Qualitative import risk assessment: a proposed method for estimating the aggregated probability of entry of infection

L. Kelly [1,2] R. Kosmider [1], P. Gale[1] and E.L. Snary [1]

[1] Department of Epidemiological Sciences, Animal and Plant Health Agency, New Haw, Addlestone, Surrey KT15 3NB, UK

Correspondence: Dr Louise Kelly, [2] Department of Mathematics and Statistics, University of Strathclyde, 26 Richmond St, Glasgow G1 1XH, UK

louise.kelly@apha.gsi.gov.uk

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Abstract

In the absence of sufficient numerical data, qualitative risk assessment is recognised as an important tool for providing risk managers with evidence-based predictions on which to formulate their decisions. Such approaches have been used in the area of animal health for import risk assessment for both livestock and zoonotic pathogens. Very few qualitative import risk assessments have, however, considered the aggregated probability of introduction, that is, the probability of at least one infected/contaminated entry per group of import units. Those that have are generally based on specific cases and do not follow a generic approach. In this paper, we consider whether or not it is feasible to develop a generic method and under what circumstances such an approach could be applied in practice. Our conclusion is that it would be difficult to specify a generic method because any such approach would rely on specifying numerical bounds for qualitative categories of probability as well as an idea of the number of imports and would thus be case-specific. As an alternative we propose a way of using case by case information to create a simple graphical reference tool which removes some of the subjectivity that is often associated with deriving qualitative risk. The reference tool considers various qualitative categories of individual probability and determines the relationship between this probability, the number of imports and the aggregated probability of entry. Applying the reference tool to a previously published case-study demonstrated some differences in conclusions and suggests that more subjective approaches can under-estimate probability and thus risk. It is concluded that this approach may be useful for future qualitative assessments of aggregated probability, provided that bounds for qualitative probabilities can be defined for the specific case situation.

1. Introduction

In the absence of sufficient numerical data, qualitative risk assessment is an important tool for providing risk managers with evidence-based predictions on which to formulate their decisions. Qualitative risk assessment is also widely accepted as a mechanism for rapid, reactive risk assessment, for example, during outbreaks of a notifiable exotic disease. Such assessments can enable policy-makers to formulate and compare disease control and prevention strategies. Central to each risk assessment is the risk question which is specific to the proposed disease control or prevention policy. The subsequent risk assessment may include all steps from entry assessment to risk estimation, as set out in the OIE Animal Health Code framework for risk assessment (OIE 2013). In certain circumstances, the policy question may only concern entry assessment and the resulting estimate of risk would typically be the probability of disease/infection entry. This probability may be defined at an individual or aggregated level. At the individual level, the risk question will typically be of the form, what is the probability that an individual imported animal/product (unit) is infected. The units for the individual probability are thus "per product" or "per animal" as in the case of capripoxviruses on imported ruminant skins and hides (Gale et al. 2016). When data are available on the number of units imported per year or per batch, the individual probability may be scaled up to give the aggregated probability, for example the risk question may be, what is the probability of one or more infected units being introduced per year as in the case of avian influenza virus in migratory wild birds (Gale et al. 2014). Implicit in the aggregated probability is the number of units per batch or imported over a given time period.

In quantitative assessment, estimation of the individual probability of entry is usually based on a linear, conditional probability model; each probability on the risk pathway is associated with a step which is assumed to be conditional on the previous step and the probabilities are multiplied together to give a joint probability of all steps occurring. If imports are assumed to follow a binomial process, where each import is independent and has the same probability of being infected, the

aggregated output can also be derived. In such cases, as mentioned previously, the aggregated probability is estimated as the probability of one or more infected import events occurring per specified time period or per batch. This estimation is based on a non-linear model. In qualitative assessment, there is no such set of probabilistic and distributional rules that allow for the derivation of either the individual or aggregated probabilities. There have been some attempts to define rules for estimation of the individual probability (Gale et al., 2010), however, the same is not true for the aggregated probability and any published assessments have been subjective in their estimation.

