The Application of the Appropriate Level of Protection (ALOP) and Food Safety Objective (FSO) concepts in food safety management, using *Listeria monocytogenes* in deli meats as a case study

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Abstract

To establish a link between governmental food safety control and operational food safety management, the concepts of the Appropriate Level of Protection (ALOP) and the Food Safety Objective (FSO) have been suggested by international bodies as a means of making food safety control transparent and quantifiable. The purpose of this study was to investigate how the concepts of ALOP and FSO could be applied in practice. As a case study, the risk of severe listeriosis due to consumption of deli meat products in the Netherlands was taken. The link between these concepts was explored for two situations following a "top-down" approach, using epidemiological country data as a starting point, and a "bottom-up" approach, using data on the prevalence and concentration of the pathogen at retail as a starting point. Models based on both approaches were able to describe the link between ALOP and FSO and our results showed that meaningful estimations are feasible, although interpretations need to be made with care. For the top-down approach, the mean estimated value derived for ALOP was 3.2 cases per million inhabitants per year (95% CrI: 1.1-6.6). For the bottom-up approach, ALOP values ranged considerably, 4.7-55 (with 95% CrI ranging from 2.9-162), depending on the input parameters selected. The level of detail considered in the stochastic models considerably influenced the ALOP and FSO estimates. As best practice it is recommended to develop both approaches, although depending on the application context one may appear more appropriate than the other.

Keywords: *risk assessment, stochastic modelling, foodborne disease, public health targets*

Introduction

Food safety is an issue of fundamental public health concern and providing guidance to the food industry on achieving a safe food supply poses major challenges for competent authorities who have the responsibility to articulate the level of control they expect the industry to achieve. To establish a link between governmental public health goals related to food safety and operational food safety management, the concepts of the Appropriate Level of Protection (ALOP) and the Food Safety Objective (FSO) have been suggested by respectively the World Trade Organization (WTO, 1995) and Codex Alimentarius (2010) as a means of making food safety control transparent and quantifiable. A major difficulty related to the implementation of these concepts is that they are still evolving and there is no uniform agreement with regards to their use (Stringer, 2005). A consistent approach is necessary from a legal point of view (WTO, 2000). So far very few case-studies have been published on how these concepts might work in practice (Crouch, et al., 2009; Membré, et al., 2007; Rieu, et al., 2007; Tuominen, et al., 2007). Our aim was to investigate further how the ALOP and FSO concepts could be applied in a real life example, the risk of severe listeriosis due to the consumption of deli meat products (cooked ready-to-eat meat products) in the Netherlands. In this example, two likely approaches to establish a link between the concepts have been followed. One approach was based on analysis of public health data and epidemiological surveys (from now on referred to as the top-down approach). The second approach was based on data related to the level and/or frequency of *Listeria monocytogenes* in deli meat, from which through a risk characterization curve disease incidence estimates are derived (from now on referred to as the bottom-up approach) (Codex Alimentarius, 2007). Our aim is to compare both approaches.

Materials and Methods

For the two different approaches the estimation steps in either Figure 1 or 2 were followed. Stochastic models were built in Microsoft Excel using the @RISK 5.7 software (Palisade Corporation). The dose response model was the common element in both approaches (WHO/FAO, 2004) through the formula:

$$LOP = S \cdot 10^6 \cdot (1 - \exp(-r \cdot D)) \text{ or } LOP = S \cdot 10^6 \cdot (1 - \exp(-r \cdot M \cdot 10^{SO})) \text{ where:}$$

LOP = the Level of Protection, defined as the currently achieved number of cases of severe listeriosis per million people per year in each risk group, being either the healthy or the susceptible population (Young-Old-Pregnant-Immunocompromised or YOPI)
S = the number of servings per person per year
r = the probability of a single microorganism causing listeriosis for each risk group
D = the dose consumed (log CFU)
M = the mass per serving (g)
SO = the Safety Objective, defined as the concentration of microorganisms at consumption (log CFU per g)

The FSO was considered to be the stricter of the two estimated SO in the top down approach. The ALOP was considered to be the sum of the LOPs for the healthy and the susceptible population after adjusting for the different percentages of each group in the general population in the bottom up approach. In their baseline version the models were built as simple as possible and alternative versions were included using different deterministic or stochastic input parameters for r, M and S and selecting r values based on different assumptions for the maximum dose at consumption (D_{max}).

