Food Control 58 (2015) 29–32

Contents lists available at ScienceDirect

Food Control

journal homepage: www.elsevier.com/locate/foodcont

# A risk-based microbiological criterion that uses the relative risk as the critical limit

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ARTICLE INFO

*Article history:*
Received 30 December 2013
Received in revised form
28 February 2015
Accepted 17 April 2015
Available online 25 April 2015

*Keywords:*
Risk assessment
Food safety control
Risk-based microbiological criteria
*Campylobacter*

ABSTRACT

A risk-based microbiological criterion is described, that is based on the relative risk associated to the analytical result of a number of samples taken from a food lot. The acceptable limit is a specific level of risk and not a specific number of microorganisms, as in other microbiological criteria. The approach requires the availability of a quantitative microbiological risk assessment model to get risk estimates for food products from sampled food lots. By relating these food lot risk estimates to the mean risk estimate associated to a representative baseline data set, a relative risk estimate can be obtained. This relative risk estimate then can be compared with a critical value, defined by the criterion. This microbiological criterion based on a relative risk limit is particularly useful when quantitative enumeration data are available and when the prevalence of the microorganism of concern is relatively high. The use of the approach is therefore illustrated with an example of *Campylobacter* in broiler meat. It shows that this microbiological criterion can be applied in practice. An advantage of the method is that the acceptable limit is directly defined in terms of risk, without the need to define other food safety standards.


## 1. Introduction

The purpose of a microbiological criterion (MC) is to define the acceptability of a food lot based on the results of an analytical test performed on a specified number of samples from the lot. In a traditional microbiological criterion, the limit in a two-class plan has been defined by a maximum number of bacteria ($m$) that may be found in no more than a specified number of analytical units ($c$) among a specified number sampled ($n$). The parameters are most often set on the basis of the implicated food safety, as well as consideration on what is feasible and practically possible for the food manufacturers. The precise correlation between MC and consumer risk is not well defined, in particular when dealing with hygiene indicators, but also with respect to pathogenic microorganisms in raw and ready-to-eat food.

With the advancement of microbiological risk assessment, it has been proposed to define "risk-based" MC in the context of risk-based food safety standards (Van Schothorst et al., 2009). For such risk-based MC, risk assessments are applied to link the criteria to the level of protection that can be achieved by their implementation. In some approaches this has been done by linking the Appropriate Level of Protection (ALOP) via the Food Safety Objective (FSO) and the Performance Objective (PO) to the microbiological criterion. The approach presented here describes a way to link the test results directly to a level of risk without using a microbiological limit in terms of $m$ and $c$. It falls within the definition described by the Codex Alimentarius Commission in its principles and guidelines for the establishment of an MC: "*A microbiological criterion is a risk management metric, which indicates the acceptability of a food, or the performance of either a process or a food safety control system following the outcome of sampling and testing for microorganisms … at a specified point of the food chain*" (CAC, 2013). This implies that MC need not necessarily be defined by microbiological limits; other limits, e.g. a level of risk, may be considered (CAC, 2013).

In the "relative risk limit" approach presented here, the $n$ sampling results from the food lot are used as direct inputs into a risk assessment model. This model should describe the consumer

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http://dx.doi.org/10.1016/j.foodcont.2015.04.011
0956-7135/

risk (in terms of probability of illness) associated to a concentration of a specific microbial pathogen at the point of sampling: it has to combine an exposure assessment model from the sampling point to consumption with a hazard characterisation (dose response model). Quantitative microbiological risk assessment (QMRA) models like that have for example been developed for *Campylobacter* in broiler meat (Nauta & Christensen, 2011). When using the risk assessment, the critical limit of the microbiological criterion is an acceptable level of risk, and the result of the approach (the estimated mean risk associated to the *n* samples taken) is compared to this acceptable level of risk.

To provide an understanding of the relative risk limit approach, a general description is illustrated with an example of its application for *Campylobacter* on broiler meat.

## 2. Establishment of an MC based on a relative risk limit

### 2.1. General approach

The general approach towards the application of this microbiological criterion is illustrated in Fig. 1. When the approach described here is applied, *n* samples are taken from each food lot tested, according to a specified microbiological method and at a specific sampling point in the food chain. These *n* samples provide *n* different concentration levels (in cfu/g, cfu/ml or otherwise, either quantitatively or semi-quantitatively). These *n* concentration values are used as inputs into the QMRA model, to assess the risk associated to each of the *n* samples. The estimated risk associated to the food lot is then calculated as the mean of these *n* risks.

