Working Group 1 - Scope and targets of meat safety assurance

DELIVERABLE

REPORT ON SCOPE OF MEAT SAFETY ASSURANCE SYSTEM AND COMPETENCIES AND ROLES OF RISK MANAGER

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Summary

Food safety requires a farm-to-fork approach to be efficient. Among food products, meat represents a complex issue since to reach the market; it requires several processing stages and involves live animals. Within the meat chain, animal health and animal welfare need to be considered with specific competencies. Another complexity is the risks for human health, arising mainly from farms that need to be mitigated along the meat chain. The EU-level risk based meat safety assurance system (RB-MSAS) needs to consider all these characteristics, framing them with appropriate legislation and allowing different food chain contributors to act specifically, according to their roles, with the common aim of delivering safe food to consumers. Starting from current tools, and considering the medium to long term, private RB-MSAS schemes and food chain information are promising tools.

Third party assurance schemes can partially offset the need for legal requirements and inspections; uptake of these schemes is higher where they are used to demonstrate compliance with regulation or inspection activities. An assurance scheme that simply mimics the law is unlikely to be able to frame itself as providing additional value to members. Similarly, if all RB-MSASs were equal, they could not frame themselves as better than the competition. Therefore, there is a need to identify the aspects in which different private RB-MSASs are equivalent to public RB-MSASs. It would be also helpful to learn if the equivalence is due to having equal requirements to official controls (process-based) or to enabling equivalent results (outcome-based).

FCI is a good starting point, but has space for improvement in terms of quality, quantity, effectiveness and ability to reach different actors across the production chain. FCI should exploit the potential of innovative information technologies to pair traceability and safety data, making them available to different private and public actors along the chain. Key components will be the two-way exchange of information between the primary producer and FBO as well as the availability of the FCI outside of the abattoirs.

Keywords: meat inspection, risk based meat safety assurance system (RB-MSAS), vertical integration, food chain information (FCI), third party audits

INTRODUCTION AND CONTEXT OF THE REPORT

This report was developed in the frame of the RIBMINS (Risk-based meat inspection and integrated meat safety assurance) COST project and will address current risk-based meat safety assurance systems (RB-MSASs), discussing strength, limitations and future perspectives. In particular, the report focuses on the scope and targets of RB-MSASs. The report deals with RB-MSASs from farm to cooled carcass at the abattoir with particular reference to meat inspection.
There is global interest in the topic of development of risk-based meat inspection and RB-MSAS. The Food and Agriculture Organization (FAO) has issued technical guidance principles for risk-based meat inspection and their application (2019) and a guide for ranking food safety risks at national level (2020). The novel legislation in the EU opens up more possibilities for sharing information and competitive evolution of RB-MSAS. For example, the European Commission DG SANTE (2017) has published a report on shared practices in slaughter hygiene.

The Terms of reference (TORs) were to:
A. Provide a systematic and detailed description of RB-MSASs currently in place, wholly or in part, with working examples illustrating functions and outputs.
B. Provide guidance on the transition from current RB-MSASs to the fit-for-purpose RB-MSAS of the future, while also considering the integration between private and public RB-MSASs.
C. Suggest outlines for risk ranking that could aid when designing or adjusting RB-MSAS.
D. Define the competency profiles for the risk managers.

It should be noted that maximising cost-effectiveness and cost-efficiency and facilitating technological innovation are inherent goals of the future RB-MSAS. Particular attention will be given also to the need for RB-MSAS actors to take into account aspects such as animal welfare, meat quality, ethics and sustainability.

METHODOLOGY

The working group comprised a group of experts with professional knowledge and experience in relevant areas, who analysed key elements of RB-MSASs in place. National and international literature (both peer reviewed and non-peer reviewed) and the European Food Safety Authority (EFSA) publications were consulted and complemented with the experts' scientific knowledge. This study analysed RB-MSASs (both poultry and red meat) from eight countries with regard to their focuses and impacts along the production chains. The analysis aimed to gather information on the purpose/scope, methodology, risk-based decision-making, and performance outcomes of the studied RB-MSASs.

We first reflected on the boundaries, aims and context of each RB-MSAS. This included an analysis of the current legal framework for trying alternative approaches. We also assessed EFSA's reports on meat safety. Assessing strengths, weaknesses, opportunities and threats

(SWOT) of different RB-MSASs was the chosen approach to illustrate risks, costs and benefits in the broadest sense.

We present in this report a number of case studies from the RIBMINS member states that highlight the multitude of different approaches possible for RB-MSASs. The examples cover, for example, GHP-based, hazard-based and risk-based provisions and performance outcomes. Another consideration was the use of Third party standards enforcement for complementing and informing official controls intended as control activities carried out by Competent Authorities (CAs).

Within RIBMINS, WG1 focuses on the initial stages of production/processing, up to and including the chilling of carcasses. From farm to chilled carcasses, we found there were more detailed and prescriptive EU regulations for official controls and FBOs, while at later stages the regulations were more outcome-oriented and less prescriptive. It should be borne in mind that the meat food chains we studied were usually integrated to some extent. The work was carried out with both remote and in-person meetings. WG1 had physical meetings in Sofia, Copenhagen and Uppsala.

RB-MSAS, ANALYSIS OF CONTEXT

Definitions

There is confusion in terminology and the misuse of the terms food safety, hygiene, defence, quality and fraud. This confusion is another barrier for understanding, accepting and adapting RB-MSASs.

Food hygiene is an old term that includes to some extent elements of the terms food safety, food fraud, and food defence and food quality. However, these four latter terms are overlapping and sometimes used synonymously, thereby creating confusion. Figure 1 outlines the relationship of the four latter food terms with regard to intention and whether the adulteration or contamination cause harm or economic gain. RB-MSAS can be described as all of those components of food control that collectively assure the safety of meat. It follows that RB-MSASs can be described as the systems for the handling, preparation and storage of meat to prevent and/or minimise the disease burden caused by meat consumption. This could be seen as CA's perspective. The FBO's quality assurance scheme, though, would most likely include additional aspects (such as suitability and wholesomeness of the meat), and so the RB-MSAS would probably be embedded in the FBO's quality assurance system that would have a broader scope, including meat quality and meat hygiene, meat acceptability, meat authenticity, animal and food traceability, consumer requirements.

		Intention?	
		Unintentional	*Intentional*
Consequence of hazard or action	*Gain*: economic	Food quality	Food fraud
	Harm: public health, economic, welfare or terror	Food safety	Food defense

Table 1: Matrix of different types of risks to food security. In this matrix, the risks are categorized into gain vs harm, and whether the hazard or action is intentional or not (Manning and Soon, 2016)

Food hygiene is defined in different ways. For example, Codex Alimentarius defines food hygiene as *the conditions and measures necessary for the production, processing, storage and distribution of food designed to ensure a safe, sound, and wholesome product, fit for human consumption*. Similarly, the EU legislation, from Reg. (EC) No 852/2004 onwards, defines food hygiene as *the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a food taking into account its intended use*.

Food fraud is intentional adulteration or contamination of foodstuffs (Manning and Soon, 2016). Food fraud is the economically motivated intentional adulteration or mislabelling that may or may not make the food injurious to public health.

Food defence relates to activities aimed at preventing ideologically motivated intentional adulteration or contamination that makes the food injurious to health.

Food quality has an objective dimension, which is the measurable physical-chemical characteristic inherent to a food product, and a subjective dimension framed by consumer expectations, perceptions and acceptance[1]. This includes external factors such as appearance (e.g., size, shape, colour, gloss and consistency), texture and flavour; factors such as national grade standards (e.g., for eggs) and intrinsic to the food (i.e., chemical, physical and microbial). It follows that for the FBO risk manager, the food safety responsibility is not the same as food quality responsibility.

Food safety is considered by Codex Alimentarius to be assured when the following criteria are met:

1. it has been produced by applying all food safety requirements appropriate to its intended end-use;
2. it meets risk-based performance and process criteria for specified hazards and;
3. it does not contain hazards at levels that are harmful to human health (Codex 2005).

The definition of 'safety' within RIBMINS will follow this guidance and will focus on assuring an acceptable public health impact on meat consumption.
The terminology used is truly important to avoid confusion and spurious disagreements. When developing a novel RB-MSAS, the joint terminology will be one of the critical stumbling blocks for successful completion of tasks. We decided, therefore, to define in this report all terms that

[1] EU, Knowledge for policy https://knowledge4policy.ec.europa.eu/food-fraud-quality/topic/food-quality_en

caused WG1 confusion or are likely to cause confusion amongst readers:

RB-MSAS (risk based meat safety assurance system): the whole system of measures in place along the meat chain (from farm to fork) aiming to guarantee consumer health.

Public RB-MSAS: RB-MSAS in place at EU or national level.

Private RB-MSAS: RB-MSAS in place at a private entity (usually a business in the meat chain).

FBO-RB-MSAS: RB-MSAS in place at a specific food business.

Second-party RB-MSAS: RB-MSAS defined and owned by the buyer and used to select suppliers.

Third-party RB-MSAS: RB-MSAS defined and owned by a third party and enforced by a certification body.

Assessment: a process of determining the presence or absence of a specific condition or component, or the degree to which a condition is fulfilled (*Source: CAC/GL 91-2017*).

Accreditation: third party attestation from a conformity assessment body, and which conveys a formal declaration of the first party's competence to carry out specific tasks (*Source: ISO/IEC 17000:2004*).

Accreditation body: authoritative body that performs accreditation (*Source: ISO/IEC 17000:2004*).

Assurance: positive declaration intended to give confidence (*Source: Oxford English Dictionary*).

Attestation: a statement, based on a decision following review, that specified requirements have been fulfilled (*Source: ISO/IEC 17000:2004*).

Audit: a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives (*Source: CAC/GL 20-1995*). A systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives (*Source: EU Reg. 2017/625*).

Certification body: a provider of certification services, accredited by a nationally recognised accreditation body (*Source: ISO/IEC 17000:2004*).

Conformity assessment: demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (*Source: ISO/IEC 17000:2004*).

Governance: the act or process of governing or overseeing the control and direction of something (such as a country, market or an organization**) (***Source: Webster dictionary***)**

Inspection: examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform to requirements (*Source: CAC/GL 20-1995*). Inspection is the examination of establishments, of animals and food, and the processing thereof, of food businesses, and their management and production systems, including documents, finished product testing and feeding practices, and of the origin and destination of production inputs and outputs, in order to verify compliance with the legal requirements in all cases (*Source: CE Reg. 854/2004*).

Procedure: specified way to carry out an activity or a process (*Source: ISO/IEC 17000:2004*).

Review: verification of the suitability, adequacy and effectiveness of activities, and the results of activities in place, with regard to fulfillment of specified requirements (*Source: ISO/IEC 17000:2004*).

Specified requirement: need or expectation that is stated (*Source: ISO/IEC 17000:2004*).

Background and scope

Each RB-MSAS is specific to a particular meat supply chain, but must be coherent with the overarching general food law in the jurisdictional area (region, state, federation etc.). The primary scope of a RB-MSAS is to deliver a high level of protection of human life and human health. A RB-MSAS does this by providing the means for the meat produced under its protection to be of an acceptable risk level in terms of causing human disease. However, when evaluating the benefits, risks and costs of a RB-MSAS, the system's impacts on aspects other than food safety also need to be considered. A measure that improves food safety at the expense of animal welfare, for instance, may not be acceptable. Hence, while the primary scope of a RB-MSAS is on food safety, when it is appropriate, the system must also consider effects in other areas, such as animal health, animal welfare, food fraud, food defence, food quality, plant health, the environment and sustainability. However, the consideration of aspects other than food safety indicates that applying a zero tolerance approach for human health protection might not always be possible, as this could cause the RB-MSAS to enter into conflict with other aspects (animal welfare etc.). Hence, the focus of a RB-MSAS is to protect human life and human health, but the scope of a RB-MSAS can include other aspects as appropriate.

A food policy in place guarantees food safety through a hybrid approach based on prescriptions, outcomes and process indications. In the EU, the General Food Law (Reg. (EC) No 178/2002) and hygiene package regulations (Reg. (EC) No 852/2004, Reg. (EC) No 853/2004, and Reg. (EU) No 2017/625) define public RB-MSASs as also being the framework for private RB-MSASs owned by FBOs or third parties.
Three types of RB-MSAS (as defined above) are recognised:

1. Public RB-MSAS (policy based) with different levels (international, EU, national, third countries)
2. FBO-RB-MSAS (owned by a FBO)
3. Third party RB-MSAS (owned by a third party); adoption is voluntary.

The FBO-RB-MSASs are privately owned, apply directly to the supply chain under consideration and take into account prescriptions, outcome or processes (Table 2).
The broad scope of modern quality assurance systems means that we are in the realm of multifactor regulatory decision-making, often having to consider non-food safety (and even non-regulatory) factors when weighting inputs and arriving at decisions. While food safety is the primary focus of a RB-MSAS, additional aspects could be embedded in the FBO's quality assurance system and RB-MSAS.

Guidance here is important, especially given World Trade Organization Sanitary and Phyto-Sanitary Measures (WTO-SPS) trade considerations of equal protection, evidence-based and proportionate measures. A RB-MSAS requires risk assessments to be updated frequently. This allows the risk manager to choose the most appropriate mitigation strategies based on information such as food chain information (FCI) for incoming animals and abattoir operations. Control

measures should be flexibly implemented, evidence-based and adapted to the health status of the incoming animals intended for slaughter.

Strengths:	***Weaknesses:***
Large FBOs often have in-house quality assurance programs in which a RB-MSAS can be implemented quickly.	Plant-specific RB-MSASs require large in-house resources both to be implemented and to operate. These costs could overwhelm small- and medium-sized meat businesses.
RB-MSASs are more fit-for-purpose, flexible and adaptive to changing risks, and are cost-efficient when compared to a static regulatory approach.	The novel roles and skill requirements for the risk managers could require expensive training and novel skills.
Together with food safety, other aspects can be delivered, e.g., meat quality, knowledge of origin and provenance, protection against fraud and intentional threats.	Food businesses are often small- or medium-sized low margin operations with limited resources for research, innovation and development.
Better transparency of the meat food chain e.g., for animal welfare, is possible.	
Opportunities:	***Threats:***
A RB-MSAS could open up opportunities for more exports if the RB-MSAS is recognised as affording equivalent or better food safety than the current system.	Costs are seen as prohibitive for food businesses.
Collaborative or cooperative RB-MSAS solutions could be developed for small- and medium-sized meat businesses.	Guidelines or industry standards may end up with box-ticking or compliance with documentation only.
A RB-MSAS could follow industry guidelines that are fit-for-purpose and adaptive.	Failure to develop a food safety culture.
Evolution of RB-MSAS by learning from best practices and results.	Failure to gain acceptance from the CA and official veterinarians.
Competitive advantage to those meat businesses that adopt a RB-MSAS.	
Easy to integrate food safety with other concerns such as animal welfare and feed safety.	

Table 2 SWOT analysis of FBO-RB-MSAS

A RB-MSAS has numerous elements that are applied at relevant steps in the farm-to-fork food control continuum, with the FBO and the CA having both separate and overlapping roles. FBOs have the primary responsibility for ensuring food safety and food suitability throughout the food chain, while the CA has the primary responsibility for auditing compliance with regulatory requirements.
The CA has additional important roles in developing the implementation of food safety legislation at international, national or regional levels, and in providing inputs for the development and evolution of appropriate legislation. Hence, good partnerships between the CA and FBOs, which share their input and experiences, are needed to build a strong culture for a successful RB-MSAS.

Roles of risk analysis and risk ranking

For many years, RB-MSASs have been moving towards risk-based management options. The core rationale of risk-based activities is that high-risk issues need higher priority than low-risk issues. In food safety, a risk-based system is "a system that demonstrates to consumers and other stakeholders that foods are being produced under conditions which minimise adverse health effects. This is achieved by using information on the nature of human health hazards associated with particular food products, the likelihood of consumers being exposed to these hazards, the consequences of exposure and the capacity of the production and processing system to mitigate risks arising from hazards which are above a threshold of concern" (Stärk et al. 2006).

Risk assessments must be updated on a regular basis and be informed by a hierarchy of sources – EU, national or regional. We propose, therefore, a tiered process whereby the types of risk assessment are classified as:

1. Tier 1 – these EU and national risk assessments are conducted and updated annually and whenever new epidemiological information is available. Tier 1 (EU and national risk assessment) informs the lower tiers.
2. Tier 2 – these regional and local risk assessments are updated whenever necessary to comply with the tier 1 risk assessments.
3. Tier 3 – these risk assessments are conducted for the herds of origin, the incoming animals and the abattoir operations. Tier 3 risk assessments are specific for each FBO and will need frequent updating.

