A guide for accessing relevant data and models for quantitative microbial risk assessment

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Preface

This document has been prepared in the context of the EJP-OH CARE (Cross-sectoral framework for quality Assurance Resources for countries in the European Union). This document is part of WP4 : Investigate, benchmark and improve the availability and the quality of the existing data relevant for risk assessment.

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To learn more about CARE project visit https://onehealthejp.eu/jip-care/.

1 Introduction

By the late 1990s, concepts of risk and risk assessment have been employed to inform decision-making for the management of food safety risks. Modern food safety policies are intended to be risk-based (Koutsoumanis and Aspridou 2016).The framework for carrying out risk assessments of foodborne pathogens is well established (*Microbiological Risk Assessment – Guidelines for Food* 2021) and relies on four components including hazard identification, hazard characterization, exposure assessment and risk characterization Figure 1.1.

If the QMRA approach is well structured, the method used by the risk assessor can vary. One may adopt qualitative and/or quantitative method. It may consider determnisitic or stochastic

The QMRA approach can help to answer various questions. For examples, (Mota et al. 2022) identified the following objectives:

- evaluation of illness risk,
- assessment of interventions,
- simple exposure assessment,
- or risk ranking.

Each objective is associated to specific starting point (farm, food industry, retail,…), output (score or risk, mean annual risk, DALY,…) and data needs.

One of the main challenge is to identify the appropriate approach to tackle the risk question. In this context, EJP OH COHESIVE proposes a decision support tool to help risk assessor: COHESIVE Decision Support Tool. The tool helps to define the best approach according to the objective and time available.

Once the approach has been chosen, the main challenge is to gather data. Different types of data can be collected (microbial concentrations, daily consumption, etc.). The collected data should be fit for purpose, representative and allow a meaningful analysis (Haberbeck et al. 2018).

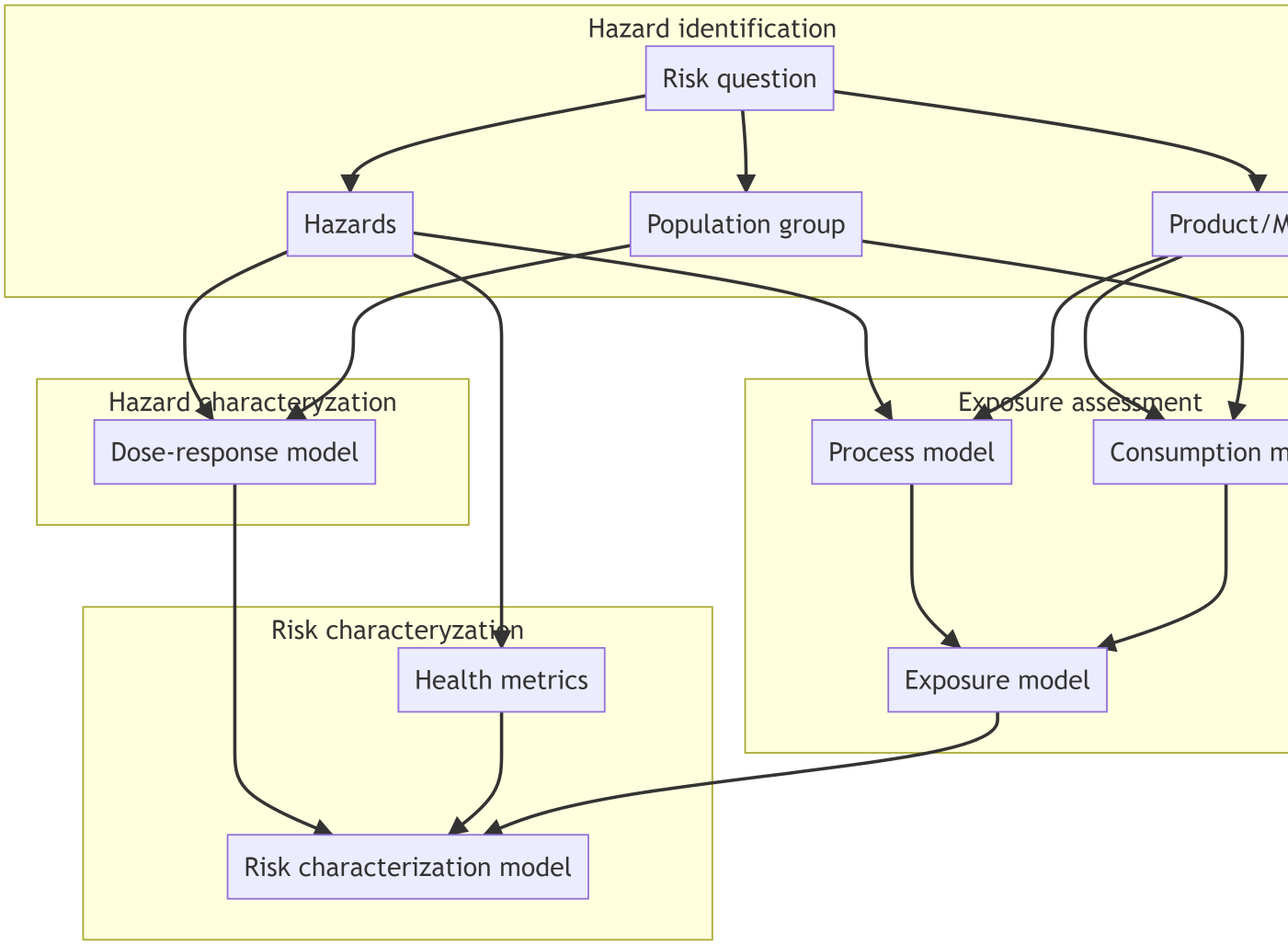


Figure 1.1: Main stages of QMRA model

Objective of this document

Our goal is to provide an help to identify data/knowledge that risk assessors and data scientists need at the start of their projects.

