Evaluation of the risk assessment based procedures for setting UK target to reduce *Campylobacter* in chickens

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1. Overview of the modeling frame used for setting the UK-target:

The aim of this report is to give a critical evaluation of the published *Campylobacter* target proposed by the Food Standard Agency (FSA) of the UK. Setting of this target was in cooperation with stalk holders from the broiler meat industry. The proposed target was released in December 2010, and was informed largely by a mathematical model (simulation) in order to estimate levels of *Campylobacter* through the broiler supply chain.

The model used for setting the present UK-target was developed further from the initial (UK-) model of Hartnett et al., 2001. The source of infection is not explicitly modeled; infection is randomly assigned within the flock. The model uses a two-stage semi-mechanistic modeling method, which assumes the transmission of infection changes few days after the initial infection of the flock. The first stage assumes one or more birds become colonized with *Campylobacter* on the first day of infection, and then the subsequent spread of infection is through the fecal-oral route with birds within the social cluster of the initially infected bird(s). Once infection is introduced, transmission is modeled using a stochastic transmission model. A deterministic (logistic growth) model was assumed to be sufficient to model the spread of transmission throughout the flock. Parameter estimates for both stages (within flock and between flocks) are based on published literature and expert opinions relevant to the UK situation. The UK-target setting model focuses on the mechanistic contamination of birds at the farm level and to a lesser extent during transport.

The simulated outputs from the farm-transport level model feeds into a slaughterline phase model. Changes in *Campylobacter* concentrations on the carcasses during various stages of broilers industrial processing are derived by analyses of input-output relationships (modular process model approach) of data obtained from national, published articles, national project reports, and experts' consultation. The effects of selected interventions are assessed with the assumption that the change of concentration in a specific processing step is independent of the input distribution of concentrations in that processing step.

2. Evaluation procedures:

Considering the scope of the UK-target and the model-based approach used for setting it, the present evaluation report focuses on the following:

- ***Fitness of the risk assessment modeling approach for the intended purpose;***
- ***Strength and weaknesses of adopting the web based tool recently released by the CODEX COMMITTEE (FAO/WHO) for broiler slaughterhouses;***
- ***Appropriateness, weakness, and gaps of the input model data;***
- ***Model robustness;***
- ***And future improvement possibilities.***

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FITNESS OF THE RISK ASSESSMENT MODELING APPROACH FOR THE INTENDED PURPOSE

The present UK-target for reducing *Campylobacter* in chicken meat is an **innovative** and **challenging** approach for risk management. On one hand, **it is a science based target**; as it benefits from conclusions of previous risk assessment studies on *Campylobacter* in chicken meat. These risk assessment studies came to consensus that the **most effective intervention measures are those aiming at reducing the *Campylobacter* concentration, rather than reducing the prevalence in broilers**. Added to that, an important finding, shared by almost "**all**" of the published European risk assessment studies, is that the **tails of the distributions** describing the variability in *Campylobacter* concentrations between meat products and meals **determine the human infection risks**, and not only the mean values of those distributions. Thereafter, the present UK-target aiming at reducing number of carcasses at the highly contaminated counts band (> 3 $\log_{10}$ CFU/g of neck skin) would be expected to have the most positive impact on public health. On the other hand, application of such target is indeed a challenge to the chicken meat industry. The industry needs to be well prepared for monitoring such target constantly, despite absence of a legal binding microbiological criterion (neither in EU nor in UK in general) for *Campylobacter* in broiler meat. Monitoring of such target is a voluntary task for the broiler meat industry, but yet it is indeed a resource demanding task. With this regard, we find that **the FSA attitude toward involving/working with the industry is a very interesting approach,** and **such engaging approach could facilitate the efforts toward implementing this *Campylobacter* target**. By doing so, this FSA cooperative approach with the industry provides example of putting the risk-based target (even if a voluntary one) on the correct path that ensures its practical application among stalk holders.