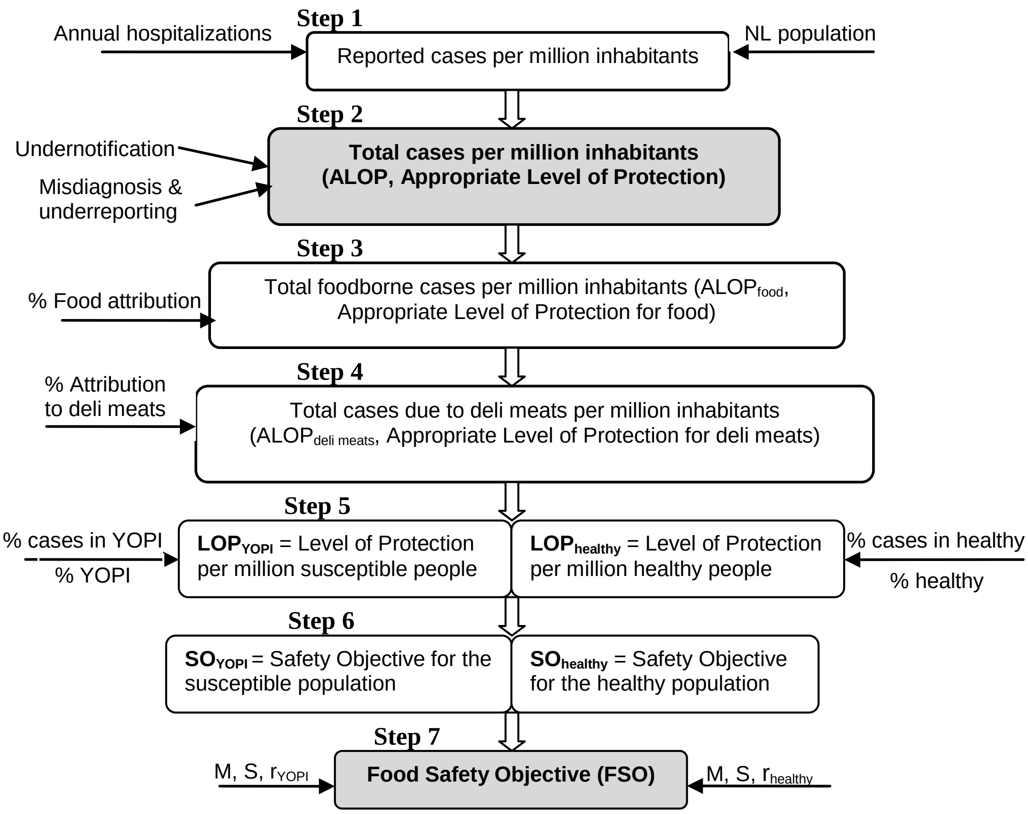

Figure 1: Outline of the estimation steps in the top down approach model.

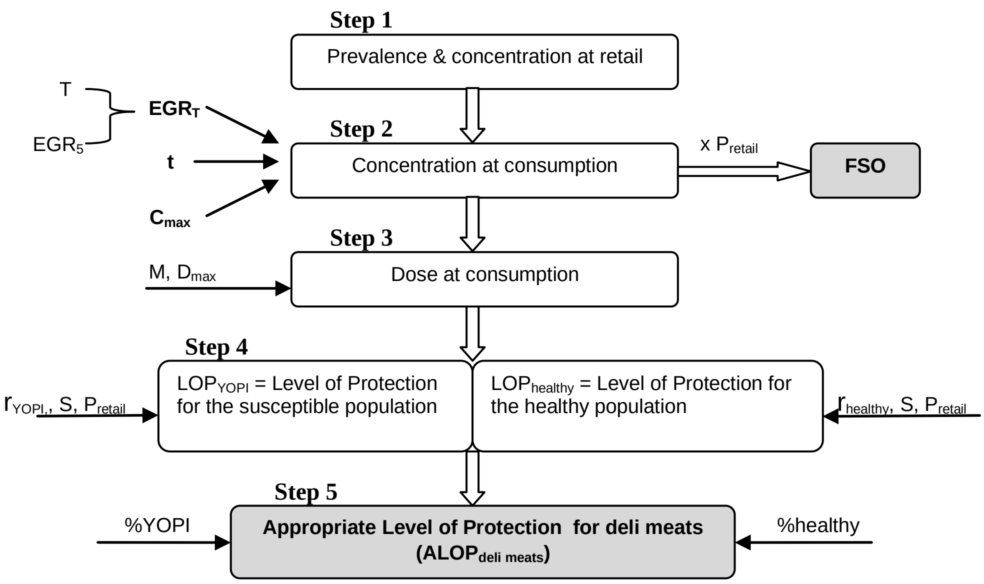

Figure 2: Outline of the estimation steps in the bottom up approach model.

