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Advisory Committee on the Microbiological Safety of Food

Fixed-term group on multidimensional representation of risks

Advises the Food Standards Agency on the Microbiological Safety of Food

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Section 1 - Introduction and background

1. The Advisory Committee on the Microbiological Safety of Food (ACMSF) identified the need to develop a multi-dimensional risk assessment framework for use in risk assessments considered by the Committee relating to microbiological hazards associated with food. In November 2018, the ACMSF established a sub-group to address this issue specifically. The group is comprised of existing ACMSF members and members co-opted for their expertise in the area. The group met for the first time in November 2018 and has met four times in total.

2. The FSA's current approach to microbiological risk assessment was endorsed by the Committee in 2012 and is based on an internationally recognised framework adopted by EFSA. The approach has also been one that the Committee has taken when offering risk assessment advice to the FSA. The approach assesses risk using a one-dimensional qualitative scale with six risk level descriptors based on the probability of an adverse effect occurring (negligible, very low, low, medium, high, very high) and is discussed further in the remainder of this paper. In 2012 the Committee considered a number of other possible approaches to represent qualitative risk assessment outputs at the time but concluded that the approach used by EFSA was the most suitable in terms of estimating the risks that are considered by ACMSF (Paper ACM/1065)[1].

3. Severity/impact were considered by the Committee when evaluating methods in 2012, but the EFSA approach (which does not consider impact) was deemed at the time to be the most straightforward and substantially better than previous approaches. This system has served the needs of ACMSF and the FSA well, but the Committee has increasingly become aware of examples

- [1] Paper ACM/1065 https://acmsf.food.gov.uk/sites/default/files/mnt/drupal_data/sources/files/multimedia/pdfs/committee/acm_1065.pdf provides further details and the ACMSF
- Minutes of May 2012 provide a record of the Committee's rationale https://acmsf.food.gov.uk/acmsfmeets/acmsf2012/acmsf290512/acmsfmin290512).

where the current framework has deficiencies for the types of risks it has been required to assess.

4. One drawback is that one-dimensional scales, where frequency is the sole indicator of risk, can lead to bias. For example, when considering the hazards *Campylobacter* and *Clostridium botulinum*, campylobacteriosis occurs more frequently than botulism which could result in the interpretation that it is more important, when using occurrence as a sole indicator of risk.

5. In 2012, the Committee also discussed approaches to assigning uncertainty to risk assessment (ACM/1065). As a result, uncertainty has been assigned routinely in risk assessments presented to the Committee and discussed by the Committee using the approach adopted by EFSA[2] where uncertainty (high, medium, low) is assigned to risk based on amount/quality of information/data. This framework is understood well in all areas of the risk analysis process and therefore advantageous over a numerical/statistical scale where it's possible that not everyone believes in the model used to generate the uncertainty. A drawback with this approach, is that it does not indicate the origin of the uncertainty; not all uncertainties can be attributed to lack of data, some are more profound, so there should be some way of representing different uncertainties. Over the course of discussions of this subgroup, it became apparent that in addition to data uncertainty, there is a need to consider both variability and model uncertainty. Model uncertainty or deeper uncertainty should encompass whether the science that has been included in the risk assessment is complete, incomplete etc.

6. This sub-group therefore saw the need to develop an improved risk assessment framework more suitable for the types of assessments that are currently handled by the ACMSF, a framework where risk is expressed in terms of both probability and impact in a two-dimensional manner, in addition to improvements in the communication of uncertainty.

[2] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5123

7. Multi-dimensional representation of risk was discussed by the group, but two-dimensional representation was agreed to be most appropriate form of representation at this stage. The group discussed in detail the most suitable ways to express risk in terms of probability and impact, reviewing qualitative, semi-quantitative and quantitative approaches. The group also reviewed the current approach to assigning uncertainty, making a small number of important improvements to the current approach.

8. The aim of this group's work is to produce a short, functional paper which proposes a new framework that is appropriate for food-specific risk assessments that are considered by the ACMSF. The group's proposed approach was presented in summary format to the main Committee in June 2019 and endorsed. A further update in a more finalised format will be presented to the Committee in October 2019.