In this paper, we consider what has been done for qualitative estimation of the individual probability and extend this to propose a general procedure for estimating the aggregated probability of disease entry for animal import risk assessments. We investigate the usefulness of the procedure by applying it to a previously published case study. Although the subject of the case study was risk prioritisation, we here compare our results on a case-by -case basis and draw conclusions on how general the procedure can be made. We also consider limitations of the approach.

2. Methods

2.1 Derivation of a general equation

Many quantitative import risk assessments for the entry of infected/contaminated animals/products assume that the individual units are independent and have the same probability of being infected (Goddard et al, 2012). Thus, entry of infected/contaminated units can be assumed to follow a binomial process with p being the probability of infection/contamination of an individual unit and n being the number of individual units imported (over the given time period or per batch). The aggregated probability, P say, is normally defined quantitatively as:-

$$P = 1 - (1 - p\ )^n \qquad (1)$$

The animal health risk assessment literature provides a number of qualitative definitions of probability. These are generally based on expert consultations or definitions used in other areas of risk assessment application, for example, chemical risk assessment. Table 1 presents the definitions provided by EFSA (2006). These definitions consider the likelihood of events occurring in an ordinal manner without giving quantitative comparisons or bounds. In contrast, EFSA (2012) describes qualitative probabilities in terms of numerical bounds (see Table 2). There are a limited number of studies that have considered qualitative evaluation of the aggregated probability given in Equation (1) (Snary et al, 2012; Gale et al, 2014). In the examples which do exist, the estimate of probability has been undertaken subjectively, with assumptions being made on how to combine, for example a low p with a high n or a high p with a low n. To determine the most appropriate way to formalise this estimation, we break down Equation (1) into separate components.

We first consider the term $(1-p)^n$ and determine how this can be derived qualitatively. Literature searches (based on searching for animal health qualitative import assessments) have not identified any published papers that have formally considered this step. However, the evaluation of the product of two qualitative probabilities has been tackled. Several matrices for this product have been published (Gale et al, 2009; Gale et al, 2010; Wieland et al, 2011; Gale et al, 2014). Of these, the matrix of Gale et al (2010) is considered most appropriate from a mathematical point of view because it is based on the premise that probabilities can only take values between 0 and 1 and that the product of two probabilities is at most, the minimum of the two values (see Table 3). Wieland et al. (2011) present a matrix which follows the same approach, discussing the idea of conditional dependence between the two probabilities. The other papers have presented modifications to the matrix of Gale et al. (2010), at the lower end of the ordinal scale (Gale et al., 2009; Gale et al., 2014). These modifications are, to some extent, subjective and arise because of assumed quantitative ranges for the lower end qualitative probabilities in an attempt to account for the

problem that, for example, the product of two low probabilities may be lower than low. They are thus case-specific rather than general as per the case for the matrix in Table 3. Matrices also exist in other areas of application, for example, antimicrobial resistance (CVM, 2003), however they do not give justification for how probabilities are combined.

The evaluation defined in Table 3 for two qualitative probabilities could, in theory, be repeated n times to evaluate the term $(1-p)^n$. Because this matrix assumes that the product of two probabilities is at most the minimum of the two, the end result of the multiplication of n probabilities is the minimum of all n probabilities. In our case, because all n probabilities have the same value, that is, $(1-p)$, then the end result is $(1-p)$ and thus independent of n. Using this leads to a worst-case assumption; in reality the result may be a probability of a lower qualitative category and this effect will be amplified as n becomes larger.

Now that we have evaluated the component $(1-p)^n$ as $(1-p)$, we can substitute this result into Equation (1) and evaluate the remaining component. Substitution gives

$$P=p \qquad (2)$$

and thus the aggregated probability is independent of n. For the higher levels of p (e.g. Very High, High, Medium) this makes sense because if an individual unit is likely to be infected/contaminated then for a batch of units there will be a high chance of it containing at least one infected/contaminated unit. For the lower levels of p, the aggregated risk could, however, be under-estimated, that is, assessed as being of a lower qualitative category than is probably realistic, if n is high enough. This results because of the potential over-estimation of the product $(1-p)^n$ as discussed previously; if we over-estimate $(1-p)^n$ then we under-estimate $P=1-(1-p\ \ )^n$, that is P (Equation 1).

