Outsourcing activity 2: quantitative risk characterization on *L. monocytogenes* in RTE foods

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Stakeholder meeting on draft scientific opinion on Listeria monocytogenes contamination of ready-to-eat foods and the risk for human health in the EU

Parma, 19-20 September 2017

Outline

- Introduction and model scope
- Listeria risk assessments
- Selection of D-R models
- Exposure assessment
- Simulation and output
- An easy-to-use framework: Excel Add-in “Lis-RA”
- Conclusions

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- ❑ **Introduction and model scope**
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Introduction and scope

Probabilistic risk assessment of *Listeria monocytogenes* for in RTE foods developed by EFSA in collaboration with the University of Córdoba (Spain) and IRTA (Spain)

Closing gaps for performing a risk assessment on *Listeria monocytogenes* in RTE foods: Activity 2, a quantitative risk characterization on *L. monocytogenes* in RTE foods; starting from the retail stage[1]

- packaged (hot, cold) smoked or gravad fish (not frozen),
- packaged heat-treated meat products (cooked meat, sausages, pâté)
- soft or semi-soft cheeses (excluding fresh cheeses)

The risk assessment covers from retail to home, considering Listeria growth up to consumption

Contract number: OC/EFSA/BIOCONTAM/2014/02CT1

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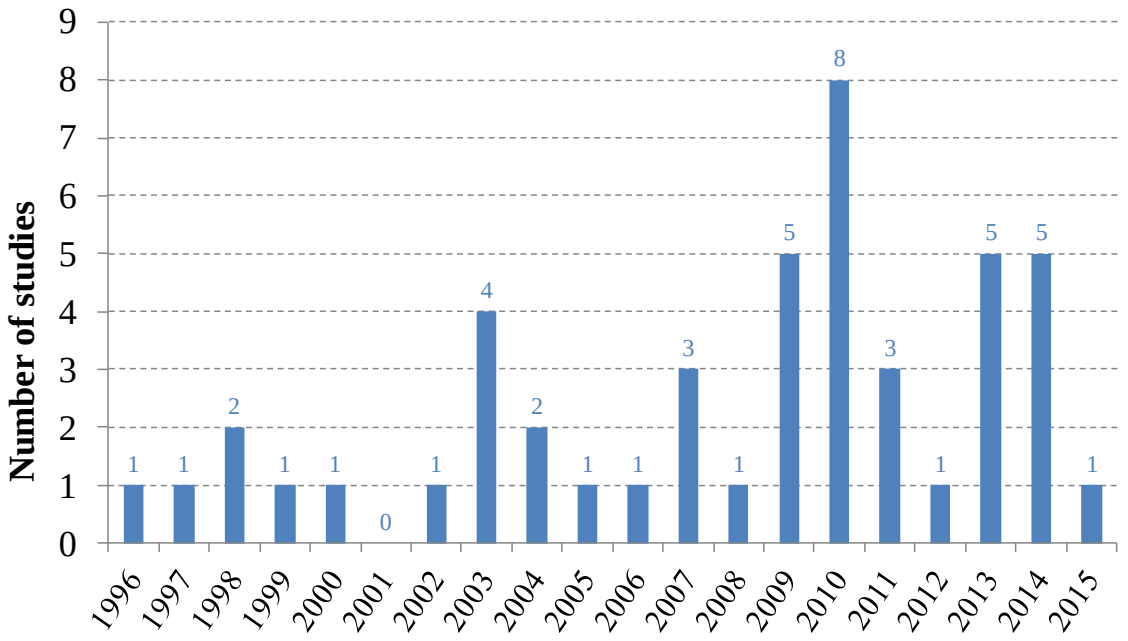
Systematic review for Listeria risk assessments



Distribution of the selected (47 included) references by year of publication

(Objective 1)

Systematic review for Listeria risk assessments

Approach & Technical aspects	Number of references	%
Approach I		
1-Qualitative	3	6%
2-Semi-quantitative	3	6%
3-Quantitative	42	89%
Approach II		
1-Stochastic (probabilistic)	41	87%
2-Deterministic (point estimate)	1	2%
Not applicable	5	11%
Variability/ uncertainty management		
1-1st order	14	30%
2-2nd order	2	4%
1,2-1st and 2nd order	25	53%
Unknown/not available/not applicable	6	13%
Peer-review level		
1-Public consultation for comments	8	17%
2-Sci referees (journal peer-reviewed article)	40	85%
3-Conference abstract	0	-

Relevant info about EA	Number of references	%
Steps of the food chain		
1-Primary production	8	17%
2-Food Production	18	38%
3-Distribution	20	43%
4-Retail	47	100%
5-Consumer storage	35	74%
6-Other	3	6%
Inputs (factors)		
1.1-Retail storage temperature	23	49%
1.2-Consumer storage temperature	36	77%
2.1-Retail storage time	22	47%
2.2-Consumer storage time	35	74%
3.1-Temperature during transportation to retail	7	15%
3.2- Temperature during transportation from retail to home	14	30%
4.1- Time for transportation to retail	6	13%
4.2- Time for transportation from retail to home	15	32%
5-Food characteristics (pH, a_w,...)	10	21%
6-Extrinsic factors (MAP,...)	3	6%
7-Processing treatments (heat, pressure,...)	7	15%
8-Transfer/partitioning/mixing	10	21%
9-Lag	6	13%
10-EGR	12	26%
11-Log increase	4	9%
12-Competing microbiota	3	6%
13-Max. Density Population (MDP)	11	23%
Unknown/not available/not applicable	10	21%
Inputs data type		
1-Point estimate	3	6%
2-Distribution	20	43%
3-Both depending on the input	22	47%
Unknown/not available/not applicable	2	4%

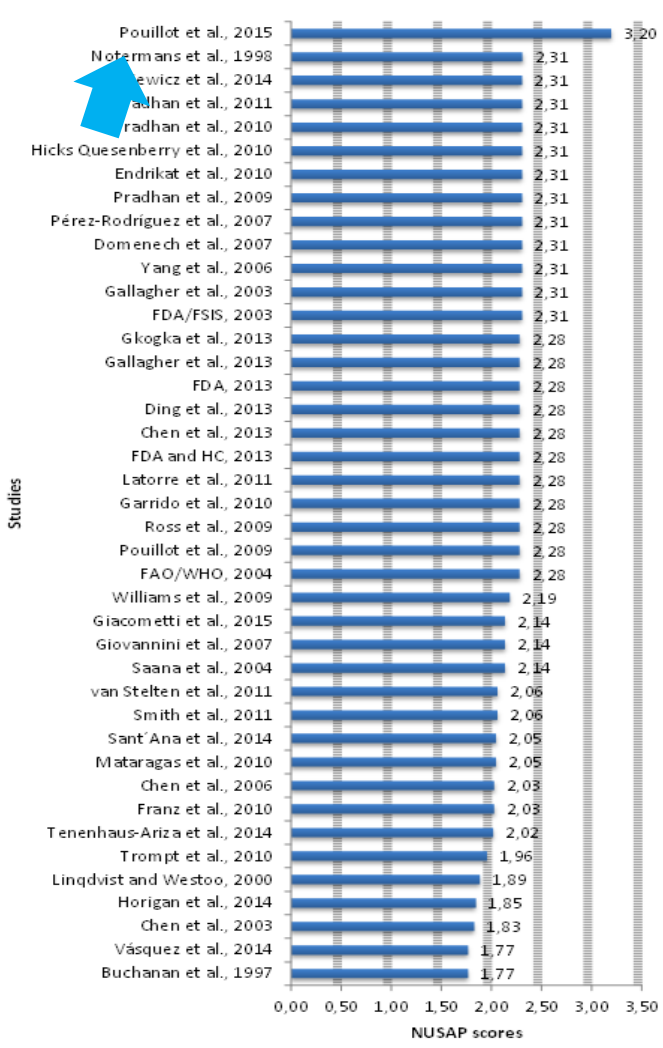
Systematic review for Listeria risk assessments

