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Auditing of Danish pig herds for controlled housing requirements and *Trichinella*

Lis Alban [a,b,*], Heidi Enemark [c], Heidi Huus Petersen [d], Lisbeth Harm Nielsen [e]

[a] *Dept. for Food Safety and Veterinary Issues, Danish Agriculture & Food Council, Copenhagen, Denmark*
[b] *Dept. of Veterinary and Animal Sciences, Faculty of Health and Medical Sciences, University of Copenhagen, Denmark*
[c] *Dept. of Animal and Veterinary Sciences, Aarhus University, Tjele, Denmark*
[d] *Animal Health Division, Danish Veterinary and Food Administration, Glostrup, Denmark*
[e] *Veterinary & Quality Services, Danish Agriculture & Food Council, Copenhagen, Denmark*

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ABSTRACT

Trichinella is a zoonotic parasite, which historically has been of large concern for public health in Europe. Consequently, testing of all pigs for *Trichinella* has been mandatory in many European countries, even though *Trichinella* is almost exclusively found in outdoor or backyard production. The idea therefore emerged that auditing for biosecurity should replace testing in indoor production. In the European Union (EU), pigs raised under so-called controlled housing conditions are exempt from testing. The specific requirements for a pig production to be considered a controlled housing holding are described in Annex IV in the EU *Trichinella* Regulation No. 2015/1375. In Denmark, the controlled housing concept is used extensively, not to omit *Trichinella* testing but to allow visual-only post-mortem inspection at export-authorized abattoirs. The Danish pig industry has established a quality assurance scheme called DANISH Product Standard, which is used to assure that the pig production maintains specific standards. This paper describes how the control, including the auditing, is set up and shows how the EU requirements regarding controlled housing are controlled. Moreover, the EU requirements are compared with the recommendations issued by the International Commission on Trichinellosis and the World Organisation for Animal Health. Finally, strengths, weaknesses, opportunities and threats of the Danish way of documenting indoor finisher herds' compliance with controlled housing as specified by the EU are discussed. It is concluded that the validity of the system is high.

1. Introduction

1.1. Signs, symptoms and global burden of trichinellosis in humans

Consumption of raw or undercooked meat from food-producing domestic animals or wildlife infected with nematodes of the genus *Trichinella* can result in trichinellosis, which is a zoonosis occurring in many parts of the world. Trichinellosis can present with serious illness or even death. The signs and symptoms of trichinellosis can range from none to severe or fatal, depending on the specific *Trichinella* species and the dosage. Joint and muscle symptoms in humans diagnosed with acute trichinellosis ($n = 98$) were described by Akar et al. (2007) during a *Trichinella britovi* outbreak that occurred in Izmir, Turkey, in 2004. The most common signs and

* Corresponding author at: Danish Agriculture & Food Council, Copenhagen, Denmark.
E-mail address: lia@lf.dk (L. Alban).

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symptoms were muscle pain, joint pain, subjective muscle weakness, and restriction of joint movements. All of these were reported by more than half of the patients (Akar et al., 2007). Historically, human cases have occurred in the form of outbreaks due to consumption of infected, ready-to-eat foods such as sausages (ECDC, 2022). Consumption of meat from some game species, such as bears and wild boars, may pose a high risk for humans and, therefore, deserves high focus on heat treatment before consumption (Balić et al., 2023; Murakami et al., 2023). Horse meat has also been associated with human cases due to consumption of inadequately heat-treated meat from horses that had been fed slaughterhouse waste (Boireau et al., 2000).

The number of human cases in the European Union (EU) and the European Economic Area (EEA) is low. In 2020, no cases were reported in 18 countries, whereas nine EU/EEA countries reported a total of 181 cases of trichinellosis. Among these, 117 were confirmed and 64 were probable. Bulgaria, Italy and Poland accounted for 88 % of the confirmed cases. In 2020, the largest outbreak occurred in Italy and involved 79 human cases. It was caused by a salami sausage produced with wild boar meat from the Susa Municipality in Piemonte, near the Mediterranean Alps (ECDC, 2022).

According to the FERG Report from 2015, the total global burden of *Trichinella* was ascribed to 550 disability-adjusted life years (DALYs), including 4 DALYs ascribed to fatal outcomes of infection. In line with the approach of DALYs, this should be interpreted in comparison with the full life expectancy of a person, which in Denmark is 92 years (Georgiadis and Pires, 2018). The estimated human burden is substantially lower than the burden ascribed to other foodborne parasitic diseases. For example, infections caused by the cestode *Taenia solium* was ascribed to 2.8 million DALYs (FERG, 2015). According to Devleesschauwer et al. (2015), the European region, as defined by the World Health Organisation (WHO), is responsible for 69 % of the global burden of *Trichinella*. In conclusion, trichinellosis is an infection with a low human burden and mainly occurs in one part of the world.

1.2. The role of testing and biosecurity for prevention of exposure of humans to Trichinella

According to the World Organisation for Animal Health (WOAH – previously known as OIE) infection with *Trichinella* does not result in clinical signs in animals (WOAH, 2023). Therefore, testing meat of susceptible animals intended for human consumption has been the customary way of ensuring that consumers are not exposed to infected meat. Exposure of domestic animals is prevented through use of biosecurity practices, focusing on eliminating the presence of *Trichinella*-infected animals such as rodents and wildlife as well as abolishing feeding food waste of animal origin (WOAH, 2023). This has been documented through extensive surveillance undertaken in the EU over decades. The EU surveillance data show absence of *Trichinella* in pig productions with a high level of biosecurity. In 2022, this involved 33.7 million fattening pigs and 0.5 million breeding pigs (EFSA/ECDC, 2023). In contrast, sporadic cases in pigs are still detected in free-ranging and backyard pigs. In 2022, this implied 71 pigs, of which 59 were detected in Romania, followed by Croatia ($n = 8$), Spain ($n = 2$), Bulgaria ($n = 1$) and Poland (n = 1). No *Trichinella* was detected in domestic horses tested in the EU in 2022. However, *Trichinella* was detected in hunted wild boar (0.08 %) and in fox (0.95 %) that is an indicator animal for *Trichinella* (0.95 %) (EFSA/ECDC, 2023).