9. **Proposed Terms of reference for the group**

- To propose a multidimensional representation of risk and total uncertainty that is suitable for food risks considered by ACMSF.
- The group's remit will include continued communication of its work and outputs to the ACMSF and the FSA.
- The group's remit will **not** include consideration of issues relating to risk management and risk communication (including perception).

Section 2 – Structure for representation of risk

1. ACMSF provides advice to the FSA on microbiological food safety and this advice often includes an expert risk assessment. Microbiological food safety issues considered by ACMSF often identify particular infectious micro-organisms and particular foods but also include risks from toxin producing bacteria and from more complex scenarios such as anti-microbial resistance. Recently, in many cases, the ACMSF assessment has included a summary in

the form of an assignment of the assessed risk to one category from a standard six category scale of risk (Negligible, Very Low, Low, Medium, High, Very High). This scale is used internationally by organizations such as EFSA (EFSA 2006). Additionally, ACMSF considerations generally include a standardised indication of uncertainty (Low, Medium, High) in relation to the information used in the assessment of risks (e.g. EFSA 2006)[3].

2. Both of the categorised scales used by ACMSF include some natural language interpretations to assist their implementations (See below). The qualitative risk level classification operated by ACMSF includes interpretations, as a guide for implementation, that relate most clearly to the frequency of occurrence of detrimental events e.g. a “Low” risk is interpreted as “rare but does occur”. This interpretation implies a dominantly one dimensional structure for ACMSF risk assessments, emphasizing the likelihood for occurrence and underplaying the role of severity and other components of risk, and there is some evidence that this is restrictive. At the 2018 ACMSF horizon scanning exercise the development of an extended scheme, which identifies and assesses additional components of risk explicitly, was established as a priority (ACM 1272).

3. A progression to multi-dimensional representation of risks is timely in relation to ongoing changes in the risks that are assessed by ACMSF. Risks associated with foodborne microbial hazards are experiencing a rapid increase in complexity and significant disaggregation. Changes are driven by new rapid and possibly conflicting sources of information. For instance, the increasing complexity of foodborne hazards can easily be observed in the advance of genotyping for bacterial pathogens and in the multi-objective outcomes that dominate many modern food safety issues e.g. simultaneous optimization of food safety and food waste or conflict between microbial safety

[3] [Microbiological risk assessment is very different from chemical risk assessment. Chemical risks generally involve cumulative exposures and chronic detriments in contrast to isolated exposures to microorganisms that cause acute illness (e.g. National Research Council of the National Academies 2009) In addition chemical risks can often be identified with particular modes of action, at molecular level, that are difficult to identify for microbiological agents. Structural motifs can be used to build systematic risk assessment strategies for chemical risks, such as ‘read across’, that reduce disaggregation and are currently unavailable for microbiological risk assessments.]

and chemical safety. Additionally, throughout risk science, there is an increasing awareness of the significance of low frequency and high impact events, so called “black swans” or “perfect storms”, which emphasizes the consideration of multi-dimensional representations for risk. Low frequency high impact events have recently been emphasized in cross-government considerations of risks e.g. Blackett Review of high impact low probability risks (GOS 2011). ACMSF progression to a multi-dimensional framework for representation of microbiological risks is consistent with the ongoing initiative of the FSA Science Council concerning best practice for establishing and communicating risk and uncertainty.

4. Multidimensional representations for risks are included in many current risk assessment frameworks. The Codex Alimentarius principles for risk analysis include two dimensions in a definition for risk as “A function of the probability of an adverse health effect and the severity of that effect, consequential to hazards in food”. The UK National Risk Register of Civil Emergencies (UK Cabinet Office 2017) includes risk matrices that employ “Impact Severity” and “Likelihood of Occurring” as two separate components. A two dimensional representation that includes the frequency of occurrence and the detriment (adverse effect) associated with an event as distinct components of risk is identified as the most suitable higher dimensional representation for the risks that are generally considered by ACMSF. This limited extension includes;

- Strong compatibility with the existing working practice of the ACMSF
- Implementation that is commensurate with the majority expertise of ACMSF members
- Consistency with many other schemes being used for representation of complex risks
- Increased ability to express discrimination between the risks that are considered by ACMSF and, therefore, potential for provision of improved advice to the FSA.

