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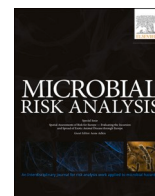
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Full length article

A procedure for surveillance data-driven risk assessment to inform *Campylobacter* risk-based control

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ABSTRACT

In this study is presented a procedure for surveillance data-driven risk assessment, which can be used to inform inter-sectorial *Campylobacter* risk-based control, e.g. within National Action Plans and One Health (OH) systems. *Campylobacter* surveillance data (2019 to 2022) and a published quantitative microbial risk assessment (QMRA) model were used, to show the procedure. Moreover, an interface tool was developed in Excel for showing descriptive statistics on measured apparent flock prevalence (AP) and concentrations (colony forming units per gram, cfu/g) on the meat, together with their related QMRA outputs. Currently (mid-2024), Danish fresh broiler meat is produced by four slaughterhouse companies (A, B, C and D), where approximately 30 % of the annually slaughtered broiler flocks are randomly culture tested, on one leg skin (LS) sample per flock sampled from chilled carcasses. Data variables were: date of sampling, farm-ID, within farm house-ID, flock-ID, slaughterhouse name, sample-ID, and *Campylobacter* concentrations. Flocks were classified as carcass positive with a concentration ≥ 10 cfu/g. The data was fed into the QMRA model to assess: a) the average risk of human campylobacteriosis per serving (during a month or year), and b) the monthly/annual risk of 2022 relative (RR) to the baseline (average) risk from the previous three years. The descriptive statistics and the risk assessment (RA) were carried out at national level and for each slaughterhouse. In 2022, the national RR was 1.03, implying that the average annual risk increased by approximately 3 % compared to the baseline. Nevertheless, for slaughterhouses A, B and D, the annual risk decreased by ≈ 22 %, 21 % and 43 %, respectively; whereas for slaughterhouse C it increased by 48 %. Monthly risk estimates showed seasonal variations, according to the visualized changes of AP and meat contaminations. The national monthly RR was >1 in July and from September to December. During those months: slaughterhouse C had always $RR > 1$, slaughterhouse A had a relative increase of risk in July, slaughterhouse B in July and November, and slaughterhouse D in October and December. The procedure and the tools used in this study, allow identifying the impact of seasonality and food-chain stages (i.e. slaughterhouses and their broilers sourcing farms) on the risk per serving, so that *Campylobacter* risk-based control could be implemented accordingly, from farm to fork, across consecutive surveillance periods. The same principles could be applied in other countries, food chains, and/or for other foodborne pathogens, when similar data and QMRA models are available.

1. Introduction

Campylobacter spp. is the main cause of foodborne gastroenteritis in humans, who can be infected especially through contaminated poultry meat (Hansson et al., 2018; EFSA and ECDC, 2022).

In Denmark, the *Campylobacter* Action Plan has been in place since 2008 (Gantzhorn et al., 2018) and is reviewed each 3-4 years, with updated targets for reducing flock prevalence, carcass contaminations and human risk of disease (Gantzhorn et al., 2018; Petersen et al., 2023).

In that context, since 2014, a quantitative microbiological risk assessment (QMRA) model (Nauta et al., 2012) is used to estimate the risk of human disease (campylobacteriosis) posed by a meal contaminated from fresh broiler meat. Moreover, the average annual relative risk (RR) per serving is calculated, to get an overview of the change in risk compared to the past. The outputs of the QMRA model are shared and discussed within the National *Campylobacter* Working Group, which is composed by representatives of: the Danish Veterinary and Food Administration (DVFA), the National Food Institute-Danish Technical University

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(DTU-Food), the Danish Agriculture and Food Council (L&F) and the Danish poultry industry, with the public health institute (SSI) invited when needed. Within the Action Plan is applied a systematic and inter-sectorial approach for the risk-based control of *Campylobacter* along the broiler meat chain. For that purpose, the QMRA model is used to relate the surveillance information collected on farm/flock infection status (positive or negative) and from the slaughterhouse level (on carcass contamination), with the risk of human disease (Foddai et al., 2022a and Foddai et al., 2023).

QMRA models are useful tools for informing the decision making process in the control of foodborne pathogens like *Campylobacter* (Havelaar et al., 2008; Nauta et al., 2009; Nauta and Christensen, 2011; Chapman et al., 2016) because they can “translate” the information obtained through the surveillance data, into human risk estimates. At the same time, such models have some level of uncertainty, due to limitations in both the available data and the required underlying assumptions. Thus, firstly, it is important that, effects of the relationship between the data fed into the model and its outputs, are distinguished as much as possible, from the impact of the model’s structure, assumptions and limitations. Secondly, although the main result of interest for public health decision making is the risk of human disease, it is also fundamental to know how such a risk is affected by the seasonality and by the different food chain stages, to target risk-based control at its sources (e. g. farm and/or slaughterhouses) in a cost-efficient manner. Therefore, it is essential for risk communication to risk managers (including food business operators (FBOs) in broiler meat production) to report the surveillance data, including the epidemiological information on seasonality and pathogens’ occurrence at different food chain stages, alongside the risk assessment results.

To better understand how *Campylobacter*’s epidemiology along the Danish broiler meat chain, can be reflected in the estimated risk, the Action Plan requested, in 2022, the development of an interface tool, which allows visualizing how the risk estimates relate to the surveillance data fed into the model. This is in line with an increased international demand for improving surveillance data-driven decision making processes and risk assessments (RAs). For example, the European (EU) project ORION (ORION, 2018), was an international initiative aimed to support the inter-sectorial harmonization and integration of surveillance data used to inform decision making across One Health (OH) (Bordier et al., 2020) surveillance sectors (e.g. animal health, food safety and public health). A new project from the European Food Safety Authority (EFSA) is aimed at improving the international reporting and integration of surveillance data used for RAs (Colangeli et al., 2023). Moreover, the COST Action RIBMINS (Risk-based meat inspection and integrated meat safety assurance system), is aimed to modernize meat safety controls, by focusing on the risk categorisation of farms and slaughterhouses, and to develop new tools for cost- effective meat safety assurance (RIBMINS 2023). At the same time, the Risk Assessment Knowledge Integration Platform (RAKIP) (RAKIP, 2023, Filter et al., 2022), is aimed to harmonize data formats and knowledge annotation in RA modelling.

The objective of this paper is to provide an example of a practical procedure for quantitative surveillance data-driven risk assessment, including the visualization of surveillance data alongside the risk assessment results, and their subsequent interpretation to support risk-based control. The example is based on Danish *Campylobacter* surveillance data, but in general this procedure can be used internationally within National Action Plans, OH systems or other projects aimed to control foodborne zoonosis like campylobacteriosis.