The first step in a risk-based approach to meat hygiene is hazard identification. Microbial hazards that occur in the animal or meat type (beef, lamb, pork or poultry) and that are transmissible to humans should be identified. This is often achieved using peer-reviewed scientific literature, textbooks, official data, EFSA opinions or other appropriate sources. Where necessary, expert knowledge is elicited.
Once the hazards have been identified, they are ranked in terms of the risk they present and whether they can be controlled by meat hygiene measures or inspection practices (EFSA, 2018). In other words, the question is asked: can the public health risk associated with this specific hazard be controlled by effective meat hygiene measures or inspection procedures?
Risk ranking is a helpful tool for prioritising the risks in the food chain. Risk ranking is updated regularly and can be done at different levels (EU, national, regional, and FBO or business

levels). The EU and national risk ranking is updated at regular intervals, and whenever the epidemiological situation changes. The FBO's own risk ranking should be updated more frequently, specifically following changes after own-check analyses produce results that indicate the potential emergence of new risks. The risk ranking should be informed by the FCI for each batch of animals. The updates could derive from new knowledge about the farms supplying the abattoirs or from data about the abattoir itself, i.e., the results from microbiological testing for food process hygiene criteria or the withdrawal of meat from the food chain. Another piece of information relevant for risk ranking is the data from the official controls and the CA's audits of the RB-MSAS and other control systems put in place by the FBO. The risk rankings done at the FBO level are informed by the risk rankings done regionally, nationally and at EU levels.

We believe that the risk assessment technique used in EFSA's opinions on the modernisation of meat inspection offers one template for other, future risk assessments. This is a simple risk ranking procedure based on the frequency and severity of the hazards in question at the level of chilled carcasses.

A procedure for risk ranking presented by a meat-borne hazard can be described as addressing three questions systematically to rank the risk as high or low. For example, the following questions could be asked:

1) Is the hazard meat-borne? If yes, the hazard is included; if no, it is excluded.
2) Are at least two of the following criteria fulfilled:

- Carcass prevalence of hazard is above 0.1% according to findings in literature or EFSA reports,
- Scientific literature (case-control, cohort or outbreak investigations) indicates a high relative risk, odds ratio > 3, that disease will occur after the meat in question is consumed.
- Scientific literature indicates a strong association (genetic fingerprinting, case studies, ecological studies) or justifies a strong suspicion that the meat in question is a risk factor for the human disease,
- Comparative considerations raise concerns. For example, if *Trichinella* is classified as a high risk in domestic pigs, *Trichinella* could also be believed to be a high risk in wild boars,
- Expert opinion – is there evidence justified on a case-by-case basis that consumption of the meat in question is a risk factor for human disease from a hazard,
- Successful control efforts are not achieved through meat hygiene measures or inspection procedures.

3) Does the hazard cause severe or frequent human disease?
    - Is the hospitalisation rate > 100 per million, case fatality rate > 0.1% or does the scientific literature evidence serious clinical disease for infected persons?
    - Is the human incidence above 1 per 10000 persons (100 per million)?

In the procedure, the hazards introduced during the processing stages are excluded (cross contamination, in-house microbiota, e.g., *Listeria*).

EFSA provided a decision tree to facilitate this process in their various publications on meat inspection (EFSA, 2011, 2012, 2013). We believe this decision tree or one adapted from it are

practical tools that can be applied in any future risk-based MSAS. To be effective and adaptive, risk-based meat inspection and RB-MSAS requires timely and updated information on zoonotic risks. FCI in its current format does not serve as sufficient basis for effective risk management at an abattoir (i.e., during meat inspection). From a RIBMINS perspective, it is clear that risk assessment (most likely risk ranking) is too cumbersome to be performed on a daily basis. Therefore, we suggest a tiered approach where the risk manager is informed by:

1. EU risk assessments;
2. national and regional risk assessments (e.g., in some countries MRSA is a risk in pork);
3. assessment of the food chain information (FCI) accompanying each animal consignment.

Risk assessments at the EU, national and regional levels should be updated regularly and posted on the CA's site to inform the risk managers at abattoirs. A practical, proactive approach is for the CA to provide the FBO risk managers with access to the EU, national and regional risk assessments, and notify them when updates are available.

The risk manager manages the risks facing the particular abattoir and assesses the FCI for all incoming consignments with a view to taking appropriate mitigation actions. The purpose is to categorise the incoming batches according to risk e.g., high and low risk. This could be a tiered approach – the basic risk mitigation must be sufficient to reduce the risks identified at EU, national and regional levels. In addition, if the FBO's risk assessment or the FCI of particular batch identifies additional risks, then additional measures might be needed. For example, if slaughtering free-range pigs, the abattoir could freeze the pork to eliminate *Toxoplasma* and *Trichinella*. If taking delivery of broilers from a farm with a history of consistent *Campylobacter* contamination in the summer and autumn seasons, the abattoir could consider freezing the carcasses. The choice of risk mitigating measures should be made before slaughter.

It is important to recall that the risk manager at an abattoir will probably deal with a multitude of different risks. In addition to the primary food safety risks, other non-food safety aspects that should be considered are animal health, animal welfare, authenticity, labelling, and composition and consumer expectations. Examples of consumer expectations include welfare, halal, organic, country of origin and health claims. The food business, and therefore its risk manager, also could have to deal with other risks in terms of food quality, environmental protection, sustainability, occupational health and profitability. The difficult part balancing these different concerns and objectives without affecting public health.

Risk considerations in current meat inspection

The EFSA opinions on meat inspection formed the backbone for the discussions in RIBMINS on the development of future risk-based MSASs. While not a blueprint or template, the EFSA opinions give a conceptual framework for the development of risk-based and fit-for-purpose RB-MSAS.

Currently meat inspection comprises two main elements:

1. Ante-mortem inspection
2. Post-mortem inspection

Ante-mortem inspection

Strengths – the public health-related strengths of ante-mortem inspection include:

1. Inspection of individual animals
2. Animal identification
3. Evaluation of animal welfare (e.g., cleanliness)
4. Use of FCI

Since animals carrying the relevant zoonotic agents rarely show clinical symptoms, the strengths of ante-mortem inspection relate to animal welfare and animal health. In this regard, Riess and Hoelzer (2020) noted that a risk-based meat inspection system will require evidence-based data to identify what FCI best predicts herd health and meat borne hazards.

Weaknesses – FCI is still not as useful for risk management as it could be, because of the lack of adequate and harmonised epidemiological indicators that could classify the animals according to the public health risks.

Post-mortem meat inspection

Strengths – mainly related to animal welfare and animal health aspects. Classical zoonotic diseases, such as trichinellosis, are controlled in many countries, so the ability of post-mortem meat inspection to detect classical zoonoses is only relevant in countries where they are still present. Septicaemia can be detected by post-mortem inspection, but can be detected before slaughter too (on farm or at *ante-mortem* inspection). Septicaemia associated with some foci of infection (i.e., abscesses) can be less acute and detectable only at post-mortem examination.

Weaknesses – post-mortem meat inspection is not able to detect foodborne pathogens. Post-mortem inspection can currently detect pathological/anatomical abnormalities in pigs, the causative agents of which are mostly non-zoonotic or are non-relevant to public health (for example *Mycoplasma, Pasteurella multocida,, Streptococcus, Sthapylococcus. aureus).* However, these organisms are important with regard to animal welfare, animal health, meat quality issues.

Pigs and meat thereof

The public health hazards to be covered by inspection of pigs were assessed by EFSA in 2011 (Scientific Opinion; EFSA Journal 2011; 9 (10): 2351). Data collected in the EU following Directive 2003/99 do not take in account whether pork was a source of human cases. In addition, there is great variability among reporting countries, and the different notification rates of the pig-related public health hazards might be not only related to the different incidences of diseases, but also to the different surveillance systems used in different countries.

The biological hazards were classified according to frequency and severity (case fatality rate) of infection in humans. The biological hazards identified from chilled pork carcasses as a source in the EU were *Salmonella* (high relevance), *Yersinia enterocolitica, Trichinella* and *Toxoplasma gondii* (these last three are medium relevance). *Ascaris suum* and *Echinococcus, Brucella suis, Erysipelothrix rhusiopathiae, Streptococcus suis* and *Leptospira* are hazards assessed by EFSA as having no association of human diseases with pork meat consumption. These hazards were not subjected to any further EFSA risk assessment process. *Taenia solium* was was assessed as not

being present in Europe in 2011, so this organism was not subjected to any further EFSA risk assessment process.

However, caution and continuous vigilance are needed. As an example, *Taenia solum* was reported recently in Greece (Symeonidou et al., 2018). A risk manager for that particular region of Greece would have to consider this change and implement appropriate mitigation measures. Furthermore, hepatitis E virus (HEV) has received more attention as the number of human cases is increasing in both healthy individuals and at-risk groups. Consuming non-heat-treated pig meat or products from wild boars and domestic pigs, or venison and products thereof from deer, are suspected routes of transmission for HEV (EFSA, 2017). A risk manager for a pig abattoir in a region/country where HEV is increasing would have to update their risk mitigation strategies; in particular this requires foreseeing if the pig meat or products thereof might be consumed without heat treatment or other treatments that kill HEV. Both examples illustrate the need for every risk assessment to be regularly and frequently updated so that it is useful for proper management of the risk in a specific farm/meat plant.

Cattle and meat thereof

EFSA (2013) identified *Salmonella* and Shiga-Toxin Escherichia coli (STEC) as the high risk microbial hazards using the same methods as outlined for pork. EFSA proposed that the risks of *Salmonella* and STEC be mitigated/handled by establishing targets (performance objectives) on chilled carcasses.

In addition, monitoring and surveillance for epizootic diseases, such as foot and mouth disease and bovine tuberculosis, are important objectives depending on the geographical area within which the RB-MSAS is located. Thus, the risk managers in areas with such epizootic diseases must also be able to handle these objectives.

Poultry and meat thereof

EFSA (2012) identified *Campylobacter*, *Salmonella* and Extended Spectrum Beta-Lactamase coliforms (ESBL) as high relevance microbial hazards using the same methods as outlined for pork. None of the main microbial hazards of public health relevance that are associated with poultry meat can be detected by traditional visual poultry meat inspection. Therefore, EFSA (2012) proposed that performance objectives, i.e., prevalence targets, be established for *Salmonella*, *Campylobacter* and ESBL-/AmpC-producing *Escherichia coli*.

During the last ten years, several performance targets for poultry have been established for *Salmonella* and *Campylobacter*. To date (January 2021), the EU has set the following prevalence targets for primary production:

- For broiler flocks by Reg. (EC) No 200/2012 as last amended. The maximum annual percentage of flocks of broilers positive for *Salmonella* Enteritidis and *Salmonella* Typhimurium equal to 1% or less.
- For turkey flocks by Reg. (EC) No 1190/2012. The maximum annual percentage of breeding or fattening turkey flocks positive for *Salmonella* Enteritidis and *Salmonella* Typhimurium to 1% or less.
- For for chilled broiler carcasses, the EU process hygiene criteria is in Reg. (EU) No 2017/1495 updating Reg. (EU) No 2073/2005. Out of 50 sampled carcasses, a maximum

15 or 30% can contain >1000 cfu/g of *Campylobacter*.

These prevalence targets are reached by implementing an integrated RB-MSAS i.e., combining a range of preventive measures and controls applied both on the farm and at the abattoir in an integrated way. This can be a fit-for-purpose approach as the targets are output-based. A major advantage of the modern RB-MSAS is its flexibility and the adaptiveness of control programs to local conditions. Each FBO in a meat chain has responsibility for their own system, while compliance is audited and verified by the CA. The key idea is to differentiate the batches of live poultry entering the abattoir as outlined in Figure 7. For example, it will be helpful to categorise the incoming batches as high vs low risk for *Salmonella* and/or *Campylobacter*.

Chemical residues and contaminants

RB-MSAS should not overlook chemical residues and contaminants in slaughter animals. Most of these compounds do not commonly pose an immediate or short-term health risk for consumers. However, some contaminants can bio-accumulate in the food chain, thus contributing to the overall exposure in consumers. In addition, the presence of specific chemical residues is indicative of non-compliance with existing regulations or of illicit use of non-authorised substances, with implications for risk management.

The current meat inspection methodology comprises two major steps (ante- and post-mortem inspection) at the abattoir level that might sometimes identify animals that should be subjected to sampling for the presence of residues and contaminants. The sole intervention at abattoir level is the isolation of a suspect carcass as potentially unfit for human consumption, pending results of residue testing.

Ante-mortem inspection can identify some animals with signs of intoxications, welfare issues, signs of recent medication (e.g., injection sites), loss of body fat or alterations to the reproductive organs. Post-mortem inspection is less useful for this purpose, since in most cases, evidence for the presence of chemical residues and contaminants will not be apparent during the current visual inspection of pig carcasses. Therefore, the meat inspection approach based on detecting and immediately eliminating the suspect animal/meat is generally not applicable to chemical hazards.

Strengths of the current meat inspection methodology include:

- Across EU member states, residue and contaminant testing is performed by accredited laboratories (ISO/IEC 17025).
- Follow-up on non-compliant samples through intensified sampling (suspect sampling), condemnation of non-compliant carcasses, and on-farm investigations potentially leading to penalties.
- The regular sampling and testing for chemical residues and contaminants at the national level is a disincentive for the development of bad practices.
- The combination of FCI, ante-mortem inspection and post-mortem gross tissue examination has been frequently found to be supportive of the collection of appropriate samples for residue monitoring.

Weaknesses of the current meat inspection methodology include:

- Chemical hazards are not detected by current ante-/post-mortem meat inspection.

- Limited flexibility to include emerging chemical substances in residue monitoring programmes.

In the future, the abattoir should be a key monitoring point for baseline studies of chemicals and contaminants entering the post-harvest meat chain. Hence, it should be clarified whom is responsible for taking of those samples needed. It would logically be the FBO under the CA's supervision. FCI will be crucial to identify if there are any risks of chemical hazards from the incoming animal batches.

In the EU (Council Directive 96/23/EC), member states are obliged to implement national residue control plans (NRCPs) for defined groups of substances. The groups of substances may be of different concern in carcasses in respect to their illicit use in live animals (Group 1), their occurrence in feeds (Group 3) or the amounts of their residues (Group 2). EFSA has not identified any major chemical hazard in their opinions. However, this is a dynamic situation and will be reviewed regularly.

The history of feed-related scandals in the EU includes:

1. dioxins and PCBs in Belgium 1999 (Covaci et al., 2008) that affected 2500 poultry and pig farms;
2. dioxins and PCBs in Ireland 2008 causing total recall of pork produced in Ireland from September to December 2008 (Casey et al., 2010);
3. dioxins in Germany 2011 that affected 4700 poultry and pig farms (Abraham et al., 2011).

These incidents are reminders that chemical hazards must always be on the radar for the risk manager. Of 23 main incidents in the last years more than 20 were related to chemical hazards. This means that food incidents involving chemical hazard contamination are nearly annual events, requiring actions by CAs and FBOs. Frequently, these events are linked to contaminated animal feedstuffs.
Rapid action is crucial for maintaining consumer confidence. The danger of chemical hazards in meat highlights the importance of effectively working feed controls and a seamless interface between the abattoir risk managers and the feed control. The CA has an important role in facilitating communication along the food chain from farm to fork and ensuring prompt action to remove products at high risk from the food chain.

Public RB-MSAS – regulatory framework

The Codex Principles and Guidelines for National Food Control Systems (NFCS) (CAC/GL 82-2013) foresee CAs taking into account quality assurance systems in their national food control system and their design and implementation of audits and control programs. 'Where quality assurance systems are used by food business operators, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade' (CAC/GL 82-2013).
When developing a risk-based MSAS, the process should be informed by the Codex Alimentarius code of hygienic practice for meat, CAC/RCP 58-2005, general principles of meat hygiene. In particular, the following points provide useful guidance:

- Point II: The competent authority should have the legal power to set and enforce regulatory meat hygiene requirements, and have final responsibility for verifying that regulatory meat hygiene requirements are met. It should be the responsibility of the establishment operator to produce meat that is safe and suitable in accordance with regulatory meat hygiene requirements. There should be a legal obligation on relevant parties to provide any information and assistance as may be required by the competent authority.
- Point VI: Meat hygiene requirements should control hazards to the greatest extent practicable throughout the entire food chain. Information available from primary production should be taken into account so as to tailor meat hygiene requirements to the spectrum and prevalence of hazards in the animal population from which the meat is sourced.

Reg. (EC) No 853/2004 defines the specific requirements for FBOs producing food of animal origins. The majority of requirements are related to the meat supply chain. In this regulation, as well as in regulations setting microbiological and chemical criteria, specific requirements, outcomes and processes are set. These define the basis of minimum requirements to be considered.

