

C0401

Sources of data and assessment for microbiological risk characterisation

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Risk characterization represents the final step in risk assessment. As such, it should provide an integrative and balanced overview of the preceding steps of risk assessment, i.e., hazard identification, dose-response and exposure assessment, so as to generate reliable information for risk managers and communicators within a sound risk analysis agenda. Therefore, major concerns for reliable risk characterization are data sources and quality, coupled with appropriate inferences given variability and uncertainty. This rationale becomes particularly relevant considering the ubiquity, inherent sensitivity and complexity of the dairy chain. In the case of microbiological risk characterization, an often overlooked issue relates to pathogen pre-exposure to non-lethal stressors, which induces substantially increased resistance to subsequent exposure to lethal levels of the original stressor, in addition to cross-protection of the pathogen to a broad range of other stressors and increased virulence. As a result, key issues starting with hazard identification should also account for possible physiological states of the pathogen as altered by stress factors, the approximate statistical distribution of the pathogen in relevant points of the dairy chain, and the sensitivity of reference pathogen quantification methods given an often assumed, typically conservative minimum infective dose (MID). In turn, the latter is challenged in two fundamental ways: increased, and often unpredictable, sensitivity of important consumer sub-populations, such as the elderly, infants, pregnant and immunocompromised individuals, which may be further potentiated by increased pathogen virulence due to stress factors. This renders the interpretation of possibly available dose-response curves a challenging proposition. Finally, exposure assessment poses similar challenges, given the uncertainty and variability associated with the actual exposure of the target populations to the relevant dairy foods. This critical overview presentation explores these issues as especially applied to the severe infective pathogens *Listeria monocytogenes* and *Cronobacter sakazakii*, both of major concern for the dairy chain worldwide. Collectively, the evidence herein presented suggests that the quality of microbiological risk characterization protocols, and of the resulting broader risk analysis agenda, would benefit from increased awareness and careful computation of these influential issues.

