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1	Risk-based surveillance for meat-borne parasites
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17	Abstract
18	There is a plethora of meat-borne hazards – including parasites - for which there may be a need for
19	surveillance. However, veterinary services worldwide need to decide how to use their scarce resources and
20	prioritize among the perceived hazards. Moreover, to remain competitive, food business operators –
21	irrespective of whether they are farmers or abattoir operators - are preoccupied with maintaining a profit

and minimizing costs. Still, customers and trade partners expect that meat products placed on the market
 are safe to consume and should not bear any risks of causing disease.

24 Risk-based surveillance systems may offer a solution to this challenge by applying risk analysis principles; first 25 to set priorities, and secondly to allocate resources effectively and efficiently. The latter is done through a focus on the cost-effectiveness ratio in sampling. Risk-based surveillance was originally introduced into 26 27 veterinary public health in 2006. Since then, experience has been gathered, and the methodology has been 28 further developed. Guidelines and tools have been developed, which can be used to set up appropriate 29 surveillance programmes. In this paper, the basic principles are described, and by use of a surveillance design 30 tool called SURVTOOLS (<u>https://survtools.org/</u>), examples are given covering three meat-borne parasites for 31 which risk-based surveillance is 1) either in place in the European Union (EU) (Trichinella spp.), 2) soon to be 32 officially implemented (Taenia saginata) or 3) only carried out by one abattoir company in the EU as there is 33 no official EU requirement (Toxoplasma gondii). Moreover, advantages, requirements and limitations of riskbased surveillance for meat-borne parasites are discussed. 34

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36 Keywords: Risk analysis; Priority-setting; Parasites; Monitoring; Meat

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38 1. Introduction

There is a plethora of meat-borne hazards, which represent a potental risk to humans. In the European Union (EU), bacteria such as *Campylobacter* spp. and *Salmonella* spp. are causing the highest number of human foodborne disease cases (EFSA/ECDC, 2018). However, not just the number of cases but also the severity of infection is relevant when judging the importance of a hazard. To include this, the WHO Foodborne Disease Burden Epidemiology Reference Group (FERG) estimated the disability-adjusted life-years (DALYs¹) of various

¹ DALYs are calculated by adding the number of life years lost due to mortality (YLL) to the number of years lived with disability due to morbidity (YLD): DALY = YLL + YLD (FERG, 2015)

potential foodborne hazards including microbiological and chemical contaminants. The FERG report contains a list of prioritised food-borne parasites, and among these, some are meat-borne (FERG, 2015). Among the meat-borne parasites, *Taenia solium* was identified as associated with the highest burden of disease, resulting in a world total of 2.8 million DALYs, in particular on the African continent. *Toxoplasma gondii* came in third, with 1.7 million DALYs, and *Trichinella* spp. was identifed as the hazard with the lowest burden of disease, 550 DALYs, among the all the hazards included in the final FERG analysis (FERG, 2015).

In a world with unlimited resources, there would be surveillance in place for all potential hazards. But resources are scarce and both private and public decision-makers need to take decisions on what hazards and activities to prioritise and how to use existing resources efficiently. Such processes are complicated by a variety of (and sometimes competing) demands; food business operators being under pressure to operate in a profitable manner, customers and trade partners expecting safe and affordable products, and public services being asked to ensure that food systems function reliably to the benefit of many in society.

Risk-based surveillance and control may offer a solution to the challenge by applying risk analysis principles;
first to set priorities and secondly to allocate resources, effectively and efficiently. Risk-based surveillance
makes use of information about the probability of occurrence and the magnitude of the biological
and/or economic consequence of health hazards to plan, design and/or interpret the results obtained
from surveillance systems.

Risk-based surveillance and control was originally introduced into veterinary public health by Stärk et al. (2006). Since then, the approach has been used in many countries for a range of hazards, validated and refined. Guidelines and tools have been developed that can assist, when setting up a risk-based surveillance programme adequate for the issue and including the context. The approach has already been used for *Trichinella* spp., but there is scope for enhanced use of risk-based surveillance with the potential to increase cost-effectiveness of surveillance for similar pathogens. 67 In this paper, the basic principles of risk-based surveillance are described. Next, the surveillance of three 68 meat-borne parasites is described using the so-called SURVTOOLS (https://survtools.org/) approach (Fig. 1), 69 which was developed as part of the RISKSUR project (https://www.fp7-risksur.eu/). The parasites are 70 Trichinella spp., Taenia saginata and Toxoplasma gondii. The first two were chosen because they are 71 covered in international legislation and risk-based surveillance is either in place (Trichinella) or soon to be 72 implemented (T. saginata) in the EU. As the last example, T. gondii was chosen, because the FERG report 73 identified this hazard as the third-most important parasite worldwide (FERG, 2015), although no official 74 requirements for surveillance are in place in the EU. By use of these selected, illustrative examples, the 75 progress made in risk-based surveillance for meat-borne parasites, the implications thereof, and the 76 opportunities for the future are described and discussed.

