means they have preferential access to feed (Copado et al., 2004). Farmed wild boar can have an extended lifespan and the origin of the animals may be difficult to trace back. However, if farmed wild boars are reared under the same conditions as fattening pigs from non-controlled housing and meet the same criteria for traceability, they should be seen as belonging to that category.

Extended lifespan and difficulty of traceback are issues that also apply to horses. According to Regulation (EC) No 2075/2005, horses for human consumption have to be tested for *Trichinella*. The regulation was put into place because of outbreaks occurring between 1975 and 2004 (Liciardi et al., 2009) that linked the consumption of *Trichinella* infected raw horse meat with a large number of human trichinellosis cases in some EU MS. While the results of testing horses for *Trichinella* are of limited epidemiological value because they only represent a small and biased part of the total population, they are important for protecting public health.

In conclusion, testing of sows, boars, backyard and outdoor pigs (including farmed wild boar) for *Trichinella*, as well as horses, enables public health to be protected firstly, by the removal of any infected individual animals that are identified, and secondly, by providing evidence of the status of the population from which they originated. If infection were disclosed, then further investigation and control could be initiated. Testing of these groups is essential for risk-based surveillance, because they act as sentinels for the indoor finisher pigs. Furthermore, it provides useful information describing the prevalence of these parasite species in Europe.

3.2.3. Wildlife

Trichinella spp. are endemic in wildlife in all MS, with the exception of Cyprus, Malta, and Great Britain, although accidental introduction could occur in all of those areas. The most relevant wildlife species to be monitored in the EU is the wild boar, because of consumption of wild boar meat, followed by red foxes (*Vulpes vulpes*) and raccoon dogs (*Nyctereutes procyonoides*), because of their suitability as indicator animals for *Trichinella* spreading (Pozio and Murrell, 2006). Currently, wildlife monitoring in MS is carried out in the following contexts:

a) Direct protection of human health when wildlife enters the food chain (primarily if game meat is not supplied directly to the final consumer as written in Regulation (EC) No 2075/2005)
b) Regions where the risk of *Trichinella* in domestic swine is officially recognised as negligible (according to Article 3, paragraph 2 (ii), Regulation (EC) No 2075/2005)
c) For officially recognised *Trichinella*-free holdings, where piglets have outdoor access during the first weeks of life (prior to weaning) (Regulation (EC) No 2075/2005)
d) For officially recognised *Trichinella*-free holdings in MS, where *Trichinella* has been detected in domestic swine in the last 10 years (Regulation (EC) No 2075/2005), if susceptible wildlife and holdings in that area coexist
e) For research into the epidemiology of *Trichinella*

Table 1 shows the number of samples taken from wildlife, categorised by free-roaming wild boar, foxes and other wildlife. It is noted that there is substantial variation in the number of samples taken and the proportion of positive samples.

On average, free-roaming wild boars have a longer life expectancy and a wider home range compared to domestic fattening pigs, which allows them more contact with wildlife or other potential sources of infection over a longer period. Hence, all hunted wild boar submitted to a game handling establishment or placed on the market, or directly supplied to a consumer or a restaurant are required by law to be tested for *Trichinella*, whereas this is not the case when hunted and consumed in a private setting. In Europe, wild boars are a good indicator for the presence of *T. spiralis* and *T. pseudospiralis*; they are less important as an indicator of *T. britovi*; and are not relevant for *T. nativa* (Pozio and Murrell, 2006; Pozio et al., 2009a).

Generally, foxes are present and abundant across EU MS and they occupy a high position in the animal food chain. They are not important in the context of meat inspection; however, they are considered an adequate indicator species, especially for *T. britovi* (Pozio, 1998) and are often used in monitoring programmes, for epidemiological studies or to document presence or absence of *Trichinella* around pig farms. *T. spiralis* can also be detected in foxes, though in MS where wild boar is present, wild boar should be considered the preferred indicator for *T. spiralis* (Pozio et al., 2009b). However, the *Trichinella* species that foxes harbour seem to vary within MS and the relevance to the domestic cycle seems not comparable in each MS. Most (about 90%) of *Trichinella* infected carnivores harboured *T. britovi* whereas most (about 80%) of *Trichinella* infected domestic pigs harboured *T. spiralis* (Malakauskas et al., 2007; Széll et al., 2008; Pozio et al., 2009a).