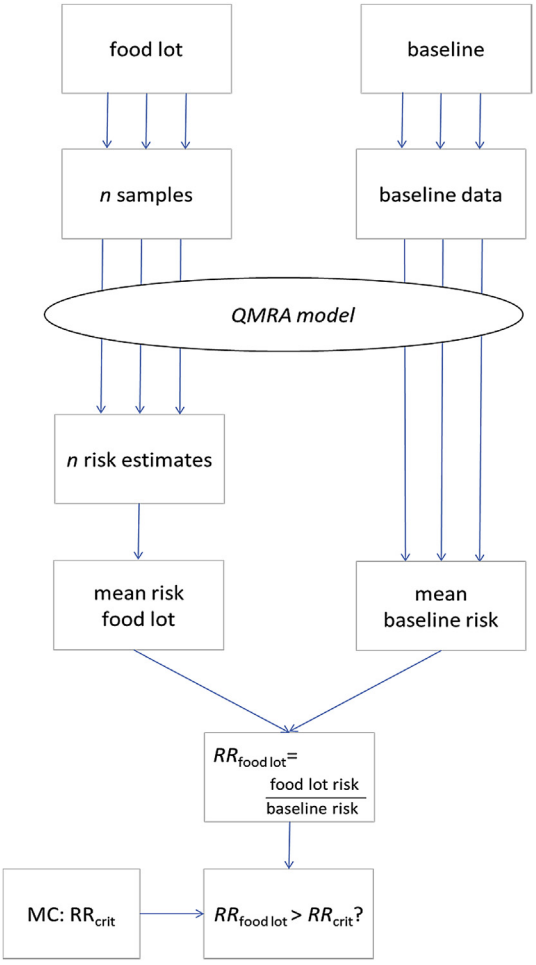


**Fig. 1.** Schematic overview of the approach towards to application of a relative risk-based MC. As in any MC, *n* samples from a food lot are evaluated to check the compliance of a food lot. The relative risk of the food lot $RR_{food\ lot}$ is calculated as the quotient of the mean risk of the food lot and the mean baseline risk, both assessed with the same QMRA model, on the basis of a number of samples. The critical limit of the MC is a critical relative risk $RR_{crit}$. If $RR_{food\ lot} > RR_{crit}$ the food lot is not complying to the MC.

The result of the risk assessment is expressed as a relative risk ($RR_{food\ lot}$), the mean risk estimate of the food lot divided by a "baseline risk". This baseline risk is the risk estimate that is obtained by the same QMRA model on the basis of a (larger) set of representative food samples. It can for example represent the mean annual risk associated with the food product in a certain region, but it can also be the seasonal risk of a specific food category in a region. The critical limit of the microbiological criterion is a level of the relative risk, $RR_{crit.}$; i.e. the level that distinguishes acceptable from unacceptable risk. Hence, the method applies a relative risk limit in terms of $RR_{crit}$ instead of a microbiological limit in terms of *c* and *m*. If $RR_{food\ lot} < RR_{crit}$ the food lot is complying with the MC. The interpretation of RR is clear. If, for example, $RR_{crit} = 5$, a food lot with more than a fivefold risk compared to the baseline will not be complying.

### 2.2. Quantitative risk assessment model

The establishment and application of an MC based on relative risk requires that a QMRA for the relevant combination of pathogen and food commodity is available. This QMRA model should link the concentration of the pathogen of concern in the sample taken to the associated human health risk. For the *Campylobacter* example, a suitable QMRA model is used that combines an exposure assessment model from processed broiler carcasses to consumption and a dose response model, linking the level of *Campylobacter* contamination in samples obtained from processed broilers to the risk of getting campylobacteriosis from the finished meal. The consumer risk is estimated from exposure to *Campylobacter* after preparing contaminated broiler meat in the kitchen (Christensen et al., 2013; Rosenquist, Nielsen, Sommer, Nørrung, & Christensen, 2003).

### 2.3. Baseline risk

To calculate the relative risk of a food lot, the "baseline risk" must be established. This requires a representative data set, or "baseline data". Whether a data set is considered "representative" is a subjective decision and will depend on the situation. It may be relevant that the baseline includes samples from all seasons, from different parts of the country, imports and domestic production, frozen and fresh products, *etc*. It may also be possible to use a limited baseline or a baseline based on data from another country as a "surrogate baseline" and assess the relative risk based on this. By setting a critical limit on the relative risk referring to a surrogate baseline, it will still be possible to sanction lots with the highest risk, even if the relative risk is not with reference to the actual situation in the region: the batches with the highest risk estimate will be the same independent of the choice of the baseline. However, when using a surrogate baseline, one has to be careful with interpreting the relative risk in quantitatively terms, like a "tenfold risk".

### 2.4. Number of samples

To be able to perform a QMRA on the results of analysis of a food lot, it is necessary to have a certain amount of concentration data. The reliability of the risk estimate will increase with increasing amounts of data and ideally the number of analytical units'