77

78 2. Basic principles of risk-based surveillance and control

79 In the RISKSUR project it was suggested that risk-based surveillance could include one of several of 80 the following four elements: Risk-based prioritisation, risk-based sampling, risk-based requirement, 81 and risk-based analysis. Risk-based prioritisation involves a determination of which hazards to select 82 for surveillance, based upon the probability of their occurrence and associated consequences. Risk-83 based sampling covers designing a sampling strategy to reduce the cost or enhance the accuracy of 84 surveillance by preferentially sampling strata (e.g. age groups or geographical areas) within the 85 target population that are more likely to be exposed, affected, detected, become affected, transmit 86 infection or cause other consequences (e.g. large economic losses or trade restrictions). Risk-based 87 requirement deals with use of prior or additional information about the probability of hazard 88 occurrence to revise the surveillance intensity required to achieve the stated surveillance purpose. 89 Risk-based analysis make use of prior or additional information about the probability of hazard 90 occurrence, including contextual information and prior likelihood of disease to revise conclusions 91 about disease status. In this paper, focus is on risk-based prioritisation and risk-based sampling.

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93 2.1. Setting the priorities – Risk-based prioritisation

94 The higher purpose is mitigation, where surveillance and intervention are two elements of the mitigation 95 aim. Surveillance provides the information, intervention the action. But an intervention is not always 96 necessary. Therefore, first it should be assessed where there is a need for surveillance, why, and which kind 97 of knowledge is expected to be provided by the surveillance. This is general for all kinds of surveillance. This 98 constitutes the strategic part of the analysis. Often, it starts with a perceived or actual risk that needs to be 99 dealt with or a requirement set by regulatory bodies. In the present context, risk is seen as the product of 100 probability of the occurrence of the hazards and the extent of biologic and/or economic 101 consequences of their occurrence. Regarding consequences, these may include production losses, animal 102 welfare problems, human disease (specific to zoonotic infections), trade loss, reputation loss, loss of 103 ecosystem services and food security.

Perturbations may be defined as a deviation of a system or process from its regular or normal state or path, 104 105 caused by an outside influence. If a high capacity to cope with perturbations is judged as vital by decision-106 makers or society, indicators of consequences might be required as part of the surveillance. In international 107 trade in meat, findings of unwanted hazards such as Salmonella, residues or Trichinella may be interpreted 108 as incidents leading to perturbations - such as withdrawal of the meat from the market or a ban on export. 109 In line, outbreaks due to foodborne hazards may result in consumer boycotts, leading to a switch to other 110 products. Hence, one sector's loss may be another sector's gain. Moreover, in extreme cases as currently 111 seen with the spreading of African swine fever, food security issues on a local market due to culling of many 112 infected herds may evolve unless handled by the government.

Governments and the livestock sector often have ambitions for improving public and/or animal health and/or expanding the access to the export market. If improvement of public and animal health is the objective, information about the burden of different diseases is the basis, for humans as well as animals. The FERG Report may come in useful for public health as it contains an assessment of the human burden of different foodborne diseases in the world, divided into regions (FERG, 2015). Next, a source account is needed, whereby the contribution to human exposure of each kind of food consumed is assessed. For example, if the highest burden of foodborne disease is ascribed to campylobacteriosis, and poultry meat is the main source, then the value of surveillance in pig meat would be limited. For animal health, disease recordings may also be considered a good indicator for productivity, in the absence of recording systems for production.

123 If access to a foreign market is the objective, then first an identification of the requirements regarding food 124 safety and the zoo-sanitary status for the foreign market is needed. Next, establishment of a specific 125 surveillance may be required. Although the outcome of a burden of disease assessment and a source account 126 may show that a specific risk is negligible in given commodity, a surveillance may still be needed - if required 127 by the importing country. That could be the case for Trichinella in pig meat. After access to the foreign 128 market, a continued documentation of a high zoo-sanitary status and food safety level may be essential, 129 requiring continued surveillance. Alternatively, bilateral negotiations may lead to acceptance of equivalence 130 on other terms such as a risk-based surveillance in the high-risk sub-population. A country may be in a 131 position where it is considered too costly to implement certain food safety standards for the entire 132 production. In response, the country may decide to limit the surveillance programme to animals due for 133 export, or farms or abattoirs that export their produce, to be able to export to countries with a high level of 134 animal health or food safety.

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136 2.2. Designing the surveillance - risk-based sampling

Once the relevant hazards have been identified, then technical and operational considerations should be made regarding how to design the surveillance. Here, the surveillance objective should be further defined, and surveillance designers should discuss which kind of surveillance is needed to meet the objective.

140 Surveillance involves use of the obtained information for decision-making regarding whether to initiate 141 action or not. For example, actions may be required when positive samples are found or when the prevalence 142 gets above a certain accepted threshold. In contrast, monitoring differs from surveillance in the sense that 143 no actions are planned (Hoinville et al., 2013). In the following, "design of surveillance" is used in a broad meaning, not differentiating between monitoring or surveillance. During the design of surveillance, design 144 145 tools may be used. One example is the SURVTOOLS, which guides the user through key elements of 146 surveillance (Fig. 1). Such a standardized approach ensures that all elements are carefully considered before 147 decisions are taken.

148 Information about the biology of the hazard is commonly needed when designing surveillance. For parasites 149 this implies the lifecycle. Moreover, information about the prevalence of infection in different animal species, 150 knowledge about risk factors, ways of spreading and the effects of infection or disease is relevant. All this 151 information may be used to identify where the risk is high, enabling targeting of sampling to the sub-152 populations or commodities that harbor the highest risk (Stärk et al., 2006). As described above, in the 153 context of risk-based surveillance, risk is seen as the product of probability and consequences. Therefore, the 154 highest risk may be found either in the population strata with the highest expected prevalence of the hazard 155 or the strata, where the impacts of having the hazard may be highest.