Under-estimating risk is not desirable and thus it would not be appropriate to use Equation (2) as a general rule. The degree of under-estimation will depend on the value of n, that is, the number of times that the term $(1-p)$ is multiplied together. As an alternative approach, we consider the qualitative value of n at which Equation (2) underestimates P. To investigate this, a semi-quantitative approach has been adopted. This approach creates a reference tool which can be shown in a graphical form.

2.2 General reference tool

Consider a qualitative probability category j (for example, Low or High) which covers a range of quantitative values from a lower bound (L_j) to an upper bound (U_j). If the value of individual probability p falls in this qualitative category then its value will lie in the range (L_j, U_j); when j=3 for example (Table 2), that is Low, the range is (L_3, U_3). In the previous qualitative derivation of Equation (2) it was concluded that the aggregated probability could be set to the same qualitative category as the individual probability p but that this may under-estimate risk We can investigate what value n would need to be for the aggregated probability to move to j+1, that is, the next level on the qualitative scale. Knowing this value of n would indicate where the assumption of P=p (Equation 2) breaks down and thus at what point a higher qualitative probability would need to be specified.

From Equation (1), for the aggregated probability to be a higher level than p we need

$$1-(1-p)^n > U_j \qquad (4)$$

Solving Equation (4) for n gives

$$n > \frac{ln(1-U_j)}{ln\ \ (1-p)} \qquad (5)$$

The inequality (relationship) in (5) can be considered in relation to the equation of a straight line to define cut-off values between qualitative levels with assumed bounds. From this, we see that the value of n depends on both the individual probability p and the upper bound. In many import risk assessments, the magnitude of n is known because the estimate is based on, for example, trade data. The problem of evaluating the aggregated probability is thus related only to where the individual probability lies on the (0,1) axis, assuming a set of bounds for the qualitative categories and a value of n. This can be represented graphically for a given set of qualitative bounds. A number of reports have proposed such bounds. However, many of these introduce different terminologies to describe the qualitative levels. For consistency, we use the definitions described by EFSA in their review (EFSA, 2012). These definitions match with those used by Gale et al. (2010) and are given in Table 2. The values shown in Table 2 were used to define a set of quantitative bounds (L_j, U_j) and P was calculated for values of p within these bounds and n ranging from 0 to 10^{10}. The calculated values of P were plotted as a contour plot as shown in Figure 1. The boundaries of the contours represent the inequality in Equation (5), for each qualitative category. For the Very Low category, the value of n which will result in P being of a higher order will cover a wide range because the range for this category is wide. For example, if the individual probability p is of order 10^{-7} (near the lower end of Very Low) then the value of n which will result in the aggregated probability P being Low will be of order 1,000. In contrast if p is of order 10^{-5} (near the upper end of Very Low) then for P to move to the Low category, n would need to be of order 10. For the other categories, the smaller ranges of p result in smaller ranges of n; a maximum of n=10 would be required for P to move to the next category. Note for plotting purposes, the negligible range is defined as 0 to 10^{-10}. In reality the lower bound for negligible will be infinitely small but not zero. Choice of this value could, of course, be considered subjective and could affect the aggregated probability calculations for negligible individual probabilities.

This graphical tool can be used to give an indication of the likely level of qualitative aggregated probability, given an individual probability level and magnitude of n. As an example, we can consider an individual probability p to be Very Low and n to be of order 10^6. Assuming that p falls in the middle of the Very Low range (on the log scale as in Figure 1) would give an aggregated probability of Medium. If p was in fact closer to Low then the resulting probability could be Very High. Even though this application relies on making assumptions concerning the possible magnitude of the individual probability p it can give an idea of the possible magnitude of the aggregated P and provide a range of uncertainty around that P.

