Challenges and opportunities related to the use of innovative modelling approaches and tools for microbiological food safety management

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Abstract

Modelling in food microbiology has become an indispensable approach in food safety to generate predictions about the microbial behaviour. One of its weaknesses is the lack of reliable and relevant data for mathematical modelling. The increasing amounts of data and innovative modelling tools have the potential to provide relevant information on hazard, exposure, and surveillance reports. They can be combined to reduce the time needed to perform a risk assessment, improving food safety management decisions. Future tools will follow a multidisciplinary scope of action, including food microbiology, process engineering and technology, innovative mathematical modelling approaches, holistic perspective in risk assessment and multi-criteria analysis beyond the health impact (risks-benefits) to provide appropriate risk mitigation and control options. When predictive modelling is used to establish risk management strategies able to reduce food safety risks, uncertainty analysis and communication is needed to provide a transparent answer indicating the limitations of the outcome.

Key words: Predictive microbiology, microbiological risk assessment, food safety management, risk management strategies

Introduction

Modelling approaches for microbiological food safety have evolved toward the use of effective mathematical models able to describe the introduction of pathogens into food, the growth of microorganisms in food over time, the inactivation-destruction of microorganisms, the consumption of microorganisms that the food is carrying and the event of the subsequent illness [1]. Predictive food microbiology, also known as quantitative microbial ecology, aims at characterizing the behaviour of microorganisms (in terms of growth, inactivation, toxin production, growth/no growth boundaries and transfer models) in a food as a function of relevant factors, such as intrinsic, extrinsic and microbial interactions (i.e. implicit) [2,3]. It offers powerful tools and approaches to investigate and synthesize in a structured manner the effect of a variety of conditions. Within the wide variety of applications in the framework of microbial risk assessment (MRA), predictive microbiology models have been recognized as key components for modelling the exposure to foodborne microorganisms [4]. They aim to deliver science-based outputs to support decision making in the prevention and mitigation of food safety issues and they have served as the basis for innovative modelling approaches that contribute to cover the gaps to perform a full MRA.

The accuracy and robustness of the modelling approaches strongly depends on the amount, representativeness and quality of the data used to build them, but also to apply them. For this reason, the lack of data and knowledge about food safety hazards is an eternal complaint of researchers, risk assessors and risk managers. Inadequate data and lack of knowledge about foodborne hazards, including factors and drivers for the associated risks, lead to poor food safety management systems (FSMS), which are associated with misinformed decision-making and ultimately inaccurate conclusions or inferences [5]. Changes and advances in the food industry and supply chains have generated large quantities of data, which have been explored in innovative ways and they continue to improve the safety of the food supply. The reality is that although there are more data available that can be used to establish microbiological risk assessment and food safety, they are not always easily accessible in a compatible format. This limits their implementation in modelling tools to answer questions related to microorganism/food combinations. To solve these problems, recent advances in the data science and predictive modelling approaches to food safety have led to the emergence of Big Data analytics applications in this area [6]. It is often produced with high velocity from various types of sources and is demanding new tools and methods, such as powerful processors, software, and algorithms [7,8]. Recent studies have shown that the ability to extract value from these data while ensuring the interoperability of different sources to enable food safety and quality is the future challenge to establish up to date food safety strategies and policies [8]. The scientific opinions of EFSA related to biological hazards and reports of the national food safety agencies in the EU are perfect examples of this situation. In most cases these scientific reports indicate the lack of data as a factor that limits risk assessments. This drawback could be at least partially overcome with the use of Big Data.

The aim of this work is to illustrate the opportunities posed using innovative modelling tools and big data for microbiological food safety management and the challenges that accessing and implementing them can raise.