156 Unlike bacterial foodborne pathogens, where cross-contamination and bacterial growth along the food chain 157 is a major concern, meat-borne parasites do not multiply in the food chain. It is important to identify infected 158 animals or their products in food systems to manage the risk and avoid human exposure. Risk-based sampling 159 may be focusing on meat originating from animals raised outdoors and not indoors – if outdoor-raising is 160 perceived as a risk factor for the hazard of concern. Moreover, one should have a view on the intended use 161 of the meat. If the hazard is eliminated during processing, then there will be no need for surveillance in that 162 part of the production or afterwards. But there may be a need for surveillance in another part of production. 163 This implies that a meat value chain perspective is useful as it might offer novel opportunities for risk-based 164 sampling.

165 Feasibility of sampling and its cost-effectiveness are also important to consider. In 2011, EFSA introduced the 166 concept of harmonised epidemiological indicators, consisting either of direct measurements of the hazard 167 itself or an indirect measurement based upon the production system. Using the latter approach, a farm or a 168 herd could be categorized into low- or high-risk (EFSA, 2011a). Regarding direct measurements, sampling at 169 the abattoir is easier and cheaper than sampling on the farm, because for each abattoir there is a high 170 number of farms delivering animals for slaughter. Choice of laboratory methods requires considerations 171 regarding whether a high sensitivity or a high specificity is needed - and whether more methods should be 172 used and interpreted, in parallel or in series. Regarding choice of sampling material (matrix) to use in the 173 laboratory, meat may be easier to collect than blood. However, care should be taken before deciding, 174 because the laboratory method may have been validated for one matrix and not for another. Finally, when 175 estimating the prevalence of a given infection, the test characteristics need to be considered as well as the 176 cut-off used when judging whether an individual sample is positive or not. Here, parasites may represent a 177 challenge as many different tests are available and used, unfortunately sometimes without knowing the 178 sensitivity and the specificity, hampering comparisons of prevalence estimates (Felin et al., 2017; Olsen et 179 al., 2019).

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181 3. Surveillance for Trichinella

Trichinella infection in humans may result in life-threatening disease. *Trichinella* was first detected in its larval form in a human cadaver in 1835 and in a human clinical case in 1859 (Campbell, 1983). Following this discovery, many European countries implemented inspection and control of *Trichinella* in meat using trichinoscopy (Boireau et al., 2015). In the USA, *Trichinella* testing was also put in place, but mainly with a focus on export of pork to Europe. Today, *Trichinella* is under control not just in Europe and the US, but in most parts of the world and is, therefore, associated with a low burden of disease worldwide (FERG, 2015). 188 Several animal species may get infected with Trichinella, although consumption of meat from pigs, horses 189 and wildlife has been ascribed to most of the human cases observed. Trichinella infection can only occur if 190 an animal or a human ingest muscle tissue containing infective larvae (Gamble et al., 2019). This implies that 191 infection cannot spread from one pig to the next, unless cannibalism takes place. It also means that feeding 192 of raw waste containing infected meat to pigs (which is not allowed in the EU due to the probability of 193 spreading infectious disease such as African or Classical swine fever), as well as unsafe handling of dead 194 animals are major risk factors. Moreover, presence of a high number of rodents and outdoor-raising of pigs 195 have been identified as risk factors. The longer an animal lives, the higher is the probability that it may get 196 exposed. Therefore, age may be interpreted as a risk factor.

197 The general surveillance for Trichinella in the EU is described in Table 1, based upon Alban & Petersen (2016) 198 and the EU legislation (Anon., 2015). Until 2014, all pigs raised in the EU were supposed to be tested, unless 199 the Member State had obtained an official recognition of having a negligible risk of Trichinella in its domestic 200 pigs, which only Denmark and Belgium had obtained (Alban & Petersen, 2016). Then, the EU legislation 201 adopted a risk-based approach for surveillance of Trichinella in pigs and officially required testing only of pigs 202 raised in the low-biosecurity compartment, such as outdoors or backyard production (called the non-203 controlled compartment in the EU). As an intermediate stage, a Member State was obliged to test 10% of 204 the pigs (finishers, sows or boars) from the controlled housing compartment. This was to continue until the 205 Member State was able to document, using historical data on continuous testing carried out on slaughtered 206 swine population, that the prevalence of *Trichinella* was below 1 per million in the controlled housing 207 compartment. Denmark and Belgium were excepted from this requirement because of their negligible risk 208 status (Anon., 2015). The move towards a risk-based sampling was due to an overwhelming amount of data 209 showing that Trichinella spp. is absent in the controlled housing compartment (Alban et al., 2008; Alban et 210 al., 2011).

This moved focus from testing pigs individually to auditing of biosecurity on-farm. Such indirect measurements are much cheaper than testing all pigs for the presence of the parasite, in particular if an 213 auditing system is in place already for other reasons (Alban & Petersen, 2016). To ensure acceptance of the 214 risk-based sampling, compliance with the requirements for controlled housing should be checked at regular 215 intervals and ideally, the frequency of the auditing should be risk-based. These requirements are described 216 in detail in Annex IV to the EU Trichinella Regulation (Anon., 2015). For many years, the International 217 Commission of Trichinellosis (ICT²) has published guidelines for pre-harvest control of Trichinella in food 218 animals. The ICT guidelines have recently been updated (Gamble et al., 2019); they are almost equal to the 219 requirements listed in the EU Trichinella Regulation. Either the veterinary authorities or a third-party 220 independent auditor may do the auditing. The latter is undertaken as part of a private standard, building on 221 top of national and international legislation. Such private standards are common in many parts of the world, 222 and it may be expected that they will increase further in use and importance (Alban & Petersen, 2016).