The setting of the UK-target was based on a mathematical risk assessment approach. **The model was evaluated as fit for the purpose. *However*, the present model does not aim to give the precise figure for the target, but rather provide a starting point for discussion around which practical issues could be overlaid.**

Such modeling approach has some advantages:

- The model build up is **not mathematically complex**, and could be generally communicated to most stalk holders;
- It is a **very flexible** model that accommodates for future improvements and for quick changes in the intervention input parameters;
- The majority of the **model input data** are updated based on results from **UK-based** projects. Added to that, experts from the industry stalk holders were encouraged to have there inputs and share expertise.

Also, we find some drawbacks/points of attention of the present modeling approach:

- The assumption that **infection does not occur in birds less than 21 days old** (cells: C20 and F20) brings a great deal of sensitivity into the model. Compared to other published models on *Campylobacter* in broilers (e.g. CARMA, and Danish models), the value of only 14 days old was the most commonly used.

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- In same line with the previous point, **the modeling of the source of infection**, and hence the timing of initial introduction of *Campylobacter* into the flock, was not considered in the present model version. This is needs to be considered in order to provide a base for a choice between 21 or 14 days as input value for the period where flock infection is not considered.
- The Dutch, CARMA, model showed that the source of infection can be included into the model by accounting for transmission between farms. This could be complementary to the current model version.
- Another option to handle such problem is to describe the period of which infection does not occur in birds as a probability distribution, instead of just using a fixed value (point estimate).
- The inclusion of two-stage transmission at farm level (within flock, and between flocks) is rather complex and very uncertain approach. One parameter model, as used within the second stage of the presented farm colonization model, should be satisfactory and more appropriate to describe the spread of *Campylobacter* within an infected flock. In our opinion, low *Campylobacter* prevalence flocks are not easily to be detected, which may result in the occurrence of false negative flocks and underestimated flock prevalence in a monitoring program. Added to that, the discrepancy between the routine detection methods (direct plating versus enrichment) adds also to the underestimated flock prevalence.
- The slaughterline phase of the model adopts a very mechanistic approach in order to describe the non-linear effects of processing stages. Indeed such approach is the most appropriate to compare the relative effects of risk management intervention options (as fits for the purpose of this target setting procedures). However, if this model will be extended in the future to measure the current health risks, this mechanistic approach may not be preferable.

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STRENGTH AND WEAKNESSES OF ADOPTING THE WEB BASED TOOL RECENTLY RELEASED BY THE CODEX COMMITTEE (FAO/WHO) FOR BROILER SLAUGHTERHOUSES

The procedures followed in the model used for setting the UK-target for *Campylobacter* reduction in broiler are in line with the flow of the web tool recently released by CODEX for broiler slaughterhouse processes. However, **the UK model is more detailed, better structured, and more transparent**. Our group was selected by the FAO/WHO committee to take part in evaluating the CODEX web tool (CWT) before having it released recently in its final version. In the CWT, changes in prevalence and numbers of *Campylobacter* along the broiler production and processing chain have to be described to be able to predict risk and the decrease in these risks that can be achieved by interventions along the broiler chain. As the prevalence and numbers of *Campylobacter* along broiler slaughterline are variable and the dynamics are uncertain, the CODEX tool accommodates for probabilistic models to be constructed. A range of probability distributions is provided to the user, in addition to the option of just using fixed values (then deterministic and not probabilistic) is also provided as an alternative.

Comparing results from the UK-target setting models with those from the CWT might be a good attempt for model validation. However, it should be noted that results can not be directly comparable as the two modeling approaches are variable in the setting and in the scope.