2. Materials and methods

2.1. The national surveillance data

Currently, Danish fresh broiler meat is produced by four slaughterhouse companies, here called: A, B, C and D. At each slaughterhouse, approximately 30 % of their annually slaughtered broiler flocks are

randomly culture tested, on one leg skin (LS) sample per flock.

The Danish national data was obtained from the Danish Veterinary and Food Administration (DVFA), for years 2019 to 2022. The meta-data variables were: date of sampling, farm-ID (the Central Husbandry Register number, CHR), within farm house-ID, flock-ID, slaughterhouse name, sample-ID, and culture results (i.e. microbial concentration in colony forming unit per gram, or cfu/g). The combination of the first four variables was used to identify a flock, while the surveillance period (month and year) was extracted from the sampling date. Moreover, flocks were classified as carcass positive if ≥ 10 cfu/g and otherwise as negative (i.e. if <10 cfu/g).

2.2. The QMRA model

In the Danish Action plan, the QMRA model relates: i) the apparent flock prevalence (AP)¹ and the *Campylobacter* concentrations from the LS data, with ii) the probability of human campylobacteriosis caused by a meal contaminated from fresh broiler meat (i.e. meat ready for retail). Accordingly, the AP represents a simplified-combined probability that the broiler meat used for human consumption, arrives from a chilled contaminated carcass, which belonged to a positive flock, because this was infected at the farm and/or because cross-contaminated during transport/slaughter (Foddai et al., 2022b).

In the model, the concentration on flocks classified as carcass negative (i.e. <10 cfu/g) is set at 0 cfu/g, while the positive flocks are entered in the model with the concentration found on the LS sample, which is log 10 transformed within the model (Foddai et al., 2022a; Foddai et al., 2023). Next, the model combines a consumer-phase section, which includes: i) the transfer-survival of *Campylobacter* during food preparation and ii) the exposure of the consumer (Nauta et al., 2008), with a dose-response section (Teunis and Havelaar, 2000), as explained in Nauta et al. (2012); where more detailed information can be found.

The first two outputs of the model are the average human risk per serving per month (or monthly risk per serving) and the average annual risk per serving (which is calculated from the average of the 12 monthly risk estimates). Hence, each monthly risk estimate represents the average probability that in a specific month (e.g. July 2022), a person consuming a meal based on fresh broiler meat gets ill. Similarly, the average annual risk, represents the average probability that during a specific year a person consuming a broiler-meat meal gets ill.

Furthermore, from 2014 until 2021, the annual relative risk of illness (RR) was calculated by dividing the average annual risk during the year of interest (e.g. 2021); by that of 2013, which was the initial reference (or baseline) year of the Danish Action Plan. For the new Action Plan 2022-2026, the Working Group decided to set a new “baseline” risk, by combining the risk estimates from 2019, 2020 and 2021 (see next Section). This decision was aimed to include more recent epidemiological information (i.e. on AP, meat contaminations and risk patterns) and inter-annual variations, within the risk of reference.

2.3. New baseline risk used for the RR calculation

The monthly and annual RRs were calculated at country level (i.e. considering combined LS data from all four slaughterhouses) and per slaughterhouse (i.e. using LS data from each slaughterhouse separately). For both situations, the new baseline risk was calculated for monthly and annual surveillance periods. Thus, firstly, each of the 12 “monthly baselines” were calculated from the average of the three monthly risk estimates of 2019, 2020 and 2021. For example, for January, the new baseline risk was given by the average of the three January’s risk estimates from 2019 to 2021 (and so on for the other 11 months, from

¹ Not corrected for the sensitivity (Se) and specificity (Sp) of the test (Rogan and Gladen, 1978; Foddai et al., 2022b)

February to December). Secondly, the new “annual baseline”, was the average of the 12 monthly baselines. Finally, the monthly and annual RRs were calculated as the ratio between: i) the monthly/annual risk estimated for the year of interest (2022 here), and ii) the baseline monthly/annual risk. Consequently, a monthly/annual RR = 1 implies no change in the average risk per serving, compared to the average risk from the baseline years, whereas $RR < 1$ or $RR > 1$ can be interpreted as a relative decrease or increase (respectively) in the risk per serving.

2.4. New interface tool and procedure

As requested by the Action Plan, an interface tool was created in Excel 2016, to visualize the data and the risk assessment results of managerial interest. The tool combined into graphs, the results of the descriptive statistics on: a) the number of culture tested flocks, b) the number of positive flocks, c) the related AP (i.e. from b/a) and d) the median cfu/g (across carcass positive flocks). These descriptive statistics were carried out in R (R Core Team, 2013). Additionally, the monthly risk estimates (from each of the four years) were copied from the QMRA model into the interface tool, providing the monthly/annual risk values and the RRs, as well.

As a next step in the procedure, the data and results shown by the tool, were discussed in the Action Plan. Based on that, the tool could support decision making for control measures. When interpreting the RRs of interest (usually those that are considerably larger than 1) a trace back to the epidemiological data fed into the model (by surveillance period and units) can be done. In this way, the relative impact of surveillance periods and food chain stages on the mentioned risk estimates could be shown, so that, if needed, risk-based control actions can be targeted to the identified processing plants affecting most of the change in the national risk per serving, and/or (eventually) to the farms delivering them the broiler flocks; time by time. In general, the procedure

helps answering four main managerial questions (Q1 to Q4), in the following systematic and standardized order:

Q1) Is the risk increased, decreased or the same compared to the baseline years?

Q2) Where and when did it (or didn't it) change? (consider the impact of seasonality and/or slaughterhouses and/or farms on prevalence and contaminations)

Q3) What are the sources of uncertainty (e.g. impact of sampling strategy)?

Q4) Where and when could control measures be implemented, and what control measures are feasible?

In Denmark, these questions are typically addressed in the Working Group, where the risk assessors are typically responsible for answering the first three questions, whereas the risk managers are responsible for answering the last question.

3. Results

The outputs of the interface tool are shown in Sections 3.1 to 3.3 for the national level and in Appendixes A to D for each slaughterhouse separately. Next, in Section 3.4, a practical example is given for the procedure outlined in 2.4, aimed to inform risk-based control along the food chain, by considering all outputs.