2.3 Case Study

To investigate the use of Figure 1 in practice, it was applied to the import problem considered in a previously published qualitative release assessment for the likelihood of henipavirus entering the UK from a number of global zones via several import pathways (Snary et al, 2012). The table of results from Snary et al (2012) was modified to include only those zone and pathway combinations for which there was a quantitative estimate for the annual number of imports. In their study, pathway combinations were considered on a case-by-case basis and the aggregated probability was determined in a subjective way rather than by using any formal methodology. The main purpose of their paper was prioritisation of import pathways and the absolute estimates of probability were of less relevance. The authors do not provide details of how they aggregate n and p other than to say that if p is estimated as Negligible then the aggregated risk is also taken to be Negligible. They use the EFSA (2006) definitions for qualitative probability and the matrix of Gale et al. (2010) to estimate p. We compare the results of Snary et al. (2012) to the results we obtain from using Figure 1 on a case by case basis, that is, for each import pathway, rather than in terms of prioritisation. Our aim is to determine under what circumstances, if any, our approach would give a different aggregated probability. We determine the aggregated probability as well as a range to represent uncertainty. The ranges of uncertainty are derived by considering the upper and lower bounds of p.

3. Results and discussion

3.1 Case study

Table 4 compares the estimated aggregated probabilities from the original paper (Snary et al., 2012) with those evaluated using Figure 1. Where appropriate, estimates for P are also given in terms of a range. This range corresponds to the values of P resulting from p at the lower and upper bounds of the qualitative ranges on which Figure 1 is based. The ranges give an indication of the uncertainty associated with the aggregated probability arising from the fact that we cannot say with certainty where, between the lower and upper bounds, the probability lies. Results for 15 zone/pathway combinations are provided. From Snary et al. (2012), the majority of individual probabilities were estimated as Negligible (10 out of 15) with the remaining split between Very Low (4 out of 15) and Low (1 out of 15). The combinations are thus representative of the situation discussed previously whereby, for the lower categories on the qualitative scale, the value of n will be important in determining whether or not the aggregated probability is of a higher qualitative level than the individual probability.

Overall, the qualitative categories derived for P using our framework are of a higher order than those derived by Snary et al. (2012). In general, the aggregated probabilities reported by Snary et al. (2012) appear to follow the theory proposed in Equation (2), that is, the aggregated probability being assessed as equal to the individual probability meaning they could therefore be under-estimated The zone/pathway combinations for which there is concordance between our framework and the published results are mostly associated with Negligible individual probabilities and very small numbers of imports (of order 10). The exception is companion animals from zone 1, where both the individual probability and number of imports are higher. The ranges of uncertainty,

derived by considering the upper and lower bounds of p rather than the mid-points, are, to a certain extent, related to the value of n; the larger the value of n the wider the range. If prioritisation were to be considered, the overall results are consistent between the two methods; identifying Fruit from Zones 1 and 2 as the imported commodity with the highest probability. The results presented in Table 4 are dependent on the quantitative bounds, and thus the range of values within each category, given in Table 2 and assuming that the aggregated probability has the same defined bounds. Different results will likely be derived for a different set of bounds and there will be a relationship between these and the value of n. The FAO/WHO ranges for Low, Medium, High and Very High are relatively narrow and thus lead to wide ranges in the aggregated probability when n is large. Thus the bounds are important not only for the estimated P but also for the uncertainty.