We also should note to certain weaknesses of the CWT:

- For input data describing variability in bacterial concentration, the CWT seems to have a technical problem that does not allow the user to insert certain concentration ranges. For example, we tried to enter values of a mean *Campylobacter* concentration of 1.8 $\log_{10}$ CFU/g with standard deviation of 1.9 $\log_{10}$ CFU/g in order to describe a normal distribution for the variability in *Campylobacter* counts (log scaled counts). In fact, these values (mean and standard deviation) are based on summary statistics from a recent (year 2008) national survey in Belgium. Unfortunately, the CWT could not accommodate for these values. Thus, to carry on; the user might needs to change input values to keep the CWT running (but then the concentration values are no more representative).
- For input data describing prevalence, it is not clear why there was no option to include a probability distribution around this parameter. In the evaluated version of the CWT, prevalence is entered as a fixed value only.
- Only limited probability distribution choices are allowed in the CWT; for instance, binomial distribution (which was extensively used in the UK-target model) can not be used.

The comparison between the CWT and the current UK-target model **should be limited to comparing effects of the selected management options**. However, it should be noted that the UK-target model provides only a very limited number of intervention options. On the other hand, **the CWT provides much more options that worth exploring** (e.g. crust freezing; and other interventions might not be applicable to the UK situation (e.g. chemical decontamination)).

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APPROPRIATENESS, WEAKNESS, AND GAPS OF THE INPUT MODEL DATA

The data used as inputs for the UK-target model are **very much appropriate** to the local setting and to the scope of the model.

Two important features of the input data makes it advantageous, compared to previous UK-based models, and these are:

- Utilization of the recent data from the **EU baseline survey on *Campylobacter*** counts and prevalence in broilers in 2008. This is the first intensive quantitative data set, and the survey provided more epidemiological insights on the broiler chain in the UK (e.g. thinning, carcasses vs. caecal prevalence, and organic birds).
- **Engaging the industry stalk holders** whenever needed to get experts insight on certain parameters. This is a very innovative approach that completed well the input data from the 2008 baseline survey and from recent UK-funded projects.

On the other hand, there is ***a weakness that should be pointed to*** with regard to the selected slaughterhouses interventions. In **all** of the intervention options (cells D8, D13, D19, D24, D33) **the probability distribution parameters are based on just "one single study"**. There is obvious variation in the published data on the efficacy of each of these interventions. Thus, the choice of just one single study to draw the distribution parameters from is not appropriate, and also was not well justified. Variability between studies was not considered. Such variability should not be underestimated as many of these studies are based on laboratory models or a prototype version (not industrially applicable) of the intervention option. It would be important to thoroughly list different studies per each interventions, then either to justify why one is used (or preferred) than others, or to combine results from different studies (per intervention) based on weighting factors. Such weighting factors might include; appropriateness of the study to local setting in UK slaughterlines, appropriateness of the study methodology, results repeatability and reproducibility, applicability of the intervention to the daily use in broiler slaughterline.

On another aspect, there was no attempt to provide **a preliminary comparative cost of the economic aspects of application of the different proposed interventions**. There is indeed a gap of knowledge on this area, and more data need to be gathered in future studies.

With respect to the intervention **modified atmosphere packaging (MAP)** in cell D33; in Table 6, the indicated uniform distribution values are 2.0 and 2.6 log. However, in the excel sheet model these values are reported as 1.0 and 1.3 log. This is needed to be checked and corrected.

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MODEL ROBUSTNESS

A risk assessment model is robust when it has a broad domain of validity and accuracy comparable to that expected based on model development. With this regard, the team behind this model was apparently keen to validate estimations from this model (simulated results) against real field data. The simulated output of the farm module (the proportion of flocks contaminated at slaughter) were validated against the prevalence estimate concluded from the baseline survey in 2008. **There was a very good concordance between the simulated flock prevalence (73.96%) compared to the prevalence concluded from the 2008 survey (75.81%).** Such validation check indicates that the **farm level model has a good validity and sound robustness**.

