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Mapping ways of detecting and handling antimicrobial residues in pigs and pig meat in- and outside Europe

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ABSTRACT

Withdrawal periods after antimicrobial treatment have been defined as preventing in meat the presence of residues above the maximum residue limits (MRLs). However, errors can lead to residues above MRLs. The RIBMINS COST Action network investigated the question of how detection and handling are applied in different countries, and what the best practices may be, when balancing consumer safety with EU policy on minimising food waste. Two questionnaires were developed focusing on pigs, targeting the competent authority and the food business operator. The survey was undertaken in spring 2022 and resulted in 78 answers representing 27 countries. The results showed that most countries operate their system as a kind of monitoring, where the tested carcass is not detained. We suggest two best practice models where Model A (monitoring) could reflect small abattoirs placing meat on the national market, whereas Model B (surveillance) could reflect abattoirs also trading and exporting. In Model A, detection of a residue above the MRL is interpreted in the same way as a process hygiene criterion, requires on-farm inspection to correct mistakes only, and therefore no retention of tested carcases. In Model B, detection of a residue above the MRL is interpreted as a food safety criterion, requires on-farm inspection and the tested carcass is retained to avoid expensive recalls in case residues are found.

1. Introduction

The European Commission (2017) has encouraged the judicious use of antimicrobials to limit residues in agri-food goods and slow down development of antimicrobial resistance (AMR) in animal and human health. Hence, the livestock producer should pay attention when animals require antimicrobial (AM) treatment. In the European Union (EU), the AM is prescribed by a veterinarian and the prescription contains information about the withdrawal period needed before the animal can be sent for slaughter (EU Parliament and Council, 2019). Compliance with the withdrawal periods is required to ensure that residues of prescribed AM will be below the established maximum residue limits

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(MRLs) in targeted animal tissues (EU Commission, 2010).

As noted by the Codex Alimentarius in their guidelines related to residues of veterinary drugs, actions taken pre-harvest are the primary means for avoiding the presence of residues in meat and other edible tissues, whereas the role of the competent authorities (CAs) is to verify that such actions are in place and are well-functioning (Codex Alimentarius, 2014). Thorough marking and registration by the primary producer of treated animals helps to prevent unacceptable levels of residues in the meat that reaches the consumers (EU Parliament and Council, 2019). Hence, procedures are supposed to be identified and put in place on the individual farms to help avoid delivery animals to the abattoir prior to the end of the withdrawal period. Still, residues can occasionally be present in animals sent for slaughter. This can happen, e.g., if the treated animal was not properly marked, registration was inadequate, a human error occurred leading to awrong use of a medicine mixer, or there was a miscommunication between the person treating the animal and the person sending the animal for slaughter (Alban et al., 2014). These mistakes may have potential consequences along the whole meat chain due to a need for recalls.

In the EU, the General Food Law Regulation 178/2002 states that food such as meat should not contain residues (EU Parliament and Council, 2002), continuing the policy of the former EU Residue Directive 96/23 (EU Council, 1996). To document the compliance with acceptable levels of residues of medicinal products in target tissues, monitoring should be conducted. Monitoring can be established and run by the CAs in accordance with legislation (EU Commission, 2022a), or by the abattoirs in the form of their own check programmes if their hazard analysis so indicates. Some parts of a programme can be run as a surveillance programme, e.g., when the release of a tested carcass is pending a negative test result, in line with the definition of surveillance suggested by Hoinville et al. (2013).

Earlier work by Alban et al. (2018) has shown there are diverse interpretations of the EU legislation, leading to different ways of detection and handling AM residues. This is exacerbated by the different perceptions in the countries regarding the food safety risk related to residues of AM origin. Moreover, large, exporting abattoirs may prioritise the issue more than non-exporting abattoirs. This can be reflected in the way the programme is set up, e.g., in the sampling frequencies, use of risk-based approaches, types of matrix and use of chemical detection methods as direct verification such as HPLC/LC-MS (Alban et al., 2018).

The responsibility concerning AM residues in the slaughter chain relies primarily on the food business operators (FBOs). The role of the veterinary practitioner is to help the pig producer developing safe practices regarding use of AM, whereby the risk of sending animals for slaughter too early will be reduced. The primary producer must deliver food chain information (FCI) for the slaughter animals that includes a declaration of passed withdrawal times in cases of treatment with AMs. The abattoir must ensure that the FCI is correct and check the compliance of delivery guarantees (EU Parliament and Council, 2004). Any animal that does not comply with these requirements must not enter the food chain. Still, mistakes can happen – and that is likely the reason for the observed ineffectiveness of FCI (Wagenberg et al., 2012). Hence, meaningful FCI, enabling applicable risk-based decisions, is still missing (Antunović et al., 2021). Moreover, for pigs it is challenging for the abattoir to check the quality of the FCI, because treatment of pigs is not registered individually.

In a recent survey (EFSA, 2022a), residues of pesticides, AMs, hormones or steroids in food topped the list of food safety-related concerns among European consumers, despite the prevalence in meat being low. For 2020, EFSA reported a prevalence of 0.12% for legal AMs above the MRL in 36,262 pig samples (EFSA, 2022b). Moreover, only a few cases have documented that a person has fallen ill due to consumption of meat with residues in concentrations above the MRL, and these cases were mainly related to penicillin allergy (Baptista et al., 2010; Arsèneh et al., 2022).

The overarching aim of the EU legislation in this area is to keep the prevalence of residues in meat low. Non-compliance can lead to carcass condemnation and allocation of the meat to animal by-product category 2, for which pressure sterilisation is required as described by the EU Animal By-product Regulation 1069/2009 (EU Commission, 2009). However, this may easily contradict the European Green Deal that contributes to the UN sustainable development goals by reducing food losses and waste without impairing food safety (EU Commission, 2022b).

