TECHNICAL REPORT

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Outcome of the public consultation on the draft Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat foods and the risk for human health in the EU

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) carried out a public consultation to receive input from the scientific community and all interested parties on the draft Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU. The document was prepared by an ad hoc working group of the EFSA Panel on Biological Hazards (BIOHAZ Panel) and endorsed by the BIOHAZ Panel for public consultation at its Plenary meeting of 6 July 2017. The public consultation for this document was opened from 24 July 2017 to 29 September 2017. EFSA received 219 comments from 18 interested parties. EFSA and its BIOHAZ Panel wish to thank all stakeholders for their contributions. This report presents the comments received and provides a summarised description of how the comments were addressed in the finalisation of the document. The stakeholders' valuable and detailed comments were taken into account by the BIOHAZ working group to prepare an updated version of the Scientific Opinion. The Scientific Opinion was discussed and adopted at the BIOHAZ Plenary meeting on 6-7 December 2017, and is published in the EFSA Journal.

Key words: ready-to-eat food products, *Listeria monocytogenes*, human listeriosis, Time Series Analysis, Quantitative Microbial Risk Assessment, public consultation

Requestor: EFSA

Question number: EFSA-Q-2017-00413

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

In 2015, the Panel on Biological Hazards (BIOHAZ Panel) of the European Food Safety Authority (EFSA) initiated a self-tasking mandate to deliver a Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU. The opinion draws conclusions on the two terms of reference: (1) to summarize and critically evaluate the most recent information on *L. monocytogenes* in RTE foods and (2) to discuss and evaluate the factors related to the contamination in the food chain and the consumption patterns that may contribute to the reported trend of listeriosis incidence rate in the EU. The focus was on the time period after the adoption of the previous Scientific Opinion of the BIOHAZ Panel, i.e. 2008-2015 (EFSA BIOHAZ Panel, 2008).

Considering that the risk assessment was of particular interest to the public and scientific community, it is deemed appropriate to undertake a public consultation on the draft Scientific Opinion before its final adoption by the BIOHAZ Panel. The public consultation should last at least 6 weeks.

In line with EFSA's policy on openness and transparency, and in order for EFSA to receive comments from the scientific community and stakeholders, EFSA shall release the draft Scientific Opinion on *L. monocytogenes* contamination of RTE foods and the risk for human health in the EU for public consultation.

The comments resulting from the public consultation will be published in a technical report that compiles the comments received and explains how these will be addressed. Before its adoption by the BIOHAZ Panel, the abovementioned draft Scientific Opinion needs to be revised, taking into account the comments received during the public consultation.

1.2. Consideration

The draft Scientific Opinion on *L. monocytogenes* contamination of RTE foods and the risk for human health in the EU food was prepared by an ad hoc working group of the BIOHAZ Panel and endorsed for public consultation by the BIOHAZ Panel at its Plenary meeting of 6 July 2017. The draft opinion was published on the EFSA website for comments from 24 July 2017 to 29 September 2017 (see Appendix A).

The working group prepared an updated version of the Scientific Opinion, taking into account the comments received. The updated Scientific Opinion was discussed and adopted at the BIOHAZ Plenary meeting on 6-7 December 2017 during its 117th Plenary meeting, and is published in the EFSA Journal (EFSA BIOHAZ Panel, 2018).

EFSA is committed to publishing the comments received during the public consultation, as well as a short report on the outcome of the consultation.

2. Screening and evaluation of comments received

2.1. Comments received

All the comments received were scrutinised and subsequently tabulated with reference to their author(s) and the section of the draft guidance to which they refer. References to sections and annexes in the comments or the answers to the comments refer to the draft Scientific Opinion. The total number of comments was 219, from 18 different parties. Comments submitted formally on behalf of an organisation appear with the name of the organisation. A statistical summary of the comments received is provided in Tables 1 and 2.

Table 1: Comments received on the draft Scientific Opinion per section

Section	Number of comments
Abstract	1
Summary	21
1. Introduction	24
2. Data and Methodologies	42
3. Assessment	80
3.1. Evidence for hazard identification	25
3.2. Evidence for hazard characterisation	11
3.3. Evidence for exposure assessment	21
3.4. Evidence for risk characterisation	11
3.5. Evaluation of the epidemiological trend of human listeriosis	1
3.6. Evaluation of factors that may explain the epidemiological trend of human listeriosis	11
4. Conclusions	5
5. Recommendations	5
Appendices	30
Generic comments	11
Total number of comments	**219**

Table 2: Comments received on the draft Scientific Opinion per organisation

Name	Organization	Country	Number of comments
	Anses	France	118
Jens Kirk Andersen	National Food Institute/DTU	Denmark	2
Gary Barker	Quadram Institute Bioscience	United Kingdom	9
Bert de Vegt	Micreos	The Netherlands	1
Kieran Jordan	Teagasc	Ireland	2
Mats Lindblad	National Food Agency	Sweden	8
	Food Standards Agency	United Kingdom	8
Brankica Lakicevic	Institute of Meat Hygiene and Technology	Serbia	2
	CNIEL (French Dairy Board)	France	7
Bertrand Lombard	Anses-Laboratory for Food Safety	France	2
Thomas Lüthi	Federal Food Safety and Veterinary Office (FSVO)	Switzerland	7
Stefano Morabito	Istituto Superiore di Sanità	Italy	9
Ivan Nastasijevic	Institute of Meat Hygiene and Technology	Serbia	2
Sven Qvist	NordVal International	Denmark	1
Hélène Simonin	European Dairy Association (EDA)		1
Marina Steele	Canadian Food Inspection Agency - Food Safety Science Services – Microbiology	Canada	6
Marjon Wells-Bennik	NIZO	The Netherlands	19
Marcel Zwietering	Wageningen University and Research	The Netherlands	15

2.2. Comments received and how they were addressed

A general overview of the comments received per section on the draft Scientific Opinion and the general answers are presented in Table 3. Many comments were deemed appropriate and contributed to an enhancement in the scientific quality and clarity of the Scientific Opinion, and thus the opinion was revised accordingly, providing additional clarifications and explanations. Comments related to policy or risk management aspects were considered to be outside the scope of the consultation, and are not covered in this report. Some comments, especially those suggesting editorial changes, have been directly addressed in the text of the Scientific Opinion, if they were considered appropriate.

Table 3: General overview of the comments received per section on the draft Scientific Opinion and the general answers by the BIOHAZ Panel

Section	Comment and justification by BIOHAZ Panel
Abstract	
Summary	• The comments related to the summary have been summarized in the various sections below (e.g. Conclusions Section).
1. Introduction	
1.1. Background and Terms of Reference (ToR) as provided by the requestor	
1.2. Interpretation of the ToR	• It has been clarified that the focus is on **invasive** listeriosis (due to its greater impact on the public health burden and since surveillance of human listeriosis focuses on severe invasive forms) and that control and intervention measures are outside the scope of the mandate.
1.3.1. Additional background information	• The BIOHAZ Panel added that the guidance document on *L. monocytogenes* shelf life studies[1] for RTE foods includes a section on historical data that can be used for trend analysis. The BIOHAZ Panel included the EU Reference Laboratory for *L. monocytogenes* (EURL *Lm*) guidance document to evaluate the competence of laboratories implementing challenge tests and durability studies related to *L. monocytogenes* in RTE foods Version 2 – 17 January 2017 together with its aim.
2. Data and Methodologies	
2.1. Data	• It was commented that, according to international publication, it is not correct to exclude cases under one year old from the time series analysis (TSA) because they were mainly related to pregnancies. The BIOHAZ Panel clarified that the current EU case definition (under revision) defines the neonatal case if the infection occurs within the first month of life but the age of the neonate is not reported in the EU system. • The BIOHAZ Panel clarified that the monitoring data should be considered in the light of certain assumptions and decisions as spelled out in EFSA and ECDC (2016). These data were only used for evaluating the compliance with the food safety criteria (FSC) for *L. monocytogenes*. Studies assessing the performance of in-house methods (i.e. a minority of studies) were excluded to minimize sampling bias and because most of them lacked of a clearly reported sampling period.
2.2. Methodologies	• It was suggested to apply an additional TSA technique (such as a three state model approach) that does not depend heavily on the existence of a single underlying stochastic process. The BIOHAZ Panel considered the three (or less/more) states model(s) but these were not tested for following reasons: over-parameterization, the scattered nature of the listeriosis outbreaks and the fact that most cases appear sporadic, the presence of strong seasonality. The three state model may not be the most optimal model for testing changes in the surveillance system and a possibly more appropriate change point model did not discover such a change. It was clarified that the choice not to distinguish outbreaks from other observations may have been investigated through models with several states but this was not tested. • It was commented that the assumption that that the two types of smoked fish, i.e. cold smoked and hot smoked fish, have the same distribution of initial *L. monocytogenes* counts may not be valid. The BIOHAZ Panel did not agree and justified the assumption based on the distribution frequency of *L. monocytogenes* counts in cold-smoked and hot-smoked fish samples from the EU-wide baseline survey (BLS). • The BIOHAZ Panel clarified that the maximum initial *L. monocytogenes* concentrations used align with the maximum *L. monocytogenes* counts at the end of shelf-life in the RTE food categories as sampled in the BLS. • Some of the values of remaining storage time (up to 519 days for fish) are considered quite unrealistic (high). The BIOHAZ Panel clarified that the values shown are those observed through the BLS and that the distributions used reflect the distributions of the BLS samples.

[1] https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidance_document_lysteria.pdf

	• The BIOHAZ Panel added that the option 3 for the initial *L. monocytogenes* concentration was chosen because the model is including growth after retail and so concentration data observed at the end of the shelf life cannot be used. • It was commented to compare the growth predictions using the exponential growth rate with those of sophisticated models. The BIOHAZ clarified that the variability of the growth rate is already taken into account and that therefore more complicated models are not needed. • The BIOHAZ Panel justified the assumption of no lag phase as it was considered that the lag phase is finished before the RTE foods are purchased. This assumption is conservative in the sense that it may overestimate the risk. • It was remarked to reconsider the standard deviation of the log-normal distribution of 1.62 in the dose response (DR) model as more heterogeneous populations are considered in the assessment compared to the "homogeneous" populations in Pouillot et al. (2015). The BIOHAZ Panel did not consider 1.62 as not describing a homogenous population and estimated this variability irrespectively of the chosen 11 populations in Pouillot et al. (2015). In the absence of data the same estimate as in this paper was used. • Several clarifications were made in Appendix C based on the suggestions and small changes were made in the R-code that did not impact on the outcome of the model.
3. Assessment	
3.1. Evidence for hazard identification	• It was clarified by the BIOHAZ Panel that among all *Listeria* species, *L. monocytogenes* is by far the most important species from a human health perspective, followed by *Listeria ivanovii* that might be found in food in very rare cases. • The BIOHAZ Panel added a short paragraph on global burden and disability adjusted life years (DALYs), as suggested. • The BIOHAZ Panel acknowledged that data on underlying diseases/conditions of invasive listeriosis cases have not been collected at EU level. • The BIOHAZ Panel agreed to remove the comparison *(i.e. less than 4% of total reported cases during the period)* between outbreak and sporadic cases as reported to the European Surveillance System (TESSy) as both are based on two different specifications. It has been added that most invasive listeriosis cases appear as sporadic infections and the detected outbreaks are usually small. • It was commented that 41% of the outbreaks are linked to foods that are not considered in the Scientific Opinion. The BIOHAZ Panel highlighted that other foods are considered in terms of reference (ToR) 1 when relevant and that the choice of focussing on the three RTE food categories in ToR2 was due to data availability. In addition, the outbreak data referred to are not as clear cut as to say that 41% are due to other foods as some of the outbreaks in the other category may be/include RTE foods of the categories considered (e.g. buffet meals, sandwiches) but without the full information these were not included among the three food categories. This has been clarified and the limitation of focussing on three food categories was considered, whenever appropriate. • The representativeness of the selection of 1,143 *L. monocytogenes* by Møller Nielsen et al. (2017) has been added by the BIOHAZ Panel stating that, as the food isolates in this study were focussed on the food categories represented in the BLS, the study supports the conclusions in relation to these sources, but it limits concluding on other potential food sources, such as non-animal sources. • The BIOHAZ Panel agrees that also WGS requires epidemiological investigation follow up. This has been clarified.
3.2. Evidence for hazard characterisation	• The BIOHAZ Panel added studies on the competition between *Listeria* species and other flora, that had been shared by the EURL for *L. monocytogenes*, after a revision and full validation through an inter-laboratory study on the performance of the standard reference method for *L. monocytogenes* detection in food, EN ISO 11290-1. This point was also taken on board for revising the conclusions. • It was questioned whether the r values of the DR model could not have been defined for the age/health status category instead of the 14 categories of defined population. The BIOHAZ Panel indicated that the lack of reliable data on the distribution of human listeriosis cases for the different underlying conditions groups prompted the approach based on epidemiological data available in the European Union and European Economic Area (EU/EEA).
3.3. Evidence for exposure assessment	• The BIOHAZ Panel agreed that there is contrary evidence on the coping of persistent and non-persistent strains with conditions in the food environment and that the question of definition between persistence versus recurrence remains. • Possible reasons why older people could be more at risk have been provided that the BIOHAZ Panel agrees upon and are considered as covered. The panel agreed that the maintenance of low temperatures in refrigerators and of the adherence to 'use-by' dates is of importance.

	• The additional references provided on the growth, survival and inactivation of *L. monocytogenes* in food and in the food chain have been added by the BIOHAZ Panel, also in Appendix H.
3.4. Evidence for risk characterisation	• The BIOHAZ Panel agreed that little information on leafy vegetables is available; also few quantitative microbiological risk assessment (QMRA) studies consider leafy vegetables. Therefore a recommendation was added to implement innovative programmes to generate data on *L. monocytogenes* in RTE foods (not only the classical food categories) that are comparable across Member States (MSs) and time in the EU.
3.5. Evaluation of the epidemiological trend of human listeriosis	• The BIOHAZ Panel, following the comment received, clarified that the TSA indicated the presence –not the trend– of seasonality of invasive listeriosis cases. It was added that the presence of seasonality is interesting, and could be due to several factors, such as hygienic, climatic human behavioural factors and seasonal consumption patterns.
3.6. Evaluation of factors that may explain the epidemiological trend of human listeriosis	• The relevance of choosing option 3 for the initial *L. monocytogenes* concentration was questioned. The BIOHAZ Panel reminded that the observed growth mainly depends on the temperature and duration of storage after retail. When running the model with the other options the same order in percentage of cases attributable to the storage conditions are obtained (data not shown). • It was explained why the QMRA is sensitive to maximum population density (MPD), but questioned whether a change in the MPDs is expected. The BIOHAZ Panel clarified that no data are available that supports a change in MPD and that hypotheses why an increase in mean concentration/MPD has occurred can be put forward but cannot be supported. • The BIOHAZ Panel agreed that the "average" (arithmetic mean) concentration in RTE that causes listeriosis is probably much higher than 2,000 CFU/g and therefore revised the sentence to *"Assuming an average serving size of 50 g, this would correspond to an average L. monocytogenes concentration in RTE foods* ***above*** *2,000 CFU/g at the time of consumption"*.
4. Conclusions	• The conclusions in Section 4 have been shortened considerably and therefore the comments might not be relevant to this section anymore. The concluding remarks in the various sections and the summary still contain the original text. • The statement that under-reporting/under-ascertainment of human invasive listeriosis is low compared to many other foodborne pathogens was questioned as there may be many additional deaths from listeriosis in nursing homes and other care facilities for elderly because causation of a systemic infection is seldom determined for these individuals. The BIOHAZ Panel agreed and added that the causes of deaths among elderly in nursing homes and care facilities may remain undetermined and therefore mortality may be underestimated for these groups. • The BIOHAZ Panel weakened the statement that any *L. monocytogenes* strain has the ability to result in invasive human listeriosis. • It has been clarified by the BIOHAZ Panel that the attribution of cases to the pregnant population through the QMRA results appears to be an overestimation compared to the distribution of invasive listeriosis cases reported during the period. Some potential reasons for the discrepancy have been added. • It was suggested that the increasing average age of the first pregnancy could lead to an increase in the proportion of near-40 year old pregnant woman, for whom the susceptibility to *L. monocytogenes* infection could be different. The BIOHAZ Panel considers this as a hypothesis. There is only estimated and/or provisional evidence for a small increase in the mean age at childbirth in the EU from 29.7 years in 2008 to 30.5 years in 2015. • It was commented that a harmonised sampling strategy can be achieved if each MS sets as a priority in its multi-annual national control plan (MANCP) the official controls to assess compliance with *L. monocytogenes* criteria in RTE foods, according to Regulation EC 2073/2005. The BIOHAZ Panel acknowledged, as spelled out in Section 3.6.3, that the monitoring data have several limitations for the purpose of evaluating any changes in prevalence of *L. monocytogenes* in RTE foods as also stated by Boelaert et al. (2016).
5. Recommendations	• Based on several comments, the recommendations have been elaborated. • It was commented that awareness campaigns targeting elderly populations and a better understanding of dietary practices and food handling practices among elderly groups should be ascertained. Therefore the BIOHAZ Panel added examples of stakeholders. • A recommendation was added by the BIOHAZ Panel on the promotion of the use of next generation sequencing (NGS)/ whole genome sequencing (WGS) in routine epidemiological surveillance of food and humans to improve the detection of outbreaks, the understanding of

	the distribution of different virulent strains in food and to enable better source attribution. This will translate molecular information, relating to *L. monocytogenes* in RTE food, into implementable action for the appreciation and management of risks". • It has been recommended to apply the *Listeria monocytogenes* generic QMRA (gQMRA) model with additional food categories when data become available and for MSs to apply the gQMRA model and TSA model with their specific data.
Generic comments	• It was commented that the BIOHAZ Panel missed an opportunity to explore regional variations in the incidence of listeriosis. Without considering each country independently, a simple regionalization might have provided some interesting clues to explain the pattern of listeriosis cases. The BIOHAZ Panel considered that the analysis of listeriosis incidence by region and/or MS was out of the scope of the Scientific Opinion as the ToR was to evaluate the trend in listeriosis in the EU/EEA, but agreed that an analysis at country or regional level would be worthwhile to investigate the trends in human listeriosis cases and/or incidence and the factors behind this trend. This has been recommended. • It was remarked that the whole Scientific Opinion uses the very strong assumption that all cases of listeriosis in the EU are linked to three types of RTE only. This assumption is acknowledged, but its limitation should be thoroughly discussed. The observation of outbreaks linked to complex foods (sandwiches), vegetable/fruits and the new trends of consumption observed in the EU (more RTE) should trigger some discussions regarding these potential sources. The hypothesis of an increase in the listeriosis incidence linked to food other than the "usual suspects" should be considered. The BIOHAZ Panel believes that all foods are covered in ToR1 but not specifically in the ToR2. Data from the three RTE food categories are used in the evaluation of factors that may explain the trend. The QMRA approach is to construct a generic RTE food based on the properties and the consumption of these three food categories. The uncertainty of the evaluation of contributing factors, in relation to food categories not considered, depends on the degree that the non-considered foods would differ in terms of prevalence, initial contamination, growth, storage, consumption, etc., to those considered. For instance, the effect of an increased consumption or prevalence would be the same independent of the food, but of course the indicator data for these foods (change over time period) were not included in the analysis. It should be noted that this would impact only on the factors that are related to the food (assessment questions (AQ) 2.1–2.4; i.e. *L. monocytogenes* prevalence and concentration in RTE food, storage conditions (temperature, time) and consumption (serving size and frequency). The gQMRA model can be updated with additional food categories when data become available. • It was remarked that the results rely on the hypothesis that the distribution of virulence of the strains is the same between the different food categories. Although some strains/clonal complexes are equally distributed between the different food categories, small differences in relative percentages of high/medium/low virulent clonal complexes could lead to huge differences (because most listeriosis are linked to virulent clonal complexes). The BIOHAZ Panel agreed with this and added this assumption in the uncertainty Section of the gQMRA model and exemplified with the reference of Fritsch et al. (2017). In addition, the opportunity for risk assessment taking this into consideration has been added to the summarising remarks in Section 3.2.

