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Review Article

The importance of validated kill steps and thermal death kinetics of *Salmonella* in food safety management

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Abstract

Food safety is a paramount concern worldwide as consumption of contaminated food products can result in foodborne illness outbreaks, hospitalization and even death. Each year, millions of people around the world are affected by foodborne illness outbreaks, and thousands succumb to these outbreaks. It is important to note that most of the *foodborne illness outbreaks are preventable*. This is where the validated kill-step (baking, cooking, roasting, boiling, extrusion etc.) during the food processing plays a critical role in achieving food safety. The “kill-step” in food manufacturing is the point at which potential harmful pathogens are controlled ensuring the safety of the finished food product. As most of these kill steps are thermal processing steps, the destruction of a potential bacterial pathogen is dependent on the oven temperature, dwell time and nature of the food composition (high-protein, high-fat, high-salt, high-carbohydrate matrices). It is important to note that the set temperature and time during a kill-step depends on the thermal death decimal reduction time (*D-value*) and thermal death decimal reduction temperature (z-value). Therefore, determining the D and z values of a potential bacterial pathogen associated with a specific food matrix is crucial for a resilient food safety system.

Keywords: Foodborne Pathogens; *Salmonella; D*-Value; Z-Value; Thermal Processing; Food Safety

Introduction

Foodborne illness outbreak is a complex issue that has impacted all the segments of society, from general public, food industry with significant effect on the economy [1]. Foodborne pathogens which include bacteria, molds, viruses, and parasites are biological agents that can enter the food chain through raw ingredients and are capable of causing foodborne illness outbreaks if we fail to control them at the processing steps or critical control points. According to the U.S. Food and Drug Administration (FDA), if the same contaminated food or drink causes illness in two or more people, it is known as a foodborne illness outbreak (FDA 2022). Amongst foodborne pathogens, bacterial pathogens cause maximum outbreak due to their ubiquitous nature, wide adaptability (0 to 45 °C), ability to form spores and due to their heat resistant characteristics [2]. Some of the common bacterial pathogens that cause foodborne illness outbreaks are *Salmonella*, Shiga toxin producing *Escherichia coli, Clostridium botulinum, Staphylococcus aures, Listeria monocytogenes, Campylobacter jejuni* etc. Among these, *Salmonella* is considered a remarkable foodborne pathogen due to its adaptability to extreme low-moisture conditions, wide range of pH values (4 to 8), wide range of temperatures (2°C and as high as 54°C) and due to its unusual heat-resistant characteristics [3]. In addition to contaminated raw ingredients, cross-contamination is another significant route of transmission for *Salmonella*. There are more than 2,579 serovars of *Salmonella* in the nature [4]. *Salmonella* can be introduced into food chain through a wide range of ingredients such as egg, milk products, flour, milk, chocolate, coconut, peanut butter, fruit, spices, milk powder, vegetables, meat, water, and due to other environmental factors [5,6]. *Salmonellae* pathogen belongs to the Enterobacteriaceae family, grouped in Gram-negative, rod-shaped bacteria with 2 to 5 micros length and 0.5 to 1.5 micros in wide [7]. According to the Center for Disease Control and Prevention (CDC), *Salmonella* is responsible for about 1.35 million infections, 26,500 hospitalizations, and 420 deaths in the United States each year and the majority of illnesses are caused by consumption of contaminated food (CDC 2024). Therefore, it is important to understand the thermal resistance of *Salmonell*a in various food matrices to effectively control this pathogen assuring food safety. This article discusses the importance of validated kill-step, thermal resistance characteristics of *Salmonella* pathogen in various food matrices and their relevance to food safety.

Significance of preventive controls in controlling pathogenic microorganisms

Thermal processing is one the most effective way for controlling foodborne pathogens during food manufacturing [8]. Although it is estimated that the use of fire to cook food for human consumption began nearly 2 million years ago, the first scientific evidence of controlled use of fire by prehistoric humans' dates back to 780,000 years ago [9]. In this study, the scientist found evidence of burned seeds, wood and the leftovers of a roasted carp dinner at the Acheulian site of Gesher Benot Ya`aqov in Israel [10]. The process of cooking involves the use of controlled heat to produce edible, tasty, safe, digestible foods while preserving their nutritional value. There are different ways of cooking namely, baking, roasting, grilling, boiling, broiling, cooking, steaming, braising etc. The main goal of cooking is to transform raw ingredients into delicious, nutritious, and safe finished food products, without which the food would be unfit for human consumption. The temperature and time during thermal processing play a critical role in effectively eliminating harmful pathogens that cause diseases in humans. Since the thermal processing step helps in achieving lethality of harmful pathogens associated with raw ingredients thus rendering a product safe for human consumption, it is also called a kill-step. Lethality is the relative effect of specific temperature and the time of exposure used to destroy a specific or group of microorganisms in a product to make it safe for human consumption (USDA 2021). Since most food products have unique formulations and intrinsic characteristics, it is important to choose the right temperature and time during cooking. Therefore, for an effective thermal processing regime, it is important to understand the common foodborne pathogens and their thermal resistance (*D* and *z* values) characteristics to achieve food safety. Additionally, the nutritional composition of the food matrix, including its pH, water activity, moisture contents, salt, fat, and sugar contents, must be considered to ensure food safety and to protect consumers from foodborne illness outbreaks. This is where FDA's Food Safety Modernization Act's (FSMA) validation requirement (CFR 121.160) plays a critical role in food safety (FDA 2023). The US FDA's FSMA empowers the FDA to protect public health by strengthening the preventive controls thus preventing food safety problems rather than relying primarily on reacting to food safety failures (FDA 2018). The FSMA act, which was enacted in 2011, focuses more on preventing food safety problems rather than primarily reacting to food safety failures. According to the U.S. Code of Federal Regulations Title 21, Sec. 117.160 requirement, one must validate the preventive controls identified in a food manufacturing establishment and implemented in accordance with § 117.135 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system (FDA 2023).