Description of existing modelling tools for microbial food safety

There are many online food safety databases and modelling tools available which contain relevant information on hazard, exposure, and surveillance reports [9]. A classic example is the Rapid Alert System for Food and Feed (RASFF, https://webgate.ec.europa.eu/rasff-

window/screen/search), which is the main food safety online database used by authorities, industry, and scientists in Europe. It aims to ensure the flow of information and rapid reaction when a public health risk is detected in consignment(s) of a food or feed.
There is an extensive list of modelling tools in food that were reviewed [10,3]. Table 1 describes the nature and purpose of the different groups of tools, providing examples of the main ones. Generally, they are regularly upgraded with improved algorithms or new applications. They can be classified as Databases-repositories, Dose response models, predictive microbiology models and risk assessment tools (Table 1). In addition to simulation tools, model fitting applications for estimating kinetic parameters of microbial growth and inactivation were developed as Excel Add-ins, e.g., DMFit, GInaFiT, iPMP. More recently, R-Shiny based applications, accessible on-line with advanced features regarding modelling options, including stochastic modules, statistical indicators and usability have been developed, e.g., Bioinactivation [11], Microrisk Lab [12] or Biogrowth (Table 1).
Tools to carry out quantitative microbiological risk assessment for multiple hazards in relation to multiple foods are available (e.g. FDA-iRISK). Also, tools for specific food categories such as fruits and vegetables from primary production to processing (QPRAM, and – GIS-Risk), can be found. The web-based database Pathogens-in-Foods (table 1) gathers occurrence (prevalence and concentration) data of pathogens in a wide variety of food categories from EU compiled from scientific articles and enables the user to produce dynamic charts and summary statistics. These predictive tools and databases can be used reducing the time needed to perform a risk assessment. However, data and information exchange can be a limitation as data extraction and comparison among the different tools can be difficult. Therefore, harmonization of tools and the development of a communication language with compatible data format was pointed out as a key aspect for an efficient exchange of data and information [13]. Stochastic models that integrate intra-species variability, e.g. in *B. cereus* group [14], can contribute to describe variability in QMRA.

There are several applications (past and ongoing) that are relevant in this field; two case-studies are described for illustration. They have been selected as they cover well known concerns of biological food safety issues that we consider as good examples of the use and limitations of some of these applications.

Current applications of modelling tools in Food Safety and limitations observed

1. Incidence of *Listeria monocytogenes* in RTE

EFSA developed a conceptual model to identify those factors along the food chain that could lead to *L. monocytogenes* contamination of RTE foods and listeriosis cases. A huge amount of information was taken into consideration, such as the EU-wide baseline survey, the monitoring data of the EU (including the time series analyses between 2008 and 2015) and three outsourcing activities funded by EFSA related to *Listeria monocytogenes* in RTE foods, on top of all the research carried out in this field at international level.
A conceptual model was developed, based on a *L. monocytogenes* risk assessment [15]. Several modelling tools were used: To calculate prevalence and model initial concentration of *L. monocytogenes*, the EU-wide baseline survey and the EU monitoring data from 2011-2014 were applied. The EFSA Food consumption database [16] with an expanded hierarchical structure, Mintel database for New Products, Eurostat and Fishstat, FRISBEE Project database, all contributed to establish the consumer behaviour and the relevant products for the study (food consumption, serving size, fisheries statistics, time-temperature profiles, etc.) [15]. Then, Combase database was used to obtain growth data (Table 1). All of them were integrated as variables in the risk model. Factors related to the food change driving to *L. monocytogenes* contamination of RTE foods were host (population size of elderly and susceptible consumers),

the food (prevalence and concentration at retail, etc.), the national surveillance systems and the bacterium (virulence).
Even with such an extensive use of different tools, it was also reflected that, "Due to data limitations, the present evaluation of contributing factors was based on only three RTE categories which is a limitation of the assessment" [17]. So, there is still a need for data, especially in a format that can be integrated in these evaluations.