Raccoon dogs are considered as equally likely or more suitable indicator hosts for *Trichinella* than foxes and often harbour higher amounts of *Trichinella* larvae per gram of infected muscle compared to red foxes (Oivanen et al., 2002). Raccoon dogs are continuously spreading throughout the MS. At present, large populations of raccoon dogs are present in Finland, Estonia, Latvia, Lithuania, Poland, Germany and Denmark. Furthermore, this species has also been detected in France, Italy, Sweden, Switzerland, the Netherlands and Belgium and it is expected that the current area of distribution will expand further in the near future. The relative frequencies of the four different *Trichinella* species in raccoon dogs reflect the geographical distribution of the raccoon dog. Today, of 71 *Trichinella* isolates from raccoon dogs in the EU, 14% were *T. spiralis*, 24% *T nativa*, 56% *T. britovi* and about 6% *T. pseudospiralis* (www.iss.it/site/Trichinella/index.asp).

In conclusion, wildlife surveillance can directly contribute to the protection of human health when wildlife is consumed but also provides useful information on the epidemiology of the parasite species. However, the driving force behind wildlife monitoring in EC legislation framework is considered the protection of human health, and here the focus should be on meat, i.e., carcasses. Hence, monitoring in wildlife should primarily be carried out if required to document absence or low prevalence of infection in relation to a certification programme.

3.3. Risk classes for member states

For the proposed monitoring and surveillance schemes, animal populations were divided into six categories: (1) wildlife, (2) backyard or outdoor pigs, (3) sows and boars, (4) finisher pigs from non-controlled housing, (5) finisher

pigs from controlled housing, (6) horses. Hence, we distinguish between pigs from controlled and non-controlled housing in accordance with regulation (EC) No 2075/2005 and Regulation (EC) No 1244/2007. In the following we shall present a surveillance programme that includes all six categories.

3.3.1. Allocation into risk classes

Based on the degree of confidence that *Trichinella* is absent in pigs in a MS (or a geographically separated part of a MS) three risk classes were defined: endemic, low and negligible risk. Only endemic and negligible classes are described in the current EU legislation (2075/2005). The low risk class has no significance for the testing that is currently carried out in EU and it is proposed to be considered for the future legislation. Table 2 lists the specific requirements for a MS to go from the endemic to the low risk class or from the low risk to the negligible risk class. The three classes are defined in the following:

Class 1 – Endemic: Unless proven otherwise a MS is allocated into class 1 where *Trichinella* is assumed to be present in livestock. All *Trichinella*-susceptible animals destined for human consumption should be tested by artificial digestion, according to the EC Regulation (EC) No 2075/2005. In this situation, wildlife does not need to be monitored (unless required for certification of *Trichinella*-free holdings). However, wildlife should be tested if it is destined for human consumption, independently if it is for the local market or for personal consumption. The information from meat inspection can be used for surveillance and control.

In endemic MS, individual holdings may apply for *Trichinella*-free certification in accordance with current Regulation (EC) No 2075/2005. In this case, risk-based wildlife sampling is required to be carried out in the area of the holding. The results of this sampling should be reported to EFSA with positive and negative animals identified. The wildlife sampling strategy in this situation is not yet defined and needs to be harmonised between MS.

Class 2 – Low-risk: Low-risk refers to the risk of *Trichinella* in fattening pigs from controlled housing. A MS in this class must provide evidence that *Trichinella* is absent and that the surveillance sensitivity is 95% or greater (Table 2) in fattening pigs from controlled housing. Based upon formula (1) it was calculated that this could be obtained by testing 6 million pigs and finding them all negative. To increase confidence in absence of infection, data might be required to cover a time period of 5 years period. In this case, historical data might be used. It should be required that trichinellosis has not been reported in the domestic swine population for at least 5 years. All sows and boars, fattening pigs from outdoor and non-controlled indoor housing and wildlife for human consumption should be tested as stipulated in the EC Regulation (EC) No 2075/2005. All samples from pigs from controlled housing (including sows and boars) must test negative before a class 2 status can be assigned. Once a MS has been granted low risk status, a sample of fattening pigs from controlled housing ensuring a confidence level of 95% of freedom from infection should be sampled. Sampling should be stratified by slaughterhouse throughput to ensure a representative sample of the population (Table 2).