3.1. Simultaneous visualization of surveillance data fed into the QMRA model and related risk

Fig. 1 a-d show the monthly national descriptive statistics, for 2019 to 2022. During those four years, the annual number of LS tested flocks

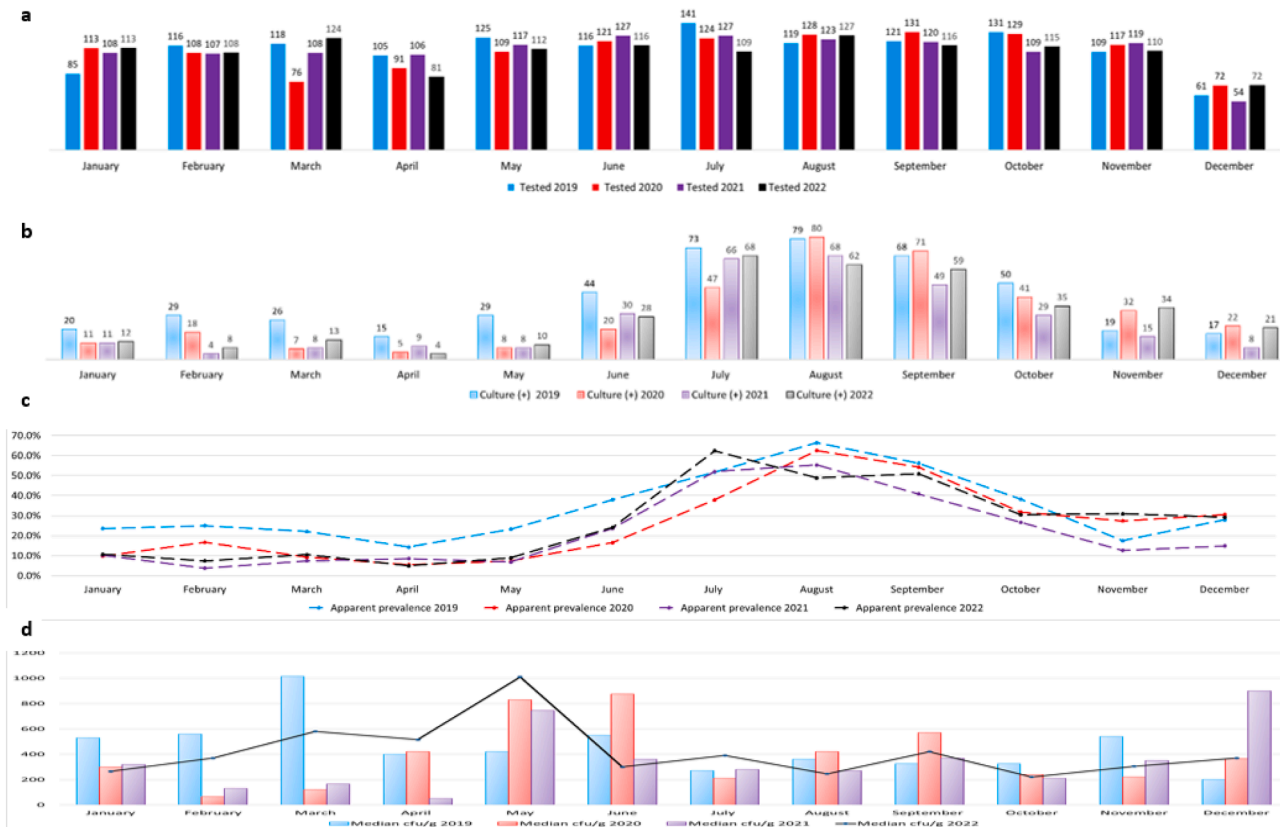


Fig. 1. Country level descriptive statistics from 2019 to 2022: a) Monthly number of leg skin (LS) culture tested flocks; b) Monthly number of (LS) positive flocks; c) apparent prevalence (AP = b/a) and d) Monthly median colony forming unit per gram (cfu/g), across the culture positive flocks.

was: 1,347; 1,319; 1,325; and 1,303; respectively. While the median monthly number of tested flocks was: 117 (min = 61; max = 141) in 2019, 115 (72; 131) in 2020 and 113 in both in 2021 (54; 127) and (72; 127) in 2022 (Fig. 1a).

The annual number of positive flocks was: 469 in 2019, 362 in 2020, 305 in 2021 and 354 in 2022. While the median monthly number of positive flocks was: 29 in 2019 (min = 15; max = 79), 21 in 2020 (5; 80), 13 in 2021 (4; 68) and 25 in 2022 (4; 68).

Therefore, while the sampling sizes of each month were mostly similar across years (Fig. 1a), the (within-year) monthly variations, in the number of positive flocks (Fig. 1b) and in AP (Fig. 1c), reflected the seasonality of flock prevalence, that in Denmark is known to peak during summer (Gantzhorn et al., 2018; Wedderkopp et al., 2000, Kuhn et al., 2020; Foddai et al., 2022b). Accordingly, the monthly median AP was 26.4 % in 2019 (min = 14.3 %; max = 66.4 %), 22.0 % in 2020 (5.5 %; 62.5 %); 13.7 % (3.7 %; 53.3 %) in 2021 and 26.7 % (4.9%; 62.4 %) in 2022 (Fig. 1c).

The national monthly median concentrations across LS positive flocks, are given in Fig. 1d. Descriptive statistics at slaughterhouse level are shown in the Appendices, using the same format.

Fig. 2a shows the monthly risk estimates from the three baseline years (2019 to 2021), which were averaged to calculate the monthly baseline risk. The latter (green line) and the monthly risk of 2022 (black bars) are compared in Fig. 2b. This shows that, the national monthly risk of 2022 exceeded the baseline in July and from September to December.

Moreover, the graphical outputs of the tool show that, within all four years, the monthly risk estimates (Fig. 2a-b) well reflect the seasonality-shape of the APs (Fig. 1c). In contrast, the median concentration did not show particular within-year seasonality (Fig. 1d). Those patterns can also be noted at the slaughterhouse level (Appendices A-D), although in some situations, the monthly risk appeared to relate similarly or more to the meat concentration. For example, at slaughterhouse A, the increase of risk in March 2022 (Appendix A, Figs. 2b and 3), related to both the increased prevalence (Appendix A, Fig. 1a to c) and the very large meat concentration (median cfu/g > 1000) observed across the positive flocks (Appendix A, Fig. 1d). Alternatively, at slaughterhouse D, in June 2021, a very high median concentration (7,600 cfu/g) (Appendix D, Fig. 1d), caused a very high risk (≈ 1.6 %, Appendix D, Fig. 2a), which has also driven a peak in the overall baseline risk value (≈ 0.8 %) (Appendix D, Fig. 2b). This happened even though the AP of 2021 was lower than that

of the other two baseline years: 2019 and 2020 (Appendix D, Fig. 1c).