223 According to the EU legislation, carcasses of horses, wild boar and other farmed and wild animal species 224 susceptible to Trichinella infection shall be systematically sampled in slaughterhouses or game-handling 225 establishments as part of the post-mortem examination (Anon., 2015). Hence, testing will only take place if 226 the meat is intended to be consumed by humans. For foxes or other indicator animals, monitoring is 227 encouraged but not required in the EU Trichinella Regulation, despite wildlife potentially having a higher 228 prevalence of Trichinella spp. than livestock, reflecting that food safety is the overall objective of the 229 surveillance. Moreover, surveillance in outdoor pigs can be interpreted as an early warning for indoor pigs, 230 raised in the same geographical area.

Despite the FERG report pointing to a marginal negative impact on human health and the EU legislation allowing no testing for *Trichinella* spp. of pigs raised under controlled housing conditions, extensive testing is still taking place in the EU, because of trade requirements from countries outside the EU (Alban & Petersen, 2016). This shows the importance of international harmonization regarding surveillance and control of the

² <u>http://www.trichinellosis.org/</u>

most common animal health and food safety issues - as it could lead to a more effective distribution of
 resources spent on assuring food safety and animal health and welfare.

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238 4. Surveillance for Taenia saginata

239 Humans are the definitive host of the cestode T. saginata. If humans are exposed to live cysticerci, by eating 240 undercooked beef, infection in the form of a tapeworm may develop, where after the tapeworm will begin 241 excreting infective eggs. The presence of the tapeworm will usually result in very mild infection or no 242 symptoms at all (Laranjo-González et al., 2016). Contrary to T. solium (the swine tapeworm) the eggs of T. 243 saginata are not infective to humans (Gerts, 2015). Neurocysticercosis is therefore not related to T. saginata. 244 Hence, the human burden of disease related to *T. saginata* is assessed as low, although no precise studies 245 have been undertaken. In line, the FERG report excluded T. saginata from their priority list due to the 246 presumed low burden of disease (FERG, 2015).

247 Infection of cattle with the eggs of T. saginata, resulting from exposure to human feces, results in 248 development of cysticerci, located in the muscle, enabling infection of humans as described above. Natural 249 infections in cattle are normally asymptomatic (Laranjo-González et al., 2016). Like cattle, reindeer and 250 buffalo can also act as an intermediate host. Exposure of cattle to human fecal material is the main risk factor 251 for infection of cattle. Taenia infection cannot be spread from one bovine animal to the next. Age is a risk 252 factor, as it has been documented that animals slaughtered before the age of 2 years has a very low 253 probability of being infected. Moreover, sex is a risk factor, with male cattle having a lower risk than females 254 (Calvo-Artavia et al., 2012). However, sex and age at slaughter are confounded, as male cattle are usually 255 slaughtered before the age of 2 years, while females are kept longer.

The general surveillance for *T. saginata* in the cattle in the EU is described in Table 1, based on a systematic review undertaken by Laranjo-González et al. (2016), the EU legislation (Anon., 2004) and other selected publications.

259 As stated above, the human burden of disease related to T. saginata is assessed as low (FERG, 2015). 260 Moreover, the prevalence of infected cattle found at meat inspection is very low (Laranjo-González et al., 261 2016) and the sensitivity of meat inspection of lightly-infected animals is very low, implying that most 262 infected carcasses are overlooked. Kyvsgaard et al. suggested that the sensitivity for lightly infected animals was around 15%, (Kyvsgaard et al., 1990). The value of the routine inspection has therefore been questioned 263 264 (Calvo-Artavia et al., 2012). Alternative suggestions are risk-based surveillance and/or use of serology 265 (Laranjo-González et al., 2016). A risk-based approach could involve inspection limited to the high-risk sub-266 population consisting of adult cows (Calvo-Artavia et al., 2012). Adult cows were also found as the sub-267 population with the highest prevalence in the United Kingdom (Marshall et al., 2016) and in France (Dupuy 268 et al., 2014). A new risk-based meat inspection system for bovines, making use of age and production system 269 as risk factors, will come into force in December 2019. This will imply that bovines, either raised indoors and 270 slaughtered before the age of 20 months, or slaughtered below 8 months of age will be excepted from 271 incisions into the masseters (Table 2 and Fig. 2) (Anon., 2019).

272 Serological tests for detection of antigens or antibodies again T. saginata are available, and the EU Meat 273 Inspection Regulation 854/2004 allows use of serology as a replacement for meat inspection for T. saginata 274 (Anon., 2004). However, such tests are associated with additional costs. Therefore, before being 275 recommended for routine use, the economic efficiency should be carefully considered. A recent study using 276 a mathematical model estimated a prevalence of 43% of T. saginata (in the form of viable, degenerated or 277 calcified cysticerci) in Belgian cattle (Jansen et al., 2018). Somewhat similar, Eichenberger et al. (2013) 278 estimated the prevalence to be 15.6% in Swiss cattle. This high prevalence warrants further investigations 279 into the ways that Belgian, Swiss and maybe other cattle get exposed: grazing practices, availability of toilets 280 for farm workers and others, and handling of the sewage system. In this way, it may be possible to identify 281 and rectify systematic risky practices in place. This may be more cost-effective than subjecting all Belgian 282 cattle to a serological test for T. saginata. Alternatively, individual farmers may be interested in documenting 283 freedom from infection, using serology at meat inspection on a subset of their animals. Such meat would be

safe to use for ready-to-eat beef products, but a higher price would most likely be required before a larger
 number of farmers would embark on this strategy.

