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Comments to Draft Assessment of the relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods – **III. Exposure Assessment, Appendix 2, and Appendix 5.**

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Main topics

1. Assumptions and surrogate data sources used when specific data were unavailable.

- Generally, I think assumptions are clearly stated.

p. 24. *'It was also presumed that some foods that are cooked just prior to consumption ... low likelihood of containing L. monocytogenes when consumed and were not included in this risk assessment.'*

- The above statement makes clear why you did not include these foods. However, undercooking of products is one of the major contributing factors for foodborne illnesses, so I am somewhat surprised by your choice.

p. 28. *'However, it is estimated that unpasteurized milks accounts for less than 1% of the total volume of milk sold ...., the consumption of this food category was modeled by estimating it as 0.5% of the amount consumed per serving of pasteurized milks (54%x1%).'*

- I do not understand why you use 54%x1% instead of 50%x1%.

2. Modeling approaches and techniques used in developing the exposure assessment

Some examples of the use of frequency distributions throughout the Exposure Assessment:
p. 30. *'Empirical distributions were used to describe the serving sizes...'*
p. 37. *'The resulting data points were fit with curves corresponding to Log normal, Weibull-Gamma, and Beta-Poisson distributions.'*
p. 42. *'The uniform distribution for temperature is used to determine the exponential growth rate.'*
p. 42. *'...multiplied by storage time, also a uniform distribution, to estimate the amount of growth.'*
p. 44. *'For categories with fewer than five datapoints, a Triangular distribution was defined ...'*
etc.

- I think that in the area of Microbiological Risk Assessment we definitely need structural discussions on the use of probabilistic methods, and specifically on the choice of frequency distributions. We all seem to agree on the benefits of probabilistic methods to describe uncertainty and variability in risk estimates. There is however no agreement on the probability models (frequency distributions) that we use under various circumstances.
- For instance, what are the reasons for choosing a uniform distribution to describe storage temperature (p. 42); why is this more plausible than a normal distribution in this case? Are there significant grounds to assume that all temperatures between the minimum and maximum temperatures have the same probability of occurrence? Moreover, are the assumed mimimum and maximum the absolute minimum and maximum as they represent in the uniform distribution?
- More important: what are the consequences of the assumption of a certain frequency distribution on the final risk estimate? In a comprehensive probabilistic risk assessment it is very difficult to have a transparent overview of all assumptions with effects on the risk estimate.
- I very much appreciate the remark at page 45: 'There is no theoretical support for one distribution to be more appropriate than any other distribution.' This remark was used in the context of the Exponential Growth Rate, but I think it is applicable to many other situations with the current knowledge we have.

p. 33. *'Data from presence/absence studies ... 25-g sample (0.04 cfu/gra, ı of food). Thus, both qualitative and quantitative data were used ...'*

and

p. 37. *'Quantitative data on L. monocytogenes contamination are presen ed as colony forming units per gram of food (cfu/g) and negative presence/absence data are converted ı › a level of < 0.04 cfu/g.'*

- How did you treat < 0.04 cfu/g in the distribution? Which value did ·ou use, or which distribution? A short explanation would be useful.
- I think it would be interesting to evaluate the consequences of your ɛ pproach compared to other approaches. For instance, another approach would be to estimate pre ·alence on the basis of the number of positive/negative samples (for instance with a Beta distrit ution) and the concentration on the basis of quantitative levels in positive samples. See FAO/WH) Exposure Assessment of *Listeria monocytogenes* in ready-to-eat foods (MRA 00/02).
- An advantage of the latter approach is that you do not need the extra weighing step for data at higher levels (p. 38).

p. 38. *'In this example the Weibull-Gamma and Beta distributions have 4. and 35% of the weight, respectively.'*

- Table A5.1.4. indicates 42 and 30% of the weight for Weibull and Bɛ ta respectively.

p. 44. *'T_0 values were estimated from four sources ... and an average of th ɜse values (-1.18 ^{0}C) was used in the model.'*