Results and Discussion

The results for the different models used in the top down and bottom up approach to estimate the ALOP can be seen in Table 1. For the bottom up approach the estimated FSO was the same for the different combinations of input parameters tested with a mean of -0.82 log CFU per g (95% CrI: -3.2 to 5.6). For the top down approach mean estimates for the FSO varied from 2.3 to 3.9 log CFU per g with 95% CrI covering the range 1.6-4.4 log CFU per g (data not shown).

Table 1: ALOPs (cases of severe listeriosis due to the consumption of deli meat per million people per year) estimated with both the top down approach and bottom up approach for different combinations of input parameters.

Parameter	Description	$ALOP_{deli\ meat}$ Top down approach	$ALOP_{deli\ meat}$ Bottom up approach
		Mean (95% CrI)	Mean (95% CrI)
Baseline	r, M, S fixed	↑	12 (8.8-15)
Alternative 1	r stochastic, M & S fixed		44 (5-118)
Alternative 2	r, M, S fixed, D_{max}=7.5 log CFU		4.7 (3.5-6.0)
Alternative 3	r, M, S fixed, D_{max}=8.5 log CFU		6.8 (5.1-8.8)
Alternative 4	r, M, S fixed, D_{max}=9.5 log CFU		12 (9.0-16)
Alternative 5	r, M, S fixed, D_{max}=10.5 log CFU		6.1 (4.5-7.9)
Alternative 6	r stochastic, M,S fixed, D_{max}=7.5 log CFU		4.8 (3.0-7.0)
Alternative 7	r stochastic, M,S fixed, D_{max}=8.5 log CFU		7.0 (4.3-10)
Alternative 8	r stochastic, M,S fixed, D_{max}=9.5 log CFU		13 (7.9-19)
Alternative 9	r stochastic, M,S fixed, D_{max}=10.5 log CFU	3.2 (1.1-6.6)	6.2 (3.9-9.1)
Alternative 10	r fixed, M,S stochastic		15 (8.1-25)
Alternative 11	r fixed, M,S stochastic, D_{max}=7.5 log CFU		5.9 (3.2-9.9)
Alternative 12	r fixed, M,S stochastic, D_{max}=8.5 log CFU		8.7 (4.7-15)
Alternative 13	r fixed, M,S stochastic, D_{max}=9.5 log CFU		16 (8.3-26)
Alternative 14	r fixed, M,S stochastic, D_{max}=10.5 log CFU		7.8 (4.2-13)
Alternative 15	r, M, S stochastic		55 (6.0-162)
Alternative 16	r, M, S stochastic, D_{max}=7.5 log CFU		6.1 (2.9-11)
Alternative 17	r, M, S stochastic, D_{max}=8.5 log CFU		8.9 (4.3-16)
Alternative 18	r, M, S stochastic, D_{max}=9.5 log CFU		16 (7.7-29)
Alternative 19	r, M, S stochastic, D_{max}=10.5 log CFU	↓	7.9 (3.8-14)

The mean estimates of the ALOP and FSO were different for most of the combinations of input parameters used in the two approaches although considering the uncertainties involved they are not so far apart. Moreover, the interpretation of the concepts suggests that comparisons should be made taking into account the frequency of the hazard in the case of FSO (Codex Alimentarius Commission, 2010) or the credible intervals in the case of the ALOP (FAO/WHO, 2002). Keeping this in mind, for several of the bottom up approach outcomes the 97.5th percentile of the ALOP estimates is well in agreement with the 97.5th percentile of the ALOP based on the top down approach, being different by a factor smaller than two. With regards to the FSO however this was less the case, with the 97.5th percentiles being 1 to 3 log CFU per gram different. Obviously, with comparisons based on other percentiles these differences might be smaller or greater depending on the input parameters used. An important finding is that the level of detail encompassed in the risk assessment process (bottom up approach) influenced considerably the risk estimates with the introduction of additional stochastic parameters instead of point estimates leading to higher mean estimates for the ALOPs and larger credible intervals. Uncertainty related with the maximum dose at consumption was another parameter that also considerably influenced our risk estimates as observed by other authors (Pouillot & Lubran, 2011). Although ideally the two approaches should yield comparable results (Whiting, 2010), in reality a single approach should be used for consistency purposes (WTO, 2000). Nevertheless, as a best practice we recommend that both approaches should be used to allow validation of the risk estimates, although depending on the application context one may appear more appropriate than the other.

Conclusions

It was found to be better practice to base decisions for ALOP and FSO values on both different approaches considering the level of detail encompassed in the base data.

Acknowledgements

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