Monitoring of residues concerns legal and illegal veterinary substances as well as environmental pollutants. In this paper, focus is on legal AMs only. Annex III in EU Regulation 2022/1644 specifies that sampling for residues of legal AMs should be targeted towards products from those animals that are most likely to have been treated (EU Commission, 2022a). According to Filippitzi et al. (2019), the greatest use of AMs in livestock is associated with pigs. It is, therefore, important to investigate the issue of AM residues in pig meat. In general, FBOs should implement procedures along the entire supply chain to control food hazards (Blagojevic et al., 2021). The question is how to do this in a cost-effective way for AM residues in pigs.

To look at these issues, a study was undertaken by a working group within the European COST Action, RIBMINS CA18105. RIBMINS is an acronym for risk-based meat inspection and integrated meat safety assurance. Please see https://ribmins.com/for more information. In this paper, the aims were to:

1. Collect information about current ways of detecting and handling the presence of AM residues in pigs and pork, and
2. Develop best practices depending upon the objective of detection and handling in the individual country.

2. Materials and methods

2.1. Description of the development of the questionnaire and the survey

Two questionnaires were developed, each consisting of 1) a general description, 2) a description of the monitoring/surveillance programme in force, 3) food chain information and 4) a special case when a pig producer contacts the abattoir because one or more pigs have been sent in before the end of the withdrawal period. The responses given to section 4 will be presented elsewhere. During the development of the questionnaire, input was received from several CAs and FBOs, mainly in Europe. Thereafter, a pilot study was undertaken, involving 19 respondents. This showed that it took around 30 min to fill in the questionnaire if the respondent was familiar with the issue, and longer if not. One version of the questionnaire targeted the CA, and the other targeted the FBO. Ethical approval for the questionnaire was received from the Research Ethics Committee of Science and Health at the University of Copenhagen on March 29, 2022 - Journal no. 504–0308/22-5000. The questionnaires can be found on the RIBMINS website https://ribmins.com/survey-on-residues-of-antimicrobials-in-pigs/.

Access to the questionnaires was made possible through a link on the RIBMINS website (https://ribmins.com/survey-on-residues-of-antimicrobials-in-pigs/). The link was open from 29 March to July 5, 2022. The intention was to have a minimum of one answer from a CA and minimum one answer from an FBO per country. Monitoring of illegal veterinary substances or environmental pollutants was not covered by the questionnaire, and neither was monitoring of AMs in live animals on the farms.

2.2. Statistical methods and development of best practice models

The statistical analysis was carried with the statistical software programme SAS version 9.4 (SAS Institute, Inc., Cary, North Carolina, USA). For quantitative questions, the chi-square test was used (or Fisher's test, if one or more of the cells in the contingency table had an expected cell count of <5) to determine statistical differences between

the CA and FBO responses. Unless mentioned specifically, the group of answers saying "I do not know" was not included in the analyses. For qualitative questions, the text was condensed to produce a short summary using grounded theory (Creswell & Poth, 2017, p. 488).

Two different models for a set of best practices for detection and handling in relation to AM residues in pigs were developed. To do so, we used a schematic description of risk-based surveillance, developed as part of the RISKSUR project (https://www.fp7-risksur.eu/) and further developed for residue monitoring/surveillance by Alban et al. (2018). The model is depicted in Fig. S1 and contains 12 elements, beginning with the objective and expected outcome of the system. Thereafter, we analysed the results of the survey, which showed that there basically are two different systems in place, one where the carcass is detained and one where it is not detained. To understand these two different approaches, we made use of the definition of monitoring and surveillance proposed by Hoinville et al. (2013), who specify that the main difference between the two is that surveillance is done to inform decisions about interventions to mitigate risk (so an action plan is implicit), whereas monitoring is not commonly associated with a pre-defined action plan. Hence, one may argue that when a programme is designed for monitoring, the tested carcass does not have to be detained. To further understand the difference between the two approaches, we looked at the general principles of the EU Regulation 2075/2005 on microbiological criteria for foodstuffs (EU Commission, 2005). In that Regulation, a distinction is made between a requirement for immediate action, such as a recall because of a perceived food safety risk, and a requirement for investigating the process due to an observed deviation that raises suspicion that the procedures in place were not employed correctly. Moreover, a set of guidelines developed by Codex Alimentarius were used, which present the principles for the design and implementation of food safety assurance programmes associated with the use of veterinary drugs (Codex Alimentarius, 2014).

In the following, the information collected is presented and divided into sections. The main part of the tables are placed in the Supplementary materials.

3. Results

3.1. Description of respondents and programmes in place – Q1-Q36

In total, 78 responses to the questionnaires were received during the collection period. Of these, 42 were from CA representatives and 36 from FBO representatives (Table S1). These responses covered 27 countries, among which 11 were from Northern Europe (Denmark, Finland, Iceland, Norway, Sweden), 26 from Western Europe (Austria, Belgium, France, Germany, Netherlands, Switzerland, United Kingdom), 18 from Southern Europe (Cyprus, Greece, Italy, Portugal, Spain), and 19 from Central/Eastern Europe Bosnia and Herzegovina, Croatia, Latvia, North Macedonia, Poland, Romania, Serbia and Montenegro, Ukraine). Moreover, two responses were received from Australia and two from New Zealand.