3.2. Monthly RR

In Fig. 3, the absolute monthly risk estimates (from Fig. 2b), are translated into RR estimates by dividing the risk estimate from 2022 (Fig. 2b, black bars) by the baseline risk estimate 2019-2021 (Fig. 2b, green line). Thus, in Fig. 3, the monthly baseline RR was = 1 for all months (green line), while the monthly RRs of 2022 vary (black bars). It shows that the national monthly RR was >1 in July and from September to December 2022. In those months, the national monthly risk per serving increased by approximately 70 %, 10 %, 50 %, 60 % and 20 % (respectively) compared to the baseline period (Fig. 3).

In the individual slaughterhouses, the 2022 relative increase of risk (i.e. RR > 1) occurred in four months at slaughterhouse A (in March and from May to July), in two months at B (in July and November) and D (in October and December); but in eight months at slaughterhouse C (in January, April, May, July, and from September to December) (Appendices A to D: Figs. 2b-3).

3.3. Annual RR

In 2022, the mean national annual risk per serving was (approximated) 0.30 %. As the national annual baseline risk (i.e. the average of the 12 monthly estimates from Fig. 2b) was 0.29 %, the national annual RR was: $0.30 \% / 0.29 \% = 1.03$ (Fig. 4). Therefore, in 2022, the national average risk per serving increased by about 3 % compared to the baseline from the previous three years. At individual slaughterhouse level, the annual risk decreased by approximately 22 %, 21 % and 43 % for slaughterhouses A, B, and D, respectively. On the other hand, for slaughterhouse C, an increase of 48 % was estimated (Fig. 4).

3.4. Practical application of the procedure to inform risk-based control

The results obtained from the interface tool, as presented above, can be interpreted to support decision making on control measures. The procedure starts by addressing the first managerial question (i.e. Q1 from Section 2.4): *Is the risk increased, decreased or the same compared to the baseline?*

According to Fig. 4, the first answer could be that in 2022, the

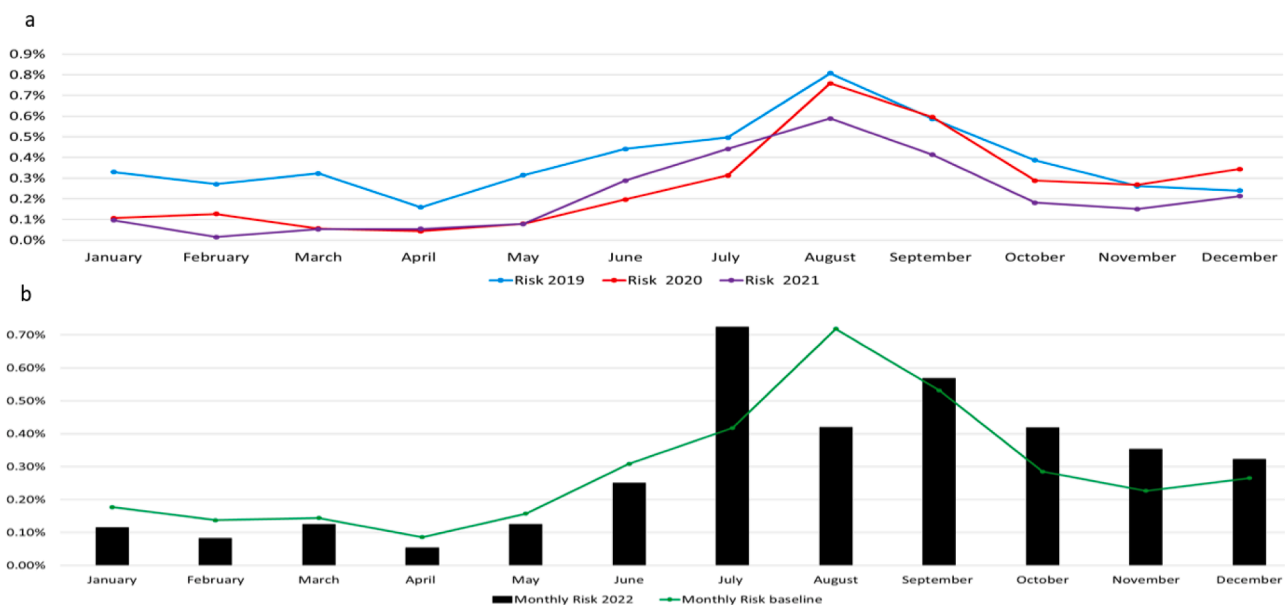


Fig. 2. Country level: a) Monthly risk during the baseline years 2019, 2020, and 2021; b) Monthly risk 2022 (black bars) vs. baseline monthly risk (green line = average of the three monthly dots from Fig. 2a)

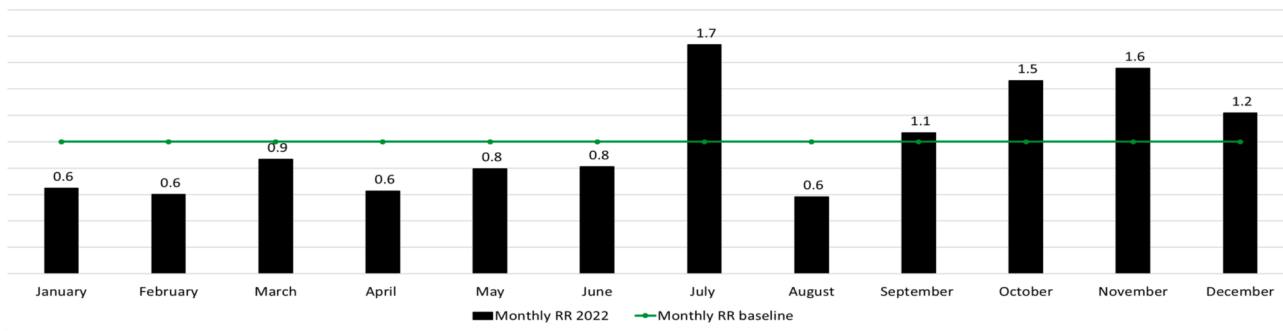


Fig. 3. Country level, monthly relative risk (RR) in year 2022 vs. monthly baseline RR set = 1 (green horizontal line). If the bar of the year of interest is > 1, it means that (for the specific month) the risk increased compared to the baseline, while if it is < 1 it reduced. If RR = 1 it can be considered similar to the average monthly risk across baseline years 2019, 2020 and 2021.