Versioning of the document

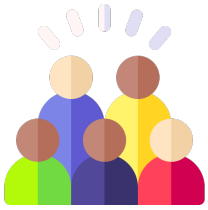
This is the first release (September 2022) of the "Guide for accessing relevant data and models for quantitative microbial risk assessment". The document is uploaded in Zenodo, lastest relase can be find here: . This document will be maintained by authors according to the sustainability plan of CARE. All stakeholders, including students, researchers,risk assessment teams, are encouraged to use this document. This document is always a work in progress and everyone is encouraged to help us build something that is useful to the many.

Part I

Hazard identification

A QMRA has always for origin an initial statement on the specific objectives of a risk assessment (the risk question). The risk question should precisely define (see Figure 1.2):

- the microbiological hazard causing the adverse effect
- the foods of interest
- the population of interest



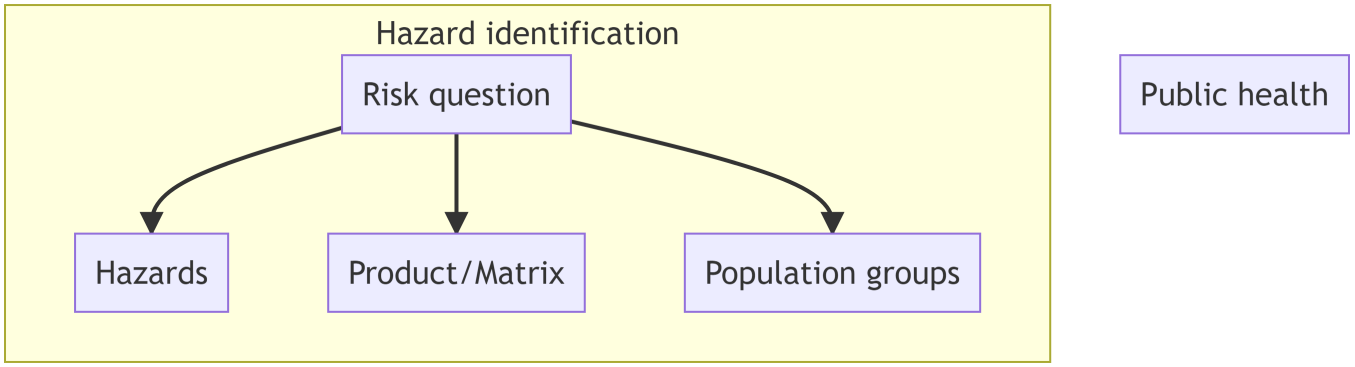


Figure 1.2: Components of hazard identification

The following chapters aims at identifying the data of interest for characterizing the pathogens contamination of foods and the population.

2 Hazards

Food contamination can occur at all stages of the food chain and by various microorganisms including bacteria, viruses, molds, parasites, and unconventional agents. Among these microorganisms responsible for foodborne diseases, bacteria, viruses, and parasites are the most common. Definition of microbiological hazards in hazard identification is a key step. It involves to define the microbiological agents (Hazard) capable of causing adverse health effect considered by the risk assessment. The following sections describe the resources that provide formalized lists of microbiological hazards.

2.1 SSD

2.2 Other relevant resources

2.2.1 NCBI Taxon ontology

This ontology has been used to describe the hazard term of the

This ontology has been to defeine hazard categories in EJPOH ORION Health Surveillance Ontology dedicated to human and machine-readable knowledge model for surveillance (see https://w3id.org/hso)

2.2.2 LPSN - List of Prokaryotic names with Standing in Nomenclature

10.1099/ijsem.0.004332 https://lpsn.dsmz.de/

2.2.3 The Cohesive information system

The EJP COHESIVE propose a demonstration on the tools to collect data related to the area of risk-analysis, aims today at integrating also genomics data from human and veterinary domains involved in genomics-based surveillance. In this context, the COHESIVE Information System (CIS) has been created (Mangone et al. 2021) with separate instances of several Member States, in order to provide a proof of concept showing the advantages for surveillance and investigation of outbreaks. The CIS include a table related to information on the species of the microorganism.

2.2.4 Ressources for antimicrobial resistance

https://bitbucket.org/genomicepidemiology/resfinder_db/src/master/ ChEBI ontology CARD,

2.2.5 QPS biological agents

The list of biological agents that are notified to EFSA in the context of a technical dossier to EFSA (for intentional use directly or as sources of food and feed additives, food enzymes and plant protection products for safety assessment), is kept updated every 6 months. The Updated list of QPS-recommended biological agents for safety risk assessments carried out by EFSA is available at https://doi.org/10.5281/zenodo.1146566.