4. Conclusion

Very few qualitative import risk assessments have considered the aggregated probability of introduction, that is, the probability of at least one infected/contaminated entry per group of import units. Those that have, are generally based on specific cases and do not follow a generic framework. Matrices for qualitatively evaluating the multiplication of qualitative probabilities, have been published. Applying such published matrices, could lead to assuming that individual and aggregated probability are equivalent. However, when the individual probability p is on the lower end of the qualitative scale and n is high, this assumption may break down and could lead to under-estimation of probability and thus risk. Here, as an alternative, we have used a transparent graphical tool for the qualitative derivation of the aggregated probability. Although using the graph relies on defining quantitative bounds for qualitative categories as well as an idea of the number of imports, and is thus case-specific, it removes some of the subjectivity that is often associated with deriving qualitative risk. Applying it to a previously published case-study demonstrated how it could provide more transparent estimates of probability and be more reliable for higher import numbers. It can thus be concluded that this approach may be useful for future qualitative assessments of

aggregated probability, provided that bounds for qualitative probabilities can be defined for the specific case situation.

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Table 1: Qualitative definitions of probability from EFSA (2006)

Probability category	**Interpretation**
Very high	Event occurs almost certainly
High	Event occurs very often
Medium	Event occurs regularly
Low	Event is rare but does occur
Very Low	Event is rare but cannot be excluded
Negligible	Event is so rare that it does not merit to be considered

Table 2: Quantitative bounds corresponding to qualitative categories from FAO/WHO reported by EFSA (2012)

Qualitative level	**Quantitative bounds**
Negligible (N): j=1	Indistinguishable from 0
Very Low (VL): j=2	$<^{10-4}$, except 0
Low (L): j=3	10^{-3} to 10^{-4}

Medium (M): j=4	10^{-2} to 10^{-3}
High (H): j=5	10^{-1} to 10^{-2}
Very High (VH): j=6	$>10^{-1}$, not 1
Certain: j=7	1

1

2

3

Table 3: Evaluation of the product of two qualitative probabilities from Gale et al. (2010)

Probability 2	**Probability 1**					
	Negligible	Very Low	Low	Medium	High	Very High
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
Very Low	Negligible	Very low	Very Low	Very Low	Very Low	Very Low
Low	Negligible	Very Low	Low	Low	Low	Low
Medium	Negligible	Very Low	Low	Medium	Medium	Medium
High	Negligible	Very Low	Low	Medium	High	High
Very High	Negligible	Very Low	Low	Medium	High	Very High

1 Table 4: Qualitative release assessment for the likelihood of henipavirus entering the UK:
2 comparison of the estimates of aggregated probability from Snary et al. (2012) and using the
3 framework in Figure 1.

4

Entry route	**Zone**	**p[1]**	**n[2]**	**P**	
				Snary et al. 2012	**Aggregated Method[3]**
Fruit bats	3	Very Low	22	Negligible	Very Low (Very Low – Low)
Companion animals	1	Very Low	1765	Very Low	Very Low (Very Low – High)
	2	Negligible	26	Negligible	Negligible
	3	Negligible	33,834	Negligible	Very Low (Negligible – Very Low)
Pigs	3	Negligible	438,725	Negligible	Very Low (Negligible – Very Low)
	2	Very Low	3	Negligible	Very Low
Raw/frozen pork products	1	Negligible	28	Negligible	Negligible
	3	Negligible	402,542	Negligible	Very Low (Negligible – Very Low)
Processed pork products	3	Negligible	369,771	Negligible	Very Low (Negligible – Very Low)
Fruit	1	Low	38,832	Low	Very High

	2	Very Low	117,823	Low	Medium (Very Low – High)
	3	Negligible	2,310,452	Negligible	Very Low (Negligible – High)
Fruit juice	1	Negligible	743	Negligible	Negligible (Negligible – Very Low)
	2	Negligible	10,209	Negligible	Very Low (Negligible – Very Low)
	3	Negligible	12,188	Negligible	Very Low (Negligible – Very Low)

1 [1]Denoted by Snary et al. as P

2 [2]Denoted by Snary et al. as N

3 [3] To determine P, the mid-point on the qualitative range is used. Ranges are also given for p at the

4 lower and upper bounds.