The French Agency for Food, Environmental and Occupational Health & Safety (Anses) has provided EFSA with 118 comments as listed in Appendix B. In addition, Anses published an opinion following the public consultation (Anses, 2017). In this Anses opinion, the expert committee "Assessment of the biological risks in foods" (BIORISK) emphasised the exhaustive and rigorous nature of the work presented in EFSA's draft opinion. Although the study has many limitations, these are presented and discussed, thus ensuring transparency and a clear understanding of the European approach.

For each part of EFSA's analysis, the BIORISK expert committee has submitted requests for justification/arguments on the choices and assumptions made. Proposed reformulations and clarifications have been added.

The main limitation identified by Anses is the lack of availability and inconsistent quality of data specific to the European scale (socio-economic data, contamination data, consumption data by population category, data on meal preparation/storage, etc.) to respond to the questions asked. Many sources of uncertainty can result in an erroneous interpretation of the impact of certain factors taken into account in the QMRA model. The BIOHAZ Panel agrees with this statement but has been careful in pointing out the assumptions and limitations. At the same time, it is believed that this general statement is relevant to any risk assessment. Therefore, care was taken when identifying potentially contributing factors in relation to the identified sources of uncertainty to classify the conclusions with regard to the available evidence. However, in the same way as for the TSA it should be pointed out that the analysis of contributing factors at EU/EEA level may not be representative for all MS for the reasons mentioned by Anses. Consequently, text was added in the uncertainty Section of the gQMRA model and one of the conclusions was amended to reflect this and to encourage MS to apply the generic model with their specific data.

The other limitations (only three categories of RTE food products, regional variations) have been addressed in Table 3 under general comments.

The BIORISK expert committee issued the following conclusions and recommendations:

- considering that the heterogeneity of detection and surveillance systems and consumer practices has been taken into account, it would have been interesting to conduct an analysis by geographical clusters, for example. Implementing models with more complete data and in a limited number of MSs would be more relevant;
- considering the widespread circulation of *L. monocytogenes* from its animal and environmental reservoirs up to the consumer, it would be useful to broaden the analyses beyond RTE foods, the only category studied in the document.

The BIORISK expert committee further concluded that, after having acquired additional data, new studies should be undertaken in order to draw up some concrete recommendations for management at European level. To reduce the level of uncertainty and enable an analysis, the BIORISK expert committee suggests conducting a debate on the data to be acquired and the methods to be used to provide a convincing explanation for the increase of the incidence of human listeriosis in Europe.

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Abbreviations

Anses	The French Agency for Food, Environmental and Occupational Health & Safety
AQ	assessment question
a_w	water activity
BIOHAZ Panel	EFSA Panel on Biological Hazards
BIORISK	The Anses expert committee "Assessment of the biological risks in foods"
BLS	EU-wide baseline survey
CA	Competent Authority
CC	clonal complex
CDF	cumulative distribution function
CFR	case fatality rate
CFU	colony forming units
cgMLST	core genome multilocus sequence typing
CI	confidence interval
DALYs	disability adjusted life years
DLM	dynamic linear model
DR	dose response
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
ECDF	empirical cumulative distribution function
EFSA	European Food Safety Authority
EGR	exponential growth rate
EURL *Lm*	EU Reference Laboratory for *Listeria monocytogenes*
Eurostat	The Statistical Office of the European Union
FAO	The Food and Agriculture Organization of the United Nations
FBO	food business operator
FPE	food processing environment
FSC	food safety criteria
GI	gastrointestinal
gQMRA	*Listeria monocytogenes* generic QMRA
HACCP	hazard analysis and critical control points
MANCP	multi-annual national control plan
MIC	minimum inhibitory concentration
MLST	multilocus sequence typing
MPD	maximum population density
MRA	microbial risk assessment
NGS	next generation sequencing
PAR	Poisson autoregressive model

QMRA	quantitative microbiological risk assessment
RASFF	EU Rapid Alert System for Food and Feed
ROP	reduced oxygen packaging
RTE	ready-to-eat
SNP	single nucleotide polymorphism
TEO	total number of eating occasions per year
TESSy	The European Surveillance System
ToR	terms of reference
TSA	time series analysis
WGS	whole genome sequencing

Appendix A – Public consultation on the draft Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat foods and the risk for human health in the EU

EFSA has launched an open consultation on its draft scientific opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU. This document summarises and critically evaluates the most recent information on *L. monocytogenes* in RTE foods, and evaluates the factors related to the contamination in the food chain and the consumption patterns that may contribute to the reported trend of listeriosis incidence in the EU.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders, EFSA has launched a public consultation on the draft document developed by the BIOHAZ Panel of EFSA.

Interested parties are invited to submit written comments by 29 September 2017. Please use the electronic template provided to submit comments and refer to the line and page numbers. Kindly note that after 2 hours of non-activity your working session will expire and comments submitted after that time will not be recorded and transmitted. Therefore, if the page is left inactive for more than 2 hours, please re-open it from the link before restarting to comment. If you would like to submit additional data to support your comments or files send an email to: BIOHAZ.PublicConsult.98@efsa.europa.eu. Please note that comments will not be considered if they:

- are submitted after the closing date of the public consultation;
- are not related to the contents of the document;
- contain complaints against institutions, personal accusations, irrelevant or offensive statements or material;
- are related to policy or risk management aspects, which are out of the scope of EFSA's activity.

EFSA will assess all comments from interested parties which are submitted in line with the criteria above. The comments will be further considered by the relevant EFSA Panel and taken into consideration if found to be relevant.

Persons or entities participating in the EFSA Public Consultation are responsible for ensuring that they hold all the rights necessary for their submissions and consequent publication by EFSA. Comments should inter alia be copyright cleared taking into account EFSA's transparency policy and practise to publish all submissions. In case your submission reproduces third party content in the form of charts, graphs or images, please ensure that the required prior permissions of the right holder have been obtained.

All comments submitted will be published. Comments submitted by individuals in a personal capacity will be presented anonymously. Comments submitted formally on behalf of an organisation will appear with the name of the organisation.

Appendix B – Full list of comments received

Table of comments received during the public consultation on the draft Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU. Comments are organised by sections of the opinion.

N	Contributor/organisation	Section	Comment received	How addressed
1	Mats Lindblad/National Food Agency	Abstract	Line 27-31: The sentence *"Among the evaluated factors, those considered likely to be responsible for the increasing trend in cases are the increased population size of the elderly and susceptible population except for the 25-44 female age group"* is a bit difficult to understand since it is not obvious that the 25-44 female age group should be considered as part of a susceptible population (or how the susceptible population is defined). Also, the increasing trend in cases (line 30) has not been mentioned previously in the abstract.	The abstract has been revised. It was added that the increasing trend of the monthly notified incidence rate of confirmed human invasive listeriosis of the female age group between 25 and 44 years old was probably related to pregnancies.
2	Thomas Lüthi/ Federal Food Safety and Veterinary Office (FSVO)	Summary	We suggest to structure the summary according to MRA to quickly find relevant information. Alternatively structure table of contents (line 270) more clearly and therefore more readable.	The summary without the headings of a microbial risk assessment (MRA) was kept to be able to draw information from different parts into concluding sections. The alternative proposal has been addressed since in the Assessment Section (Section 3) the evidence is structured into the steps of a MRA and this is clear in the table of contents.
3	Marcel Zwietering/Wageningen University and Research	Summary	Line 77: Despite the application of the new food safety criteria (FSC) for *L. monocytogenes* in (RTE) foods from 2006 onwards (Commission Regulation (EC) 2073/20051) and the outcome of the BLS, a statistically significant increasing trend of human listeriosis was reported in the European Union and European Economic Area (EU/EEA) over the period 2009–2013 (EFSA and ECDC, 2015). If there is no trend information on the data of the BLS this cannot be said with the word despite.	The sentence has been rephrased to "*Despite the application of the new food safety criteria (FSC) for L. monocytogenes in (RTE) foods from 2006 onwards (Commission Regulation (EC) 2073/2005), a statistically significant increasing trend…."*
4	Anses	Summary	Line 102-104: The invasive forms have undeniably the heaviest public health impact. But no information is available on the non-invasive cases associated to a non-harmless clinical picture (flu syndrome, digestive symptoms) which certainly also impact on the public health. Gastroenteritis is now well established for *L. monocytogenes* infection but are widely underestimated and reported. Some management of gastroenteritis could avoid its evolution to invasive forms, as suggested by Allerberger and Wagner (2010).	It is acknowledged that high doses of *L. monocytogenes* bacteria in food may cause acute, self-limited gastrointestinal (GI) symptoms in healthy persons, which usually don't require medical treatment. The assessment was however focussed on invasive listeriosis due to its greater impact on the public health burden and since surveillance of human listeriosis focuses on severe invasive forms of *L. monocytogenes* infection. The focus on invasive listeriosis has been emphasized in the interpretation of the terms of reference (ToR) (Section 1.2).

5	Anses	Summary	Line 115: Please specify with: "are rarely isolated from *invasive* form clinical samples" (indeed only invasive form are investigated).	The change has been made in summary and the document was checked and "invasive" was inserted where appropriate. The focus on invasive listeriosis has been emphasized in the interpretation of the ToR (Section 1.2).
6	Marcel Zwietering/Wageningen University and Research	Summary	Line 120: Any? That is quite a strong statement	The statement has been weakened by using "almost every", also in the conclusions. This is justified as the statement refers to listeriosis cases in general.
7	Marjon Wells-Bennik/NIZO	Summary	Line 123: please remove 'The Fact that' and start the sentence with 'Most …'	This editorial change has been made.
8	Marcel Zwietering/Wageningen University and Research	Summary	Line 124: make	This editorial change has been made.
9	Marina Steele/ Canadian Food Inspection Agency - Food Safety Science Services – Microbiology	Summary	Line 124-125: A comment was made that WGS may have the potential to improve detection of links between human cases and causative food. Inability to establish links between human cases and causative food is more likely to be due to failure to isolate the causative organism or unavailability of the positive food sample than to lack of good typing tools. The following text may be more appropriate: *"The fact that most listeriosis cases appear to be sporadic, and reported outbreaks are commonly small, makes it difficult to establish links between human cases and causative foods. However, it has been suggested that next generation sequencing (NGS) techniques may make it easier to attribute relatedness within a cluster and thus establish stronger links between human cases and causative foods."*	The sentence has been revised in the Scientific Opinion where appropriate.
10	Anses	Summary	Line 135-137: Why is ice-cream included here? (Plant-derived origin and not RTE milk derived products). Please argue the use of the term "unexpected" or reformulate.	The word "unexpected" has been removed.
11	Mats Lindblad/National Food Agency	Summary	Line 145-146. Be consequent with decimals; write either "0.4 % above 100 CFU/g" for RTE meat or "0.06 % above 100 CFU/g" for RTE cheese.	The changes have been made for consistency when referring to the prevalence of *L. monocytogenes* in the food categories of the EU-wide baseline survey (BLS).
12	Anses	Summary	Line 157: Reporting minimum and maximum values of a series is not meaningful here.	The minimum and maximum values show the range of temperature and it is considered meaningful to be presented.
13	Anses	Summary	Line 159-160: "Since the majority of studies of food handling are from few countries only, this may lead to some uncertainty": please precise or rephrase. Suggestion: "There is an uncertainty on the actual	The sentence has been rephrased where appropriate.

			distribution in the EU because the studies were developed in few countries only".	
14	Anses	Summary	Line 167-169 and 218-220: May you precise and discuss the impact on security microbiological criteria for *Lm* in EC 2073/2015 regulation, on analysis at shelf life of the products and possible interpretation of this data by food operators.	This is a comment related to management and is not within the scope of the mandate. However, a general conclusion has been added about the need for continuous review of the food safety management system to achieve the appropriate level of protection as the increase in the trend of listeriosis for some population groups may potentially be attributed to numerous factors which not only include the contamination levels in food, but also other factors, such as consumption, strain virulence, health status of consumer and demographic changes.
15	Marcel Zwietering/Wageningen University and Research	Summary	Line 169: reference	The reference to Pouillot et al. (2015b) has been added and clarified that this dose response (DR) model applied to US exposure data showed that most cases are expected to be caused by highly contaminated food items.
16	Anses	Summary	Line 176-178: How do these QMRA results align with observations?	The alignment of the quantitative microbiological risk assessment (QMRA) results with the observations has been discussed. It has been clarified that the attribution of cases to the pregnant population appears to be an overestimation compared to the distribution of invasive listeriosis cases reported during the period, where about 8% of reported cases were related to the 25-44 year female age group. Some potential reasons for the discrepancy have been added.
17	Anses	Summary	Line 179-181: What about other food?	The food categories considered in the outsourcing activity 2 (Pérez-Rodríguez et al., 2017) are the same as the ones from the BLS and therefore other foods have not been assessed. It has been clarified that cases due to other foods were not considered.
18	Anses	Summary	Line 182: *"median number of cases"* What is the corresponding distribution? What is the uncertainty? Please rephrase or precise somewhere in the report if it is variability distribution or uncertainty distribution.	It has been clarified that the results refer to the outsourcing activity 2. In Section 3.4.2 it is clarified that the distribution used in the QMRA reflects mostly variability and that the only uncertainty evaluated was in the prevalence estimate.
19	Anses	Summary	Line 219: We understand that $10^5/50$ is 2000. However, the "average" (arithmetic mean) concentration in RTE that causes listeriosis is probably much higher than 2000 CFU/g. Few servings with 10^8, 10^9	The sentence has been rephrased.

			CFU would shift this mean. The sentence would be more correct if written *"Assuming an average serving size of 50 g, this would correspond to an average L. monocytogenes concentration in RTE foods above 2,000 CFU/g at the time of consumption"*.	
20	Anses	Summary	Line 231: Suggestion: The increasing average age of the first pregnancy could lead to an increase of near-40 year old pregnant woman proportion, for whom the susceptibility could be different.	This is a hypothesis, but we are not aware of EU data that show this increase in age of first-age pregnancy during the time period. The mean age at childbirth in the EU increased from 29.7 years in 2008 to 30.5 years in 2015 but the data for the last three previous years were only estimated and/or provisional. This has been added in Section 3.6.5 of the Scientific Opinion.
21	Marina Steele/ Canadian Food Inspection Agency - Food Safety Science Services – Microbiology	Summary	Line 252-255: One data gap outlined is a lack of representative data collected across the EU/EEA using a harmonized sampling plan suitable for surveillance over time on prevalence of different risk groups by age and gender. However, use of a Eurostat data set on demographics is described (line 724). Did this data set not provide age and gender information to determine the prevalence of different risk groups?	The risk groups referred to are defined not only by age and gender but by susceptibility, i.e. medical conditions leading to increased susceptibility. This has been clarified.
22	Marina Steele/ Canadian Food Inspection Agency - Food Safety Science Services – Microbiology	Summary	Line 256-269: This paragraph raises an important point. Awareness campaigns targeting elderly populations and a better understanding of dietary practices and food handling practices among elderly groups should be ascertained.	This has been elaborated in the recommendation by adding examples of stakeholders.
23	Caroline Le Poultier/CNIEL (French Dairy Board)	1. Introduction	The safety of dairy products is a major concern of the French dairy industry and it is in this context that the French Dairy Interbranch Organization has paid particular attention to the opinion published by EFSA. The results were taken as a whole, and then with a specific interest for those concerning soft cheeses and semi-soft cheeses as mentioned in the opinion. The purpose of this answer to the public consultation is to clarify the position of the French dairy industry regarding the risk of listeriosis linked to cheese consumption and the associated management measures, in the light of the results of this scientific opinion.	This clarification is acknowledged.
24	Thomas Lüthi/ Federal Food Safety and Veterinary Office (FSVO)	1.1. Background and Terms of Reference (ToR) as provided by the requestor	Line 357-415: ToR might be added in an annex to focus the main text on the MRA mainly.	The Scientific Opinion follows the EFSA template.
25	Marina Steele/	1.1. Background	Line 400-401: TOR 1 is to summarise and critically evaluate the most	The isolates used in the outsourcing activity 3 (Møller