Hence, the importance of *Trichinella* lies in the food safety risk and the costs of prevention and control in domestic animals intended for consumption as well as game. In pig production, the type of production system is the main risk factor (EFSA, 2011). This has led to an international discussion of how requirements could be set up for a pig production to be recognized as having a negligible risk of *Trichinella*. The International Commission on Trichinellosis has formulated requirements for the type of pig production defined as "controlled management". According to the International Commission on Trichinellosis, individual testing of pig carcasses at slaughter for *Trichinella* should not be required, when these requirements are implemented and verified routinely (Gamble et al., 2019).

1.3. The international legislation

According to Gamble (2022), WOAH introduced the concept of *Trichinella* free countries or regions in 1999 (Cited from Gamble, 2022: WOAH, Terrestrial Animal Health Code, 8th edition, 1999 - out of print). WOAH maintained the view that freedom could be ascribed to a country or a region at least until 2011 (WOAH, 2011) even though the International Commission on Trichinellosis in their recommendations from 2000 stated that it is not possible to recognize geographic regions as *Trichinella* free (Gamble et al., 2000). As pointed out by e.g., Pozio and Murrell (2006), *Trichinella* may be present in wildlife but not in domestic pigs living in the same region. Based upon this, WOAH changed the definition, from freedom to negligible risk, and from the level of a country or region to an individual pig production or a compartment. A compartment with a negligible risk of *Trichinella* infection in domestic pigs (*Sus scrofa domesticus*) means a group of pig herds that all comply with the requirements for controlled housing (called controlled management conditions by WOAH). The Terrestrial Animal Health Code issued by WOAH dedicates an entire chapter to *Trichinella*, which contains the specific requirements for recognizing a pig herd as complying with controlled housing. WOAH states that the competent authority may recognize the pig herd as being under controlled housing conditions. Here, compliance with the listed requirements is essential. Moreover, WOAH requires that the pig herds in the compartment have been complying with the requirements for controlled housing for at least 24 months. During that time, surveillance is anticipated to enable documentation of absence of *Trichinella* in the compartment in the form of entirely negative testing results taken in relation to slaughter. Thereafter, an auditing system should be established and undertaken in all pig herds belonging to the compartment. If deviations from the listed requirements are demonstrated during the audit, and the competent authority determines that this constitutes a substantial breach of the biosecurity, the concerned herds should be removed from the compartment until compliance is reestablished (WOAH, 2023). Hence, auditing is a way of verifying compliance, and the auditing visits should be made periodically at a risk-based frequency. This should be based on historical data such as results from abattoir testing, knowledge about risky farm management practices, and presence of susceptible wildlife. Based on the elements mentioned above, WOAH states that *Trichinella*-safe trade in pig meat can be established without testing (WOAH, 2023).

In line with this, Codex Alimentarius states that post-harvest control measures to protect consumers from exposure to *Trichinella* in pig meat should be risk-based. Moreover, guidelines on risk-based control measures have been developed to provide guidance to governments and industry. Apart from the traditional measures to render pig meat safe such as freezing, heat treatment and irradiation, Codex Alimentarius mentions the use of the negligible risk concept and the establishment of negligible risk compartments and different ways of monitoring and reviewing evidence from auditing and slaughterhouse testing to ensure public health protection (Alimentarius, 2015).

In the EU, the former *Trichinella* Regulation from 2005 required carcass testing of all pigs, wild boar, horses and relevant game species that were destined for human consumption (EU Commission, 2005). The Regulation also allowed EU Member States to apply for a negligible risk status for *Trichinella* for the domestic population of pigs in a country or region (EU Commission, 2005). In 2007, Denmark and Belgium were granted such a status (Alban et al., 2008; Anonymous, 2007). No other EU Member States received this status.

In 2015, the current EU *Trichinella* Regulation No. 2015/1375 laying down specific rules on official controls for *Trichinella* in meat came into force. Since then, a negligible risk status for a country or region is no longer recognized. Instead, negligible risk is defined as related to a pig production belonging to a compartment of pig productions applying controlled housing conditions. This means a type of animal husbandry where pigs are always kept under conditions controlled by the food business operator regarding feeding and housing (EU Commission, 2015). According to the current *Trichinella* Regulation, testing should be risk-based and focus on pigs raised in non-controlled housing. However, as a transition, each year all carcasses of breeding sows and boars or at least 10 % of the slaughtered carcasses from each holding officially recognized as applying controlled housing conditions, must be examined for *Trichinella*. This requirement can be abolished once an EU Member States is able to document with at least 95 % confidence that the prevalence of *Trichinella* does not exceed one per million in that pig population. Alban et al. (2011) calculated the sample sizes necessary for documenting this for different population sizes. Due to their previous negligible risk status, Denmark and Belgium were granted exemptions from these transitional measures and were allowed to go directly to only testing pigs from non-controlled housing (EU Commission, 2015).

1.4. The Danish situation

In Denmark, testing for *Trichinella* continues due to export requirements. This implies that in 2022 a total of 17.1 million domestic pigs, 403 farmed or privately hunted wild boar as well as 487 horses were tested. No positives were detected. The last positive case found in pigs dates to 1930 (Ministry of Food, Agriculture and Fisheries of Denmark, 2023). Moreover, screening of foxes was undertaken in the hunting seasons 1995/96 and 1996/97. In the first screening, three positive foxes were found among 3133 foxes investigated, whereas no positives were detected in the second screening involving 3008 foxes. The positive foxes were shot in the vicinity of a small village in the north-western part of Denmark. All three had a low burden of *Trichinella* larvae; about one larva per 10 g muscle tissue (Enemark et al., 2000).

Despite the massive testing for *Trichinella*, the controlled housing concept is used extensively to allow visual-only post-mortem inspection of finishing pigs slaughtered at the large abattoirs that are all export-authorized. Visual-only inspection implies that the heart is not cut open routinely. Moreover, the mandibular lymph nodes, the gastro-intestinal lymph nodes, the liver and the lungs are inspected visually, whereas traditional inspection involves incisions and palpations (Alban et al., 2021). The Danish pig industry has established a quality assurance scheme called the DANISH Product Standard. This standard covers all areas of relevance for live pigs. Auditing is done by an independent third-party auditor as previously described by Alban and Petersen (2016).