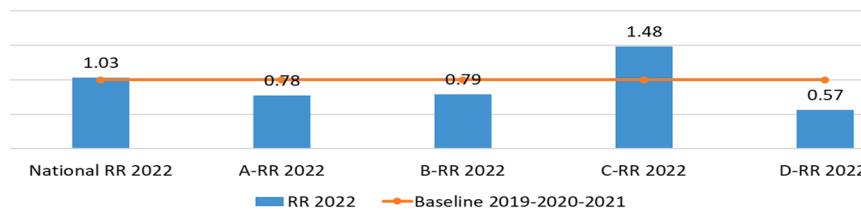


Fig. 4. Average annual relative risk (RR) for 2022 (blue bars) vs. annual baseline RR from 2019, 2020 and 2021 (visualized as RR = 1, horizontal orange line). The blue bars represent the RR at national level (i.e. feeding into the model the leg skin (LS) testing data from all 4 slaughterhouses altogether) and at slaughterhouse level (i.e. feeding into the model the leg skin (LS) testing data from each individual slaughterhouse, separately). If the bar of the year of interest is > 1, it means that the risk increased compared to the baseline, while if it is < 1 it reduced. If RR = 1 it can be considered similar to the average annual risk across baseline years 2019, 2020 and 2021.

absolute annual risk per serving increased at national level and at slaughterhouse C, while it reduced at slaughterhouses A, B and D. Note that the absolute risk estimates are known to be more uncertain than the RRs, which is a reason that usually relative risk estimates are preferred (Nauta et al., 2009). Next, to have a more practical (managerial) use, some more details are needed, i.e. to understand the causes behind the observed RRs.

Therefore, Q2 should be addressed, to understand what affected the mentioned changes of annual risk (When and where did they occur along the food chain? Driven by prevalence and/or concentrations?). In fact, at a first glance, since only slaughterhouse C showed annual RR > 1 (Fig. 4), it could be concluded that this was the only slaughterhouse driving the national increase of risk per serving, through its proportional contribution to the national AP (Fig. 1c) and concentration distribution (Fig. 1d). Thus, through its tested (Appendix C, Fig. 1a) and its positive (Appendix C, Fig. 1b) flocks fed into the QMRA model, when this was used to assess the national annual risk.

On the other hand, the effect of seasonality and broilers farms, on both the national and individual slaughterhouses risk, should be considered as well, by looking at Figs. 1a-d, 2a-b, and 3 (Results and Appendixes) altogether. Then, at national level, from Figs. 2b-3 (Sections 3.1 and 3.2), we would conclude that in 2022, the increase of risk occurred during some specific months, i.e. in July and from September to December (i.e. when the national monthly RR was >1). Thereafter, by checking the graphical results for individual slaughterhouses (Appendixes A to D: Figs. 2b-3), it can be concluded that in July, the national increase of risk occurred from slaughterhouses A, B and C. In September, the change of risk was driven by slaughterhouse C alone; in October and December by slaughterhouses C and D; and in November by slaughterhouses B and C.

The national monthly sample sizes used as denominators to estimate the AP were more or less homogeneous across the four years, as mentioned in Section 3.1 and as shown in Fig. 1a. Hence, if sampling was carried out randomly (as required from the Action Plan) and if monthly sample sizes were not remarkably different across the years, then we can

also address Q3. We would conclude that the observed relative risks changes were more likely caused by actual epidemiological factors affecting the AP and/or the meat contaminations in the field (i.e. at farm and/or at slaughterhouses), rather than by changes in the numbers of monthly tested flocks.

Finally, from the managerial point of view, it can be checked if the identified patterns of inter-annual risks changes, according to seasonality and slaughterhouse/farms contributions, are repeated across years; and if additional risk-based surveillance and/or control could be prioritized accordingly (i.e. addressing Q4); at the slaughterhouses and/or at the farms, which deliver them the broiler flocks. The positive farms (end even their within-farm house units) causing the increases of risk, can be traced through their ID (namely the CHR and the house unit number), which are recorded in the surveillance data used to produce Fig. 1a, b, c, and d. Thus, if needed, year by year, the changes of national risk per serving could be traced back to their most likely sources, so that a list of “high risk” surveillance units (farms and/or slaughterhouses) could be created, and it could be prioritized for (eventual) additional help to farmers and Food Business Operators (FBOs) to control *Campylobacter* in a risk-based and cost-efficient manner.

4. Discussion

This article gives a practical example of how inputs and results of surveillance data-driven risk assessment for *Campylobacter* can be visualized and presented in a standardized manner, and how this can facilitate the risk communication process between risk assessors and risk managers, across sectors of National Action Plans and OH systems. The procedure shown in this study (Section 3.4), can be extended to the surveillance and control of other foodborne pathogens (e.g. *Salmonella*), and/or to other food chains and countries; where similar data and QMRA models are available. In that case, obviously, the consumer phase model (CPM) and/or the dose-response section of the used QMRA model could be very variegated, as previously reviewed for *Campylobacter* (Nauta et al., 2009; Nauta and Christensen, 2011; Chapman et al., 2016);

and should be set according to: i) the specific transfer-survival-epidemiological characteristics of the pathogen of interest and ii) the food item/s considered.

4.1. Procedure for *Campylobacter* control based on surveillance data and risk assessment

In Section 3.4, we presented a practical application of the procedure to inform risk-based control, guided by the surveillance and risk assessment results, visualised through the interface tool (Figs. 1a-d, 2a-b, 3 and 4). It was shown how the *Campylobacter* risk estimates can be traced back in “time” (surveillance periods) and “sources” (food chain stages) according to the surveillance data fed into the QMRA model, and can be used to answer the managerial questions Q1 to Q4, from Section 2.4.

By applying the procedure, it becomes clear that, to interpret surveillance data and risk estimates altogether, the monthly sample sizes of tested flocks (Fig. 1a) and the respective number of positives (Fig. 1b) are reported (see Section 4.4); because both help interpreting the accuracy of the estimated changes in AP (Fig. 1c) and meat contaminations (Fig. 1d). These, in turn, will affect the managerial use of both the average risk (Fig. 2a-b) and the RRs (Figs. 3-4) (see limitations in Section 4.4).