	Canadian Food Inspection Agency - Food Safety Science Services – Microbiology	and Terms of Reference (ToR) as provided by the requestor	recent information on *L. monocytogenes* in RTE foods. One of the sources of information outlined for TOR 1 is the comparison of isolates from different compartments along the food chain, and in humans using whole genome sequencing. Since WGS similarities between food and humans can't be used on their own, without epidemiological information, to establish a link between clinical isolates and foods, this source of information may not be supportive of TOR 1.	Nielsen et al., 2017) have epidemiological information included. As mentioned in the report, the database was constructed with the available metadata for the isolates with links to the genome sequences.
26	Food Standards Agency	1.1. Background and Terms of Reference (ToR) as provided by the requestor	Three strategic observations continued: 2 – The opinion captures a very large range of scientific inputs, as part of a complex information system, and integrates these into a picture for the developing trends in disease in the EU in 2015. However it appears that a significant fraction of the scientific information for understanding *Listeria* in RTE food, particularly the information from the third outsourced activity, has very little impact on the conclusions reached in the opinion (and particularly very little influence on "closing gaps for performing a risk assessment on *L. monocytogenes* in RTE foods" – line 383). The WGS activity is undoubtedly high quality and represents a substantial effort (more than 1100 new whole genome sequences and associated analyses) but, in conclusions, is represented by (line 4174) "12 CC make up almost 80% of all isolates and that different levels of virulence may be associated with these", (line 4198) "Results from the outsourced study to attribute human cases to different animal sources are limited", (line 4196) "NGS techniques … may have the potential to improve this detection". The opinion was unable to translate an extensive WGS study, in the third outsourced activity, into a frame of traditional virulence or other features that contribute to understanding risk (line 1722 and line 1720 "The main findings of the WGS study are in line with 'stable core genome theory'") so that it appears a major resource has limited impact. Similarly although the opinion points to studies (including the third outsourced activity) that have identified important high frequency gene mutations in Listeria (e.g. Appendix F) it is not clear whether there is a belief that this information can be incorporated into improved appreciation of risk e.g. can the statistics of the internalin genes generate reduced uncertainty surrounding dose-response for *Listeria* in RTE food in the EU? The third outsourced activity for this opinion, and many similar studies, are a significant resource and the opinion would be improved by a conclusion that expresses the value of this approach (or otherwise) in terms of improved risk assessment/management. In practice this	It is acknowledged that the report of the outsourcing activity 3 (Møller Nielsen et al., 2017) is a useful source of information. It is believed that the Scientific Opinion captured the main points (epidemiological information, virulence and persistence, source attribution, outbreak information) of the outsourcing activity 3 in relation to the ToRs of the mandate. The recommendation has been included *"To promote the use of next generation sequencing/whole genome sequencing (NGS/WGS) in routine epidemiological surveillance of food and humans to improve the detection of outbreaks, the understanding of the distribution of different virulent strains in food and to enable better source attribution. This will translate molecular information, relating to L. monocytogenes in RTE food, into implementable action for the appreciation and management of risks".*

			conclusion may point to a completely new recommendation - "To obtain better understanding of new methods and analyses that are necessary to translate novel molecular information sources, relating to *Listeria* in RTE food, into actionable information for the appreciation and management of risks".	
27	Thomas Lüthi/ Federal Food Safety and Veterinary Office (FSVO)	1.2. Interpretation of the ToR	Line 357-415: ToR might be added in an annex to focus the main text on the MRA mainly.	The Scientific Opinion follows the EFSA template.
28	Anses	1.3.1. Additional background information	Line 427-428: Add the prevalence: *"the higher the pathogen concentration and the higher the prevalence is, the more effective the control processes need to be in order to reduce concentrations"*	It is not agreed that more effective control processes are needed to reduce concentrations when the prevalence is higher.
29	Anses	1.3.1. Additional background information	Line 436-437: Inhibition of growth does not reduce microbial load.	The sentence has been revised to clarify that it refers to microbial load at the time of consumption.
30	Brankica Lakicevic/Institute of Meat Hygiene and Technology	1.3.1. Additional background information	Line 442-443: Sources of contamination may be: food products, food contact surfaces (knives, cutting boards, gloves), equipment (slicers, refrigerated storage units such as display cases and coolers, cooling fans in display cases), environment (drains, floors, walls, airvents, areas where rodents or insects may enter the establishment), workers.	As the sentence refers to post processing contamination, it is considered that changes are not needed.
31	Anses	1.3.1. Additional background information	Line 443-445: *L. monocytogenes* is able to form biofilm. But in the given example (=cutting and slicing), *L. monocytogenes* is transferred on surfaces with other micro-organisms and food materials. Rephrase with *"L. monocytogenes can adapt to (and persist in) a biofilm environment in addition to its ability to form biofilms"* (maybe more adapted to the given examples).	The biofilm formation may result in enhanced resistance to disinfectants and antimicrobial agents and thus lead to contamination with *L. monocytogenes* after heat processing during further handling.
32	Anses	1.3.1. Additional background information	Line 446: Please remove *"sanitisers"* (sanitizers are disinfectants).	The word "sanitisers" has been removed.
33	Anses	1.3.1. Additional background information	Figure 1: Suggestion: Add an arrow from "raw material" to "Domestic environment".	"Raw material" relates to the raw material as input for the RTE food processing.
34	Brankica Lakicevic/Institute of Meat Hygiene and Technology	1.3.1. Additional background information	Line 461-relatively closed food processing plant with many controls (footbaths, sanitizer misters, clean rooms, protective clothing and rigorous personal hygiene standards). Later info by e-mail: Dear Sir/Madame, this is the link which support my comments:	The text is based on the reference by Lakicevic and Nastasijevic (2017) and therefore it is considered that changes are not needed.

			https://www.slideshare.net/aphisvs123/control-of-listeria-in-retail-estab Also, some atypical, hemolytic positive *Listeria innocua* strains were described which were surprisingly difficult to identify to the species level due to contradictory results in standards confirmatory tests. In the literature, there are data for *Listeria innocua* J1-023 and PRL/NW 15B95. It would be good to mention these natural, rare, atypical, hemolytic strains of *Listeria innocua* and in this respect, emphasize the importance of molecular methods.	
35	Anses	1.3.1. Additional background information	Line 472: Sources may also be environmental. Furthermore, raw products were not taken into account here.	Please note that "other niches in the kitchen" includes environmental and raw material contamination.
36	Anses	1.3.1. Additional background information	Line 494: There are other reasons than bacteriocin productions, simple competition with LAB (Jameson effect) can be another pertinent one (e.g. Lardeux et al. (2015)).	The revision of the statement was accepted and has therefore been modified accordingly in the Scientific Opinion, including the addition of the proposed reference (Lardeux et al., 2015).
37	Anses	1.3.1. Additional background information	Line 496: Differences between strains do exist (Ariany et al. papers, Koutsoumanis review on intraspecific variability) but the variability of parameters values has never been pointed out in exposure/risk assessment as a major source of variability compared to other sources. See papers that conducted a sensitivity analysis (Ellouze et al., 2010; Duret et al., 2014).	The revision of the statement as suggested was accepted and has therefore been modified accordingly. In addition, the proposed references (Ellouze et al., 2010; Duret et al., 2014; Aryani et al., 2015b) were included to support the revision.
38	Anses	1.3.1. Additional background information	Line 498: It would be interesting to highlight that monitoring and sanitary programs are very heterogeneous across European member states.	This is management related comment.
39	Marcel Zwietering/Wageningen University and Research	1.3.1. Additional background information	Line 506: 10 samples; line 509: 5 samples; line 511: 5 samples.	The sample units have been added.
40	Stefano Morabito/Istituto Superiore di Sanità	1.3.1. Additional background information	Lines 518-525: footnote 7 refers to "Guidance Document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under Regulation (EC) No 2073/2005" and footnote 8 refers to "Guidance Technical Document for conducting shelf-life studies on *Listeria monocytogenes* in ready-to-eat foods" Despite the availability of these documents, in our experience we have verified that not all laboratories are able to conduct shelf life studies (challenge tests and durability studies) correctly. Furthermore, we have also noticed that shelf-life studies assessment by the competent authorities is not harmonized. These conditions result in	The reference to the EU Reference Laboratory for *Listeria monocytogenes* (EURL *Lm*) Guidance Document to evaluate the competence of laboratories implementing challenge tests and durability studies related to *L. monocytogenes* in RTE foods and its aim have been added in Section 1.3.1 of the Scientific Opinion.

			costs for FBOs conducting shelf-life studies in non-competent laboratories, and in the circulation of potentially hazardous food. For the above reasons we suggest adding the following document*: "EURL Lm Guidance Document to evaluate the competence of laboratories implementing challenge tests and durability studies related to Listeria monocytogenes in ready-to-eat foods Version 2 – 17 January 2017"*. The aim of this guidance document is to set up a harmonized approach to evaluate the competence of laboratories conducting shelf-life studies (challenge tests and durability studies) and it is intended for use by national Competent Authorities (CAs), NRLs and other organizations that are involved in assessing whether laboratories are competent to conduct shelf-life studies related to *Listeria monocytogenes*. This document can serve as a tool to implement footnote 5 to criterion 1.2 of Regulation (EC) 2073/2005, which specifies that manufacturer shall be able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 CFU/g throughout the shelf-life.	
41	Marjon Wells-Bennik/NIZO	1.3.1. Additional background information	Section Introduction, section 1.3.1, line 519. The document referred to in footnote 7, namely 'https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidance_document_lysteria.pdf' has the status DRAFT (on the front page, it reads Brussels, XXX, SANCO/11510/2013, (POOL/G4/2013/11510/11510-EN.doc), […](2013) XXX draft). This means that this document has not been adopted. Under 'Examples for the necessary steps for decision of the shelf-life studies' under Question 4 (p 27), it notes: 'According to footnote 8 of Annex I of Regulation (EC) No 2073/2005, the following products could be directly included in this group: • products with pH ≤ 4.4 or a_w ≤ 0.92, • products with pH ≤ 5.0 and a_w ≤ 0.94, • products with a shelf-life of less than five days, • frozen products, • other products based on the scientific justification. However, footnote 8 of the Commission Regulation (EC) No 2073/2005, does not include frozen products and reads: '(8) Products with pH ≤ 4,4 or a_w ≤ 0,92, products with pH ≤ 5,0 and a_w ≤ 0,94, products with a shelf-life of less than five days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.'	The guidance document published through the link is the final document. The cover page will be updated and the document will be replaced on the Commission webpage.
42	Marcel Zwietering/Wageningen University	1.3.1. Additional background information	Lines 519-524: this are still draft documents	See the reply to comment 41 for the guidance document on *L. monocytogenes* shelf life studies for RTE foods. Note that also the EURL *Lm* technical

	and Research			guidance document is not a draft document.
43	Anses	1.3.1. Additional background information	Line 526: Does these guidelines on sampling (or other guideline) include trend analyses on product's contamination or environmental contamination?	The guidance document on *L. monocytogenes* shelf life studies for RTE foods[2] aims to guide RTE producers in identifying the *L. monocytogenes*-associated risk in their RTE foods and to provide general principles on when and which shelf life studies are needed. This document includes a section on historical data (raw material quality, sampling from processing areas and equipment and product testing) and clarifies that these data can be used for trend analysis.
44	Anses	1.3.1. Additional background information	Line 539: It may be noted that it is possible to rate the virulence (InIA sequencing or CC setting).	It should be noted that this section summarizes the previous Scientific Opinion of the BIOHAZ Panel.
45	Thomas Lüthi/ Federal Food Safety and Veterinary Office (FSVO)	1.3.1. Additional background information	Line 574-665. put information in an annex	This is an editorial comment. The text has been kept as it helps the further understanding of the three reports.
46	Thomas Lüthi/ Federal Food Safety and Veterinary Office (FSVO)	1.3.2. Approach to answer the ToR	Line 574-665. put information in an annex	This is an editorial comment. The Scientific Opinion follows the EFSA template.
47	Caroline Le Poultier/CNIEL (French Dairy Board)	2. Data and Methodologies	A comprehensive update on the risk of listeriosis in Europe related to the consumption of RTE foods: This opinion is based on an extensive study carried out by EFSA's Biohaz panel, which is itself based on three studies carried out by external organisms and mandated by EFSA, focusing on prevalence and risk factors contamination by *L. monocytogenes* of ready-to-eat foods in Europe (Jofré et al., 2016), the risk characterization of listeriosis in Europe (Pérez-Rodríguez et al., 2017) and the use of total sequencing techniques (Møller Nielsen et al., 2017). A comprehensive review of the scientific literature and data available to date has been conducted. The information and data available were selected and used in the opinion after an evaluation of their relevance and reliability. The dairy industry recognizes that this opinion provides a comprehensive update on the risk of listeriosis linked to the	This positive feedback is acknowledged.

[2] https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidance_document_lysteria.pdf

			consumption of ready-to-eat foods in Europe.	
48	Anses	2.1.1. Human data	Line 670: You don't refer to this WHO Global burden study and discuss it against your data (Maertens de Noordhout et al., 2014).	The WHO global burden paper publishes estimates for listeriosis cases in sub-regions, which don't match fully with the EU/EEA countries but provide with estimates that are close to the reported case numbers in 2010. A short paragraph on global burden and disability adjusted life years (DALYs) has been added under Section 3.1.2 of the Scientific Opinion.
49	Anses	2.1.1. Human data	Lines 677-678: later in the paper, Germany is taken into account (and not Belgium) as mentioned here. How do you explain the coverage improvement for Belgium/Germany (mentioned later)?	The improved coverage in Belgium and Germany is based on the survey performed among countries' experts who are working with listeriosis surveillance at the national level. Germany is already mentioned in the Scientific Opinion. The improved coverage of Belgium has been added in Section 3.6.3.
50	Anses	2.1.1. Human data	Lines 687-689: The fact that cases under one year old were excluded from the TSA because they were mainly related to pregnancies is not correct according to international publication on the subject. It is recognized that child with an age less than 28 days or 1 month is a pair with the mother and was counted as one case. After this period 1 month, it becomes two cases. If not, e.g. you introduce a bias on nosocomial contamination in hospital or eat of specific food possibly contaminated combined to infant food formulae. A sentence shall be put to modulate the report on this point.	The current EU case definition defines the neonatal case if the infection occurs within the first month of life but the age of the neonate is not reported in the EU system. The EU case definitions are under revision and this has been added in the text.
51	Anses	2.1.1. Human data	Lines 698-701: The described PCR serogroup is wrong for Ilb because Ilb is serovar 1/2b and 3b. The scheme is supplemented by WHOCC with IVb-V1 so refer to Leclercq et al., 2011. In the scheme of Doumith the PCR group L missing so all other serovars not described before. Please, correct the PCR group according to Doumith et Leclercq publication (Leclercq et al., 2011).	The codes available through the EU-wide surveillance system are being referred in this section. The serotype 3b has been added under serogroup IIb to be in line with the codes, but no cases exist in the European Surveillance System (TESSy) database with that serotype.
52	Anses	2.1.1. Human data	Lines 702-706: Not take in account Ilc and Ilb is not scientifically correct. We need to know where we are with this last two PCR serogroup. It is a bias in the analysis.	As the serogroups IIa and IVb constituted 87% of all reported cases with known serogroup/serotype, it was decided to focus on these two groups only. In addition, as already stated in the Scientific Opinion, the case numbers with serogroups IIb and IIc were relatively low which did not make it possible to perform meaningful analyses.
53	Anses	2.1.1. Human data	Line 755: "The prevalence of pregnant women": please rephrase, pregnancy is not a disease (suggestion: "proportion of pregnant women").	"Prevalence" has been replaced by "proportion".
54	Anses	2.1.2. Data on *Listeria*	Line 781: Could you remind briefly how the samples were chosen (was it random sampling?) and what was the size of each tested	The random sampling and sample size (at least 100 g) have been added.

		monocytogenes contamination of ready-to-eat (RTE) foods	sample (25 grams?, more?)?	
55	Anses	2.1.2. Data on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods	Line 790-791: analytical methods are harmonized as it is an EN ISO 11290-1/A1 standard and validated by a European project SMT4 from European Commission in 2000 so *"to a certain extent"* means that you have an analytical bias that impact directly your estimation of CFU/serving value and the target of EURL is to harmonize in Europe the analytical methods so it is a direct critic of its work. Please rephrase *"to a certain extent"*	It has been added that the text from Boelaert et al. (2016) refers to the second category of monitoring data, of which *L. monocytogenes* is part of.
56	Anses	2.1.2. Data on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods	Line 806-819: This paragraph implies issues with quantitative interpretation in this study: a considerable proportion of detection in 25 g of food will not be taken into account quantitatively or can be assigned to 10 CFU/g (while a positive detection can concern a large quantity = 10^6 CFU/g).	These data were not used for quantitative purposes but for evaluating the compliance with the FSC for *L. monocytogenes* as laid down in Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. It has been clarified in Section 2.1.2 of the Scientific Opinion that these data should be considered in the light of certain assumptions and decisions as spelled out in EFSA and ECDC (2016).
57	Anses	2.1.2. Data on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods	Line 873: Why are the in-house method evaluation excluded from the study? Indeed, the reference method is often specified in those studies and sampling methods are not systematically biased.	Studies assessing the performance of in-house methods for detecting *L. monocytogenes* in the main three RTE food categories were excluded to minimize sampling bias, as well as because most of them lacked of a clearly reported sampling period. These studies constitute the minority (18 out of 952) of the total studies meeting the above three criteria for inclusion in the analysis. This was inserted in the Scientific Opinion.
58	Gary Barker/Quadram Institute Bioscience	2.1.2. Data on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods	Line 877, figure on p26: The opinion captures a very large range of scientific information but it is not immediately clear how that information has been used to form the opinion. In particular it would be advantageous if the impact of ongoing research in forming the opinion could be identified. This applies to the large volume of molecular information from the third outsourced activity, and elsewhere, which clearly contributes to ongoing tracking activities but, in many respects, appears disconnected from the risk assessment. Investment in this kind of research is substantial but this opinion does not express a significant value in relation to risk assessment.	It was attempted to be very clear on what data was used and how the conclusions were formed in both "parts" of the Scientific Opinion. For instance Figure 2 illustrates this. ToR1 is a descriptive update of new information where for e.g. outsourcing activity three is described. ToR2 objective is to evaluate contributing factors where QMRA in outsourcing 2 forms a basis for the QMRA described in Figure 3. In ToR2 a main focus is to support conclusions with data and results from ongoing research. The purpose of ToR2 (Figure 3) is not to carry out a risk assessment but to use this as a tool to evaluate factors contributing to trend. The usefulness of activities such

				as activity 3 and the potential of these methods is agreed upon. This has been clarified by modifying the conclusions in the appropriate sections.
59	Anses	2.1.3. Data on consumption of RTE foods	Line 910: Please specify the total number of studies by EU member state (to specify the distribution of studies).	As mentioned in the Scientific Opinion, the most recent survey per Members State (MS) (and age class) was used.
60	Anses	2.1.5. Surveillance of human listeriosis	Lines 956-963 and Lines 982-995: French NRC for *Listeria* and Sante Publique France were participants (member of FWD ECDC WG) by providing metadata: microbiological/epidemiological data but were not referred in the acknowledgments of this report.	A sentence has been added in the acknowledgment part in the Scientific Opinion.
61	Stefano Morabito/Istituto Superiore di Sanità	2.2.1. Time Series Analysis (TSA) of human listeriosis trends, 2008-2015	Line 987 – 988: sentence: *'Data from countries which had not reported data for the whole study period 2008–2015 were excluded'*. The sentence should be revised as it is not clear which type of data were excluded given that countries had not provided any data for the period. Maybe they refer to the population data…	The sentence has been revised to clarify that it refers to data on cases of human listeriosis.
62	Anses	2.2.1. Time Series Analysis (TSA) of human listeriosis trends, 2008-2015	Line 988-994: Not sure that the fact that the dataset is in a "wide" or "long" shape is of interest for the reader.	The word "long" has been removed.
63	Stefano Morabito/Istituto Superiore di Sanità	2.2.1. Time Series Analysis (TSA) of human listeriosis trends, 2008-2015	Aggregated time series analysis: it is not clear if the outcome variable for the trend identification was the incidence rate (line 998) or the count of number of cases (line 983/982). This is important in light of the comment on sentence in line 987/988 on which type of data were excluded.	The outcome variable for the trend analysis of the aggregated data was the number of confirmed *L. monocytogenes* cases as spelled out before and not the incidence rate as was wrongly stated.
64	Food Standards Agency	2.2.1. Time Series Analysis (TSA) of human listeriosis trends, 2008-2015	There are some features of the opinion that could be reviewed with advantage. Considering difficulties expressed about the integrated time series analysis (line 999) it may be advantageous to include an additional time series analysis technique (such as a three state model approach) that does not depend heavily on the existence of a single underlying stochastic process. In the current form the analysis may be affected strongly by any large outbreak events or by changes in surveillance methodology etc. that fall outside a homogeneous dynamical process.	The option of the three (or less/more) states model(s) was considered – but not tested - as one of the options to fit the data. Even if fitting such a model may have been interesting from a methodological standpoint, it was not done for following reasons. Firstly a three regime model (low, medium, high levels) is probably over-parameterized relative to the current model used. Secondly, the listeriosis outbreaks are usually of scattered nature; either expressed as small clusters or dispersed across countries, and most cases appear sporadic. Finally, the presence of strong seasonality as detected with the dynamic linear model (DLM), may further blur/confuse the presence of states. The three state model may further not be the most optimal model to test changes in the surveillance system but a possibly