2. Multiple Foodborne Hazards in Fresh Produce

Food safety of fresh produce has been a long-standing challenge worldwide. Several foodborne outbreaks have been linked to the presence of pathogenic microorganisms in fresh produce in Europe [18] and other parts of the world. Several models have been used for modelling the interface between the environment and produce [19]. This is the case of the FDA iRisk®. However, this model only compares risks posed by multiple food/hazard combinations taking into account consumption, dose-response relationship, and contamination in the food supply system (Table 1). Therefore, this QMRA tool does not represent the best alternative to model contamination of fresh produce during growth, harvest, processing, transport, retail, and preparation for consumption, considering the individual facility perspective of contamination events, the potential interactions among produce units and specific risk factors in the produce environment and the contamination status of units of fresh produce with respect to time during multiple stages. In an attempt of providing a solution, the FDA is working in the Quantitative Produce Risk Assessment Model (QPRAM), which is an agent–based, virtual laboratory that models specific practices and risk factors (Table 1).
Apart from well-known QMRA tools, current trends include the use of Big Data to predict the presence of pathogens or contaminants, by linking environmental information with pathogen growth and/or hazards occurrence [9]. To reduce food safety risks, data needs to be collected and interpreted from all the steps of the supply chain. An example of this application is FACT, a tool that is being developed by the University of Illinois, as an innovative big data analytics technology for microbiological risk mitigation assuring fresh produce safety [20]. This tool will be able to develop a real-time data retrieval mechanism to extract relevant information from diverse digital on-line sources, design big data storage fusing risk pattern data sets, discover event patterns about safety risks in fresh produce chains, design machine learning models for predicting outbreaks early, and implement a web-based early warning interface for stakeholders to visually explore levels of risks [20]. The great advance is that information from an individual producer can be integrated with data from other farmers to enhance the value of that data through the development of a decision models such as dashboards, apps and other software applications [21]. Consequently, the information gathered can be used for the application of more prescriptive inputs to improve food safety management decisions, by giving real-time data, facilitated by smart technologies including artificial intelligence (AI), to implement direct mitigation measures [8].

Innovative modelling tools

In general, new modelling tools need to overcome the limitations described of the existing ones. They should enable easy access to the data available and allow to combine all the relevant factors in food safety decision-making. Implementation of environmental data is a growing area that will increase in the coming years. Several tools have been produced recently that allow to solve one or more of these aspects.
Differences in the software tools used to generate microbial models can limit the access to the predictions as they can be generated in non-compatible formats. These different access systems have driven to the development of approaches that can allow a harmonized information exchange. In this context, the Risk Assessment Modelling and Knowledge Integration Platform (RAKIP)

aims to enable the exchange of models relevant for biological risk assessment. Remarkably the Food Safety Knowledge Markup Language (FSK-ML) defines a framework for encoding all relevant data, metadata, and model scripts in a readable format. FSK Lab allows the use of published data to provide model scripts in several languages as a free, open-source toolkit for food safety models integration [22,23]. This tool, which can help solve the limitations of data use from different tools, requires some IT knowledge as the user needs to provide a model script.
Strawn et al. [24] demonstrated how data from available water storage in soil, temperature, and proximity to specific land cover classes could be used to predict the likelihood of detecting *L. monocytogenes*. Recently, the possible impact of climate change on food safety and spoilage was discussed [25], concluding that multidisciplinary approaches are needed to identify in depth emerging risks. Microorganisms will be affected by the modifications in weather expected.
As already predicted by [8], the devices used for data collection and the generated databases will be interconnected to provide the data needed to enhance source attribution analysis in foodborne outbreak scenarios and enable more precise farming for food safety attributes, using the term "precision food safety" to describe all the various new data sources that can be used to fine tune microbial risk assessment and improve food safety risk management.
The food safety databases can be also combined with other ones, such as workers health status, water quality and usage, meteorological information, animal movement records and farm audit certification records among others, to create decision support models [26, 27].
It is foreseen that future tools will need to tackle a multidisciplinary scope of action, gathering different research fields dealing with (i) food microbiology (including both pathogenic and technological bacteria and their interaction), from classical and molecular standpoints, including virulence and stress resistance studies as well as modern food microbiome approaches by means of "omic" techniques [28]; (ii) processing engineering and technology (classical, emerging and new food processing and preservation treatments, application of mass transfer law, process control, efficiency and optimization) with microbial population processes at different scales, from sub-cellular (system biology), individual cell vs population and food microstructure [29, 30]; (iii) innovative mathematical modelling approaches for the Optimal Experimental Design [31], model fitting, meta-analysis stochastic approaches accounting for variability and uncertainty (iv) holistic perspective in risk analysis, applied to food systems (e.g. One Health approach); (v) multi-criteria analysis beyond the health impact (risks and benefits) to complement aiming to provide appropriate risk mitigation and control options taking into account their technological feasibility at industrial level and sustainability (social acceptance, economic cost, environmental impact).