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287 5. Surveillance for Toxoplasma gondii

288 Felids, such as cats, are the definitive hosts of the protozoan parasite Toxoplasma gondii. Infected felids can 289 shed millions of oocysts through their feces for a limited time period. Contamination of the environment with 290 such oocysts takes place through water, soil, feed and food, whereby a wide range of host gets infected. If 291 Toxoplasma infection takes place in a pregnant woman, infection may result in abortion of the unborn child, 292 or in life-long impairment of normal functionality of the child. In adults, infection usually has a mild course 293 with few symptoms, however there are indications that infection with T. gondii might be associated with 294 schizophrenia (Burgdorf et al., 2019). According to the FERG report, Toxoplasma gondii is the third-most 295 important parasite worldwide, associated with 1.7 million DALYs (FERG, 2015). Consumption of meat has 296 been ascribed to a large, but unknown proportion of the human cases observed (Cook et al., 2000; FERG, 297 2015). Freezing and heat treatment render infected meat safe to consume, whereas curing requires that the 298 meat product is subjected to high saline concentrations over a longer time to be effective (Dubey et al., 1997). 299 This implies that there are only few meat products which will contain viable parasites at the time of 300 consumption. Therefore, ready-to-eat products such as mildly cured products may be considered as high-301 risk.

302 *Toxoplasma gondii* cannot easily be detected directly, but serological testing can be used as an indirect 303 measurement. According to a recently published systematic review, the seroprevalence is highest in wild 304 boar followed by sheep, moose, and cattle, and lowest in indoor finishing pigs (Olsen et al., 2019). For pigs, 305 Limon et al. identified three confounded risk factors: 1) small herds, 2) outdoor-rearing and 3) farm cats with 306 access to sow feed and concluded that in the United Kingdom most batches of pigs delivered to slaughter consists of negative animals (Limon et al., 2017). Moreover, sows and boars have a higher probability of being
 infected than finishing pigs (Olsen et al., 2019).

309 The non-negligible importance of T. gondii for human health has been recognized both by WHO (FERG, 2015) 310 and EFSA. The latter identified T. gondii as a relevant hazard in their Opinion on hazards to be covered by 311 meat inspection of pigs (EFSA, 2011b). Still, in the EU and elsewhere, there is currently no official requirement 312 for surveillance for T. gondii in any livestock. Overall speaking, the higher purpose is mitigation, where 313 surveillance and intervention are two elements of mitigation. Surveillance provides the information and 314 intervention the action, but intervention is not always necessary. The current stage of mitigation may be 315 called investigation, and it is about understanding the situation and getting ready for intervention strategies, 316 if needed (Häsler et al., 2011). Depending upon the outcome of this exercise, the risk manager may decide 317 upon moving to implementation of a mitigation phase or accept the situation as it is.

318 In the following, considerations regarding how to set up a future surveillance programme for T. gondii in 319 swine is described, following the key areas defined in SURVTOOLS. The overall objective should be to protect 320 consumers against being exposed to infective meat. This can be done through identification of herds with an 321 unacceptable high prevalence of T. gondii (estimate within-herd prevalence). The kind of surveillance to put 322 in place could be monitoring or surveillance. As age and way of raising are risk factors, there are four potential 323 sub-populations for which a surveillance component could be set up for swine: finishing pigs/sows combined 324 with controlled housing/non-controlled housing. A discussion should be taken to set the threshold between 325 acceptable and unacceptable, while knowing that such a threshold can later be changed. Experience from 326 the Danish Salmonella surveillance programme may come in useful; after some years into the programme, 327 the within-herd seroprevalence of Salmonella was lowered from 70% to 65% for allocating pig herds into the highest risk category, for which there is requirement for risk mitigation, as described by Alban et al. (2012). 328

Actions related to detection of an unacceptable high seroprevalence may involve visit at the farm of origin, including evaluation of current biosecurity practices and correction of potential weak points. Farmers could

be notified and payed less for their pigs or asked to pay for the follow-up visit on the farm. Outdoor raising is known as a risk factor, making it a priority to develop recommendations to ensure safe ways of housing and feeding of outdoor pigs. For herds with an unacceptable high prevalence of *T. gondii*, a recommendation could be to freeze meat intended for production of risky ready-to-eat (RTE) products.

335 Serological testing may constitute a feasible way of detecting herds with a high prevalence. One important 336 question is whether to initiate surveillance in all four potential sub-populations or not, and if so, how. Here, 337 a farm categorization may be used in line with what is seen for *Trichinella*. This could imply that all meat from 338 the sub-population with the highest prevalence may be considered as high-risk requiring freezing if the meat 339 is intended for risky RTE products. Following upon this view, surveillance may target the low-risk sub-340 population such as indoor finishing pigs. One drawback about this approach is that a substantial number of 341 samples would have to be tested before infection can be detected, due to the low prevalence. This issue was 342 raised by EFSA, who recommended to use auditing of biosecurity for controlled housing instead of testing for 343 T. gondii for low-risk farms (EFSA, 2011a). To make a testing programme economically feasible, only few 344 samples may be taken at each delivery. This would imply that longer time might pass, before infection would 345 be detected.