3 Foods

3.1 FoodEx2

3.1.1 Scope

In 2015, EFSA developed a food classification and description system called FoodEx2 ((EFSA) 2015), which is used for its data exchange with Member States. This system describes a large number of individual foods, grouped into food groups and broader food categories, classified using a formal hierarchical parent-child relationship (ontology). Most of the food names are generic, allowing the user to classify several similar foods under one name attached to a unique code. Facets" can be used to add details about the characteristics of the food. The current version of FoodEX2 has eight hierarchies: six pre-selected domain-specific food hierarchies based on an intended target use (exposure, zoonosis, veterinary residue, etc.). There is also a complete hierarchy ("Master hierarchy"), for terminology management, and a general hierarchy oriented towards data capture ("Reporting hierarchy"). The latter has been used to select the food categories of interest, providing a common repository of food descriptions. It comprises 10,366 terms divided into three broad categories, "Food", "Feed" and "Non-food matrices", up to 10 levels deep (hierarchy levels H1 to H10).

FoodEx2 also offers facets, which are used to add more detail to the information provided by the selected term in the food list. These facets are collections of additional terms describing the properties and aspects of the food from different angles. Thus, it is possible to provide information on the source of the food, the preservation process, the intended use, etc.

3.1.2 Accessibility

Latest Foodex2 version is available in Efsa knowledge junction in Zenodo (Authority 2022). The list of terms can be accessed by exploring the FOODEX.xlsx file or by using the catalogue browser. It's is a Java-based application that allows to use and browse catalogues released by EFSA in the Data Collection Framework. The Food Standards Agency also provide an web-page allowing to navigate at the different levels of the FoodEx2 hierarchies: FSA_foodtype.

Another way to access FoodEx2 is to use the EFSA FoodEx2 Smart Coding Application. It can be accessed in the R4EU platform (users should register). The tool aims to simplify the coding process by making use of AI techniques. Starting from the food description given as input, the tool provides suggestion of complex FoodEx2 terms (combination of base term and facets). Figure 3.1 shows an example of use of EFSA-SCA.

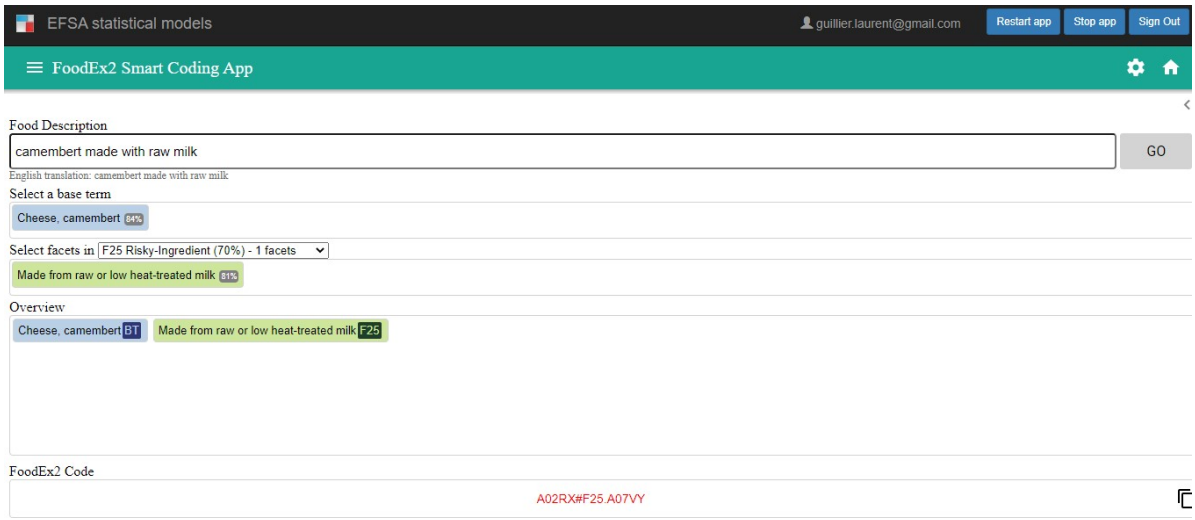


Figure 3.1: Example of use of the Smart Coding Application

3.2 IFSAC categorization schema

3.2.1 Scope

The IFSAC food categorization scheme (Richardson et al. 2017) has a multilevel structure (up to five distinct levels) to which foods can be assigned. The first level of the hierarchy defines four food groups (aquatic animals, land animals, plants, and other). Food groups then include increasingly specific food categories that are further subdivided into more specific categories Figure 3.2. The nature of the subcategories are established based of the food source or the process. The IFASC results in a total of 78 food categories.

