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Risk-based surveillance in the pork chain – requirements and challenges

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In the pork chain, there is a plethora of food-borne hazards for which there is a need of monitoring or surveillance: bacteria, parasites, viruses, toxic and pharmacological residues and drug-resistant microbes. In the European Union (EU) , *Salmonella* is currently number two, when it comes to the number of human cases, causing 91,662 human cases, and number one when focus in on cases ascribed to pig meat (EFSA/ECDC, 2018). Parasites – and in particular *Taenia solium* - play a large a devastating role on the African continent (FERG, 2015). Moreover, there is an increasing attention on antimicrobial resistant bacteria on pig meat without much knowledge about the full implications of human exposure– see e.g the annual reports from the Danish DANMAP surveillance on https://www.danmap.org/.

However, resources are scarce among veterinary services. Likewise, the food business operator – irrespective of whether this is the farmer or the abattoir–is preoccupied about maintaining a profit to be able to remain in business, also in the future. Still, customers and trade partners expect that meat products placed on the market are safe to consume and do not bear any risks of causing disease outbreaks. In this situation, risk-based surveillance systems may offer a solution by applying risk analysis principles to set priorities and allocate resources effectively and efficiently through a focus on a high cost-effectiveness ratio in sampling.

Risk-based surveillance and control was originally introduced into veterinary public health by Stärk et al. (2006). Since then, experience has been gathered, and the methodology has been further developed. In the following paragraphs, relevant steps to move towards a risk-based surveillance system are described and discussed.

First, it should be assessed where there is a need for surveillance, why, and which kind of knowledge is expected to be provided by the surveillance. Often, it starts with a risk that needs to be dealt with. In the present context, risk is seen as the product of probability and consequences. if a high capacity to cope with perturbations is judged as vital, indicators of consequences might be required as part of the surveillance. All this constitutes the strategic part of the analysis.

A government in collaboration with a livestock sector may have ambitions for improving animal and human health and/or expand the access of e.g. pork to the export market. If improvement of the national 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 human 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 of each kind of food consumed is assessed. For example, if the highest burden of foodborne disease is ascribed to poultry meat, then the value of surveillance in pig meat would be limited. That would be the case for *Campylobacter*. For animal health, disease may also be considered a good indicator or productivity, in particular in low-income countries where a sophisticated registration of production data is not feasible.

Requirements for trade resilience is also a part of this step. Hence, even though the outcome of a burden of disease assessment and a source account may show that the need for a given surveillance is negligible in a given population, it may still be needed to access or stay on a certain market. *Trichinella* in pig meat is an example of the latter (Alban & Petersen, 2016). Moreover, a country may decide to implement certain food safety standards for a part of its production – e.g. farms delivering to selected, large abattoirs – to be able to export to the EU, USA or similar countries with a high level of food safety.

Once the relevant indicators 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.

Surveillance involves that some pre-planned action is taken, when positive samples are found or when the prevalence gets above a certain threshold. In theory, monitoring differs from surveillance in the sense that no actions are necessarily taken immediately after results are made available (Hoinville et al., 2013). Antimicrobial resistance programmes might in some cases be considered as operating as monitoring programmes: Every year, the Danish DANMAP program publishes a report showing what has been found. For most findings, there is no immediate associated action, but if an unexpected finding is made, which is also considered as worrying, actions will be taken. The microbiological criterion for *Salmonella* in minced meat intended to be consumed raw is an example of a surveillance, where immediate action is taken, if *Salmonella* is found in just one out of five 25 g samples from a batch–as required by the EU legislation (Anon., 2005). Likewise, if *Salmonella* is found on the carcasses above the defined threshold of 3 out of 50 carcasses, actions must be taken immediately related to improvements of the slaughter hygiene and the process controls. This may also imply the biosecurity measures applied on the farms of origin of the delivered animals (Anon., 2014).

During the design of surveillance, design tools may be used. One example is the RISKSUR surveillance design tool, which guides the user through key elements such as 1) objectives and expected outcome, 2) surveillance components, 3) actions related to suspects and positive findings, 4) preventive actions, 5) testing protocol, 6) study design, 7) sampling strategy, 8) data sampling process (https://www.fp7-risksur.eu/). Such a standardized approach ensures that all elements are carefully considered before being decided.