Recently, a discussion between the Danish Veterinary and Food Administration, representing the competent authority, and the Danish Agriculture & Food Council has taken place regarding how to ensure compliance with the EU *Trichinella* Regulation 2015/1375 in particular concerning controlled housing while using third-party auditing. This resulted in an evaluation, led by the Danish Agriculture & Food Council, of the use of the DANISH Product Standard as a way to ensure compliance with controlled housing.

Aims of the present work

1. To describe the DANISH Product Standard and its way of controlling and auditing,
2. To assess the compliance between this standard and the requirements listed in the EU *Trichinella* Regulation regarding controlled housing,
3. To assess the agreement between the requirements listed by the EU legislation, WOAH's terrestrial animal code and the International Commission on Trichinellosis,
4. To assess the overall validity of the Standard with respect to auditing of controlled housing conditions.

2. Materials and methods

To describe the DANISH Product Standard, detailed information was retrieved from the following website: The Danish product standard (pigresearchcentre.dk). Moreover, the auditor instruction and the associated checklist developed by the company responsible for auditing by July 2024 were retrieved and inspected (DNV, 2024a, 2024b).

To enable a comparison of requirements listed by the EU, the DANISH Product Standard, the International Commission on Trichinellosis and WOAH, the following documents were retrieved and inspected: the current EU *Trichinella* Regulation 2015/1375 (EU Commission, 2015), Gamble et al. (2019), and Chapter 8.18 in WOAH's Terrestrial Animal Health Code (WOAH, 2023).

To assess the validity of the Standard with respect to its way of auditing controlled housing conditions, all information retrieved

was evaluated. In this evaluation, the focus was primarily on the extent of compliance provided by the Standard and the intentions of the EU *Trichinella* Regulation, the International Commission on Trichinellosis and WOAH. Moreover, we conducted an analysis of the strengths, weaknesses, opportunities and threats (SWOT). This is a qualitative approach, which is developed to evaluate the planning and functioning of a business in a structured manner. Strengths and weaknesses are usually referred to as the internal issues involving an examination of all aspects of the business activity, including its organisation, coverage, personnel, facilities, location, products and services. Likewise, when examining the external issues to identify opportunities and threats, the focus is on the political, economic, social, technological and competitive areas of business activity. Brainstorming is the usual approach to provide input for a SWOT analysis (Dyson, 2004). No metrics are used in SWOT analysis, as it is a qualitative approach developed to ensure a broader description of an activity than using only traditional quantitative methods. We retrieved input for the SWOT analysis for the part of DANISH Product Standard that deals with controlled housing through a brainstorm among the coauthors of the present paper. The coauthors represent academia, the livestock industry and the competent authority.

3. Description of the DANISH production standard and its way of auditing for controlled housing

The DANISH Product Standard deals with production of live pigs in Denmark and is the Danish pig producer's quality assurance scheme. The standard forms the basis for accredited certification, which is carried out by a certification body accredited to the international standard ISO 17065:2012 – scope DANISH Product Standard (Danish Agriculture and Food Council, 2024). More specifically, the accreditation organ DANAK ensures the quality of the way that controlling is made. Germany is one of the primary export markets for export of Danish pigs and pig meat. Moreover, the German standard called 'Qualität und Sicherheit GmbH' (QS) recognizes the DANISH Product Standard as equivalent to QS' quality standard'Agriculture Pig Farming'. This implies direct access to live pigs and pig meat in the German market (Danish Agriculture and Food Council, 2024). If pigs are raised in a herd which is not part of the DANISH Product Standard, they cannot be slaughtered on a QS-approved abattoir.

The standard requires auditing visits conducted by third-party independent auditors. These auditors must have practical experience in pig production and preferably training at the technician level. At a minimum, all auditors must complete a training program that includes audit techniques, basic quality management, Hazard Analysis of Critical Control Points (HACCP), medicine, and livestock training, including health and animal welfare. The training program consists of two training audits, a shadow audit, and four annual calibration meetings where new technology, knowledge, legislation, and more are shared with the auditors. Additionally, a monitoring audit for all auditors is conducted at least every two years.

An ordinary audit is conducted every 3 years. In some herds, the visits are done annually, e.g., for herds complying with specific animal welfare requirements, destined for the United Kingdom. At least 20 % of the re-certification audits must be unannounced implying that contact is made less than 48 h before the planned visit. The remaining visits are announced 2–3 weeks in advance (Danish Agriculture and Food Council, 2024; DNV, 2024a). Only herds producing pigs can be registered for certification, and the certification covers only self-produced products. Hence, producers cannot receive certification for products not produced by themselves (Danish Agriculture and Food Council, 2024).

A typical visit takes from 1.5 h to 2.5 h in a herd with 1000 sows or 5000 finishers on-site. The costs of the visit are entirely paid by the Danish Pig Levy Fund, whereas additional visits due to non-compliances are paid by the individual pig producer. Focus during the visit is on animal welfare, housing and management, feed and water, medicine, traceability, biosecurity, and transport. Overall, the purpose of advisory visits is to assist and motivate producers to do what is necessary to stay in business, implying complying with the legislation, ensuring that the pigs have their needs fulfilled, and maintaining job satisfaction including a decent income. By July 2024, a total of 4622 Danish pig herds were part of the DANISH Product Standard based on data from the Danish CHR register. This corresponds to 73 % of the Danish pig farms. Based on data on movement of pigs during 1–31 May 2024, it was revealed that 99 % of the pigs produced originated from DANISH approved pig herds (Table 1).

Before and during the visit, the auditor follows instructions and a checklist developed by the auditing company. The checklist can be found here: DANISH Produktstandard (svineproduktion.dk). The instructions used by July 2024 are very detailed consisting of 59 pages (DNV, 2024a). Some requirements are of administrative character that can be checked before the visit by retrieving data from different registries such as the pig movement database Svineflyttedatabasen (fvst.dk).

