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Definition and usage of food safety margins for verifying compliance of Food Safety Objectives

Eva Doménech [a, *], Sebastian Martorell [b]

[a] Institute of Food Engineering for Development (IUIAD), Department of Food Technology (DTA), Universitat Politècnica De València, Camino de Vera, 16, 46022 Valencia, Spain

[b] Department of Chemical and Nuclear Engineering, Universitat Politècnica De València, Camino de Vera, 16, 46022 Valencia, Spain

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ABSTRACT

Over the last decade, risk analysis has gradually been introduced as a tool to make decisions about food safety policies. In this framework, the ALOP (Appropriate Level of Protection) concept, which can be seen as a statement of the degree of public protection that should be attained in a country, was introduced. In addition, FSO (Food Safety Objectives) was introduced to provide a link between the ALOP and target points/goals in the supply chain. Historically, ALOP and FSO decisions have been based on the ALARA (As Low As reasonably Achievable) approach. Since an ALARA approach is based on the status of current technology, it is likely that the ALOP is attainable, provided a substantial portion of the industry complies with technological requirements or adopt “best practices” that will achieve the FSO. Food managers must control and government agencies must enforce and monitor the fulfilment of FSO. Once FSO has been established and adopted by the food industry, a major concern is to evaluate the results of the implementation of FSO in order to verify compliance. This paper introduces the concept of food safety margin (FSM) and its formulation based on classical and probabilistic approaches, which are intended to be used as a tool to measure the degree of compliance with FSO. For a better understanding of how food safety margins perform, FSM are estimated for *Listeria monocytogenes* in three different products, (semi-soft cheese, heat treated meat and cold smoked salmon). The results obtained, adopting both classical and probabilistic approaches, are discussed.

1. Introduction

The globalization of food markets as well as the fact that hazards, e.g. microbial growth, can appear at any stage of the food chain has increased regulators' concern about the new challenges to manage food related risks to human health in order to guarantee food safety.

Over the last decade, risk analysis has been gradually introduced as a tool to make decisions on food safety management policies. Following the Commission's Green Paper on food law (COM, 1997), and subsequent consultations, a new legal framework was proposed. This covers the whole of the food chain, including animal feed production, establishing a high level of consumer health protection and clearly attributing primary responsibility for safe food production to the industry, producers and suppliers. The White Paper on food safety proposed risk analysis as the baseline of food safety policy (CCE, 2000). The European Union (EU), through Regulation (EC) No 178/2002 laid down the general principles and requirements of food law, emphasizing that in order to achieve the general objectives of a high level of protection of human health, food law shall be based on risk analysis. In 2007 the Codex Alimentarius Commission published the principles of risk analysis for food safety to be applied by governments. The standard was intended to provide guidance to national governments for risk assessment, risk management and risk communication with regard to food related risks to human health (CAC, 2007a). More recently, the European Food Safety Agency (EFSA) highlighted risk analysis as the starting point for setting priorities and allocating resources effectively based on risk (EFSA, 2012).

Risk assessment provides a systematic means for assessing, in a qualitative or quantitative way, the probability of occurrence and the severity of known or potentially adverse health effects in a given population based on hazard identification, hazard characterization, exposure assessment and risk characterization. The

* Corresponding author.
E-mail address: evdoan@tal.upv.es (E. Doménech).

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results obtained through risk assessment are the foundations of good safety/risk management policies.

Risk management is defined for the purposes of the Codex Alimentarius Commission as 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 (CAC, 2007b). Thus, the reduction of potential hazards associated with food typically involves the application of preventive and control measures in the food chain, from primary production to consumption. Therefore, one important aspect of risk management involves verification of the effectiveness of these measures and their capability to control the hazard. These goals have traditionally been managed through the establishment of Microbiological Criteria, Process Criteria, and Product Criteria (CAC, 2007b). However, these traditional safety criteria have not generally been linked directly to a specific level of public health protection (CAC, 2007b; Manfreda & De Cesare, 2014).

To advance risk management, new risk management tools emerged where food safety issues moved from a hazard-based approach to a risk-based approach (CAC, 2007b). Consequently, safety goals had to be developed taking into account the levels of illness associated with a pathogen/food combination, and the need for a continuous improvement in public health, while acknowledging that zero risk cannot be attained (Walls, 2006). In this framework, the ALOP (Appropriate Level of Protection) concept was introduced in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (ICMSF, 2002). The ALOP is viewed as a statement of the degree of public protection that must be achieved within a country as a consequence of the presence of a hazard in a food. One difficulty when implementing the ALOP concept is that the ALOP cannot be used directly by the food industry or government regulatory agencies to set a target for food safety systems (Doménech, Amorós, Martorell, & Escriche, 2012).