				more appropriate change point model did not discover such a change. A sentence has been added in Table 21 of the Scientific Opinion for completeness: *"The choice not to distinguish outbreaks from other observations could have been investigated through models with several states but this was not tested."*
65	Food Standards Agency	2.2.1. Time Series Analysis (TSA) of human listeriosis trends, 2008-2015	Reducing some of the inconsistency in mathematical representations would add considerable assurance to this opinion. • Equation 7 does not include an equals sign?	It has been clarified that equation 7 is not an equation but a trend component.
66	Caroline Le Poultier/CNIEL (French Dairy Board)	2.2.1. Time Series Analysis (TSA) of human listeriosis trends, 2008-2015	A quantitative, scientific and transparent approach to dismiss received ideas: The approach adopted by EFSA makes it possible to identify certain factors affecting the incidence of listeriosis in Europe and to attribute to each a qualitative probability level ("likely", "as likely as not" and "inconclusive"). It also allows the identification of missing data to be collected when it is not possible to conclude. Finally, this methodical and quantitative approach makes it possible to evaluate the relevance of several hypotheses. The approach used is of major importance since it makes it possible to quantify the relative impact of certain factors and to objectively dismiss some received ideas.	This positive feedback is acknowledged.
67	Mats Lindblad/National Food Agency	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1180-1182: There is no reason to assume that the two types of smoked fish have the same distribution of initial concentrations. Hot smoking can reduce concentrations of *Listeria* significantly, whereas cold smoking has only minor effects if any. Based on the production processes, it would be more logical to assume that the distributions for cold smoked and gravad fish are similar.	It has been added that this assumption is justified based on the distribution frequency of *L. monocytogenes* counts in cold-smoked and hot-smoked fish samples from the BLS.
68	Marcel Zwietering/Wageningen University and Research	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1193: In log CFU/g.	The unit $\log_{10}$ colony forming units (CFU)/g has been added.
69	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1193: The distributions used a maximum of 6.1 $\log_{10}$ CFU/g. This parameter is very important (see sensitivity analysis). It might have been taken from Pouillot et al. (2015b), who took it from Chen et al. (2003). You should provide the reference for this value; discuss it and how it aligns with the observations of the baseline survey data or the exposure model from the QRA.	*Listeria monocytogenes* concentrations (at decimal logarithm scale) in RTE food were modelled using beta-general distributions with a maximum equal to the maximum concentration observed for the different food categories (see column max in Table 33) and not using a value of 6.1 as was wrongly mentioned. It has been added that the maximum value aligns with the maximum *L. monocytogenes* counts at the end of

				shelf-life in the RTE food categories as sampled in the BLS.
70	Marcel Zwietering/Wageningen University and Research	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1193: Why would the maximum be 6.1?	See reply to comment 69.
71	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1196: The choice of this strong assumption should be more discussed.	This is the only information available. The samples without enumeration have concentration less than the limit of the quantification. The data included in the model is not equal to 10 but less than 10. The assumption is mainly related the choice of the probability distribution.
72	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Figures 4 and 5: Figure 5 should include the empirical cumulative distribution function (ECDF) from figure 4 for a better comparison. Or, alternatively, Figure 4 should have the modeled CDF overplotted so that we can check the good fit of the beta generalized models to the data.	The modeled CDF has been overplotted in Figure 4.
73	Mats Lindblad/National Food Agency	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Page 29, Figure 5: Gravad fish is misspelled (Graved).	The editorial change has been made.
74	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1232: The choice of this strong assumption should be more discussed.	It has been added that option 3 was chosen because the model is including growth after retail and so concentration data observed at the end of the shelf life cannot be used. Note that the impact of this assumption was shown in Fig 31.
75	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Sophisticated models exist for growth rate prediction. It would have been of interest to show comparison for some of the 13 categories of exponential growth rate (5°C) and these models.	The variability of the growth rate is already taken into account and therefore more complicated models are not needed. The exponential growth rates (EGR) are derived from the systematic review undertaken by activity 2. The EGR are assumed variable. This variability captures the different situations where the EGR may influenced by the pH, organic acid, water activity (a_w), salts. Therefore there is no need for more sophisticated model. The only parameter that needs to be included is the temperature.
76	Anses	2.2.4. Listeria monocytogenes generic QMRA (gQMRA) model	Line 1250: The T_min value (-1.18°C) originates from FDA and FSIS (Food and Drug Administration of the US Department of Health and Human Services and Food Safety and Inspection Service of the US Department of Agriculture) (2003). Please refer to this report.	The reference has been added.
77	Anses	2.2.4. *Listeria*	Line 1251: The EGR should be set to 0 when T < Tmin.	This has been added in the equation.

		monocytogenes generic QMRA (gQMRA) model		
78	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1253: In the R- code (Line 6304 Appendix C of the document) the temperature is truncated to -2°C and 15°C. Please specify it here.	It has been added that the temperature was truncated to -2°C and 15°C.
79	Gary Barker/Quadram Institute Bioscience	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Equations 7, 9, 10, 11, 12, 14 and figure 6: The use of mathematical representations, throughout the opinion, is quite poor and could reduce the overall value. As examples there is an inconsistent definition of the dose response parameter r (eqns. 11, 12, 14), equation 7 is difficult to interpret, the details of bacterial population growth are misrepresented in equations 9, 10, the logarithmic axis in figure 6 is a mis-representation, some of the references to computation (beta-general line 1193) are proprietary rather than analytic etc.	The equations have been checked for consistency.
80	Food Standards Agency	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Reducing some of the inconsistency in mathematical representations would add considerable assurance to this opinion. • Assuming equation 9 represents the solution of a logistic growth equation it expresses the concentration of bacteria, C(t), as a density (units of inverse volume). In contrast, in equation 10, C(t) appears as an exponent (dimensionless) and is most likely a logarithm? • The y-value of initial points on figure 6 are interpreted as (1-Prevalence) (line 1298) even though the x-axis is clearly logarithmic (i.e. a zero corresponds to one cell per gram)? • The definition of the r parameter in dose response differs at line 1315 and 4242. • How is a beta-general distribution (e.g. line 1193) distinct from a beta distribution? • Discussion of dose-response in section 2.2 and in section 3.2.3 is confusing (c.f. eqs 11, 15)	The equations have been checked for consistency.
81	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1258: This is the Rosso model. Please refer to it. Also, there is a "1 + "missing in the denominator (the denominator is OK in the R code line 6252).	The mistake in the equation has been correct and it has been added that it is the Rosso model.
82	Marcel Zwietering/Wageningen University and Research	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1258. Check equation: must be 1+(Cmax/C(0) etc in the denominator ? Line 6248. R-code is correct: rosso=function(time,egrm,lag=0,x0,xmax){x0=10^x0 xmax=10^xmax	See the reply to comment 81.

			den=1+(xmax/x0 -1)*exp(-egrm*(time-lag)) log10(xmax/den)	
83	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1260: "This primary growth model does not consider a lag time". No justification for this assumption?	The starting point of the risk assessment model is at retail level. It is considered in general that the lag phase is finished before the RTE foods are purchased by the consumers at retail. This assumption is conservative in the sense that it may overestimate the risk.
84	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1287: Please precise the Unit of C(t).	The unit of C(t) has been added, i.e. CFU/g.
85	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Figure 6: Precise and rephrase legend and title of Y-axis.	The y-axis represents the cumulative distribution function (i.e. the probability that the concentration will take a value less than or equal to a specific concentration). This is specified in the legend of Figure 6.
86	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1326: Re-Specify here what TEO means (total number of eating occasions).	The total number of eating occasions per year (TEO) has been spelled out before and has been added in the list of abbreviations.
87	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1332: The Pouillot et al. (2015b) dose-response model uses a standard deviation of the log-normal distribution of 1.62 because they consider "homogeneous" populations (e.g. transplant individuals, pregnant women, see Table 12). By considering more heterogeneous populations (example: Male >=75 yo category include individuals in good shape and individuals with severe underlying conditions), the assessors should reconsider and evaluate their own parameter.	It was considered 1.62 as not describing a homogenous population. This variability was estimated irrespectively the chosen 11 populations in Pouillot et al. (2015b). In the absence of data the same estimate as in this paper was used.
88	Anses	2.2.4. *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 1339: It should be mentioned that the model is actually scaled to the number of cases.	This has been added.
89	Anses	3.1.1. Introduction to the species *L. monocytogenes*	Line 1378: Some new species have been identified in primary production samples and in food processing environment. For *L. fleischmanii*, see den Bakker et al. (2013)and Bertsch et al. (2013). For *L. newyorkensis* and *L. booriae* see Weller et al. (2015). For *L. rocourtiae*, it comes from lettuce (Leclercq et al., 2010). Line 1378: You have to complete your sentence to underline the rare case of *L. ivanovii* contamination that it becomes a reality and some foods are heavy contaminated.	The focus of the Scientific Opinion is on *L. monocytogenes* and the paper by Orsi and Wiedmann (2016) reviews the *Listeria* genus composition. It has been clarified in the text that "Among all *Listeria* species, *L. monocytogenes* is by far the most important species from a human health perspective, followed by *L. ivanovii* that might be found in food in very rare cases.

90	Ivan Nastasijevic/Institute of Meat Hygiene and Technology, Belgrade, Serbia	3.1.1. Introduction to the species *L. monocytogenes*	Line 1392 and onwards: the following text can be added: *The most frequent scenario that led to foodborne outbreaks is related to the post-thermal treatment cross contamination of deli (meat) products during slicing and modified atmosphere packaging (MAP), i.e. in vacuum or gas mixtures. The essential precondition for such cross contamination is the previous introduction of L. monocytogenes into the food (meat) processing facility and subsequent colonization of production environment, associated with formation of biofilms resilient to common sanitation procedures regularly applied in meat establishments (Bolocan et al., 2016).* *Identification of the main entry routes for L. monocytogenes into food (meat) establishments and tracking the routes for spreading the pathogen onto food contact surfaces (FCSs) are of essential importance to define appropriate risk mitigation strategies to prevent and control the presence of L. monocytogenes in FPEs and its subsequent transfer to RTE meat products (Nastasijevic et al., 2017). The use of Whole Genome Sequencing (WGS) can facilitate the understanding of contamination/ colonization routes of pathogens within the food production environment (FAO, 2016). It can also enable efficient pathogen tracking among different departments within a food (meat) establishment and along the meat establishment–retail–consumer continuum, in order to facilitate foodborne outbreak investigations (Wang et al., 2016). Therefore, WGS is a novel and powerful tool for obtaining genomic data, which gives a higher level of resolution discrimination, i.e. better information about genetic similarity between isolates than conventional molecular typing such as fAFLP or PFGE. Such molecular methods only determine if isolates are the same or different but not how closely related they are genetically. Therefore, implementation of WGS is likely to be beneficial for many countries in the foreseeable future, in support of food safety management systems (Nastasijevic et al., 2017).* Food and Agriculture Organization of the United Nations, 2016. Applications of Whole Genome Sequencing (WGS) in food safety management. http://www.fao.org/3/a-i5619e.pdf (accessed on 28 September 2017).	The addition of this text is not considered needed as most text applies for using WGS as a powerful method.
91	Caroline Le Poultier/CNIEL	3.1.1. Introduction to	A relevant microbiological criterion for *Listeria monocytogenes* in cheeses:	This comment is acknowledged.

	(French Dairy Board)	the species *L. monocytogenes*	Lines 2154 and 2155: EFSA concludes that "*L. monocytogenes* can be detected in most FPEs over time to a varying degree, and a total absence of *L. monocytogenes* in the FPE cannot be expected", based on the literature review performed. In this context it is necessary to assess the level of contamination of European products on the market and their impact on the risk of listeriosis in relation to the European microbiological criterion. Concerning cheeses in particular, the results of the simulations of the EFSA model show that 92% of the cases are attributable to concentrations of 5 log CFU per serving or more, ie for a portion of cheese of 40 grams (average EFSA database), a resulting concentration of 3.4 CFU/g or more. However, data from the Baseline Listeria Survey (Jofré et al., 2016) show that the presence of *L. monocytogenes* was detected in 0.47% of the 3452 samples of soft and semi-soft cheeses analyzed and that 0.06% of the concentrations were greater than 100 CFU/g. In addition, analysis of RASFF data (126 cheese data between 2008 and 2015) shows that the average concentration of the recalled lots is 2.6 log CFU/g. Finally, the EFSA model shows that the proportion of cheese with concentrations greater than 3 log and 4 log CFU/g is about 1% and 0.3% respectively at the time of consumption. Coupled with a very low contribution of cheeses to the risk of listeriosis in Europe (19 simulated cases out of 2318), these results confirm the relevance of the European microbiological criterion for cheese, including raw milk cheese, and the ability of the manufacturers to comply with it and to guarantee the safety of their products.	
92	Anses	3.1.2. Epidemiology of human listeriosis in the EU/EEA	Line 1411: The exhaustibility and reliability of data that support the sentence "most-travel-related cases have acquired the infection within the EU/EEA" are not really present and this sentence has a great impact for image of Europe outside.	The reference EFSA and ECDC (2016) has been added to support this statement.
93	Anses	3.1.2. Epidemiology of human listeriosis in the EU/EEA	Line 1417: The sensitivity of the surveillance system was estimated at 83% by capture-recapture studies in France (Goulet et al., 2001).	In France, the sensitivity for detecting cases of bacteremia and meningitis was estimated at 76% (95% confidence interval (CI) 72-81%) in 1997, which represents a highly sensitive surveillance system with low under-estimation in France. A sentence and the reference to the paper by Goulet et al. (2001) have been added to Section 3.1.2.

94	Anses	3.1.3. Pregnancy-associated human listeriosis cases	Lines 1470-1475: This is unclear. Are the values reported only for the cases for which you had the information regarding pregnancy? What could be the bias, if any, of this underreporting?	The values presented in Table 5 are based on the reported, known data. The last sentence about overall proportions (8-14%) is confusing in this context and has been deleted. In addition, a footnote has been added to Table 5 to clarify this.
95	Anses	3.1.3. Pregnancy-associated human listeriosis cases	Table 5: There might be a typo for % in the 15-24 year old group in 2010 (14.3% seems too low).	There was not a typo but the values in Table 5 have been rechecked and the table has been updated accordingly. Based on this, the value for the 15-24 year old group in 2010 is now 20.0%. See also the reply to comment 94.
96	Anses	3.1.3. Pregnancy-associated human listeriosis cases	Lines 1467-1480 and lines 1885-1941 and lines 4163-4165: The largest reported cohort in the literature has been published by France where an exhaustive system of surveillance exists for human cases. May you compare your results at European level with the study of Charlier et al. (2017)?	This is unfortunately not possible because data on underlying diseases/conditions of invasive listeriosis cases have not been collected at EU level.
97	Anses	3.1.4. Reported food-borne listeriosis outbreaks	Lines 1486-87: first may you complete *Listeria* with *monocytogenes*. Please correct in other part in the report. A drawback of the chapter is the definition of outbreaks and food alerts that you not clearly defined and studied. Moreover, the human cluster is not really defined: it is really important for *L. monocytogenes* to have this terms and categories defined and studied.	It should be considered that, as mentioned in Section 2.1.1, data has been extracted from the EFSA zoonoses database considering strong evidence outbreaks caused by *Listeria*. For three of the 37 outbreaks the evidence that the causative agent was *L. monocytogenes* was not available in the extracted file but was found in the annual report of a MS (as specified in Appendix E). It has been added, in Section 3.1.4, that all outbreaks were caused by *L. monocytogenes*. In Section 2.1.2 it has been added that the technical specifications for harmonised reporting of food-borne outbreaks can be found in EFSA (2014).
98	Stefano Morabito/Istituto Superiore di Sanità	3.1.4. Reported food-borne listeriosis outbreaks	Line 1489 and line 1665: Estimates of the proportion of outbreak cases out of total cases of Listeriosis may be biased by a different definition of cases adopted by the TESSy (based on a standard case definition) and cases reported to EFSA as 'outbreak cases' (all persons meeting the outbreak case definition, including those who were hospitalised or who died as a result of the food-borne outbreak). No standard case definition exists for outbreak cases and a different case definition may be adopted in different outbreaks, depending on the settings and circumstances. Moreover it is possible that MS report not only 'confirmed outbreak cases' but also outbreak cases defined as 'possible' or 'probable' cases. So it is possible that not all cases reported to EFSA match the TESSY case definition. Similarly it cannot be excluded that gastroenteric listeriosis is reported among outbreaks	The reason for doing the comparison is that it conveys the message that only a low proportion of cases is detected as outbreaks. As it may be misunderstood, and it has been agreed that comparison is not valid as the number of cases reported in outbreaks with those reported to TESSy is based on two different specifications, the following has been removed *(i.e. less than 4% of total reported cases during the period)*. It has been added that *"Thus, most invasive listeriosis cases appear as sporadic infections and the detected outbreaks are usually small"*.