In case of non-compliance, different actions are possible. The first action is relevant for simple mistakes that are easily corrected. In this case, documentation e.g., in the form of a photo, must be sent to the certification body. The second type of action involves unannounced spot audits undertaken by the certification body. The third type of action implicates three counselling visits carried out

Table 1
Distribution of pig herds in Denmark divided according to herd size category and certification according to DANISH Product Standard, 17th July 2024 based on data from the national pig movement database and the SPF-Sund database.

Certified according to DANISH Product Standard	Herd size[a] category	Number of herds	Proportion of herds	Number of animals present	Proportion of animals
No	≤10	1500	23.7 %	4.664	0.04 %
No	>10	197	3.1 %	126.303	1.01 %
Yes	≤10	190	3.0 %	838	0.01 %
Yes	>10	4432	70.1 %	12,345,897	98.94 %
Total		6319	100 %	12,477,702	100 %

[a] Number of animals in the herd.

within 6 months after detection of non-compliance. The first of these three visits will deal with corrective actions: What has been done to rectify the incident? The second visit will involve a root cause analysis revealing why the incident occurred, and the third visit will focus on the identification of measures to prevent similar incidents from happening in the future. These visits must be conducted by an independent veterinarian different from the certification body and the herd veterinarian with whom a health advisory agreement has been made. However, a veterinarian from the same practice as the herd veterinarian is allowed to conduct the counselling visit. The certification body will follow up these advisory visits within 12 months to verify that the visits have taken place, and that the advice has had an effect (Fig. 1) (Danish Agriculture and Food Council, 2024).

4. Results and discussion

4.1. Compliance between the DANISH production Standard's way of auditing for controlled housing and the requirements listed in the EU Trichinella regulation

Table 2 contains a detailed list of the EU requirements for a herd to be recognized as applying controlled housing conditions (EU Commission, 2015). There are 10 requirements listed from (a) to (j). For each of these requirements, the relevant area of the DANISH Product Standard is explained with a reference to whether it refers to administrative requirements (A) or production-related requirements (P). Generally, the DANISH Product Standard has translated the 10 EU requirements directly.

In the EU, it is mandatory for the producer to send food chain information prior to the delivery of every batch of pigs for slaughter (EU Commission, 2004a). Moreover, regarding requirement (a), the producer must report - as part of the food chain information and the DANISH Product Standard - whether the pigs have been raised under controlled housing conditions (Fødevarekædeoplysninger for svin, kvæg, får, geder, heste m.v. - Fødevarestyrelsen (foedevarestyrelsen.dk)). Prior to the visit, the auditor checks the information, which has been submitted by the herd owner Fødevarekædeoplysninger - Status (landmand.dk). Lack of agreement between observed and reported food chain information, e.g., regarding in- or outdoor production facilities, is noted and reported to the abattoir companies that have an export to the USA. Additionally, the herd owner is advised to update the food chain information. Moreover, the auditor checks whether windows and doors in the herd are closed, and if not, nets must be in place to avoid birds and mice entering the premises. Here, the rules from the Danish SPF-system are used, implying that the maximum hole size is 2 cm × 2 cm. This entails that veranda stables without nets are not considered as controlled housing. In the SPF-programme, herds not complying with this requirement are given the status of free range (SPF-Sus, 2024).

Among the 10 requirements listed in the EU *Trichinella* Regulation, only requirement (f) dealing with rubbish dumps is not covered by the DANISH Product Standard. According to the Regulation, the operator must inform the competent authority if there is a rubbish dump in the neighborhood of the holding. Subsequently, the competent authority must assess the risks involved and decide whether the holding is to be recognized as applying controlled housing conditions. In Denmark, there are no free-ranging wild boars (Jordt et al., 2015). Moreover, rubbish dumps have in general been replaced by recycling stations on which waste food is handled. Moreover, dead animals and animal byproducts arising from slaughter of livestock are sent to and processed at the rendering plants. It seems

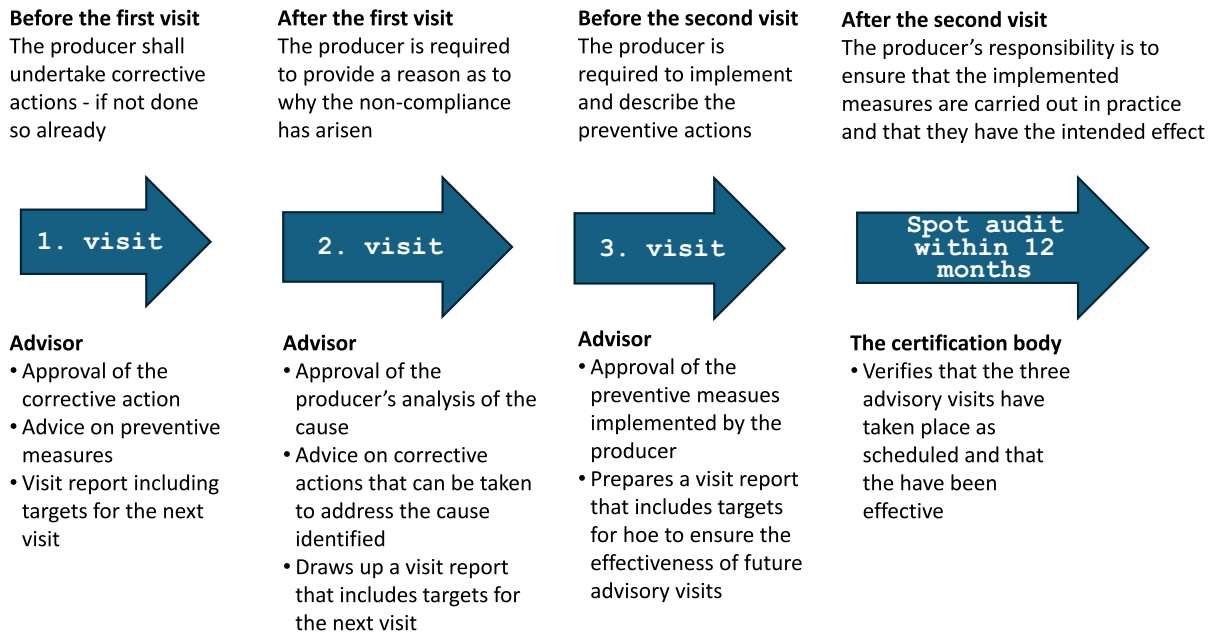

Fig. 1. Graphical description of how the auditing is designed to handle more serious lack of compliance with the DANISH Product Standard, noted during an auditing visit. Modified after: DANISH Product Standard, Appendix 2.