In the EU, three regulations are to be adhered to when considering official controls for the meat supply chain:

- Reg. (EU) No 2017/625 (official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products);
- Reg. (EU) No 2019/624 (specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Reg. 2017/625) and;
- Reg. (EU) No 2019/627 (laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Reg. No (EU) 2017/625).

Reg. (EU) No 2017/625 lays down rules for the performance of official controls and other official activities by the CAs of the member states to verify compliance with EU legislation in the area of food safety at all stages of production, processing and distribution. The CAs in the EU regulate and control the FBOs, based on the risks and at an appropriate frequency, taking account of the reliability and results of the FBOs' own controls (i.e., those performed by the FBO), or those performed by a third party. This could include verifying the compliance of private quality assurance schemes with the rules in the areas of:

- food and food safety, food integrity and food wholesomeness at all stages of production, processing and distribution, including rules aimed at ensuring fair practices in trade and protecting consumer health, interests and information, and the manufacture and use of materials and articles intended to come into contact with food;
- feed and feed safety at any stage of production, processing and distribution of feed and the use of feed, including rules aimed at ensuring fair practices in trade and protecting consumer health, interests and information;
- animal health requirements;
- prevention and minimisation of risks to human and animal health arising from animal by-

products and derived products;
- welfare requirements for animals;
- protective measures against plant pests;
- requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticide application equipment;
- organic production and labelling of organic products;
- use and labelling of protected designations of origin, protected geographical indications and traditional specialties guaranteed.

Many problems concerning meat safety arise during primary production and can have a strong impact on human health. Apart from microbiological hazards, chemical hazards are also considered in food of animal origin, including residues of veterinary drugs, residues of unauthorised or prohibited substances, pesticide residues and other chemical contaminants.
A more general opening statement is found in Articles 6 of Reg. (EU) No 2019/627 and 16.2 in Reg. (EU) No 2017/625 – member states and the EU shall take note of current progress in scientific evidence and technical innovation to modernise the meat inspection and control of foodstuffs of animal origin. In addition, Article 6 of Reg. (EU) No 2017/627 obliges the member states to notify each other on the scientific and technological developments, for consideration and further action as appropriate. This Article defines neatly the ultimate aims of RIBMINS.
Flexibility of distribution of tasks is possible based on the derogations found in Articles 18 (3) and 18 (9) of Reg. (EU) No 2017/625 that allow for the reassignment of tasks between official veterinarians and assistants, and allow pilot trials on novel procedures. In particular, Article 18 (9) of Reg. (EU) No 2017/625 allows for member states conducting pilot trials to evaluate alternative practical arrangements of meat safety assurance. Hence, the results from RIBMINS could and should be used to propose changes in current procedures.

The FBO's responsibility includes that products of animal origin comply with EU legislation in regards to:
- microbiological criteria laid down by Reg. (EC) No 2073/2005;
- maximum residue limits for pharmacologically active substances laid down by Reg. (EU) No 37/2010 and Reg. (EU) No 2018/470;
- prohibited and unauthorised substances having hormonal or thyrostatic action and β-agonists, in accordance with Reg. (EU) No 37/2010 and Council Directive 96/22/EC;
- residues of contaminants, in accordance with Reg. (EC) No. 1881/2006 and Reg. (EC) No124/2009 setting maximum levels for certain contaminants in food;
- pesticide residues, in accordance with Reg. (EC) No 396/2005.

In addition, FBOs must ensure that products of animal origin do not contain physical hazards, such as foreign bodies, which can range from metal or glass fragments, to insects and bones. In the case of game meat, this would include bullet fragments.
The EU legislation is reviewed and updated frequently. For example, Reg. (EU) No2017/625 has recently been updated by Reg. (EU) No 2019/624 (official controls for the production of meat and production and relaying areas of live bivalve mollusks) and by Reg. (EU) No 2019/627 (practical arrangements on official controls on products of animal origin intended for human

consumption).
Concerning meat safety, Article 45 of Reg. (EU) No 2019/627 lists cases of non-compliance with the legal requirements that, consequently, make fresh meat unfit for human consumption. Specifically, some of these are related to the absence of ante-mortem and/or post-mortem inspection of animals and/or offal, respectively, or meat from animals that are dead before slaughter. Other cases of non-compliance could be addressed by the implementation of good farming practices and veterinary controls on the farm, or good hygiene practices at slaughter.
Official controls at slaughter are specifically mentioned for *Salmonella* and *Campylobacter* contamination of carcasses (Articles 35 and 36 of Reg. (EU) No 2019/627, respectively). The CA audits and verifies the correct implementation of Reg. (CE) No 2073/2005 by the FBO in regard to the process hygiene criteria for *Salmonella* (carcasses of cattle, pigs, horses, sheep and goats and poultry) and *Campylobacter* (carcasses of broilers).

Reg. (EU) No 2019/2009 lays down rules for official controls for cases of non-compliance or suspected non-compliance with the use of authorised, unauthorised or prohibited pharmacologically active substances on food-producing animals and their residues. In particular, when the maximum residue limits for pharmacologically active substances authorised in veterinary medicinal products or as feed additives, have been exceeded, non-compliant carcases and products are declared unfit for human consumption and disposed of as category 2 material. In the case of illegal treatment with unauthorised or prohibited substances, carcases or products are declared unfit for human consumption and disposed of as category 1 material.

FBO-RB-MSAS

The FBO holds the primary legal responsibility over the safety of produced/delivered food, as stated in the EU General Food Law Reg (EC) 178/2002. The EU legislation clarifies the tasks and obligations of FBOs and competent authorities (CA).

Different policy structures imply different tasks for the FBOs (see Table 3). In the meat chain, for example, we recognise specific prescriptions set in Reg. (EU) No 853/2004, specific outcomes (safety and hygiene criteria) set in Reg. (CE) No 2073/2005 and specific processes to be applied (namely Hazard Analysis and Critical Control Point (HACCP)) as defined by Reg. (CE) No 178/2002.
Competencies depend on the supply chain and on the stage of the supply chain wherein the FBO operates. In the meat chain stages considered in this report, we recognise the abattoir FBO has competencies that cover live animals, slaughter processes and meat safety.
The FBO and its team need to be competent not only in food safety but in additional topics that could be partly included in the FBO-RB-MSAS, but are included in the FBO's quality assurance system. These include: Animal welfare, food quality, food sustainability and any other guarantee required by applicable third party assurance systems (third countries or certifications).

	Policy activity	FBO activities	Space for private regulation	Legislation	Example
Prescription-based system	Set requirements (=effective control measures)	Apply the requirements	Low. The addition of requirements to legal mandatory ones risk to cause overregulation	Specified Risk Material Reg. CE 999/2001; Reg. EU 1162/2015; Reg. EU 2018/969) Animal welfare (Reg. CE 1099/2009) By-products (Reg. CE 1069/2009) Meat inspection (Reg. EU 2019/624 ; Reg. EU 2019/627)	The majority of practicalities to be carried out during meat inspection at abattoirs are specified in Reg. EU 2019/627.
Outcome based system	Set Outcome (=criteria to meet FSO, PO)	Define the requirements to achieve outcome	Medium. Additional requirements may be useful to achieve outcome	Microbiological criteria (Reg. CE 2073/2005)	*Salmonella* should be absent in several categories of meat products. However, regulation does not specify how this goal is to be achieved as the decision is up to FBO.
Process based system	Set scope (Food safety)	Define the outcome and the requirements to deliver safe food	High. The freedom in defining the process implies a low number of legal requirements thus space for additional ones.	HACCP (Reg. CE 852/2004)	Shiga toxin-producing *Escherichia coli* (STEC) contamination is not included in the microbiological criteria laid down by Reg. CE 2073/2005. Nevertheless, FBOs commonly test beef products for STEC.

Table 3: Different policy structures and different tasks for FBOs

FBO-RB-MSAS is built on top of legislation and eventually third party RB-MSAS. Ideally, FBOs should be able to manage the risk within their premises starting from international and national requirements and adding their own specific ones. The real situation is far more complex, as FBOs hold very different levels of competencies linked also to the nature and dimension of the food businesses under their responsibility. In addition, FBOs need to manage not only food safety aspects, but also an increasing number of quality aspects linked to sustainability, animal welfare, organic and so on.

Third party RB-MSAS

A third party RB-MSAS can result from:

1 – A third country RB-MSAS that needs to be fulfilled for export purposes;

2 – Buyer requirements (second party) are generally set within buyers' RB-MSASs. The verification of fulfilment, usually by audit, is up to the buyers' FBO;

3 – Third party schemes are set by standard owners. Criteria fulfilment is verified, generally through audits, by certification bodies that release certification upon successful evaluation. These certifications are often recognised by buyers, so they can reduce the numbers of audits carried out by buyers and audits received by FBOs.

Assurance schemes, which are also referred to as certifications, are organised efforts that offer a

guarantee of adherence to a given set of standards (FSA 2019). These schemes are not as novel as often assumed. The National Fire Protection Agency (NFPA), for example, one of the world's largest such organisations, has been around since 1896. However, assurance schemes have been enormously popularised in the past few decades as part of a move from government to governance (Hutter and Jones 2007) that has led to a regulatory system characterised by complex interactions between state and non-state actors (Eberlein et al. 2014; Mills 2016; Lambin and Thorlakson 2018). In the meat sector, for instance, businesses are legally required to meet official controls, but the use of assurance schemes like the ISO 22000 and Red Tractor is now also commonplace.

These industry standards or certification schemes come in different flavours, of which some examples are given in Table 8. They are classified into:

1. Certification scheme: relies on a third party attestation procedure.
2. Self-declaration scheme: does not have third party attestation. Adherence to the scheme is attested to by either: a) the scheme operator (in the case where the operator is not a certification body), or; b) the producer or retailer.
3. Umbrella food labelling scheme: a collection of food labelling schemes with similar characteristics.
4. Public food labelling scheme: clearly state it is owned or managed by a public body.

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London Economics (2014) in a report to the European Commission on food labelling schemes identified 901 different schemes across the EU. They covered different supply chains, but the meat chain had the highest number (469) of related schemes of which the majority were certification-based (377). Key policy areas of certification schemes in the meat supply chain were origin (540 schemes), organic farming (234 schemes) and traceability (214 schemes). Food safety/hygiene ranked 7th with 174 schemes.

Scheme	Applicability	Location/Origins	Target	Audience	Type	Safety	Traceability	Sustainability	Welfare	Social responsability
HACCP	Processing			BtoB		X	X			
BRC	Processing	UK	General	BtoB		X	X			
IFS	Processing	Germany, France	General	BtoB		X	X			
FSSC22000	Processing		General	BtoB		X	X			
Global Gap	Primary production	EU	General,Meat	BtoB	Umbrella	X	X	X	X	X
SQF 1000	Primary production	Australia	General,Meat	BtoB		X	X			
SQF 2000	Processing	Australia	General,Meat	BtoB		X	X	x		x
GFSI	Processing			BtoB	Umbrella	X	X			
Global red meat standard	Processing			BtoB						
Carbon trust	Primary production, Processing		General	BtoC				X		
Dutch HACCP	Primary production, Processing	The Netherlands	General	BtoB		X	X			
Fair Trade	Processing		General	BtoC						X
Halal	Primary production, Processing		Meat	BtoC						
Kosher	Primary production, Processing		Meat	BtoC						
ISO 26000	Primary production, Processing		General,Meat					X		X
Organic	Primary production, Processing		General,Meat	BtoC				X		
QS	Primary production, Processing	Germany	General,Meat			X	X		X	

Table 4: Examples of meat supply chain certification schemes(more details available at https://ec.europa.eu/info/sites/info/files/food-labelling-scheme- final-report_en.pdf. BtoB means business to business, while BtoC means business to consumer)

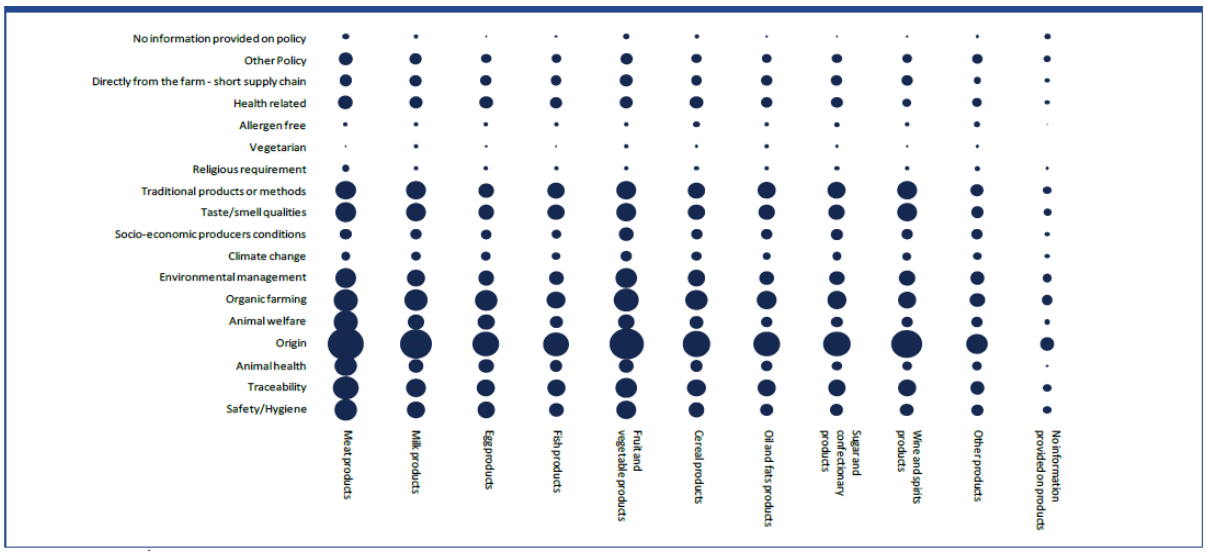

Figure 1: scheme number distribution according to supply chain and policy area. 2 Acknowledging the topic analyses provided in this section by Dr Jose A Bolanos, Research Officer, Centre for Analysis of Risk and Regulation (CARR), London School of Economics, and Food Standards Agency (FSA). J.bolanos@lse.ac.uk, jose.bolanos@food.gov.uk.

In many countries, industry or third party standards or certification schemes are important parts of food safety assurance systems. The food safety elements are often embedded in broader food quality schemes that cover food fraud, quality and safety. The scopes of a quality assurance program beyond food safety, animal welfare and animal health could include: (a) wholesomeness – absence of characteristics objectionable to the consumer; (b) authenticity – the chilled carcass/meat is free from adulteration and is what it says it is (food fraud issues) and/or; (c) specific consumer expectations e.g., organic, halal, or locally produced.

As an example, the BRC Food Safety standard provides a framework to manage product safety, integrity, legality, quality, and the operational controls in the food and food ingredient manufacturing, processing and packing industries. The BRC Food Safety standard was developed with an emphasis on management commitment, a HACCP-based food safety program and supporting quality management systems. It is intended to assist organisations and their customers to comply with food safety needs through the foundation of a HACCP- or risk-based approach to the management of food safety. Its objective is to focus the audit on the implementation of good manufacturing practices during production with additional emphasis on areas that have traditionally resulted in recalls and withdrawals (e.g., label and packing management). These food standards should inform the development of the fit-for-purpose RB-MSAS.

Co-regulation, considerations about RB-MSASs harmonisation

Several RB-MSASs rule over the meat supply chain, with some being mandatory, others being voluntary and/or required to reach third country markets (RB-MSASs defined by third country legislation), and yet others being to comply with the requirements of a specific market (third

party RB-MSAS). The co-existence of RB-MSAS at different levels, with overlapping coverage and overlapping requirements, raises the need to think about the harmonisation of activities aimed at verifying FBO compliance, reducing the burden of inspection activities and using public resources efficiently.
Third party RB-MSASs partially answer to the need of efficiency and harmonisation, replacing second party RB-MSAS and answering to the specific needs of clients along the chain. Clients can recognise third party certification and rely on it for supplier selection.

In the future RB-MSAS, the necessary shift of the CA's main activities from inspection to auditing raises an additional point of discussion. This is the possible overlapping with audits from certification bodies enforcing third party RB-MSASs, where essentially a third actor audits the FBO-RB-MSAS against the requirements of a private standard. In this context, providing that the private standard comprises at least the minimum legislative requirements, it will be of interest to integrate the public and private systems in order to avoid duplication and maximise resource efficiency.

For integration to be possible, thus, the CA needs to assess not only if the public and private RB-MSASs' requirements are equivalent, but also, if the integrated RB-MSAS will reliably deliver adherence despite the enormous non-compliance risks.

Equivalence
It would be a mistake to think that a private RB-MSAS must be equivalent to public RB-MSAS. Non-equivalent assurance schemes are decidedly not pointless. They can fill in regulatory gaps (Amengual 2010; Montiel, Husted, and Christmann 2012), push practices beyond legal requirements (Barry et al. 2012, 95), and help businesses to meet regulatory requirements (Raines 2002, 425).