Class 3a – Negligible risk in controlled housing: MS in which there is a negligible risk that *Trichinella* is present in the sub-population consisting of pigs from controlled housing, given a design prevalence of 1 per million, might apply for this status. One method of providing this evidence is to show that the sensitivity of the surveillance in pigs from this sub-population is high, e.g., 99% (Table 2). This can be obtained by testing 10 million pigs and finding all negative results. In both this group and in class 3b, as will be described in the following section, fattening pigs from farms that comply with the definition of controlled housing do not require testing. Sows and boars from these farms as well as all other pigs will need to be tested according to legislation 2075/2005. In this context, these animal groups can be regarded as sentinel or indicator animals. Furthermore, wildlife meant for human consumption ideally should be tested irrespective of whether the meat will be consumed by hunters and their relatives and friends or will be put on the market. Again, all samples from pigs from controlled housing (including sows and boars) must test negative before a class 3 status can be given, and data covering a 2-year period might be required to ensure confidence in the absence of infection (Table 2).

Class 3b – Negligible risk in all pigs: A MS in this class should provide evidence that the likely occurrence of *Trichinella* in all pigs is less than one per million. The method of providing this evidence is to show that the sensitivity of the surveillance in all pigs is high, e.g., at least 99% (see Table 2). In MS allocated to class 3b, a sample of pigs from non-controlled housing should be tested. The possibility of further classification within this group (pigs born, reared and finished under non-controlled conditions versus pigs born and reared under non-controlled housing but finished under controlled conditions) has been proposed for further consideration.

Regulation (EC) No 2075/2005 requires that a MS with a status of negligible risk has put in place a risk-based monitoring programme in those areas where wildlife and pig production co-exist. It is suggested that for a MS in class 3b, wildlife should be tested to confirm that if *Trichinella* is present, then the prevalence is equal to or less than 0.1% in the sampled population over a minimum of 10 years. An alternative for MS with small wildlife populations could be the detection of a prevalence (or prevalence estimation if *Trichinella* is found) of 0.1% with 95% confidence, based on local estimated populations of target animals (e.g., foxes, wild boars, raccoon dogs). It is suggested that these areas are identified through geographical analysis of the domestic pig and wildlife populations or on previous occurrences of *Trichinella* in wildlife or pigs. The area to be covered by the targeted surveillance will be defined by the MS and sampling should be carried out to enable the estimation of prevalence of *Trichinella* over a period of 10 years (or shorter if larger numbers of foxes are available). The best digestion method used for wildlife species (muscles used, tissue sample size, test operating procedure, etc.) needs to be fully validated. Furthermore, it should be stated that the dynamics of *Trichinella* in wildlife populations are not fully understood and the threshold prevalence of 0.1% is arbitrary.

Table 2
Suggested framework for simplified sampling scheme for *Trichinella* in European Union.

Population to be surveyed	Surveillance in class 1 Endemic risk	Criteria[a] to move class	Surveillance in class 2 Low risk	Criteria[b] to move class	Surveillance in class 3 Negligible risk	
					(a) Pigs from controlled housing	(b) All pigs
Fattening pigs from controlled housing	ALL	No positive finding within previous 5 years	Proportionate sample to demonstrate surveillance sensitivity of ≥95%[b] to detect infection of ≥1 case/million in fattening pigs	No positive findings in MS for additional 2 years to demonstrate surveillance sensitivity of ≥99% in (a) pigs from controlled housing or (b) all pigs	No testing required	
Fattening pigs from non-controlled housing	ALL	NA	ALL	No positive findings in previous 2 years, need to contribute to surveillance sensitivity above to move to class 3b	ALL	Proportionate sample to demonstrate surveillance sensitivity of, e.g., 90%, 95% or 99% to detect infection of 1/million in combination with wildlife testing
All sows and boars, horse farmed or hunted wild boar	ALL	NA	ALL	NA	ALL	
Other wildlife	Optional	NA	Mandatory if move into class 3b (all pigs) anticipated, otherwise optional	If class 3b (all pigs) then prevalence of ≤0.1% must be demonstrated. Otherwise optional.	Optional	Proportion to demonstrate a low level in wildlife <0.1%

NA: not applicable.
[a] Historical data might be used.
[b] A confidence of 95% or 99% in the absence of infection might be obtained by sampling 6 or 10 million pigs, respectively – and finding them all negative. For national pig populations smaller then 10 million, please see Table 3 for suggested sample size where a correction for finite populations. If all tests taken among all pigs are negative, the samples can be part of the sample required to demonstrate absence of infection.