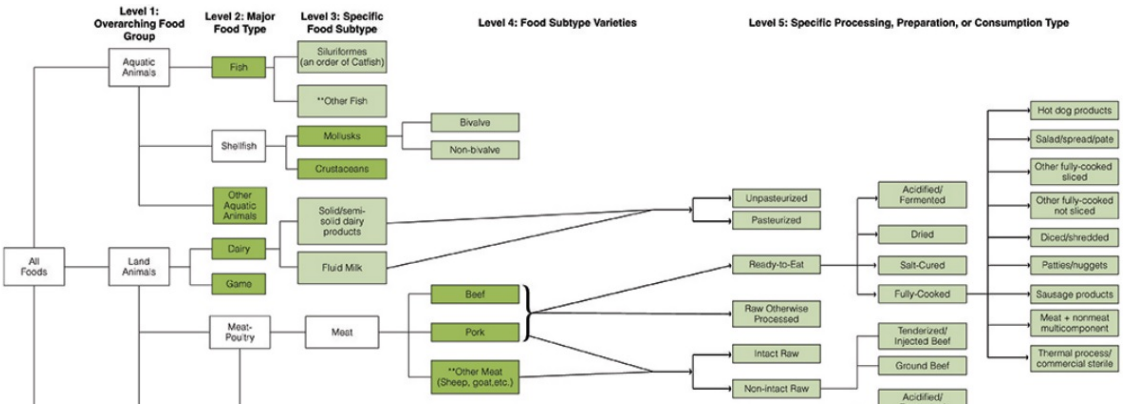


Figure 3.2: Illustration of the IFSAC Food Categorization Scheme

3.2.2 Accessibility

The IFASC is accessible online: IFASC_groups.

Some adaptions of these scheme are available:

- in GenomegraphR tool (Sanaa et al. 2019)
- IFSAC+ categories have been recently proposed (Balkey et al. 2021). These categories are being used in ncbi see e.g. nbci_ex.

4 Contamination data

Investigations addressing the identification and quantification of biological hazards in foods surveyed at various stages in the farm-to-fork chain is essential for building QMRA models. These data are primarily intended to be used as input data of the exposure assessment module but they can also be used as way to validate some output of the modelling approach (e.g. data observed at retail level could be used to validate the output of a model simulating the contamination along the farm to fork framework).

4.1 EFSA-ECDC zoonoses report

4.1.1 Scope

The European Union (EU) has been collecting for more than 20 years data on zoonoses that integrate their occurrence in food, animals and feed (together with the information from human cases see) . The data collection system also covers antimicrobial resistance. Member states (MS) and non-Member State (non-MS) European Free Trade Association (EFTA) countries submitted data a Data were submitted electronically to the EFSA zoonoses database, through EFSA's Data Collection Framework (DCF) (European Food Safety Authority (EFSA), Amore, et al. 2022; European Food Safety Authority (EFSA), Boelaert, et al. 2022).

4.1.2 Accessibility

Overview tables (and or graphs) presenting all the countries that reported data during a five year time-frame are made available, with key summary statistics. These summary statistics only focus on official sampling. Thus they are taking into account other reported data:

- from industry own-control programmes,
- data from suspect sampling, selective sampling,
- or data associated to outbreak or clinical investigations.

insert: https://zenodo.org/record/5761142#.YvTdGHZBy70 (how to get data from dashbord)

4.2 Pathogens-in-Foods database

4.2.1 Scope

Pathogens-in-Foods (PIF) is a database constructed upon systematic literature searches of occurrence data (prevalence and enumeration) of important pathogenic agents (insert ref Sofia). The database considers:

- bacterial hazards: *Bacillus cereus*, *Campylobacter* spp., *Clostridium perfringens*, *Listeria monocytogenes*, *Salmonella* spp., Shiga toxin-producing *Escherichia coli*, *Staphylococcus aureus*, *Yersinia enterocolitica*
- *parasites: Cryptosporidium* spp., *Giardia* spp., *Toxoplasma gondii*,
- and viruses: Hepatitis A virus, Hepatitis E virus and Norovirus

Presently (August 2022), the PIF database includes 1153 primary studies, with over 5200 bacteria, 200 virus, and 40 parasite entries spanning data published from 2000 on-wards to the present day. Systematic reviews are conducted periodically to ensure that new data is continuously added, and the database is kept up to date.

4.2.2 Accessibility

PIF is accessible through the main page at https://fsqa.esa.ipb.pt/. There are two different ways to access data. A Shiny app is provided in order to explore the database https://fsqa.esa.ipb.pt/shiny/apps/. PIF can be also accessed through the "Access System" (an email should be provided to log in).

Several variables for exploring the database of contamination can be defined. In the first section the pathogen of interest, the nature of data (prevalence, enumeration) the food characteristics can be filtered (see Figure 4.1).

