Food Control 58 (2015) 1–6

Contents lists available at ScienceDirect

Food Control

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

Editorial

The development of illustrative examples for the establishment and application of microbiological criteria for foods and their role in international standard development

Each paper presented in this special issue describes an example of how microbiological criteria (MC) may be established and applied. In this paper we will provide the background to their development, explaining the work of the Codex Alimentarius Commission (CAC) in this area and the need for guidance on establishing and applying MC related to foods in a risk-based food control environment and the approach taken by the Codex Committee on Food Hygiene (CCFH) to develop these examples during the revision process. This contextual background aims to help the reader understand the reason for developing these examples, as a means of increasing the awareness of the range of approaches for MC development and application. The MC example papers are not intended to be directly applicable but rather provide an overview of potential approaches for consideration by the reader. The process of elaborating the examples has helped the participating countries to understand where the difficulties lie in terms of both the science behind the use of MC and the practicalities of their application, and allowed countries to gain an understanding, not only on MC, but the Codex process itself and its usefulness and importance for their countries.

1. Background

Over the last 150 years or so our understanding of foodborne microbiological hazards has evolved tremendously as well as the approaches through which we can manage these hazards and the related burden of foodborne disease. Microbiological criteria (MC) emerged and evolved as part of that progress. Traditionally, microbiological criteria were used to define the acceptability of a food product or food production lot, based on absence or presence, or number of microorganisms per unit of mass, volume area or lot.

However, with the modernization of food safety control systems, the management of the microbiological safety of foods moved towards a preventative approach which emphasized the effective implementation of control measures throughout the food chain to minimise contamination and improve food safety. The introduction of the concept of risk and risk based approaches to the food safety arena has also fueled changes in the way we approach the management of microbiological hazards in food. Risk is defined by the Codex Alimentarius Commission[1] (CAC) as "a function of the probability of an adverse health effect and the severity of the effect, consequential to a hazard(s) in food". Advances in risk-based management systems have set the stage for a science-based food safety system that aims to achieve the goals of public health protection with optimal use of resources, and providing the basis for managing risks in line with their impact on public health. New metrics that link food safety requirements and criteria to public health outcomes have changed the way risk managers utilize information, i.e., effects of interventions along the food change, public health impacts of control measures (Mead et al., 2010).

The consideration of risk has become an integral part of how safe food is produced. With the development and implementation of the risk management framework, new microbiological risk management metrics (MRM) appeared and were adopted (CAC, 2007). Food safety objectives (FSO), performance objectives (PO) and performance criteria (PC) became the new metrics to articulate the expected performance of control measures and food safety control systems in terms of the necessary management of public health risks. There have been efforts to relate traditional MC to FSOs and POs (van Schothorst et al., 2009) and, more recently, to design sampling plans that allow detection of low levels of foodborne pathogens (Valero, Pasquali, De Cesare, & Manfreda, 2014). With all of these developments the question arose "Do microbiological criteria, the traditional metric used to demonstrate that food was safe, still have a role to play?"

The CAC developed guidance for the establishment of microbiological criteria in the 1990s which aimed to standardize the way in which criteria were established for their traditional use as a means of defining acceptability of a food product or lot. When the aforementioned question was raised in the discussions of one of the technical committees of the CAC, the Codex Committee on Food Hygiene (CCFH), food regulatory authorities in many countries agreed that there was a need to expand the global guidance on how MC could be established and used in the new risk driven paradigm, and that the Codex meetings provided the venue in which to elaborate this.

However, this guidance revision was not to be an easy one. Three years of discussions within CCFH underlined the challenges many countries, especially developing ones, faced in understanding, establishing and applying microbiological criteria in the new environment. CCFH recognized that the subject matter in the guidelines under revision was complex, required substantial efforts and

[1] The FAO/WHO Intergovernmental body responsible for the development of standards, guidelines and related texts for the safety and quality of foods traded internationally.

http://dx.doi.org/10.1016/j.foodcont.2015.06.043

resources and, that the development of consensus guidelines for use by countries with heterogeneous food safety control systems and at different levels of advancement needed a more novel approach. A clear consensus emerged during discussions among Codex member countries that examples were needed to illustrate how MCs are established and applied in a range of scenarios from the more traditional context to the risk based environment. It was also recognized that the exercise to select and develop relevant examples would only be successful if it also stimulated and supported the participation and meaningful contribution of countries with a range of different experiences in the area of MC and in different stages of development and capacities in food safety management.

