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# Development of food chain safety risk evaluation systems

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A témavezető jóváhagyása

## 1. BACKGROUND OF RESEARCH, OBJECTIVES

In order to guarantee food chain safety risk-based control systems are operated by the Member States of the European Union. The aim of risk-based control systems and their legal background is to ensure the protection of people, animals, plants and the environment from any adverse effects. Requirements for control systems allow flexibility for Member State authorities in many aspects, in order to take into consideration their characteristics when control systems are set up, however, in some cases clear rules are formulated. Regarding control systems to be established, it can be said that, legal requirements are limited with a few exceptions to the definition of the framework, detailed structure of the control system and applicable tools are not covered, mostly recommendations are given. This kind of flexibility can be considered to be both an advantage and disadvantage, and authorities can face difficulties when taking efforts to establish control systems.

A risk-based control system is able to operate efficiently with limited resources by allowing resource allocation to high risk areas, as well as it can provide objective evidence for resources allocation, and it can support the management of legislative risks. At the same time it has to be ensured that low-risk businesses or products have the right level of control, the right frequency of control and the flow of information is guaranteed, and the degree of bias resulting from risk-based selection is low. In a well-functioning control system, it is essential to introduce documentable procedures supporting structured data collection and providing traceability to official decision-making processes.

Challenges described above are regular characteristics of all official control systems, regardless of field of expertise. However, it

is not possible to examine and analyse individual problems without the analysis of a practical approach or sub-area. Therefore, the objective of my research was the examination of the Hungarian risk-based control system and related processes supporting decision making that were narrowed to the part of product sampling, and proposing adaptation and development of new methods. In addition to the examination of general, discipline-independent systems, my research also covered the examination of decision support systems that can be applied within a given field. As a part of risk-based control system, microbiological hazards in food, especially the food safety risks posed by *Campylobacter* species were chosen, considering their importance in food safety.

One of the fundamental pillars of risk-based monitoring systems' – especially of the sampling systems' – operation, is the identification and monitoring of hazards in the food chain. In order to establish a flexible system, that is suitable for continuous improvement, based on the information available, it is of key importance to assess and rationalize the data collection process related to hazards and the application of proper decision supporting tools at the right process steps.

Thus, the objective of my research was to adapt and develop methods supporting official decision-making in order to identify, monitor and rank hazards in the food chain, and it can be broken down into the following sub-objectives:

- Modelling of the process of hazard identification and monitoring;
- Identification and promotion of decision process related to new hazards;

- Development of a data systematisation and management model for supporting decision making;
- Introduction of a new sampling plan;
- Cause analysis and risk evaluation of *Campylobacter* spp. in the broiler production chain;
- Cost-utility assessment of interventions aiming to reduce *Campylobacter* contamination of broiler flocks.

## 2. MATERIALS AND METHODS

The aim of my dissertation was the adaption of existing data systematisation and ranking processes and development of methods supporting official practice, that is defined as the official practice of the Nation al Food Chain Safety Office (NÉBIH), and all presented research aimed to support decision making processes of NÉBIH.

In each case, the research workflow began with the emergence of a problem or a request that was a question regarding the solution of an official procedural issue or methodological problem. After the problem was proposed, information was collected, which included literature review, expert interviews, and the development of ideas based on our own experience. This was followed by the development of the model or the tool to be used, its submission for opinion, and its correction and testing, if it was necessary.

### 2.1. Problem identification

Activities that address the management of risks in the food chain are not always or can be regulated by procedures. In many cases, practices that were developed several years ago and are being used for a long time are ineffective regarding the achievement of objectives and resources utilization. The easiest way to describe a process is by the definition of its goal or outcome. Among topics discussed, a need for identification and review of existing processes and introduction of new processes, procedures and tools occurred several times and all of them were closely related to official decision-making concerning planning of sampling.

## 2.2. Information collection

The first step in renewing a process, introducing a new process, or developing a tool for supporting a decision making was the mapping of existing knowledge through literature review and interviews with representatives of the technical field concerned. Narrative literature review has been carried out by means of scientific databases and the internet. Collection of other information (institutional or field related) was carried out mainly via expert interviews and/or small workshops.