That said the possibility and motivation for private RB-MSAS to be at least equivalent to public RB-MSAS exist. Assurance schemes can offset the need for legal requirements and inspections (Sharma, Teret, and Brownell 2010, 240; Higgins, Dibden, and Cocklin 2008, 25), and uptake of these schemes is higher where they can substitute regulation or inspections (Anderson, Daly, and Johnson 1999, 40–41). Thus, many private RB-MSASs could opt to be equivalent to official controls in at least some respects. There is a world of possibilities implied in this, though. A private RB-MSAS that simply mimics the law is unlikely to be able to frame itself as providing much additional value to members. Similarly, if all private RB-MSASs were equal, they could not frame themselves as better than competitors. So, there is a need to identify the aspects in which different private RB-MSASs are equivalent to public RB-MSAS, and it also would be helpful to learn if the equivalence is due to having equal requirements to official controls (process-based) or to enabling equivalent results (outcome-based).

Reliability
The second part of the challenge is reliability i.e., the ability to trust that a RB-MSAS delivers in practice. This challenge results from a certification body inability to enforce compliance as do CAs. One approach to reliability is have a more or less independent RB-MSAS, a decision that links to the independence and accountability of non-state actors involved in regulation (Alkoby

2003; Mattli and Büthe 2005; Black 2008; Mattarocci 2013; Anand and Sossin 2018). For a private RB-MSAS that is entirely independent of the law, revoking a membership is a punishment with economic implications. A private RB-MSAS that is required by the CA to ensure an FBO meets legal requirements is less independent, but can, on revoking membership, render the business unable to operate – a more significant punishment. In sum, then, requirements by CAs limit private RB-MSASs independence but, at the same time, can increase their enforcement capacities. An example is the UK FSA's Earned Recognition programme. This option could increase the appeal of complying with the private RB-MSAS's requirements and, subsequently, raise the impact of losing membership.

Furthermore, a CA could endorse several private RB-MSAS on the basis of an assessment of their quality, thus allowing these selected RB-MSAS to be a little more aggressive in their verification efforts. Next, a CA can ask all RB-MSASs to include minimal thresholds, such that the RB-MSAS' right to operate is linked to continued verification of these thresholds. In this approach, the responsibility for verification of some requirements would be transferred to the RB-MSAS, and the CA would need to inspect RB-MSAS processes, not the FBOs. Given the above, two plausible approaches to managing integration exist. These two approaches are broadly describable as Earned Recognition (Benson 2018) and Regulated Private Assurance (Purcell 2018).

Earned Recognition: Within the food control domain - Earned Recognition schemes is described as a way to reduce the burden for compliant businesses that allows enforcement activity to concentrate on less compliant businesses. Those who qualify for Earned Recognition will benefit by receiving less frequent visits by the enforcement authority. Earned recognition schemes could also be described as risk based food control schemes.

Regulated Private Assurance: When enforcement is possible, integration is best pursued by developing a regulatory framework that covers both the RB-MSAS and its relations with members. For instance, regulations requiring the RB-MSASs to ensure their members meet 'X' are best when accompanied with regulations requiring FBOs to use a RB-MSAS for this purpose.

The question of which is the best path for integration in a country comes down to whether that country can change the independence/control ratio. If a country cannot change this ratio, it likely is because it cannot impose requirements on RB-MSAS. For these countries, an Earned Recognition approach seems the only viable path of action.

This section does not argue that a specific independence/control approach is inherently better than other approaches. All the arrangements noted above exist (Barry et al. 2012, 74–75) and, therefore, must be considered as part of the spectrum of possibilities open for the definition of future RB-MSASs.

Unsurprisingly, examples of efforts to integrate assurance schemes into official controls exist both outside and inside the food sector. An example from outside the food sector is the European Union's Eco-Management and Audit Scheme (EMAS), which encourages the usage of ISO

14001. EMAS has enabled reduced fees and frequencies of inspections, simplified procedures, and reduced monitoring or reporting across the whole of Europe (Dahlström et al. 2003, 188–89). An example from the animal feed and food hygiene sectors is, as already noted, the UK FSA's 'Earned Recognition' program, which aims to reduce inspections for those food businesses certified by an approved assurance scheme (Benson 2018; FSA 2020).

Equivalence between a RB-MSAS's requirements and official controls, however, does not suffice for integration. The FSA's work on the matter has found that while equivalence is vital, differences "in the purpose, assessment focus and approach" between a RB-MSAS and official controls mean that equivalence does not equal the ability to function as replacements for official controls (Robinson 2017, 4). This finding is in line with writings about certifications and assurance schemes that emphasise that these cannot typically enforce standards through direct legal sanctions (Cashore 2002, 504; Black 2009, 13). Assurance schemes can, to a degree, punish non-compliant behaviour by refusing (or removing) membership. However, only CA can force a business to comply with official controls or close its doors.

For these reasons, assurance schemes should not be understood as control mechanisms but rather, influences to the risk management (Hutter and Jones 2007, 36–39) or, as shown in Figure 11, the organisational culture (J A Bolanos 2020, 26) of food businesses. The perceived 'softness' of an influence-like mechanism is a challenge when it comes to thinking about integration into official controls. Food businesses in the meat sector face enormous financial pressures, and even small incidents can have systemic impacts. The massive risk of non-compliance is a concern for CAs because, while the industry is responsible for ensuring food safety and suitability, CAs own the responsibility for verifying compliance with regulatory requirements (RIBMINS 2020, 4).

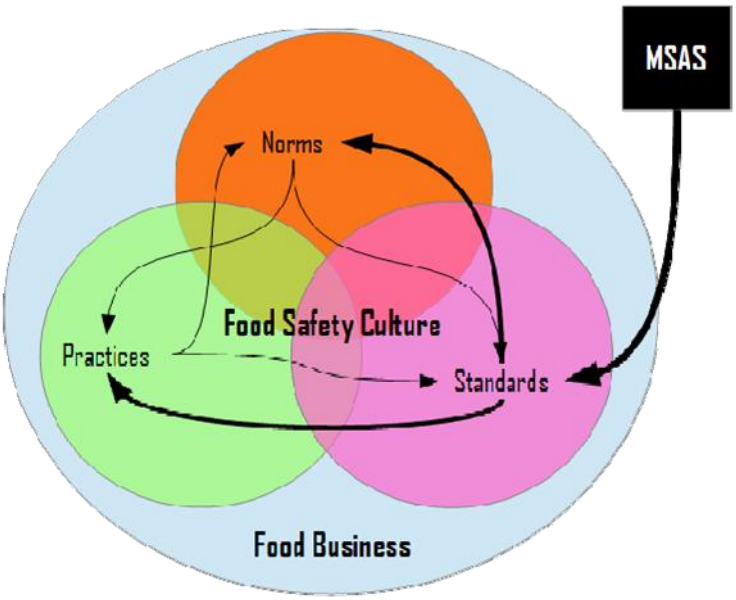

Figure 2: RB-MSAS influence on a food business' food safety culture

Future of RB-MSAS

The future RB-MSAS (yet to be built) should be able to maximise efficiency and food safety given the need to meet other goals, such as animal welfare and sustainability. In particular, the future RB-MSAS should:

1. be risk-based;
2. be fit-for-purpose to flexibly adapt to the nature and characteristics of food businesses;
3. ensure traceability for meat and meat products;
4. effectively integrate and utilise safety and suitability information from throughout the food chain, improving existing options (such as FCI) to rank and manage risks;
5. contribute to surveillance of animal health by the compulsory notification of findings during ante- and post-mortem inspection, with sample collection when needed;
6. contribute to assessment of animal welfare, signaling findings such as sub-cutaneous bleeding, tail-biting or other lesions during transport and lairage;
7. allow data collection in order to facilitate priorities in surveillance and risk mitigation to be set and to clarify endpoints of interventions;
8. provide interfaces between feed businesses, food business (FBOs, in this text), CAs and abattoirs that are crucial to handle and mitigate chemical and biological hazards;
9. be built upon co-regulation that joins the efforts of private and public RB-MSASs with a single scope in mind: to deliver safe meat.

We foresee the meat control system will evolve into the RB-MSASs that we expect legislation will facilitate. The focus should be on finding working practical solutions. However, a RB-MSAS might be embedded in a FBO's quality assurance scheme. A RB-MSAS should assure the suitability characteristics of meat as specified in legislation, operate in an integrated manner from farm to fork, and be tailored to the health status of the slaughter population. It is important the RB-MSAS is designed and implemented with regard to the conditions of the meat chain, the abattoir and the consumer of the meat/meat products.

In addition to the principles outlined by the Codex Alimentarius, we believe the following actors all have roles to play in order to assure meat safety and are relevant for developing the future RB-MSAS:

- government, policymakers;
- CAs;
- FBOs from farm to fork (feed, farm, processing);
- third party safety assurance scheme owners and assessors;
- consumers.

As stated above, the legal framework will have to evolve further to support practical solutions for RB-MSAS. There should be clear differentiation between industry and regulatory roles and responsibilities. As laid down by Reg.s (EC) No 852/2004 and No 853/2004, the FBOs are solely responsible for the safety of the products they place on the market. Similarly, they are responsible for all the operations described in their private RB-MSAS. For small- and medium-sized FBOs, industry-issued guidelines can help in the implementation of an internal RB-MSAS in terms of being compliant both with regulatory requirements and food safety assurance.

An exception to this general rule of responsibility is meat inspection (ante-mortem and post-

mortem inspection at the abattoir) that is now carried out by official veterinarians (employed by the CA) according to Reg. (EU) No 2017/625.

One possible direction for the RB-MSAS to develop, and which would improve the involvement of FBOs and their RB-MSASs in assuring the production of safe meat, could be for FBOs to cover some tasks for which CAs curently have responsibility. To date in the EU, relatively few duties (i.e., just pre-selection of animals) can be carried out by official auxiliaries under the responsibility of the official veterinarian (the CA's employee). In the future RB-MSAS, ante-mortem inspections could be performed by veterinarians with appropriate knowledge of the legislation on animal health, animal welfare and meat-borne diseases, but who are employed by the FBOs. To replace official veterinarians, FBO veterinarians (for ante-mortem inspections) will have to pass official examinations imposed by the national CA and have the same competencies as the official veterinarians.

As regards post-mortem inspections, to date, bovines, pigs, equines, sheep and goats must be inspected by an official veterinarian or by an official auxiliary under the responsibility of an official veterinarian (Reg. (EU) No 2019/627). In the future RB-MSAS, they could undergo post-mortem inspection under the responsibility of the FBO veterinarians assisted by abattoir staff. This system is currently in use for poultry and lagomorphs (Article 25 and 26 of Reg. (EU) No 2019/627). For these species, official veterinarians or official auxiliaries (in accordance with Article 18 (2) (c) of Reg. (EU) No 2017/625) carry out: daily inspection of carcasses and viscera of a representative sample of each flock; detailed inspection of a random sample of carcasses declared unfit for human consumption by the abattoir staff, and; additional investigations when the meat could be unfit for human consumption. The inspection of only a representative sample of each flock of birds is allowed only when the FBO can demonstrate that (a) a system is in place to the satisfaction of the official veterinarian, that allows the detection and the separation of birds with abnormalities, contamination or defects; (b) the abattoir has a longstanding history of compliance with the requirements; (c) no abnormalities that could indicate a serious problem for human or animal health or that could indicate the need for measures laid down in Articles 40 to 44, have been found during ante-mortem inspection or verification of food chain information.

Translating these rules in the bovine, pigs, sheep, ovine and horse compartments, the CA would carry out post-mortem inspection on representative samples of each batch of animals only when the FBO-RB-MSAS has given the guarantees required by Reg. (EU) No 2019/627.

However, before FBOs can be solely responsible for the safety of meat, including ante-mortem and post-mortem inspections at slaughter, many changes at EU level will have to occur. For example, new techniques (infrared imaging, video cameras, etc.) should be available to assist post-mortem operations, thus facilitating detection of abnormalities and lesions. In addition, an improvement of monitoring programs for zoonoses at pre-harvest level is needed for the risk-based planning of slaughtering operations. Monitoring programmes at pre-harvest level in animals other than poultry (such as *Salmonella* control programmes in pigs) must have regard to the most common zoonotic diseases transmissible by consumption of meat. Pathogen control programmes in the EU countries should be risk-based and modified whenever the epidemiological situations change at national/regional level.

In this future RB-MSAS, the CA is expected to be responsible for the approval of private RB-MSASs and in charge of auditing plant operations, RB-MSAS documents, reports and analytical

test results. The risk management carried out by abattoirs will have to be transparent and fully available to the CA. Another CA task will be issuing certificates for export and other trade purposes.

We foresee at least two future roles for veterinarians:
- As a risk manager working onsite and employed by the FBO hence force defined as the "FBO risk manager",
- As an official veterinarian whose primary tasks are auditing the controls carried out by the FBO risk manager and verifying that regulatory meat hygiene requirements are met.

In addition, the official veterinarian will take into account the simplified inspection rules proposed for poultry and lagomorphs by the current legislation (Reg. (EU) No 2019/627). Currently, the official veterinary inspector has the major task of controlling individual animal carcasses for cattle, pigs, sheep, goats and horses. We foresee that inspection role for these individual animals and carcasses could be taken over by FBO-RB-MSAS staff (auxiliaries and veterinarians), as is already the case for poultry and lagomorphs, working under the supervision and responsibility of the FBO risk manager. Nevertheless, official veterinarians will be in charge of daily inspections on randomly selected animals and on animals declared unfit for human consumption by the FBO risk manager.

This two role model should work well for large abattoirs or companies with large in-house resources. However, cooperative or collaborative solutions are needed for medium- and small-scale enterprises. For example, cooperative solutions involve FBO risk managers that would be employed by several abattoirs jointly, while there are possibilities for remote solutions in meat inspection. The use of remote control activities would provide for greater use of second opinions (i.e., consulting another veterinarian on an uncertain carcass judgment) thus facilitating more consistent meat inspection.

The role of food chain information

FCI will be critical for building risk-based future RB-MSAS. In our judgement, while FCI information systems are in operation in most EU member states, the utility of FCI is limited so far and is insufficient to profile the risks presented by the incoming animals.

To inform the risk management at slaughter, the future FCI should identify high priority hazards and summarise harmonized epidemiological indicators for those hazards. FCI could efficiently collect and collate all necessary food safety, animal health and animal welfare data for wider monitoring purposes.
All involved in the RB-MSAS, including official veterinarians, official auxiliaries, abattoir staff, farmers, and official microbiological and chemical residue testing laboratories, have a role to play in collecting and collating FCI. They should, therefore, be updated on their responsibilities in a modern RB-MSAS.

FCI is an integral part of ante-mortem inspection in modern meat inspection systems and could be the key element in the future RB-MSAS, based on streaming incoming batches into high-risk and low-risk groups. The FCI will then be used to determine the risk mitigation measures applied at the abattoir. Thus, if animals arrive at the abattoir without sufficient FCI, the animals

will be treated as high-risk animals.

A key component of the FCI is the two-way exchange of information between the primary producer and FBO, as this should result in better FCI. Moreover, this mutual exchange of information will enhance the contributions of FCI to a more cost-effective meat inspection system.

In addition, where relevant, FCI will be sent outside the abattoir so the data reaches the food processing plants before the arrival of the meat batches. Ideally, the destination of meat batches should be partly defined according to the FCI.