5. Many additional components, particularly those identified by social and behavioural sciences, can be considered in extended (multi-dimensional)

representation of risks. Social constructs such as the source of risks or psychological factors such as dread and control have been considered in higher dimensional representation of risk. These factors impact on the perception of risks, and affect behaviours with respect to risks, but their consistent representation is currently beyond the scope of the ACMSF.

6. The frequency of occurrence, and the detriment, associated with food borne hazards can often be considered in both qualitative and quantitative frameworks. Fully quantitative expressions are often considered superior but generally involve data resources and expertise that are not always accessible. ACMSF experience is dominated by qualitative representation of risks but FSA aims and aspirations include a much stronger quantitative appreciation. Efficient progression to a multi-dimensional view of risks, for ACMSF, maintains a default qualitative representation but acknowledges parallel quantitative expressions where these are useful and easily accessible.

7. The six category qualitative scale (EFSA 2006) previously used by ACMSF for expression of risk in a one dimensional framework is a natural choice for the representation of the frequency of occurrence component of adverse events in a two dimensional representation. In this scheme the terminal categories for the frequency of occurrence are “Negligible” (So rare that it does not merit to be considered) and “Very high” (Events occur almost certainly). The boundaries between categories for the frequency of occurrence are not uniquely defined so that assignment of the frequency to any particular category includes some subjectivity in the risk assessment. However, this scheme has an improved clarity when it is used to assess the frequency of occurrence of foodborne hazards in isolation as a component of a multi-dimensional representation.

A qualitative scale for the frequency of occurrence of foodborne risks (EFSA 2006):

Frequency category	Interpretation
Negligible	So rare that it does not merit to be considered
Very Low	Very rare but cannot be excluded
Low	Rare but does occur
Medium	Occurs regularly
High	Occurs very often
Very High	Events occur almost certainly

8. Within the proposed ACMSF scheme for representing risks the qualitative intervals, and their natural language descriptions, are the primary means for assigning a frequency to a risk event (Alternative descriptions of the category definitions are included in Kahn et al. 1999). However, to assist dialogue, the qualitative scale can be aligned with an indicative numerical scale for the frequencies of occurrence of risk events considered by ACMSF. An indicative numerical scale would assign frequencies 0.0017, 0.05, 1.7, 50 and 1700 cases per 100,000 person years to the category boundaries of the ACMSF qualitative scale (See Annex B). The upper boundary of the category representing negligible risk is consistent with a 'safe' condition, a probability of 10^{-8} per event, that is widely accepted in consideration of foodborne botulism (this condition is distinct from the twelve orders of magnitude reduction in spore numbers that sets the criterion for a safe botulinum cooking process.

9. Adverse effects associated with food-borne illness vary from mild self-limiting symptoms of gastrointestinal infection to very severe potentially fatal systemic conditions such as HUS. It is particularly difficult to provide a single scale of detriment which captures the full variation in outcomes some of which may be long term and complex. Although there have been some attempts to translate all health outcomes onto a unifying scale, such as Mortality, DALYs, QALYs, the fraction of severe cases or the cost per case, these all introduce problems associated with interpretation and communication and therefore are not suitable for primary representation of the risks considered by ACMSF. A descriptive four category scale used by the International Commission for

Microbiological Specifications of Foods (ICMSF 2002)[4] identifies severity categories Negligible, Low, Medium or High accompanied by natural language definitions (see below). Although this assessment of severity includes some element of subjectivity (e.g. different experts might assign the severity associated with *Campylobacter* as Low or Medium) it is considered most suitable for an extended representation of risk by ACMSF. Alternative qualitative categorizations of impact severity are used by the WHO and by the UK National Risk Register etc. (UK Cabinet Office 2017).