Relevant info about RC	Number of references	%
Type of output (endpoint)		
1-Risk per (No) serving/s	21	45%
2-Risk per (No) habitant/s	6	13%
3-Risk per annum (annual risk)	27	57%
4-other	9	19%
Simulation method		
Monte Carlo	26	55%
Latin Hypercube	9	19%
Bootstrap	1	2%
Unknown/not available/not applicable	12	26%
Software used		
@Risk	23	49%
Aladin	2	4%
Analytica	2	4%
Excel	1	2%
i-Risk	1	2%
JAGS	2	4%
Matlab	1	2%
R	4	9%
Risk Ranger	1	2%
SAS	1	2%
VBA	2	4%
Unknown/not available/not applicable	12	26%
Sensitivity analysis		
1-Yes	23	49%
2-No	24	51%
Application (exploitation of results)		
Scenarios, cases, evaluation of interventions, ALOP/FSO link, etc.		

Relevant info about HC-DR	Number of references	%
DR model type		
1-Exponential	37	77%
2-Weibull-Gamma	6	13%
3-Logistic	2	4%
4-Linear	1	2%

(Objective 1)

Selection of D-R models for risk assessment



Tool to evaluate the quality of the Exponential dose-response models currently available:

Application of Numeral Unit Spread Assessment Pedigree (NUSAP) system

NUSAP scoring system

Objective scores
Assessors

Weights to Pedigree Criteria
Experts

Use of the dose-response models by Pouillot et al. (2015)

(Objective 1)

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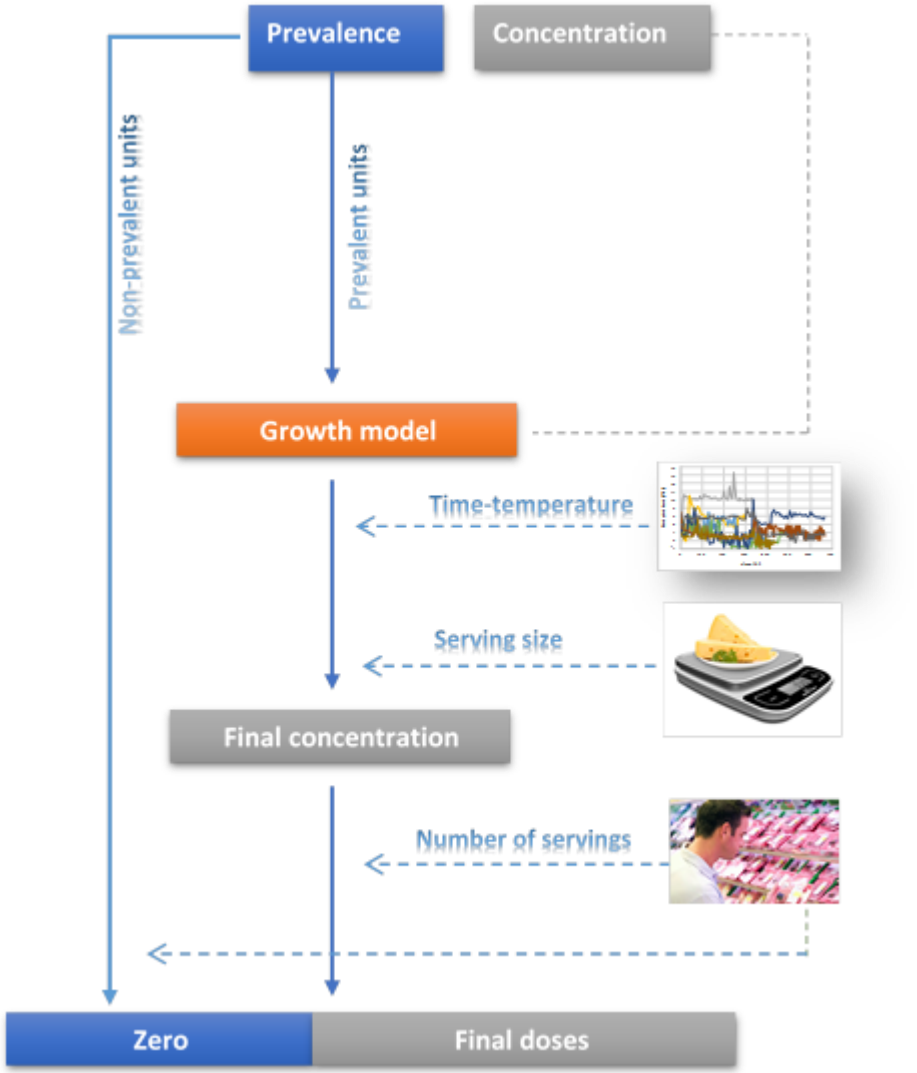
Exposure Assessment



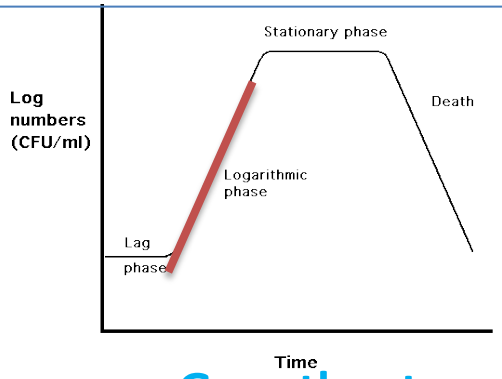
MAIN VARIABLES:

- Prevalence/concentration distributions of *L. monocytogenes*
- Stochastic model for the growth of *L. monocytogenes*
- Temperature-time profiles from retail to home
- Time to consumption
- Food serving size and number of serving per year

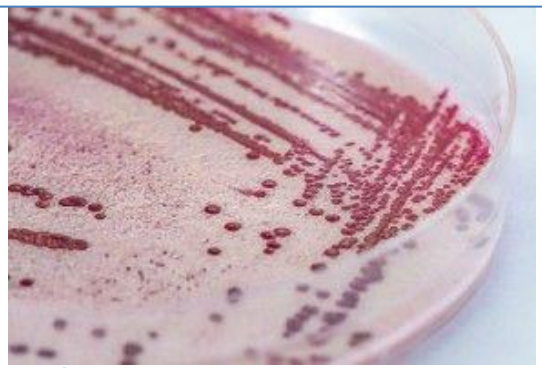
(Objective 2)

Structure of exposure assessment

Categories	Sub-Categories	Scenarios
Packaged heat-treated meat products	Cooked meat, sausage, Pâté	*ROP/normal; Sliced/non-sliced
Soft or semi-soft cheese	-	Sliced/non-sliced
Packaged (not Frozen) smoked and gravad fishs	Cold and hot smoked fish and gravad fish	ROP/normal; Sliced/non-sliced



Growth rate



Prevalence & Concentration

(Objective 2)