- Maybe I misunderstand the use of T_0 in your calculations; in the way I read it, you use a point estimate for T_0 (-1.18 ^{0}C). To my opinion this is not consistent with tl e fact that you choose distributions for both temperature and time. I do not see a difference l etween storage temperature and T_0 that justifies the use of an existing frequency distribution for tl e one, and a point estimate for the other.

p. 44. *'In some food categories, the L. monocytogenes levels declined ... Tl e rate of decline was modeled with the same square root model..' 'Negative EGR values from th literature were combined with positive data to create one distribution,..'*

- From a biological point of view, growth is a different phenomenon th n inactivation.
- I realise that the square root model is an empirical model, so in that se ıse it makes no mechanical difference whether you apply it to growth or decline. The model has h ›wever been extensively tested for growth, so there are reasons to assume it is suitable for grow th predictions. As far as I am aware of, there are no experimental data that prove the use of the r ıodel for decline.
- Shortly, I think a more comprehensive explanation of your choice is n cessary to prevent misinterpretation.

p. 47. *'The BetaPert was modified by increasing the weight for the central alue from 4 to 7.'*

- I am not familiar with quantitatively describing expert judgements, bu the above sentence gives me the impression that this was a kind of 'hobbyhorsing', just to make he data look more beautiful than they are. I would appreciate an explanation for changing the weig ıt for the central value.

p. 48. *'The uncertainty was also described using a ±20% uniform distributi ·n for the most frequent value and a 50% uniform distribution for the maximum value, with a 100% correlation between the two distributions.'*

- Could you explain the background for choosing 20% and 50% respecti ·ely? What is the background of choosing the uniform distribution?

and

p. 51. *'A uniform variation of one logarithm was designated for each of the naximum growth levels'.*

- Why a uniform distribution instead of for instance a normal distributioı ? Why a one log variation?
- You quantify uncertainty, but a well-considered background for choosi ıg values and distributions is not mentioned. This makes me doubt about the meaning and value oı the uncertainty estimate.

p. 53. *'Reductions in L. monocytogenes were calculated by estimating a distribution of cooking temperatures with a triangular distribution having a minimum of 54 ^{0}C, most frequent temperature in the range of 69 to 73 ^{0}C, and a maximum of 77 ^{0}C.'*

- Reading the above, I wondered where the temperatures came from. This appears to be the experimental temperature range in the experiments of Juneja (p. 52) I do not think this is a good ground for estimating real life heating temperatures in a different product. To my opinion, the temperatures are quite out of the blue and I seriously doubt whether it is sensible to describe them as a frequency distribution in this case. It makes you wonder about the relevance of the uncertainty estimates related to risk assessment.

Appendix 2, page 220. *'The magnitude of the variance for the product of two distributions is much larger than the variances of the original distributions. The practical effect of this is that multi-step calculations have increasingly wider output distributions.'*

- I think this is very relevant information for well-interpretation of the resulting risk-distributions!
- I find it a pity that this information is somewhat 'hidden' in an appendix.
- Also, I miss practical consequences of the information. By only mentioning it without practical consequences, it seems as if we should take it for granted.
- I would suggest to compare the outcomes of a probabilistic risk assessment to the outcomes of risk assessments using interval and/or fuzzy arithmetic. The latter do not increase the variance by multiplication (for fuzzy I am not sure however).

4. Transparency of the risk assessment document.

- Qualitative assumptions are quite clearly stated. Quantitative assumptions are however not always clear; I do not think I will be able to recalculate (parts of) your risk assessment with the information that is available from the document. If more sub-results were presented in Appendix 5, small steps of the risk assessment could be recalculated (I usually recalculate steps to really understand the process).

For instance:

p. 37. *'A comparison of the results of studies conducted before and after 993 was done.'*

- How did you compare the results of studies? What were the criteria to base significant differences on? Appendix 7 only shows the data (total samples and % positive samples).