Most of the CA respondents (57%) were affiliated with the central CA, followed by the local CA (21%) and the regional CA (17%). Among the FBO respondents, the majority represented large abattoirs (58%) followed by medium-sized abattoirs (28%), whereas small abattoirs were only represented by 6% of the respondents (Table S2). The most common marketing strategy was to place meat on the national market (89%), followed by the export market (53%) and the intra-communitarian market (implying inside the EU) (50%). The least common strategy was to place meat on the local market (44%). For the small abattoirs, the meat was only placed on the local or national market (Table S2). Despite these differences, there was no statistical association between the size of the abattoir and the type of market ($P_{Fisher} = 0.21$).

According to both CA and FBO respondents, the most important objective of the system was to detect and handle residue-positive samples, followed by compliance with the legislation. Assessment of the prevalence of residues in pig meat came in as a clear third objective for the CA respondents, whereas for the FBO respondents, the prevalence assessment was just as important as showing the pig producers that monitoring is taking place, i.e., as a way of increasing the compliance of the pig producers. FBO answers were more concentrated around middle values, whilst the CA answers showed more variation. The number of respondents choosing "other objectives" was much lower than seen for the other options (Table 1).

In around half (53%) of the official surveillance programs, pigs were divided into categories and mainly into sows/boars and finishing pigs (Table S3). If the answer was "yes, but divided differently", the CA respondents were asked for additional information in a subsequent question. CA representatives from three countries replied that, for residues, they also focused on piglets slaughtered at a weight below 20 kg.

More than half (57%) of the CA respondents mentioned that at least some or all samples were taken in a risk-based way, whereas around one third (36%) indicated that only random sampling was in place (Table S3). According to the answers from CA respondents, the following were used as risk factors for risk-based sampling: intensive production system, non-compliant results in the past, irregularities related to the treatment of animals, incorrect documentation and pigs or carcasses with visible injection sites.

More than half of the respondents indicated that the carcass is not detained. Country-wise, respondents from eight out of the 27 countries indicated that the carcass is detained. The FBO reported more often that the carcass is detained compared to the CA, but the overall difference between CA and FBO regarding handling of carcasses was not statistically different ($P_{Fisher} = 0.28$). Among FBO respondents, mainly those from large abattoirs replied that the carcass is detained until a result below MRL becomes available (Table 2).

According to almost half of the CA representatives and the FBO representatives, detaining carcasses helps to avoid corrective measures if a sample is residue-positive. The second most common reason for detaining carcasses is export requirements. Again, half of the respondents indicated that the carcasses are not detained (Table 2). There was no statistical difference between CAs and FBOs regarding reasons for detaining the carcass ($P_{Fisher} = 0.68$).

Most CA and FBO respondents (CA:69% & FBO:63%) stated that actions are taken on-farm, when AM residues are found at levels above the MRLs. Around one quarter also take actions when residues are detected, irrespective of residue concentration. One FBO respondent answered, "no action taken"; however, we believe this respondent possibly lacked knowledge of how the CA proceeds in such cases. There was no statistical difference between the answers of CAs and FBOs ($P = 0.77$) (Table S4).

To ensure that the withdrawal period is complied with, almost all CA (93%) and FBO (100%) respondents stated that all AM treatments should be registered. Marking treated pigs was the second most common preventive action suggested by FBOs (33%), whereas CAs mostly suggested moving treated pigs to separate pens (24%). There was no

Table 1
Ranked list of objectives for the official programme/quality assurance programme in the countries, where 5 = the most important objective, and 1 = the least important, divided into CA and FBO, sorted by average value.

Objective of the monitoring	Average value		Average value	
	CA Q5	No. of answers	FBO Q9	No. of answers
Detect and handle positive samples	4.3	42	3.7	34
Show compliance with legislation	4.1	41	3.6	34
Assess the prevalence of residues in pig meat	3.6	42	3.4	34
Show pig producers that monitoring is taking place	2.9	41	3.4	34
Other objectives	2.1	22	3.2	23

Table 2
When a sample is taken from a pig carcass, how is the carcass handled, and what are reasons for detaining the carcass until a result below MRL becomes available? (More than one answer possible).

When a sample is taken from a pig carcass, how is the carcass handled?						
	The carcass is detained, until a result below MRL becomes available	The carcass is not detained	Other handling	I do not know	Total No. of answers	No. of respon-dents
CA Q12	5 (12%)	28 (67%)	7 (17%)	2 (5%)	42 (100%)	42 (100%)
FBO Q13	9 (24%)	19 (51%)	8 (22%)	1 (3%)	37 (106%)	35 (100%)

Is the carcass is detained until a result below MRL becomes available?							
	Yes, to avoid corrective measures imposed by the CA in case a sample is test-positive	Yes, due to export require-ments	Other reasons	Not relevant, because tested carcasses are not detained	I do not know	Total No. of answers	No. of respon-dents
CA Q14	13 (46%)	5 (18%)	3 (11%)	14 (50%)	2 (7%)	37 (132%)	28 (100%)
FBO Q15	12 (41%)	8 (28%)	1 (3%)	13 (45%)	2 (7%)	36 (124%)	29 (100%)

statistical difference between the answers given by CAs and FBOs ($P = 0.62$) (Table S4).

According to the respondents, meat is the main test matrix used in the official programme for AM residues in pigs (CA:90% & FBO:91%). Kidney/kidney fluid is the second most common matrix, according to both CAs (76%) and FBOs (50%) followed by serum and other tissues (Table S5). There was no statistical difference between CA and FBO regarding choice of matrix ($P_{Fisher} = 0.07$). Information about other matrices covered the following, mentioned in decreasing order: liver, fat, serum, urine, feed, blood plasma, other organs, and the water given to piglets.