Implementation of uncertainty in modelling approaches

Despite the advantages and the improvements in the implementation of predictive microbiology within the remit of food safety, there is only one certainty, which is that there is always an uncertainty associated with a prediction, which implies that we can never be completely certain about the future. Therefore, uncertainty analysis is an important part of predictive modelling and risk assessment, which should be implemented in each analysis from the earlier steps, contributing to get more robust results in a more transparent manner. EFSA defines uncertainty as the process of identifying limitations in scientific knowledge and evaluating their implications for scientific conclusions. To identify and address uncertainty, different approaches (from qualitative to quantitative) can be applied depending on the scope and needs of the risk assessment. In general terms, the nature and the causes of uncertainties should be systematically identified considering every part of the assessment, covering data sources and inputs for the models, modelling approaches, model structure, etc. The overall impact of the identified uncertainties on the risk assessment outcome (e.g. overestimation or underestimation) should be characterized [32].

The most precise form of expressing uncertainty is using quantitative terms to express the combined impact of as many as possible of the identified uncertainties. This is relatively easy to implement when results are obtained from a quantitative manner and numerical outputs are

obtained. However, in many cases, data is not available, and results are obtained from an expert judgement. This is the case when probability judgements are made by semi-formal expert knowledge elicitation (EKE) procedures.
Expert knowledge elicitation (EKE) refers to the technique of obtain results out of knowledge from one or more experts. Experts can be asked for specific information (facts, data, sources, requirements, etc.) or for judgements about things (preferences, utilities, probabilities, estimates, etc.) [33]. When an EKE is performed, the overall evaluation of the uncertainty is also needed [34].
While risk assessors analyze the uncertainty, the risk managers have to resolve the impact of the uncertainty on the decisions taken. Therefore, the scientific uncertainty needs to be informed to decision-makers. A guidance on uncertainty communication was developed in the context of food safety with the involvement of social scientists with expertise on people's understanding of uncertainties [35]. Overall, uncertainty analysis also provides opportunities to identify and prioritize knowledge gaps for future research.

Conclusions and take-home message

There is a wide range of modelling approaches and tools to describe microbial behavior that can be integrated in biological risk assessment. However, there are limitations to their use, as there is not a common data format so to generate information can be time consuming or require advanced IT skills. New alternatives consider the development of open access software that allows a harmonized information exchange. The development of user-friendly tools related to models continues to be a priority to enable the general use of all the data available. In terms of new modelling approaches, those that can integrate multidisciplinary information such as quality, safety aspects, weather conditions, food chain, water sources, WGS data, etc. offer a new horizon for predictive models and their integration in next generation risk assessment.

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Table 1. Tools for predictive modelling applied to microbial food safety