*ROP: REDUCED OXYGEN PACKAGING

Defining prevalence at retail

BASELINE MODEL

Food category	Subcategory	Scenario	Fitted Beta distributions[a]	Mean [C.I. 95%]
RTE fish products	Cold-smoked fish	Sliced	Beta(76+1;511-76+1)	**0.151** [0.116-0.186]
		Non sliced	Beta(18+1;102-18+1)	**0.183** [0.103-0.270]
	Hot-smoked fish	Sliced	Beta(20+1;239-20+1)	0.087 [0.049-0.130]
		Non sliced	Beta(12+1;273-12+1)	0.047 [0.021-0.078]
	Gravad fish	Sliced	Beta(30+1;219-30+1)	**0.140** [0.091-0.194]
		Non sliced[b]	Beta(0+1;33-0+1)	0.029 [0.005-0.103]
RTE meat products	Cooked meat	Sliced	Beta(43+1;2297-43+1)	0.019 [0.013-0.026]
		Non sliced	Beta(3+1;193-3+1)	0.021 [0.003-0.045]
	Sausage	Sliced	RiskBeta(11+1;548-11+1)	0.022 [0.009-0.037]
		Non sliced	RiskBeta(2+1;214-2+1)	0.014 [0.001-0.034]
	Paté	Sliced	RiskBeta(7+1;114-7+1)	0.069 [0.023-0.125]
		Non sliced	RiskBeta(2+1;70-2+1)	0.042 [0.003-0.010]
RTE cheese products	Soft and semi-soft cheese	Sliced	RiskBeta(5+1;816-5+1)	0.007 [0.002-0.015]
		Non sliced	RiskBeta(8+1;2298-8+1)	0.004 [0.001-0.007]

- Baseline study for *L. monocytogenes* in RTE products

(Objective 2)

Defining concentration at retail

BASELINE MODEL

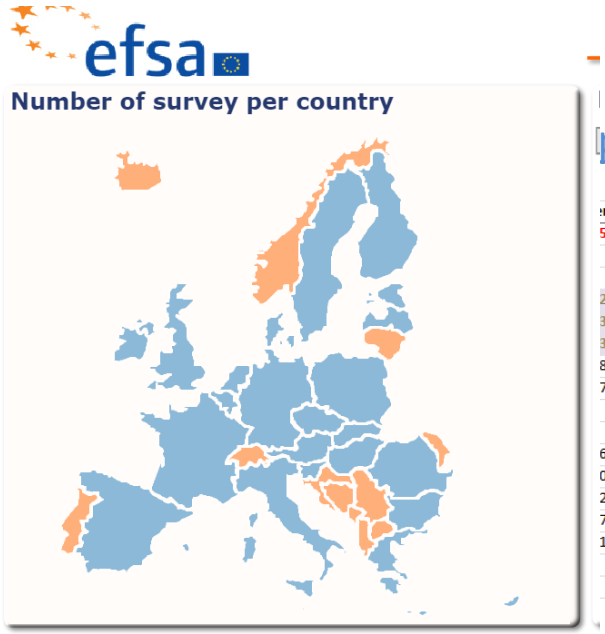
Food subcategory	Mean	SD	50th Perc.	5th Perc.	95th Perc.	LogL	AIC	BIC
Cold smoked fish	0.867	1.842	1.248	0.394	4.620	-1.50×10^3	3.12×10^3	3.14×10^3
Hot smoked fish	-0.271	0.943	1.318	-0.511	1.593	-1.79×10^3	3.59×10^3	3.60×10^3
Gravad fish	1.011	1.931	1.236	0.524	4.950	-2.39×10^2	4.83×10^2	4.92×10^2
Cooked meat	1.100	2.119	1.241	0.523	5.453	-7.10×10^2	1.42×10^3	1.44×10^3
Sausage	2.194	2.704	1.151	1.598	7.482	-3.22×10^1	6.84×10^1	7.53×10^1
Pâté	1.461	2.334	1.213	0.852	6.240	-1.86×10^3	3.73×10^3	3.74×10^3
Soft and semi-soft cheese	0.909	1.917	1.252	0.389	4.886	-3.14×10^2	6.32×10^2	6.46×10^2

Higher maximum concentration

- Outsourcing activity 1
- Monitoring data
- Baseline study for *L. monocytogenes* in RTE products

(Objective 2)

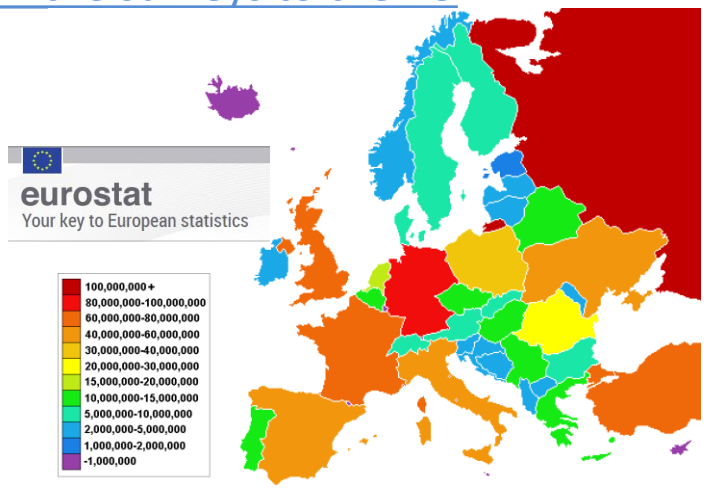
Serving size and number of servings



	Austri		rland	Romania
TOTAL consumption	1.7		5E+10	1.38E
Susceptible populatio	NA			NA
Healthy population	NA			NA
Elderly population	3.7		2E+10	3.14E
Healthy population	1.3		3E+10	1.07E
Pregnant women	1.(		3E+08	5.30E
Total/person	2034.(		8E+03	6.92E
#Servings (50g)	3.4		7E+09	2.76E
APROXIMATION				
Total consumption	1.7		6E+10	5.74E
Total population	8!		0E+06	1.68E
Elderly population	1.!		2E+06	3.30E
Healthy population	6.8		7E+07	1.65E
Pregnant population	7.8		1E+05	1.81E

The EFSA Comprehensive European Food Consumption Database for surveyed country and subpopulation

polation from the surveys to the EU



Demographic data per country and subpopulation

- *When there are missing population groups, the available groups are used for extrapolation to the rest*
- *When there are missing countries, the available countries are used for extrapolation to the rest: no pattern*

(Objective 2)


efsa
European Food Safety Authority
EFSA Journal 2013;11(6):3241

SCIENTIFIC REPORT OF EFSA

Analysis of the baseline survey on the prevalence of *Listeria monocytogenes* in certain ready-to-eat foods in the EU, 2010-2011 Part A: *Listeria monocytogenes* prevalence estimates[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

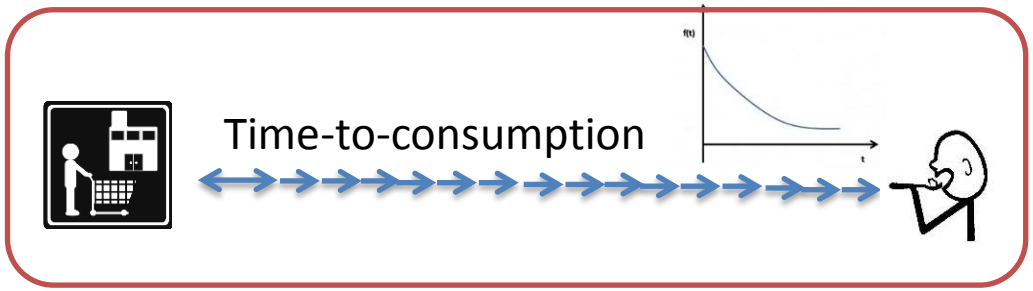
A European Union-wide baseline survey on *Listeria monocytogenes* was carried out in 2010 and 2011 with the aim of estimating the European Union level prevalence of *Listeria monocytogenes* in certain ready-to-eat foods at retail. A total of 3 053 batches of packaged (not frozen) hot or cold smoked or gravad fish, 3 550 packaged heat-treated meat products and 3 452 soft or semi-soft cheeses were sampled from 3 632 retail outlets in 26 European Union Member States and one country not belonging to the European Union. The fish batch samples were analysed on arrival at the laboratory as well as at the end of shelf-life, whereas the meat products and the

Time to consumption

BASELINE MODEL

EU-wide Baseline

Scope of the model



Remaining shelf-life

UBD

Shelf-life

UBD

Exponential distribution to describe TTC by means of the 99% percentile (a statistic from the remaining shelf-lives calculated) and a minimum value (uniform (0.01; 0.04) months as initial guess).