A qualitative scale for the severity of detriments of foodborne risks (ICMSF 2002):

Severity category	Interpretation
Negligible	No effects, or so mild they do not merit to be considered
Low	Mild illness: not usually life-threatening, usually no sequelae, normally of short duration, symptoms are self-limiting (e.g. transient diarrhoea)
Medium	Moderate illness: incapacitating but not usually life-threatening, sequelae rare, moderate duration (e.g. diarrhoea requiring hospitalisation)
High	Severe illness: causing life-threatening or substantial sequelae or illness of long duration (e.g. chronic hepatitis)

10. Within the proposed ACMSF scheme for representing risks the categories of the qualitative scale, and their natural language descriptions, are the primary means for assigning a detriment to a risk event. However, to assist dialogue, the qualitative scale can be aligned with an indicative numerical scale for the impact of risk events considered by ACMSF. An appropriate indicative numerical scale uses time as a common metric to capture the impacts of foodborne illness, including important sequelae, and specifically is based on Disability Adjusted Life Years; DALYs are an international concept for representing the burden of disease. The indicative scale assigns values of 0.001, 0.01, 0.1 DALYs per case to the category boundaries of the proposed ACMSF qualitative scale for detriment (See Annex B). The upper boundary for the Negligible category of detriment corresponds with less than half a day lost

[4] The ICMSF scale of detriment is updated in the second edition of volume 7 of Microorganisms in Foods (ICMSF 2018) and extends the scale of severity to 5 categories by partitioning the highest severity into three sub-categories based, to some extent, on the nature of the exposed population. This extension is not included in the proposed ACMSF scheme for assessment of severity.

through disability following foodborne illness. The DALY values for particular foodborne illnesses are regularly reported and updated e.g. WHO (It is important to acknowledge that in other considerations of food borne risks, notably in the assessment of the UK population burden of food borne illness, the FSA adopts the closely related QALY scale to quantify detriments).

11. Expression of uncertainty, as an integral part of risk assessment, has recently been the subject of major considerations by the FSA Science Council and by the EFSA. Total uncertainty, often partitioned into reducible information uncertainties and irreducible population variabilities, arise from many sources within each risk assessment. Information uncertainty encompasses both statistical uncertainty associated with incomplete data and 'deeper uncertainty' associated with incomplete knowledge about underlying science etc. e.g. Spiegelhalter and Riesch (2011). An extended ACMSF scheme for representing risks should incorporate expressions of uncertainty for each component of the risk. As a first approximation the two components of uncertainty are considered to be independent although, in practice, correlations may exist (and strictly a joint probability is appropriate).

12. Uncertainty associated with the assessment of the frequency of occurrence, for a particular foodborne risk, is most clearly identified with statistical (data) uncertainty. EFSA, and currently ACMSF, express the uncertainty associated with incomplete data using a qualitative scale that has three categories, Low, Medium and High, which are given natural language interpretations (see below and Annex A). This scheme is suitable, and relatively easily implemented, for an ACMSF assessment of the frequency of occurrence component of a foodborne risk. For clarity this expression of statistical uncertainty should also include a description (free text) of the population at risk e.g. all consumers, consumers of rare burgers etc.

A qualitative scale for the level of uncertainty in food risk assessment:

Uncertainty category	Interpretation
Low	There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions
Medium	There are some but no complete data available; evidence is provided in small number of references; authors report conclusions that vary from one another
High	There are scarce or no data; evidence is not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them

13. Uncertainty associated with the assessment of the severity of the impact, for a particular foodborne risk, is most clearly identified with population variabilities. Relevant variability may occur in multiple populations simultaneously e.g. in the population of exposed cases, in the population of agents, in the population of doses etc. Additionally, there is often information uncertainty associated with specification of the (parameters of) population variabilities. Complexity ensures that detailed specification of uncertainty, for the assessment of severity of the impact for a foodborne risk, is impractical. For consistency an extended ACMSF multidimensional representation of risks adopts the same qualitative three category scale (above) for assessment of the uncertainty associated with detriment. In addition, the assessment of the uncertainty associated with detriment should including a remark (free text) concerning the variability in the populations considered.

14. Complete implementation of the extended multi-dimensional representation of risks, outlined above, includes 5 steps;

- Assign the assessment of the frequency of occurrence for an adverse event to one of six exclusive and exhaustive categories for frequency (Negligible, Very Low, Low, Medium, High, Very High)
- Assign the assessment of the severity of the detriment for an adverse event to one of four exclusive and exhaustive categories of severity (Negligible, Low, Medium, High)
- In a remark assign the statistical uncertainty associated with the assessment of the frequency of occurrence to one of three exclusive and exhaustive categories of uncertainty (Low, Medium, High) and identify the exposed population that underlies the frequency assessment.
- In a remark assign the statistical uncertainty associated with the assessment of the detriment to one of three exclusive and exhaustive categories of uncertainty (Low, Medium, High) and identify variabilities in the populations that underlie the assessment of severity of detriment (particularly the populations of exposed individuals and harmful agents).
- In a remark address the level of confidence, doubt and caution surrounding the science that underlies the assessment of risk.