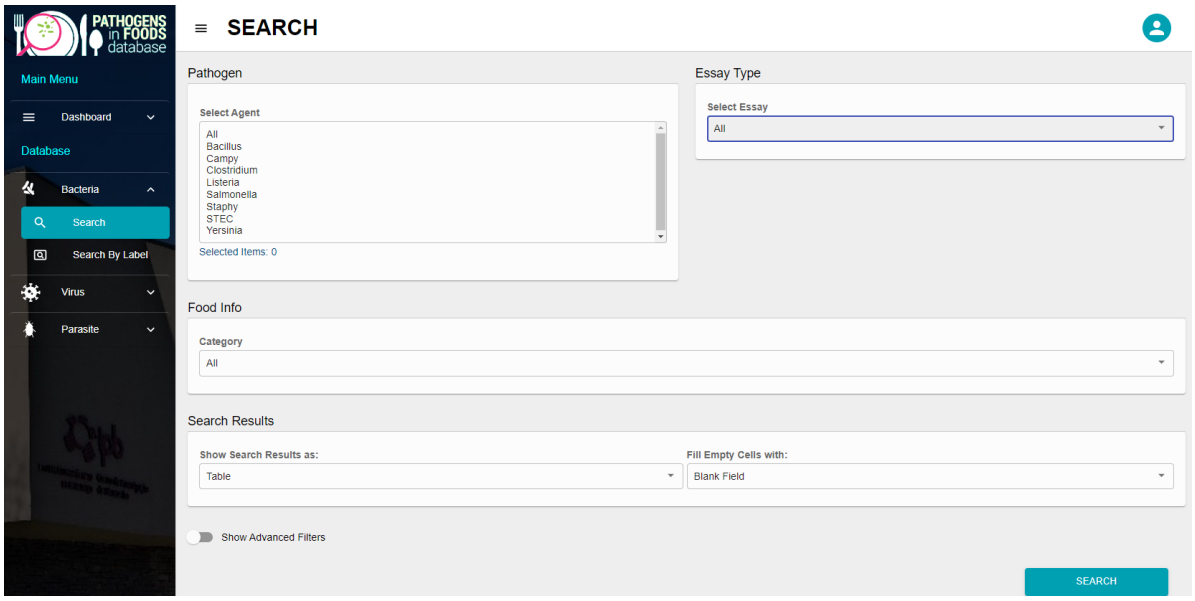


Figure 4.1: PIF database searching criteria

Through advanced filters, further features such as country of food origin, StudyID, label, packaging status, sampling stage, method used, can be included in the search. The results can be presented as a table in the database interface or downloaded as CVS or JSON format files.

5 Public health data

5.1 The European Surveillance System (TESSy)

5.1.1 Scope

The European Surveillance System (TESSy) is provided by ECDC in order to collect, analyse and distribute surveillance data on infectious diseases in Europe. The EU member States provide data according to the founding regulation of the ECDC (Regulation (EC) 851/2004). Surveillance data collected are mainly case-based and include demographic, clinical, epidemiological and laboratory information. They are reported annually or more regularly as needed for specific objectives, outcomes and resulting public health actions.

5.1.2 Accessibility

TESSy is not publicly available. In order to consult it, it is necessary to send a specific request indicating the required metadata and assuring that the data will be destroyed after its use. The metadata dictionary is available in excel format https://www.ecdc.europa.eu/sites/default/files/documents/MetaDataSet_50%20%282022-09-30%29.xlsx.

Since June 2021, The EpiPulse portal integrates TESSy with the five Epidemic Intelligence Information System (EPIS) platforms and the Threat Tracking Tool (TTT). The portal facilitates collection, analysis and dissemination of indicator- and event-based surveillance data on infectious diseases and associated health issues, including global epidemic intelligence, whole-genome sequencing, and health determinants.

5.2 Surveillance Atlas of Infectious Diseases

5.2.1 Scope

The Surveillance Atlas of Infectious is an interactive tool that allow users to manipulate aggregate EU surveillance data from The European Surveillance System (TESSy) to produce a variety of tables and maps.

5.2.2 Accessibility

The Surveillance Atlas of Infectious is accessible through the main page Surveillance Atlas of Infectious Diseases (europa.eu).

Several infectious diseases are available in the atlas and for each of them, the user can choose the subpopulation, the indicator and the years. The user then has access to tables showing the distribution of the disease according to the chosen indicator by country, year and age and a European map showing the diseases distribution according to the chosen indicator (Figure 5.1).