3.3.2. Movement between the three risk classes

The suggested framework harbours the possibility for a MS to move, e.g., from class 1 (endemic) to class 2 (low risk) or from class 2 (low risk) to class 3 (negligible risk). The requirements for such movements are listed in Table 2 and will be dealt with here in brief by use of three scenarios.

Scenario 1: It can be assumed that all pigs in a MS allocated initially to class 1 (endemic risk) have been tested for *Trichinella* as required under the legislation and no positive pigs have been found for more than, e.g., 5 years. As in the previous example, the pig population in the MS consists of 15 million fattening pigs from controlled housing. The expected number of positive animals from this subpopulation – if all animals are tested under the design prevalence of 1 per million – is therefore 15 per year.

If the Se is 0.4 (Alban et al., 2008) and all animals are tested and found negative for *Trichinella* in that year, then the surveillance system sensitivity of the fattening pig surveillance is:

$$SSe = 1 - (1 - 0.4)^{15} = 0.999$$

Hence, the MS is granted class 2 status and can change the surveillance to a sample of fattening pigs from controlled housing that results and a surveillance system sensitivity of ≥95% to detect at least one case per million in fattening pigs (Table 2).

Scenario 2: The MS wishes to apply for negligible risk status (class 3) in its pig population as no positive pigs have been found. The MS wants to stop surveillance in fattening pigs from controlled housing and to sample a proportion of pigs from non-controlled housing. While putting together the documentation, a wildlife sampling programme is put into place and 1000 foxes and/or raccoon dogs are sampled with a maximum of one positive animal detected (prevalence ≤ 0.1%).

As part of the application process, the MS must show that the sensitivity of the surveillance system in the whole pig population is ≥99%.

In addition to the 15 million fattening pigs the MS has tested 3 million pigs from non-controlled housing and 500,000 sows and boars per year. This makes a total of 18.5 million animals which were all found to be negative. If *Trichinella* were present in the population, a minimum of 19 positive animals would be expected.

For one year of testing, the surveillance system sensitivity is therefore:

$$SSe = 1 - (1 - 0.4)19 = 0.999$$

Table 3
Sample sizes corrected[a] for size of absolute population – for use in demonstrating low (95% confidence in absence) or negligible risk (99% confidence in absence) of *Trichinella* in pigs.

Size of population (N)	Resulting sample size (n) after correction for size of total population N	
	To move to Group 2	To move to Group 3
10,000	9983	9990
50,000	49,587	49,751
100,000	98,361	99,010
500,000	461,539	476,191
1,000,000	857,143	909,091
5,000,000	2,727,273	3,333,333
10,000,000	3,750,000	5,000,000
15,000,000	4,285,714	6,000,000
20,000,000	4,615,385	6,666,667

[a]Correction was made according to the following formula: $1/n = 1/N + 1/n^*$, where N = size of population and n^* = initially calculated sample size, and n = resulting sample size (Canon and Roe, 1982). The initially calculated sample size for moving to higher class was 6 million and 10 million for moving to class 2 and class 3, respectively.

Together with this evidence and a monitoring programme in wildlife, the MS is granted negligible risk status for its entire pig population for as long as no positive pigs are identified, assuming that the test sensitivity is at least 0.4.

In both scenarios, if a MS has a small pig population, or it does not currently test all pigs, historical data can be used. The number of positive animals in the sample is multiplied according to the total number of animals tested, e.g., in the above mentioned example, for 2 years of sampling the expected number of positive animals – if infection were present – would be 38.

Scenario 3: The MS detected a positive pig on an outdoor farm the previous year. The controlled and non-controlled sectors of the industry are distinct and separated and the MS wishes to apply for negligible risk in its fattening pigs from controlled housing so it no longer has to test these while maintaining the testing of the outdoor finishers as well as sows and boars and all other pigs from non-controlled housing.

Using the calculation of surveillance sensitivity above, the sensitivity of the surveillance in fattening pigs has already been shown to be 99.9%. The MS has therefore satisfied the criteria that there is negligible risk of *Trichinella* being present in controlled housing for fattening pigs and it can stop monitoring this sub-population. To demonstrate freedom from infection and to protect human health, the MS will continue to test all pigs from non-controlled housing, all sows and boars and wildlife for human consumption as described in legislation 2075/2005.