To facilitate the future RB-MSAS, FCI will include the following information;

- animal identity/tag number
- animal movements over the course of its life
- information on the animal health status of the farm and/or region
- farm audits
- feed composition, storage and use
- biosecurity measures
- environmental management
- mortality data
- veterinary treatment records
- microbial hazard testing data – e.g., *Salmonella, Campylobacter,* STEC
- chemical hazard data – e.g., drug residues, heavy metals, dioxins, etc.
- information on stocking density
- animal welfare data including housing and handling
- relevant reports of ante- and post-mortem inspections of other animals from the same farm
- production data when this might indicate the presence of disease
- name and address of the veterinarian attending the farm

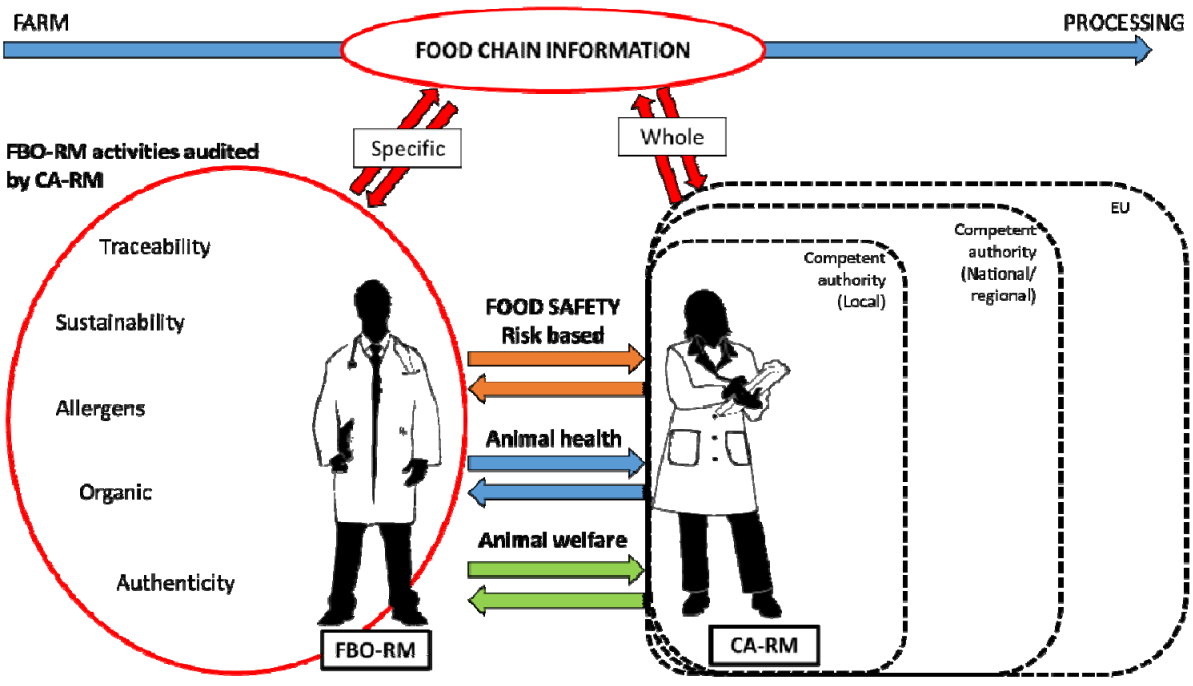

Figure 5: Food chain information flow

In a future RB-MSAS, FCI could be used for the following activities:

- ensuring that animals accepted onto the abattoir premises do not come from a farm or area subject to prohibition or other restrictions for animal or public health reasons
- establishing the health status of the animals concerning notifiable diseases, as these are a priority (e.g., bovine tuberculosis, brucellosis and leucosis for cattle; Aujeszky disease, trichinellosis and swine vesicular disease for pigs; salmonellosis and campylobacteriosis for poultry);
- risk categorisation of animal herds/flocks/ batches based on: Farm descriptors; historical data and; herd-specific information, including monitoring of harmonised epidemiological indicators (HEI);
- assessing the risk-associated and protective factors for animals/herds related to specific target hazards;
- checking for the occurrence of diseases that could affect the safety of the meat and defining the destination of meat batches according to the results;
- ensuring the required withdrawal period for veterinary medicinal products or other treatments has been observed;
- facilitating the specific actions needed to high risk carcasses;
- forewarning the abattoir of any potential disruption to normal slaughter activities.

The role of food safety culture

It appears that foodborne disease and incidents are more often caused by failures of good manufacturing practices (GMPs) and more rarely caused by food safety system failures. Hence, the food safety attitudes, values and beliefs shared by a group of people can be described as the company culture of food safety. A high level of food safety culture is integral to success, given that the FBO has the primary responsibility for food safety. In effect, the food safety culture reflects “how we make safe food around here”.

Building on this insight, in September 2020, the Codex Alimentarius Commission adopted a revision of its global standard on General Principles of Food Hygiene (CXC 1-1969). The revised standard introduced the concept of food safety culture as a general principle. The food safety culture should enhance food safety by increasing the awareness and improving the behaviour of employees in food establishments. The concept fits neatly with the development of future RB-MSAS. As Codex sets global standards, consumers in the EU and abroad and in countries to which RIBMINS countries export would expect compliance with this concept.

Consequently, during the autumn of 2020, the EU Commission proposed amendments to Reg. (CE) No 852/2004 such that FBOs are required to have a food safety culture. We believe this requirement is in line with, and probably a prerequisite for, establishing any future risk-based RB-MSAS.

The proposed addition to the regulation will require food businesses to establish, maintain and provide evidence of an appropriate food safety culture by fulfilling the following requirements:

- commitment of the management and all employees to the safe production and distribution of

food;
- leadership towards the production of safe food and that engages all employees in food safety practices;
- awareness of microbial, chemical and physical hazards and of the importance of food safety and hygiene by all employees in the food business;
- open and clear communication between all employees in the food business, within an activity and between consecutive activities, including communication of deviations and expectations;
- availability of sufficient resources to ensure the safe and hygienic handling of food.

Clearly, this list encompasses the terms of reference for the CA auditing of the RB-MSAS. To some extent, it is also a job description for the FBO risk manager or rather the risk management functions fulfilled at the food business. Furthermore, the FBO management's commitment will have to include:

- ensuring that roles and responsibilities are clearly communicated within each activity of the food business;
- maintaining the integrity of the food hygiene system when changes are planned and implemented;
- verifying that controls are being performed timely and efficiently;
- maintaining up-to-date documentation;
- ensuring that the appropriate training and supervision are in place for personnel;
- ensuring compliance with relevant regulatory requirements;
- encouraging continual improvement of the food safety management system and food safety culture, where appropriate, taking into account developments in science, technology and best practices.

The last point highlights also what we foresee as the strategy for the continuous evolution of future RB-MSAS within the RIBMINS member countries. Both FBOs and CAs in the RIBMINS member countries will be obligated to facilitate the needed development of food safety culture to improve food safety.

A selection of case studies with a focus on national RB-MSASs

Here, a few cases from different, mostly European, countries are presented to exemplify the current state of the art. Even if European countries have to comply with the same EU legislation, wide variations in context and circumstances in Europe are seen. Our report below is not intended to be comprehensive, but rather gives an overview of the variations in local circumstances and contexts to inform the future risk-based MSAS.

Finland

Country structure

In Finland, there are 15 abattoirs slaughtering each more than 5,000 red meat animal units and more than 300,000 birds per year. These abattoirs each have an adjacent cutting plant. Additionally, there are 85 small abattoirs, slaughtering 5,000 or less red meat animal units and

300,000 or less birds per year. Out of these 85 small abattoirs, 56 are active, and 50 of them slaughter less than 1,000 animal units or less than 150,000 birds per year at the moment.
All official veterinarians and red meat official auxiliaries working in abattoirs are employed by the Finnish Food Authority (the CA), which is responsible for the organisation, steering and guidance of official control in abattoirs and adjacent cutting plants. The OAs in the poultry abattoirs are employed by the FBOs.

The two biggest meat companies in Finland (HKScan: https://www.hkscan.com/en/investors-information/Releases-and-publications/annual-report-2018/ and Atria: https://www.atria.fi/en/group/investors/financial-information/annual-reports/) are also big players in Sweden and Estonia. Hence, meat businesses from Finland, Sweden and Estonia could benefit from collaborating on future RB-MSAS design and implementation benefiting from already-present business integration.

Towards risk-based meat inspection – prerequisites of risk-based meat inspection of pigs in Finland

The case for using FCI and pre-harvest information to inform meat inspection was presented in the doctoral thesis by Elina Felin, Helsinki University (Felin, 2019).

On-farm health and animal welfare status indicators (such as tail biting and coughing) together with previous meat inspection results could be used as FCI to risk-rank the batches beforehand (Felin, 2019). This would enable decisions regarding the meat inspection procedure: visual-only or additional inspections. The partial carcass condemnation rate for a batch was best predicted by the partial carcass condemnation rate of the pigs from the same farm within one year. In addition, constant coughing and tail biting at a farm were associated with partial carcass condemnations (Felin, 2019).

As part of a comprehensive pork carcass safety assurance system, serological monitoring of *Salmonella*, *Yersinia*, *T. gondii* and *Trichinella* could be used to risk-categorise pig farms, thereby allowing properly targeted control measures to be applied. Risk mitigation targets and procedures could be carefully adjusted for each pathogen. Based on a survey performed in pigs at slaughter from 2012 to 2013, the highest levels of antibodies were found against pathogenic *Yersinia* (60%). The seroprevalence of antibodies was 18% for *Salmonella* and 1% for *T. gondii*, while *Trichinella* antibodies were not detected (Felin, 2019).

In the respect of the future RB-MSAS, serological *Salmonella* monitoring would enable to farm-level trends to be followed and would detect changes readily and sensitively. *Yersinia* serological results should be included in FCI thus providing the abattoir with the opportunity of logistic slaughter for high-risk batches or implementing other risk mitigating measures (Felin, 2019). Although the seroprevalence of *T. gondii* was very low, the monitoring could be targeted to small fattening farms and outdoor farms. By including *T. gondii* serological results in FCI, abattoirs could risk-rank farms according to their *T. gondii* risk and freeze or heat carcasses from high-risk farms. Serological monitoring of *Trichinella* is not necessary in the current situation, as virtually all pigs are tested at slaughter using the digestive methods, and the seroprevalence is 0%. However, as routine *Trichinella* testing is to be diminished, sero-surveillance could be used to verify the biosecurity of controlled housing conditions.

In conclusion,

1 Records for on-farm health/animal welfare indicators such as tail biting or coughing, previous post-mortem findings from a pig herd, and condemnation rates, could be useful for RB-MSAS.

2 The architecture of the data flows between farms, abattoirs and CA (and other meat chain actors) will be critical for effective RB-MSAS. Who owns the data and who has access to them will be critical questions? The management of data will be crucial in any RB-MSAS.
3 The usefulness of monitoring antibodies against food safety hazards such as *Salmonella* or *Yersinia* could enable adapted risk mitigation strategies at slaughter.

Estonia – RB-MSAS

Country structure

In Estonia during 2018, 537,632 pigs, 35,036 cattle, 9,331 sheep and around 12 million broiler chickens were slaughtered. Forty-six companies were authorised to slaughter animals, of which 40 were active in 2018. There are 28 abattoirs in Estonia that are authorised to slaughter cattle; 27 abattoirs to slaughter pigs; 20 abattoirs for sheep; 11 for goats; 1 large-scale for broiler chickens, 2 for horses, and 1 is authorised to slaughter rabbits.
The numbers of slaughtered animals in the two biggest Estonian abattoirs were 106,309 and 288,347 pigs and 4,076 and 11,410 cattle, respectively. Currently there are 80 authorised meat-handling establishments (abattoirs not included) dealing with production of minced meat, mechanically separated meat, meat preparations and products thereof.

Certification of meat industry companies in Estonia

The certification schemes or industry standards in use are ISO 22000:2005 (8 meat companies) and FSSC 22000 (one meat company). All other meat enterprises do not have certified food safety systems but are acting in accordance with Reg. (EC) No 852/2004, Article 5 point 1, which says the FBO shall put in place, implement and maintain a permanent procedure based on the HACCP principles.

RB-MSAS example – vertically integrated management system

In the only large-scale chicken meat production unit in Estonia has vertically integrated production through ownership or control by one feed production company, farms, abattoirs and meat processing plants. This vertical integration enables in-house data sharing, as well as decisions on where the optimal risk mitigation efforts should be set in feed production, on farms, at the abattoir or at meat processing. The company handbook of integrated management system (IMS) is electronic and available for all company employees, business partners, the CA and certification bodies. It contains all applicable procedures, instructions, requirements and forms required by the chicken meat producing company. The IMS handbook also provides an overview of the processes and requirements that are monitored in process management. A more detailed description is given in the relevant procedures, manuals and other documents to which the relevant parts of this manual refer. At planned intervals, i.e., once a year, the management of the company reviews the IMS to ensure its continuing suitability, compliance and verified performance.

The meat company has cereal-based full-feed, mostly from its own production units. The on-farm focus on housing with carefully monitored conditions; there is strictly controlled use of medications/antibiotics and hygiene guidelines including all in-all out (batch) production. The company has its own accredited laboratory carrying out 150,000 analyses per year. Most

analyses relate to fresh meat, drinking water and hygiene control for machinery and other production surfaces.

The company's integrated management systems include:
- FSSC 22000 certificate for its food safety management system;
- ISO 17025 certificate for its laboratory management system;
- ISO 14001 certificate for its environmental management system;
- OHSAS 18001 certificate for its occupational health & safety management system.

The goals of the IMS indicate the complex contexts any RB-MSAS will be working within, and include to:
1. Ensure product safety through risk assessment, risk prevention and HACCP systems for raw materials, production processes and final products;
2. Be reliable and customer-oriented, and do not pose food safety risks to consumers;
3. Ensure the safety of employees through risk assessment of the work environment and the measures taken, and take preventive action to prevent damage to health and the environment;
4. Reduce the environmental impact of production through the efficient use of resources and materials and the use of the best available technology;
5. Ensure compliance with legislation and good practices;
6. Contribute the company's practical knowledge towards the development of future RB-MSAS;
7. Continually improve and share the company knowledge in food safety, the environment and the working environment and direct staff, suppliers, customers and consumers to implement them through the appropriate communication;
8. Require that suppliers and partners comply with relevant food safety, environmental and occupational safety requirements;
9. Ensure continuous improvement of the management system by assessing the effectiveness of the management system and keeping it up-to-date.

Food safety risk assessment (ranking)

In the IMS handbook, the risk assessment procedure is reviewed at least annually and before the introduction of new products and processes as well as after the occurrence of food safety incidents. A food safety team led by a quality manager assesses the food safety risks. The Head of Food Safety has responsibility for assessment of food safety related risks. During hazard analysis, the food safety team identifies the potential hazards in and threats to the product and the appropriate risk ranking in terms of high, medium and low risks.

Sampling – an example of broiler chicken meat production

In addition to Reg. (CE) No 2073/2005 criteria, the meat company undertakes further sampling and analyses for the purpose of detecting and measuring other microorganisms, their toxins or metabolites, as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis within the framework of the self-control plan. The company has developed guidance documents for sampling, e.g., taking faecal, sock and surface samples to detect *Salmonella.* The additional microbiological criteria for meat preparations and meat products include *Clostridium perfringens, Bacillus cereus, Staphylococcus aureus,* and *Enterobacteriaceae*. Production environment surfaces undergo additional testing include aerobic plate count; *Enterobacteriaceae* count; presence of *Salmonella*, allergen residues, detergent/disinfectant residues.

In conclusion,

1. Vertically integrated production systems enable the establishment of RB-MSAS, but are not prerequisites;
2. The integrated management systems (IMS) from farm to chilled carcass and meat processing enables RB-MSAS to be embedded at all stages;
3. The example of risk ranking of hazards is one practical way of handling the risk managers' risk ranking problem.

In recommendation,
We recommend vertically integrating meat production systems to facilitate RB-MSAS. This does not necessarily mean one owner or company, but there has to be joint ownership or full collaboration of the RB-MSAS along the food chain.

Italy – RB-MSAS in Parma Ham production

Italy is divided into 21 regions. In the Emilia-Romagna region (Northern Italy), Parma Ham is produced in the small territory of Parma province. In Emilia-Romagna region, 119 pig abattoirs are active but have very different slaughter capacities, since only 5 can process more than 9,000 pigs/week. Only 10 abattoirs are certified to export outside the EU. Parma Ham production is strictly controlled by the Parma Ham Consortium in terms of pig breeds, pig provenance (10 regions only can rear pigs for Parma ham production), pig farming and pig weight at slaughter.

Case one – Antimicrobial residues in pork
During 2017, official controls according to the national residue control program detected sulfadimethoxine in pig meat from a batch of 135 pigs. The level of sulfadimethoxine in meat was 245 µg/kg, while the MRL was 100 µg/kg (Reg. (EU) No 37/2010). The FBO's traceability system was able to identify all further meat chain customers (but not all individual consumers after retail) supplied with the sulfadimethoxine-positive fresh meat. From the positive batch, a total of 18,000 kg of meat and 270 hams were obtained. However, not all the meat could be withdrawn from the market because 15 days had elapsed before the results were available.

Therefore, fresh meat could not be withdrawn from the market because it had already been sold and probably eaten by consumers. Processed products (cured hams, salami and other products) could be withdrawn from the market because the seasoning period had not yet come to an end (for Parma Ham and other long-cured meat products), or because they were still for sale (short-cured salami sausages).

The FBO carried out audits of the pig farm that supplied the animals treated with sulfadimethoxine. The farmer admitted that a mistake had been made, i.e., the antimicrobial was given to fattening pigs instead of to post-weaning animals on the day before slaughter.