In principle, the risk estimates are the main information of interest for risk managers, as the public health perspective is the main driver for having a National Action Plan against *Campylobacter*. Still, it may be challenging for FBOs and other risk managers, to understand the risk estimates well, and especially to figure out how they can be traced back to their food chains source/s, in an inter-sectorial manner. Within some managerial groups, the relationships between RA inputs and outputs may be considered just “a technical detail”, which is irrelevant for selecting the best risk management options. By application of the proposed procedure (Section 3.4) we could show why this kind of consideration would be incorrect and why it could hamper the most effective prioritization of control measures across OH sectors. In inter-sectorial discussions (e.g. within National Action Plans and OH systems), the first step is to ensure that all the surveillance actors and stakeholders involved have a clear understanding of how the risk estimates are informed through the surveillance data, which represents the pathogen's epidemiological information from along the food chain. This provides a common understanding of the basic technical relationships between data inputs and models outputs, while keeping track of main assumptions and limitations. Thereafter, once the impact of the different sample sizes, surveillance periods and food chain stages is highlighted, the risk management can be considered across monthly-annual surveillance periods, farms risk strata and slaughterhouses (Foddai et al., 2022a-b; Foddai et al., 2023).

Within the Action Plan, the annual RR (Fig. 4), gives a quick overview of the annual (2022 here) change in risk per serving, relatively to the baseline years, at both national and slaughterhouse level. This can help to answer Q1 (*Is the risk increased, decreased or the same compared to the baseline years?*); but will promptly lead to new managerial questions (Q2 to Q4). For instance, if the RR is = 1, it could be questioned why the risk is not reducing across years, despite the implemented control actions. Instead, if the RR is >1 it would be interesting to understand during which periods and in which slaughterhouses/farms the risk increased. Therefore, more detailed investigations of the used data, can clarify if the estimated change (or no change) in risk, was due to: a) variations of the actual pathogen's epidemiology (from farm to fork); or b) if the surveillance data was very different compared to previous surveillance periods, and thus, the impact of uncertainty on the RR interpretation is too high. In the former case (a), the managerial decisions could be prioritized differently along the food chain. In situation (b), if the altered samplings have had a relevant impact on the RRs, updates of the surveillance activities could be prioritized to reduce uncertainty. In Section 3.4 we showed how to proceed, in a standardized

manner, to understand which of the two situations (a or b, above) apply.

Following the proposed procedure, QMRA outputs can be systematically traced to the actual food chain epidemiology of the pathogen, through descriptive statistics of the surveillance data. The latter, when representative, is an objective and transparent link between the inter-sectorial epidemiological information (in this study the AP and the concentrations) and the risk estimates. The more representative and understandable the surveillance data fed into the QMRA model, the more informative and realistic the RA. Consequently, the more objective, cost-efficient and fit-for-purpose would be the pathogen's risk-based control. Such a consideration should be always made, when cost-benefits about having a surveillance component (e.g. its size, costs and representativeness), are discussed (see Section 4.3).

4.2. Surveillance data-driven risk assessment and risk management

On one hand, control targets to be achieved at farm, flock and/or at slaughterhouse level, could be more easily understood (and accepted) by the FBOs and decision makers, if based only on the AP and/or on contamination thresholds (Commission Regulation (EC), 2073/2005; Commission Regulation (EU) 2017/1495; Petersen et al., 2023). On the other hand, by interpreting such thresholds as two independent managerial parameters, it could be difficult translating their relative importance for the human risk of disease. For that reason, both parameters need to be combined and translated into human risk estimates (or, for example, into expected human incidence). One of the main advantages of QMRA models, is that they can address this aim and can give a combined translation of the prevalence (probability of carcass contamination) and of the bacterial concentrations (found on contaminated carcasses), into a probability of illness for humans (namely the monthly/annual risk). This is possible because the average risk estimates are a function of (and sensitive to) the AP of carcass positive flocks and their observed *Campylobacter* concentrations.

Therefore, in Denmark and internationally, *Campylobacter* risk assessments have previously been used to compare the effect of different control measures along the food chain and to support the establishment of national/international risk-based microbiological criteria and control (Christensen et al., 2001; Rosenquist et al 2003; Nauta and Havelaar, 2008; Nauta et al., 2009; EFSA BIOHAZ Panel, 2011; Christensen et al., 2013; Andersen et al., 2015; Nauta et al., 2015). Additionally, in this study, surveillance data-driven risk assessment is proposed as a systematic process that allows identifying the specific surveillance units (slaughterhouses and the farms providing them the flocks) causing the main changes of risk across specific surveillance periods (months and years), within a country. This helps prioritizing where and when risk mitigation actions along the food chain could be targeted (Foddai et al., 2022a; Foddai et al., 2023).

The rationale behind our procedure is that, once the AP and the concentrations are combined into the QMRA model, we still need to keep track of their relative contribution to the final risk estimate, and thus, we need to understand how the epidemiological patterns affect those two parameters, and in turn, the risk estimates. In RAs for *Campylobacter* in broilers, we know that (most often) the monthly variance in risk, is predominantly driven by the variance in AP and less by the variance in concentration (FAO, 2001; Christensen et al., 2001; Nauta et al., 2009; Foddai et al., 2023). This different relationship between those two inputs and the risk estimate, was visualized in Section 3.1 by comparing Figure “1c” (AP) and “1d” (median cfu/g) against Fig. 2a-b (the monthly risk). However, in some situations, the average risk can also become more sensitive to the meat contamination data. The procedure used in this study, allows identifying the surveillance periods (when) and units (where) this could be the case, as described for slaughterhouses A and D (Section 3.1), regarding their increased risk in March 2022 and in June 2021, respectively (Appendixes A and D). At the same time, it must also be checked if the observed change of risk could have been affected by sample size issues, i.e. by interpreting Fig. 1c-d

together with Fig. 1a-b (e.g. to check if too few samples could have caused evident changes of prevalence and/or contaminations, through a few positive results) (see limitations Section 4.4).

The different importance of seasonality, for the AP (Fig. 1c) and for meat contaminations (Fig. 1d), and consequently their effect on the related risk estimates, is in line with the *Campylobacter*'s epidemiology and with the fact that, this pathogen is not expected to multiply outside the host, even during warmer summer months. In contrast, during that period of the year, seasonal changes of AP are usually observed in Northern EU countries like Denmark (Gantzhorn et al., 2018; Wedderkopp et al., 2000, Kuhn et al., 2020; Foddai et al., 2022b). Those changes are supposed to be caused by epidemiological factors, which favour the probability of between-flocks and between-farms spread of *Campylobacter* (e.g. increased water run-offs, flies abundance, etc.) (EFSA BIOHAZ Panel, 2011). The QMRA model allowed including these epidemiological characteristics from the data into the risk estimates, while the interface tool facilitated the combined interpretation of both data and risk estimates.

4.3. Perspectives on potential uses of the procedure and tools at national and international level

Within the Danish Action Plan, the QMRA model (Nauta et al., 2012) has been used for a decade, to assess and control the risk of human campylobacteriosis due to fresh broiler meat (Gantzhorn et al., 2018; Petersen et al., 2023). Now, from this study, the updated baseline risk and the new interface tool, can allow having a more updated approach of surveillance data-driven risk assessment at both national and slaughterhouse/farm level.