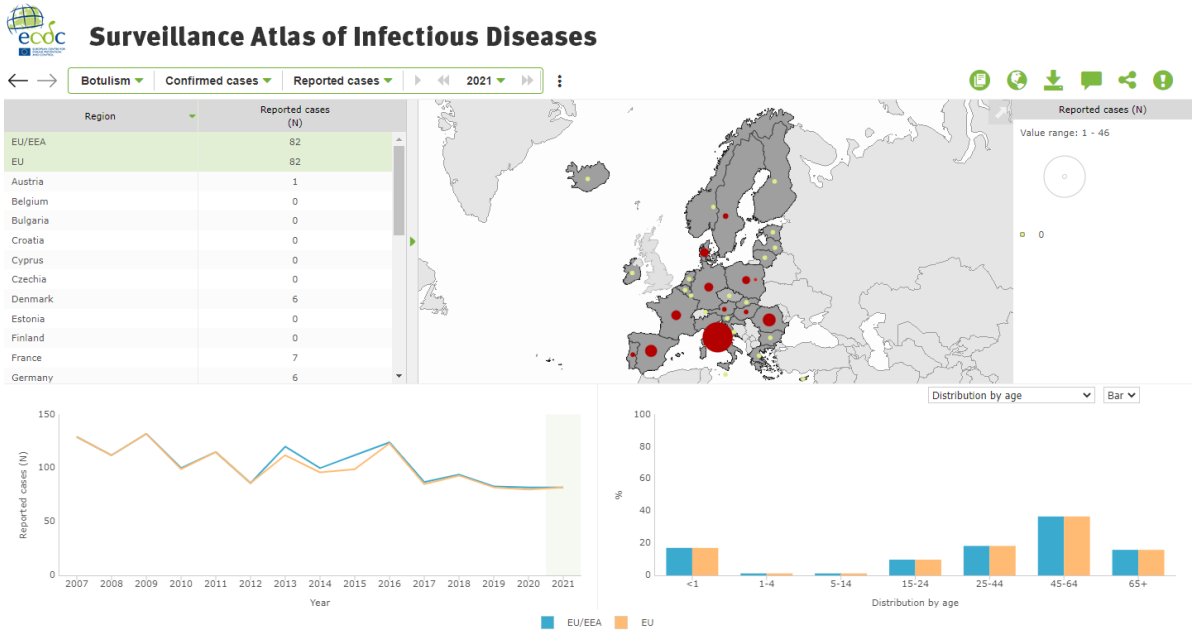


Figure 5.1: Surveillance Atlas of Infectious Diseases

5.3 The EFSA foodborne outbreak story map

5.3.1 Scope

The EFSA FBO story map provides general information on foodborne outbreaks, their causative agents and implicated food vehicles. This tool is more dedicated to provide information than to share data. Yet, the tool can provide maps presenting the geographical distribution of the number of outbreaks across reporting EU countries. The users can generate also maps showing different outputs: human cases, hospitalisations and deaths.

5.3.2 Accessibility

5.4 The EFSA dashboard on foodborne outbreaks

5.4.1 Scope

The EFSA dashboard on foodborne outbreaks allows for searching data on foodborne outbreaks collected by EFSA from the EU Member States (and several other reporting countries). This reporting is carried out in the context of the Zoonoses Directive 2003/99/EC. The dashboard can display the FBO data interactively though graphs and maps. The main statistics can also be downloaded in the .csv format. A user guide describes the content and functionalities of the dashboard and provides step-by-step information to make full use of the tool.

5.4.2 Accessibility

5.5 Ressources available in Member states

The information collected at European level is also reported by the EU Member States. Information available at national level can provide complementary information to that used at transnational level. The Table below lists the references to the data collected on the identified foodborne outbreaks (please do not hesitate to contact the authors of this report to provide missing or corrected information).

Table 5.1: Food-borne outbreak surveillance system at Member State level

Country	Access	Data
France	https://www.santepubliquefrance.fr/	Pdf report
Belgique	https://www.favv-afsca.be/	Html report

5.6 Relevant information related to EJP OH projects

Part II

Exposure Assessment

Exposure assessment is the evaluation of the likely intake of microbiological hazards via food (as well as exposures from other sources if relevant). It results from the combination of the process model and the consumption model.

6 Consumption data

A consumption model describes the amount of food consumed during a particular eating occasion (i.e., a serving) and/or the frequency of the consumption of these servings, or an average amount of food consumed per day. This amount may vary in time, between individuals, between the different population groups of interest and the considered exposure type.

6.1 The EFSA Comprehensive European Food Consumption Database

6.1.1 Scope

The Comprehensive Food Consumption Database gathers information on food consumption across the EU member states. The database is dedicated to be used in risk assessments related to possible chemical and microbiological hazards. The database is also relevant for the assessment of nutrient intakes. The food classification system 'FoodEx2' is used to categorise all foods and beverages included in the Comprehensive Database.

6.1.2 Accessibility

6.2 FAO/WHO GIFT | Global Individual Food consumption data Tool

6.2.1 Scope

6.2.2 Accessibility

6.3 Food safety collaborative platform (FOSCOLLAB)

WHO | Food Safety Collaborative Platform

7 Process model

Process model describes how the concentrations of the hazard change along the different modules of the food production chain (potentially from farm to fork). The module definition comes from the Modular Process Risk Model methodology developed by Nauta (2001). Each module is defined to reflect one of the six basic process: growth, inactivation, mixing, partitioning, removal and cross-contamination . A module may combine several processing steps if they have a similar impact on the microorganism.

7.1 Predictive microbiology models (growth and inactivation)

PM models are used for describe the microbial responses towards environmental conditions, such as storage and processing conditions and product characteristics. Traditionally, models in predictive microbiology are classified as primary and secondary models. Numerous models have been developed (Tenenhaus-Aziza and Ellouze 2015). Some tertiary tools provide secondary models to predict the behavior of various pathogens in various conditions (e.g. ComBase Predictive Models, Food Spoilage and Safety Predictor, SymPrevius, GroPIN Modelling DataBase,...).

In order to identify the list of existing models, Food risk labs website maintain an exhaustive list of predictive models: FoodRisk-Labs.