The next question was related to the laboratory method used for screening in the official programme. Chemical methods, such as high-performance liquid chromatography – mass spectrometry (HPLC/LC-MS), are the most common (CA:33% & FBO:50%). This is followed by biological methods, i.e., involving use of agar plates, enzyme-linked immunosorbent assay (ELISA) or other immunochemical methods. There was a non-significant difference in the answers between CAs and FBOs (PFisher = 0.28), as the FBO respondents leaned slightly more towards chemical methods than the CA respondents (Table S5).

The question about choice of laboratory test in the official programme was repeated, this time for confirmation. Again, the most common tests are chemical methods (CA:63% & FBO:56%), followed by a minority who indicated biological methods, other kinds of methods or lack of knowledge (Table S5). There was no difference in answers between CA and FBO ($P_{Fisher} = 0.61$) (Table S5).

Most respondents (CA:43% & FBO:57%) indicated that there is no focus, or it is not relevant to have focus on farms from which residues above the MRL have been detected, because either it has never happened, or it is an infrequent finding. About one third of the respondents (CA:38% & FBO:31%) indicated that detection of residues in an animal from a farm would result in a subsequent focus on animals delivered from the same farm (Table S6). The difference in answers between CAs and FBOs was close to being statistically significant ($P_{Fisher} = 0.06$).

Most CA respondents (60%) indicated that the ante-mortem inspection could be of importance to identify clinical suspects among pigs arriving at the abattoir, whereas the most common answer for FBO respondents (41%) was that this is not used (Table S6). The discrepancy in views between CAs and FBOs was not statistically significant ($P_{Fisher} = 0.12$). The respondents were asked about how suspect pigs with residues were identified more precisely. The most common markers were signs of infection or signs of injections.

Most respondents in both groups (CA:62% & FBO:53%) considered the information from the pig producer regarding the possible presence of an injection needle in a pig delivered for slaughter as important in principle, but it hardly ever occurred in practice. A minority view (CA:12% & FBO:25%) was that they would not consider this information, and we hypothesise this is perhaps because the event so rarely occurs. There was no difference regarding the CA and FBO answers ($P_{Fisher} = 0.33$) (Table S6).

According to the respondents, it is uncommon to see emergency slaughter animals *per se* as suspects for residues (CA: 17% & FBO: 6%) (Table S6). Still, according to around half of the CAs (54%) and a third of the FBOs (36%), emergency slaughter animals are considered as suspects if specific information is found in the FCI, or some suspicious findings are detected during inspection. Around one third of the FBOs responded that animals for emergency slaughter are euthanised on the farm. The answers differed statistically between the CA and the FBO ($P_{Fisher} = 0.02$) (Table S6).

Regarding reporting of data from the official monitoring (Table S7), the most common answer from CA respondents (55%) was that their annual report will be compiled to target the EU Commission or EFSA, followed by a report in a national language (52%). For the FBO respondents, the answers were more scattered, with an almost equal proportion stating other ways of reporting (29%), not reporting (29%), annual report to the CA (26%) or annual report in a national language (26%). The answers differed between CA and FBO ($P < 0.0001$), most likely reflecting the separate obligations of the CA and FBO, as the CA is the competent authority in its jurisdictional area, whereas the FBO mainly focuses on its national reporting duties for this question (Table S7).

Most CA respondents (50%) did not know whether the results from monitoring are used to update the official programme. This contrasted with the FBO answers, where the majority (53%) indicated that the results are used to update the own check programme (Table S7). Among CA and FBO respondents who thought the results from monitoring are used for updating, the majority stated that the results are used to update and review the annual national monitoring programme, whereas a minority indicated that the results are used to modify withdrawal periods in the legislation or that results are used to train farmers and improve farmers' activities (Table S7). The difference in answers from CA and FBO did not differ statistically ($P = 0.99$).

3.2. Food chain information – Q37-Q48

According to most CA and FBO respondents (86% for both), for FCI, the most common data type concerning AM residues is a statement regarding the farmer's compliance with the withdrawal periods. The second most common data type (for FCI and concerning residues) is specific information about AM use in the batch, chosen by 40% of the CAs, whereas this was only mentioned by 14% of the FBOs. The difference in views differed between the CAs and the FBOs ($P_{Fisher} = 0.03$) (Table 3).

Most FBO respondents (65%) indicated that FCI is used in the abattoir company's quality assurance programme. In general, both CA (43%)

Table 3
Questions related to Food Chain Information (FCI) (more than one answer possible for Q37).

Which kind of data regarding antimicrobial use must be provided as FCI?						
	Statement regarding compliance with withdrawal period	Information about antimicrobial use in batch	Other kind of information	I do not know	Total No. of answers	No. of respondents
CA Q37	36 (86%)	17 (40%)	1 (2%)	1 (2%)	55 (131%)	42 (100%)
FBO Q37	31 (86%)	5 (14%)	4 (11%)	3 (8%)	43 (119%)	36 (100%)

Is FCI used by the abattoir company's quality assurance programme?				
	Yes, it is used	No, it is not used	I do not know	No. of respondents
FBO Q40	22 (65%)	6 (18%)	6 (18%)	34 (100%)
Do you find that the FCI used in relation to residues is useful?				
	Yes	No	I do not know	No. of respondents
CA Q40	18 (43%)	9 (21%)	15 (36%)	42 (100%)
FBO Q42	21 (60%)	3 (9%)	11 (31%)	35 (100%)
Do you have any suggestions for improvements of the FCI regarding residue programmes?				
	Yes	No	I do not know	No. of respondents
CA Q43	5 (13%)	22 (55%)	13 (33%)	40 (100%)
FBO Q44	6 (17%)	19 (54%)	10 (29%)	35 (100%)

and FBO (60%) respondents found that the FCI is useful, although around one third of the respondents (CA:36% & FBO:31%) did not know. There was no statistical difference in answers between CA and FBO ($P = 0.08$) (Table 3).