3.3.3. Contingency plan

Details on requirements for contingency plans can be found in Regulation (EC) No 2075/2005, and should identify: (1) the origin of the infected pig, (2) the presence of other infected pigs, and (3) the source of infection. It is important that contingency plans lead to corrective measures and increased biosecurity. If a confirmed positive case is found in the population, which was assumed to have negligible risk (either fattening pigs from controlled housing in class 3a or all pigs in class 3b – and a positive case was found in wildlife in the latter example), MS should have contingency plans in place. This may involve an investigation into the source of the positive animal and whether further cases exist in the population. During the investigations, the status of MS will not change until the investigation is complete. If the investigation reveals more positive animals, the status might be lost; if no further positives are found then evidence is accumulated and status is kept.

3.3.4. Horse

All horses should be tested in accordance with the current legislation (Table 2), because horses have been the source of major outbreaks in the past, the population of horses slaughtered for human consumption is relatively small (compared to domestic pigs) and the traceability of horses sent for slaughter is often quite poor. Furthermore, there is an epidemiological link between the occurrence of *Trichinella* infection in horses and in domestic pigs, i.e., infected horses have been detected only where a high prevalence of *Trichinella* infection occurs in the pig population (Pozio, 2001; Murrell et al., 2004).

3.3.5. Correction for finite population size

It is noted in Table 3 that the smaller the population size, the higher the proportion of the population that needs to be sampled. In fact, for a population consisting of up to 100,000 almost all individuals have to be tested.

4. Discussion

4.1. Reasons for current status

The lack of *Trichinella* infection in humans in many MS is mainly because of three reasons: (1) national food habits (Boireau et al., 2000; Blaga et al., 2007; Gottstein et al., 2009), (2) the low, national prevalence of the infection in animals (Gottstein et al., 2009) and (3) the efficacy and quality of the controls conducted in relation to meat inspection.

4.2. All species are included in monitoring

4.2.1. The parasite

When discussing the *Trichinella* species relevant to be monitored it needs to be stressed that for this par-

ticular parasite at this point, this is only of theoretical relevance. Analytical methods (artificial digests) used for monitoring meat/muscle tissue will automatically detect any *Trichinella* larvae, regardless of the species (Nöckler and Kapel, 2007). According to Regulation (EC) No 2075/2005, Article 6, each *Trichinella* finding has to be confirmed by the Reference Laboratory and the species has to be identified, as this provides important epidemiological information.

4.2.2. Livestock and wildlife

Parasite species are often reported in a wide variety of hosts. However, not all of them necessarily play a role in the transmission of the infection, have an impact on the human food chain or are suitable for surveillance in a public health context (Pozio, 1998). Therefore, the aim was to identify which species would be suitable for surveillance with respect to protection of human health. Moreover, consideration was given to existing surveillance carried out in MS.

Only pigs play a role in the domestic cycle of *T. spiralis* transmission (Pozio and Murrell, 2006). *T. spiralis* is the primary aetiological agent in domestic pigs and also the most-frequently encountered species in human infections. In addition, horses have been implicated in several major outbreaks of trichinellosis in the EU (Pozio and Murrell, 2006). Therefore, domestic pigs and horses are listed by the EU as livestock species to be monitored for *Trichinella* at slaughter.

The role that wildlife plays in the epidemiology of *Trichinella* varies depending on the aetiological agent(s) present in the MS and on livestock-rearing practices (Pozio and Murrell, 2006). Consequently, the role of wildlife in monitoring schemes varies among areas as to its importance in protecting human health. This needs to be addressed and justified as to its suitability for a defined area. None of the currently existing wildlife sampling schemes provides suitable data for monitoring and trend analysis on a Community level as the sampling involves different wildlife species, sampling protocols, time frames and purposes as also noted from an inspection of Table 1. To be able to maximise the use of data that are being collected for different purposes in the MS, we recommend that those data should be centrally recorded and reported to EFSA and to the Community reference laboratory for parasites with information on the animal species, the origin or collection points of the animals (GIS coordinates data or nearest towns), test results (positive and negative results, *Trichinella* species, infection level) and test sensitivities. The data can be compiled in maps and can be updated over the years, which reflect the actual situation more accurately than existing approaches.