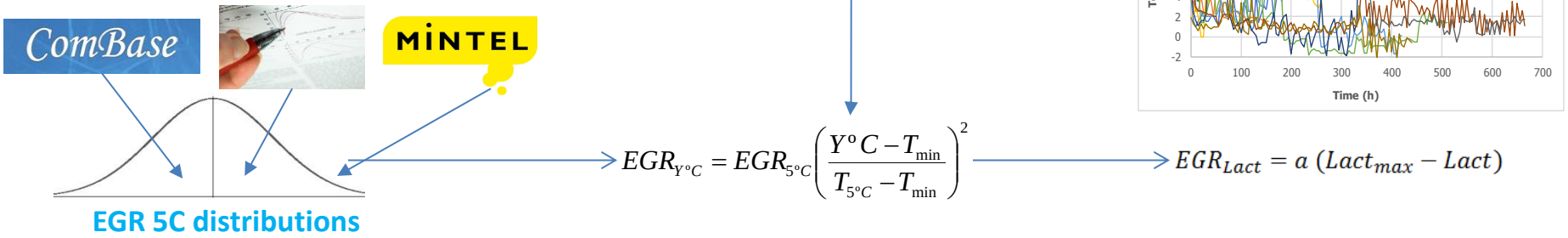
(Objective 2)

Growth model

BASELINE MODEL

Cooked meat & sausage/Pate/ smoked and gravad fish/ soft and semisoft cheese

- Semi-stochastic model for listeria growth rate:



- Growth model for temperature dynamic conditions:

Initial guess

$$\frac{1}{N(t)}\frac{dN(t)}{dt} = EGR \cdot \alpha(t) \cdot f(t)$$

Distribution DB

Growth model

BASELINE MODEL

- The effect of LAB on Maximum Population Density (MPD) of *L. monocytogenes* can be simulated i) interaction term and ii) using a probability distribution for MPD obtained from experiments in naturally contaminated foods.

EXPERT OPINION; LITERATURE AND MINTEL

INPUT variables (DIST)

(Devlieghere et al., 2000; Mejlholm et al., 2010; Mejlholm and Dalgaard, 2013; Mejlholm and Dalgaard, 2007; Østergaard et al., 2014).

Deterministic model

GROWTH RATE

$$\frac{1}{N(t)}\frac{dN(t)}{dt} = EGR \cdot \alpha(t) \cdot f(t) \longleftarrow f(t) = \left(1 - \frac{N_{list}(t)}{N_{\max\ list}}\right)\left(1 - \frac{N_{LAB}(t)}{N_{\max\ LAB}}\right)$$

(Objective 2)

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Risk characterization: cases/year

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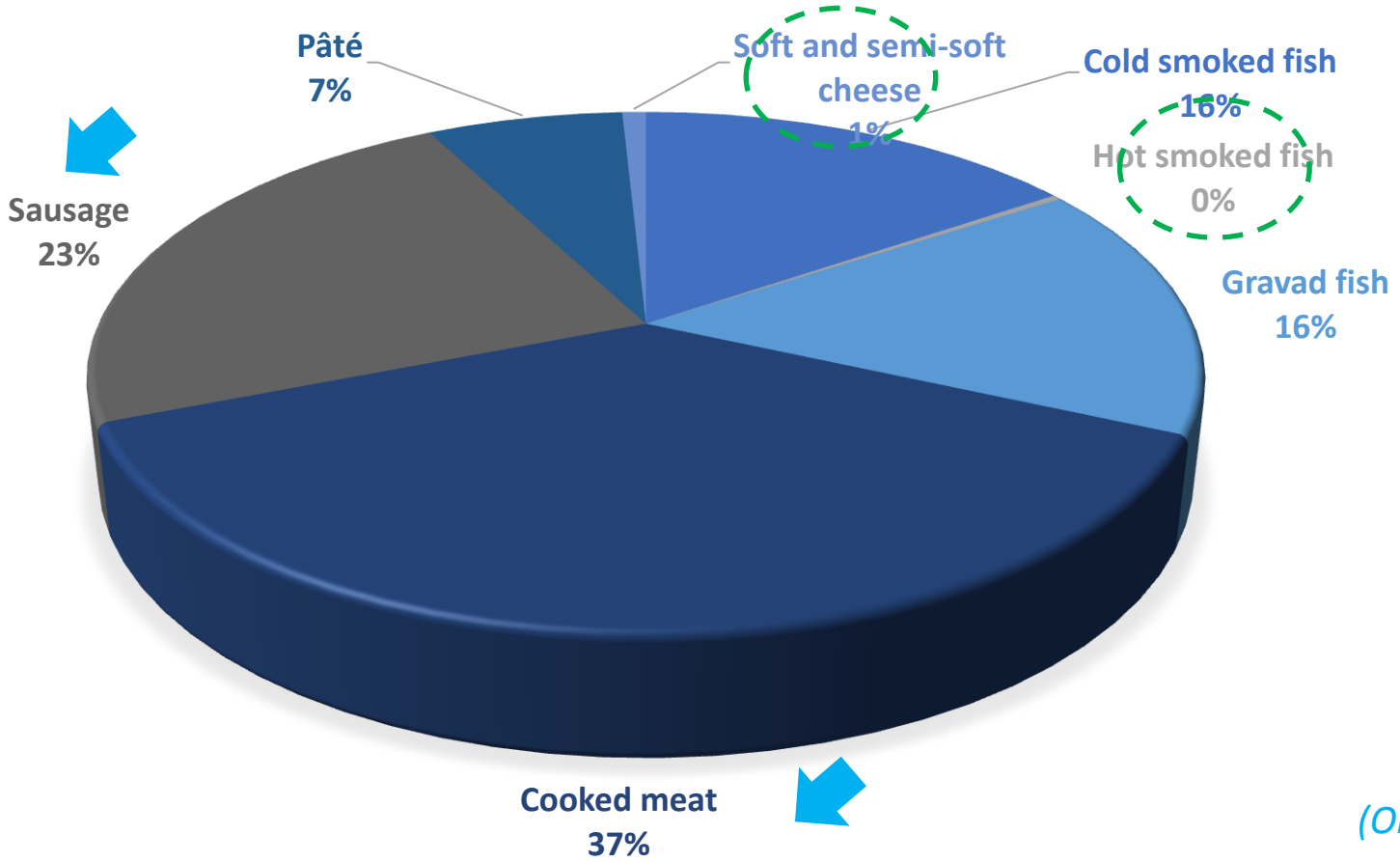

(Objective 4)