346 Hence, the point of sample collection is the abattoir, and the testing protocol could involve serology (blood) 347 or meat-juice. Although EFSA recommends use of blood (EFSA, 2011a), collection of meat-juice samples is 348 much more convenient. The approach used in the Danish Salmonella surveillance in finishing pigs may be 349 used, implying automatic identification of carcasses to be sampled in the cooling room as described by Alban 350 et al. (2012). The sampling strategy could be risk-based sampling restricted to either high-risk or low-risk, as 351 explained further up. The study design could consist of a two-stage sampling, where farms with no testpositives are placed in the low-intensity part of the programme involving e.g. one sample per delivery, and 352 353 farms that have tested positive are re-tested in relation to the next delivery of pigs with a higher number of 354 samples to estimate the within-herd prevalence.

The choice of cut-off to be used wen judging the individual sample constitutes a challenge for *T. gondii*, as pointed to by Felin et al. (2017). For the low-risk sub-populations such as the indoor finishing pigs, the major part of the apparently seropositive pigs may be false-positives. An example of this could be seen in a study by Kofoed et al. (2017). That challenge could be solved by re-testing more animals from the herd and allowing a certain number of reactors within a given sampling period. The data handling process would be a continuous evaluation of samples to confirm the seroprevalence level of each farm.

So far, only one EU abattoir company has a surveillance programme for *T. gondii* in place, like described above, implying one sample tested per delivery of pigs from low-risk herds, and six samples from herds with a higher risk. Farms are re-tested when positives are found to determine the within-herd prevalence more precisely. A within-herd prevalence below 5% is considered as low-risk, and above 15% as high-risk, and inbetween as moderate risk (Heres et al., 2015).

366 More work is needed before a surveillance programme for *T. gondii* can be recommended widely. Such work 367 would include a burden of disease assessment for *T. gondii* for the country of interest, followed by a source 368 account or an exposure assessment for the most important sources of human exposure. That information 369 could be included in a cost-benefit analysis, addressing different kinds of surveillance systems. In Denmark, 370 a source account has been made for congenital toxoplasmosis, showing a lower annual disease burden than 371 expected. A total of 123 DALYs was found, of which 78 were due to fetal loss and 2 were due to neonatal 372 death, and hence 43 DALYs for the persons who will have to live with congenital toxoplasmosis. This is 373 substantially lower than the burden caused by campylobacteriosis (1,586 DALYs) and salmonellosis (379 374 DALYs) (Nissen et al., 2014). However, this figure does not include the potential burden represented by 375 schizophrenia, where T. gondii infection might be a contributing causal factor for some cases of schizophrenia 376 - as suggested by Burgdorf et al. (2019). In Denmark, the next step involves a source account or an exposure 377 assessment for selected food sources such as pig meat.

379 6. Advantages, requirements and limitation related to risk-based surveillance and control

380 The three examples of surveillance in foodborne parasites presented above show that there are several 381 advantages of using risk-based surveillance systems: targeted efforts resulting in a better cost-effectiveness 382 ratio, if planned well. One example is the Danish *Trichinella* programme in pigs, where only the pigs from 383 non-controlled housing are subjected to individual testing whereas the controlled housing herds are 384 subjected to auditing of biosecurity practices every 3 years (Alban and Petersen, 2016) Hence, risk-based 385 surveillance and control harbors the opportunity to achieve the same surveillance performance at lower cost 386 or to increase performance using the same resources. The approach is based on knowledge of the food 387 system, the epidemiology of the hazard, contextual factors and risk factors, where sampling can be targeted 388 to the population strata with the highest risk.

389 To ensure confidence in risk-based surveillance, documentation of all elements of the risk-based approach is 390 crucial. Here, reporting guidelines may be useful, and example of this can be found in 391 https://github.com/SVA-SE/AHSURED. However, in many cases it can be difficult or even impossible to get 392 enough data to estimate e.g. the size of a risk factor precisely. One example is the area of surveillance for 393 residues of antimicrobial origin in meat, where a risk-based approach is encouraged (Anon., 1996). Detailed 394 studies of the cases seen in Denmark indicate that use of injectable antimicrobials is the primary cause and 395 that a high within-herd prevalence of chronic pleurisy (where treatment is often done using injectable 396 antimicrobials) may be a risk factor or an indicator. However, the number of cases in Denmark is so low that 397 it disables a precise estimate of this risk factor. Here, a comparison with Dutch data helped to estimate the 398 relative risk (Alban et al., 2014; Veldhuis et al., 2018). Still, prudence should be used to avoid over-confidence, 399 and the impact of uncertainty on the risk to be estimated should be studied - e.g. in the form of scenario 400 analysis - to ensure robustness of the system.

401 Livestock farming is not static; and major shifts in production have been observed in Europe in the last 402 decades. This implies fewer and larger farms and a specialization, resulting in a change in the trade flows. For

403 pigs, a specialization into breeding, growing or finishing farms is taking place (Marquer et al., 2014). 404 Moreover, the preferences of the consumers are not stationary. Therefore, changes in risk distribution should 405 be foreseen and incorporated into surveillance e.g. as an early warning system. A solution to this could be to 406 expand surveillance efforts to food systems to characterize and monitor their changes over time and trigger 407 alerts of major changes that may require further investigation and adaptation of surveillance programmes. 408 An example is when livestock is raised in new ways or regions, where there might be an increased exposure 409 to certain hazards, compared to the traditional production. Outdoor-raising of pigs may be an example of 410 this – and the combination with an increase in the preference for pink pork may imply a higher exposure to 411 T. gondii than seen before. Similar considerations should be made regarding climatic changes, which may 412 lead to presence of infections or vectors of infection not previously seen in the area. For both examples, 413 focus should be on the capacity of the livestock system to cope with perturbations.