Table 2
Overview of how the requirements for a pig farm to be considered a controlled housing holding according to Annex IV, Chapter 1 in the EU *Trichinella* Regulation 2015/1375 is audited according with the DANISH Product Standard. Source: Danish Agriculture & Food Council (2024).

EU Requirement	DANISH Product Standard[a]	Detailed description
(a)… practical precautions with regard to building construction and maintenance to prevent rodents, any other kind of mammals and carnivorous birds from having access to buildings, where animals are kept	Appendix 4. A.8.4. Indoor/outdoor registered correctly P.5.7. Requirements for windows/doors in indoor herds P.5.4. Rodent prevention	Herd owner's reporting regarding compliance with housing condition requirements as part of food chain information is checked. If the herd is registered as indoors, it must be ensured that there are no open doors/windows allowing birds or other animals from outside to enter the herd. Guide to good production practice - an industry code: https://svineproduktion.dk/viden/paa-kontoret/love-_regler-og-standarder/-/media/7BD7E882BC144F8499933191D644FE31.ashx Fertilizers and waste food must be removed regularly to reduce odor and prevent flies, rats, mice and other pests.
(b)…. apply a pest-control programme for rodents, effectively to prevent infestation of pigs, and keep records of the programme	P.5.4. Rodent prevention	Refers to "Guide to good production practice - an industry code" which among others contains the following: Secure feed stocks and herd as best as possible against pests. This is done through regular observations for signs of pest infestation. Poison boxes are supervised around and inside buildings. Moreover, order should be kept in- and around buildings, and documentation for pest control should be kept.
(c)… feed has been obtained from a facility that produces feed in accordance with the principles described in EU Regulation 183/2005	P.2.6. No feeding with food waste A.2.2. Purchase of feed from an approved supplier A.2.3. Inserts and/or mixing recipes	It is prohibited to use food waste including processed commercial kitchen waste containing animal products. Purchased feed (raw material, finished feed, supplementary feed and additives) must be from a supplier listed on the DANISH positive list. Package insets/mixing recipes must be available for all feed.
(d)… feed is stored in closed silos or other containers that are impenetrable to rodents. All other feed supplies must be heat-treated or produced and stored to the satisfaction of the competent authority	P.2.7. Storage of feed A.2.2. Procurement of feed from approved suppliers See above.	The auditor must review feed barns and rooms and check whether feed is stored and handled in accordance with "Guide to good production practice - an industry code".
(e) … dead animals are collected, identified and transported without undue delay in accordance with EU Regulation 1069/2009 and EU Regulation 142/2011	P.5.1. Storage of dead animals A.5.2. Collection of dead animals	Dead animals must be stored properly (covered and in a ventilated space, away from public roads). Dead animals must be handled in accordance with the legislation and collected and approved by the rendering company.
(f) … risk related to presence of rubbish dump in the neighborhood of the holding	Not covered by the Standard	Today, recycling stations have replaced rubbish dumps in Denmark. There are no free-range wild boars in Denmark. Moreover, pigs that die on-farm are placed in closed containers to avoid access to wildlife due to a perceived risk of ASF. Similarly, food waste is placed in special containers.
(g) … domestic swine are identified so that each animal can be traced back to the holding	P.6.2. Breeding animals must have approved ear tags A.6.1. & A.6.2. Pig movements A.6.3. Danish origin A.6.4. DANISH approved suppliers of pigs A.6.5. Removal of dead animals	All breeding animals must be provided with an approved ear tag when they are moved from the herd of origin. This also applies to deliver to slaughterhouses. An approved ear tag is yellow, with a CHR number from the herd of origin. Movement of all pigs to and from the herd must be registered in the Central Livestock Register (CHR) no later than 7 days after the move. All pigs must be of Danish origin. Herd owners who purchase pigs must ensure that the pigs come from a DANISH approved herd. Movement of dead animals must be registered in the CHR register.
(h) … domestic swine are only introduced onto the holding if they originate in and come from holdings officially recognized as applying controlled housing conditions	A.6.3. Danish origin A.6.4. DANISH approved suppliers of pigs	See above. See above.
(i) …no access to outdoor facilities unless a risk analysis shows that the time period, facilities and circumstances of outdoor access do not pose a danger for introduction of *Trichinella* in the holding	P.5.7. Requirements for windows/doors in indoor herds Appendix 4. A.8.4.	See above. This requirement implies that veranda stables are considered as non-controlled housing. See above
(j) …no swine for breeding and production has been unloaded after leaving the holding of origin at an assembly center unless specific requirements are met	A.7.3. No animals from collection centers	No animals may be transported from a collection center to the herd.

[a] The requirements in the DANISH Product Standard are divided into two groups. The first (A) covers those related to administration, where there is a need for written documentation. The second (P) covers those of relevance for the actual production, as shown during the auditing visit. The letters (A) or (P) and the number refer to the section in the Standard in which the requirement is specified (Danish Agriculture and Food Council, 2024).

unlikely that Danish rubbish dumps nowadays present a risk with respect to *Trichinella* spp.

Another issue relates to requirement (h) dealing with introduction of pigs to the holdings. Here, the EU *Trichinella* Regulation specifies that incoming pigs must originate in and come from holdings officially recognized as applying controlled housing conditions. The corresponding requirements listed in the DANISH Product Standard cover the following four elements: 1) all pig movement must be registered in the Pig Movement Database, which is run by the Danish Veterinary and Food Administration, 2) the entire herd must be of Danish origin, 3) all suppliers must be approved for the production of DANISH pigs, and 4) movements of dead animals must be registered correctly in the pig movement database. Hence, by use of the Standard it is ensured that only Danish pigs, from herds that are approved for production of DANISH pigs are moved into a finishing herd.