Sensitivity analysis tools could be used to aid in identifying the important uncertainties for the purpose of prioritizing additional data collection or research. Furthermore, sensitivity analysis can play an important role in model verification and validation throughout the course of model development and refinement. Sensitivity analysis also can be used to provide insight into the robustness of model results when making decisions. **We performed a sensitivity analysis using regression coefficients and correlation coefficients methods in @Risk software (where the model was initially built).** The sensitivity analysis looked at all of the slaughter model output variables. It was very evident from the sensitivity analysis that the input **variable describing the initial concentration in caeca on entering slaughterhouse** (log CFU/g) is of major relative importance and that drives the majority of uncertainty in this model. This is logical, as the level of *Campylobacter* in birds gut would be expected to play a major role in the dynamic change in levels of carcasses contamination. This finding out of the performed sensitivity analysis calls for *two recommendations*:

- **For researchers**; there is a need to gather **more quantitative data on *Campylobacter* levels in caecal samples**. This will reduce a lot the uncertainty and variability of the whole model. With this aspect also the attention should be paid to **the data handling aspects**; for instance, handling negative results (data below *Campylobacter* limit of quantification), and also it is advisable to use the whole distribution (categorical count bands) of *Campylobacter* counts instead of just using the mean and standard deviation. The mean could be susceptible to extreme counts, and this could overestimate the numbers of *Campylobacter*.

- **For risk management**; as shown in the sensitivity analysis of the slaughter model, numbers of *Campylobacter* in caecal contents were the major factor that drives variations in *Campylobacter* numbers on carcasses (and also that impact the effectiveness of slaughterline interventions). It would be interesting to include in future research (and in future management options) **interventions aiming at reducing the number of *Campylobacter* in birds at the farm level**. This is for instance could include aspects of using organic acids, feed additives, natural antimicrobials in feed and water, competitive exclusion, and enhancing biosecurity and flock management.

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SUMMARY AND FUTURE IMPROVEMENT POSSIBILITIES

Through this evaluation report the following conclusions could be drawn:

- The present UK-target for reducing *Campylobacter* in chicken meat is an **innovative** and **science based** management approach;

- Setting of this target was achieved in **coordination with the broiler industry**, and such engaging approach is very beneficial for the future application of this target;

- The setting of this target was largely informed by a mathematical risk assessment model. Throughout our review, we find **the model fit for the purpose**. However, this model-based approach should be regarded as a starting point for discussion around which practical issues could be overlaid;

- **There is a room for improving the present model**; especially with regard to modeling of the source of infection, sound justification of the time period of which infection does not occur in birds (21 versus 14 days), and easing the mechanistic pattern of cross-contamination across the slaughter model;

- Compared to CODEX web tool model (which we have evaluated for the account of FAO/WHO), we conclude that **the present UK model is more detailed, better structured, and more transparent**. However, limited management options were evaluated in the UK-target model as compared to the CODEX web tool model;

- Data source for the UK-target model were found to be very appropriate to the purpose of setting the target. However, **a weak aspect was in defining the interventions distribution parameters**. The intervention parameters were based on single study per each management option. Selection of such single study was not well justified for us, also this does not consider the conflicting results between some of these studies (e.g. on steam effect for instance);

- **Interventions cost** worth further considerations and more data are needed to be gathered with this respect;

- The **model shows a good validity and sound robustness**. This was evident by the close concordance by the simulated model output and output from field data;

- **Sensitivity analysis** showed that the initial concentration in caeca on entering slaughterhouse (log CFU/g) is of major relative importance. More data are needed on this aspect. And this also allows us to conclude that interventions aiming at reducing *Campylobacter* numbers in the gut of the bird, at farm level, should not be overlooked.

- **Adopting of this target for reducing *Campylobacter* in chicken meat, calls for future research/work on; development of online monitoring tools (e.g. labOnChip), searching for hygienic indicator that surrogate for *Campylobacter*, industry guide on how to act/what to do with *Campylobacter* positive samples (flocks); study the impact of this target from a point of public health benefits is still lacking (that should be done by extending this model to retail and consumption phases).**