15. The proposed ACMSF scheme for representing risk assessment does not include an indicative scale for quantification of the uncertainties associated with the assessments for frequency or detriment. Although many other areas of science include scales for uncertainties (notably based on multiples of standard deviations etc.) these are usually associated with random observation errors (Type I). In relation to food risk assessment this could be misleading because both the frequency of occurrence and the severity of the detriment are subject to very complex sources of uncertainty.

16. Increasingly risks, including those considered by ACMSF, include elements which are not easily placed within the scope of current peer reviewed science and this introduces uncertainties or indeterminacies that are called “deeper uncertainties”, “unknown unknowns” or model uncertainties. These uncertainties are often the major source of criticism or conflict in relation to risk analysis or decision making. Detailed consideration or analysis of these elements is outside the scope of ACMSF risk assessment but, in relation to the provision of advice, it is prudent to include a remark alongside risk assessment that expresses confidence, doubt or caution in the underlying science (and so separates model uncertainty from other sources). Caution may include identification of any situation in which the assessment of risk is

strongly sensitive to particular input information or where the tails of statistical distributions are considered important etc. Some risk assessment processes, in particular that suggested by the Intergovernmental Panel for Climate Change, have introduced systematic structures for expressing levels of understanding of complex risks and quality of evidence (e.g. GRADE Spiegelhalter and Reisch 2011) but currently these do not fit into an extended scheme suitable for ACMSF.

17. The ACMSF extended multidimensional scheme for representing risks can be considered as a 4x6 risk matrix construction that is supported by three remarks that relate to uncertainty (the 24 two-dimensional categories are not annotated). Although the two dimensions of risk can be assigned to indicative numerical scales the categorical assignments are the default implementation (numerical values can contribute to expert dialogue but are not intended to be part of risk communications). Risk matrix constructions are known to have some drawbacks in relation to risk assessment, e.g. Cox (2008), Kelly et al. (2018), but are considered optimal for implementation within the structure and role of the ACMSF.

18. Implementation of the proposed scheme does not require short term changes for operations of the FSA or the ACMSF. In particular risk assessments, prepared by the FSA and the ACMSF secretariat, in accord with the established framework that includes hazard identification, exposure assessment, dose-response and risk characterizations support the two-dimensional representation of risks. The processes for evaluation of evidence, and the development of advice, which are used by the ACMSF are unchanged although the deliberative output is extended with additional structure and improved clarity. As a consequence the ACMSF risk assessment and decision support process, operating according to the proposed scheme, is (as illustrated in case studies below) substantially backwards compatible with established operations. In medium and long term the risks considered by the FSA are expected to increase in complexity and assessments may involve increasing elements of quantification. The functional separation of the frequency of occurrence and the severity of the

detriment, and the additional explicit considerations that relate to the quality of science and evidence, enables the proposed assessment scheme to accommodate some of the current trends in risk science. In particular the progressive structuring of risks included in the proposed scheme increases the opportunities to combine quantitative components of an assessment with semi-quantitative or qualitative elements without necessitating a complete probabilistic model development. Mathematical modelling and machine learning etc. are increasingly important components in the appreciation of complex systems, such as food risks, and the proposed scheme for assessment can accommodate some of these developments within a practical approach that is essential for efficient FSA and ACMSF operation.