			and not only invasive listeriosis.	
99	Caroline Le Poultier/CNIEL (French Dairy Board)	3.1.4. Reported food-borne listeriosis outbreaks	Cheeses are low contributors to the risk of listeriosis in Europe: Four out of thirty-seven (4 out of 37) listeriosis outbreaks in Europe were attributable to cheeses between 2008 and 2015. In addition, simulations carried out with the model from the Pérez-Rodríguez et al. (2017), on which the EFSA opinion is based, show that only 19 out of 2318 cases are attributable to soft and semi-soft cheeses. This figure gives an order of magnitude of the proportion of sporadic cases attributable to cheeses (for which no surveys are carried out). These results are representative of the high level of control of the dairy products safety by cheese manufacturers in Europe, and in particular in France which is among the most important cheese producer country in Europe, and the low contribution of soft and semi-soft cheeses to the risk of listeriosis in Europe.	The clarification has been acknowledged.
100	Anses	3.1.4. Reported food-borne listeriosis outbreaks	Line 1492: Leaving 41% of the outbreaks linked to foods that are not considered at all in this report.	Other foods are considered in ToR1 when relevant. The choice of focussing on the three RTE food categories in ToR2 was due to data availability. The outbreak data referred to are not as clear cut as to say that 41% are due to other foods. Some of the outbreaks in the other category may be/include RTE foods of the categories considered (e.g. buffet meals, sandwiches, mixed food with various ingredients) but without the full information these were not included among the three food categories. This has been clarified and the limitation of focussing on three food categories was considered, whenever appropriate.
101	Anses	3.1.4. Reported food-borne listeriosis outbreaks	Line 1530: This caramel apple outbreak is also interesting as young healthy children got listeriosis.	This has been clarified in the Scientific Opinion.
102	Anses	3.1.4. Reported food-borne listeriosis	Lines 1530-1536: More cases (10) were observed in this outbreak (see CDC https://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/index.html).	The number of cases has been revised to 10.
103	Marina Steele/ Canadian Food Inspection Agency - Food Safety Science Services – Microbiology	3.1.5. Epidemiological relationship between *L. monocytogenes* isolates of human and food origin along the	Line 1577-1582: In most cases, processing of raw sequence WGS data is still a complex process. It may not be accurate to say that *"Processing of raw sequence data nowadays is fully automated and harmonisation of data is simpler than with pulsed field gel electrophoresis or other molecular technologies"*.	The sentence has been revised to *"Major advancement to an automated processing of raw data was made in the recent years and data exchange is now simpler."*

		food chain		
104	Anses	3.1.5. Epidemiological relationship between *L. monocytogenes* isolates of human and food origin along the food chain	Line 1582: Could you say one word about the sampling of the strains (representativeness), notably for the food isolates? More generally, for all these studies regarding comparison of clinical and food strains, please provide a better description and discussion of the representativeness of the samples. If the sample is not representative of *Listeria* in food, the report of percentage is meaningless.	Specific criteria were applied in the outsourcing activity 3 (Møller Nielsen et al., 2017) for the selection of 1,143 *L. monocytogenes* isolates. This has been added in Section 2.1.2. In addition, it has been added in Section 3.1.5 that, as the food isolates in this study were focussed on the food categories represented in the BLS, the study supports the conclusions in relation to these sources, but it limits concluding on other potential food sources.
105	Marina Steele/ Canadian Food Inspection Agency - Food Safety Science Services – Microbiology	3.1.5. Epidemiological relationship between *L. monocytogenes* isolates of human and food origin along the food chain	Lines 1583-1590: This paragraph illustrates the benefits of WGS while making it clear that even this higher resolution typing tool requires epidemiological investigation follow up.	This has been clarified in Section 3.1.5 of the Scientific Opinion.
106	Anses	3.1.5. Epidemiological relationship between *L. monocytogenes* isolates of human and food origin along the food chain	Line 1588: May you refer to cgMLST scheme used as it is not the Moller Nielsen scheme but perhaps the one describe in Moura et al. (2017).	It has been clarified that the comparison was based on single nucleotide polymorphisms (SNPs), seven locus multilocus sequence typing (MLST) or core genome MLST (cgMLST) and that the latter one was based on the Pasteur's cgMLST nomenclature scheme as described (Moura et al., 2017).
107	Ivan Nastasijevic/Institute of Meat Hygiene and Technology, Belgrade, Serbia	3.1.5. Epidemiological relationship between *L. monocytogenes* isolates of human and food origin along the food chain	Line 1588 and onwards: The following text can be added: *In addition, the use of Whole Genome Sequencing (WGS) can become a strong food safety management tool since it can facilitate the understanding of contamination/ colonization routes of L. monocytogenes within the FPEs (FAO, 2016). It can also enable efficient pathogen tracking among different departments within a meat establishment and along the meat establishment–retail–consumer continuum, in order to facilitate foodborne outbreak investigations (Nastasijevic et al., 2017).* *In recent years, the cost of WGS has lowered significantly allowing its use in more routine applications (Kwong et al., 2016) (FAO, 2016). For example, the price for bacterial genome sequencing fall to less than $50/isolate, in case that a considerable number of isolates is*	This paragraph describes the findings of the outsourcing activity 3 and such a general statement would therefore not fit here.

			sequenced at the same time on a given instrument to achieve maximum economy of scale. Hyden et al. (2016) stated that WGS is currently becoming the method of choice for characterizing L. monocytogenes isolates in national reference laboratories. However, the data in available literature on practical WGS usage in food production establishments to track the routes of contamination/colonization with L. monocytogenes, are still scarce. References Food and Agriculture Organization of the United Nations, 2016. Applications of Whole Genome Sequencing (WGS) in food safety management. http://www.fao.org/3/a-i5619e.pdf (accessed on 28 September 2017).	
108	Anses	3.1.5. Epidemiological relationship between *L. monocytogenes* isolates of human and food origin along the food chain	Line 1594: What about other sources (Non animal sources)?	It has been clarified that, as explained under comment 104, that the selection of food isolates in this study focused on the food categories sampled in the BLS and therefore non-animal sources are not considered in this source attribution analysis.
109	Anses	3.1.6. Analysis of Rapid Alert System for Food and Feed (RASFF) data on *L. monocytogenes*	One point that we want to see with RASFF is the efficacy of the system so in how many RASFF cases we could detect human cases associated with reported foods in Europe.	This is outside the remit of the Scientific Opinion.
110	Anses	3.1.7. Summarizing remarks for hazard identification	Line 1638: Was the evolution of "pregnant 15 to 24 year old woman" reported proportion between 2008 and 2015 taken into account ? Indeed, this proportion decreases since 2008.	The data on pregnancy-association were reported since 2009 into EU level surveillance. The denominator, i.e. number of reported female cases in the age group 15-24 years does not change between 2009 and 2015 (22 and 23 females reported in 2009 and 2015, respectively) but the denominator is much lower in 2013 (N=12) compared to 2015 (N=23). As the case numbers are small, these changes should be interpreted with caution. The note of change in the proportion of pregnancy-associated cases in the age group 15-24 years between 2013 and 2015 has been

				deleted in Section 3.1.3 of the Scientific Opinion.
111	Anses	3.1.7. Summarizing remarks for hazard identification	Lines 1646-1648: It is immunocompetent people or no?	As the European Centre for Disease Prevention and Control (ECDC) does not have any information about underlying conditions, it cannot be stated whether these persons were immunocompetent or not.
112	Stefano Morabito/Istituto Superiore di Sanità	3.1.7. Summarizing remarks for hazard identification	Line 1675: since many of the strong-evidence outbreaks were reported by UK, it is to mention that UK does not report outbreak data for household outbreaks. This means that the true proportion of household outbreaks is probably higher than estimated while those connected to other settings may be lower.	In the evaluation of the strong-evidence outbreaks, the foodborne outbreak data as reported by the EU MSs have been used without considering possible reporting bias.
113	Anses	3.1.7. Summarizing remarks for hazard identification	Line 1682: Do you mean food (rather than food-borne) isolates?	A change has been made to food isolates.
114	Anses	3.2.1. Biology and virulence of *L. monocytogenes*	Line 1703: for gastroenteritis, please refer to Ooi and Lorber (2005).	The reference has been added.
115	Anses	3.2.1. Biology and virulence of *L. monocytogenes*	Lines 1716-1739: Moura et al., 2016 have also showed some of the findings that you underlined. Please refer.	This paper by Moura et al. (2017) and another one from Kuenne et al. (2013) have been added for completeness.
116	Anses	3.2.1. Biology and virulence of *L. monocytogenes*	Line 1784: Could you recall and discuss briefly how the strains were obtained in this study, representativeness? Indeed, a large sample doesn't make it representative.	The strain set from the paper by Maury et al. (2016) included all isolated that were collected in France by the French Listeriosis Reference Center as a central unit over a 9 year sampling period resulting in 6,633 isolates, including 2,584 clinical and 4,049 food isolates. The representativeness is fully given and stated in the paper and this has been stated in Section 3.2.1 of the Scientific Opinion.
117	Anses	3.2.1. Biology and virulence of *L. monocytogenes*	Line 1806: Avoid "food-borne" origin. Prefer "food origin".	This has been changed where appropriate.
118	Stefano Morabito/Istituto Superiore di Sanità	3.2.1. Biology and virulence of *L. monocytogenes*	The graphs in figure 8 are misleading as they adopt a graphical pattern typically used for a comparative approach among different data series. Indeed, by representing the data series one close to each other, one is invited to conclude about the relative frequency of CC in the different matrix (e.g. CC6 strains in fish are comparable to milk).	It has been added in the legend that the number of strains is presented.

			On the contrary, this conclusion cannot be drawn because the number of strains is represented in the bars instead of the % out of total strains per matrix. Confusion originate also by scaling to 100 the Y axis in the right graph. We suggest to represent the data series separately or to switch to %. At least specify that the number of strains are represented on the Y axis.	
119	Bertrand Lombard/Anses-Laboratory for Food Safety	3.2.1. Biology and virulence of *L. monocytogenes*	Lines 1847-1883: Our laboratory, ANSES-Laboratory for Food Safety, designated EURL for *Listeria monocytogenes* (*Lm*), has conducted several studies on the performance of the Standard reference method for *Lm* detection in food, EN ISO 11290-1, published this year after a revision and full validation through an interlaboratory study that we have lead. These studies, investigating in particular the competition between *Listeria* species and with other flora, have been published: - Evolution of *Listeria* populations in food samples undergoing enrichment culturing, Gnanou Besse et al, IJFM, 104 (2005) (Gnanou-Besse et al., 2005) - The overgrowth of *Listeria monocytogenes* by other *Listeria* spp. in food samples undergoing enrichment cultivation has a nutritional basis, Gnanou Besse et al, IJFM, 136 (2010) (Gnanou-Besse et al., 2010) - Evaluation of reduction of Fraser incubation by 24 h in the EN ISO 11290-1 standard on detection and diversity of Listeria species, Gnanou Besse et al, IJFM, 224 (2016) (Gnanou-Besse et al., 2016) - Modellling the behavior of *Listeria monocytogenes* during enrichment in half Fraser broth; impact of pooling and the duration of enrichment on the detection of *L. monocytogenes* in food, Augustin JC et al, Food Microbiology, 60 (2016). (Augustin et al., 2016) - Applicability of the EN ISO 11290-1 standard method for *Listeria monocytogenes* detection in presence of new Listeria species, Barre L. et al, IJFM, 238 (2016) (Barre et al., 2016) Our studies have been conducted on both naturally and artificially contaminated samples. We have found a very good growth of *Lm* strains during primary enrichment in half-Fraser broth, whatever the strains initially present.	Thank you for sharing this information. The text in Section 3.2.1 of the Scientific Opinion has been elaborated on by adding "*A follow-up study on this issue showed that overgrowth of L. monocytogenes most likely has a nutritional basis (Gnanou-Besse et al., 2010). Hypovirulent strains have generally a reduced PI-PLC and haemolysis activity, leading to less characteristic colonies on isolation media, in particular on Listeria Agar according to Ottaviani and Agosti, prescribed as first medium in EN ISO 11290-1. The results of co-culture experiments conducted at the EURL Lm demonstrated that newly described Listeria species did not have inhibitory activities affecting L. monocytogenes growth (Barre et al., 2016).*"

			We found a competition with overgrowth and no isolation for only some rare strains during secondary enrichment in Fraser broth. A characterization of strains after primary enrichment is recommended since a wider diversity of strains is obtained at this stage than after secondary enrichment. We have not found any fitness linked to serogroups. The Brun study cited in the draft opinion was conducted with UVM broth which is not included in the Standard method EN ISO 11290-1. Hypovirulent strains have generally a reduced PIPLC and haemolysis activity, leading to less characteristic colonies on isolation media, in particular Agar *Listeria* according to Ottaviani and Agosti (LOA agar), prescribed as first medium in EN ISO 11290-1. For this reason, TAG 17 *Listeria* of CEN/TC 275/WG 6, which has developed the recently published version of the Standard method, has agreed to add the following paragraph in the standard, clause 9.5.2.1: "Rare strains of *L. monocytogenes* do not show beta-haemolysis or a positive reaction to the CAMP test under the conditions described in this document. If typical colonies on Agar Listeria according to Ottaviani and Agosti with PIPLC activity even if it is low, are negative for haemolysis, it is recommended to perform additional tests (e.g. Gram stain, catalase, motility, CAMP test, PCR), in order to determine whether this isolate is a non-haemolytic *L. monocytogenes*." In addition, concerning the possible impact of the presence of 11 new *Listeria* species on *Lm* detection, the results of co-culture experiments conducted by our laboratory showed that the new Listeria spp. do not have inhibitory activities affecting *L. monocytogenes* growth, when using the method of EN ISO 11290-1 (Barre et al., 2016). In conclusion, we consider that the European and international reference method, Standard EN ISO 12290-1 recently revised, shows a satisfactory performance for *Lm* detection in samples from food chain (food, feed and environment of food production).	
120	Anses	3.2.2. Clinical picture of reported human listeriosis cases in the EU/EEA	Line 1893: Data are available for only 39.2% of cases. Could we expect a bias (more info for specific clinical picture) or should we consider that these data miss at random?	The proportion 39% is indicative and it has been assumed that the data are missing at random.
121	Anses	3.2.3. *Listeria*	The r values have been inferred for each of the 14 categories of	In Section 2.2.4 it was stated that *"However, the lack*

		monocytogenes dose-response relationships	defined population. The status of population (cancer, HIV, etc.) is not taken into account. Wouldn't have been possible to define age/health status category?	*of reliable data on the distribution of human listeriosis cases for the different underlying conditions groups as in the Goulet et al. (2012) study prompted the application of another approach based on epidemiological data available in the EU/EEA using the same 14 subpopulations defined by age and gender as in the TSA."* Yes, this was the reason and motivated some of the new DR work in the Scientific Opinion. This was emphasized in the conclusions.
122	Anses	3.2.3. *Listeria monocytogenes* dose-response relationships	Line 1982: FDA and FSIS (Food and Drug Administration of the US Department of Health and Human Services and Food Safety and Inspection Service of the US Department of Agriculture) (2003) used the exponential dose response only for mice models. The human model is much more complex than that.	The reference to FDA and FSIS (Food and Drug Administration of the US Department of Health and Human Services and Food Safety and Inspection Service of the US Department of Agriculture) (2003) has been deleted.
123	Anses	3.2.3. *Listeria monocytogenes* dose-response relationships	Line 2003: Note that the outcome of the FDA and FSIS (Food and Drug Administration of the US Department of Health and Human Services and Food Safety and Inspection Service of the US Department of Agriculture) (2003) model was death (to be compared with other models, considering invasive listeriosis).	This comment is not considered relevant as the FDA and FSIS (Food and Drug Administration of the US Department of Health and Human Services and Food Safety and Inspection Service of the US Department of Agriculture) (2003) model is predicting the number of listeriosis cases.
124	Anses	3.2.3. *Listeria monocytogenes* dose-response relationships	Line 2020: The FDA and FSIS (Food and Drug Administration of the US Department of Health and Human Services and Food Safety and Inspection Service of the US Department of Agriculture) (2003) should not be considered as an exponential model.	There is no link with the comment as the sentence is not about exponential models.
125	Food Standards Agency	3.3.1. Persistence of *L. monocytogenes* strains in the food processing environment	Three strategic observations continued: 3 – Many RTE food manufacturers have recently changed their manufacturing practice with respect to the use of disinfectants and cleaning practice. Although data is likely sparse in relation to the effect on *Listeria populations* it would be helpful to access EFSA opinion concerning the effect of these changes on the risk for human health with respect to *Listeria* contamination of RTE foods.	This is outside the remit of the mandate.
126	Anses	3.3.1. Persistence of *L. monocytogenes* strains in the food processing environment	Lines 2151-2154: Applicable for the "raw products sector" but not always relevant for the "cooked products sector" (including RTE Food).	This sentence is also considered applicable to RTE foods.
127	Kieran Jordan/Teagasc	3.3.1. Persistence of *L. monocytogene*	Lines 2165-2172: The statement on biofilm is not accurate. It is based on two strains, and there are very many contrary publications. Such a statement cannot be made on one publication. The comment on a	References to additional papers have been added and it has been stated that there is contrary evidence on the coping of persistent and non-persistent strains

		s strains in the food processing environment	limitation of biofilm studies is not accurate either. There are many biofilm studies with stainless steel coupons. Finally, while some evidence exists that persistent strains may cope better with acidic conditions than non-persistent strains, there is also contrary evidence, as far as I know, and this should be stated.	with conditions in the food environment.
128	Anses	3.3.1. Persistence of *L. monocytogenes* strains in the food processing environment	Line 2172: Precise what does "tolerate" means?	Tolerate has been replaced by grow/survive.
129	Anses	3.3.1. Persistence of *L. monocytogenes* strains in the food processing environment	Line 2242: To be mentioned here: the question of definition between persistence vs recurrence remains. Regular contamination by the same strain from the primary production can lead to an inaccurate status of *L. monocytogenes*.	It has been acknowledged in the Scientific Opinion that a definition for persistence is hard to provide and that recurring genetically indistinguishable *Listeria* strains might not be persisters in a sense that they stably colonize a particular ecological niche.
130	Marjon Wells-Bennik/NIZO	3.3.2. Prevalence and concentration of *L. monocytogenes* in RTE foods	Figure 11, Line 2257. The non-compliance of hard cheeses is indicated to be 0-0.3%. However, it is unclear if this cheese was made from pasteurised or unpasteurised milk. This is a crucial factor for these types of cheeses, as various challenge studies have indicated that, for instance, Cheddar, Gouda and Swiss-type cheeses do not support growth of *L. monocytogenes* (see comments related to section 3.4.1, Dairy products. If this information is not available, please replace '(0-0.3%)' in line 2257 with '(0-0.3%; unknown if milk was pasteurized)'.	The reported data on compliance of hard cheeses have been pooled across animal species and heat treatment of the milk. In the EU summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016, these data will be presented separately (EFSA and ECDC, 2017).
131	Kieran Jordan/Teagasc	3.3.2. Prevalence and concentration of *L. monocytogenes* s in RTE foods	Figure 11. The source of the data should be specified; what was the sample number; was the sample number relatively equal across the different foods?	The source of the data and the range of the sample numbers have been specified in the title and legend of Figure 11, respectively.
132	Anses	3.3.2. Prevalence and concentration of *L. monocytogenes* in RTE foods	Figure 11: Specify when it is at the end of processing or during the processing. Mention "During cutting plant" is not specified in any food types (x-axis).	When the samples had been taken at the cutting plants these have been pooled with those at the processing plant, independent of the food category. It is unknown at which step in the processing the samples have been taken.
133	Anses	3.3.2. Prevalence and concentration of *L. monocytogenes* in RTE foods	Figure 12: The use of the box plot should be considered with caution as the sample size (number of samples per study) and the sampling design vary from one study to the other.	This is agreed and a relevant statement has been included in the Scientific Opinion.