414 In this paper, risk-based surveillance to ensure safe meat has been the focus. Still "safe meat" may have 415 different meanings to the consumers, and some may be willing to take a risk for the taste, e.g. for tartare 416 (raw beef). This implies that resilience as well as risk and risk evaluations may vary at different levels of the 417 consumer and production cycle. In line, one group of consumers may perceive outdoor raising as associated 418 with high animal welfare as well as a more resilient form of production compared to indoor production. For 419 others, outdoor production may be perceived as a risk for animal welfare because of exposure to harsh 420 climatic conditions and as a risk of introduction of various infections. In response, the authorities in 421 collaboration with the food business operators may need to look more carefully into how we may frame risk, 422 production and consumption in a way where the various aspects can be encompassed in a transdisciplinary 423 process, with many perspectives are considered simultaneously. Knowledge integration and multi-criteria 424 decision-making is crucial here, but slow, complicated, and difficult to obtain.

Risk-based surveillance require that many kinds of information are gathered and carefully evaluated. This implies an opportunity to (re-)assess and evaluate traditional surveillance approaches and identify areas for enhancement, change or innovation. However, it also encompasses a weakness, because such systems may 428 not necessarily be known a priori to the trade partner and the veterinary authorities in the importing country 429 (Stärk et al., 2006). Hence, any risk-based surveillance programme can only realise its full economic efficiency 430 potential, if trade partners and veterinary authorities are informed in detail about the specific approach, 431 which implies that it should be transparent and evidence-based. Here, it should be borne in mind that trust 432 is built up gradually but can be destroyed fast. Furthermore, it may be confusing, if each country defines their 433 own risk-based surveillance for a given hazard, and some level of harmonization would be useful. To obtain 434 this, open access to information about surveillance systems would be helpful for the process of identifying 435 the systems that work best, depending on the settings. In case of sensitive issues, a controlled disclosure 436 could be used.

437 In the EU legislation, an unclear terminology is sometimes used, such as targeted surveillance, and with no 438 distinction between monitoring and surveillance. For example, in the EU Residue Directive 96/23, it says: 439 "The samples must be targeted taking account of the following minimum criteria: sex, age, species, fattening 440 system, all available background information, and all evidence of misuse or abuse of substances of this group" 441 (Anon., 1996). However, for finishing pigs, which are the large numbers, not much help is provided to identify 442 how to go risk-based. Although sows have a documented higher probability of harboring residues than 443 finishing pigs, an extensive surveillance in sows does not help, if the objective is to demonstrate absence in 444 finishing pigs to a trade partner, as explained by Alban et al. (2018).

445 In line with the recommendations by Ruegg et al. (2017), a collaboration between authorities, academia and 446 food business operators should be encouraged. Such a collaboration might make it possible to develop an 447 effective surveillance for a given hazard or indicator, based upon experience, feasibility and economics. 448 Hereby, compliance with the surveillance system may be improved. Moreover, surveillance programmes 449 need to be set up in a way which facilitates control, implying timely actions which can be made in an easy 450 way. Again, a collaboration with the stakeholders may be beneficial, because it will also be in the interest of 451 the stakeholders to ensure fast detection and effective handling of unwanted cases, including trace-back. 452 This is already recognized by many Food Business Operators who have routine data collection and Hazard

453 Analysis of Critical Control points (HACCP) in place for their production. This will minimize the perturbation 454 to the system and, hereby, maintain consumer confidence and access to export markets. Still, in some 455 cultures or countries, there is a lack of confidence in industry data. Given their business nature, the industry 456 may have more interest and resources to set up surveillance in the form of own control than the national 457 authorities. An example of this can be seen in Denmark (Alban et al., 2018) and the Netherlands (Veldhuis et 458 al., 2019), where the own control for residues of antimicrobial origin is involving many times more samples 459 than the official sampling undertaken in line with the EU Residue Directive (Anon., 1996). However, such 460 private surveillance data are only of use to public decision-makers (who have a mandate to promote and 461 protect public health), if the information is shareable and can be trusted.

Development of meat safety assurance systems (MSAS) as suggested by EFSA (2011b) may help to help categorize farms and slaughterhouses according to the risk they represent. This involves setting appropriate targets for the final chilled carcasses. Such MSAS would involve a careful selection of harmonized epidemiological indicators, depending on the purpose and the epidemiological situation in a country. Private standards covering food are increasingly including MSAS, see for example the Global Red Meat Standards (https://grms.org/). For more details about the status and the challenges related to the development of MSAS, please see Buncic et al. (2019).

Regular evaluation of surveillance is recommendable. This will among others ensure that the latest technical achievements are incorporated, the objectives are met, and the cost-effectiveness is maintained. Tools developed for evaluation should preferably be used, e.g. the SURVTOOLS described above. Such tools as meant for inspiration to ensure that all relevant issues are dealt with.

A broader evaluation framework to consider has been developed by the Network for Evaluation of One Health (NEOH). NEOH is intended for the evaluation of any initiative addressing the health of people, animals and the environment. The framework is based upon a system's approach and provides a basis for assessing the integration of knowledge from diverse disciplines, sectors, and stakeholders through a systematic description of the system at stake and standardised sets of indicators. It illustrates how cross-sectoral, participatory and interdisciplinary approaches evoke characteristic One Health operations, i.e., thinking, planning, and working, and require supporting infrastructures to allow learning, sharing, and systemic organisation. It also describes systemic One Health outcomes, which are not necessarily possible to obtain through sectoral approaches alone (e.g. trust, equity, biodiversity etc.), and their alignment with aspects of sustainable development based on society, environment, and economy (Ruegg et al., 2017; <u>http://neoh.onehealthglobal.net/</u>).