4.3. Risk-based surveillance for pigs

Within the EU, surveillance for *Trichinella* is currently being carried out according to Regulation (EC) No 2075/2005. This regulation stipulates that all pigs for human consumption must be tested but also permits various derogations for pigs and other species if certain conditions are met. This forms the basis for MS applying different sampling schemes in different populations, according to the epidemiological situation. Various testing methods are also specified in the regulations. Whereas this approach is useful from an epidemiological perspective, it makes it difficult for analysing data and comparing results on a Community level. One of the notable issues is that the definition of negligible risk according to the Regulation (EC) No 2075/2005 is not well described and a further clarification would be helpful. So far, Denmark is the only EU MS that has been officially recognised as an area with a negligible prevalence of *Trichinella* in pigs (Alban et al., 2008). However, other MS are expected to apply for this recognition in the near future.

We propose a simplified standard, as described above. This would allow MS with little or no historic data to reach a status, based on gathered evidence over a relatively short period of time, resulting in reduced testing of low-risk pig populations. The evidence and information gathered over successive years of the proposed scheme would allow broad-scale trends in the status of MS to be followed for targeted livestock populations. In this framework, we also address the possibility of having a negligible status for all fattening pigs including outdoor-reared pigs in combination with wildlife testing. The requirements used in our framework (test sensitivity/prevalence) are consistent with Regulation (EC) No 2075/2005 as far as possible and with current practices and precedence cases, where the regulations do not provide sufficient guidelines. However, we do advise, that these parameters should eventually be clarified as proposed in the recommendations above.

In our approach above we used a sensitivity of 0.4 based on Alban et al. (2008). This is the probability that a test will find a truly infected sample positive, assuming a low level of infection (1 larva per g) and when using 1 g of tissue. This is not the same as the recovery rate (ability of finding all larvae in a sample). The latter parameter is often used to evaluate the quality of laboratory performance in so-called ring tests (Vallée et al., 2007; Marucci et al., 2009). The value of 0.4 is considered a conservative estimate when compared to results from proficiency testing in Danish and French laboratories (Vallée et al., 2007; H.L. Enemark, pers. comm.). EU ring trials have shown that there is room for improvement with respect to the ability to identify the correct number of larvae in an infected sample (the recovery rate) (Vallée et al., 2007; Marucci et al., 2009). It is therefore recommended that the quality of testing among the laboratories is to be monitored carefully by the Community Reference Laboratory. Overall sensitivity can be increased by increasing the amount of tissue digested from each animal (Forbes and Gajadhar, 1999). Besides the digestion, other tests to detect *Trichinella* status in a herd can be considered, e.g., serological tests (Gamble et al., 2004). However, the usefulness of serological assays is under debate (Gamble et al., 2004; Teunis et al., 2009). Please see EFSA (2010a) for a review of serological testing. Testing for *Trichinella* is by no means perfect; hence, the results should be interpreted with caution. However, absence of positive findings in an animal population despite a high number of tests conducted over a longer time period gives credence to the conclusion that infection is absent or occurring at a very low level in a given population.

According to the current legislation (Regulation (EC) 2075/2005, a category of holdings can be recognised as free from *Trichinella* where the surveillance has been carried out to provide at least 95% confidence that where the prevalence of *Trichinella* exceeds 0.0001%, any infestations will be detected. However, no guidance is given as to how this should be demonstrated. A number of different statistical approaches to demonstrating disease freedom have been proposed in the recent literature (Martin et al., 2007; Böhning and Greiner, 2006; Ebel et al., 2008; Branscum et al., 2006). These methods differ not only in the statistical methodology but also with respect to data requirements.

The present work was inspired by the methods to demonstrate freedom from infection developed by Martin et al. (2007), which has been adapted by Alban et al. (2008) to demonstrate negligible risk of *Trichinella* in fattening pigs from controlled housing in Denmark. It is judged that the method provides an adequate approach for the needs of this work as this method is simple and transparent, yet provides adequate support for demonstrating that there is negligible risk of *Trichinella* in the defined population. None of these methods, however, can overcome the basic limitations of sampling theory, which means that in populations with a very low prevalence the number of animals that must be tested in order to detect disease is very large. This causes difficulties for countries with small pig populations and sufficient flexibility should be allowed, e.g., through the use of historical data over a number of years (e.g., >10 years), to ensure these countries are not penalised. Other options include merging with a larger MS in order to increase overall pig population, but only if there is homogeneity in the pig rearing practices. A third option is to adjust the initially calculated sample size by taking into account that the population is finite as suggested by Canon and Roe (1982). Hereby, even smaller populations might be able to document absence of infection from their national herd of pigs, while basically testing their entire population for a specified number of years – and not finding any positive samples (Table 3).