134	Anses	3.3.2. Prevalence and concentration of *L. monocytogenes* in RTE foods	Figure 13: Incomplete unit for x-axis	The figure now correctly presents the unit on the x-axis as log CFU/g.
135	Anses	3.3.3. Consumption and food handling	Line 2542: Assumption potentially inaccurate: thermal profile of a can of Rillettes for example is different: it does not only depend on time and temperature in fridge (but also of the exits frequency from the fridge for example).	We fail to understand the comment in relation to the line number indicated.
136	Food Standards Agency	3.3.3. Consumption and food handling	Pregnant women • Communications messages on what foods are higher risk or be avoided could differ between EU countries? General population • some may be more unwilling to throw food away due to economic circumstances. *L. monocytogenes* • Could the number of countries reporting or better reporting be a factor in the increase of the number of reported listeriosis cases? General thought on sampling: are enough samples being taken, taking into account the amount of food portions sold	The first three comments are agreed upon and/or covered in the Scientific Opinion. The last comment is outside the remit of the mandate as it is management related.
137	Food Standards Agency	3.3.3. Consumption and food handling	Possible reasons why older people could be more at risk: • May have less money so may be more unwilling to throw food away • Rationing/make do and mend attitude • More likely to live alone (and may have less help) • Divorce or widowhood in men (women may still be main cooks in the older generation) • May be more likely to eat RTE foods as can't prepare food (problems standing up and/or manual dexterity issues) • Increase in elderly population • Living longer but with illness (immunocompromised) • May be unfamiliar with 'use by' dates • Appetite decreases with age so may not want full meals and may choose a restricted diet • May not be able to read labels due to failing eyesight	The comments are agreed upon and most of them are considered as covered in the Scientific Opinion.
138	Gary Barker/Quadram Institute Bioscience	3.3.3. Consumption and food handling	Lines 2667 & 4055: There is also a need to emphasise the importance of maintenance of low temperatures in refrigerators and of the adherence to 'use-by' dates (this is particularly relevant because of a complex interplay with communications about food waste, and the	The importance of storage temperature and time has been stressed in the Scientific Opinion. The impact of the trend of reduction food waste in connection to time and temperature was mentioned in the response

			EFSA opinion would have more impact if this competition was addressed explicitly).	to the assessment question (AQ) 2.3.
139	Anses	3.3.3. Consumption and food handling	Table 16: The work of Derens-Bertheau et al. (2015) could be also cited.	This work by Derens-Bertheau et al. (2015) is now cited in Table 16 of the Scientific Opinion.
140	Anses	3.3.4. Factors impacting the prevalence and concentration of *L. monocytogenes* in RTE food	Lines 2718-2755: please provide confidence intervals around the OR.	The 95% CI's have been added.
141	Marcel Zwietering/Wageningen University and Research	3.3.5. Growth, survival and inactivation of *L. monocytogenes* in food and in the food chain	Line 2833. Also reference could be made to Diah C. Aryani, Heidy M.W. den Besten, Wilma C. Hazeleger, and Marcel H. Zwietering. 2015. Quantifying strain variability in modelling growth of Listeria monocytogenes. International Journal of Food Microbiology 208 19–29 Containing strain variability for the effects of pH, a_w, HLa and temperature (and also Heidy M.W. den Besten, Diah C. Aryani, Karin I. Metselaar, Marcel H. Zwietering. 2017. Microbial variability in growth and heat resistance of a pathogen and a spoiler: all variabilities are equal but some are more equal than others. IJFM 240: 24-31)	Both references (Aryani et al., 2015b; den Besten et al., 2017) were included in the appropriate parts of the sub-session on the impact of strain variability on modelling the growth *L. monocytogenes*.
142	Marjon Wells-Bennik/NIZO	3.3.5. Growth, survival and inactivation of *L. monocytogenes* in food and in the food chain	Lines 2838-2840: This section reads: '… the MIC of *L. monocytogenes* to various organic acids has been shown to be strain and pH dependent, especially close to the growth limiting pH (e.g. <4.8), with the highest observed variation being almost 9.0 mM (Wemmenhove et al. 2016)'. As corresponding author of the latter publication, I would like to comment. Firstly, it should be the MIC of an acid for *L. monocytogenes*, not the MIC of *L. monocytogenes* to an acid. Secondly, the MIC is not necessarily pH dependent, but the concentration of undissociated acid is pH dependent and at low pH values, growth ceased at pH 4.8 in the presence of organic acids. Thirdly, 'the highest concentration of 9.0 mM' is mentioned in one breath with low pH 4.8. This gives the reader the impression that that value was measured at low pH, but in fact, this concentration was measured for one strain at a high pH (where the increments between undissociated concentrations were high due to the high pH). The real MIC was somewhere between 5.8 (growth observed) and the next assessed concentration of 9.0 mM (clear well in assay). In a more	The text has been amended accordingly.

			precise, detailed study, Aryani et al. (2015b) established the MICs of undissociated lactic acid for 20 different *L. monocytogenes* strains, with a maximum value of 5.1 and a 95% prediction interval of 4.2 to 5.9. The highest MIC value seen in their data was 6.35 mM undissociated lactic acid. To incorporate this information, please replace the sentence 'For instance, … 2016)' p 68, lines 2837-2840 with the following: 'For instance, differences in MIC values of various undissociated organic acids have been reported for different L. monocytogenes strains (Wemmenhove et al. 2016), with the concentrations of the undissociated forms of these acids depending on the pH. In a detailed study by Aryani et al. (2015b), the impact of strain variability on maximum specific growth rates was quantified for twenty different *L. monocytogenes* strains as a function of pH, a_w [NaCl], undissociated lactic acid (HLac) and temperature (T). This showed that L. monocytogenes had an average pHmin of 4.5 (5-95% prediction interval (PI) 4.4-4.7), [NaCl]max of 2.0 mM (PI 1.8-2.1), [HLac]max of 5.1 (PI 4.2-5.9) and Tmin of -2.2 (PI(-3.3) – (-1.1)). The maximum concentration of undissociated lactic acid found for one strain under one condition was 6.35 mM.' The reference is: Aryani DC, den Besten HMW, Hazeleger WC and Zwietering MH, 2015. Quantifying strain variability in modeling growth of Listeria monocytogenes. International Journal of Food Microbiology, 208, 19-29. doi: 10.1016/j.ijfoodmicro.2015.05.006.	
143	Marcel Zwietering/Wageningen University and Research	3.3.5. Growth, survival and inactivation of *L. monocytogenes* in food and in the food chain	Line 2850: Also reference could be made to D.C. Aryani, M.H. Zwietering, H.M.W den Besten. 2016. The effect of different matrices on the growth and thermal inactivation of pathogen and spoilage microorganisms. Int J Food Microbiol 238: 326-337	This is agreed and the suggested reference is included in the Scientific Opinion along with a relevant statement, in the sub-session of 3.3.5, dealing with the impact of food matrix on the growth of *L. monocytogenes*. The correct title of the reference (Aryani et al., 2016) is: "The effect of different matrices on the growth kinetics and heat resistance of *L. monocytogenes* and *Lactobacillus plantarum*".
144	Marcel Zwietering/Wageningen University and Research	3.3.5. Growth, survival and inactivation of *L. monocytogenes* in food and in the food chain	Line 2911: Also reference could be made to Diah C. Aryani, Heidy M.W. den Besten, Wilma C. Hazeleger, Marcel H. Zwietering. 2015. Quantifying variability on thermal resistance of *Listeria monocytogenes*. International Journal of Food Microbiology 193: 130-138. Containing a rich data set on thermal inactivation of 20 strains (also around 6559 these papers could be mentioned, since the strain variability quantified in growth limits is also relevant for the text as	It is agreed and the suggested reference (as Aryani et al. (2015a)) is included in the Scientific Opinion in 3.3.5, in the sub-session for thermal and non-thermal inactivation models. Aryani et al. (2015b)(related to strain variability in the growth limits) was also added in Appendix H.

			given there).	
145	Anses	3.3.6. Summarizing remarks for exposure assessment	Lines 2990-2995: The authors of this publication proposed two distributions for describing temperature distribution (one for North EU one for South). Yet, their data analysis didn't prove this.	In the abstract of this paper it is stated:" Analysis of temperature distributions revealed that the countries were separated into two groups: northern European countries and southern European countries. The overall variability of European domestic refrigerators is described by a normal distribution: N (7.0, 2.7)°C for southern countries, and, N (6.1, 2.8)°C for the northern countries".
146	Anses	3.4.1. Results from the review of QMRA outputs	Line 3090: Please, update the review with the reference FDA-FSIS, 2013 (notably on the potential contamination of the environment from products that do not support growth to products that support growth).	The suggestion was accepted and both the FDA and FSIS (2013) reference and the one by (Pouillot et al., 2015a), along with a relevant addition were included in the Scientific Opinion.
147	Marjon Wells-Bennik/NIZO	3.4.1. Results from the review of QMRA outputs	Line 3137: '… pose a 53 and 112 times higher risk,' – higher than what? Please complete.	The two numbers refer to Canada and the United States and express how many times higher is the risk posed by cheeses made of non-pasteurized milk in each country, compared to cheeses made from pasteurized milk, which represented the baseline risk. This has been clarified.
148	Anses	3.4.1. Results from the review of QMRA outputs	Line 3140: Williams et al, 2009 paper is not on that subject.	The paper is a QMRA case study that uses Mexican style soft cheese that may also be from unpasteurized raw materials, especially when imported. We decided to keep it, even though with indirect relevance to this specific paragraph.
149	Marjon Wells-Bennik/NIZO	3.4.1. Results from the review of QMRA outputs	Line 3142-3145: gives examples of soft cheeses	The comment is not fully clear. The type (origin) of the two soft cheeses is further specified in the Scientific Opinion.
150	Marjon Wells-Bennik/NIZO	3.4.1. Results from the review of QMRA outputs	Line 3146-3150 of soft-ripened cheeses: We strongly suggest to add info on semi-hard and firm cheeses. At the end of L3150 '… (Tenenhaus-Aziza et al., 2014).' please add the following: 'For semi-hard/firm or hard cheeses such as Cheddar, Gouda, Swiss-type or Parmesan cheeses, several challenge studies have demonstrated that these cheeses do not support growth of *L. monocytogenes* (Buazzi et al. 1992, Dalmasso and Jordan, 2014, Northolt et al. 1988, Ryser and Marth 1987, Shrestha et al. 2011, Wemmenhove et al. 2013, 2014, Yousef and Marth, 1990). If such cheeses are made of raw milk, *L. monocytogenes* present in raw milk may be carried over to the cheese and may pose a risk but numbers may decline during ripening. At an industrial scale, such cheeses are made using pasteurized milk ensuring inactivation of *L. monocytogenes* in the cheese milk, and hygienic design of the processing facilities prevent post-	The issue was discussed and it was decided that, so far, semi-hard and firm cheeses do not represent any major safety issue, due to the low a_w and sometimes low pH, depending on the cheese. Available evidence on resistance of *L. monocytogenes* to simulated gastric fluid following habituation on semi-hard cheeses, showed no major safety implication associated with survival the gastric acidity while residing on or in a semi-/hard cheese matrix. As such, the decision was unanimous not to elaborate on these two low-risk types of cheeses. Nonetheless, reference to the inhibitory effect of lactate in cheese on growth of *Listeria* and its inclusion as predictor variable in the secondary model is worth being made. With this

			contamination. In nature-ripened Gouda cheese, the different factors that inhibit growth of *L. monocytogenes* were recently deciphered. It was established that undissociated lactic acid plays an important role and can prevent growth of *L. monocytogenes* as a sole factor in this cheese (Wemmenhove et al. 2018). Undissociated lactic acid can therefore be included as a factor in predictive models for *L. monocytogenes* in cheeses. Concentrations of undissociated lactic acid in the water phase of Gouda cheese will fully inhibit growth of *L. monocytogenes* when the concentration of the undissociated lactate is >6.35 mM. Concentrations of this undissociated acid in the water phase of Gouda cheese exceed this value when the total lactic acid content is >0.86% w/w at a pH < 5.25 (relevant to young Gouda cheese with moisture content of 42% w/w), or >1.26% w/w at a pH < 5.50 for mature Gouda cheese (moisture content of 35% w/w) (Wemmenhove et al., 2018). Corresponding references: Buazzi MM, Johnson ME, Marth EH, 1992. Survival of Listeria monocytogenes during the manufacture and ripening of Swiss cheese. Journal of Dairy Science. 75(2):380-6.Dalmasso M, Jordan K, 2014. Absence of growth of Listeria monocytogenes in naturally contaminated Cheddar cheese. J Dairy Res. 81(1):46-53. Northolt MD, Beckers HJ, Vecht U, Toepoel L, Soentoro PSS, Wisselink HJ, 1988. Listeria monocytogenes: Heat resistance and behaviour during storage of milk and whey and making of Dutch types of cheese. Netherlands Milk Dairy, 42, 207–219. Ryser ET, Marth EH, 1987. Behavior of *Listeria monocytogenes* during the manufacture and ripening of Cheddar cheese. J Food Protect, 50:7-13. Shrestha S, Grieder JA, McMahon DJ, Nummer BA, 2011. Survival of *Listeria monocytogenes* introduced as a post-aging contaminant during storage of low-salt Cheddar cheese at 4, 10, and 21°C. J Dairy Sci. 94(9):4329-35. Wemmenhove E, Stampelou I, Van Hooijdonk ACM, Zwietering MH, Wells-Bennik MHJ, 2013. Fate of *Listeria monocytogenes* in Gouda microcheese: No growth, and substantial inactivation after extended ripening times. Int Dairy J. 32, 192–198. Wemmenhove E, Beumer RR, Van Hooijdonk ACM, Zwietering MH, Wells-Bennik MHJ, 2014. The fate of *Listeria monocytogenes* in brine and on Gouda cheese following artificial contamination during brining. Int Dairy J. 39, 253–258.	regards, the use of organic acids as controlling variables in models (along with their minimum inhibitory concentration (MIC) values) is already mentioned in the section for cardinal models. See also the response to comment 142.

			Wemmenhove E, van Valenberg HJF, van Hooijdonk ACM, Wells-Bennik MHJ, Zwietering MH, 2018. Factors that inhibit growth of Listeria monocytogenes in nature-ripened Gouda cheese: A major role for undissociated lactic acid. Food Control 84, 413-418. Available online https://doi.org/10.1016/j.foodcont.2017.08.028. Yousef AE, Marth EH, 1990. Fate of *Listeria monocytogenes* during the manufacture and ripening of Parmesan cheese. J Dairy Sci. 73(12):3351-6.	
151	Thomas Lüthi/ Federal Food Safety and Veterinary Office (FSVO)	3.4.1. Results from the review of QMRA outputs	Line 3151: Leafy vegetables: Pre-cut and pre-washed salads are often contaminated with *L. monocytogenes*. More information on these kind of products are desired.	It should be reminded that the Section 3.4.1 aims to review the available QMRA studies from the literature (as retrieved by Pérez-Rodríguez et al. (2017)). Few QMRA studies consider leafy vegetables. Note that more information on the occurrence of *L. monocytogenes* on leafy greens can be found in Section 3.3.2. In addition, a recommendation was added *"To implement innovative programmes to generate data (i.e. prevalence and concentration, preferably coupled with sequencing) on L. monocytogenes in RTE foods (not only the classical food categories) that are comparable across MSs and time in the EU as existing monitoring has other objectives and is not appropriate for evaluating trends over time."*
152	Anses	3.4.1. Results from the review of QMRA outputs	Lines 3151-3156: Vegetables should be an iceberg in terms of knowledge of contamination by Lm and consumer eat more raw vegetables (and fruits) with direct transmission from producers and biological culture. This paragraph underlined that this report gave no more additional data. Study shall be conducted on this topic.	Reply: see reply to comment 151.
153	Anses	3.4.2. Results from the outsourcing activity 2 risk assessment	Lines 3182-3205 (and in the whole section): Can you explain what are the intervals presented lines 3184-3185? Do they represent uncertainty (serving to serving variability being integrated), variability, or a mix of both? If it is "mostly variability" as indicated line 3195: what variability is considered (it can't be serving to serving as the lower bound should be 0 to account for non-contaminated products).	These numbers have been extracted from Table 51 (Appendix I) and are an outcome of the outsourcing activity 2. Numbers between brackets represent the maximum range between the estimated 2.5 and 97.5th percentiles of the different atmosphere and slicing combinations within the food category.
154	Anses	3.4.2. Results from the outsourcing activity 2 risk assessment	Line 3207 and further: Please specify for the "median": in what dimension. Appendix I should provide some more details.	It has been clarified that distributions mostly reflect variability (also in the footnote of Table 51 in Appendix I).
155	Anses	3.4.2. Results	Line 3237: Is the dose response model calibrated to provide the	The DR model of Pérez-Rodríguez et al. (2017) was

		from the outsourcing activity 2 risk assessment	observed number of cases? If yes, it should be reminded.	not calibrated to provide the number of cases.
156	Anses	3.4.3. Summarizing remarks for risk characterization	Line 3333: Remind that these numbers reflects the strong assumption that all cases are linked to these three RTE foods in EU.	This has been added to the bullet.
157	Anses	3.5.2. Results of the disaggregated TSA	Lines 3448-3450: There is probably an over-interpretation about potential factors here, in the light of the concerned population size (EU level).	The sentence has been deleted in the Scientific Opinion.
158	Anses	3.6.1. *Listeria monocytogenes* generic QMRA (gQMRA) model: baseline	Line 3589: It is expected because the dose response model is scaled to the epidemiological data: it should be reminded to the readers.	This has been added in the Scientific Opinion.
159	Anses	3.6.1. *Listeria monocytogenes* generic QMRA (gQMRA) model: baseline	Lines 3614-3618: it is important to discuss here about the relevance of the option 3 (use US contamination data).	The observed growth is depending mainly on the temperature and duration of storage after retail. In case of option 1 (i.e. the use of data observed at the end of the shelf life), the initial concentration distribution will allow for more food with high concentration before storage. In one hand, this fact will probably reduce the impact of storage on the number of cases. On the other hand, starting with higher concentrations will lead to higher concentrations at the time of consumption -under the same storage conditions- and so this will probably increase the impact of storage on the number of cases. When running the model with the other options the same order in percentage of cases attributable to the storage conditions are obtained (data not shown).
160	Caroline Le Poultier/CNIEL (French Dairy Board)	3.6.3. Indicator data	Lines 3691 and 3743: The management of *L. monocytogenes* in sensitive products is constant over time: The evolution of the prevalence of contamination of RTE foods and their level of contamination was also considered to explain the increased incidence among these categories. However, despite of great uncertainty in the results, the available data do not allow to conclude that these two indicators increased between 2008 and 2015. These results are of great importance for the RTE foods sector, and in particular for the	This clarification is acknowledged.