Several other tools are currently available for evaluation of surveillance. A comparison of such tools is currently undertaken in an international project called "Convergence in evaluation frameworks for integrated surveillance of AMR: Moving towards a harmonized evaluation approach" (Co-Eval-AMR), where the focus is on characterizing evaluation tools for evaluation of surveillance systems for antimicrobial resistance. The intent is to identify which protocols or tools are good at evaluating what and – if possible – to move towards more harmonized evaluations. The output from this project may provide insights for surveillance in other fields including meat-borne parasites.

491

492 **7.** Conclusion

493 Surveillance and control can be considered a continuous, iteratively adaptive process, which can respond to 494 changing food systems, risk patterns, consumer behaviors and trade dynamics. It is therefore important that 495 the surveillance is set up to produce fit-for-purpose information that allows making decisions for control 496 where needed and react to changing circumstances. Risk-based surveillance systems may imply a higher 497 effect of surveillance at a lower level of costs, through a targeted focus on the hazard that matter the most 498 to a society or an industry. Similar considerations should be made for risk management. For meat-borne 499 parasites, risk-based surveillance is well-established for *Trichinella*, and coming into force in December 2019 500 for T. saginata. For T. gondii, the current official mitigation stage is to evaluate how large the risk is, and

501	whether intervention is needed. There are opportunities to expand similar principles to other hazards as well.
502	Collaboration with the food business operator, consumers, NGOs and other organisations in the food system
503	should be considered by identification of values, common interests, sharing of data and joint action. Finally,
504	the surveillance system should be evaluated in a systematic way on a regular basis to ensure that the
505	resources spent are providing value for money.
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632	Figure captions
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634	Figure 1. Graphical description of the key areas to consider when setting up surveillance programmes.
635	Modified after <u>https://survtools.org/</u>
636	
637	Figure 2. Graphical description of a risk-based approach to meat inspection for tuberculosis and <i>T. saginata</i>
638	cysticercosis in bovines making use of knowledge about the risk factors age, sex and production system.
639	This approach is part of the new EU Meat Inspection Regulation 2019/627 on bovines coming into force in
640	December 2019.

Hazard	Objectives ^a and expected outcome	Sub-populations to consider for surveillance components	Actions related to suspects and positive findings	Preventive actions	Testing protocol	Study design	Sampling strategy	Data handling
Trichinella	Populations not free from infection: to ensure food safety by identifying infected animals and take them out of the supply chain (case finding) Populations free from infection: to document freedom from disease continuously to enable trade and avoid perturbations of export	Two individual risk factors: age and production system 1. Indoor finishers 2. Indoor sows/boars 3. Outdoor finishers 4. Outdoor sows/boars	Condemnation of carcass Trace back to the farm of origin and an investigation of the source of infection	Actions to ensure a high level of biosecurity following the EU requirement for controlled housing as specified in Annex to the EU <i>Trichinella</i> Regulation 1275/2015	At abattoir: artificial digestion of single meat pieces or a pooled sample of meat pieces from different pigs. Confirmation testing for positive samples. Serology may also be used for monitoring purpose <u>On farm</u> : auditing of biosecurity in accordance with EU Trichinella Regulation ^b	One-stage sampling with the individual pig as the target	Census implying that all animals are tested OR Risk-based involving pork for export out of the EU or high- risk sub-populations such as pigs from non-controlled housing If Member State has not yet documented that prevalence is <1 per million, then 10% of pigs from controlled housing should be tested	Continuous evaluation of samples and reporting to the national authorities
Taenia saginata	To ensure food safety by identifying infected animals and take them out of the supply chain (case finding)	Three confounded risk factors: sex, age, and raising 1. Young bovines 2. Adult bovines 1. Females 2. Males 1. Indoor raising 2. Outdoor raising OR Combination of above	Few cysticerci found in carcass: the parts not infected may be declared fit for human consumption after having undergone a cold treatment <u>Many cysticerci</u> found in carcass: condemnation	Application of Good Agricultural Practices regarding application of human sewage on fields and grazing of cattle Ensuring toilets for farm workers and people walking in area with bovines (hikers, scouts, tourists)	At abattoir: meat inspection of individual bovines through examination of the masseter muscles in which incision must be made as well as opening if the heart OR Serology	One-stage sampling with the individual bovine as the target	Currently: all bovines > 6 weeks of age unless holding has been officially certified to be free of cysticercosis ^c <u>EU Commission's new legislation^d:</u> Only testing of All bovines > 20 months AND Bovines >8 months raised outdoors	Findings will be reported from the abattoir to the cattle producer, who will be paid less or nothing fo positive cattle depending on the judgment of the carcasses

Table 1. Overview of selected surveillance design elements for *Trichinella* and *Taenia saginata* in the European Union, 2019

643 a: For both hazards, surveillance is a prerequisite for trade and export. b: EU Regulation 2015/1375 (Anon., 2015). c: although allowed for in the EU

644 Meat Inspection Regulation 854/2004, such systems are not in place in the EU according to the knowledge of the authors. d: New EU Regulation

645 2019/627 on meat inspection of bovines coming into force in December 2019 (Anon., 2019).