Figures

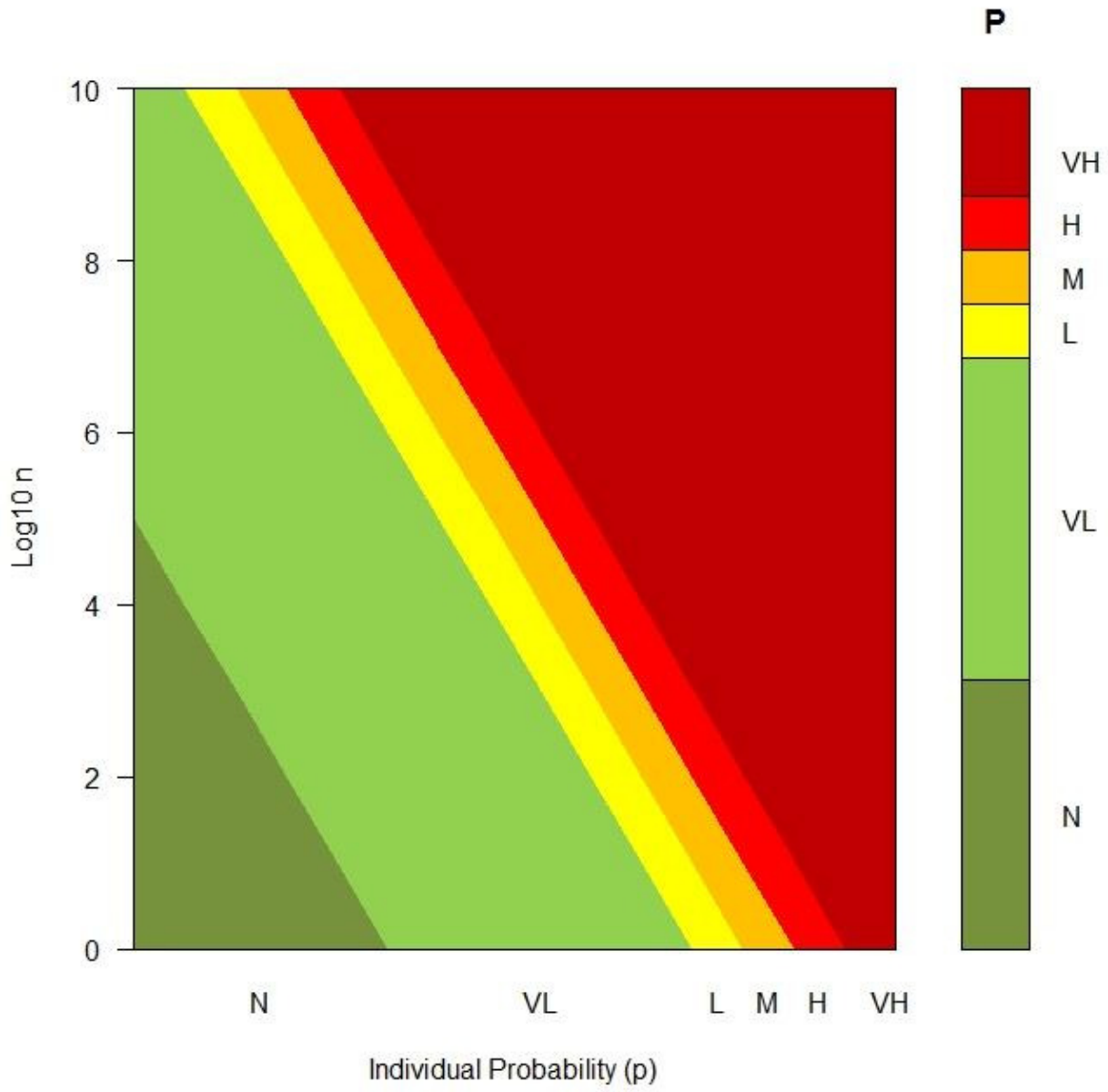

Figure 1: Contour plot for the aggregated probability P corresponding to the FAO/WHO qualitative bounds for the individual probability p. Note for plotting purposes, the negligible range is defined as 0 to 10^{-10} and thus the Very Low range is 10^{-10} to 10^{-4}