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Risk assessment and risk management for safe foods: Assessment needs inclusion of variability and uncertainty, management needs discrete decisions

M.H. Zwietering *

Wageningen University, Laboratory of Food Microbiology, PO Box 17, 6700 AA Wageningen, The Netherlands

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ABSTRACT

The introduction of relevant food safety changes in legislation, like time–temperature criteria for pasteurisation and sterilisation, microbiological criteria, HACCP and FSOs, generally took several decades. All these approaches have helped to define specific targets or systems to improve the management of food safety. More and more the measures could be related to specific efficiency in public health protection. With the use of quantitative risk assessment, theoretically the effect of all interventions on the final risk can be determined, which can help to design the appropriate controls in the food safety management system. In such an assessment in practice, however results have understandably large variability and also uncertainty. There is large variability and uncertainty in the biological parts of the assessment, the dose response (infectivity, human susceptibility) the micro-organism kinetics in the chain (growth, inactivation, stress response) and also in the more technological parts, the conditions in the chain and the consumer behaviour. Often the results of risk assessments are probability distributions of the variability in illness probability, also sometimes represented with their uncertainty. To make a link from these distributions to managerial decisions, that need to be black and white, should not be considered the job of risk managers. This link needs investment from both the assessor and the manager.

1. Introduction

From the creation of relevant new knowledge in food safety to implementation into legislation takes in many cases a long time. For example the knowledge that heat treatments in closed jars can largely increase the shelf life and safety of foods was already described by Appert (1810), while the mechanism through inactivation of micro-organisms, was described by Pasteur around 1860. But it took until the 1920s until sterilisation and pasteurization became apparent in (national) legislations (Fig. 1). So it took about a century to get them into legislation. Of course the methods were already used largely to make shelf stable foods and improve quality and safety. Specific methods to count groups of micro-organisms were developed in the start of the 20th century, but it took until the 1960s before microbiological criteria came into legislative documents especially due to the creation of the Codex Alimentarius in 1962, taking about half of a century. HACCP was developed for the NASA around 1970, was more and more used also in the food industry, but it became mandatory for food industries to follow the HACCP principles in Europe end 1995 (EC, 1993), taking about 25 years. Quantification of microbial behaviour started with the Bigelow model for microbial destruction (Bigelow, 1921), while in the 1980s also models for bacterial growth started to be developed (Fig. 2). This then resulted in that from the 1990s the domain of quantitative microbiological risk assessment started to be developed. From 2000 on, there was more and more inclusion of variability and uncertainty in quantitative risk assessment. The FSO (Food Safety Objective) concept was developed in 1990 and was adopted in CODEX documents in 2004 (CAC, 2004). What can be seen is that it generally takes long before

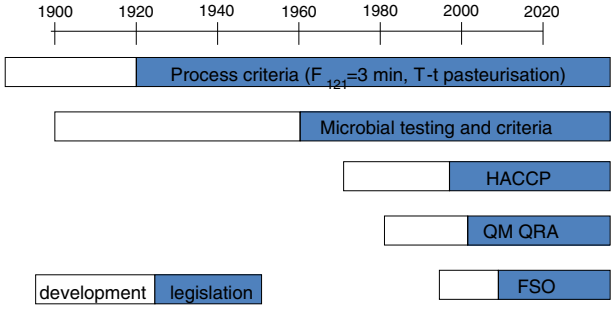

Fig. 1. Historical overview of main changes in food safety management in the last century.

* Tel.: +31 317 482233, +31 317 482887.
E-mail address: marcel.zwietering@wur.nl.

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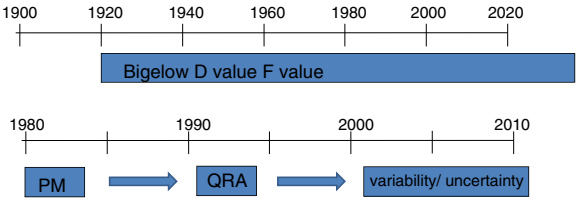

Fig. 2. Historical overview of quantitative approaches in food safety microbiology in the last century.

new concepts are implemented in legislation, but times are getting shorter. It is however also necessary that certain aspects and procedures are evaluated, tested and used during some time and can get some maturity, and also legislation should not react too fast to new developments.