Information about the biology of the hazard may come in useful in the process of designing surveillance or monitoring. This includes the prevalence of infection in different animal species, knowledge about risk factors, and ways of spreading. All this information may be used to identify where the risk is, implying that sampling is intensified in subpopulations that harbour the highest risk (Stärk et al., 2006). As described above, in the context of risk-based surveillance, risk is seen as the product of probability and consequences. Therefore, the highest risk is either found in the population strata with the highest expected prevalence of the hazard – or the strata, where the implications of having the hazard may be highest. For *Trichinella*, this means that sampling of outdoor-raised pigs is preferred to wildlife sampling, although wildlife may have a higher prevalence of *Trichinella* than outdoor-raised pigs.

Likewise, for meat, surveillance may be focusing on meat originating from animals raised outdoors and not indoors – if outdoor-raising is perceived as a risk factor for the hazard of concern. Moreover, one should have a view on the intended use of the meat. If the hazard is eliminated during ordinary processing, then there will be no need for surveillance in that part of the production, but there may be a need in another part of production. This implies that a pork value chain perspective is useful as it would offer novel opportunities for risk-based sampling.

A value chain perspective should also be used for *Toxoplasma gondii*, where data show that the prevalence is low in indoor raised finishing pigs, medium in outdoor raised finisher pigs, and high in sows (Kofoed et al., 2017; Olsen et al. 2019). Freezing and heat treatment eliminates the parasite, whereas curing requires that the meat product is subjected to high saline concentrations over a longer time to be effective (Dubey et al., 1997). This implies that there are only few pig meat products which will contain viable parasites at the time of consumption. All such information may be used when designing surveillance and mitigation measures to decrease the exposure of humans to *T. gondii* due to consumption of pig meat.

Feasibility of sampling and the related economics are also important to consider. In general, sampling at the abattoir is easier and cheaper than sampling on the farm. Choice of laboratory methods requires considerations regarding whether a high sensitivity or a high specificity is needed – and whether more methods should be used and interpreted, in parallel or in series. Regarding choice of sampling material (matrix) to use in the laboratory, meat may be easier to collect than blood. However, care should be taken before deciding, because the laboratory method may have been validated for one matrix and not for another.

In 2014, the EU legislation adopted a risk-based approach for *Trichinella spp.* in pigs (Anon., 2015). This implies that the official requirement for testing is applied only to pigs raised in the low-biosecurity compartment, which is called non-controlled in the EU and mainly implying outdoors or backyard production. This is due to data showing that *Trichinella spp.* is absent in the controlled housing compartment. This has moved focus from testing of each pig to auditing of biosecurity on-farm. Such indirect measurements are much cheaper than testing all pigs for the presence of the parasite. The compliance with the requirements for controlled housing should be checked at regular intervals. These requirements are described in detail in Annex IV to the EU *Trichinella* Regulation (Anon., 2015). Either the veterinary authorities or a third-party independent auditor may do the auditing. The latter is undertaken as part of a private standard, building on top of national and international legislation. Such private standards are common in many parts of the world and it may be expected that they will increase further in importance. Despite the EU legislation on *Trichinella* allowing no testing of pigs raised indoors, 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 on the 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.

There are several advantages of using risk-based surveillance systems: targeted efforts resulting in a low cost-effectiveness ratio, if planned well. Such systems require that there is knowledge about risk factors. However, in many cases it can be difficult or even impossible to get sufficient data regarding the exact size of a risk factor. One example may be presence of residues of antimicrobial origin in pig meat. Detailed studies of the cases seen in Denmark indicate that primarily injectables are the cause and that a high within-herd prevalence of chronic pleurisy may be a risk factor. However, the number of cases in Denmark is so low that it disables a precise estimate of this risk factor. Here, a comparison with Dutch data helped to estimate the relative risk (Alban et al., 2016). Still, prudence should be used to avoid over-confidence, and assessments of the impact of uncertainty on the risk to be estimated should be made to ensure resilience of the system. Currently, the EU Residue Directive 96/23 is being discussed – the next version of the Directive will consider risk-based principles for surveillance and control. The challenge is that the perception of the importance of minimizing presence of residues in meat varies between the European countries. In Switzerland, which has no export of pig meat, the main objective is to show compliance with EU legislation. In contrast, Denmark and the Netherlands have a large export to protect and therefore perceive surveillance for residues as more important. In this case, a balance between flexibility and harmonization should be sought, e.g. regarding the minimum number of samples to take and analyse as well as handling of suspects (Alban et al., 2018).