After 270 Parma Hams and other long-cured products had been withdrawn from the market, the CA asked the Italian Ministry of Health if there could be a tolerance in products with production recipes/procedures that cause a reduction of the antimicrobial levels. For instance, salami is made of different batches of meat, in which not-compliant meat batches can be mixed with compliant batches and other ingredients. In such products, the dilution effect caused by the compliant meat could be effective in reducing the drug level below the MRL. This proposal was accepted by the Italian Ministry of Health, and salamis did not have to be withdrawn from the

market. On the contrary, products entirely made of meat with antimicrobial residues higher than the MRLs, such as Parma Ham, were withdrawn and condemned. The FBO lost more than €70,000 refunding all customers.

Case two – Control of *Salmonella* contamination of pig carcasses

Salmonella is considered a high risk for public health in relation to the consumption of pig meat. In Italy, the FBO own-check procedure states: The FBOs should meet the process hygiene criterion set by Reg. (EU) No 2073/2005 as amended. No more than 3 *Salmonella*-positive carcasses out of 50 are accepted. If 4 or more out of 50 carcasses are contaminated by *Salmonella*, the FBO should apply corrective measures.

Following an audit by US inspectors, one FBO was asked to strengthen its control of *Salmonella*, even though the requirements for pig meat export to the US had been met. Therefore, the FBO decided to control *Salmonella* contamination of pig skin by setting the temperature of water in the scalding bath at 71.0 °C. The pigs stayed in the bath for at least 6 minutes. Microbiological testing of scalding water was always negative for *Salmonella*.

In conclusion,

1. Recalls are contingent on a working traceability system;
2. Perishable foods that are consumed quickly might present higher risks for consumer exposures due to incomplete recalls;
3. Vertical integration is possible without ownership from farm-to-fork when production rules are clear and accepted by an FBOs own production partners.

Ireland – Meat Quality Assurance Schemes – Beef, Lamb, Pigs and Poultry

There are several meat quality assurance schemes in the Republic of Ireland, most of which are operated by Bord Bia (the Irish Food Board) which is different from the Irish Food Standards Agency (the CA). All of these schemes are accredited by the National Standards Authority of Ireland and to the European Standard EN45011 / ISO 17065/2012, so they are recognised internationally. They cover from farm, including feed production, to meat processing.

These schemes include the Sustainable Beef and Lamb Assurance Scheme (SBLAS), the Pigmeat Quality Assurance Scheme, the Meat Processor Quality Assurance Scheme and the Poultry Products Quality Assurance Scheme. The aim of these schemes, which are voluntary and based on current legislation, relevant industry guidelines and international standards, is to promote best practice in farming and processing.

The Sustainable Beef and Lamb Assurance Scheme includes such activities as; [1] stockmanship, capability and competence; [2] identification and traceability; [3] animal remedies and related equipment; [4] animal feeds and water; [5] land management; [6] specified management tasks: bovines; [7] specified management tasks: ovines; [8] animal health and welfare; [9] biosecurity and pest control; [10] housing; [11] transport; [12] environment; [13] farm personnel: health, safety and social sustainability and; [15] pesticides (plant protection products and biocides).

The Pigmeat Quality Assurance Scheme covers; [1] identification and traceability; [2] management responsibility; [3] animal remedies; [4] residue prevention; [5] animal feed and water; [6] animal health and welfare; [7] biosecurity; [8] genetics; [9] pest control; [10] housing;

[11] pig transport; [12] environmental protection; [13] health and safety and; [14] free range farmed pigs – additional requirements.

The Meat Processor Quality Assurance Scheme focuses on control activities in; [1] animal receipt and transport; [2] animal welfare; [3] beef / pig / lamb slaughter process; [4] poultry slaughter process; [5] chilling regimes; [6] cutting and boning; [7] special requirements for value added meat products; [7] inspection and testing meat processor quality assurance standard; [8] final product release; [9] product identification / traceability, reconciliation and recall; [10] handling, storage, dispatch and transport; [11] control of non-conforming product; [12] internal audits; [13] control of inspection, measuring and test equipment; [14] corrective and preventive action and customer complaints; [15] plant and facilities; [16] cleaning and sanitation; [17] pest control; [18] maintenance; [19] breakables; [20] exterior, structure and grounds; [21] interiors: general; [22] entry to production; [23] interior walls (processing and product storage areas); [24] ceilings and overheads; [25] floors; [26] drainage; [27] doors; [28] windows; [29] lighting; [30] knives, sterilisers, hoses and other equipment; [31] extraction and ventilation; [32] cleaning materials and storage; [33] effluent treatment; [34] food trays; [35] waste disposal general; [36] general; [37] medical records; [38] first aid; [39] personal hygiene; [40] personnel clothing and locker rooms; [41] personnel facilities including canteens; [42] toilet facilities and; [43] washing facilities in production.

The Poultry Products Quality Assurance Scheme includes; [1] production site; [2] housing and environment; [3] house preparation 3.5 day-olds sourcing; [4] flock health; [5] feed and water; [6] flock welfare; [7] site hygiene & biosecurity; [8] catching and transport; [9] health and safety on the farm; [10] air quality; [11] environmental protection and; [12] free range poultry.

In addition to the above, Bord Bia also operate a scheme to assure the quality of organic food and farming standards in Ireland, which describes the general standards for organic livestock production. The key elements include; [1] the requirements for the separation of organic & non organic livestock; [2] origin of livestock – stricter standards; [3] origin of livestock – EU regulations; [4] conversion of livestock & livestock products – stricter standards; [5] conversion of livestock & livestock products – EU regulations; [5] general management & welfare; [6] livestock housing; [7] bedding materials; [8] livestock diets; [9] products permitted in animal feeds; [10] animal health & veterinary treatments – stricter standards and; [11] animal health & veterinary treatments – EU regulations.

In conclusion,
The following strengths are in this set up:
- High coverage of Irish food producers;
- Accredited to national and international standards;
- The schemes are carrying out inspections independently;

The weaknesses include:
- Operated by a marketing agency rather than science-based organisation – conflict of interest?
- Not actively updated;
- Reliant on the collaboration with and input from all stakeholders.

The threats to these schemes include:
- Might become too cumbersome for FBOs and farmers;
- Lack of credibility;
- Must be updated to stay relevant.

The opportunities point also to the possibilities of integrating with a future RB-MSAS and include:

- Could complement and inform official control;
- Work proactively by educating FBOs and promoting a food safety culture;
- Active alignment of the schemes with EFSA opinions and scientific and technical progress;
- Enable working in a more risk-based manner.

Future RB-MSASs could be embedded in the Irish schemes. However, these future RB-MSASs must be updated continuously and be sufficiently funded to remain relevant and deliver high quality control. In this regard, supervision from the CA is needed.

Sweden – Removal of **Taenia saginata** *incisions in risk-based meat inspection*

One example where the current legislation supports moving to more risk-based meat inspection is the masseter incisions for *Cysticercus bovis*. The diagnostic sensitivity of the masseter incision is thought to be from 3 to 20% (Eichenberger et al., 2013 and Jansen et al., 2018), meaning only one out of 5 to 20 infected cattle will be detected at slaughter. Consequently, the test is useless as a meat safety measure for the individual carcass.

However, the incision of masseters has diagnostic value for monitoring the population of cattle going to slaughter. The incision of the heart musculature remains in force, thereby retaining the monitoring ability to detect bovine cysticercosis by post-mortem inspection. Moreover, it can confirm high-risk cohorts. If high-risk situations of beef contaminated with *C. bovis* are foreseen, then freezing or heat treatments of the beef would be appropriate risk mitigation measures.

Stopping incision of masseter muscles in beef cattle would have the following benefits:

- Economic gains, as whole beef is more valuable than incised beef – probably around €1-2 million for Swedish beef industry and cattle farmers;
- Improved occupational health, as masseter incision is linked to shoulder pains and problems for control staff – fewer days on sick leave;
- Longer shelf life of high-quality beef from reduced contamination by knives and operators – i.e., better sustainability;
- Lower risk of cross contamination of STEC and campylobacters. For example, 1-2% of Swedish cattle carries STEC. Since cattle carcasses are hung head down, the surface contamination from water at slaughter runs by gravity over the head. This water could inoculate the beef with pathogens and spoilage bacteria if the masseters are incised. When this beef is minced, one path for transmission of hazards like STEC to consumers of undercooked hamburgers is opened, as is cross contamination in the kitchen;
- Possibility of more efficient slaughter lines and control for beef.

In Sweden such a process was done during 2020 as a part of the general strategy to modernise meat inspection, making it more risk-based. According to article 30 of Commission Reg. (EU) No 2019/627, the CA may decide that incision of bovine masseters at post-mortem inspection is not compulsory if:

- the prevalence in the source population or in a well-defined subpopulation is below one in a million, as demonstrated with 95 % certainty; or
- no cases have been detected in all slaughtered animals in the past five years; or
- no cases have been detected in the last two years,

where this is supported and justified by the CA's risk analysis based on data from reporting

carried out in accordance with Article 9(1) of Directive 2003/99/EC.

The CA (the National Veterinary Institute), reported one case of bovine cysticercosis in 2017 (Table 10). Consequently, in Sweden the National Food Authority decided to go for the last approach (2 years' freedom) to be supplemented with a national risk analysis. This was done during the spring of 2020; masseter incisions were stopped by the summer 2020 and a follow-up 2-3 years later is scheduled to see if the intended benefits and savings have been realised.

Year	Nat Vet Institute (verified/ analysed)	Swedish board of Agriculture (SJV)	Swedish annual zoonoses report	Suspected findings at meat inspection	Number bovines slaughtered Sweden
2018	0/1	4 (M*, N)	0	10	409 349
2017	1/3	2 (M)	0 (1)	5	390 996
2016	0/1	4 (M)	0	7	394 932
2015	0/0	0	0	6	406 628
2014	0/0	1 (M)	0	3	406 088
2013	1/2	1 (E)	1	5	391 347

*Table 5: Incidence of bovine cysticercosis according to different notification systems. * County (län) in which the suspected animal originated (M = Malmöhus län, N = Hallands län, E = Östergötlands län).*

In conclusion some insights from the Swedish example are:

1. Some of the tools used for detecting safety and quality risks in fresh meat have low sensitivity. These tools are appropriate for population monitoring, but are not useful for individual animal testing.
2. The public health endpoint is hard to measure because infection with *Taenia saginata* is not a notifiable disease. Could proxy endpoints like use of drugs (praziquantel or niklosamid) for treating human taeniosis be used?
3. Need to weigh benefits vs risks and costs to make meaningful contributions to risk-based meat inspection. How to make simple but sufficient benefit cost analyses and risk benefit analyses seem to be a challenge.

The Netherlands – Supply Chain Meat Inspection of pork

In the Netherlands a novel RB-MSAS called the *Supply Chain Meat Inspection* was implemented for pork production in 2006. The general idea was a holistic HACCP approach to the assurance of meat safety for Dutch pork production and considering hygienic measures throughout the entire chain of production. The farm assurance system in which the pigs are raised is seen as an important basis to control relevant hazards to human health. Only pigs originating from farms participating in assurance systems recognised by the CA are allowed in this system. The idea of including critical control points at farm level which can be verified at the abattoir level are a clear example of the holistic approach.

Risk ranking of hazards

To identify relevant hazards for food safety, the system uses data on human incidence of foodborne illnesses. The frequency of occurrence of an illness and the severity of the illness, i.e., disease burden, are used to calculate the relative relevance of the hazard causing the illness. This relevance is connected with the source attribution – is pork a main source of the foodborne hazard?

To illustrate; foodborne illnesses caused by *Salmonella* are frequently reported to be attributed to pork consumption. The outcome of such an illness can be very severe, and the hazard *Salmonella* is, therefore, identified as a high-ranking hazard in pork production (Figure 3). As another example, *Campylobacter* can cause severe illness but is not frequently attributed to the consumption of pork. This hazard is, therefore, identified as a less high-ranking hazard (than *Salmonella*) in pork production. The process is repeated for all known hazards in pork production. The list is dominated by the hazards *Salmonella*, *T. gondii*, *Listeria* and mycobacteria.

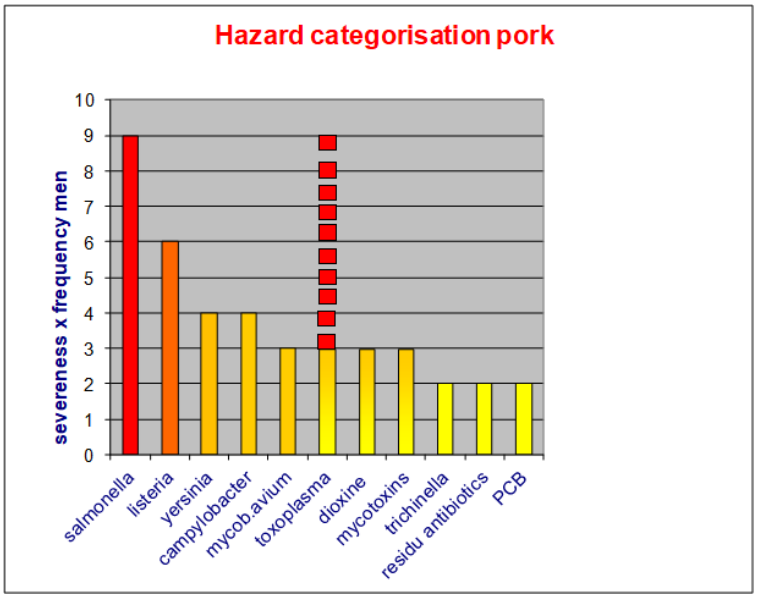

Figure 3 Hazard categorisation in the Supply Chain Meat Inspection of pork program in the Netherlands. When taking into account the effect of Toxoplasma gondii *on the health of unborn individuals, the relative position moves towards the left as the disease burden of* Toxoplasma *increases.*

For these high-ranking hazards, specific control measures have to be identified and implemented at the most effective locations (levels) in the production chain (Fig 4). This could both mean (critical) control points at farm level, slaughter and/or at further meat processing.

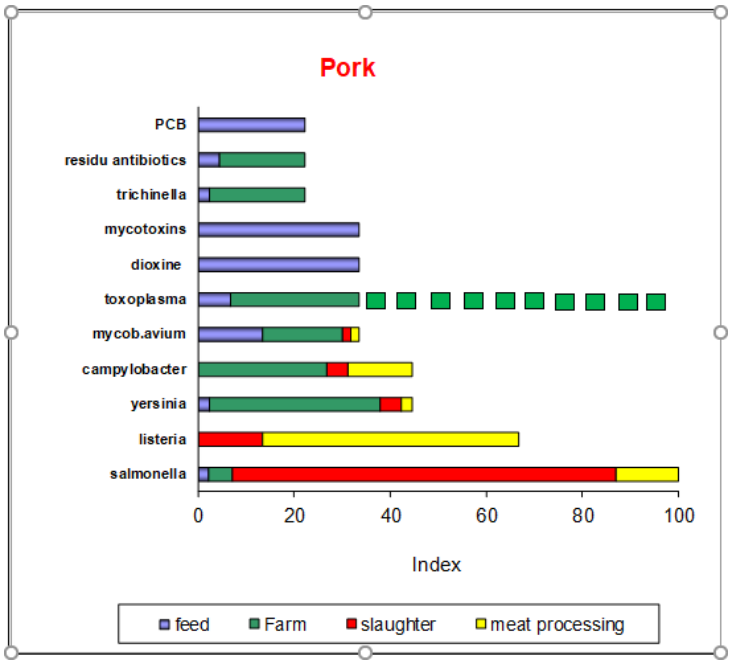

Figure 4 Estimated relative contribution in the chain to the risk for different hazards in the Supply Chain Meat Inspection of pork in the Netherlands.

To monitor and assess the performance of the farm control measures, a systematic blood sample collection at abattoir level was developed. For example, through analysing blood samples for antibodies against *Mycobacterium avium* and *T. gondii*, the system monitors the control at farm level in every batch of animals sent to the abattoir. A feedback loop ensures this type of relevant FCI finds its way back to the farm of origin, where the FCI informs corrective and preventive measures taken to control the hazard.

The system has been in place for several years and has been effective in controlling relevant hazards in pork production. It is an example of a risk-based approach to a RB-MSAS to improve meat safety and with a clear separation of responsibilities between private and public parties. Where private parties are responsible for implementation of control measures and managing performance levels, the CA supervises and audits the system. Its requirements are publicly available and are, therefore, easily integrated in existing pork supply chains.

In conclusion:
1. The Supply Chain Meat Inspection system for pork Netherlands is one example of RB-MSAS;
2. There is a clear separation of tasks between the CA and private parties running the program;
3. While the solutions to control risks can differ, this example offers a blueprint for how to assess risks and interventions.

Australia – balancing domestic and export requirements

Setting standards, official controls and third party schemes

Australia is a commonwealth of states, and according to the constitution, state governments have responsibility for agriculture, health, and therefore, for food standards. The balance of responsibilities and cooperation, developed over the 120 years of federation, has resulted in a degree of uniformity, despite the individual constitutional responsibilities of state jurisdictions, through bodies and standards developed on a voluntary basis. Uniform expectations, expressed in terms of outcomes, have encouraged the development of national schemes that contribute to compliance.