Section 3 – Example case and discussion

1. At the June 2016 meeting the ACMSF considered a draft assessment of the risk related to exposure to the Zika virus via the food chain (ACM/1220). The ACMSF agreed that the risk was “Negligible” on a one dimensional, six category, scale of risk and identified three uncertainties that were each identified with “Medium” on a three-category scale of uncertainty. Following the ACMSF consideration the draft assessment was updated by the FSA and presented to a subsequent ACMSF meeting, in January 2017, as information (ACM/1252). The same risk assessment can be considered using the proposed five step process;

- Assessment 1 (Frequency of occurrence) - ***Negligible*** (So rare that it does not merit to be considered)
- Assessment 2 (Severity of detriment) - ***Low*** (Mild illness: not usually life-threatening, usually no sequelae)
- Remark 1 (Uncertainty in occurrence) - ***Low***: The frequency of occurrence relates to all UK food consumers and to meat and fresh produce currently imported from countries where the Zika virus is present.
- Remark 2 (Uncertainty in detriment) – ***Medium***: It is possible that outcomes are more severe in vulnerable groups, such as children, and in South America there is a significant association between Zika infection and very severe outcomes (foetal microcephaly) during pregnancy.
- Remark 3 (Deeper uncertainty): The science of Zika virus is not complete and not conclusive in areas that include potential animal hosts, mechanisms for transmission to humans, stability outside the host and detection/enumeration in food.

2. This assessment is commensurate with the initial ACMSF assessment but includes additional structure and improved clarity. In particular the assessment indicates some confidence in the absence of the Zika virus in the current UK food supply but it also highlights the position of severe, but rare, outcomes that dominate some other considerations of risk.

Annex A – Interpretations of categorical scales

A qualitative scale for the frequency of occurrence of foodborne risks (EFSA 2006):

Frequency category	Interpretation
Negligible	So rare that it does not merit to be considered
Very Low	Very rare but cannot be excluded
Low	Rare but does occur
Medium	Occurs regularly
High	Occurs very often
Very High	Events occur almost certainly

A qualitative scale for the severity of detriments of foodborne risks (ICMSF 2002):

Severity category	Interpretation
Negligible	No effects, or so mild they do not merit to be considered
Low	Mild illness: not usually life-threatening, usually no sequelae, normally of short duration, symptoms are self-limiting (e.g. transient diarrhoea)
Medium	Moderate illness: incapacitating but not usually life-threatening, sequelae rare, moderate duration (e.g. diarrhoea requiring hospitalisation)
High	Severe illness: causing life-threatening or substantial sequelae or illness of long duration (e.g. chronic hepatitis)

A qualitative scale for the level of uncertainty in food risk assessment:

Uncertainty category	Interpretation
Low	There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions
Medium	There are some but no complete data available; evidence is provided in small number of references; authors report conclusions that vary from one another
High	There are scarce or no data; evidence is not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them

Annex B - Indicative scaling of frequency of occurrence for food risks

A1. The proposed ACMSF scheme for multidimensional representation of risks adopts the EFSA 6-category qualitative classification for the frequency of occurrence (Negligible, Very low, Low, Medium, High and Very high). Although the qualitative nature of this scale is dominant there may be some cases where an indicative numerical scaling is helpful. Mapping the six frequency categories onto numerical ranges is not a rigorous process but can be guided by experience of events and risks that are commonly considered by ACMSF.

A2. An effective indicative mapping of event frequencies should be intuitive and appropriate to the considerations made by ACMSF. Where possible an ACMSF scheme should maintain consistency with mappings used by other risk assessment schemes.

A3. Campylobacteriosis, Salmonellosis, Listeriosis and foodborne botulism could be considered sentinel hazards considered by ACMSF (alternative choices, including other bacteria, viruses or parasites could be chosen). The corresponding annual numbers of UK confirmed cases (based on recent communications by the UK FSA e.g. Report from the Epidemiology of Foodborne Infections group of the ACMSF 2018 ACM 1271) are approximately 72000, 9000, 200 and 1 (rates per 100,000 person years are correspondingly 120, 15, 0.33 and 0.0017). Although these numbers are uncertain and vary with time they provide convenient location points for mapping the central four categories (High, Medium, Low and Very Low) used by the qualitative classification of the frequency of occurrence for food risk. The simple quantitative interpretation of frequency does not account for temporal organization of cases (outbreaks, epidemics and seasonality) and is strictly distinct from the detriment associated with particular cases.