A search engine is available to retrieve predictive microbiology models (Figure 7.1)

7.2 Database of microbial responses

7.2.1 Combase

7.2.2 Other database of interest

7.2.3

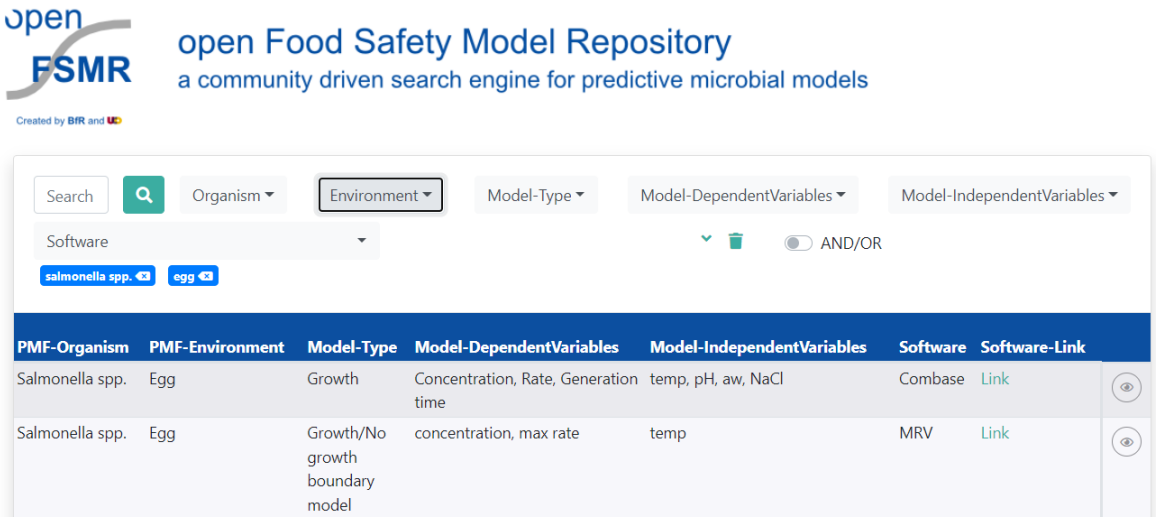


Figure 7.1: Search engine from BfR (openFMSR): example of use

8 Hazard characterization

Dose-response modelling (DR) is undertaken to quantify the likelihood of infection and disease as a function of ingested dose. Risk characterization uses the results of exposure assessment and DR modelling to derive an estimate of the risk of disease in the population.

8.1 QMRA wiki - Dose Response

8.1.1 Scope

The QMRA Wiki is a community portal for current quantitative information and knowledge developed for the Quantitative Microbial Risk Assessment (QMRA) field. It is an evolving knowledge repository intended to be the go to reference source for the microbial risk assessment community.

8.1.2 Accessibility

A dedicated section of QMRA wiki is dedicated to dose response models (QMRA wiki - DR). Completed dose response Models are available for several pathogens including bacteria, prion, protozoa and virus. For each pathogen, the data used, the model used and the parameters fitted on the different data are provided.

A synthetic table of recommended best-fit parameters is also available for each pathogen. These recommanded fitted models are recommanded to be used in most circumstances. However, it's up to the user to consider all available models to decide which one is most appropriate.

The users has also the possibility to assess through a web interface QMRA wiki - Tool :

- The probability of illness given a dose
- The dose associated to a given probability
- The possibility to fit a model for user defined data

Table of Recommended Best-Fit Parameters

Please click on the tab headings to navigate betweeen tabs.| We generally recommend a single dose response model, and we justify the decision in terms of these criteria. This decision is somewhat subjective, since dose response datasets seldom meet all of these criteria. If all available models are unsatisfactory, we choose a single model to 'recommend with reservations'. Our recommended model will seldom (if ever) be the best model for all applications. The user should carefully choose the model that is most appropriate for their particular problem.
*Please click on the tab headings to navigate between tabs.

Bacteria | Viruses | Protozoa | Prions | Criteria for Model Selection | Back to Dose Response Home Page [edit]

Agent	Best fit model*	Optimized parameter(s)	LD_{50}/ID_{50}	Host type	Agent strain	Route	# of doses	Dose units	Response	Reference
Bacillus anthracis: Dose Response Models	exponential	k = 1.65E-05	4.2E+04	guinea pig	Vollum	inhalation	4	spores	death	Druett 1953
Burkholderia pseudomallei: Dose Response Models	beta-Poisson	α = 3.28E-01 , N_{50} = 5.43E+03	5.43E+03	C57BL/6 mice and diabetic rat	KHW,316c	intranasal,intraperitoneal	10	CFU	death	Liu, Koo et al. 2002 and Brett and Woods 1996
Campylobacter jejuni and Campylobacter coli: Dose Response Models	beta-Poisson	α= 1.44E-01 , N_{50} = 8.9E+02	8.9E+02	human	strain A3249	oral (in milk)	6	CFU	infection	Black et al 1988
Coxiella burnetii: Dose Response Models	beta-Poisson	α= 3.57E-01 , N_{50} = 4.93E+08	4.93E+08	C57BL/1OScN mice	phase I Ohio	intraperitoneal	10	PFU	death	Williams et al, 1982
Escherichia coli enterohemorrhagic (EHEC): Dose Response Models	exponential	k=2.18E-04	3.18E+03	pig	EHEC O157:H7, strain 86-24	oral (in food)	3	CFU	shedding in feces	Cornick & Helgerson (2004)

Figure 8.1: Example of recommended Best-Fit Parameters for different pathogens in QMRA wiki

8.2 Other tools

Several r packages dedicated to dose-response modelling have been proposed:

-

Part III

Risk characterization

Risk characterization is defined as "*The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment*" (Codex Alimentarius Commission, 1999; Haberbeck et al., 2018).

