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How does industry validate elements of HACCP plans?

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Abstract

Validation is defined as the element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the hazards. The primary focus of validation for industry is to determine that critical limits at critical control points are capable of controlling the identified hazards; however, other elements such as monitoring can also be validated. Validation may involve the use of scientific publications, historical knowledge, regulatory documents, experimental trials, and other approaches. This paper reviews how the industry in the United States has validated elements of HACCP plans.

Keywords: HACCP; Validation; Scientific documentation

1. Introduction

Validation is defined by the US National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1998) as the element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the hazards. Verification is defined as activities other than monitoring that determine the validity of the HACCP plan and that the system is operating according to the plan (NACMCF, 1998). Similarly, Codex (1997, pp. 19–26) defines validation in terms of the effectiveness of the elements of the HACCP plan and verification as determining compliance with the plan. These two terms are often confused, in part because validation is a component of verification, and there are times when there are not clear distinctions between the two. Here the focus will be on validation activities to determine that the HACCP plan is scientifically and technically sound, that all the hazards have been identified, and that the control parameters are operating such that the hazards are controlled. Validation can help ensure transparency of HACCP plans—through validation and verification industry can demonstrate to regulators and to their customers that hazards are being properly controlled.

2. Approaches to validation

Validation of elements of food industry HACCP plans primarily involves validating that critical limits at critical controls points are capable of controlling the identified hazards. However, the justification for why a hazard is or is not reasonably likely to occur (to evaluate whether it needs to be addressed in a HACCP plan) can also be viewed as a form of validation. The monitoring frequency and where the monitoring occurs (e.g., the coldest point in a product during a heating process or the warmest product during cooling; the location of temperature monitoring devices in a smokehouse or a chiller) can be validated. Processing equipment, monitoring devices and electronic record keeping systems can be validated to ensure the system performs accurately and reliably in controlling the hazards (NFPA, 2002).

There are a number of approaches to validation of control measures. These include use of scientific publications, historical knowledge, regulatory documents, experimental trials, scientific models, operational data, and surveys. Generally a combination of these approaches will be used.

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2.1. Scientific publications

Probably one of the most common approaches is to use scientific publications that document the effectiveness of a control measure. These publications may be specific validation studies that evaluate the effect of defined parameters on the hazard of concern (e.g., the effect of an antimicrobial compound on growth of a pathogen or the inactivation of a pathogen by a specific process). For example, in the US the Food and Drug Administration considers *Cryptosporidium parvum* a hazard that must be addressed in HACCP plans for apple juice. In order to preserve a fresh-pressed apple flavor, companies are investigating alternatives to heat treatment, such as the use of ultraviolet (UV) irradiation. Hanes et al. (2002) conducted a study demonstrating that 14.3 mJ UV/cm^2 for $\leqslant$1.9 s achieves a 5-log reduction of oocysts of *C. parvum* in fresh apple cider. This study can serve as the basis for validating a process for apple juice using the equipment and the parameters described in the study; the processor would further validate the process by demonstrating that the parameters can be delivered consistently in plant.

Books that evaluate the existing literature and outline control parameters such as minimum and maximum growth temperatures, pH values, etc. for pathogens, e.g., ICMSF's *Microorganisms in Foods 5, Microbial Characteristics of Food Pathogens* (1996), can also be used as part of validation. For example, a processor of ready-to-eat salads concerned about growth of *Listeria monocytogenes* can determine that if the pH is maintained below 4.4, *L. monocytogenes* growth will not occur. Inoculation of *L. monocytogenes* into salads to validate the efficacy of the pH in inhibiting growth would be a waste of resources; the processor would simply demonstrate that the formulation achieves the desired pH and verify this during production.

2.2. Historical knowledge

In some instances, historical knowledge alone can serve as the basis for a validated control measure. It is well known that a pH of 4.6 or less controls outgrowth of *Clostridium botulinum* spores, and that a heat process with an F_0 of 3 will kill the spores. It has also been established that heating milk at 72 °C for 15 s inactivates pathogens. Companies should not be required to show studies proving the efficacy of these process parameters.