## 2.3. Modelling

During my research, modelling involved two types of activities. On the one hand, it represented the definition of an existing or a new process, on the other hand, it meant the development of a tool that could optimize the related planning and decision-making tasks and support their implementation.

### 2.3.1. Description of the hazard identification and monitoring process

The description of the hazard identification and monitoring process included the characterization of certain decision and ranking sub-processes as well as the outline of both current and proposed versions of the studied process.

### 2.3.2. Mapping of production process

During my work, collection of information was limited to data on broiler chicken farming and processing, including the management of parent flocks and hatching also. Actions significantly influencing the entry of *Campylobacter* spp. into the food chain were studied.

Based on the literature data, I outlined the process describing the poultry breeding and production chain, and in order to identify the causes contributing to the spread of the pathogen, all process steps were analysed.

### 2.3.3. Determination of the decision process regarding new hazards

Deciding whether the identified hazard is covered by the authority's activities is a crucial step. The sub-process where the selection of hazards relevant to a given activity happens from the set of all existing hazards, can be described by a series of yes/no questions or decisions, thus it can be easily characterized by a decision tree. In order to achieve a documentable process, I developed a simple (web-based) questionnaire on the basis of the outlined decision tree.

### 2.3.4. Development of a data systematisation and management model

In order to process the scientific literature in a traceable way, an Excel-based data organization template was developed, which allows on the one hand the recording of the processed literature and on the other hand the systematic collection and evaluation of the data included.

Data structure of the template is based on the publications processed and the data discussed by them, which are assigned to a hazard-product pair related to a food chain position. The developed template allows the recording of the processed information and the

weighting and evaluation of it. The data sets to be recorded were determined on the basis of the publications and data included therein that were processed during the hazard analysis of *Campylobacter* species.

### 2.3.5. Introduction of a new sampling plan

In the course of my work, I had the opportunity to participate in the Twinning project SR/13/IB/AG/01 as a short-term expert, where a sampling plan for microbiological hazards was developed to be introduced by the Serbian authority. The compilation of the plan included a review of EU and Serbian legislation, as well as several expert interviews and a small number of workshops. In order to allocate the sampling budget in a documented and repeatable way, an Excel-based model supplemented with macros was adapted for the ranking. Once the sample numbers have been determined, an Excel template was also developed that allows the distribution of the sample number based on the ranking by specifying the total number of samples and the average test, sampling and transport costs, as well as the cost calculation for product-hazard pairs.

### 2.3.6. Cause analysis and risk evaluation of *Campylobacter* spp.

Following the description of the poultry production chain, causes contributing to the spread of *Campylobacter* spp. in the chain were collected, categorized, and paired with literature data. The data available in studies were not based on uniform mathematical methods, thus, in order to perform a risk assessment, odds ratios and other data regarding the probability of occurrence of the microorganism had to be weighted and converted. During the evaluation of each process, relevant hygiene and legal requirements, the adherence to the

available good practices, and the complexity of the given "step" were considered. The determination of the risk values for the elements of the production chain was followed by the examination of the possibilities for the elimination of problems associated with each processes that can contribute to the minimization of the risk represented by *Campylobacter* spp. entering the food chain.

### 2.3.7. Cost-utility assessment of interventions aiming to reduce *Campylobacter* contamination of broiler flocks

My objective was to adapt and validate a model previously prepared for the European Commission in order to provide a cost-benefit analysis for interventions aiming to reduce *Campylobacter* contamination of broiler carcasses, by means of the utilization of data representing more specifically Hungarian characteristics.

The validation covered the combination of currently available measures, namely enhanced biosecurity, removal without thinning (all in all out), double testing (before slaughter, at farm and after slaughter, at the processing plant), and best hygiene practices during slaughter.

## 2.4. Collection of opinion on models developed, testing and application

The processes and tools developed on the basis of the literature review and expert interviews were submitted for opinion to the representatives of the technical field concerned, that was followed by the incorporation of comments, and the testing of the tools. When it was necessary, opinions were collected in multiple cycles.

# 3. RESULTS

## 3.1. Description of the hazard identification and monitoring process

During the modelling of the hazard identification and monitoring system, my goal was the understanding of the process steps, outlining the process, identification of the points that needed to be revised and making proposals for possible amendments.