Food standards, including the primary processing aspects, are embodied in the Australia New Zealand Food Standards Code developed by Food Standards Australia New Zealand (FSANZ) a statutory authority in the Australian Government Health portfolio (FSANZ, 2023a). The standards in the Australia New Zealand Food Standards Code are legislative instruments. There are standards for poultry meat and other meat, both of which only apply to Australia (FSANZ, 2023b). State laws also govern on-farm activities and meat processing activities, so the Australia New Zealand Food Standards Code only provides statements of the outcomes to be achieved and references standards enforced by state laws.

With respect to non-poultry meats, the Australian Standard for Hygienic Production and Transportation of Meat and Meat Products for Human Consumption, AS 4696: 2007 (CSIRO, 2007) applies in all states, although they differ in their administrative structures and methods of

enforcement. Standard AS 4696: 2007 combines the statement of outcomes expected to be achieved by each part of the Standard with prescriptive approaches to achieving the outcome. Standard AS 4696: 2007 is centered around meat processing operations, but it is pivotal to the whole chain because it includes the supply and admission of animals for slaughter as well as traceability, storage, handling and transportation of meat. Significantly, Standard AS 4696: 2007 states, in the preface: 'Where a meat business proposes a technique different from one detailed in this Australian Standard the assessment of equivalence is to be determined by the relevant controlling authority.' and then provides a conceptual framework for establishing equivalence.

For the purpose of export, importing country requirements must be met. These requirements can be thought of as either technical or administrative. Some importing countries require additional technical requirements (e.g., EU requirements concerning hormonal growth promoters), while others require additional administrative requirements (e.g., advising which CA has provided certification). For this reason, amongst others, the Australian Department of Agriculture, Water and the Environment (2023), supervises and certifies most meat processing establishments packing product for export. For export of product to the EU, the systems at the meat processing establishments are periodically audited by the EU Food and Veterinary Office (FVO).

The need to operate a national system within a federated country has lent itself to development of industry-wide systems to assist in compliance with outcome-based regulations. Third party compliance and verification schemes are, thus, an essential part of a thorough system and will be described in the following section.
In conclusion, according to the Australian experience:

1. Outcome-based regulation allows for multiple methods of compliance;
2. Equivalence determination provides a risk-based method of maintaining public health;
3. Third party schemes can be an efficient means of complying and demonstrating compliance;
4. Third party schemes can be flexibly applied to new risks to a meat safety outcome.

Schemes contributing to compliance

A critical aspect of a RB-MSAS is the health and safety of animals coming to slaughter, particularly for aspects that are not easily assessed at ante-mortem or post-mortem inspection.

In the Australian red meat (beef, sheep meat, goat meat) supply chains, the most fundamental system requirement is for identification of animals (National Livestock Identification System). Additionally, requirements exist for managing the safety, welfare and biosecurity aspects of the animals (Livestock Production Assurance) and passing that information through the supply chain (National Vendor Declaration).

The NLIS (National Livestock Identification System) enables livestock to be traced from their property of birth to slaughter (Integrity Systems, 2023a). All animals are identified with an accredited NLIS tag or device from their property of birth (identified with a property identification code). As animals are bought, sold and moved along the supply chain, each movement is recorded centrally on the NLIS database. Using this information, the NLIS is able to provide a life history of an animal's movements. Using NLIS is the only means of meeting the requirements of state-based legislation on recording animal movements. It is an industry-owned and -operated system, complying with rules agreed between state jurisdictions and industry bodies.

LPA (Livestock Production Assurance) is an on-farm food safety and quality assurance accreditation program (Integrity Systems, 2023b). The requirements include assessing the property for risks such as persistent chemicals from contaminated sites, application of animal treatments, providing safe feed, ensuring animals are fit for travel prior to leaving the property, ensuring biosecurity, ensuring animal welfare and recording animal movements. The LPA program operates under Rules and Standards agreed to and maintained by the Integrity Systems Taskforce. Accredited producers must operate in accordance with these Rules and Standards, and agree to do so as part of the LPA accreditation and reaccreditation process. LPA is a voluntary accreditation and audit system that is commercially required by most meat processors because it provides the necessary assurance of supplying animals that comply with the requirements of Australian legislation.

The NVD (National Vendor Declaration) provides food safety-related information about the animals being transferred from one owner to another and can only be used by an LPA-accredited animal owner (Integrity Systems, 2023c). The NVD communicates the food safety and treatment status of every animal every time it moves between properties, to sale-yards or processors. NVDs are a legal document that are key to Australian red meat traceability and market access, and act as movement documentation throughout the value chain. The farmer's declaration must be backed up by accurate farm records. Hence, the farmer pledges that the meat from the farm has been produced safely, ethically and meets biosecurity requirements. Moreover, the NVD specifies whether an animal has been fed restricted materials, by-products (anything other than fodder crops), been on a property with persistent chemical residues or with areas affected by sprayed crop chemicals, i.e., critical food safety-related information, This allows the purchaser (another farmer or abattoir) to assess the food safety risks of the animals, whether additional actions (such as residue testing) are necessary, and for which markets the animal is suitable (e.g., based on use of hormonal growth promoters). A paper-based system is giving way to electronic completion of declarations by sellers and transmission of data to purchasers.

There are a number of other schemes associated with feed production, use of agricultural chemicals, and operation of feedlots, sale-yards, and animal transport etc. but the above systems form the basis for the assurance of red meat safety. The system is overseen by a government-industry partnership aptly named SAFEMEAT (2023).

In conclusion:

1. Quality assurance schemes allow a flexible and responsive approach to meeting meat safety requirements;
2. Open dialogue about the operation of schemes, and verification of effective operation are both necessary;
3. The operation of schemes can provide opportunities for ongoing education and involvement of the whole supply chain in delivering the standard of safety required.

UK – Results of a Food and Veterinary Office (FVO) inspection on synergies between official controls and third party certification schemes

An EC FVO report describes the outcome of a fact-finding mission of the Directorate-General for Health and Food Safety in the United Kingdom carried out from 4 to 12 October 2017, as part of its planned work program (European Commission, 2017). The objective of the mission

was to gather information on the way and the extent to which the CAs take account of the results of own-check systems and third party assurance schemes in organising official controls in food of animal and non-animal origin.

There have been synergies between third party certification schemes and official controls in the UK for many years. Under the Earned Recognition program, the UK FSA recognises membership and certification for specific schemes, enabling reduction of the frequency of official controls. The requirements of the program and obligations of the parties involved, namely the FSA and the scheme concerned, are laid down in joint memoranda of understanding. Both the UK FSA and the schemes concerned have introduced measures to ensure the reliability of the information. Furthermore, the required self-auditing functions as a reminder to the farmers/FBO and staff of the requirements of the scheme and their obligations. Audits also act as tools for training staff allowing them to learn what and why something is required, how and when a check is done and where the relevant documentation is located. In addition, the UK FSA provides pre-recognition assessment of the schemes, thorough theoretical and practical training of (CB) auditors on a scheme's requirements, organised and delivered by the scheme and witness audits of CB auditors both from the FSA and the scheme's owners.

The approved assurance element of the Earned Recognition program is, to date, limited to the primary production sector. However, the UK FSA has been exploring the possibility of extending this system to include the processing sector by recognising additional third party certification schemes. The system has led to reductions in the frequency of official controls, freeing up resources for other issues. The degrees of reduction in the frequency of official controls vary across the UK, even though the same commodities were concerned. However, in some cases, the frequencies established mean that some FBOs will never be subject to an official control in a lifetime.

Although synergies between official controls and third party certification schemes have reduced official controls and saved resources for the CAs, they do not necessarily contribute to a reduction on the regulatory burden of FBOs. This is because official controls constitute only a minor part of the scrutiny the FBOs are under.

In conclusion:

- Third and second party verification schemes could be efficient options risk based meat safety;
- Often these schemes are linked to food retailers' private labels thereby facilitating vertical integration of the food chain;
- The FBOs' regulatory burdens may not diminish, as the second and third party schemes might just as onerous as the official controls;
- The official controls should recognise but also supervise and audit the second and third party schemes if they are to replace the on-site official control;
- Second and third party schemes could rapidly promote the spread of best practices in the meat chain;
- Earned recognition schemes could be important elements of future RB-MSASs.

A conceptual framework for pork RB-MSAS

Maximising **cost-effectiveness** and **cost-efficiency**, together with facilitating technological innovation, will be the inherent goals of future RB-MSAS. The modern meat safety system is: (1) risk-based (focused on the high-risk hazards with the aim of reducing the overall meat safety risk), (2) longitudinally integrated (multiple interventions or measures along the food chain are necessary to achieve required meat safety goals), and (3) flexible and dynamic (adaptable to changes). The main responsibility for meat safety is now held by FBOs, while the CAs have advisory and auditory roles in official controls, along with their role of acting if FBOs do not comply (Blagojevic et al., 2021) and pursue important tasks in ante- and post-mortem inspections.

A future RB-MSAS will need a carefully designed flow of information between farmer and abattoir as outlined in Figure 4. Diagnostic indicators for the pork-borne hazards at farm level can be obtained by categorisation of herds using serological and bacteriological testing of herds. For *Salmonella*, *Y. enterocolitica* and *Toxplasma gondii*, sampling of blood/meat juice with serological methods can provide evidence of the exposure of the pig (and consequently of the farm) to the pathogen, but not the animal's current health status, which can be determined by microbiological testing of faeces or lymph nodes. Testing of carcasses at slaughter may not be indicative of the health status on farm, because post-farm cross-contamination can take place during transport/lairage/ slaughter. In a similar way, the ante- and post-mortem inspection findings need to be collated, aggregated and available for analyses by the risk managers.
What is important is the ownership and access to these pieces of information. The abattoir, CA and farmer all need access to these data. For the foreseen risk management model to work, we need real time access to data on the epidemiological indicators. For farmers the feedback will be important for their animal health and welfare management.

In conclusion:
1. We propose that a regular flow of information between farmer and abattoir should inform the day-to-day risk management;
2. These data will have to be available to the CA, abattoir, risk managers and farmer;
3. This would be the key element of the tier 4 risk assessment on site at the abattoir.

Managing pork borne hazards as example

Salmonella* and *Y. enterocolitica – Pigs presented for slaughter can carry *Salmonella* and *Y. enterocolitica* in their intestinal tract and/or on the skin. In addition, *Y. enterocolitica* can be present in tonsils or lymph nodes. Slaughter practices can either decrease or increase microbial contamination of pig skin; for instance, dehairing, polishing and evisceration increase the microbial load of the skin, while scalding, singeing and final washing decrease it (EFSA, 2006). In the pork chain, a 2-log reduction (99%) of *Salmonella* numbers on carcasses would result in 60-80% reduction of human cases due to pork consumption (EFSA, 2010). Several measures could reduce *Salmonella* and *Y. enterocolitica* contamination of pig carcasses (Alban and Stark, 2005), e.g.,

1. reducing transport and lairage time;
2. effectively sanitising the lairage environment;
3. replacing tank scalding with spray-scalding;
4. plugging the anus before the dehairing machine;

5. repeating the singeing step after polishing;
6. reducing slaughter-line speed;
7. hot water decontamination of carcasses;
8. completely separating the heads from carcasses before any handling and;
9. using blast-chilling.

The differences amongst abattoirs in terms of reducing microbial contamination of carcasses could suggest the need to categorise abattoirs in respect to risk management abilities concerning *Salmonella* and *Y. enterocolitica.*

Toxoplasma gondii – Positive pigs can only be detected by laboratory testing, but to the test is not as sensitive as needed, so low densities of parasites in tissue muscle (1 cyst per 25 gram or more) are difficult to detect. An alternative is on-farm serological testing of meat juice and categorisation of farms. Pig carcasses originating from *T. gondii*-infected farms should undergo a reliable and validated cyst-inactivation method, such as freezing (-20°C for 11 days) or heating (58°C for 9.5 min or 61.3°C for 3.6 min) (Dubey, 1974; Dubey et al., 1990).

Trichinella – does not cause symptoms in pigs and therefore larvae encysted in muscle can only be detected post-mortem by laboratory testing. As for *T. gondii*, it seems that inactivation of *Trichinella* larvae is the most suitable approach to pork safety assurance. For example, heating meat at 71 °C for at least 1 min, freezing at -15 °C for 3 weeks (meat pieces up to 15 cm in thickness) or 4 weeks (meat pieces up to 50 in thickness) or irradiation (e.g. 0.3 kGy for sealed, packaged food). Smoking and curing are not reliable enough because of difficulties in monitoring and standardising the processes (Gamble et al., 2000).

Since cross-contamination at slaughter does not occur for these parasites, it is not necessary to separate pigs from positive or negative herds.

Possibilities for risk management of pork-borne hazards

EFSA proposed setting ***Salmonella*** **and** ***Y. enterocolitica*** **targets for chilled pig carcasses** (EFSA, 2011a)**.** These abattoirs should achieve these targets, but should have several degrees of freedom on how to achieve them. Achieving the targets is a function of a) abattoir process hygiene; b) presence/level of the hazards in incoming pigs (EFSA, 2011a). A risk analysis should inform the choice of ways and means to achieve the targets (Figure 5).

Trichinella **and** ***T. gondii*** **targets –** The appropriate level of protection for *Trichinella* is foreseen to be no *Trichinella* food safety risk, i.e., absence of its viable forms in pork. This criterion would have to be defined as absence in a sample of e.g., 25 grams of pork. This could be achieved through biosecurity on farms thereby ensuring that the compartments are *Trichinella* free, by testing as for the conventional method today or by freezing or heat treatments. A similar approach could be taken for *Toxoplasma*, although there is as yet no agreed acceptable level of protection. Figure 6 outlines a possible pork carcass safety assurance with respect to *Trichinella* and *Toxoplasma gondii* (EFSA, 2011a).

Figures 5 and 6 outline how the risk management might work. The key principle is to split incoming animals according to the risk they present, at least into high- and low-risk bacthes, and then to have appropriate processing to ensure the performance objective or prevalence targets on the chilled carcass are met. High-risk batches will undergo different handling, additional

treatments or processing compared with low-risk batches. Further post-harvest, carcass refrigeration and maintenance of the cold chain will remain key elements of the pork safety assurance framework.

In conclusion,

1. Risk based meat inspection the incoming animals should be ranked according to the risk they present, at least into high or low risk batches.
2. The slaughter and processing will have to be different to ensure that both high-risk and low-risk batches achieve the same targets in terms of chilled carcass prevalence (Performance Objectives).

DISCUSSION AND SYNTHESIS

The overall pattern in Europe and globally is a move towards risk-based meat safety assurance. This has been through changes of legislation in the EU. By reducing incisions and palpation of carcasses and viscera, the between-carcass cross-contamination by biological hazards was reduced. For example, Regulation (EU) 2017/625 and 2019/627 allow visual-only inspection for pigs, young domestic sheep and goats, and solipeds (with the exception of grey horses inspected for melanosis). For other animals, palpation and incisions was reduced to a few organs and parts of the carcass. Only in the case of high-risk animals, when risks for human health, animal health or animal welfare were suspected, will the official veterinarian palpate and incise parts of the carcass (Reg. (EU) No 2019/627 Article 24).

In this context of visual inspection of carcasses, novel technologies, sensors and cameras coupled with artificial intelligence (AI) might help in detecting gross lesions, such as imaging for faecal contamination, abscesses and haemorrhages. Detection of faeces or abscess gives rise to the suspicion of the presence of pathogens and/or contaminants (antibiotics). Sensors can aid the monitoring of chilled carcasses and indicate need for specific laboratory testing.

The current EU legal framework enables pilot or proof of concept studies in current operations as a way to test novel concepts and develop a more RB-MSAS. We foresee many pilot and proof of concept studies assessing different approaches to meat safety assurance. It is, therefore, important that member states notify each other, on scientific and technological progress.

As a special case, the incision of bovine masseter muscles for recognition of *Taenia saginata* cysts can be terminated according to the procedure in Reg. (EU) No 2019/627 Article 30. The key concern is whether the procedure contributes to lowering the risk to consumers. Therefore, a review and assessment of changes in the food safety risks, derived from the reduction in incision of masseter muscles in bovines should be done according to the procedure in Article 30. .

In the future, risk managers employed by FBOs and official veterinarians will work side by side, communicate risks and solve problems together, although with a clear division of responsibilities – risk management and auditing of RB-MSAS, respectively. Large-scale businesses are more equivalent partners with the CA and are able to protect their economic interests. However, this future approach of RB-MSAS could be a challenge in small- or medium-sized family businesses, where their meat safety assurance culture is influenced by long-lasting traditions and limited economic resources. We suggest that industry or collaborative solutions should be developed e.g., the FBO can comply with joint industry guidelines or can employ equivalent risk mitigation alternatives. The CA’s job is to supervise the joint industry

guidelines or the risk mitigating alternative. Official veterinarians will continue performing official controls for food of animal origin, as stated by EU legislation.