This method is dependent on the number of positive animals assumed to be present in the sampled population. However, it does not take into account the risk that disease is introduced into the population during the monitoring period. To account for this, Martin et al. (2007) and Alban et al. (2008) have presented models that extend the equations presented here to incorporate probability of disease introduction.

A substantial part of the more than 167 million pigs that are tested annually are low-risk pigs, whereas high-risk populations often remain untested, e.g., pigs slaughtered for private consumption or direct supply to consumers, i.e., within a circle of family and friends. This is because such pigs are not officially required to be tested, although voluntary schemes may be in place. While it is acknowledged that testing may be more difficult and more costly for individual animals in remote geographical regions of a MS, from a public health point of view this cannot be considered acceptable and it is strongly recommended that these exceptions to testing must be addressed.

In some MS, live animals are imported for slaughter. In this case, the origin of an animal will become an important part of food chain information that will need to be exchanged routinely prior to slaughter if a MS intends to make use of reduced testing, because this will allow to identify whether a positive test originates from the national herd or not and which sub-populations to test.

Other approaches to *Trichinella* surveillance exist in the world. Compared to our approach and the current EU approach, the OIE has set a higher target prevalence. Moreover, in the OIE approach the sample size is not specified and there are no requirements to the housing system (OIE, 2010).

5. Conclusion

At present, more than 167 million pigs are tested in the EU for the presence of *Trichinella* even though all pigs from indoor modern housed production have tested negative since 1960. The proposed sampling scheme is a preliminary framework that in parts deviates from current EC regulations. It is suitable for a harmonised approach of data collection and data analysis within EU MS and was developed to accommodate MS that do not have years of historic data and cannot demonstrate a high certainty about their situation with respect to *Trichinella*, to be able to gather relatively quickly sufficient evidence for reducing the number of low-risk pigs to be tested. If carried out reliably, it does not compromise public health needs, but would have large economic benefits and free resources that could then be focused on the populations posing a higher risk and, therefore, more efficiently protect consumer health. Moreover, we suggest that testing of horses should continue. Wildlife surveillance should focus on the species that are consumed whereas other wildlife should be tested when needed, e.g., in relation to outbreak investigation or change of *Trichinella* status.

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Appendix A

Criteria for controlled housing are defined according to COMMISSION REULATION (EC) No 1244/2207 (European Commission, 2007).

(a) All feed has been obtained from a facility which produces feed in accordance with the requirements provided for in Articles 4 and 5 of Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (1); when roughage or crops are provided to the animals as feed, it shall be treated appropriately, and where possible, dried and/or pelleted.
(b) An all-in/all-out system is applied as far as possible. Where animals are introduced into the herd, they shall be kept in isolation as long as required by the veterinary services to prevent the introduction of diseases.
(c) None of the animals has access to outdoor facilities unless the food business operator can show by risk analysis to the satisfaction of the competent authority that the time period, facilities and circumstances of outdoor access do not pose a danger for the introduction of disease into the herd.
(d) Detailed information is available concerning the animals from birth to slaughter and their management conditions as laid down in Section III of Annex II to Regulation (EC) No 853/2004.
(e) If bedding is provided for the animals, the presence or introduction of disease is avoided by the appropriate treatment of the bedding material.
(f) Holding staff comply with the general hygiene provisions as laid down in Annex I to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
(g) Procedures are in place that control access to the premises where animals are kept.
(h) The holding does not provide facilities for tourists or for camping unless the food business operator can show by risk analysis to the satisfaction of the competent authority that the facilities are sufficiently separated from the animal rearing units that direct and indirect contact between humans and animals is not possible.
(i) Animals do not have access to rubbish dumps or household waste.
(j) A pest management and control plan is in place.
(k) Silage feeding is not used unless the food business operator can show by risk analysis to the satisfaction of the competent authority that the feed cannot transmit any hazards to the animals.
(l) Effluent and sediment from sewage treatment plants are not released in areas accessible to animals or be used for fertilising pastures used to grow crops, which are used to feed animals, unless treated appropriately and to the satisfaction of the competent authority.

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