Risk characterization: cases/year

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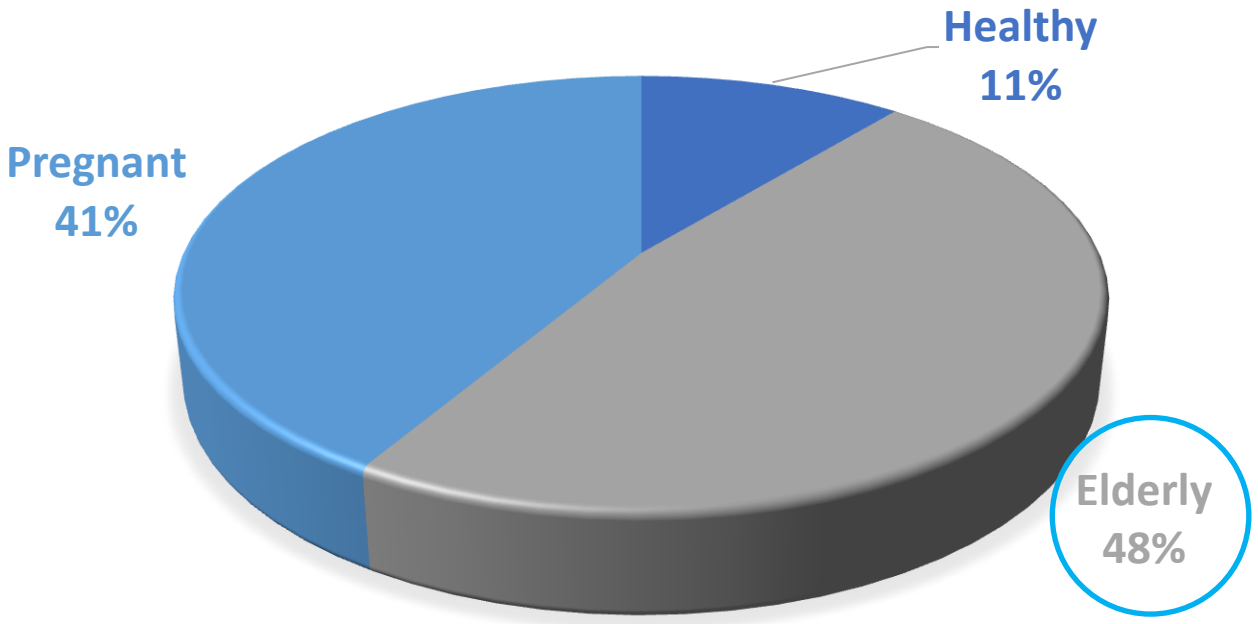

(Objective 4)

Risk characterization: cases/year

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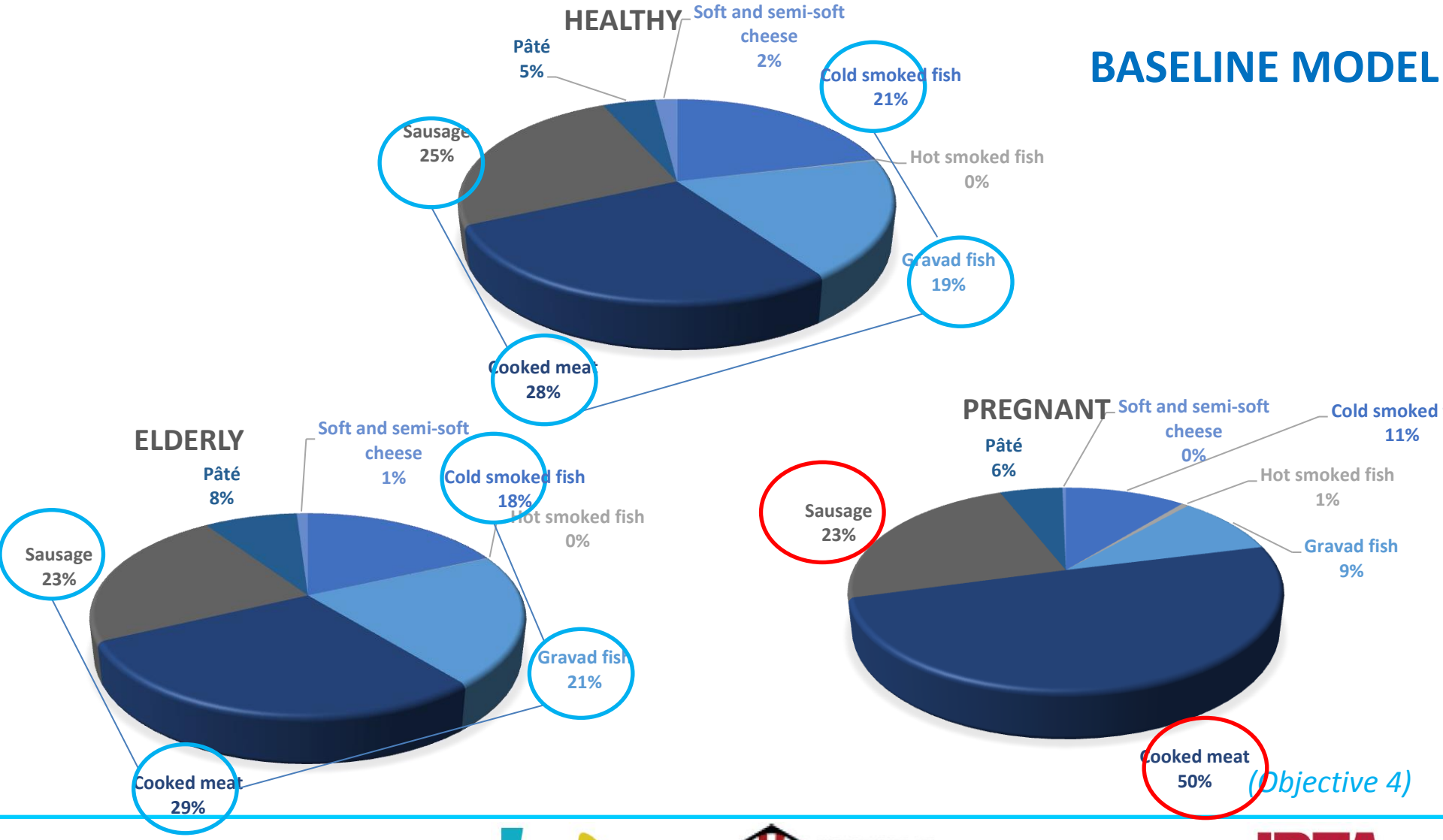
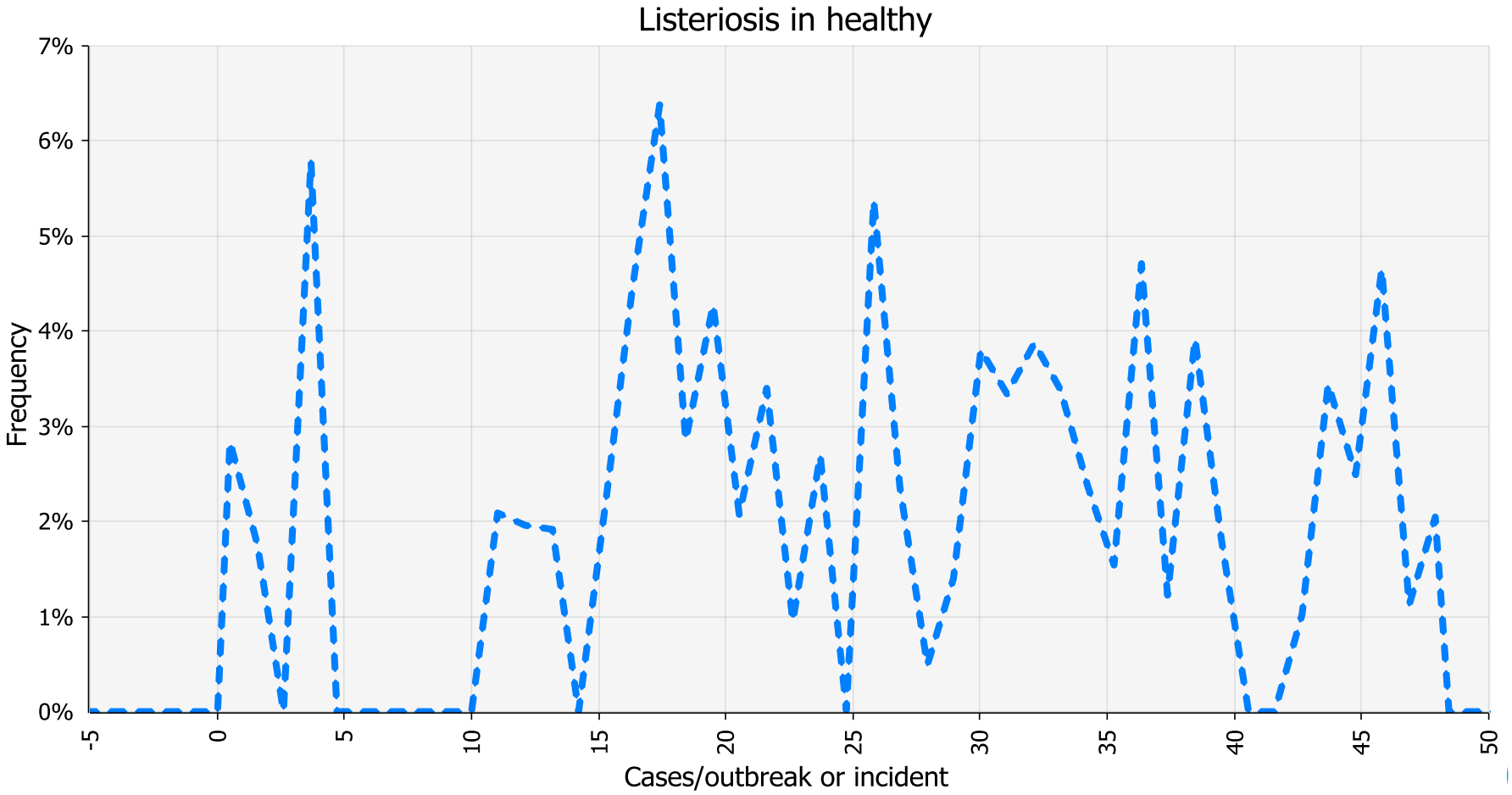