2.3. Regulatory documents

An approach closely related to the use of scientific publications is the use of regulatory documents and publications. Government agencies may develop regulatory requirements or produce guidance documents, generally based on scientific information, that, when followed, are considered to be validated control measures. For example, in the US, the Department of Agriculture's Food Safety and Inspection Service has developed guidance documents for lethality (USDA FSIS, 1999b) and cooling (USDA FSIS, 1999c) of ready-to-eat meat and poultry products. An establishment following the guidance only needs to validate that the times and temperatures are met during cooking or cooling. The US Food and Drug Administration (FDA, 2001b) has a Compliance Policy Guide for patulin in apple juice that establishes an action level of 50 ppb and expects this to be used as the critical limit in juice HACCP plans for apple juice (FDA, 2004).

2.4. Experimental trials

A common approach to validation is to conduct scientifically valid experimental trials to document the adequacy of the control measure. This may be laboratory challenge testing to assess the effect of a control measure, it may be in-plant challenge tests using surrogate microorganisms, or it may be in-plant trials to document the detection or removal of a physical or chemical hazard (e.g., demonstrating that a screen can remove foreign material or that processing procedures remove pesticides).

While challenge studies can be an important component of validation, there are many considerations that must be addressed. Challenge studies using pathogens are usually restricted to a laboratory environment, although some pilot facilities are equipped to deal with pathogens. It may be difficult to replicate in-plant conditions in a laboratory. For this reason, surrogate organisms that have resistance characteristics similar to the pathogen of concern are generally used to assess efficacy of a process or treatment in a plant. However, the selection of non-pathogenic surrogates is not simple. For some pathogens no surrogates have been identified, e.g., *Cryptosporidium*. In other cases it may be difficult to find a surrogate that has resistance similar to the organism of concern. Even when a surrogate exists, e.g., *E. coli* for *E. coli* O157:H7, there may be reasons for plants to restrict use of the surrogate. In the US, slaughter plants must test carcasses for *E. coli* as a measure of process control; these facilities may not wish to bring in *E. coli* to test the efficacy of, for example, an organic acid or hot water wash because of the potential to contaminate the environment and have a negative impact on process control measurement. Similarly, an establishment producing ready-to-eat products would be reluctant to use *Listeria innocua* as a non-pathogenic surrogate for *L. monocytogenes* in testing a control measure in-plant if it tests for *Listeria* spp. in the environment to verify its *Listeria* control program.

2.5. Scientific models

Microbiological growth and inactivation models such as the USDA Agricultural Research Service's Pathogen Modeling Program (PMP) (2002) or the UK Food MicroModel are frequently used by the food industry to validate whether in-plant processes are controlling foodborne pathogens. In other cases, companies have developed their own models.

2.6. Operational data and surveys

Another approach involves collecting biological, chemical or physical contamination data during operation. This approach is designed to demonstrate that a plant can routinely meet scientifically documented parameters. FDA (2004) recommends that to determine that control measures for patulin are effective, an apple juice processor should analyze at least three samples of juice for patulin taken during one year (each analyzed in duplicate and sampled under conditions where the occurrence of patulin is most likely, e.g., after apples are stored for the longest potential storage time). If all patulin levels are below FDA's action level of 50 parts per billion and the value achieved by adding 2 standard deviations to the mean is below FDA's action level, the control measures are considered to be effective.

And finally, validation may involve the use of surveys. In the US, USDA conducted extensive surveys of prevalence and levels of pathogens on raw meat and poultry that have served as a basis for the level of inactivation or control that may be needed in HACCP plans (USDA FSIS, 1998). Surveys of consumer storage temperatures for refrigerated products such as those conducted by Audits International (1999) can be useful in validating storage time or shelf life of a refrigerated product.

3. Examples applying these approaches

Generally these approaches are not used alone; rather a combination of these would be used to validate elements in HACCP plans. Almost all validation includes not only the scientific basis for the control, but also the collection of data in plant to demonstrate adherence to parameters that control the hazard.

3.1. Cooling meat and poultry

For cooling certain meat and poultry products, USDA has a performance standard that specifies no growth of *C. botulinum* and no more than one log growth of *C. perfringens* during cooling (USDA FSIS, 1999a). USDA's guidance document for cooling (USDA FSIS, 1999c) describes cooling processes that are considered valid to meet the performance standard (Table 1). Companies have obtained cooling data on products and then determined whether the processes meet the "safe harbors" in the USDA guidance document. If so, the process is considered to be validated. Companies with cooling processes that do not meet the USDA guidance have used the Pathogen Modeling Program (USDA ARS, 2002) to evaluate whether their cooling processes comply with the performance standard (Fig. 1). In some cases, especially where the cooling process may approach the performance standard of one log growth or where the process is questionable (Fig. 1b), companies have conducted challenge studies with *C. perfringens*.

