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## **FOOD SAFETY BEYOND GUIDELINES AND REGULATIONS**

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### **Introduction**

Americans increasingly are demanding food that is more convenient, but with a higher level of safety assurance. These changes in the market and evolving federal regulations are creating a need for better information related to inactivation and growth of pathogens in meat and poultry products. Regulatory changes are shifting the burden to processors to ensure, through scientific rationale, that a new or modified process meets performance standards for pathogen reduction and control. Although product and process variables are known to affect thermal resistance of bacteria, most reported information is from laboratory studies that encompass a limited range of conditions. In most cases, the validity of this information for commercial processes is uncertain. Therefore, the purpose of this article is to address three questions: (1) How do food safety regulations relate to the current state-of-knowledge? (2) What is currently known about various factors that might affect thermal inactivation of pathogens in meat and poultry products? and (3) What should be done to account for these complicating factors, now and in the future?

### **Relating Regulations and Guidelines to the State-of-the-Art**

Heat is the primary means for both adding value and ensuring microbial safety of meat and poultry products. Although numerous technologies (e.g., irradiation, ultra high pressure, pulsed electric fields) loom on the horizon for the broader food industry, the application of heat will certainly continue as the dominant means to impart desirable characteristics, add economic value, and ensure product safety. Additionally, major shifts in consumer demand and regulatory burden are increasing the importance of thermal processing. Therefore, this article focuses on thermal processing as the key step in ensuring the safety of ready-to-eat (RTE) products.

#### ***Regulatory evolution***

In terms of regulatory pressures in this domain, there is an evolving shift from a command-and-control paradigm (i.e., meeting specific endpoint temperatures) to lethality performance standards (USDA 1999, 2001). A central theme to these regulatory changes is the emphasis on developing science-based regulations. For example, processors are no longer held to specific endpoint temperatures; however, they "must validate new or altered process schedules by scientifically supportable means" (USDA 1999). These are suggested to include "...using information obtained from the literature" or conducting an inoculated challenge study (adding pathogens to a real food product prior to processing). The proposed rule changes (USDA 2001) extend the same general approach to all RTE products containing meat or poultry. Although the new regulatory paradigm creates greater opportunities for customized processes, it clearly puts significant pressure on the industry to document process lethality for any new product or process.

#### ***State-of-the-Art***

If the state-of-the-art encompasses two domains, knowledge and tools, then it is important to assess the intersection of these domains with the evolving regulatory domain described above (Fig. 1). In this case, the knowledge base is comprised of the latest research related to pathogen response to processing, product effects, etc., which will be discussed in the next section. A fair amount of previous research has been aimed at developing this type of knowledge. However, mere knowledge that these effects exist is insufficient to aid a processor in designing, operating, or evaluating the efficacy of a thermal process, in terms of the relevant lethality performance standards. Quantitative analysis requires tools. Operating in the area where the regulatory and knowledge domains overlap may result in food safety decisions that are essentially “educated guesses”. However, if that knowledge has been used to develop validated tools, then operating in the area where the regulatory and tool domains overlap should result in reliable assessments of process lethality and product safety.

Unfortunately, the current state-of-the-art, regarding validated tools, is insufficient for reliable lethality predictions in commercial processes. The strengths and weaknesses of the two general methods (challenge studies and predictive models) are listed in Table 1. In general, challenge studies (i.e., inoculation of real products with target organisms) are impossible in commercial facilities, where pathogens cannot be brought on site. If the capacity does exist to conduct such tests, they have the advantage of directly accounting for any product effects by virtue of using the actual product in the tests. However, it is important to understand that direct matching of the conditions in a pilot-scale test with those in an actual commercial process can be extremely difficult, due to process scale-up issues.

Additionally, existing pathogen inactivation data and models (as described in the next two sections) have been developed primarily with pathogen cultures grown under ideal laboratory conditions, inoculated into model products, and subjected to isothermal laboratory conditions; therefore, the resulting models are not necessarily valid for conditions occurring in many commercial processes. In fact, one of the greatest dangers in using predictive models from the literature is extrapolation to conditions for which the model has not been validated. When this is done, the reliability of the prediction is impossible to quantify.

## **Factors Affecting Thermal Inactivation**

Obviously, heat inactivates bacteria. However, when evaluating thermal process lethality, it is essential to understand the wide range of factors, beyond just temperature, that affect the process outcome. These factors can be classified as pathogen, product, or process parameters. This section briefly summarizes the state-of-knowledge in this area.