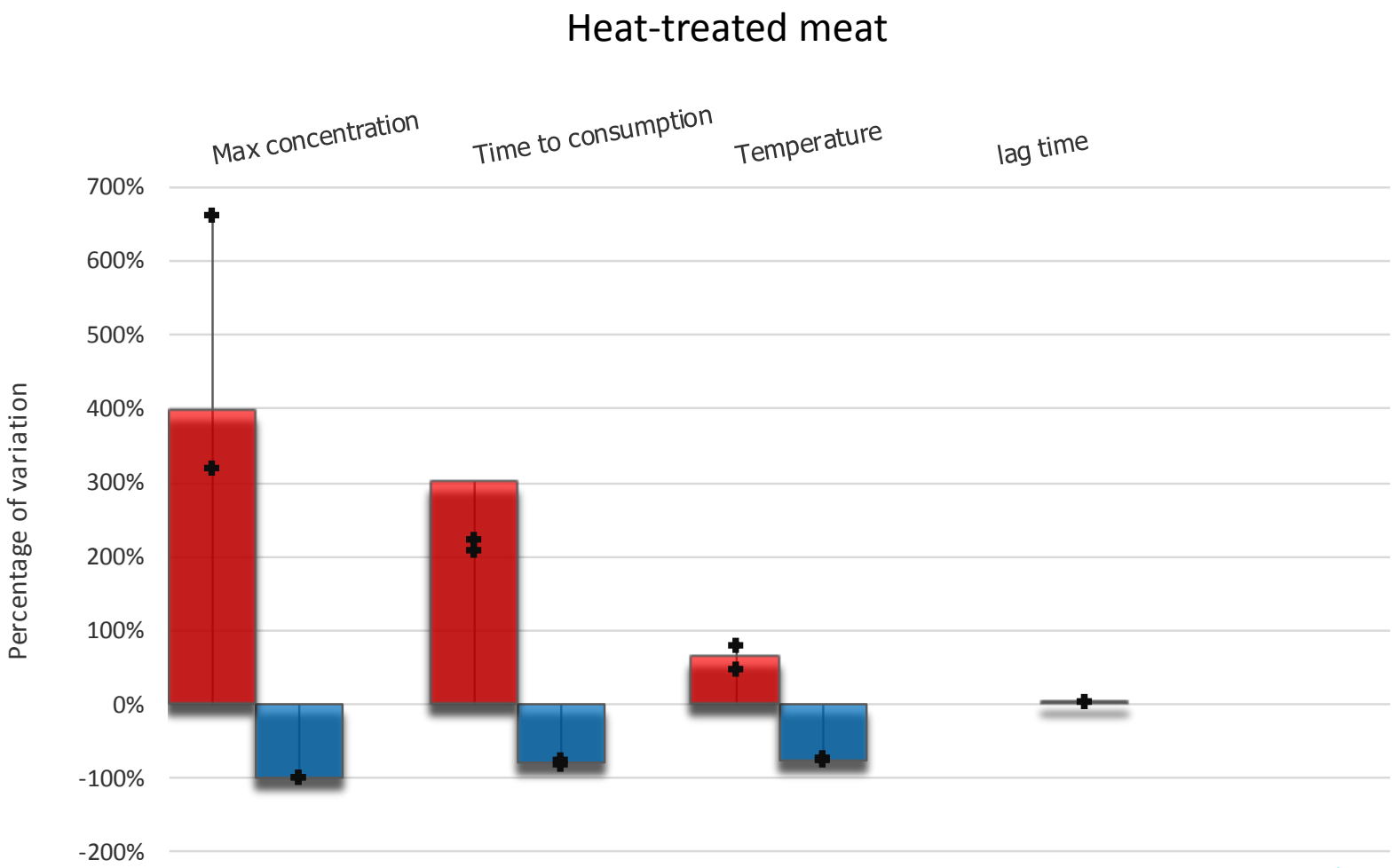
(Objective 4)