4.2. Agreement between the EU Trichinella regulation, the WOAH and the international commission on Trichinellosis regarding requirements for a herd to be recognized as a controlled housing herd

It is noted from Table 3, there is a general agreement between the EU *Trichinella* Regulation, the WOAH and the International Commission on Trichinellosis regarding the requirements for a herd to be recognized as a controlled housing herd. In the following, the focus is on the few issues where there is disagreement. The first issue deals with requirement (f) in the EU *Trichinella* Regulation regarding rubbish dumps. Neither WOAH nor the International Commission on Trichinellosis mention rubbish dumps. It may reflect that this requirement is beyond the on-farm premises. In fact, infections may be spread from rubbish dumps, unless preventive measures are taken. An example is African swine fever, where an outbreak in Sweden was detected in Fagersta in September 2023. The outbreak seems to have been caused by uncontrolled access of free-ranging wild boar to a rubbish dump managed by the municipality (Cedersmyg, 2023). In any case, the risk is considered minute in Denmark, because there are no free-ranging wild boar.

Moreover, there is some discrepancy between the three sets of requirements regarding introduction of new pigs into a herd. The EU *Trichinella* Regulation and WOAH require that pigs entering a herd must come from herds that are also recognized as applying controlled housing conditions. However, the EU *Trichinella* Regulation also states that if some of the pigs have access to outdoor facilities, then the operator must be able to show that this does not pose a risk for introduction of *Trichinella* into the herd. It is stated that

Table 3
Comparison of requirements for controlled housing listed in the EU *Trichinella* Regulation with the similar requirement listed by WOAH and the International Commission on Trichinellosis.

Requirement listed by		
EU Regulation[a]	WOAH[b]	The International Commission on Trichinellosis[c]
(a) Buildings	(a) Facilities and the surrounding environment should be managed to prevent exposure of pigs to rodents and wildlife	Swine housing includes physical barriers which prevent swine from being exposed to wildlife (including birds) and carrion derived thereof and which greatly reduces swine from being exposed to rodents.
(b) Rodents	(d) A rodent control programme should be in place	A documented rodent control program is maintained by a pest control provider or an employee(s) of the production facility and regular inspection for rodent activity is performed. When properly performed and documented, there should be no evidence of active rat infestations.
(c) Feed origin	(b) Raw food waste of animal origin should not be present on pig establishments and should not be fed to pigs	Feed which is not produced on-site is purchased from an approved facility, which conforms to good production practices (e.g., see Chapter 6.4. Waste food, if fed to pigs, must not contain meat products.
(d) Feed storage	(c) Feed should comply with the requirements in Chapter 6.4. and should be stored in a manner to prevent access by rodents and wildlife	Feed, and feed components, are stored in closed silos or containers, which do not attract or allow rodents or wildlife to enter.
(e) Dead animals	(e) Dead animals should be immediately removed and disposed of in accordance with Chapter 4.13	Dead animals are promptly removed from the pig housing areas and disposed of off-site or stored in animal-proof containers for removal from the premises
(f) Rubbish dump	Not mentioned	Not mentioned
(g) Animal identification	(4) An animal identification and animal traceability system for domestic pigs is implemented in accordance with Chapters 4.2 and 4.3	Documentation exists so that movements of pigs and/or lots can be traced.
(h) Introduction of new pigs	(f) Introduced pigs should originate from herds officially recognized as being under controlled management conditions, or from herds of a compartment with a negligible risk of *Trichinella* as described in Article 8.18.5.	New animals, excluding piglets under 5 weeks of age, entering the production site must originate from farms that also apply controlled management conditions and have attained *Trichinella* negligible risk status
(i) No outdoor access	Not mentioned	See above under (a) - excluding piglets under 5 weeks of age as mentioned in (h)
(j) Assembly centres	Not mentioned	Not mentioned

[a] The letters refer to the letters in the EU Regulation 2015/1375 (EU Commission, 2015).
[b] The letters and figures refer to Article 8.18.4 in Volume 2 of WOAH's Terrestrial Animal Health Code (2023), whereas the chapters refer to Volume 1 Terrestrial Code Online Access - WOAH - World Organisation for Animal Health.
[c] Gamble et al. (2019).

the time period, the facilities and the circumstances of the outdoor access are the variables to consider when assessing the risk. Moreover, article 3 of the EU *Trichinella* Regulation 2015/1375 states that carcasses and meat of not weaned domestic pigs less than 5 weeks of age shall be exempt from *Trichinella* examination. This is in accordance with the International Commission on Trichinellosis that has made an exception for pigs under 5 weeks of age. This is likely due to an assessed low probability of *Trichinella* larvae being present in pigs at that age. In practical terms, this could imply that piglets born outdoors and weaned at 5 weeks of age in principle could be allowed to enter a controlled housing herd. Specifically for Denmark, the extensive number of tests with negative results for decades, adds to the confidence that although some piglets could have been born outside and raised indoors since weaning, the risk of *Trichinella* infection is negligible. Still, the Danish Veterinary and Food Administration is of the view that pigs that are introduced to controlled housing herds must originate from herds also applying controlled housing (Ministry of Food, Agriculture and Fisheries, 2014), despite that a previous executive order from 2008 allowed controlled housing pigs to be born outdoors, on the condition that they were raised indoors since weaning (Ministry of Food, Agriculture and Fisheries, 2008). This risk-averse view is in line with the former EU *Trichinella* Regulation 2075/2015 in which a set of requirements is listed for allowing outdoor access of pigs prior to weaning, including 10-years absence of *Trichinella* in the territory, appropriate fencing, and surveillance of relevant wildlife (EU Commission, 2005). In Denmark, wildlife is not monitored regularly, presumably because the outdoor-raised pigs are interpreted as a sentinel, should infection incur.