For instance:

p. 42. *'The temperature ranges and storage times for the food categories are in Table III-6. ... The uniform distribution for temperature is used ... storage time, also a uniform distribution, ..'.*

- Which parameters did you use in the uniform distribution? From table III-6 I assume that you used 1 and 5 ^{0}C as the minimum and maximum temperature, but it is not clear which minimum and maximum storage time were used. I can only guess.

Appendix 5, page 232. Figure A5.1.2.

- I do not understand the 16 datapoints in figure A5.1.2. Where do they come from?
- Table A5.1.3. shows 15 references, figure A5.1.2. shows 16 datapoints. The difference in number is unclear to me.
- Table III-4, p. 35, mentions that there were 4 quantitative studies out of 12. I assume that the qualitative studies resulted in outcomes of 0.04 cfu/g in the case of 'absence' (see p. 37). What quantitative level was applied in the case of 'presence'?
- Figure A5.1.2. only shows one datapoint at 0.04 cfu/g at a cumulative frequency of about 0.93. Does this mean that the datapoint is from one reference where 93% of the data showed 'absence'? Where is the other 7%?

As you notice, the meaning of the figure is not clear to me!

Appendix 5, page 234. Table A5.1.8.

- The values are also presented in Table III-7. The values are howeve not used in the risk assessment: (p. 44) 'The modeling process used a cumulative table o the actual data points, not the means and standard deviations presented in table III-7'.
- To prevent confusion, I would leave out table A5.1.8., since the data are not used anyway.
- Table A5.1.8. gives as Number of samples (N) 25. Figure A5.1.3. sh ws 28 datapoints. This difference is confusing.

Appendix 5, page 234. Figure A5.1.3., page. 47. refrigeration temperatur s.

- The shows the distribution of EGR at 5 ^{0}C. It is not clear to me how ou included other temperatures in the calculations.

Specific Questions:

1. Foods were grouped ... at consumption.

b. Would pooling of all data ...effective means of describing and mode ling the pattern of *L. monocytogenes* contamination?

- To be able to answer this question I think it would be an interesting e ercise to do the risk assessment for pooled data, and compare the results of pooling to non pooling.
- I think the same exercise should be done for some specific foods, to c l eck whether grouping the foods in the categories highly affects risk estimates.

2. Currrent and Quantitative Contamination Data.

a. Can you provide more recent contaminant level (enumeration) data'

- For the FAO/WHO Exposure Assessment of *Listeria monocytogenes* i ready-to-eat foods, ICD (Industry Council for Development of the Food and Allied Industries) rovided contamination data on presence/absence of *Listeria monocytogenes* in consumption ice-cre am (no quantitative data on levels of *l. monocytogenes*).
- The data were sent to Bob Buchanan (FDA/CFSAN) for use in the FD risk assessment.

b. Data to support or modify the assumptions used to model reheating f r the Frankfurter food category?

- I am highly suprised that you use a thermal inactivation model for *E. co 'i* O157:H7 in hamburgers to describe thermal inactivation of *Listeria monocytogenes* in frankfurte s!
- Without a justification of the assumption that *L. monocytogenes* has sim ilar thermal resistance to *E. coli* O157:H7 I think you cannot simply use an inactivation model fo a different organism for predictive purposes.
- I do not understand why you did not choose one of the existing inactiva on models for *Listeria monocytogenes* (various models available from the literature).

4. Is there additional information that could be provided that would bett r describe the conduct of this assessment? How might the results be better presented?

- I think a valuable addition to the risk assessment is to refer to the FAO/W HO Exposure Assessment and Hazard Characterisation for *L. monocytogenes* in ready- o-eat foods.
- Basic assumptions could be compared, approaches could be compared, a d –obviously- outcomes could be compared.
- Since risk assessment is inherently related to many uncertainty and varia ility and the truth is very difficult to capture, I think it is valuable to compare the two independent, extensive exercises.