Reply of the European Union to

CL 2021/4/OCS-FH:

Draft Guidance for the Management of Biological Foodborne Outbreaks

Mixed Competence European Union Vote

The draft guidance at step 6 appears very advanced and logically sound, addressing all aspects of detecting and monitoring foodborne outbreaks with associated risk communication and risk management within a network setting. Accordingly, the European Union and its Member States have only few comments as follows for possible improvements.

1. INTRODUCTION

<u>Point 2:</u> For reasons of consistency, the words 'food-borne' should not be hyphenated and should read 'foodborne' as is spelled throughout the remainder of the document.

Furthermore, we suggest that: [...] be mild with recovery in days [..] is changed to [...] be mild with recovery within days [...].

<u>Point 7.</u> If e.g. biogenic amines or toxins are responsible for the outbreak, molecular methods are of limited use.

Furthermore, this point addresses the molecular methods that may be used to detect outbreak strains that may be associated with clusters of human cases. The methods mentioned here include pulsed field gel electrophoresis (PFGE), whole genome sequencing (WGS) and multilocus sequence typing (MLST). Points 48 and 49 (Foodborne Outbreaks-Preparedness System; Section D, Analytical Methods) address serotyping (point 48), PFGE, multi-locus variable number of tandem repeats (MLVA) as well as WGS (point 49). The section Foodborne Outbreak Management; Section C, Combining Epidemiological and Laboratory Data discuss with regard to WGS differences cut-off values for strains according to alleles (which relates to cgMLST) or single nucleotide polymorphisms (SNPs), which relates to SNP analyses of WGS.

While we do appreciate that different countries or participating laboratories have different methodological abilities and capacities, we find that the different methods addressed in the different sections may lead to confusion as to the relevance why these were proposed in the different sections. Harmonization regarding the methods proposed in the document would lead to a clearer understanding that all methodologies may be relevant and would avoid confusion. Alternatively, the methodologies in the sections may be harmonized or moved to a table and referred to in the different sections.

Furthermore, point 48 (section Foodborne Outbreaks-Preparedness System; Section D, Analytical Methods) states that "In some cases basic typing information such as serotype may be enough to allow such linkage" (of pathogen with food source and outbreak cluster). We

think that this could lead to potential problems, as this method in some cases clearly may not have enough resolution to confidently link a strain to both food source and human outbreak cluster. Halbedel et al. (2018) showed that different clonal lineages from outbreak strains in Germany had the same serotype. Accordingly, serotyping of an outbreak strain from a human cluster may not suffice if different clonal lineages are circulating at a specific time as in the case of concurrent outbreaks. Thus, advanced methods such as cgMLST or SNP analyses of whole genome sequences would be far more suitable for such typing of pathogens.

Reference:

Halbedel, S., Prager, R., Fuchs, S., Trost, E., Werner, G., Flieger, A. 2018. Whole-genome sequencing of recent Listeria monocytogenes isolates from Germany reveals population structure and disease cluster. Journal of Clinical Microbiology 56:e00119-18. https://doi.org/10.1128/JCM.00119-18.

<u>Point 64:</u> In the Section Foodborne Outbreak Management; Section A, Identifying and Investigating a Foodborne Outbreak it is stated that "information on the food item consumed, the place and time of consumption etc...." should be included. This assumes that the consumer is capable of clearly identifying which food item was the cause for the illness. However, as pathogens (a) typically occur in low numbers and do not impart sensory defects on the contaminated food item and (b) have differing incubation times until onset of the disease symptoms, it would be important to define the time span (i.e., 24 h or 48 h?) for which the consumer should recall which food items that could a be possible source of the infection were consumed.

<u>Point 95:</u> In the section Maintenance of the Networks; Section A, Review of Existing Preparedness, the monitoring and evaluation of networks are addressed. Specifically, it is stated that "An 'after action review system' for foodborne outbreaks should be implemented within the network". The wording for this is quite non-specific and the phrase 'after action review system' is in quotation marks. We suggest that a better description could possibly be: a 'post-outbreak network review system', as this would describe what the system is about in more accurate terms.

Annex III: Annex III gives an example of a template for an outbreak analysis. In the second category ("Analytical Information / Human cases") for human cases it is stated that an overview of human cases reported including hospitalizations and deaths, as well as the severity of the illness, should be supplied. We suggest that this information would benefit from supplementary data such as the affected subgroups of the population (e.g. elderly or children), as this would also be in line with the recommendations in section Foodborne Outbreak Management- Section D, Rapid Risk Assessment and Outbreak Analysis, point 85, where it is mentioned that "results from epidemiological and microbiological investigations of human outbreak cases, considering severity, possibly mortality, spread of cases and affected subgroups (e.g., elderly)" should be included in an outbreak analysis.