Nature	Description	Purpose/scope	Strengths	Limitations	Examples	Reference
DataBase and repositories	Outbreaks; alerts, prevalence data, official controls	Hazard identification,	Rapid information of relevant hazards present in food and feed	Full information is not available and there are many potential bias due to under-reporting, lack of harmonization, lack of detailed information about the food or settings	1. RASFF; 2. CDC Foodborne outbreaks; 3. EFSA Foodborne outbreaks – dashboard; 4. Pathogens In Foods	1. https://ec.europa.eu/food/safety/rasff-food-and-feed-safety-alerts_en 2. https://www.cdc.gov/foodsafety/outbreaks/index.html 3. https://www.efsa.europa.eu/en/microstrategy/FBO-dashboard 4. https://pathogensinfood.esa.ipb.pt/
	Food consumption	Exposure assessment	Comprehensive (age groups; populations) at EU level	It does not collect information about relevant factors affecting microbial behavior (processing, packaging, etc.).	1. EFSA Comprehensive European Food Consumption Database	1. https://www.efsa.europa.eu/en/microstrategy/food-consumption-survey
	Microbial response	Exposure assessment	Provides raw data about growth/survival/inactivation of microorganisms in food	Data is not available for all types of food and microorganisms and/or specific relevant parameters (pH, a_w, strain)	1. Combase Browser 2. Microbial response viewer	1. www.combase.cc 2. mrviewer.info/
	Big data analytics	Hazard identification	Development of a real-time data retrieval mechanism to extract relevant information from diverse digital on-line sources.	Exploit multi-source big data, including social media, news media, and government reports but there are potential bias due to under-reporting of specific sources	FACT-Innovative big data analytics technology for microbiological risk mitigation assuring fresh produce safety	Under development[a]
Dose Response models	Probability of illness as a function of pathogen dose. Fitting tool	Hazard characterization	Relevant to rank relevant hazards present in food and feed.	Only very specific models are available and relevant parameters needs to be known or estimated	Dose response calculator	http://qmrawiki.canr.msu.edu/app/#/app/dose

Predictive microbiology models	Microbial growth/survival/inactivation prediction	Exposure assessment	Generate predictions/simulations of growth/survival/inactivation of specific microorganisms as a function of intrinsic and extrinsic factors	Limited number and/or type of input factors Predictive performance not always proved for specific foods	1. ComBase Predictor 2. Pathogen Modelling Program (PMP) 3. Food Safety and Spoilage Predictor (FSSP) 4. Sym´Previus* 5. MicroHibro 6. GroPin 7. Open FSMR	1. https://www.combase.cc/index.php/en/ 2. https://pmp.errc.ars.usda.gov/PMPonline.aspx 3. www.fssp.food.dtu.dk 4. https://symprevius.eu/software/ 5. https://www.microhibro.com/ 6. https://www.aua.gr/psomas/gropin/ 7. https://knime.bfr.berlin/openfsmr/
	Fitting tools. Growth curves	Exposure assessment	Estimate the kinetic parameters using selected primary models	Limited flexibility to modify the model equation, fix parameters	1. DMFit 2. iPMP 3. Biogrowth 4. MicroriskLab	1. https://www.combase.cc/index.php/en/ 2. https://www.ars.usda.gov/northeast-area/wyndmoor-pa/eastern-regional-research-center/docs/ipmp-global-fit/ 3. https://www.foodmicrowur.shinyapps.io/Ddatabase/ 4. https://microrisklab.shinyapps.io/english/
	Fitting tools. Inactivation/survival curves	Exposure assessment	Estimate the kinetic parameters using selected primary models	Limited flexibility to modify the model equation, fix parameters	1. GInaFit 2. Bioinactivation	1. https://cit.kuleuven.be/biotec/software/GinaFit 2. https://foodlab-upct.shinyapps.io/bioinactivationFE/
Risk assessment tools	Perform qualitative risk assessment	Risk characterization	Risk ranking	Required expertise and knowledge of the tool features	1. Risk.Net	1. https://www.caq.de/en/risk-management-software
	Perform semi-quantitative risk assessment	Risk characterization			1. Risk ranger	2. http://www.foodsafetycentre.com.au/docs/RiskRanger.xls
	Perform quantitative risk assessment	Risk characterization	Analyze data of hazards and return the health burden allowing a complete quantitative risk assessment	Required expertise and knowledge of the tool features	1. FDA-iRisk 2. ECDC Geoportal 3. QMRA Wiki 4. FDA QPRAM 5. JEMRA modles	1. https://irisk.foodrisk.org/ 2. https://geoportal.ecdc.europa.eu/vibriomapviewer/ 3. http://qmrawiki.org/about 4. https://irisk.foodrisk.org/ 5. http://www.mramodels.org/

[a]: further information can be found in the following link https://portal.nifa.usda.gov/web/crisprojectpages/1023720-fact-innovative-big-data-analytics-technology-for-microbiological-risk-mitigation-assuring-fresh-produce-safety.html