Finally, neither WOAH nor the International Commission on Trichinellosis mention the role of assembly centres. Assembly centres mean places such as holdings, collection centres and markets, at which domestic equidae, bovine, ovine, caprine or porcine species originating from different holdings are grouped to form consignments (EU Commission, 2004b). For pigs, this reflects that pig production is divided into 1) sows with piglets, where pigs might be sold and exported at weaning, followed by 2) weaner producers, who sell their piglets at 30 kg, and finally, 3) production of finishers, where pigs are sent to abattoirs in either Denmark or abroad. In 2022, 13.8 million piglets and weaners were exported (Danish Agriculture and Food Council, 2023), implying a very high number of transportations. Therefore, the role of the assembly centers for Denmark is mainly to minimize the probability of introducing notifiable infections such as African swine fever. The use of assembly centres implies that the livestock vehicles arriving from outside Denmark will not go to the farm but to the assembly centre as explained by Gao et al. (2023). Hence, within the EU, it is prioritised that biosecurity is complied with across the supply chain, implying that assembly centres must also have biosecurity practices in place. The DANISH Product Standard is even more demanding as it specifies that no pigs are allowed to go back to a DANISH approved pig herd after visiting an assembly centre.

4.3. Overall validity of the DANISH product standard with respect to controlled housing

Generally, the validity of using the DANISH Product Standard to ensure that finisher pigs are raised under controlled housing conditions seems high when looking at the structure of the standard and how it incorporates the requirements listed in the EU legislation, WOAH's chapter on *Trichinella* and the recommendations developed by the International Commission on Trichinellosis. It may be argued that if a pig herd is only audited every third year, then the housing or management may have changed slightly since the last visit. However, it is not likely that indoor productions will change to outdoors and vice versa. Most of the auditing visits are announced, and again it may be argued that this is a weakness as the producer may correct various issues only for the auditing visit. Still, there is a high knowledge and awareness among the Danish pig farmers regarding the importance of external biosecurity. In a study comparing biosecurity practices in six European countries, the Danish pig producers came out with substantially higher scores for external biosecurity than the pig producers from Belgium, Germany, France, the Netherlands and Sweden (Filippitzi et al., 2017). In line with this, all Danish pig herds with a herd health advisory agreement must be advised by their veterinarian on infection protection at least once a year (Ministry of Food, Agriculture and fisheries of Denmark, 2021). Moreover, practices are in place both on the individual pig farm as well as in the sector as such, which makes it straightforward to maintain a high level of external biosecurity. If the auditing had been left solely to the Danish Veterinary and Food Administration as the competent authority, the visits may have been done at an even lower frequency. In Denmark, official control of controlled housing is based on a risk-based targeted control (EU Commission, 2015; EU Commission, 2017; EC Commission, 2019; Danish Veterinary and Food Administration, 2023b, 2023c). Furthermore, it is a legal requirement, that the individual pig farmer ensures regular audits of controlled housing conditions, by an independent accredited control body, at least every third year (Danish Veterinary and Food Administration, 2015).

In Denmark, extensive testing for *Trichinella* continues despite that Denmark was granted status by the EU as having a negligible risk of *Trichinella* in domestic pigs in 2007. This is due to the large export of pig meat out of the EU, as there is no international recognition of WOAH's negligible risk status so far. The only exemption from testing is applied for pigs raised under controlled housing conditions that are slaughtered at a non-exporting abattoir. In 2022, a total of 17.8 million pigs were slaughtered in Denmark (Danish Agriculture and Food Council, 2023). During the same year, 17.1 million tests for *Trichinella* were undertaken (Danish Veterinary and Food Administration, 2023a). This implies that around 0.7 million pigs, slaughtered in abattoirs that do not export out of the EU, are exempted from testing due to controlled housing. As stated in the Introduction, there have been no *Trichinella* positive pigs in Denmark since the 1930s (Danish Veterinary and Food Administration, 2023a).

Since June 2014, the EU mandates that all pigs, regardless of their age or rearing method, must undergo visual-only inspections. This type of post-mortem inspection is less labour-intensive compared to traditional methods that involve incisions and palpations. An exception is warranted when there are indications of a possible risk to human health, animal health or animal welfare pointing to a need for traditional inspection involving incisions and palpations. Moreover, it is a requirement that food chain information is sent to the abattoir prior to the slaughter of the animals (Alban et al., 2021; EU Commission, 2019). In Denmark, the food chain information for pigs involves information about the type of rearing: indoors under controlled housing conditions or not. However, beyond the EU

there is no international acceptance of the requirement for using visual-only post-mortem inspection. Therefore, a country like Denmark with a large pig production has negotiated acceptance of equivalence with large trade partners, including the USA. This implies that if the meat is destined for export, only finishing pigs raised under controlled housing conditions can be subjected to visual-only post-mortem inspection (Alban et al., 2021). The same approach is used in the Netherlands, where the private standard IKB is in place and allows e.g. the Dutch abattoir company Vion to apply visual-only inspection for finisher pigs raised under controlled housing conditions (D. Oorburg, personal communication, April 2024).

In Denmark, there is a strong tradition for using high biosecurity in the Danish pig production to avoid introduction of infectious agents, which might impact the productivity negatively. The Specific Pathogen Production (SPF) system was established in the 1970, leading to the establishment of sow herds free from costly production infections such as *Actinobacillus pleuropneumonia*, Mycoplasma, PRRS, swine dysentery, atrophic rhinitis, scabies, and lice. The sows' free status is maintained with a fixed set of rules for infection protection, health control and transport of pigs between herds. Veterinarians with special expertise in pigs from SPF-Sund audit this. SPF-Sund is an organisation owned by the Danish Agriculture & Food Council. Auditing involves sero-surveillance. The individual sow herd's infection status can be found in an open register Health Status Management - Home (spfsus.dk). Hence, there is a tradition for using auditing as a way of ensuring that the requirements in force are being complied with. In fact, two other auditing systems are in place in Danish pig production: DANISH Transport Standard and Global Red Meat Standard. For more information, please see: DANISH quality assurance scheme (pigresearchcentre.dk). The extensive use of private standards on top of existing national and EU legislation is due to the large pig production as well as the large amount of pig meat being exported. In 2022, 1936.544 tons of pig meat were exported (Danish Agriculture and Food Council, 2023).