Only a few (CA:13% & FBO:17%) respondents stated that they have suggestions for improvements. Most CA and FBO respondents stated that they do not have suggestions for improvements of the FCI regarding the residue programme (CA:55% & FBO:54%). There was no statistical difference in answers between CAs and FBOs ($P = 0.63$) (Table 3). This may reflect the difficulty in identifying feasible FCI for this area.

Most respondents stated that residues are found only rarely or almost never (Table 3). There was a high agreement between CAs and FBOs regarding the frequency of findings, as showed by the high P-value ($P_{Fisher} = 0.97$) (Table 4).

The most common answer among CA respondents was that AM residues are very relevant as a risk for human health, whereas the most common view among the FBO respondents was moderate relevance. Only a small fraction thought the residues are irrelevant as a food safety risk. There was no statistical difference in answers regarding the human health risk between CAs and FBOs ($P_{Fisher} = 0.17$) (Table 4).

Most CA and FBO respondents indicated that the consumers perceive the food safety risk represented by AM residues as a moderate or high risk, whereas only few indicated a low risk or that AM residues are irrelevant for food safety. There was no statistical difference between the answers of CAs and FBOs ($P_{Fisher} = 0.64$) (Table 4). Hence, there was high agreement on consumer perception between CA and FBO respondents.

The dominant view among CA and FBO respondents was that the export market perceives residues as a high food safety risk. This was followed by a moderate risk, whereas only a minority indicated that the export markets perceive residues as a low risk (Table 4). Hence, there was a high agreement between CAs and FBOs on this issue ($P_{Fisher} = 0.94$).

Regarding the use of requirements other than national legislation,

Table 4
Questions related to the incidence of residues and the food safety relevance.

How often do you think meat produced in your country and placed on the market is found to have antimicrobial residues? – here evaluated as the percentage of carcasses with residues above MRL							
	Very often (>5%)	Often (>1–5%)	Regularly (>0.1–1%)	Rarely (>0.01–0.1%)	Almost never (≤0.01%)	I do not know	No. of respondents
CA Q45	0	1 (2%)	3 (7%)	21 (50%)	14 (33%)	3 (7%)	42 (100%)
FBO Q46	0	1 (3%)	2 (6%)	17 (47%)	14 (39%)	2 (6%)	36 (100%)

How would you classify the relevance of residues of antimicrobials in meat in general as a food safety hazard from a scientific/HACCP point of view?						
	Irrelevant, they do not pose any relevant risk for human health	Low, they pose a negligible risk for human health	Moderate, they pose a certain risk for human health	Very relevant, they pose a significant risk for human health	I do not know	No of respondents
CA Q46	3 (7%)	12 (29%)	11 (26%)	16 (38%)	0 (0%)	42 (100%)
FBO Q47	1 (3%)	7 (19%)	18 (50%)	9 (25%)	1 (3%)	36 (100%)
How do you think that consumers in your country perceive the food safety risk related to residues of antimicrobials in meat?						
	Irrelevant	Low	Moderate	High	I do not know	No. of respondents
CA Q47	0 (0%)	9 (21%)	18 (43%)	14 (33%)	1 (2%)	42 (100%)
FBO Q48	2 (6%)	8 (22%)	14 (39%)	12 (33%)	0 (0%)	36 (100%)
How would you classify the way export markets perceive the risk of residues of antimicrobials as a food safety hazard?						
	Low	Moderate	High	I do not know	No. of respondents	
CA Q48	3 (7%)	16 (39%)	17 (41%)	5 (12%)	41 (100%)	
FBO Q49	3 (8%)	13 (36%)	16 (44%)	4 (11%)	36 (100%)	

the majority of FBO responses mentioned different food safety standards such as IFS Food Standard (63%) followed by Russian requirements/standards (44%). The use of other private standards was chosen by 31% of the FBO respondents (Table S8).

4. Discussion

4.1. Survey results

In summary, the survey included answers from 27 countries in- and outside the EU. Detection and handling of positive carcasses is the most important objective for both the CAs and the FBOs, despite the sampling frequency (and resulting number of samples) being so low in all countries that most positive samples are not being detected as pointed to by Alban et al. (2018). Either the CA and FBO representatives are not aware of this or simply want to act upon the knowledge obtained. Regarding which categories to monitor, a few respondents pointed to the importance of young pigs. This makes sense, as most piglets are treated with long-acting coccidiostats. The withdrawal period for such AMs, commonly used against coccidia, ranges from 53 to 77 days, e.g., for Baycox® containing toltrazuril, the withdrawal period is 53 days according to the European Medicine Agency (2019). Hence, slaughter of young piglets could imply a potential risk of coccidiostat residues in meat above MRL.

The respondents pointed to use of risk factors such as intensive production, non-compliant results and visible injection sites for use in monitoring/surveillance. However, in most countries, production is intensive, and there are only a few non-compliant results or irregularities detected in a year. Regarding injection sites, the neck may be the area to target as mentioned by Almeida et al. (2019), however, animals with such marks are difficult to detect in practice during ordinary ante and post-mortem inspection according to persons working at the abattoirs (Alban et al., 2014). For sows, there is no well-known time of slaughter, as it is a multicriteria decision made on a weekly basis on many farms. This could be the reason behind the 20-fold higher prevalence of residues detected in Danish sows than in Danish finishing pigs, as shown by Baptista et al. (2012). Another hypothesis may be that some sows receive more AM treatments in the form of injections than finishing pigs, but it was outside the remit of this study to investigate this aspect. Regarding use of ante-mortem inspection to identify suspect pigs with residues as suggested by the CA, this may theoretically make sense, but in practice be of limited value, because symptoms are not necessarily easy to detect visually in the live pig.