In the course of my work, firstly the existing sampling planning process was outlined, which was then supplemented with the required and proposed modifications. After reviewing the examined process, it was recognized that the applied practice does not manage systematically the step of new hazard evaluation, data collection and systematization related to the observed hazards, their ranking and planning applicable measures. The latter is particularly important because a situation may occur when management or monitoring of a specific hazard requires not only sampling but also the introduction of additional interventions. Based on the above mentioned assumptions, I outlined the amended hazard identification and monitoring process that was supplemented by the information collection step divided into two parts, the decision point for new or yet uncovered hazards, and the process steps for planning and implementing interventions.

## 3.2. Development of a decision tree or a quick and easy ranking model

The first two steps of the proposed hazard identification and monitoring process are the mapping and identification the hazards to be managed by the competent authority. The model suggested here is

not intended and cannot fully address emerging hazards, it is mainly intended to support the introduction of a new or revised monitoring system.

Thus, the second step of the hazard identification and monitoring process can be described by a simple decision tree that is a series of consecutive questions to be answered. By the application of the questions included in the decision tree, decision can be made whether a specific hazard falls within the scope of the competent authority, namely whether the long-term management and monitoring is necessary or not. The online questionnaire developed on the basis of the decision tree is available at the following link: https://tinyurl.com/3ch8nehm.

### 3.3. Development of a data systematisation and management model

As part of my research, I developed an Excel-based data organization template that facilitates the work of authorities by providing a searchable, structured data storage. When recording data, the smallest data element to be recorded is the measured value, calculated data from a risk assessment or information from a descriptive analysis. The former may be concentration values indicating the presence of the target microorganism or values calculated by a risk assessment methodology.

The weights are normally given for a scientific publication, but in many cases, publications summarise the results of several examinations or estimates, so that data in a specific publication can be matched with more than one (differring) weights. With proper data recording, a filterable and searchable database can be created that enables the use of Pivot Tables during evaluation, making

visualisation and categorisation of the recorded data easier. The Excel worksheet is available at the following link: https://github.com/BaDoc2021/Data-collection-scheme.git

### 3.4. Introduction of a new sampling plan

In the course of my work, I had the opportunity to participate in the Twinning project SR/13/IB/AG/01 as a short-term expert, where a sampling plan for microbiological hazards was developed to be introduced by the Serbian authority. Following the review of EU and Serbian legislation, objectives and principles underlying the sampling plan were identified through expert interviews and workshops. The purpose of establishment of the sampling plan was the verification of compliance with the requirements of Regulation (EC) No 2073/2005 in the frame of an official sampling program. During the expert interviews, hazard-product pairs and sampling positions were identified that were intended to be included in the plan and the ranking was based on the available data and expert estimations. (The Excel worksheet is available at the following link: https://github.com/BaDoc2021/Easy-to-use-RiskRanking-tool.git)

Subsequently, based on the available budget and the estimated sampling and testing costs, the number of samples that can be taken, the number of samples per each hazard-product pair and sampling position and total costs were also determined.

### 3.5. Mapping of production process

Based on the data available the broiler production chain was outlined. Grandparent flocks and consumption together with the delivery to households were excluded from the model, because the role of breeding is negligible in the spread of *Campylobacter spp*.,

and handling by consumers is out of the scope of competent authorities. This production chain formed the starting point for the cause analysis and risk evaluation, which covered the spread of *Campylobacter* species within the food chain and the causes of their occurence.

### 3.6. Cause analysis and risk evaluation of *Campylobacter spp.*

Several processing steps received high risk values. For this reason, continuous monitoring is of paramount importance, as is the increased training of the staff. In total 6 steps representing “major” or “high” risk were identified, and 7 stages related to farming and processing received “medium” risk score. Values of different severity are located at different points of the food chain, which indicates that against the spread of campylobacteriosis by broiler meat, complex control measures must be applied and implemented throughout the food chain.

A review of sub-processes with a risk value of 6 or 9 is recommended, as well as a review of the legal procedures available for the minimization of the contamination should be carried out. Most of the causes that arise can be avoided by controlling processing steps, by the application of proper training of the staff, by ensuring proper flow of information, and by compliance with the relevant legislations and recommendations. In many cases, the impact of people who come into contact with the product during processing is not given sufficient emphasis.