At the same time, if the tool and the procedure used in this study, could be applied in other countries, then the *Campylobacter* flock prevalence and concentrations observed at slaughterhouses, as well as the related risk estimates, could become more internationally comparable. Therefore, this article can contribute to address the needs highlighted by recent international projects (ORION, RIBMINS and RAKIP) and by EFSA, for the standardization of surveillance data integration and analysis, within quantitative RAs, meat safety assurance systems and OH systems (ORION, 2018; Filter et al., 2022; Colangeli et al., 2023; RAKIP, 2023, RIBMINS, 2023).

Moreover, our procedure and tools could be further developed and improved, through approaches of Artificial Intelligence, which could speed-up and automatize both the descriptive statistics and the RA (i.e. also the interpretation of results). For example, with datasets similar to the Danish LS surveillance component, the R-codes used for the data handling and statistical analysis, could be provided in concomitance with the QMRA model and the interface tool. If needed, the model could also be replicated in R, in other statistical software and/or in the Food Safety Knowledge Exchange (FSKX) format (Filter et al., 2022).

On the other hand, if in other countries, similar representative LS data is not available, it could be considered using other datasets obtained from surveillance components that are already standardized at international level, for other purposes. For instance, since 2018, EU Member States delivering surveillance information to EFSA (EFSA and ECDC, 2022), are required to have a *Campylobacter* surveillance component, where pools of carcass neck skin (NS) samples, are culture tested. Such data is used to monitor that, the microbiological criteria stated in the EU law (Commission Regulation (EC) 2073/2005; Commission Regulation (EU) 2017/1495) are respected by FBOs. The NS surveillance component is also carried out in Denmark. But here, the QMRA model is still informed with the LS data, because: 1) the LS component was already in place since 2013 (i.e. if needed, more years could be considered for cohort epidemiological investigations), and 2) the number of LS tested flocks is approximately 10 times higher in the LS component than in the NS component. Thus, the LS testing is more representative and less uncertain. Therefore, to adapt (more directly) our procedure and the Danish tools in other countries, it would be

preferable passing from the NS to the LS testing. If this is not possible, it should be investigated if the model could be adapted to the current EU neck skin data instead. In that case, it should be kept in mind that, at least in Denmark, the smaller sample size (i.e. the representativeness) of the currently NS tested flocks would cause more uncertainty on the estimated AP (Foddai et al., 2022b) and its related risk estimates. Moreover, concentrations measured in pooled NS samples would have to be translated into concentrations found in single LS samples. Usually the NS have higher contaminations than the LS samples (Ellis-Iversen et al 2020).

Furthermore, if also a census component was standardized internationally, e.g. to investigate flock prevalence from the farm level, then the procedure could be extended to integrate information on farms' infection status (positive vs. negative) into the RA. Next, a comparison of prevalence estimates and their impact on risk, could be carried out across sectors, i.e. at pre and post-harvest. This was shown previously (Foddai et al., 2022a-b; Foddai et al., 2023), through the integration of the Danish cloacal swab surveillance data with the LS component used here. In Denmark, having a census component allows screening all farms and flocks on the infection status at their arrival at the slaughterhouse, and thus, to have a more objective and representative risk-based stratification of all farms and flocks present in a country; e.g. compared to the situation where only a percentage of the flocks is tested. Next, by comparing the flock status between pre and post slaughter, it can be quantified the amount of cross-contaminations occurring at slaughterhouses and their relative impact on the human risk, as shown in (Foddai et al., 2022a-b; Foddai et al., 2023). This would not be possible by using only LS testing data and without knowing the original flock status from the farm level. Nevertheless, if only a representative (carcass) surveillance component was available, as the LS testing used in this study, it could still allow having a representative "enough" prevalence/risk estimate, as well as the annual screening of the high risk farms and their flocks (at least for these contributing the most to the national flock prevalence and human risk per serving). For instance, considering the average (115) of the monthly median sample sizes and of the monthly median number of positives (22) from Section 3.1 and by using the Epitools calculator (Sergeant, 2018), it can be seen that, the "true prevalence" (or TP) (Rogan and Gladen, 1978), corrected for the sensitivity (Se) $\approx 83\%$ and specificity (Sp) $\approx 99\%$ of the culture test used in Denmark (Rosenquist et al., 2007) can be estimated with 95 % confidence at 22 % (95 %CI: 15 %; 32 %) and would be similar to the AP = 19 % (13 %; 27 %), i.e. with overlapping 95 %CI. This suggests that the sample size used for the LS testing can be representative of the sample size needed to estimate TP of carcass contaminated flocks.

Finally, if a surveillance component based on Whole Genome Sequencing (WGS) was added, to type all carcass positive flocks, then the model and the risk-interpretation procedure could be targeted even more specifically, towards particular *Campylobacter* subtypes (ST), e.g. those Anti-Microbial Resistant (AMR). Consequently, the risk-based control could be addressed to the particular ST/s of interest.

4.4. Limitations

When interpreting the QMRA models outputs, it should be taken into account that part of the variations observed on the risk and RR estimates (Figs. 2a-b, 3 and 4) could be due to the monthly/annual variations of sample sizes, at both country and slaughterhouse level. This is the reason why we suggest to report the descriptive statistics on the used surveillance data, i.e. to visualize numerators and denominators (Fig. 1a-b), together with the related AP and meat contaminations (Fig. 1c-d). For example, at slaughterhouses A and B, on average approximately 500 flocks are expected to be annually LS tested. These are the slaughterhouses processing more than 85% of the Danish conventional broiler flocks (Petersen et al., 2023). On the other hand, at slaughterhouse A, during years 2019 to 2022, the number of LS tested flocks was 495, 520, 500, and 488; respectively. Whereas at slaughterhouse B, those numbers

were 503, 474, 484 and 474; respectively (Appendixes A-B, Figures 1a). Before setting the new baseline risk, a sensitivity analysis was carried out and it was found that the slaughterhouse's change in RR, for the three baseline years, could have been minimal (<1 %), even if 500 flocks had been tested annually at both slaughterhouses (results not shown). Hence, in this study, the sampling variations observed through the Fig. 1a (in the Results and Appendixes), should not have affected the interpretations of the risk estimates remarkably. However, it is suggested that annual sampling variations continue to be monitored from the descriptive statistics, and remain within a maximum range of ± 50 flocks at national level as shown in Section 3.1 (and e.g. ± 20 flocks for slaughterhouses A-B, ± 5 for C-D), to have standardized risk comparisons across surveillance years.