2. Selection of the examples

Among the first changes which the revision of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* brought about was that of the definition of microbiological criterion. The new definition broadens the scope of the microbiological criterion to indicate the performance of a process or a food safety control system and incorporates sampling and testing, underlining the importance of sampling plans in defining MC stringency.

> *"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, their toxins/metabolites or markers associated with pathogenicity or other traits at a specified point of the food chain."* (CAC, 2013)

With this broader definition came the need to indicate how and in what context MC can be established and applied. Recognizing that MCs can be based on knowledge of the parameters of a Good Hygiene Practices (GHP) system or effective control points in a food safety control system such as HACCP, or can be generated using inputs from quantitative risk assessments, the CCFH participant countries identified a spectrum of risk management activities throughout the food chain where MC can be applied for a wide array of purposes, such as:

- Evaluating a specific lot of food to determine its acceptance or rejection, in particular if its history is unknown.
- Verifying the performance of a food safety control system or its elements along the food chain, e.g. prerequisite programs and/or HACCP systems.
- Verifying the microbiological status of foods in relation to acceptance criteria specified between food business operators.
- Verifying that the selected control measures are meeting POs and/or FSOs.
- Providing information to food business operators on microbiological levels, which should be achieved when applying best practices.

While these were all acknowledged as relevant applications, it quickly became clear that for many countries the practicalities around these including the technical or scientific basis used to establish an MC for the different applications or purposes of its use were far from clear. Thus, these five areas of application of MC were the starting point for the selection and development of examples to illustrate how the MC are established and applied in different contexts. Consequently, seven teams were created with the task of developing these examples using different approaches and pathogen/commodity pairs to illustrate the approach (see Section 3).

3. The approach

Successful development of Codex standards, guidelines and recommendations in many instances relies heavily on the quality of work done by Working Groups commissioned by parent Committees to work between sessions to develop draft texts for their consideration. The Working Groups carry out their work either by meeting physically, or by using electronic means of communicating or a combination thereof. Participation in Working Groups, physical or electronic, is not easy for member countries. In the case of physical meetings, resource constraints limit country participation as national budgets may not be available to cover the costs. Effective participation in working group discussions is often hindered by a lack of understanding and experience on how to contribute in such Codex processes in many developing and transition economy countries; further constraints revolve around the selection of the most qualified people to participate, being able to take time out from primary commitments and in some countries, even access to reliable email and internet facilities. Thus participation in these groups is often limited to a relatively small number of more experienced countries, leading to a lack of understanding of the work in progress by less experienced ones, and therefore difficulty in finalizing the work. To address some of these challenges, a proposal was made to seek support (financial and technical) from the FAO/WHO Project and Fund for Enhanced Participation in Codex (Codex Trust Fund, CTF). This proposal was accepted and the support from the CTF is described below.

The CTF was created in 2003 with the goal of helping developing and transition economy countries to enhance their level of effective participation in the CAC. The current Codex Trust Fund, which will come to an end in December 2015 and be replaced by a successor initiative, provides support for eligible countries to participate in the international food standard setting process by attending Codex meetings. The Trust Fund also supports FAO/WHO capacity-building activities aimed at helping countries participate more effectively in the Codex process. It was in this light that the Codex Trust Fund was well-placed to provide the financial support to countries to participate in an innovative process to build their understanding of, and capacity to establish and apply MCs.

In order to build the capacity of less experienced countries in this area and to enhance their participation in revising the guidelines, the 43rd session of the CCFH decided to break with the usual Codex processes and established seven drafting teams, each composed of a more experienced country or organization and less experienced countries or observer organizations with the expectation that they would undertake their work in a fully participatory and collaborative manner. Twenty three (geographically and economically diverse) Codex member countries, over two thirds of which were developing or transition economy countries, three non-governmental organizations (NGOs) and one regional body participated in this process (Table 1). The teams were charged with elaborating examples on the various uses of microbiological criteria.

To facilitate this new collaborative approach a technical team comprised of staff from FAO, WHO, the Codex Secretariat and the Codex Trust Fund Secretariat developed a set of roles and responsibilities for team leaders and other participants at the outset of work. However, each drafting team was free to decide on the process, mechanisms and tools that would be used to collectively draft the examples. The drafting groups communicated mainly electronically and in general established a work plan with clear timelines. An FAO staff member participated in an observer capacity and also provided support to the groups on communication, procedural and technical issues as required.