### 3.7. Ranking of interventions aiming to reduce *Campylobacter* contamination of broiler flocks

In the course of my work, I examined the impact of a package of measures belonging to the *Campylobacter* control program that can be introduced throughout the EU, and it includes intervention currently accepted by consumers and legally applicable. The result calculated by the modification of the original model also shows an annual cost saving of 2.45 million euro, with approximately 999 QALY gain, which would mean the prevention of 65 584 cases of human gastroenteritis in Hungary. A comparison of the results with EU data shows that in 15 Member States, including Hungary, both health gains and cost savings would be achievable. Based on the susceptibility analysis, it can be concluded that by the application of currently available interventions, even calculating with the lowest effectiveness of each measure, 51 068 cases of human campylobacteriosis could be prevented in Hungary annually, with an annual health benefit of 778 QALYs and a net annual cost saving of 1.6 million euros. By the application of the published model's original input parameters, the health and economic burden of campylobateriosis was overestimated. The revised estimate and the applied sensitivity analysis confirmed the cost-effectiveness of the package of interventions for Hungarian circumstances also.

### 3.8. New scientific results

1. In order to support the work of the Hungarian food chain safety authority, I mapped the hazard identification and monitoring process that is currently in place, and I made several suggestions for the amendment of the process with documented sub-processes and tools.

2. The decision process related to hazards in case of the planning of new control systems or during periodic reviews of existing systems was identified as a critical point in the modelled hazard identification process, since currently it is not documented. In order to supplement the identified procedural deficiency, I developed a decision tree that is suitable to support the quick assessment of hazards within the scope of the competent authority and to provide documentation by introducing an online questionnaire.

(The **online questionnaire** is available here: https://tinyurl.com/3ch8nehm)

3. In order to organize and evaluate information regarding hazards occurring in the food chain, I conducted a cause analysis and risk evaluation on the occurrence of *Campylobacter* spp. in the poultry production chain. As a result of my work, a data systematization tool has been developed that can provide structural support for the organization of data on hazard monitoring, as well as a risk evaluation scheme that allows the conversion of data of different risk assessment approaches.

(**Berkics, A.**, Varga, V., Mohácsi-Farkas, Cs., Józwiak, Á. (2020) Cause analysis and risk evaluation of the occurrence of *Campylobacter* spp. in the broiler production chain. Acta Alimentaria doi: 10.1556/066.2020.00310 IF (2019): 0,45

The **Excel worksheet** is available here: https://github.com/BaDoc2021/Data-collection-scheme.git)

4. During the development of a newly introduced sampling program, I adapted a risk ranking model that allows the simultaneous consideration of available scientific results and expert estimation with the help of an Excel-based tool.

(The **Excel worksheet** is available here: https://github.com/BaDoc2021/Easy-to-use-RiskRanking-tool.git)

5. As a result of the examination and cost-benefit analysis of interventions aiming to reduce *Campylobacter* contamination in broiler flocks, a calculation method, that's application is not widespread in the field of food safety, however it is suitable for the comparison of measures, was adapted. The cost-benefit analysis of the interventions was carried out considering domestic characteristics.

(Pitter, J. G., Vokó, Z., Józwiak, Á., **Berkics, A.** (2017) *Campylobacter* control measures in indoor broiler chicken: Critical re-assessment of cost-utility and putative barriers to implementation. Epidemiology and Infection, 1-12. doi: 10.1017/S0950268818001528 IF (2019): 1,12)

## 4. DISCUSSION AND RECOMMENDATIONS

In the course of my work, I mapped the hazard identification and monitoring process currently in place in the Hungarian official practice, as a result of which it was recognized that new hazards are not channelled in a systematic, documentable way into the planning process, and the measures related to hazard monitoring are mainly limited to sampling. The decision tree that can be filled in via an online questionnaire developed by me, amends the current information collection practices with a documented sub-process that allows systematic and retrievable data recording and supports quick consideration of hazards.