Regarding matrices for testing, meat is the most common followed by the kidney or kidney fluid. This could indicate a trend towards use of chemical methods, and this was most pronounced in relation to tests for confirmation in the official programmes. The biological methods require a subsequent chemical analysis to identify what the substance is in a putatively positive sample, followed by a chemical quantification. Compared to the biological methods, the chemical methods are more expensive but enable a direct answer on the specific substance, including quantity and, hence, a shorter time until the results become available. Moreover, the chemical methods can provide more results in one testing round and can detect more than one kind of AM (Alban et al., 2020). Provision of a result within a couple of days with chemical methods enables a better investigation on visiting the pig producer before the next delivery of pigs, which is required according to Article 4 in the EU Regulation 2019/2090 (EU Commission, 2019). Still, the biological methods have the advantage that they are cheap and easy to use and can provide an answer fast.

Two different ways were mentioned regarding inclusion of information about AM for FCI; one is to require a statement regarding compliance with the withdrawal period after treatment, and the other is to require AM use data. The latter will certainly provide more information than the former. However, the question is whether the receiving official veterinarian can make use of the information in relation to slaughter, because in most countries, registration of AM use in pigs is at herd or age group level, and not at batch or individual level.

The view on consumer relevance of residues of AM reported by the CA and FBO matches the surveys undertaken among consumers (Kantar, 2019) – consumers do care. The use of different private standards in place highlights the challenge for the abattoirs as there is no universal agreement on MRL. As an example, compared with the EU, Russian legislation has a lower MRL for tetracyclines than the EU, which demands additional restrictions on tetracycline use (Legèr et al., 2019). All in all, the survey has shown that there is a plethora of ways of setting up systems for detection and handling of AM in pig production.

4.2. Identification of best practices in relation to the objective of monitoring and handling

The key question for risk management is related to the residue-contaminated carcasses. For residues, the detected carcasses are a tip-of-the-iceberg problem, because only a minute proportion of the carcasses is tested as mentioned by Alban et al. (2018). To handle the non-detected carcasses, information derived from the tested individuals can be used to make inferences about the food safety risk. Based upon that, actions on the population can be decided. As residue prevention should take place on the farm, the monitoring results should be interpreted as verification of the risk management in place on the farm. Still, as the survey results show, there is substantial difference in the way the programmes are set up.

In the following, two different models for best practices are presented. Model A is based on the approach of monitoring, whereas Model B is based upon the approach of surveillance and requires action when deviations are noted. For each of the two models, the advantages and disadvantages are discussed. In line with Hoinville et al. (2013), the term monitoring is used for a situation where the detection of a residue-positive sample above MRL will not lead to actions such as withdrawal from the market or recalls, whereas the term surveillance is used when specific actions are required resulting e.g., in the carcass and its by-products being recalled from the market and condemned, so handled as category 2 by-products. The models are first described in detail, and an overview of where they differ is presented in Table 5. Model A could reflect small abattoirs placing meat on the national market, whereas Model B could reflect abattoirs also trading on the common market and exporting.

4.2.1. Model A – the monitoring model

The main objective in this model is to meet the minimum requirements set by the EU legislation, while spending as few resources as possible. This implies that the system will consist of one component only, the official monitoring, and it will not be further divided into e.g., high-risk and low-risk animals or farms. The number of samples taken will be in line with the minimum required by the EU legislation. For pigs, the sampling frequency is 0.02% for Group B substances (EU Commission, 2022c). Not all samples are tested for all kinds of Group B substances, and the allocation of samples is risk-based. Group B1 covers the legal AMs, and here, a realistic minimum sampling frequency is 0.01%, corresponding 10 samples per year from an abattoir slaughtering 100,000 pigs. Additionally, it is possible that no samples are taken from abattoirs slaughtering less than 10,000 animals in a year. This means that the estimated prevalence of AM residues has a large statistical uncertainty. The carcass from which a sample is taken is not by law required retained. Therefore, both carcass and edible offal are placed on the market before the outcome of testing is known.

The screening test (i.e., the initial testing of a carcass) could be a biological, semiquantitative analysis enabling detection of AM residues as recommended by Serrano et al. (2022). The biological test is a relatively inexpensive method with differing sensitivities for the various residues, and it uses mainly kidney as the test matrix, because the concentration of residues of many AMs can be high in this organ.

Table 5
Two models for best practices for AM residues systems in pigs, based on monitoring (Model A) or surveillance (Model B).

Characteristic	Type of programme	
	Model A – Monitoring	Model B – Surveillance
Objective and expected outcome	Compliance with the EU legislation	Compliance with the EU legislation Showing trading partners that the prevalence of positive samples is low More precise estimate of the prevalence of residues
Surveillance components	Only one component, which is the official monitoring	More components, e.g., the official, of which there can be two parts, as well as one or more private components (own check)
Actions related to suspect and positive findings	Carcass and by-products are not retained	Carcass is retained until a negative test result is available By-products of the tested carcass are condemned due to logistical reasons (economic loss for the abattoir)
Testing protocol	Diagnostic method: biological[a] analysis and final chemical verification (for suspect samples) Matrix: kidney	Diagnostic method: Chemical analysis (such as HPLC-LC-MS) Matrix: meat or kidney
Study design, sampling strategy	Random sampling Minimum number of samples as stipulated by the EU legislation	Random and risk-based sampling Total number of samples is higher than the minimum stipulated by the EU legislation

[a] The test can also be a chemical test.