The International Commission on Microbiological Specifications for Foods (ICMSF, 2002) proposed the establishment of FSO (Food Safety Objectives) to provide a link between the ALOP and target points in the supply chain. The FSO, which is defined as the maximum frequency and/or concentration of a microbial hazard in a food considered tolerable for consumer protection at the time of consumption, conveys the ALOP criteria into targets/goals that can be controlled by food producers and monitored by government agencies, (CAC, 2004). FSO is a risk management decision that is based on both scientific and societal attributes, whose role is to establish the level of residual risk in a food safety system that is tolerable. FSO can be used by Government regulatory agencies to communicate public health goals to the industry and other stakeholders in a form that can provide a measurable target for a hazard (Walls & Buchanan, 2005). In order to adapt the principles of FSO implementation at earlier stages in the food chain, they are linked to Performance Objectives (PO). A PO is the maximum level (frequency and/or concentration) of a hazard in food at a specified point in the food chain that should not be exceeded in order to achieve an FSO (CAC, 2004). A major concern is to set up the FSO and the corresponding PO values that must attain the FSO established in order to guarantee consumer health. Walls and Buchanan (2005) emphasised that setting an FSO involves determination of the maximum level of exposure to comply with public health goals, which must include consideration of the need to take into account the variability in food safety management performance and uncertainty in the knowledge about risk. The role of the FSO is to establish the level of residual risk in a food safety system that is tolerable. The PO at specific points of the food production chain must be set up by industries linked to such FSO.

As the FAO/WHO remarked (2002), historically, ALOP and FSO decisions have been based on the ALARA (As Low As Reasonably Achievable) approach. Since an ALARA approach is based on the status of current technology, it is likely that the ALOP is achievable, provided a substantial portion of the industry complies with technological requirements or adopt “best practices” that will achieve FSO. However, a potential limitation of this approach is that unrealistic public health goals could be specified that are not achievable by industry within a realistic time frame.

Food managers must control, and government agencies must enforce and monitor fulfilment of FSO. Therefore, once the FSO has been established and adopted by the food industry, a major concern is to verify the results of the implementation of FSO after the adoption of technological requirements or “best practices” by food industries.

This paper introduces the concept of food safety margin (FSM) that is intended to be used as a tool to measure the degree of compliance of FSO goals in a quantitative way, which could be used by government regulatory agencies, the food industry and other stakeholders. Two metrics, i.e. the classical and the probabilistic approach, are provided. For a better understanding of how food safety margins perform, FSM are estimated for *Listeria monocytogenes* in three different products, (semi-soft cheese, heat treated meat and cold smoked salmon). Finally, the results obtained adopting both classical and probabilistic approaches are discussed.

2. Dose-response. A link between ALOP and FSO

Dose–response analysis involves the study of the characterization of the relationship between dose, infectivity and the likelihood and severity of spectrum of adverse health effects associated with the hazard, H, in an exposed population (Walls, 2006). Thus, the probability that a person shows an adverse effect after consuming a product with a given toxic/microbiological load, D(H); is used to determine the FSO necessary to achieve the ALOP depending also on the expected population being exposed to this risk.

The probability density function (pdf) of the dose–response curve, D(H), is affected not only by the level of a hazard H (log (CFU/g)) but also by numerous parameters: the virulence of the pathogen, the age and immune status of the person, the food matrix (fat level, acidity) and the treatments received by the product. Therefore, establishing a value for the FSO of one particular food is complex and it may be one of the main reasons why numeric safety goals have not been regulated for FSO yet. Thus, numerical values of MC are often adopted instead of such numerical safety goals to represent FSO.

3. Exposure assessment and FSO

In this context, exposure assessment is defined as the quantitative evaluation of the likely human intake of biological, chemical and physical hazards via food (CAC, 2013). When characterizing and quantifying the exposure of one individual to microbial pathogens, data on the frequency of contamination (prevalence) and the numbers of microorganisms (concentration) in a specific food are needed. The amount of food consumed for estimating public exposure is also needed (Walls, 2006). Fig. 1 shows the relationship between the concept of Exposure-assessment, E(H), and FSO defined for a hazard, H (log (CFU/g)). In Fig. 1, two situations of Exposure assessment, $E_1(H)$ and $E_2(H)$, with different proportions of unsatisfactory results are represented. Thus, $E_2(H)$ shows the highest proportion of unsatisfactory results, i.e. major probability of the exposure to the hazard exceeding the FSO, so-called exceedance probability in Fig. 1, which may be associated with worse risk