Risk characterization: cases/outbreak

BASELINE MODEL

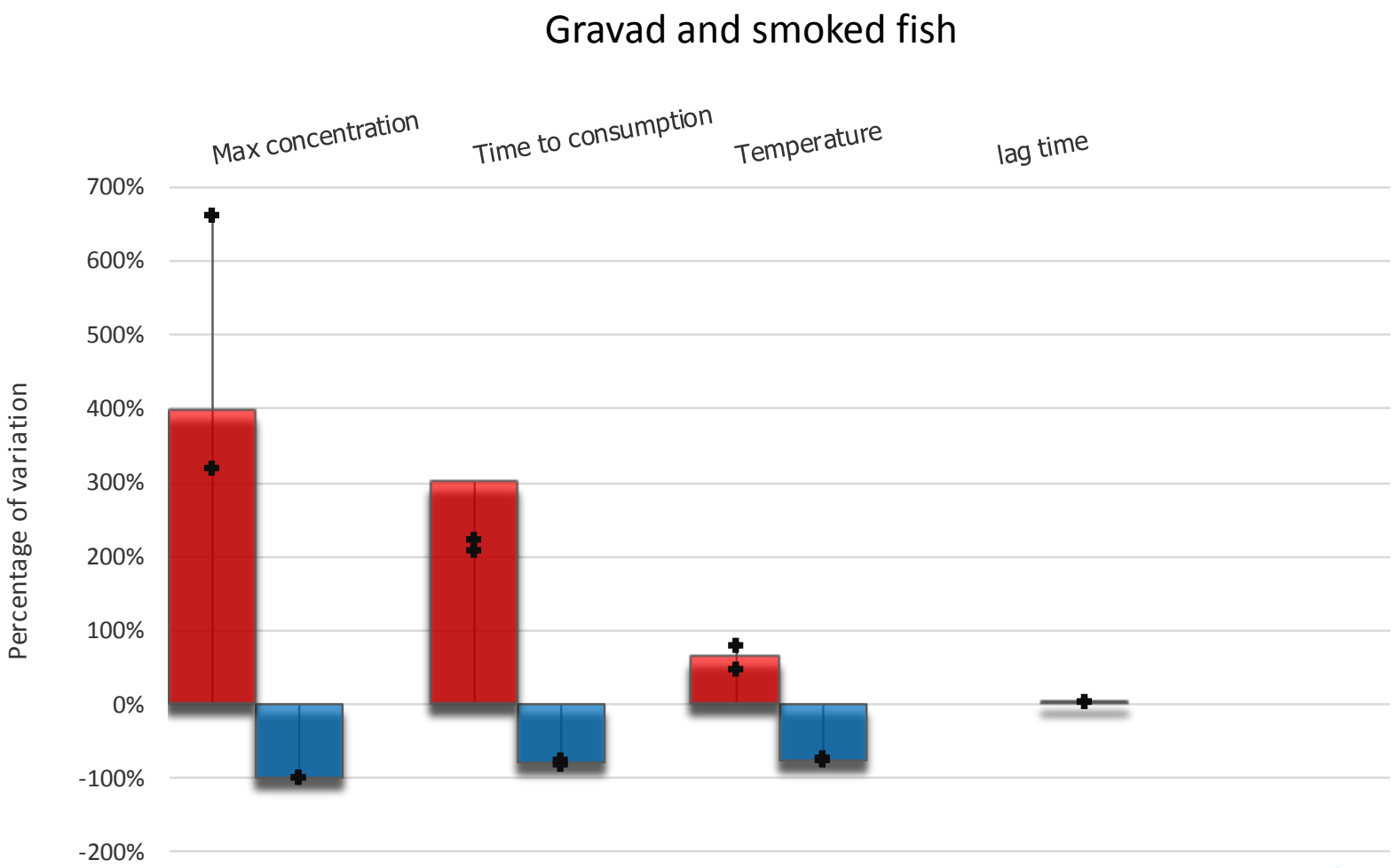


Scenario analysis



(Objective 4)

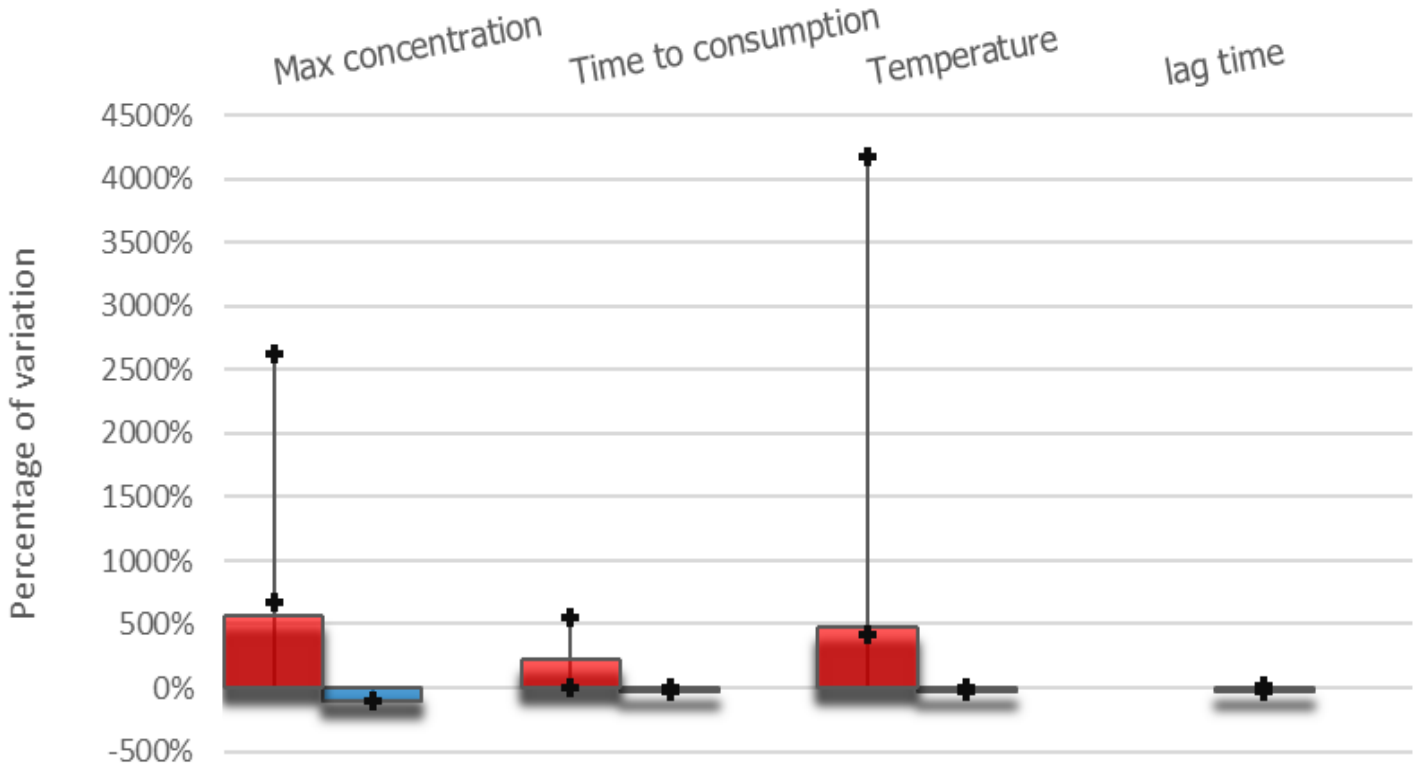
Scenario analysis



(Objective 4)

Scenario analysis

Soft and semi-soft cheese



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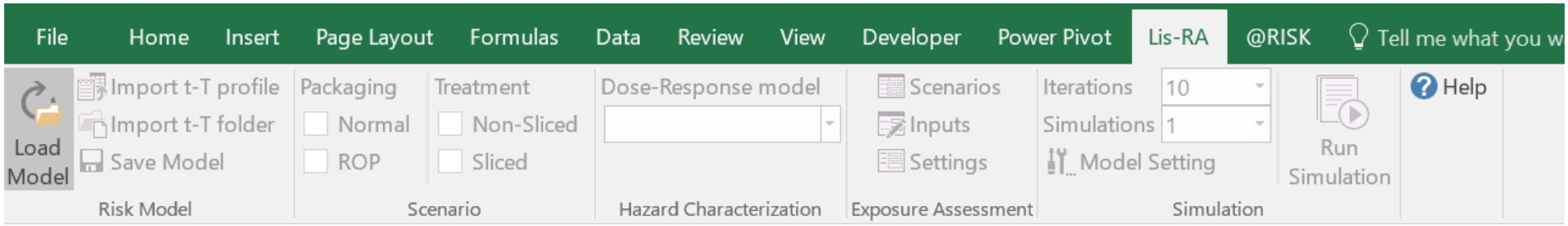
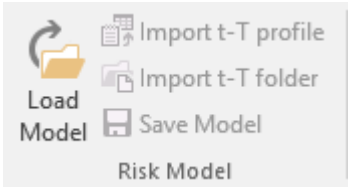
- ❑ Conclusions

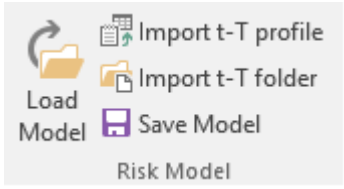
An Excel Add-in, “Lis-RA”, for listeriosis risk model simulation

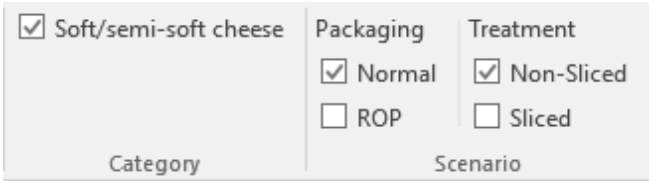
Lis-RA, a customized Ribbon-based system, was developed in VBA using libraries from @Risk software



Lis-RA allows users to select/upload models, time-temperature profiles sand scenarios.