Risk characterization is the final step in the quantitative risk assessment process. It thus integrates the findings from the three previous components presented in this guide. Generic tools can help to integrate the data collected in the risk assessment (see. Appendix 1).

At this stage, specific data related to populations and burden of disease can be integrated according to the output targeted (@fig-risk).

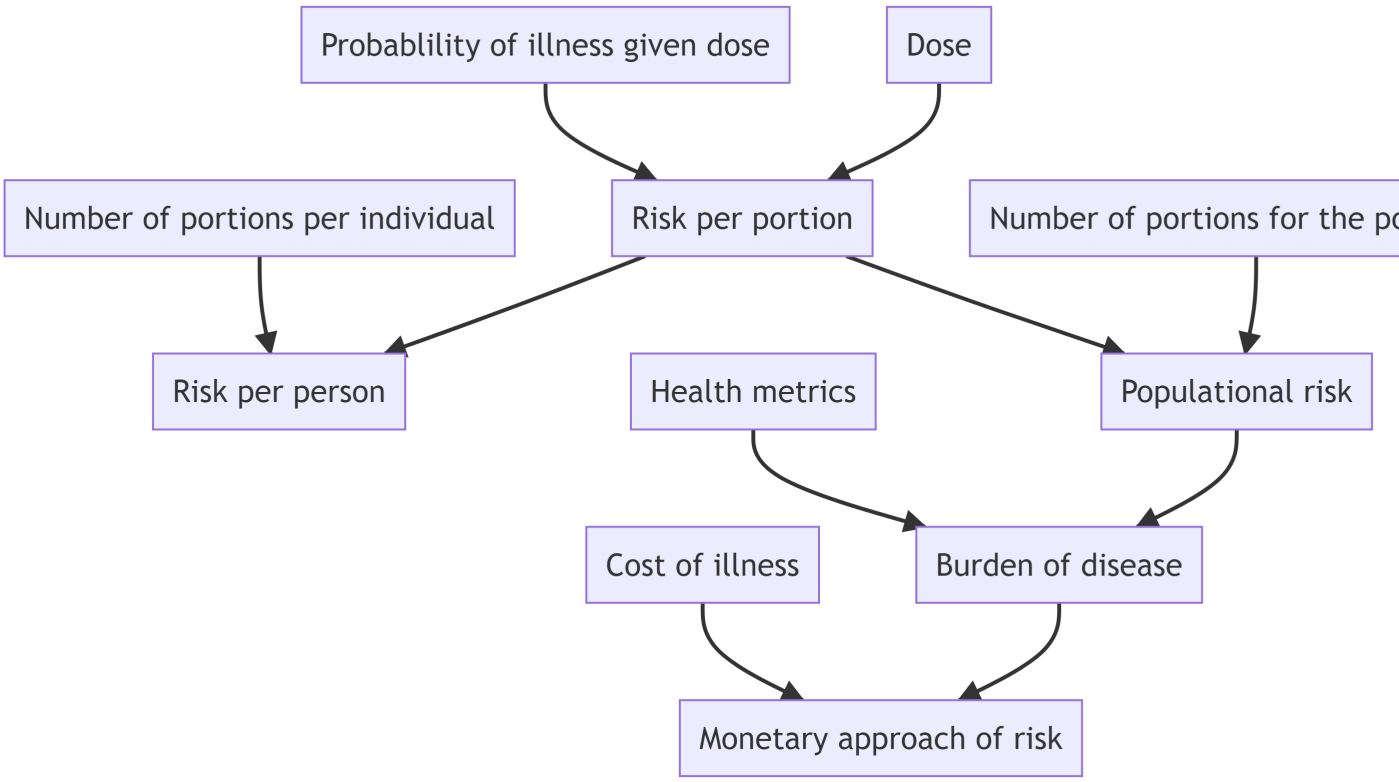


Figure 8.2: The possible outputs of the risk characterisation step

9 Burden of disease data

In order to go beyond the number of disease-related cases, two concepts are generally used: the QALY (for Quality-Adjusted Life Years) and the DALY (for (Disability-Adjusted Life Year). QALYs correspond to the life years gained with an intervention, taking into account the quality of life during these years. A QALY is assigned a coefficient of 1 if it is a healthy year and less than 1 if the quality of life is reduced. These coefficients are based on population surveys.

The DALY metric quantifies the gap between a life lived in perfect health and the current health status, as the number of healthy life years lost due to illness (as Years Lived with Disability, YLDs) and to premature death (Years of Life Lost, YLLs).

9.1 The European Burden of Disease database.

https://www.burden-eu.net/outputs/bod-database

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A Relevant generic tools for

A.1 FDA iRisk

A.2 MicroHibro

A.3 RAKIP

A.4

swift Quantitative Microbiological Risk Assessment