One of the catalysers for more quantification was the SPS agreement (WTO, 1995) describing that new regulation should be scientifically based (Box 1).

This better weighing and evaluation of risk is important to help to find a balance between public health and free trade, and to balance between relevant risks and negligible risks. This stimulated the formalization of the domain of risk analysis in food science by the CODEX.

If in a society or specifically for a food commodity a certain hazard is identified, the risk can be evaluated by the formal process of risk analysis (see Box 2).

Important to note is that risk is a combination of both the probability and the severity of an effect.

Risk analysis consists of risk assessment, risk management and risk communication (Box 3)

Risk assessment (RA) consist of Hazard Identification (HI), Exposure Assessment (EA), Hazard Characterisation (HC) and Risk Characterisation (RC) (Box 4).

For Hazard Identification objective procedures are necessary, since this process needs a structured process on the one hand, but a broad view, creativity and out of the box thinking on the other hand. Most relevant hazards need to be considered mainly, but also unexpected issues need to be evaluated.

For Exposure Assessment both information on initial contamination is necessary and furthermore the kinetics of increase and decrease. Much work on both 'growth and inactivation' conditions is done, however less effort is done on initial levels. For this not only prevalence data are needed, but also concentrations, and furthermore also the variability in contamination, both within product, within batch, between batch and between company.

In the Hazard Characterisation part large variability and uncertainty is present, which is difficult to reduce since accurate information on dose–response relations are not possible to get. Variability originates from both the micro-organism, its state, the food product, other food products consumed and the human being (host).

In Risk Characterisation probability and severity of adverse health effects should be determined and it is specifically mentioned that uncertainty should be included.

Overall Risk assessments (and also risk analyses) contain many factors with large variability and large uncertainties. On the other hand for food safety legislation or for specific management options generally strict limits need to be defined ("a line in the sand"). A microbiological criterion is a specified limit, a product specification is a limit. A time and temperature of pasteurisation need to be defined. One can in certain cases set a range (Temperature between 70 and 72 °C), but in such cases the 70 is the line in the sand, the absolute minimum. The fact that microbiological criteria consist out of multiple samples does in a way include the search for variability, but still the criteria are black and white (absence in 5 samples of 25 g, concentration lower than or equal to 100 cfu/g in 5 samples).

Risk assessment results in probability distributions of the risk, in many cases even two dimensional (both variability and uncertainty), making the link between risk assessment and management not obvious.

More and more risk assessments and quantitative methods are used in setting limits, but in this respect investigating the European limits, one could conclude that the *Salmonella* criteria for minced meat intended to be eaten raw and minced meat from poultry intended to be eaten cooked, would not be expected to be equal, if they would have been based on an assessment of the risk. The effect of cooking on *Salmonella* can be estimated to be of the order of a factor million reduction. Including variability and uncertainty, for example due to undercooking, one could maybe argue that the risk is only a factor 1000 lower, but equal is clearly not what one would expect. Still the criteria for raw meat products and poultry products to be eaten cooked are equal (Table 1). Also there are differences in criteria for meat preparations from poultry meat and for other species (5 times 25 g versus 5 times 10 g). Although maybe the prevalence of *Salmonella* in poultry and therefore the risk might be higher in poultry than some other species, there is no obvious reason why there should be another criterion between the different meats. This limit was apparently not linked to risk for consumers but to the expected results of the implementation of the Regulation 2160/2003 on the control of *Salmonella*. All these limits are defined as absence of the organism, however this is absence of

Box 1
Agreement on the application of sanitary and phytosanitary measures (WTO, 1995).
Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.

Box 2
Codex definitions of hazard, risk and risk analysis (CAC, 2014).
Hazard
A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.
Risk
A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
Risk analysis
A process consisting of three components: risk assessment, risk management and risk communication.

Box 3
Codex definitions of risk assessment, risk management and risk communication (CAC, 2014).
Risk assessment
A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.
Risk management
The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
Risk communication
The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.