A4. A natural extension of the sentinel location of the frequency classes leads to an identification of exclusive and exhaustive frequency intervals that span the range of observed frequencies of food safety risks. One set of intervals that fits with the sentinel identification would map Negligible, Very low, Low, Medium, High and Very high frequencies onto ranges < 1, 1 – 30, 30 – 1000, 1000 – 30000, 30000 – 1000000, > 1000000 UK cases per year (corresponding interval boundaries for the

rate per 100,000 person years are 0.0017, 0.05, 1.7, 50 and 1700). The development of this indicative scaling uses numbers of confirmed cases; for many pathogens the ascertainment of cases of foodborne illness is problematic so that quantitative interpretation of the frequency of occurrence includes additional uncertainties.

A5. In 1996 Sir Kenneth Calman, UK Chief Medical Officer, proposed a qualitative "language of risk" based on six categories for the probability of occurrence of general health risks with an associated numerical mapping. The probability categories were identified by Negligible, Minimal, Very low, Low, Moderate and High and these were mapped onto intervals of probability $< 10^{-6}, 10^{-6} – 10^{-5}$, $10^{-5} – 10^{-4}$, $10^{-4} – 10^{-3}$, $10^{-3} – 10^{-2}$, $> 10^{-2}$. The scheme proposed for ACMSF is only applicable to a subset of health risks (food borne illness) and the corresponding closed intervals span a larger range of values than those proposed in 1996. The language of risk showed that a numerical scale of probability in isolation could not provide strong support for risk based decision making. In the United States a numerical scale of risks, covering probability range $[10^{-12} – 1]$, the Paling perspective scale, is combined with some semantic descriptions for assessment of a wide variety of risks including toxicology and environmental risks.

A6. In the UK National Risk Assessment a Pandemic Influenza event is assigned to category 4 of the (5 category) likelihood scale. In the UK this likelihood is associated with a single event, in which 50% of the population have symptoms of influenza, occurring during a five year period. A time average (not strictly appropriate for a single epidemic event) corresponds with ~6,000,000 cases per year (10,000 cases per 100,000 person years) and would correctly map onto the Very high frequency category in the proposed ACMSF scheme.

A7. The numbers used to describe a frequency scale for food borne illness in the proposed ACMSF scheme are purely indicative and the numeric intervals should be considered to be "fuzzy" (any frequency of interest should be weighted with respect to membership of all the intervals). Alternative numerical intervals may be equally valid. Within the proposed ACMSF scheme for representing risks the qualitative intervals, and their natural language descriptions, are the primary means for assigning a frequency to a risk event. Quantitative estimates of frequencies of

occurrence for food borne hazards are intended to assist dialogue between professionals as part of risk assessment and are not intended as a part of risk communication.

Annex C - Indicative scaling of severity of detriment for food risks

A8. The proposed ACMSF scheme for multidimensional representation of food risks adopts the ICMSF 4-category qualitative classification for the severity of impacts (Negligible, Low, Medium, High). Although the qualitative nature of this scale is dominant there may be some cases where an indicative numerical scaling is helpful. Mapping the four detriment categories onto numerical ranges is not a rigorous process but can be guided by experience of risks that are considered by ACMSF and by some international efforts to quantify the burden of disease, at a population level, on a global scale.

A9. An effective indicative mapping of detriments should be accessible and appropriate to the considerations made by ACMSF. Where possible an ACMSF scheme should maintain consistency with mappings used by other assessment schemes.

A10. Quantification of the detriment for foodborne disease is particularly difficult because individual outcomes from illness vary from mild self-limiting symptoms to life threatening consequences and death. A single metric that captures the full diversity of health outcomes for food borne illness has not been established. Additionally some acute infections are associated with (and cause?) long term sequelae such as arthritis, which add to detriment, and many mild or asymptomatic cases are not reported so are statistically under weighted in an assessment of impact. An additional complexity associated with quantification of the detriment arises because the consequences of foodborne illness are often spread over time, following an initiation event, so that attribution of outcomes and aggregation of the total burden from a single infection event presents a significant methodological challenge.

A11. Case mortality rate, the fraction of hospitalizations and the economic cost per case have all been considered as measures of impact for foodborne illness but a variety of Health Adjusted Life Years metrics, and particularly Disability Adjusted Life Years (DALY), are widely considered most suitable (Murray 1994). DALYs quantify the impact of an adverse event on health as a combination of the number of life years lost due to premature death and the number of life years lost due to disability.