Biological tests are specific for compounds that present biological activity but cover a range of molecules. Therefore, a second round of biological testing is usually undertaken, where suspicious samples are subjected to verification, including quantification of the residues by a chemical test. The samples are tested as a batch, when a set number of samples have been received at the laboratory. This means that several weeks (e.g., 6–8 weeks) could have passed before information becomes available regarding the type of AM and its level in meat. Hence, in the case of residue-positive samples, the test set-up is not adequate for decision-making, so this type of screening/confirmation will work for monitoring, but not for surveillance.

If a sample tests positive for a residue, the CA evaluates whether the violation requires a recall of the affected lot or product. A recall would be required if an illegal substance is found, which is an infrequent event (Alban et al., 2020). For findings of legal AM above the MRL, we suggest that the results are interpreted the same way as if it had been non-compliant for a microbiological process hygiene criterion (EU Commission, 2005) with an accept limit of 0 positive samples. An investigation of the procedures in place on the farm would then be undertaken, and the farmer would be required to take corrective actions before further delivery of pigs for slaughter. This would be in accordance with the former EU Residue Directive 96/23, replaced by EU Regulation 2019/2090 and with the transitional measures stated in Article 150 in the EU Regulation 2017/625 on official food control (EU Commission, 2017; EU Parliament and Council, 2017, EU Commission, 2019). If the farmer delivers pigs for slaughter every week, the inspection visit would likely be undertaken before the information about the specific AM (requires chemical verification) involved has become available, hampering the investigation. In that situation, the farm visit is less informative compared to a situation where the drugs used are known (Alban et al., 2014) (Table 5).

4.2.2. Model B – the surveillance model

Alongside compliance with EU legislation, an objective of this model is to show trading partners that the number of samples with residues is very low, even when more samples than the minimum are tested (Alban et al., 2018). This implies that the official component of surveillance will be complemented by a private component in the form of own checks conducted by the abattoir. The official and private components could be further divided using risk-based principles, implying e.g., a higher sampling frequency in sows, which are known for being associated with a higher risk of residues than finishing pigs (Baptista et al., 2012). Surveillance can be risk-based. Examples of this can be seen in the Netherlands and Denmark, where finishing pig herds with a high prevalence of chronic pleurisy are perceived as high-risk herds. This reason is that chronic pleurisy could indicate use of injectable AMs, which has been associated with presence of residues (Alban et al., 2016; Veldhuis et al., 2019). The total number of samples is higher than the minimum stipulated by the EU legislation, enabling more precise estimate of residue prevalence.

The testing method should provide test results rapidly. So, it should be a validated "multi-chemical" analysis, such as HPLC/LC-MS, which rapidly analyses several AM substances simultaneously, but with significantly higher costs than biological methods. The higher costs can be diminished by introducing risk-based principles to the surveillance, implying targeting high-risk animals or farms, whereby the sample size can be reduced (Alban et al., 2016). Chemical analyses are highly sensitive and, therefore, meat can be used as a test matrix in accordance with EU Regulation 37/2010 (EU Commission, 2010). Positive samples may be re-tested to ensuring complete assessment of any detected residue regarding the MRL. Answers are available within days. Chemical analysis shows which specific molecule of the drug was used. This means that administration of illegal types of a given drug can be detected, quantified and adequate actions subsequently taken on farm. An example of this has been seen in Denmark (https://landbrugsavisen.dk/gris/kendt-svineproducent-f%C3%A5r-stor-b%C3%B8de-ulovligt-antibiotika).

The tested carcass is retained, and the by-products are disposed as category 2 to avoid restrictions for the FBO. If a sample from surveillance contains a legal AM at a level > MRL, an inspection visit to the farm by the CA or a third-party independent auditor is undertaken soon after the event, and within one week, if possible. On-farm corrections thereafter allow the farmer to deliver animals for slaughter in accordance with the EU legislation (Alban et al., 2014). At the time of the visit, the AM are already identified, allowing the inspector and the farmer to investigate the cause of the MRL breach (Table 5).

4.3. Limitations and perspectives

According to the results of our survey, there are several ways to set up programmes to detect and handle AM residues in pig production. The most important difference is whether the carcass is detained (as in surveillance) or not (as in monitoring. These two approaches probably reflect differences in levels of ambition. We, therefore, decided to develop two best practice models instead of one. The models may be interpreted in the same ways as the EU Regulation 2073/2005 dealing with microbiological criteria, which operates with two kinds of criteria. The first is called a process criterion, which indicates whether the functioning of the production process is correct. The second is a food safety criterion, which defines the acceptability of a product or a batch of food placed on the market (EU Commission, 2005). In Model A (monitoring), residues of legal AMs above the MRLs are interpreted similarly to a process criterion and require corrective measures only on the farm of origin. In contrast, in Model B (surveillance), residues of legal AMs above the MRLs are interpreted similarly to a food safety criterion and require withdrawal of the carcass from the market. To avoid withdrawal, the tested carcass in Model B is detained and the offal and animal by-products from that animal are discarded.

According to our survey, carcass detention is currently in place in only eight out of the 27 countries participating in the survey. This may partly be due to costs of keeping the detained carcass until release of the test results as well as discarding the offal in comparison with perception of the risk. The best practice models present a pragmatic way of balancing the need for consumer safety and confidence with the need for only condemning carcasses when there is a food safety risk. Hereby, unnecessary food waste is avoided, and pig production will become more sustainable in line with the European Green Deal.