It is outside the remits of the current work to assess the extent to which controlled housing is used. Based on reporting to EFSA/ECDC, seven EU Member States have reported testing of 34.2 million domestic pigs raised under controlled housing conditions and recognized by the competent authorities (EFSA/ECDC, 2023). Hence, the concept of controlled housing is still not used extensively in the EU. In the USA, the concept is being used as part of the U.S. Pork Quality Assurance Plus (PQA+), which includes five guidelines outlining the best management practices: 1) feed biosecurity, prevention of rodents, wildlife and birds, 3) no feeding with raw food of animal origin, 4) prompt removal dead pigs, and 5) documentation of arrival and departure of pigs (Gamble et al., 2024). Hence, requirements that are like those that form part of the DANISH Product Standard.

The results of the Strengths, Weaknesses, Opportunities and Threats (SWOT)-analysis using DANISH Product Standard's way of auditing and controlling for controlled housing are shown in Table 4. Generally, it is cheap and feasible to expand an existing third-party auditing system to also cover requirements for controlled housing. However, establishing a standard from the ground is a costly process and requires a united livestock industry. Therefore, it is recommendable to consider a broad scope with several objectives of such a standard right from the beginning of the establishment and specify in detail how and why each requirement should be controlled. The SWOT analysis also highlight the importance of ensuring a high level of confidence in a standard among the users and customers.

As can be noted from the above, auditing for controlled housing can be used both to identify herds where *Trichinella* testing can be omitted at slaughter, and to identify finisher pigs that can be destined for visual-only inspection. Hence, the scope of using auditing to ensure compliance with control housing requirements is wider than just focusing on *Trichinella*, as the hazards of concern in pig production have changed since the discussion of negligible risk of *Trichinella* took place. Today, African Swine Fever (ASF) is a much more relevant hazard, and here, the controlled housing concept also works, because high external biosecurity is the only way to keep

Table 4
SWOT analysis of the DANISH Product Standard's approach to auditing and controlling for controlled housing – based upon a brainstorm among the authors of the present paper.

	Positive	Negative
Issues internal to the Standard	Strengths	Weaknesses
	- Easy and cheap way of auditing for controlled housing because the Standard is already in place for other issues such as traceability and animal welfare. - Physical visit required by the certification body. - Information about deviations is sent to the abattoir without undue delay leading to immediate action. - High frequency, relatively speaking (minimum every 3 years, for some herds every year). - The sector organizes and pays (not the taxpayers). - DANAK-accreditation ensures that the certification body undertakes the auditing in a qualified way.	- Expensive to establish if there is no existing standard. - It is costly to introduce changes to the standard. - Expensive to change even details. - Not an online control system. - Most visits are announced and therefore the degree of compliance cannot be fully assessed during the visit. - It is questionable whether the farm workers have sufficient knowledge about the standard and the fact that the information is used for food chain information.
Issues external to the Standard	Opportunities	Threats
	- Can be used for much more than omitting *Trichinella* testing. - New and better ways of controlling compliance can gradually be identified and implemented. - Easy and fast to implement new specific requirements from customers and competent authorities. - Allows to gain access to new markets.	- Lack of acceptance of auditing undertaken by a third-party independent company compared to the competent authority. - Lack of trust in auditing results. - It requires a well-organized and wealthy sector, as the individual pig producer might not be motivated to pay for auditing visits.

ASF, for which there is no vaccine, at bay. Similarly, Porcine epidemic diarrhoea is an infection where auditing of the origin of feed helps to prevent entry of the infection into a herd. Different systems to assess the level of biosecurity have been developed. Other systems are in place which can be used to evaluate the quality of on-farm biosecurity for various livestock species. One particular system is Biocheck, which is an independent, scientific-based scoring system. For more information, please see: Home | Biocheck. UGent (biocheckgent.com). One of the main differences between Biocheck and the Danish SPF system, is the lack of sero-surveillance in Biocheck.

5. Conclusion

The DANISH Product Standard is a third-party independent auditing system set up for pig productions in Denmark. The Standard, among others, includes areas of relevance for documenting compliance with controlled housing as specified by the current EU *Trichinella* Regulation. A comparison of the requirements for controlled housing listed by the EU legislation, WOAH's terrestrial animal code and the International Commission on Trichinellosis showed that there is a high agreement between the requirements. Only minor discrepancies were identified. The SWOT analysis revealed that use of the DANISH Product Standard is a cheap and feasible way of demonstrating compliance with the EU requirements for controlled housing, because the standard is already in place for other purposes. The analysis also pointed out that it is important to ensure confidence in the standard among the users and customers. The overall validity of the auditing system was judged as high.

6. Epilogue

As part of the above work, the specific and detailed ways of auditing and controlling for controlled housing is currently being evaluated within the DANISH secretariat to elucidate how to update any of the existing auditing procedures. This resulted in an extension of the inspection of windows and doors from indoor finishing herds. Moreover, the Danish Veterinary and Food Administration is currently undertaking a control campaign focusing on verifying that the food chain information delivered from the herd to the abattoir is correct. A total of 40 pigs herds, 20 cattle herds and 20 small ruminant herds (April-december: Kontrol af fødevarekædeoplysninger - Fødevarestyrelsen (foedevarestyrelsen.dk)). When the campaign is over, any discrepancies of relevance for the DANISH Product Standard will be evaluated by the Danish pig industry and necessary actions will be initiated.

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CRediT authorship contribution statement

Lis Alban: Writing – original draft, Formal analysis, Conceptualization. **Heidi Enemark:** Writing – original draft. **Heidi Huus Petersen:** Writing – original draft. **Lisbeth Harm Nielsen:** Writing – original draft, Resources, Methodology.

Declaration of competing interest

Lis Alban and Lisbeth Harm Nielsen work for an organisation which gives advice to farmers and meat- producing companies.

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