Livestock farming is not static; and major shifts in pig production has been observed in Europe in the last decades. This implies fewer and larger farms and a specialization into breeding, growing or finishing farms, resulting in a change in the trade flows (Marquer et al., 2014). Moreover, the preferences of the consumers are not stationary. Therefore, changes in risk distribution should be foreseen and incorporated into surveillance e.g. as an early warning system. An example is when livestock is raised in new ways or areas, where there might be an increased exposure to certain hazards, compared to the traditional production. Outdoor-raising of pigs may be an example of this – and here, an increase in the preference for pink pork may imply a higher exposure to *T. gondii* than seen before. Similar considerations should be made regarding climatic changes, which may lead to presence of infections or vectors of infection not previously seen in the area. For both examples, focus should be on the capacity of the livestock system to cope with perturbations.

In this paper, risk-based surveillance to ensure safe meat has been the focus. Still "safe meat" may have different meanings to the consumers, and some may be willing to take a risk for the taste, e.g. for tartare (raw beef). This implies that resilience as well as risk and risk evaluations may vary at different levels of the consumer and production cycle. In line, one group of consumers may perceive pigs raised outdoors as associated with high animal welfare as well as a more resilient form of production compared to indoor pig production. For others, outdoor pig production may be perceived as a risk for animal welfare because of the climate and as a risk of introduction of African swine fever. In response, the authorities in collaboration with the food business operators may need to look more carefully into how we may frame risk, production and consumption in a way where we can satisfice the various aspects rather than optimize one or two these matters (e.g. risk and price).

Risk-based surveillance systems require that many kinds of information are gathered and carefully evaluated. This implies an opportunity to undertake a better surveillance compared to using a random approach. However, it also encompasses a weakness, because such systems are not well-known to the trade partners and the veterinary authorities in the importing country (Stärk et al., 2006). To ensure confidence in risk-based systems it is important that the design of the surveillance is transparent and evidence-based, and to have in mind that trust is built up gradually but can be destroyed fast. It may be confusing, if each country defines their own risk-based surveillance for a given hazard, and some level of harmonization would be useful. To obtain this, open access to information about surveillance systems would be helpful for the process of identifying the systems that work best, depending on the settings. In case of sensitive issues, a controlled disclosure could be used.

Moreover, a collaboration between authorities, academia and food business operators should be encouraged. In many cases, HACCP is in place for a given production and data are collected routinely. Also, livestock producers or the abattoirs have risk-mitigating actions in place, carefully selected based upon experience, feasibility and economics. Such a collaboration might make it possible to develop an effective surveillance for a given hazard or indicator.

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 RISKSUR surveillance tool described above. A broader evaluation framework to consider has been developed by the Network for Evaluation of One Health (NEOH). It is intended for the evaluation of any initiative addressing the health of people, animals and the environment. The framework 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 (http://neoh.onehealthglobal.net/).
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 focus is on surveillance systems for antimicrobial resistance. The intent is to identify which systems are good at evaluating what and – if possible – to move towards a harmonized evaluation approach. In conclusion, risk-based surveillance systems offer a way to address situations, where there is a need for surveillance, but few resources are available. Risk-based surveillance-and-control is based on risk analysis framework and it helps to identify needs, set priorities, and allocate resources. First, a strategic decision should be made regarding what to prioritize. Next, operational decisions should be made regarding how to set up surveillance, and here feasibility and costs of sampling are evaluated together with a view on the entire supply chain. Similar considerations should be made for risk management. Focus should be on high cost-effectiveness ratio in surveillance/control, and here, it is advantageous to think about biology and look at the entire supply chain, while using direct or indirect measurements. Then, collaboration with the food business operator should be considered by identification of common interests, sharing of data and joint action. Finally, the surveillance system should be evaluated in a systematic way on a regular basis to ensure that the resources spent are providing value for money. Surveillance and control can be considered a continuous, iteratively adaptive process, which can respond to changing risk patterns, consumer behaviours and trade conditions. It is therefore important that the surveillance is set up to make control timely and easy.