Validation of preventive control for food safety

Validation is a preemptive scientific evaluation that provides documentary evidence that a particular preventive control such as cooking, baking roasting etc. when properly implemented is capable of delivering a product by effectively controlling the identified hazards based on the risk analysis. In short, it is a collection of scientific evidence that demonstrates the effectiveness of the food safety plan in controlling the microbial hazards when properly implemented. The effectiveness of thermal processing steps in reducing microbial hazards is often expressed as 'log reduction'. Although there are no regulatory requirements, in general, a 5-log reduction of a potential pathogen is considered as industry standard. A microbial challenge study or a validation study involves a thorough literature review to identify the worst-case scenarios, identifying the surrogate or pathogenic bacteria, selection of cooking equipment, executing the validation experiment in a BSL-2 laboratory, analyzing the data and preparing a validation report. In the validation study, the initial 'high' log levels are intentionally selected to demonstrate a very conservative log reduction, as they are unlikely to be present in raw materials. In addition to demonstrating a 5-log reduction of the pathogen of concern, it is highly recommended to determine its thermal resistance characteristics (*D* and *z* values) of the pathogen. Once the process validation is completed, the food processing facility must optimize the thermal processing or kill-step and establish verification procedures.

Thermal death kinetics (*D*-value, *z*-value and Thermal Death Time)

Determining the *D*-value, *z*-value and Thermal Death Time (TDT) of a pathogen of concern provide a means to compare the heat resistant characteristics of various bacterial pathogens including different strains and serovars [11]. The D value is defined as the time in minutes needed at a given temperature to kill 90% of the target bacterial populations or reduce the bacterial population by one log. The *z*-value is the change in temperature needed to reduce the target bacterial population by a factor of 10. The TDT is the shortest time required to destroy a specific bacterium at a specific temperature under defined conditions. Determining *D*-value, *z*-value and thermal death time (TDT) is critical to understand the thermal resistance of a bacterial pathogen in a specific food matrix. These parameters (*D*-value, *z*-value and TDT) will aid in determining the shortest time for achieving a 5-log reduction of a specific pathogen in a specific food formulation. Furthermore, the *D* and z-values will help optimize the kill-step process to ensure food safety. It is important to note that the *D*-value, *z*-value and TDT is specific to pathogen and the food matrices. Therefore, any changes in the formulations and their associated intrinsic factors such as pH, water activity, fat composition, salt composition, sugar content, moisture content, and change in physical state (solid, liquid, semi-solid), a pathogen-product specific challenge study is highly recommended. Additionally, it is important to note that water activity (a_w) of a food matrix plays an important role in pathogen's heat resistant characteristics and its survival. For example, *Salmonella* is known to survive in low-moisture food products such as spices, dry nuts, flour, chocolate, peanut butter, cracker, milk powder, animal feed etc. [12-15]. It is important to note that *Salmonella* pathogen exhibit prolonged survivability and very high tolerance to thermal processing temperature during kill-steps with low-moisture food products (Liu et al. 2018). The research clearly demonstrated that as the water activity decreases the heat resistance capacity of *Salmonella* increases [16]. In addition, D-values may differ between different strains or serovars of bacterial pathogens. Due to all these reasons, food processors must exercise caution when choosing the right temperature and time while thermal processing low-moisture food products.

Conclusion

The food matrix characteristics, including water activity, pH, salt, fat, and sugar content, play a significant role in the thermal resistance (*D*-value, *z*-value, and TDT) of *Salmonella* [17-19]. This is further complicated in low-moisture food products with varying processing methods involving various time and temperature combinations [20]. Therefore, conducting a thorough risk assessment and understanding these factors and their quantitative relationships is highly recommended to prevent the risk of *Salmonella* contamination in low-moisture food systems. While mathematical models using product-specific *D* and *z* values can give a generalized estimate of pathogen lethality, it is important to note that this estimate is specific to the pathogen, cooking parameters, cooking equipment (convection or conventional), type of heat source (electrical, gas, radio frequency etc.), and the food matrix [21]. Therefore, it is important not to extrapolate the thermal lethality model that is based on product-specific *D* and *z* values to other food matrices and formulations. A validation study that is specific to the pathogen and specific to food formulations is highly recommended for ensuring safe and resilient food systems.

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