### ***Pathogen Factors***

Thermal resistance of pathogens can vary widely, depending on the organism being considered. Salmonella was selected as the reference organism for the lethality performance standards in part because it tends to be more thermally stable than other bacterial pathogens of concern (USDA 2001). Once the pathogens are in a food matrix, the previous conditions to which they have been subjected can also significantly affect their future response (Wesche 2003). For example, in a commercial operation, a pathogen cell on a carcass, which is held chilled before further processing, might thereby develop increased thermal resistance due to the cold stress. Likewise, pathogen cells that are exposed to, but not inactivated by, sanitizing agents, could thereafter also exhibit greater thermal resistance. Although stressed cells respond differently than cells grown under optimal conditions, it is the latter cells that are routinely used in food safety studies. Therefore, process validations based on solely laboratory studies may not be adequate to ensure the safety of RTE products.

### ***Product Factors***

In terms of product attributes, the heat resistance of pathogens can be affected by meat species, muscle type, pH, carbohydrates, fat content, water content, and salts (e.g., Juneja et al. 1997, Maurer 2000, Veeramuthu et al. 1998, Carlson 2002). In general, thermal resistance of bacteria is higher in meat products than in laboratory media. Not only do food components appear to enhance heat resistance, but cell location (surface attachment vs. interior dispersion) may also affect the resistance of Salmonella (Doyle and Mazzotta 2000). For example, Salmonella that has migrated into the interior of vacuum-tumbled, whole-muscle product appears to be more heat resistant than Salmonella in ground and formed product (Orta-Ramirez et al. 2003). Therefore, the validity of applying previous inactivation data from liquid media or meat slurries to thermal process calculations for real meat and poultry products is not well known.

### ***Process Factors***

Although product factors, such as pH, fat content, and water activity, all have an effect on thermal resistance of pathogens, the environmental conditions during thermal processing can affect the inactivation of pathogen both directly and indirectly, by changing the product properties during processing. In this context, consider process factors to be those parameters that can be controlled either by the process design or operation, such as heating (e.g., air) temperature, cooking time, humidity, and heating (or cooling) rates. With the exception of heating temperature and time, far less is known about the effects of environmental conditions on thermal inactivation, as relevant to commercial processes. As previously mentioned, these effects can be either immediate or delayed, as occurs when bacteria exhibit stress-induced tolerances to heat. For example, when a meat product is heated at a very slow heating rate (<1degree C /min), pathogens present in that product can become more heat resistant.

### **What to Do (Now and in the Future)**

Clearly, pathogen, product, and process parameters can have significant effects on the thermal resistance of pathogens in meat and poultry products. Because commercial cooking systems create complex conditions around the product, with varying temperature, humidity, airflow, etc., scale-up of laboratory-based inactivation data to commercial-scale processes, without evidence that the data account for all of the relevant process parameters, can be a dangerous leap. However, given the impracticality of challenge studies, the processor is left with predictive models as the primary means for evaluating and documenting process lethality. It is critically important, therefore, to determine the implications the aforementioned difficulties have for the present and for the future, in terms of process design, validation, and operation.

### ***For Now***

For the present, caution is the key recommendation regarding selection and use of published inactivation data and models. The most important caution about predictive models is that they must be validated, against data independent of those used to create the model, before they can be used for prediction of future results. Unfortunately, the vast majority of published data and models for thermal inactivation of pathogens are never validated as part of the original studies. Wide variability of lethality predictions can result from the use of different data and models; therefore, it is incumbent upon the processor to be extremely cautious in using published inactivation data. In particular, the user of any microbial inactivation model should be sure to use parameters that most closely match their own situation, in terms of product type, fat and water content, process conditions, etc. Given that no universally applicable modeling tool yet exists, the best that the user can do is to consider comparing results from several different models and/or parameters that are most relevant to the specific case. This can help define a range of possible lethality outcomes. Most importantly, the user should particularly avoid extrapolating a given model to conditions beyond which the model has been validated, because there is no way to know the accuracy of the resulting predictions in this case.