References

Alban, L., Petersen, J.V., 2016. Ensuring a negligible risk of *Trichinella* in pig farming from a control perspective. Vet. Parasitol. 231, 137-144. http://dx.doi.org/10.1016/j.vetpar.2016.07.014

Alban, L., Rugbjerg, H., Petersen, J.V., Nielsen, L.R., 2016. Stochastic scenario tree modelling of costeffectiveness of risk-based antimicrobial residue monitoring in Danish pork. Prev. Vet. Med. 128, 87-94

Alban, L., Léger, A., Veldhuis, A., Schaik, G.V., 2018. Modernizing the antimicrobial residue monitoring programs for pig meat in Europe—the balance between flexibility and harmonization. Food Control, 86, 403-414 https://doi.org/10.1016/j.foodcont.2017.11.040

Anonymous, 2005. Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:338:0001:0026:EN:PDF

Anonymous, 2014. Regulation (EC) No 217/2014 amending Regulation (EC) No 2073/2005 as regards *Salmonella* on pig carcases. http://eurlex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:32014R0217&rid=1

Anonymous, 2015. Commission Implementing Regulation (EU) 2015/1375 laying down specific rules on official control for *Trichinella* in meat. http://eur-lex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:32015R1375&rid=1

Dubey, J.P., 1997. Survival of *Toxoplasma gondii* Tissue Cysts in 0.85-6% NaCl solutions at 4-20ºC. *Journal of Parasitology*. 83, 946-949.

EFSA/ECDC, 2018. The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2017. EFSA Journal 16, 12, 5500. FERG, 2015. WHO estimates of the global burden of foodborne diseases. https://www.who.int/foodsafety/areas_work/foodborne-diseases/ferg/en/ WHO, Geneva, Switzerland.

Hoinville, L.J., Alban, L., Drewe, J.A., Gibbens, J.C., Gustafsson, L., Häsler, B., Saegerman, C., Salman, M., Stärk, K.D.C., 2013. Proposed terms and concepts for describing and evaluating animal health surveillance terms. Prev. Vet. Med. 112, 1-2, 12 pp. http://dx.doi.org/10.1016/j.prevetmed.2013.06.006

Kofoed, K.G., Vorslund-Kiær, M., Nielsen, H.V., Alban, L., Johansen, M.V.A., 2017. Sero-prevalence of *Toxoplasma gondii* in Danish pigs. Veterinary Parasitology: Regional Studies and Reports. 10, 136-138.

Marques, P., Rabade, T., Forti, R., 2014. Pig farming in the European Union: considerable variations from one Member State to another. Statistics in focus 15. Eurostats.
https://ec.europa.eu/eurostat/statistics-explained/pdfscache/3688.pdf

Olsen, A., Berg, R., Tagel, M., Must, K., Deksne, G., Enemark, H., Alban, L., Johansen, M.V., Nielsen, H.V., Sandberg, M., Lundén, A., Stensvold, R., Pires, S.M., Jokelainen, P., 2019. Seroprevalence of Toxoplasma gondii in domestic pigs, sheep, cattle, wild boars, and moose in the Nordic-Baltic region: a systematic review and meta-analysis. Parasite Epidemiology and Control, 3, e00100
https://doi.org/10.1016/j.parepi.2019.e00100

Stärk, K.D.C., Regula, G., Hernandez, J., Knopf, L., Fuchs, K., Morris, R., Davies, P., 2006. Concepts or risk-based surveillance in the field of veterinary medicine and veterinary public health: Review of current approaches. BMC Health Services Research. 6, 20.