Problems arise if the FBO interprets the system as monitoring and the CA sees it as surveillance when positive samples above MRL are found. Because in this case the tested carcass was not retained. When the test results become available after several weeks, the restrictions enforced by the CA can by then involve several stakeholders. Most meat would have been consumed, but some will have been further processed and distributed widely, -perhaps not only within the country of origin but also in the importing country. In this case, the stakeholders will receive rapid alerts distributed by the CA through the Rapid Alert System for Food and Feed (RASFF) system in line with Article 50–52 in the EU General Food Law Regulation 178/2002. This approach reflects the view that detection and handling of meat/carcasses with residues is one of the main objectives of the system, which was shown in our survey. Hence, CAs in the exporting and importing countries could interpret the violation of the MRL as if it were a food safety criterion; implying withdrawal of the non-compliant product from the market. Nonetheless, for a true food safety criterion, an appropriate percentage of carcasses would need to be tested, which is not the case currently in any EU Member State (just 0.01–0.02% of carcasses are tested for AM residues).

In cases where an AM is administered to a batch of pigs with shared housing and management, all pigs in the batch could likely harbour AM residues. However, according to the Danish experience, the presence of residues at the time of slaughter often results from individual treatment of single pigs with injectables close to the time of slaughter (Alban et al., 2014). Group treatment of pigs is usually per oral and involves weaners and growers, and hence, occurs weeks or months before slaughter (Moura et al., 2023). Moreover, many AMs that are administered per oral have a low degree of absorption from the gastrointestinal tract. For these reasons, it makes sense to retain only the tested carcass and not all carcasses from a batch. Moreover, retaining the entire batch is impossible from a logistic point of view, as it would involve 130–200 carcasses per tested pig. Also, economic losses would be substantially larger than seen currently, because all animal by-products, including the blood, would have to be treated as category 2 animal by-products. This means more food waste would be generated, in contrast to the ambitions of the European Green Deal. Moreover, this is not just an EU issue, because non-EU countries also need to conform to EU legislation if they wish to trade with the EU or if they are associated with the EU and comply with the food safety legislation. Switzerland and Norway are examples of the latter.

One may argue that the food safety level of Model B is much higher than in Model A, due to detaining the tested carcass. However, the official required testing frequency is so low that most carcasses (>99.9%) are not tested. Hence, the number of positives detected in monitoring or surveillance represent just a tiny tip of the iceberg. So, the difference in levels of food safety between Model A and Model B is very low - or even negligible.

According to Codex Alimentarius, the regulatory measures should be proportionate to the relative human health risk associated with the hazards. Codex Alimentarius recognises that the risk differs with the type and source of AM residues and that there is a difference between approved, non-approved and prohibited substances (Codex Alimentarius, 2014). Based on a literature reviews, Baptista et al. (2010) and Arsèneh et al. (2022) concluded that only few human cases, have been reported, where it has been documented that the cause of case was exposure to an AM residue. It may be speculated that there could be other negative effects related to exposure to residues even at levels below MRL, e.g., on the microbiota. However, no firm data have been presented so far, as also concluded by FAO in their recent report (2023).

The roles, responsibilities and rights of the CA and the FBO differ and require mutual respect. The CA has the right to decide on the extent of recalls from the market. However, if the test result arrives after several weeks, most of the fresh meat and processed products would have been consumed, leaving only canned food and long-curing products, such as cured hams, on the market. Still, extensive recalls involving the entire batch are scientifically justified in cases of illegal drugs or drugs that are faecally excreted in their original form, where the drug will recycle among the pigs due to coprophagy such as seen for sulfadimidine (Kietzmann et al., 1995).

The role of the FBO is to inform the livestock producers about the importance of complying with the withdrawal periods, and the FBO is responsible for verifying the compliance of the producers through the FBO's own check programmes. Moreover, the right of the FBO is to produce and place meat on the market.

Both CA and FBO should take into consideration that even the best surveillance system currently in force only covers a minute proportion of the pigs produced. This means that legal AM residues at levels above the MRLs will be found occasionally on the market, but only causing few documented human cases of illness. A balance between prevention and action should be sought, as reflected in our two proposals for best practices. This also points to the need of evaluating the results from the monitoring and surveillance of AM residues at slaughter carefully and regularly, as this will identify meaningful and cost-effective updates to the policies and practices in place.

5. Conclusion

This survey shows that there is a plethora of ways to detect and handle AM residues in pigs. The main difference in the systems in place relates to whether the tested carcass is detained (the least common) or not (the most common). When not detained, the system can be characterised as monitoring, where the only corrective action in case of a positive sample > MRL is to visit the farm of origin. In contrast, when the tested carcass is detained, the system can be characterised as surveillance, involving condemnation of the tested carcass if the test results indicate that the concentration is above MRL. Problems arise when the two model are mixed, e.g., the FBO sees it as monitoring and the CA interprets it as surveillance and if positive results above MRL are found require product withdrawal. Based upon this, we developed two best practice models, with specific recommendations regarding objective of programme, surveillance components and testing protocol. We suggest that Model A (based on monitoring) is used for small abattoirs that are only placing meat on the market in their own country, and Model B (based on surveillance) for all other abattoirs. The outcome of this study could act as a basis for more evidence-based and harmonised procedures in the future to improve decision-making regarding condemnation of carcasses and by-products that contain (or might contain) AM residues above the MRLs. In addition, these best practice models should reduce food waste without jeopardizing consumer safety, which is in line with the EU ambition to ensure more sustainable and climate friendly food production.

CRediT authorship contribution statement

L. Alban: Initial conceptualisation, main part of writing the submitted and revised manuscript, and lead of project. **B. Antunović:** Authors contributed to the development of the questionnaire, collection and analysis of data, discussions of results, development of best practice models as well as writing and commenting on the submitted and revised manuscript. **M. Belous:** Authors contributed to the development of the questionnaire, collection and analysis of data, discussions of results, development of best practice models as well as writing and commenting on the submitted and revised manuscript. **S. Bonardi:** Authors

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The data that has been used is confidential.

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Appendix A. Supplementary data

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