			dairy sector, since they highlight the maintenance at a stable and high level of control the safety of RTE foods, from manufacturers.	
161	Anses	3.6.3. Indicator data	Lines 3716 and further: Provide the results either in log or not in log, but not a mix.	All values have been presented in $\log_{10}$ CFU.
162	Anses	3.6.3. Indicator data	Line 3823 and Figure line 3828: it is "genoserotype or PCR group" but not "serotype/serogroup" that are obtained by agglutination of antifactor sera with antigens.	The data presented is a combined group of conventionally defined serotypes and PCR-based serogroups as explained in Section 2.1.1.
163	Anses	3.6.4. Uncertainty analysis of the gQMRA model	Line 3919: Because the DR model is scaled to the epidemiological data, the absolute number predictions have little interest here. Suggestion: remove this sentence.	The sentence has been kept as also the absolute numbers (dose-range and growth effect) are used and presented. The limitation of scaling/calibration has been considered elsewhere
164	Anses	3.6.5. Synthesis of evidence of factors that may explain the human listeriosis trend in the EU/EEA, 2008-2015	Line 3998: It might have been clearer to provide the expected evolution of the number of listeriosis cases from the change in demographics, had the incidence rates been stable from 2008 to 2014, and to compare those numbers with the observed cases (see Pohl et al. 2017).	That is possible but since the same information is in the present figures and the intention was to relate the observed changes to the estimated changes in incidence (TSA), the figures have been kept.
165	Anses	3.6.5. Synthesis of evidence of factors that may explain the human listeriosis trend in the EU/EEA, 2008-2015	Line 4026: Actually, QMRA are sensitive to maximum population density (MPD) because, with the current dose responses, the expected number of cases are proportional to the arithmetic mean concentration in food, this mean being highly sensitive to the MPD. But do we expect a change in the MPDs?	The comment is agreed with but no data are available that supports a change in the maximum population density (MPD). Hypotheses why an increase in mean concentration/MPD has occurred can be put forward but cannot be supported.
166	Anses	3.6.5. Synthesis of evidence of factors that may explain the human listeriosis trend in the EU/EEA, 2008-2015	Line 4079: No year for Thomas et al. (specify 2013)	This editorial change has been made; reference is made to Thomas et al. (2013).
167	Anses	3.6.6. Conclusions of factors contributing to the human listeriosis trend	Line 4104-4105: See previous comment. Doses > 10^5 CFU/g do not lead to a mean concentration in RTE food equal to 2000 CFU/g.	See the reply to comment 19.

		in the EU/EEA, 2008-2015		
168	Caroline Le Poultier/CNIEL (French Dairy Board)	3.6.6. Conclusions of factors contributing to the human listeriosis trend in the EU/EEA, 2008-2015	The increase of the susceptible population and that of the elderly, "likely" factors contributing to the increase of the incidence rate of listeriosis: The evolution of the number of cases and the incidence of listeriosis in Europe, and the factors contributing to this development, has been extensively studied in this opinion. First of all, EFSA shows that the incidence rate did not increase significantly between 2008 and 2015 in the general population, and that it is only for some specific categories that the increase in the rate of incidence is significant: women aged 25 to 44 and persons aged over 75 years. Between 45 and 74 years, the increase in the incidence rate is at the limit of the threshold of significance. Two factors are identified as "likely" but not exclusive to explain these phenomena: the aging of the population and the increase in the number of susceptible people (underlying factors) in size and proportion. In addition, the simulations carried out using the Perez-Rodriguez et al. model show that 50% of cases of listeriosis concern people over 75 years of age and 40% of pregnant women. The conclusion of a probable impact of these demographic and epidemiological changes on the increase of the incidence rate in Europe is of importance for the dairy sector since it makes it possible to discard objectively the hypothesis that the increase of the listeriosis incidence rate would be mainly due to a lesser safety quality of cheeses in Europe.	This clarification is acknowledged.
169	Gary Barker/Quadram Institute Bioscience	4. Conclusions	Lines 4156-4159: In the Conclusions, it is stated that under-reporting /under-ascertainment of human invasive listeriosis is low compared to many other foodborne pathogens. Buchanan et al (2017) state that "there may be many additional deaths from listeriosis in nursing homes and other care facilities for elderly because causation of a systemic infection is seldom determined for these individuals". This points to a need for investigation of such infections in order to prevent further cases of listeriosis. (Buchanan, R.L. et al. (2017) A review of *Listeria monocytogenes*: An update on outbreaks, virulence, dose-response, ecology, and risk assessments. Food Control 75, 1-13.)	The article by Buchanan et al. (2017) refers to US situation, which may be very different from EU/EEA. The post mortem practices in defining the cause of death may vary by countries as well as the reporting of these but it is true that deaths due to listeriosis in nursing homes may remain undetermined. This has been added in Section 3.1.2 of the Scientific Opinion as *"The causes of deaths among elderly in nursing homes and care facilities may remain undetermined (Buchanan et al., 2017) and therefore mortality may be underestimated for these groups."*
170	Bertrand	4. Conclusions	As a consequence of our comments on clause 3.2.1, the conclusion	This is agreed. The bullet in Section 3.2.4 has been

	Lombard/Anses-Laboratory for Food Safety		on ToR 1, we suggest that the 6th bullet point should be reworded, for the part related to the detection and isolation.	reworded to *"A non-trivial point for interpreting the concepts of 'infection-associated' and 'food-associated' strains is the detectability of different clonal complexes (CCs) in different matrices. Overgrowth of L. monocytogenes by non-pathogenic Listeria isolates during enrichment and detection has been reported and traced to composition of detection media, natural microbiota in the sample, intra-species competition, bacteriophages and cell–cell contact. The international reference method, Standard EN ISO 12290-1 recently revised, is well established and widely used for L. monocytogenes detection in samples from the food chain (food, feed and environment of food production)."*
171	Gary Barker/Quadram Institute Bioscience	4. Conclusions	Lines 4201-4205: Factory hygiene practices (cleaning and disinfecting) are widely regarded as crucial steps in the management of risks for *Listeria* but are not covered explicitly by the opinion. This is particularly relevant in relation to use of disinfectants that are subject to changing rules. The opinion would appear to be more complete if this complexity was included.	The Scientific Opinion has summarized the persistence of *L. monocytogenes* strains in the food processing environment, but specifically addressing control and intervention measures is outside the scope of the mandate. This has been clarified in Section 1.2.
172	Stefano Morabito/Istituto Superiore di Sanità	4. Conclusions	Lines 4350-4352: Given that Directive 2003/99/EC lays down that listeriosis and agents thereof are to be included in monitoring, and articles 41-44 of Regulation 882/2004/EC request that each Member State shall prepare a single integrated multi-annual national control plan (MANCP), containing prioritisation of controls, we think that a harmonised sampling strategy can be achieved if each Member State sets as a priority in its MANCP the official controls to assess compliance with *Listeria monocytogenes* criteria in RTE foods, according to Regulation EC 2073/2005.	It is acknowledged, as spelled out in Section 3.6.3, that the monitoring data have several limitations for the purpose of evaluating any changes in prevalence of *L. monocytogenes* in RTE foods. Boelaert et al. (2016) stated that '*In essence, food chain control data are compliance checks and are collected with the aim to install an early warning and initiate control measures. Although they can be used for trend watching (which covers general observations of harmonized or non-harmonized data for possible trends), these data are unsuitable for trends analyses, because a reference (study) population is mostly absent and because the sampling is risk-based and thus, non-representative.* A recommendation has been added *"To improve the monitoring and/or surveillance data reporting at EU level enabling a better assessment of compliance by food business operators (FBO) with the FSC for L. monocytogenes of RTE food categories according to Commission Regulation (EC) No 2073/2005."*
173	Anses	4. Conclusions	The outsourcing activities related to genomics (Moller-Nielsen et al,	These comments are related to risk management and

			2017) revealed that epidemiological investigations conducted at European level using whole genome sequencing (WGS) would permit to identify the origin of listeriosis sporadic cases. Efficient epidemiological investigation can also be seen as a way to reduce risk. Identifying the food origin even outside the context of an outbreak will prevent new sporadic cases if an action is taken in the food industry potentially related to the first sporadic case. As high concentrations/doses (> 2,000 CFU) are expected to explain the most listeriosis cases, one could expect strong recommendations on shelf-life determination. Most RTE food shelf-lives are not determined based on *Listeria monocytogenes* behavior within the RTE. The determination of growth potentials, as a way to simply assess if the shelf-life is appropriate should be recommended.	as such outside the scope of the mandate. The potential of WGS has been addressed in the Scientific Opinion.
174	Anses	5. Recommendations	Despite an exhaustive report, there is still a lack of understanding about the increase in the listeriosis incidence rate in the EU. However, the recommendations provided at the end of the report (less than half a page, limited to five bullet points) will probably not help to have a better understanding of listeriosis in the future. Other in-depth recommendations should be written, including, e.g., more work on source attribution (coupled with next-generation sequencing (NGS), better epidemiological record (including a better understanding on the impact of comorbidities as well as other factors (demographic, sociological, etc.)), prevalence (not limited to "out of compliance") studies beyond the three classical RTE food (with enumeration, NGS, etc. … The charge of the Panel BIOHAZ should include recommendations to the Member States, but also to the research community.	Several of these recommendations were already covered in the Scientific Opinion. The recommendations were structured into different types of recommendations considering all the points mentioned.
175	Gary Barker/Quadram Institute Bioscience	5. Recommendations	Lines 4358-4360: This recommendation states the need to raise the awareness of all stakeholder groups in the food chain of the problem of *Listeria*, but it fails to point out the need to raise awareness within vulnerable groups of the population, and of those supplying food to them, of the risk posed by some RTE foods. This could be strengthened by a recommendation to substitute particular higher-risk RTE foods with lower-risk alternatives.	It has been added in the recommendations the various stakeholders in the food chain. As it was not the objective of the Scientific Opinion to propose risk management actions or rank foods into higher or lower risk, the substitution of high risk foods was not considered.
176	Stefano Morabito/Istituto Superiore di Sanità	5. Recommendations	Lines 4361-4363: We suggest that innovative programs to generate data on *Listeria monocytogenes* in foods should also include results of self-control in finished RTE foods and in food contact/no contact surfaces, provided by FBOs.	The content or the design of proposed potential programs is not in the scope of this Scientific Opinion.
177	Gary Barker/Quadram Institute	5. Recommendations	Lines 4366-4370: The extent of the risk to vulnerable people will depend on their medical condition; present evidence makes clear a range of vulnerable groups and their need to avoid higher-risk foods.	The recommendation is about data gaps identified in the Scientific Opinion to support additional understanding of the risk and management options

	Bioscience			not only dependent on identifying and avoiding high-risk foods.
178	Gary Barker/Quadram Institute Bioscience	5. Recommendations	Lines 4371-4373: The final recommendation concerns dietary practices and food handling of elderly groups. It is necessary, however, to recognize that many of the more vulnerable elderly are in care homes or hospitals and many others who are in the community depend on institutional caterers or on commercial caterers and/or 'meals-on-wheels' for many of their meals. Information is needed, therefore, on the supply of RTE foods to vulnerable people in these situations. In 8 of the 37 outbreaks listed in this report exposure was in a hospital or other medical care facility.	This has been covered in the recommendations (and examples of stakeholders have been added), but the focus is not on risk management.
179	Sven Qvist/NordVal International	Appendix A – Food safety criteria (FSC) for *Listeria monocytogenes* in ready-to-eat (RTE) foods	Line 5401: The FBO shall ensure that the food safety criteria applicable throughout the shelf life are met. This is not possible due to the frequent presence of *L. monocytogenes* in raw foods, kitchens and processing environments. Increased production of RTE which support the growth of *L. monocytogenes* (foods without growth inhibitors) pose a serious problem. Solution: Stabilize foods using hurdle technology!	The Scientific Opinion supports the impact of growth but more specific control measures are outside the scope to the mandate.
180	Anses	Appendix B – Additional information of the Time Series Analysis (TSA)	Figure 32: What information would you get from the seasonality trend? Please discuss in the text.	There is no trend in the seasonality as such, just the presence of seasonality. The Figure referred to by the reviewer, is further purely descriptive showing some of the data presented in the main report already but in a more detailed way, and with no link to seasonality. The information of this graph is indeed discussed in the main text. In the Scientific Opinion, the following additional discussion on seasonality was added: *"The presence of seasonality is interesting, and could be due to several factors, such as hygiene, climate, human behavioural factors and seasonal consumption patterns."*
181	Mats Lindblad/National Food Agency	Appendix C – Additional information of the *Listeria monocytogenes* generic QMRA (gQMRA) model	Table 32. Comparing with table 14, it seems that wrong consumption data are given for Gravad fish.	Table 14 has a footnote that clarifies the difference. This footnote has also been added to Table 32 for clarity: *"In the gQMRA model it was assumed that the serving size of gravad fish is the same as that of smoked fish."*
182	Mats Lindblad/National Food Agency	Appendix C – Additional information of the *Listeria*	Table 33. In the footnote it is stated that a maximum equal to 6.1 was used. This is in some cases not consequent with the numbers given in the column "Max". Also, I assume that the RTE subcategory at the first line should be "Cold smoked fish", not "Smoked fish".	The first line has been changed to cold smoked fish. The footnote has been revised stating that the maximum as indicated in the table has been used (and not 6.1 as was wrongly mentioned).

		monocytogenes generic QMRA (gQMRA) model		
183	Anses	Appendix C – Additional information of the *Listeria monocytogenes* generic QMRA (gQMRA) model	Table 33: Why are the max for Smoked fish and Cheese set to 5 and 7? Also shouldn't the other be 6.1 (in accordance with the text, the footnote, and with Chen et al, 2003)?	See the reply to comment 182.
184	Anses	Appendix C – Additional information of the *Listeria monocytogenes* generic QMRA (gQMRA) model	Table 34: What are the parameters "shift". Did you fit a shifted log-normal distribution? If yes, it is not implemented in the code (Line 6294).	The column named "shift" has been deleted as a shift was not used in the distribution.
185	Mats Lindblad/National Food Agency	Appendix C – Additional information of the *Listeria monocytogenes* generic QMRA (gQMRA) model	Table 35. Some of the maximum values (up to 519 days for fish) are quite unrealistic, although I understand that they are retrieved from the BSL. Also, a mean remaining shelf of 87 days for normally packed Gravad fish simply cannot reflect the reality.	The values shown are those observed through the BLS. The distributions used reflect the distributions of the BLS samples.
186	Mats Lindblad/National Food Agency	Appendix C – Additional information of the *Listeria monocytogenes* generic QMRA (gQMRA) model	Table 36. Column p2 is quite confusing; the fraction for hot and cold-smoked fish could maybe be expressed in some other way.	It should be noted that p2 has been presented this way to facilitate the use of the table in the R script. The explanation can be found in footnote b.
187	Anses	Appendix C – Additional information of the *Listeria monocytogenes* generic QMRA (gQMRA) model	Table 37: Please provide some explanations as a foot note regarding the parameters RefSdLog and RefSdLogI.	The column RefSdLogI has been deleted as this information is not used in the R script. A footnote has been added to clarify that RefSdLog is the standard deviation of the r parameter of the exponential model as in Pouillot et al. (2015b).
188	Anses	Appendix C – Additional information of	R Code: Please review multiple typos in the comments.	The typos have been corrected.

		the *Listeria monocytogenes* generic QMRA (gQMRA) model		
189	Anses	Appendix C – Additional information of the *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 6154: Script1.R would need some libraries loaded in Script2.R (e.g. tidyverse for the %>% function).	The library has been added.
190	Anses	Appendix C – Additional information of the *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 6155-6177: Please, acknowledge or refer to Pouillot et al, 2015.	The reference to Pouillot et al. (2015b) has been added.
191	Anses	Appendix C – Additional information of the *Listeria monocytogenes* generic QMRA (gQMRA) model	Line 6308: There is an error here: the formula should set EGRr to 0 when T < Tmin.	This has been added in the R code as EGRr[Tempr<Tmin]<-0.
192	Anses	Appendix F – Overview of gene mutations in *Listeria monocytogenes* leading to a reduced virulence	Table 40: it is reduced PI-PLC activity. You can also now put hly from Maury et al. (2017)	This has been added.
193	Anses	Appendix F – Overview of gene mutations in *Listeria monocytogenes* leading to a reduced virulence	Source missing : Ragon et al., 2008, Maury et al., 2016 and Moura et al., 2017	The paper by Ragon et al. (2008) studies mutation in genes that are of housekeeping function, and therefore it is not included in the table. As the paper by Maury et al. (2016) is a comparison of WGS and pulsed-field gel electrophoresis (PFGE), it does not fit in the table either, but it has been cited in the Scientific Opinion elsewhere. The paper by Maury et al. (2017) has been added in the table (see the reply

				to comment 192).
194	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6555: At the end of this sentence, please also refer to the more recent work of Aryani et al. (2015). After '… and in the presence of sodium lactate.', please add the following sentence at the end of line 6555: "More recently, the impact of strain variability on maximum specific growth rates was quantified for twenty different *L. monocytogenes* strains as a function of pH, a_w [NaCl], undissociated lactic acid (HLac) and temperature (T) by Aryani et al. (2015)." Add to reference section: Aryani DC, den Besten HMW, Hazeleger WC and Zwietering MH, 2015. Quantifying strain variability in modeling growth of *Listeria monocytogenes*. International Journal of Food Microbiology, 208, 19-29. doi: 10.1016/j.ijfoodmicro.2015.05.006.	This was agreed. The text and proposed reference are included.
195	Marcel Zwietering/Wageningen University and Research	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6591: Table 46 1. Is the gamma model, 4 cardinal growth model is similar to the gamma model	This has been checked and clarification is provided in the title of the Table.
196	Marcel Zwietering/Wageningen University and Research	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6603: Strain variability Table 47-49: also the papers of Aryani could be referenced here.	The comment was adopted and the cardinal values of Aryani et al. (2015b) are inserted in Tables 47-49 of the revised Scientific Opinion.
197	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6607: Add reference 'Aryani et al. (2015)' before Rosenow. Add to reference section: Aryani DC, den Besten HMW, Hazeleger WC and Zwietering MH, 2015. Quantifying strain variability in modeling growth of Listeria monocytogenes. International Journal of Food Microbiology, 208, 19-29. doi: 10.1016/j.ijfoodmicro.2015.05.006.	The reference (Aryani et al., 2015b) has been added.
198	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6629: After paté, add: Strain variability was also quantified by by Aryani et al. (2015), who reported the growth rates of twenty different *L. monocytogenes* strains as a function of pH, a_w [NaCl], undissociated lactic acid (HLac) and temperature (T). Add to reference section: Aryani DC, den Besten HMW, Hazeleger WC and Zwietering MH, 2015. Quantifying strain variability in modeling growth of *Listeria monocytogenes*. International Journal of Food	The change has been made.