The second component requires some ‘disability weighting’, associated with lower quality of life in the presence of disease, which is subjective. In many cases disability weights have been agreed internationally to allow comparisons of disease burden across regions and across diseases (e.g. The Global Burden of Disease project – Murray, Lopez 1997).

A12. Recent reviews, such as that completed by the WHO Foodborne Disease Burden Epidemiology Reference Group (Havelaar et al. 2015), indicate that the number of DALYs lost per case of food borne illness has a very large range. However for the majority of diarrheal diseases DALY values are clustered in a narrower range of detriments, that cover approximately two orders of magnitude on the DALY scale, 10^{-3} < DALYs per case < 10^{-1}. This clustering prompts a simple indicative quantification for the scale of detriment that can be included in the proposed ACMSF scheme for risk assessment. In this indicative mapping detriment classes described as Negligible, Low, Medium and High map onto ranges < 10^{-3}, [10^{-3} – 10^{-2}], [10^{-2} – 10^{-1}] and > 10^{-1} DALYs lost per case; in this partition the majority of diarrheal foodborne illness is commensurate with Low and Medium severity identified by the ICMSF classification. This mapping is not unique and it is important to appreciate that the DALY quantification is not easily identified with the natural language descriptions for the categories of the detriment (the DALY quantification includes elements of integration, such as a sum over rare but severe sequelae, that may be indicated by remarks in the proposed ACMSF scheme).

A13. The evaluation of DALYs for particular foodborne illnesses is a complex process, combining collected data and expert opinion, which includes the construction of an outcome tree to capture important sequelae, definition of disability weights to quantify morbidity and integration of demographic information to account for stratification within populations. However many quantifications have been established and are regularly updated. As examples typical values ~0.07, ~0.001 DALYs per case are consistently assigned to illness associated with non-typhoidal *Salmonella* and with *Bacillus cereus* respectively (e.g. Mangen et al. 2013); these values correspond with Medium and Low categories for the detriment in the proposed ACMSF scheme for risk assessment that would be consistent with many expert assessments on the qualitative scale. The severity of illness associated with

Listeria monocytogenes can only be categorised as high and, in this case, widely used quantifications generally assign ~1 DALY per illness.

A14. Although the quantitative assessment of detriment using DALYs includes uncertainty, has some subjective elements and may omit complex dynamics it provides a consistent and accessible representation for the severity of impacts of food risks. DALY values for foodborne illness can be effectively aligned with the four categories used by the qualitative ICMSF scale for detriments. Approaches based on Health Adjusted Life Years do not fully capture some societal detriments that can be associated with foodborne illness and have only limited ability to include the effects sometimes associated with time variation of disease incidence. The DALY approach is used widely, by organizations such as the WHO, to quantify the burden of disease and so provides a method for strong comparative considerations and effective communications concerning food risks.

A15. Alternative quantifications of detriments for cases of foodborne illness are difficult to compare, directly, with the scale based on DALYs. Notably in the United States a monetary scale, Cost-of-Illness, estimates the costs of medical care and lost productivity etc. as a proxy for impact and is used widely for resource allocation and priority setting. Alternatively a willingness-to-pay metric is sometimes used to quantify health impacts and some implementations of the DALY scale are monetised to support cost-benefit analyses. Although dollar values generally stretch the scale for burden of illness of foodborne disease, e.g. in 2015 in the US the cost per case for listeriosis was estimated as more than $2M and the cost per case for non-typhoidal salmonellosis was $3000 (Hoffmann 2015), they generally preserve the ranking of detriments that arise from distinct causal agents and therefore are largely consistent with the mapping of DALYs indicated above. Often the cost associated with hospitalization and death dominates money based quantification so that economic scales are not universal.

A16. The quantification of detriments of foodborne illness, using DALYs, in the proposed ACMSF scheme are purely indicative and the numeric intervals should be considered to be “fuzzy” (any detriment of interest should be weighted with respect to membership of all the intervals). Alternative numerical intervals may be equally valid. Within the proposed ACMSF scheme for representing risks the qualitative

intervals, and their natural language descriptions, are the primary means for assigning an impact severity for a risk event. Quantitative estimates of detriments for foodborne hazards are intended to assist dialogue between professionals as part of risk assessment and are not intended as a part of risk communication.

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