## **For the Future**

Clearly there is a need for validated lethality models that have broad applicability across a range of products and processes, and which account for all of the factors known to affect lethality. Existing modeling tools, such as the USDA-ARS Pathogen Modeling Program (PMP, v. 6.1, <http://www.arserrc.gov>) and the AMI Process Lethality Spreadsheet (American Meat Institute, <http://www.amif.org/processlethalityinstr.htm>), have a number of limitations relevant to the real thermal processes. First, the current version of PMP does not include primary models for thermal inactivation of Salmonella, nor does either model account for the effects of important product and process conditions (e.g., fat content, humidity) on inactivation. Both assume first-order (log-linear) inactivation kinetics, which ignore any lag or tailing phenomena that can be important, in terms of resistant sub-populations. Additionally, neither model accounts for temperature and moisture gradients that occur in real food products and therefore cause "lethality profiles" within a meat product. Consequently, there is still a need to further extend the methods of quantitative microbiology by coupling pathogen inactivation models with process (heat and mass transfer) models to evaluate the lethality of actual commercial cooking systems.

## **Summary**

The general observation that current microbial inactivation models fail to account for all of the factors relevant to commercial thermal processes is certainly of no comfort to an industry that is increasingly being compelled to verify and prove that cooking systems are meeting lethality performance standards. There is a significant need for user-friendly, publicly available, validated models that would allow a user to enter product conditions (size, shape, composition, initial temperature) and process parameters (equipment specifications, such as temperature, time, air velocity, humidity, etc., for each stage of a multi-stage process) and get back a prediction of product temperature profiles, cooking yield, and pathogen inactivation. Such a tool could ultimately be used to design and control multi-stage processes to ensure that the lethality performance standard is met while simultaneously optimizing cooking yield and product quality. In the meantime, processors should be cautious in applying laboratory-based microbial inactivation models to their own process data. Minimally, they should be aware of the medium and heating conditions used to generate the inactivation parameters, and recognize whether their processes differ from those conditions in significant ways, such as product composition or process humidity. Even though under-cooking in food manufacturing facilities is not currently causing widespread food safety problems, continued development of new products and processes (and the ongoing regulatory changes) necessitate a proactive stance in ensuring proper evaluation of thermal process lethality.

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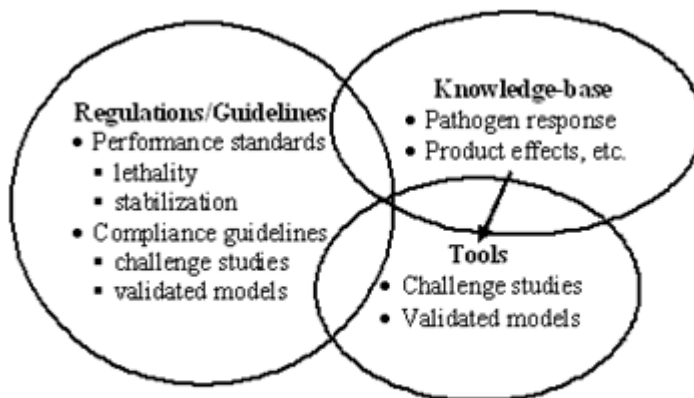


Figure 1. The intersecting domains of food safety regulations, scientific knowledge, and validated tools based on that knowledge.

Table 1. Strengths and weaknesses of tools for validating thermal process lethality.

	<b>Challenge Studies</b>	<b>Predictive Models</b>
<b>Strengths</b>	<ul style="list-style-type: none"> <li>• Product-specific results.</li> <li>• Results are lumped for an entire piece of product (i.e., the real case).</li> </ul>	<ul style="list-style-type: none"> <li>• No requirement of special biohazard facilities or testing.</li> <li>• Can compare effects of using different literature data.</li> </ul>
<b>Strengths Weaknesses</b>	<ul style="list-style-type: none"> <li>• Not practical (due to typical lack of biohazard pilot-processing facilities).</li> <li>• Results are strain-dependent.</li> <li>• It is difficult for off-line tests to exactly mimic actual process.</li> <li>• Pathogen recovery methods affect results (e.g., sub-lethally injured cells).</li> </ul>	<ul style="list-style-type: none"> <li>• Typically based on only Tcenter, which neglects the “lethality profile” in a product.</li> <li>• Few account for factors other than time and temperature.</li> <li>• Usefulness limited to domain used for model validation.</li> <li>• Unlikely to find inactivation data exactly matching specific product/process scenario.</li> </ul>