FBOs that implement private standards or third party guidelines should have the effort recognised by the CA. While the regulatory burden for FBOs may not diminish when they want to comply with private standards, other standards should be able to offer more adapted and fit-for-purpose risk management. Competition between and evolution of private or third party standards would be beneficial for food and meat safety. In the case of vertical integration of meat supply chains from farm to fork it is important to carefully design the flow of information between all stages of the meat chain, the control points best mitigating the risks and the optimal risk management. Vertical integration along the meat chain from farm to fork tends to align the incentives of all FBOs involved in terms of food safety and profitability.

This broad context of the RB-MSAS is supported by Reg. EU No 2017/625 with its scope of food safety, food integrity and food wholesomeness at all stages of food production, processing and distribution of food. This include rules aimed at ensuring fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food. The CA should perform official controls regularly, on a risk basis and with appropriate frequency, in all the sectors and in relation to all operators, activities, animals and goods governed by the EU food chain legislation. The frequency of official controls is set by the CA and is adjusted to the risk and to the level of compliance expected in different situations, including fraudulent or deceptive practices. We propose that third party schemes, industry standards and guidelines, and vertical integration are relevant elements for the CA to consider in this regard.

RIBMINS' most important aim is to spread the RB-MSAS culture to as many actors as possible, small-, medium- and large-sized FBOs and all CAs, so that new perspectives and a high level of consumer protection become a reality. In this regard, only fit-for-purpose and results oriented (output based) work will be the basic tenets. Recalling Article 14 of the General Food Law [Reg. (EC) No 178/2002], food is considered unsafe if it is injurious to human health and/or unfit for human consumption. We believe a RB-MSAS through will help the FBOs comply with the legislation, and facilitate the application of new technologies and private or industry standards (Global Red Meat Standard, ISO 22000, FSSC, IFS, BRC).

The current EU legal framework enables pilot or proof-of-concept studies in current operations as a way to test novel concepts and develop a more risk-based MSAS. It is, therefore, important that member states report to each other scientific and technological progress, such as pilot studies on novel practical arrangements of meat inspection offering equivalent food safety. A RB-MSAS for production of safe meat can be embedded in quality assurance programs or schemes with multiple purposes. This includes acceptable levels of chemical and/or biological hazards, control of food fraud, shelf life of meat products, animal welfare indicators, enhancing sustainability by limiting food waste and losses, and improving efficiency of the food value chain.

This means the FBO risk manager has to be able to work in a complex context with a multitude of aims and tasks. This has implications for the required skills of the risk manager at the abattoir and, a team approach will be required.

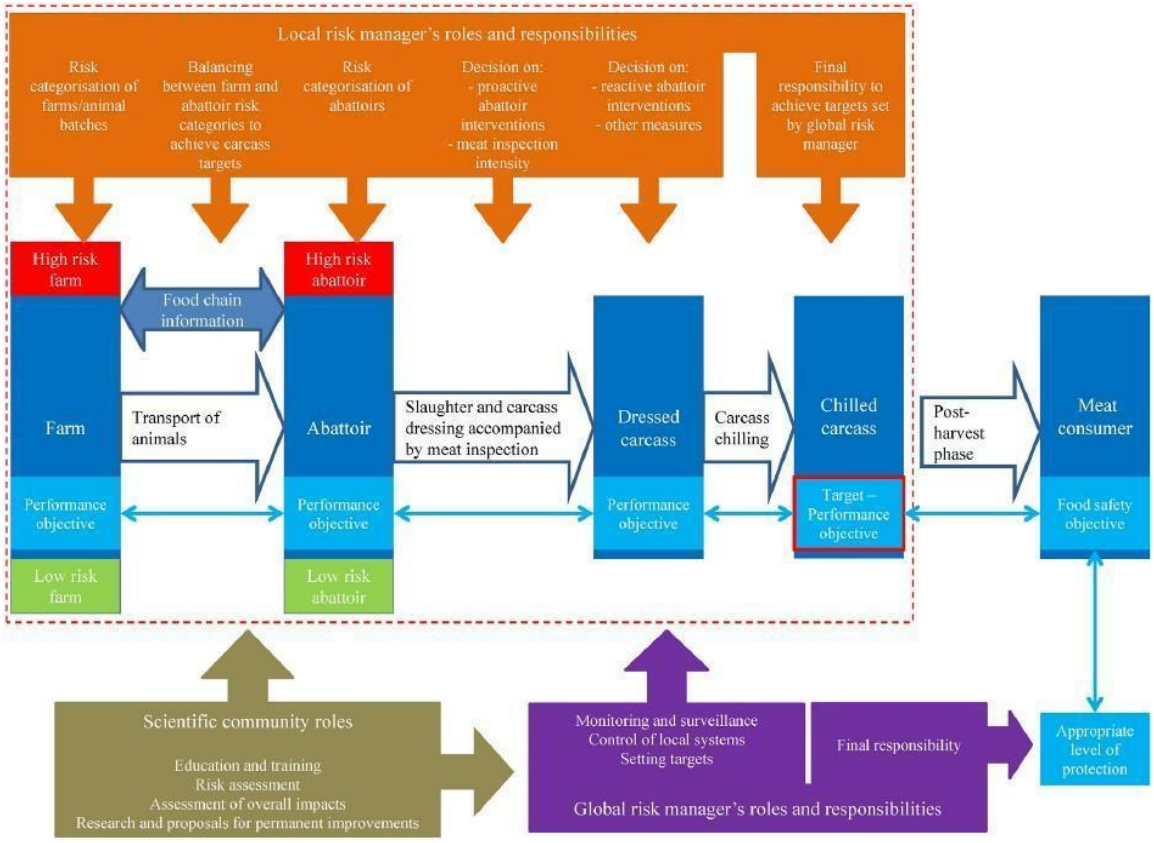

Figure 8: New RB-MSAS as defined by EFSA and described in Blagojevic et al. (2021).

CONCLUSIONS AND RECOMMENDATIONS

TOR A - To provide a systematic and detailed description of RB-MSASs currently in place, wholly or in part, with working examples illustrating functions and outputs.

Conclusions

1 FBO operated RB-MSASs are variable and highly dependent on resource availability (size of the FBO) and the collaboration with CA.

2 Current RB-MSAS reserves some tasks in many abattoirs for the OV, e.g., ante- and post-mortem inspection. In poultry, lagomorph and fish abattoirs, the situation is different, allowing more latitude for FBO risk management.

3 The most important meat-borne zoonoses (salmonellosis, campylobacteriosis, yersiniosis, STEC infection) are usually asymptomatic in food-producing animals and cannot be detected at post-mortem inspection.

4 The current meat inspection procedures do not mitigate chemical hazards.

5 Farms and abattoirs are connected by the FCI or a declaration by the supplier, which are

part of the documentation used to carry out ante-mortem inspection of animals and establish their suitability to be slaughtered for human consumption. Nevertheless, the flow of information is often ineffective, and FCI are lacking several parameters that could be crucial at slaughter (e.g., the on-farm prevalences of high-risk biological hazards in animal batches and data on the quality and safety of feed).

6 The traceability system currently in place for the beef chain is useful in cases of non-compliance to track food sources and to inform consumers about meat origins, but it is not linked to other safety information.

7 The current system is mainly based on the control of different processing plants according to their ability to guarantee the safety of food products. No categorisation exists according to the functional ability of an abattoir or meat plant to manage contaminated meat batches. As suggested by EFSA, such categorisation is very important to allow the delivery of meat batches to plant according to their risk management abilities.

8 Equivalence is a primary concept. Being able to provide evidence of a similar food safety outcome in different settings is fundamental to a risk-based approach in design and implementation of any future RB-MSAS.

Recommendations

1. The information on priority hazards should guide the focus of RB-MSAS.

2. A farm-to-chilled carcass continuum makes sense only if the health status of the animals is well known, especially for those meat-borne zoonoses which usually do not cause clinical diseases or macroscopic lesions in the infected animals. In many EU countries, proper control plans at farm level are lacking for the most important zoonotic agents (*Salmonella* in pigs; *Campylobacter* in poultry; STEC in cattle), with the exception of *Salmonella* in poultry.

3. Free-flowing FCI with all required data needs to be implemented fully.

4. Private assurance schemes are second or third party owned solutions that allow a flexible and responsive approach to meeting safety requirements, guaranteeing commercial advantages over competitors. Private and or third party assurance schemes deal with product characteristics such as quality, origin and trademark going beyond food safety and they inform and improve the launching and functioning of RB-MSAS. However, a FBO's regulatory or supervisory burden may not diminish as the second and third party schemes might be just as onerous as the official controls.

TOR B - To provide guidance on transition from current RB-MSASs to a "fit-for-purpose" RB-MSAS of the future.

Recommendations

1 The RB-MSAS of the future should be risk-based. Risk assessments needed for running a risk-based meat assurance will have to be hierarchical (tiered) from multinational (EU), to national, and regional levels. The EU-level, national and regional risk assessments will be

informed by implemented monitoring and surveillance activities. These activities should be under the supervision of the CA. Risk assessments should be updated annually or when new information is available. Private FBO-RB-MSASs can, beneficially, be embedded in FBOs' quality assurance schemes.

2 Food safety is the primary goal of RB-MSAS. The scope of the future RB-MSAS will need to take into account aspects different from food safety. Therefore, future RB-MSAS will balance competing interests and concerns.

3 The RB-MSAS of the future should be fit-for-purpose. As an example, small- and medium-sized businesses will need generic FBO-RB-MSAS or industry guidelines to enable them to achieve the same levels of protection as large-sized food businesses. However, the small- and medium-sized food businsees should have the necessary minimal expertise to apply the RB-MSAS.

4 There is a potential for remote control activities to assure meat safety in an efficient way.

5 The RB-MSAS must ensure robust provenance and traceability for animals, meat and meat products, thereby enabling some protection against food fraud and providing some food defense hurdles.

6 The official veterinarian (the CA's employee) should focus more on auditing and controlling the risk management implemented by the abattoir and less on operations like ante- and post-mortem inspection.

7 A vertically integrated RB-MSAS required the free flow of effective FCI to allow prioritisation, aggregation and accumulation of data pre-harvest, at slaughter and at post-slaughter steps in the chain. Effective FCI requires each meat batch to be matched electronically with its dataset that is available to all FBOs and the CAs in the chain to help ensure meat safety.

8 Some additional data, not currently being collected, must be added to current FCI.

9 RB-MSAS should also offer generic prevention of chemical hazards and support mitigation of such risks if they occur.

10 Traceability and FCI should work in a properly coordinated manner to allow the tracking of meat batches along the chain and to specifically manage the risks for each batch.

11 Proper categorisation of abattoirs and logistic slaughter are needed to help manage food safety risks identified on farm.

12 Private RB-MSASs cannot be understood as control mechanisms but rather, as tools for the risk management. The operation of private RB-MSASs can provide opportunities for ongoing education and involvement of the whole supply chain in delivering the standard of safety required. If a private RB-MSAS is linked to a food retailer's private label, it can facilitate vertical integration of the food chain.

13 The CA should recognise, supervise and audit second and third party RB-MSASs where these are able to supplement the on-site official controls. Schemes such as the Earned

Recognition schemes could be important elements of future RB-MSAS.

14 Equivalence between private RB-MSAS requirements and the CA's official controls is important, but does not suffice for integration. While equivalence is vital, differences in the purpose, assessment focus and approach by a RB-MSAS from official controls means that equivalence does not equal the ability to function as a replacement for official controls. A critical point is the reliability of private schemes, in which delivery in practice can be a particular challenge. This results from the RB-MSAS being unable to enforce compliance. Currently, only CAs can enforce compliance.

15 Standardised methodology to assess the effectiveness of every RB-MSAS needs to be developed. Such assessment could consider effectiveness of the controls, reliability and performance of the RB-MSAS and/or its components, and equivalence with the CA's official controls.

16 CAs, FBOs, and private RB-MSASs need to work together to the benefit of a food safety culture. A strong food safety culture in food businesses is integral to the success of future RB-MSAS, given that each FBO has primary responsibility for food safety. Food safety culture requirements provide the terms of reference for the CA to audit the RB-MSAS. The food safety culture requirements also produce job descriptions for risk managers and their functions within a food business.

TOR C - To suggest outlines for risk ranking that could aid when designing or adjusting the RB-MSAS.

Conclusions

1 EFSA identified several hazards for different slaughtered species: pigs (*Salmonella, Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella)*, poultry (*Salmonella, Campylobacter* and ESBL-AmpC producing *E. coli*) and beef (*Salmonella* and STEC). Risk ranking is a helpful tool for prioritising these hazards and enabling a RB-MSAS. Risk ranking at regional level should target identified hazards by setting food performance criteria (e.g., EFSA proposed establishing performance targets on chilled carcasses for both *Salmonella* and STEC in beef). At the time of writing (2022), the EU has established performance objectives (prevalence targets) only for *Salmonella* and *Campylobacter* on chilled poultry carcasses (process hygiene criteria).

2 Risk ranking is a helpful tool for assessing the risks and enabling a RB-MSAS. Risk ranking could be a practical risk-based tool for the FBO as input to the RB-MSAS.

3 Emergent meat-borne hazards (HEV in pigs in the EU, *Taenia solium* in pigs in Greece) deserve more attention and show how a local level risk-based system is required to address specific risks.

4 FBO risk-based management activities are often fixed in HACCP procedures and (especially in small- and medium-sized food businsses) not frequently updated according to EU and national risk rankings and evaluations.

Recommendations

1 Risk ranking at EU level needs to be regularly updated based on CA data. A more

complete FCI is needed to facilitate the exchange of relevant information along the food chain.

2 Besides EU-level risk ranking, risk should be addressed also at national and regional levels, allowing specific interventions against food safety issues within the territory.

3 The FBO risk manager's activities should address EU and national/regional risks as they are identified, while focusing on the more probable risks for the FBO according to the FCI.

TOR D - To develop the competency profiles for risk managers.

We foresee at least two profiles: one for those responsible for the CA's official controls and one for those responsible for the RB-MSAS in the food businesses .

Recommendations

1 Future risk-based MSAS needs to be evidence-based and transparent. It will include transparent and explicit documentation of the respective roles of the involved FBOs, CAs and any third party accredited inspection bodies.

2 Two roles are foreseen for veterinarians as risk managers in the future RB-MSASs, i.e., one as official veterinarian employed by the CA to audit the implementation of RB-MSASs and to enable the CA to enforce all audit outcomes that prove non-compliance, and the other as the RB-MSAS risk manager employed by the FBO.

3 The roles of risk managers working for the CA and FBO should be clearly separated.

4 We anticipate there is a need for collaborative industry solutions for future RB-MSAS to fill the expertise gap in some small- and medium-sized abattoirs.

5 The risk manager employed by the CA enforces the regulations on meat safety and animal welfare. The CA risk manager uses official controls (audits) to verify that FBOs in their jurisdiction properly manage their own food safety risks. To do an audit, the CA risk manager periodically studies specific parts of the FBO-RB-MSAS and collects relevant information for the national CA. The CA risk manager carries out ante- and post-mortem inspection duties and certifies meat fitness for human consumption.

6 The risk manager employed by the FBO manages meat safety risks on behalf of the food business. The FBO risk manager additionally deals with all other quality issues linked to the wholesomeness of meat.

7 FBOs should have more responsibilities in ante-and post-mortem inspection of live animals and carcasses (as has already happened in poultry and lagomorph abattoirs in the EU). When there are no abnormalities detected during ante-mortem inspection that indicate a serious problem for human or animal health, and the FCI is verified, and a system is in place for separation of carcasses with abnormalities, contamination or defects, the case can be made for the FBO to undertake more inspection duties. Official veterinarians, employed by the CA, will maintain their role, inspecting only a representative sample of animals according to the envisaged risk. The acquisition of

inspection duties by the FBO requires the CA to audit the risk managers employed by the FBOs for appropriate levels of food safety culture.

8 A RB-MSAS requires real time management of risks from the identified hazards. Data availability and resource constraints currently make quantitative risk assessments difficult at the FBO level. However, risk ranking is expected to be a practical tool for the FBO, and the results of risk ranking are needed as input into the FBO-RB-MSAS.

9 Private second or third party assurance schemes can be helpful for risk managers who are aiming for compliance with regulatory and/or non-regulatory requirements. These assurance schemes could allow the CA to reduce the audit frequency. However, as well as auditing the implementation of these assurance schemes, the CA must also evaluate the equivalence of such assurance schemes with the RB-MSAS that is required by regulation.

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