			Microbiology, 208, 19-29. doi: 10.1016/j.ijfoodmicro.2015.05.006.	
199	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6654-5. These sentences read: "The inhibitory effect of organic acids is mainly attributed to its undissociated molecule and to some extend to acidification (pH-reducing potential). That is why the effect increases at low pH." Please rephrase as follows: "The inhibitory effects of organic acids are mainly a result of the presence of the acids in the waterphase in the undissociated protonated form, and to some extend to acidification (pH reducing potential). At lower pH values, the concentration of the undissociated form is higher than at high pH values (where the acid may be fully dissociated). As a result, the effect of organic acids are generally higher at lower pH values."	The change has been made.
200	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Lines 6655-8 now read: 'The MIC values of *L. monocytogenes* to various organic acids is shown to be strain and pH dependent, especially close to the growth limiting pH (e.g. <4.8), with the highest observed variation being almost 9.0 mM (Wemmenhove et al. 2016)'. As corresponding author of the latter publication, I would like to comment. Firstly, it should the MIC of an acid for *L. monocytogenes*, not the MIC of *L. monocytogenes* to an acid. Secondly, the MIC is not necessarily pH dependent, but the concentration of undissociated acid is pH dependent and at low pH values, growth ceased at pH 4.8 in the presence of organic acids. Thirdly, 'the highest concentration of 9.0 mM' is mentioned in one breath with low pH 4.8. This gives the reader the impression that that value was measured at low pH, but in fact, this concentration was measured for one strain at a high pH (where the increments between undissociated concentrations were high due to the high pH). The real MIC was somewhere between 5.8 (growth observed) and the next assessed concentration of 9.0 mM (clear well in assay). In a more precise, detailed study, Aryani et al. (2015) established the MICs of undissociated lactic acid for 20 different *L. monocytogenes* strains, with a maximum value of 5.1 and a 95% prediction interval of 4.2 to 5.9. The highest MIC value seen in their data was 6.35 mM undissociated lactic acid. To incorporate this information, I suggest to replace the sentence 'For instance, … 2016)' p 68, lines 2837-2840 with the following: 'For instance, differences in MIC values of various undissociated organic acids have been reported for different *L. monocytogenes* strains (Wemmenhove et al. 2016), with the concentrations of the undissociated forms of these acids depending on the pH. In a detailed study by Aryani et al. (2015), the impact of strain variability on maximum specific growth rates was quantified for twenty different *L. monocytogenes* strains as a function of pH, a_w [NaCl], undissociated lactic acid (HLac) and temperature	The change has been made.

			(T). This showed that *L. monocytogenes* had an average pHmin of 4.5 (5-95% prediction interval (PI) 4.4-4.7), [NaCl]max of 2.0 mM (PI 1.8-2.1), [HLac]max of 5.1 (PI 4.2-5.9) and Tmin of -2.2 (PI(-3.3) – (-1.1)). The maximum HLac found for one strain under one condition was 6.35 mM.' Please add the following reference to the reference section: Aryani DC, den Besten HMW, Hazeleger WC and Zwietering MH, 2015. Quantifying strain variability in modeling growth of *Listeria monocytogenes*. International Journal of Food Microbiology, 208, 19-29. doi: 10.1016/j.ijfoodmicro.2015.05.006.	
201	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6658: Before 'The average MICs …', insert: Wemmenhove et al. (2016) reported average MICs of undissociated …	The change has been made.
202	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6659: replace 5 with 5.0.	The editorial change has been made.
203	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6660-1: Replace 'The magnitude of MIC in the latter pH range was a little higher than that at pH 4.6' with the following: 'The magnitude of the MICs of undissociated lactic acid in the latter pH range was higher than at pH 4.6 where the pH is very close to the minimum pH at which growth can occur.'	The change has been made.
204	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6661: Add after the last sentence of this paragraph: 'In the study by Aryani et al. (2015), the maximum concentration of undissociated acid was established for 20 strains of L. monocytogenes as 5.1 mM, with a 5-95% prediction interval (PI) of 4.2 - 5.9 mM, and the average minimum pH was 4.5 (PI 4.4-4.7). Add to reference section: Aryani DC, den Besten HMW, Hazeleger WC and Zwietering MH, 2015. Quantifying strain variability in modeling growth of *Listeria monocytogenes*. International Journal of Food	The sentence has been added with the reference to Aryani et al. (2015b).

			Microbiology, 208, 19-29. doi: 10.1016/j.ijfoodmicro.2015.05.006.	
205	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Table 47: For the acids indicated in the left-hand colomn, these should be indicated as 'undissociated lactic acid' 'undissociated acetic acid' 'undissociated propionic acid' undissociated citric acid'.	The change has been made.
206	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Table 49: Add cardinal values of Aranyi et al. 2015, including NaCl concentrations. In a detailed study by Aryani et al. (2015) using 20 different strains, *L. monocytogenes* had an average pH_{min} of 4.5 (5-95% prediction interval (PI) 4.4-4.7), $[NaCl]_{max}$ of 2.0 mM (PI 1.8-2.1), $[HLac]_{max}$ of 5.1 (PI 4.2-5.9) and T_{min} of -2.2 (PI(-3.3) – (-1.1)). Corresponding reference: Aryani DC, den Besten HMW, Hazeleger WC and Zwietering MH, 2015. Quantifying strain variability in modeling growth of *Listeria monocytogenes*. International Journal of Food Microbiology, 208, 19-29. doi: 10.1016/j.ijfoodmicro.2015.05.006.	See the reply to comment 196.
207	Marjon Wells-Bennik/NIZO	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6704 – should this not be Koutsoumanis instead of Koutsounianis?	Yes, this is correct. The change has been made.
208	Marcel Zwietering/Wageningen University and Research	Appendix H – Growth, survival and inactivation of *Listeria monocytogenes* in food and the food chain	Line 6846: Diah C. Aryani, Heidy M.W. den Besten, Wilma C. Hazeleger, Marcel H. Zwietering. 2015. Quantifying variability on thermal resistance of *Listeria monocytogenes*. International Journal of Food Microbiology 193: 130-138.	The comment is adopted and information from the suggested reference Aryani et al. (2015b) is included in Table 50.
209	Jens Kirk Andersen/National Food Institute/DTU	Generic comments	I would like to suggest that it is considered to measure the severity of listeriosis in terms of DALY's. It is always stated that listeriosis is a very serious disease as even if it is a rare disease the consequences are very severe because of a high mortality. However it is also a fact that most patients are old, and not only old but also suffering for serious additional disease. Therefore some patients may not have a great residual life expectancy, and they may already have a reduced quality of life. So I think an objective quantitative measure of the severity of listeriosis would be very	See the reply to comment 48.

			valuable.	
210	Jens Kirk Andersen/National Food Institute/DTU	Generic comments	The hypothesis that sporadic cases may be attributed to an infinite fraction of foods containing a high number of *L. monocytogenes* when the foods are eaten in high quantities is interesting. This corresponds well with the US risk assessment that a portion of milk has an extremely low risk, but when considered during a year milk becomes a significant risk (as I recall no 3 on the risk ranking list). However, I think that sporadic cases (as well as outbreaks) may also be caused by a total failure of prerequisite programs. HACCP may be working perfectly, but something been has been overlooked. We had a situation in Denmark with findings of *L. monocytogenes* in ready-to-drink pasteurised milk. It was found that this was caused by the tubes in the dairy being flushed with contaminated water after CIP cleaning. There are plenty of outbreaks that are explained by similar grave incidents. If the plant responsible is large and the failure results in a high level of contamination we may have an outbreak, but if the company is small or the contamination level is low we may have only few cases that will be regarded sporadic.	Thank you for the comment addressing the potential causes behind outbreaks and sporadic cases. Since this relates to control measures and risk management this is outside the scope of the mandate.
211	Anses	Generic comments	Lack of regional study: The Panel missed an opportunity to explore regional variations in the incidence of listeriosis. Without considering each country independently, a simple regionalization (2-4 regions, according to typical diets) might have provided some interesting clues to explain the pattern of listeriosis cases. Demographics are also various in these countries and a comparison could help the purpose.	The analysis of listeriosis incidence by region and/or MS was out of the scope of the Scientific Opinion as the ToR was to evaluate the trend in listeriosis in the EU/EEA. It is agreed that an analysis at country or regional level would be worthwhile to investigate the trends in human listeriosis cases and/or incidence and the factors behind this trend. This has been recommended.
212	Anses	Generic comments	Limitation to three RTE foods: The whole report uses the very strong assumption that all cases of listeriosis in the European Union are linked to three types of RTE only. This assumption is acknowledged, but its limitation should be thoroughly discussed in a report that looks for some clues in the increase of the listeriosis incidence rates, notably after the observation of "unexpected" sources of *Listeria* in the USA (produce, notably). The observation of outbreaks linked to complex foods (sandwiches), vegetable/fruits and the new trends of consumption observed in the EU (more RTE) should trigger some discussions regarding these potential sources. The hypothesis of an increase in the listeriosis incidence linked to food other than the "usual suspects" should be considered.	All foods are covered and considered in ToR1 (e.g. prevalence, outbreaks, epi, concentration data) but not specifically in the ToR2- factors. Data from the three RTE food categories is used in the evaluation of factors that may explain the trend. The QMRA approach is to construct a generic food based on the properties and the consumption of these three food categories. The uncertainty of the evaluation of contributing factors, in relation to food categories not considered, depends on the degree that the non-considered foods would differ in terms of prevalence, initial contamination, growth, storage, consumption, etc., to those considered. For instance, the effect of an increased consumption or prevalence would be the same independent of the food, but of course the

				indicator data for these foods (change over time period) were not included in the analysis. It should be noted that this would impact only on the factors that are related to the food (AQ2.1–2.4; i.e. *L. monocytogenes* prevalence and concentration in RTE food, storage conditions (temperature, time) and consumption (serving size and frequency). The gQMRA model can be updated with additional food categories when data becomes available.
213	Anses	Generic comments	The results rely on the hypothesis that the distribution of virulence of the strains is the same between the different food categories. Although some strains/clonal complexes are equally distributed between the different food categories, small differences in relative percentages of high/medium/low virulent clonal complexes could lead to huge differences (because most listeriosis are linked to virulent clonal complexes).	In Section 3.6.4 of the Scientific Opinion, this assumption has been added in the uncertainty section of the gQMRA model and exemplified with the reference of Fritsch et al. (2017). In addition, the opportunity for risk assessment taking this into consideration has been added to the summarising remarks in Section 3.2.
214	Gary Barker/Quadram Institute Bioscience	Generic comments	This document, when combined with those from three outsourced activities, is extensive and difficult to appreciate in full. A single summary, that covers this and three additional reports, would improve accessibility.	These reports can be consulted on the EFSA website.
215	Bert de Vegt/Micreos	Generic comments	Following Micreos participation to the informative and fruitful EFSA event on "*Listeria monocytogenes* contamination of ready-to-eat foods and the risk for public health in the EU", please allow us to present you with our written input on the matter. Micreos is a Netherlands-based phage and endolysin technology development company. We have developed phage and endolysin-based products against specific bacteria such as *Listeria*, *Salmonella*, and *Staphylococcus aureus* – including MRSA strains. Micreos would like to focus EFSA's attention on the microbiological criteria currently in use in the EU. During the meeting, it became clear that the presence of *Listeria monocytogenes* on ready-to-eat food of 100 cfu/gr at the end of shelf-life is no longer safe. Indeed, new data demonstrates that the infectious dose for certain groups of the population (so called YOPI's) is lower than originally foreseen and on which the current EU Regulation (EC) No 2073/2005 is constructed. Therefore, we strongly suggest that the limit of 100 cfu/gr should be lowered and preferably to move toward a zero-tolerance policy for *Listeria monocytogenes*, at least for those foods that support the growth of *Listeria monocytogenes.*	The evaluation of *L. monocytogenes* microbiological criteria as defined in Commission Regulation (EC) No 2073/2005 was not in the remit of the mandate. In addition, the setting of microbiological criteria is a task for the risk manager as has been stated in the recent Scientific Opinion from the BIOHAZ panel on requirements for the development of microbiological criteria (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5052/full). The evaluation of interventions, such as the application of Listex™ P100, to reduce the levels of *L. monocytogenes* on the RTE foods has not been specifically addressed in this draft Scientific Opinion as specified in comment 171. The BIOHAZ Panel has published in 2016 a Scientific Opinion on the evaluation of the safety and efficacy of Listex™ P100 solution intended to be used by FBOs during processing for the reduction of *L. monocytogenes* in RTE products (https://www.efsa.europa.eu/en/efsajournal/pub/4565). The authorisation of these decontamination

			Micreos also suggests that EFSA actively supports the use of phage technology to prevent (cross) contamination with *Listeria.* Bacteriophages and their derivatives have emerged as an effective and safe option for the prevention of *Listeria* in a range of foods and food processing environments. Micreos has developed Listex^{TM}P100 to prevent, and reduce the risk of, contamination with *Listeria monocytogenes* in food products including meat, fish and cheese. This product has already been evaluated by EFSA and approved for these uses in the US, Canada, Australia and Switzerland. Unfortunately, since 2015, the approval and the use of Listex^{TM}P100 on food of animal origin has been stuck in a legislative limbo. Because the European Commission has grouped this use under EC Regulation 853/2004 on Food Hygiene, its use is presently wrongly positioned as 'decontaminant'. The Commission, DG SANTE, did not realise that registration as 'decontaminant' would arouse the concern among both consumers and Member States that Listex^{TM}P100 will help hide lack of industrial hygiene [which it does not as it selectively only kills *Listeria* and leaves all other bacteria alive], while virtually disabling the use of Listex^{TM}P100 for its prime purpose: to prevent the contamination of *Listeria* on RTE products. Therefore, as Listex^{TM}P100 is an important food safety tool that could save lives, it would be helpful if EFSA supported the use of bacteriophages to reduce the risk of *Listeria* contamination on food. Thank you in advance for taking the above suggestions into account.	substances is not within EFSA's remit. EFSA's scientific advice is available in the abovementioned Scientific Opinion.
216	Food Standards Agency	Generic comments	Please be aware that I am submitting comments on behalf of the Food Standards Agency. This includes contributions from The Advisory Committee on the Microbiological Safety of Food (ACMSF), an independent scientific committee that provides expert advice to government on microbiological issues and food. One reviewer noted: It is difficult to obtain a complete appreciation of this opinion without prior knowledge of three other, very large, documents that summarise three outsourced activities (several hundred pages in total). In this respect the comments below only reflect a partial view of the full opinion. Three strategic observations: 1 – The opinion is based on a particular aggregation of data (by age	Also the proportion of susceptible persons in the elderly group may have contributed to the increase in number of cases and incidence rate in that group (this is mentioned in the conclusion above the one that is being referred to).

			groups and gender) that does not fully match the hazards being considered. This is particularly apparent because (line 537) in a previous opinion the panel concluded "The disease was found to be associated with pregnancy, but it was predominantly associated with immuno-compromised persons …". The current opinion acknowledges changes in the age profile of the population at risk but does not appear to develop on the previous opinion with respect to coincident illness. In particular the increase in the number of older people at risk may well be accompanied by an increased proportion of older people who are vulnerable for some reason (i.e. seeking medical care). If this is so a conclusion such as at line 4330, would be invalid (i.e. not only the number of cases but the incidence rate may be increasing in an elderly group).	
217	Thomas Lüthi/ Federal Food Safety and Veterinary Office (FSVO)	Generic comments	We would like to thank you for the opportunity to comment on the document and congratulate on the tremendous work the BIOHAZ EFSA Panel has done. The document is rather big and an overview difficult to achieve. However, we tried to do so. The document gives an excellent overview of the state of the arte in terms of *Listeria* in RTE but relevant information must be searched for and they are hidden behind all these technical details given. We suggest to focus in the document on the information relating to MRA mainly and to add any background information separately in further annexes.	Only the information considered necessary to address both ToR's has been covered in the document and a lot of information has already been moved to the appendixes.
218	Stefano Morabito/Istituto Superiore di Sanità	Generic comments	As underreporting of listeriosis cannot be excluded and difference in the sensitivity of the reporting countries may exist, replacing the term 'incidence rate of listeriosis' with 'notification rate' of listeriosis should be considered throughout the document, similarly to what is reported in the annual EUSR. In order to avoid discrepancies in the present document a careful revision should be considered, as 'notification rates' are mentioned in the 'introduction' and 'Approach to answer the ToR refer' sections to while 'incidence rates' are described in the 'TSA' section.	The use of wording "notification rate" and "incidence rate" has been clarified in Section 2.1.1.
219	Hélène Simonin/European Dairy Association (EDA)	Generic comments	The dairy industry recognises that the EFSA draft opinion provides a comprehensive update on the risk of listeriosis linked to the consumption of ready-to-eat foods in Europe. The approach adopted by EFSA makes it possible to identify certain factors affecting the incidence of listeriosis in Europe and to attribute to each a qualitative level of probability. It also allows the identification of missing data to be collected when it is not possible to	This clarification is acknowledged.

			conclude. This methodical and quantitative approach makes it possible to evaluate the relevance of several hypotheses. This last point is of major importance since it makes it possible to quantify the relative impact of certain factors and to objectively dismiss certain ideas received. The simulations carried out with the model from the Pérez-Rodriguez et al. (2017), on which the EFSA opinion is based, provides an order of magnitude of the proportion of cases attributable to cheeses among sporadic cases. These results are representative of the level of control of the health quality of dairy products implemented by cheese manufacturers in Europe and the low contribution of cheeses to the risk of listeriosis in Europe. The likely impact of certain ongoing demographic and epidemiological changes on the increase of the incidence rate in Europe is of importance for the dairy sector since it makes it possible to objectively dismiss the hypothesis that a lesser control of the sanitary quality of dairy products in Europe would be a major factor in increasing the risk of listeriosis in Europe. Coupled with a very low contribution of dairy products to the risk of listeriosis in Europe (19 simulated cases out of 2,318), these results confirm the relevance of the European microbiological criterion for dairy products, the ability of manufacturers to respect it and ensure the safety of their products.	