Similarly, the data collection sub-process regarding hazards that are intended to be managed by the authority is currently not supported either. Thus, information loss can easily occur, especially if more than one person is responsible for the hazard-related literature review, data analysis, and risk assessment within in a specific technical field. The developed Excel-based data systematization tool facilitates the structured collection of hazard-related data, as well as provides a risk evaluation scheme that allows the conversion of different risk assessment approaches according to a set of criteria that ensures data comparison. Due to the database nature of the tool, it is recommended to develop a data recording guide or procedure to ensure that data recording is implemented in accordance with uniform principles especially when multiple users are involved.

Another area of my research was the adaptation of a risk ranking model that could be used for the introduction of a new sampling plan and also the development of a cost calculation template. By the application of the developed Excel-based tool, it is

possible to rank microbiological hazards in a documented way on the basis of available scientific results and expert estimates. The result of ranking can be inserted into the calculation template, in which the distribution of the total number of samples that is estimated on the basis of the available budget, between product-hazard pairs and also the calculation of the costs based on laboratory tests, sampling and transport, is possible. The cost calculation template can be further specified depending on the available resources, as well as the rankings and costs can be periodically updated.

For the study and cost-benefit analysis of interventions intended to reduce *Campylobacter* contamination in broiler flocks, I adapted a model for the comparison of measures to examine the impact of a package of interventions that may be applicable as a *Campylobacter* control program in Hungary as well. Assuring comparability was a key point during the analysis, therefore a significant part of the input parameters, such as the cost of the measures and the structure of the production chain, were not modified. By updating the costs assigned to each intervention or providing additional country-specific data, the calculation can be further refined, thus providing a more comprehensive estimation of domestic opportunities.

## 5. LIST OF PUBLICATIONS

### 5.1. Journal articles in English

Berkics, A., Varga, V., Mohácsi-Farkas, Cs., Józwiak, Á. (2020) **Cause analysis and risk evaluation of the occurrence of *Campylobacter* spp. in the broiler production chain**. Acta Alimentaria doi: 10.1556/066.2020.00310 IF (2019): 0,45

Pitter, J. G., Vokó, Z., Józwiak, Á., Berkics, A. (2017) ***Campylobacter* control measures in indoor broiler chicken: Critical re-assessment of cost-utility and putative barriers to implementation**. Epidemiology and Infection, 1-12. doi: 10.1017/S0950268818001528 IF (2019): 1,12

Tima, H., Berkics, A., Hannig, Z., Ittzés, A., Kecskésné Nagy, E., Mohácsi-Farkas, Cs., Kiskó, G. (2017) Deoxynivalenol in wheat, maize, wheat flour and pasta: surveys in Hungary in 2008–2015. Food Additives & Contaminants: Part B, 2018:11(1):37–42. doi: 10.1080/19393210.2017.1397061 IF (2019): 2,951

### 5.2. Conferences

Berkics, A., Józwiak, Á., Pitter, J. G., Vokó, Z. (2016. június 24.): ***Campylobacter*: Költségek és várható haszon.** Szakmai konferencia és beszámoló a Campylobaktériumról, valamint az elmúlt három évben végzett kísérleti munkáról. 2016., Budapest

Berkics, A., Józwiak, Á., G. Pitter, J., Vokó, Z. (2015. november 18-19): **Methods for risk prioritisation to support food chain safety decision making.** Food Science Conference 2015., Budapest

Berkics, A., Bajcsi, N., Kovács, M., Belák, Á., Teparič, R., Mrsa, V., Maráz, A. (2013. április 16-17.): Hús romlási folyamatból

izolált *Candida zeylanoides* törzsek extracelluláris lipáz termelése és az enzim jellemzése. Hungalimentaria 2013., Budapest, Absztraktkönyv 45. oldal

Berkics, A., Kovács, M., Maráz, A. (2012. október 24-26.): Screening and characterisation of new lipolytic yeast strains. Annual Meeting of the Hungarian Society for Microbiology 2012., Keszthely, Abstract Book, p. 5.

Berkics, A., Bajcsi, N., Kovács, M., Belák, Á. Teparič, R., Mrsa, V., Maráz, A. (2012. szeptember 3-7.): Extracellular lipase production by *Candida zeylanoides* and characterisation of the enzyme. 23rd International ICFMH Symposium, FoodMicro 2012, Global Issues in Food Microbiology, Istanbul, Abstract Book, p. 582.

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