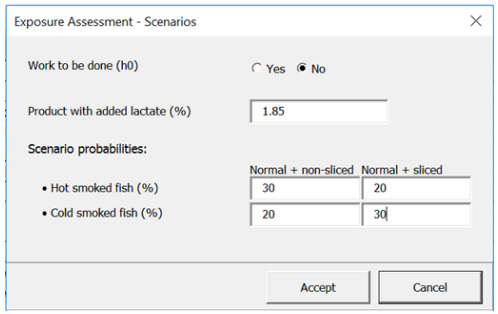


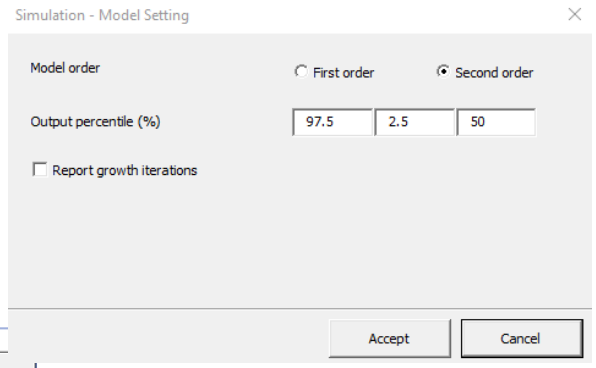


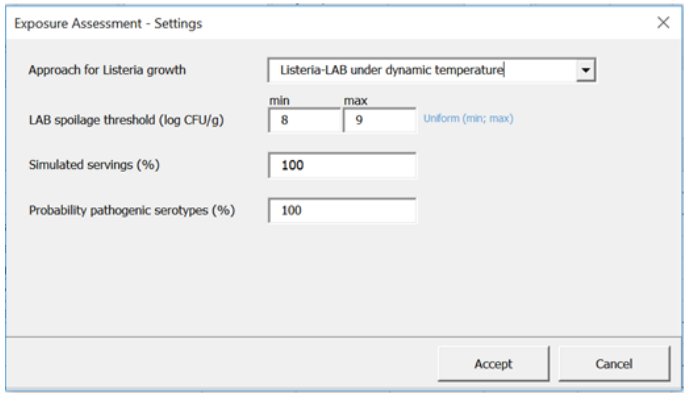


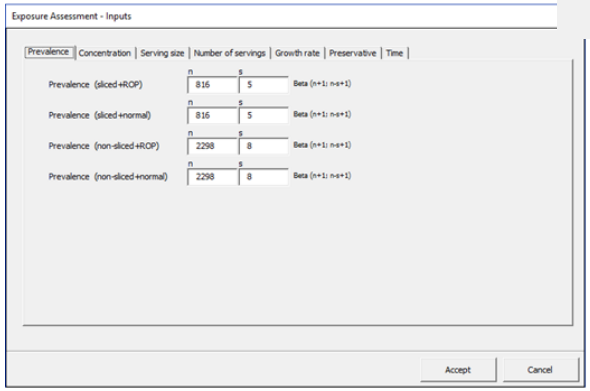
An Excel Add-in, “Lis-RA”, for listeriosis risk model simulation

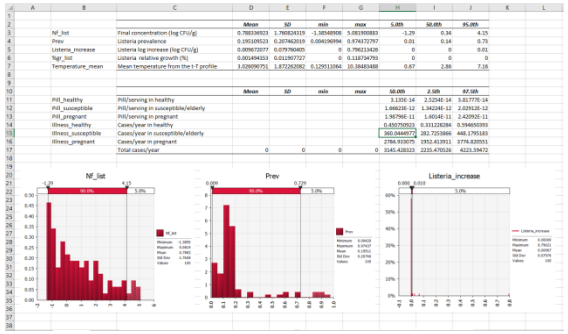
Users can introduce scenario probabilities, input values and select the model order (first order or second order), etc. Simulation results are automatically reported.











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Conclusions

Similar values to those reported by the surveillance system, confirming higher incidence in elderly population

Heat treated meat was the RTE product with highest overall risk of listeriosis specifically for the subcategory cooked meat, specially in pregnant women

Semi-soft cheese and hot smoked fish were the subcategories resulting in the lowest estimated risk

Aspects related to the consumption patterns, shelf-life and processing were key in the differences found between these subcategories

Concerning specific products, the highest risk was obtained for normal packaged and sliced Pâté in pregnant population. The lowest risk values were observed for non-sliced hot smoked fish and soft and semi-soft cheese.

Conclusions

Maximum concentration at retail and temperature were the most relevant variables for listeriosis risk: decreasing storage time by 25% and temperature 1–2 or 3–4°C can be effective in reducing listeria growth and finally risk for the consumer.

Sources of Uncertainty: maximum concentrations of *L. monocytogenes* at retail, time-temperature profiles and consumption patterns.

The developed software tool allows to simulate **alternative scenarios (country, lot, control measures)**, or **update model** inputs as new information becomes available.

In-depth and specific sensitivity analyses can be performed based on the developed risk models.

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Closing gaps for performing a risk assessment on *Listeria monocytogenes* in ready-to-eat (RTE) foods: activity 2, a quantitative risk characterization on *L. monocytogenes* in RTE foods; starting from the retail stage

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Abstract

A quantitative risk characterization of *Listeria monocytogenes* in various ready-to-eat (RTE) food categories (heat-treated meat; smoked and gravad fish; and soft and semi-soft cheeses) in the European Union (EU) was performed; starting from the retail stage. For prevalence and concentration, data from the EU-wide baseline survey was complemented with EU monitoring data and data from other sources. Food serving size and the number of servings per year were estimated from the European food consumption database. Demographical data from Eurostat were also used. Growth of *L. monocytogenes* considering interaction with lactic acid bacteria was modelled from retail to consumption using temperature-time profiles during transport and storage. This information was combined with the Pouillot dose-response models to estimate the number of listeriosis cases per 10^6 servings as well as the annual number of listeriosis cases in the EU associated with the consumption of the RTE foods. The total number of cases was estimated as 2,318 (95 confidence interval (CI): 1,450-3,612). Cooked meat and sausage presented most cases (median of 863 and 541, respectively). Sliced pâté packaged in normal atmosphere presented the highest listeriosis risk per million servings. With respect to the estimation of the total number of cases per population group, considering each food subcategory separately, the higher risk population group corresponded to elderly, followed, in most cases, by pregnant and healthy, with the exceptions of cooked meat and hot smoked fish in which pregnant presented higher risk than elderly. In the light of results, it seems necessary that educative programs and specific recommendations are specially oriented the most susceptible population groups so as to mitigate the risk. Uncertainty sources for some variables such as initial MAY prevalence should be further elucidated as well as variability in *Listeria* growth when types of product and populations are compared.

Key words: quantitative risk characterization, *Listeria monocytogenes*, ready-to-eat food, dose-response model, growth parameter, number of listeriosis cases

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