Regarding the setting of the new baseline risk, it could be argued that more (or even less) than three years of reference could have been used. Three years were considered because the Danish Action Plan is reviewed with similar frequency. On one hand, the more years included, the more difficult could become identifying (future) small annual relative changes of risk (e.g. if, for a risks change to be notable, epidemiology must be different not only compared to the previous year but compared to all the previous three years). This could also be the case, if the three baseline years are changed from year to year, e.g. by using "moving baselines" that are "closer in time" (i.e. with less variation) to the last investigated year. On the other hand, by using only one or two years, less inter-annual variability would be included on the baseline risk. Those pros and cons should be taken into account when the monthly and annual RRs are interpreted. For instance, as mentioned in Section 3.4, for slaughterhouse D, in June 2021, the very high meat concentrations (Appendix D, Fig. 1d), caused a very high absolute risk (Appendix D, Fig. 2a), which caused a peak in its baseline risk value (Figure, 2b). Thus, when compared against this baseline, the risk estimated for June 2022 (and in future years), could appear relatively low (i.e. more difficult to obtain $RR > 1$ in Fig. 3). High median concentrations (e.g. > 1000) across all positive flocks of a month, should be rare (see all Fig. 1d) and the mentioned baseline could be considered as an outlier. Accordingly, interpretations of June's RR values, for slaughterhouse D, should be made with more caution than for other months. In general, it should be noted that, at the single slaughterhouse level, sample sizes (although proportional to slaughterhouse's processing capacity) are smaller compared to the national level, and consequently, uncertainty on descriptive statistics can be higher (and outliers could occur more easily) when considering single slaughterhouse data. However, by following the procedure from Section 3.4, it can be understood when risk changes occurring at individual slaughterhouses, affect the national level RR. The mentioned increased risks observed at slaughterhouses A (March) and D (June), did not cause a change in the national RR, as instead it was the case for July and from September to December. Accordingly, only for those months, risk-based investigations and related (eventual) control measures, could be prioritized for the involved slaughterhouses and the respective farms, which delivered them the positive flocks. The decision on the control measures to apply across the different surveillance periods and at which level of the food chain, remains to the risk managers addressing Q4 (as explained in Section 2.4).

Furthermore, it could be argued that the QMRA model is relatively simple, because uncertainty around the used inputs was not directly reflected around the printed risk estimates (Figs. 2a-b, 3 and 4). On one hand, a stochastic simulation model would have been more complete, by including uncertainty on each input. For example, if more than one LS sample was collected per tested flock, the within-flock concentration distributions could have been fed into the model, instead of using a single culture result per tested flock. On the other hand, the surveillance data fed into the model (although imperfect) is collected from a quite high percentage (1 out of 3) of slaughtered flocks and should be still representative of the main epidemiological patterns affecting the risk per serving, because variability in meat contaminations on positive carcasses, is still integrated into the risk estimates, by considering the

log₁₀ cfu/g based on all carcass positive LS results fed into the model.

The exposure and dose-response sections of the model, include some more uncertain parameters (e.g. on the consumers' practices when handling food within the kitchen) (Nauta et al., 2012). But those do not change across surveillance periods. Hence, as previously described (Foddai et al., 2023); there is uncertainty on the over-estimation/underestimation of the absolute risk values (Fig. 2b), but this is the reason why, in the Danish Action Plan, the RR is calculated (Figs. 3 and 4). In fact, in the RR, the uncertainty due to the exposure and dose-response sections of the model largely cancels out, because these are simulated in the same manner across all surveillance periods (months and years). Consequently, the estimated monthly/annual relative change in risk, is entirely driven by the epidemiological changes in AP (Fig. 1c) and/or in meat concentrations (Fig. 1d) registered through the surveillance data (Fig. 1a-b). Thus, the RR shows the relative change in risk, which is likely to be caused by actual seasonal variations of the epidemiological reality along the food chain, and for which (eventually) the need for risk-based control actions can be discussed between surveillance actors and stakeholders of the Action Plan. As mentioned in the introduction, it is well known that the risk of human campylobacteriosis is mainly driven by contaminated poultry meat (Hansson et al., 2018; EFSA and ECDC, 2022), and thus, it can be assumed that, by controlling *Campylobacter* prevalence and meat contaminations along the food chain, the risk of human disease per serving should reduce concurrently, as previously investigated in Denmark (Foddai et al., 2022a). For these reasons, the Action Plan prioritizes *Campylobacter*'s control in broilers and the single meal level is considered for the risk assessment. Thus, human incidence data is not fed into the simulation model and validation of RR estimates against national disease incidence was not carried out. Also because, as previously explained (Foddai et al., 2022a; 2023), comparisons of human surveillance data against risk estimates, should be made with caution, due to the impact of underreporting/underdiagnoses on human incidence statistics (Havelaar et al., 2013; Monteiro Pires et al., 2020) and because QMRA models are expected to overestimate the risk to some extent (Havelaar et al., 2008), e.g. compared other kind of epidemiological studies. For the same reasons, the risk and the RR estimates should not have been biased by the fact that the data used for the study was partly collected during the COVID-19 pandemic, which is known to have affected the human campylobacteriosis incidence in European countries and in Denmark (Anonymous, 2023), but we do not expect it affected the flock sample sizes, the AP, and the meat contaminations observed in the study (Section 3.1).

5. Conclusion

In this study, it was demonstrated how surveillance data-driven risk assessment can be used to inform risk-based control of *Campylobacter* spp. along the poultry meat chain, by means of a risk assessment tool and a procedure, where the results are interpreted to identify the specific surveillance units to prioritize for control measures (from farm to fork). From a practical point of view, the estimated risk can be traced back to its most likely sources (slaughterhouses and their flocks source farms), while considering the importance of seasonality; so that resources and control actions can be prioritized accordingly, during a year period. Moreover, the procedure and tools used here, could be extended to other similar foodborne pathogens, food chains and countries. In this way, at international level, the reporting of surveillance data within National Action Plans and OH systems, as well as the related quantitative risk assessments; could become more standardized and comparable than is currently the case.

CRedit authorship contribution statement

Alessandro Foddai: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Methodology, Investigation,

Formal analysis, Data curation, Conceptualization. **Marianne Sandberg:** Writing – review & editing, Validation, Resources, Methodology, Investigation, Conceptualization. **Maarten Nauta:** Writing – review & editing, Visualization, Validation, Software, Methodology, Investigation, Conceptualization.

Declaration of competing interest

None.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.mran.2024.100322](https://doi.org/10.1016/j.mran.2024.100322).

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