Table 1
USDA cooling guidance ("safe harbors")

Option 1	54.4 to 26.7 °C in 1.5 h; 26.7 to 4.4 °C in 5 h
Option 2	Begin cool within 90 min; 48 to 12.7 °C in no more than 6 h; Continue chilling to 4.4 °C
Option 3 (for cured products with 100 ppm nitrite)	54.4 to 26.7 °C in 5 h; 26.7 to 4.4 °C in 10 h

3.2. Thermal processes

For thermal processes, industry generally uses heat resistance data (*D*-values) from scientific studies in the literature as part of the validation process. For example, the National Food Processors Association (NFPA) published literature reviews on the heat resistance of *Salmonella* (Doyle & Mazzotta, 2000) and *L. monocytogenes* (Doyle, Mazzotta, Wang, Wiseman, & Scott, 2001) for use by food processors. Based on published *D*-values, times and temperatures to inactivate specific levels of pathogens are determined. The level of inactivation may be based on historical knowledge, on surveys that establish incoming load (from the literature; from baseline studies conducted by government, research associations or trade groups; or from in-house studies) or on regulatory requirements, e.g., pathogen performance standards such as the requirement for a 6.5-log reduction of *Salmonella* in meat or a 7-log reduction of *Salmonella* in poultry (USDA FSIS, 1999a) or a 5-log reduction for microbial pathogens in juice (FDA, 2001a). However, for meat and poultry products, industry primarily uses USDA's lethality guidance (USDA FSIS, 1999b), which specifies times and temperatures considered valid to meet the performance standards. In-plant data are then collected to determine that the process achieves time/temperature combinations to inactivate the pathogen of concern. Fig. 2 illustrates data from one company used to validate both

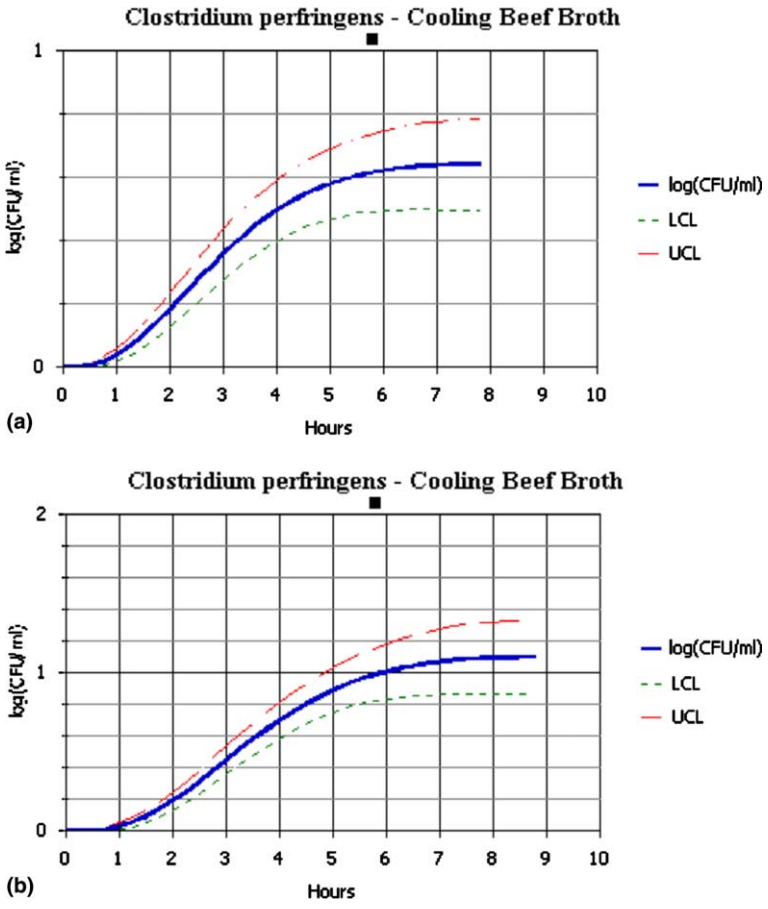

Fig. 1. Graphs from Pathogen Modeling Program; predicted growth of *C. perfringens* for a specific cooling profile. (a) Predicted growth of <1-log *C. perfringens* indicates cooling process meets requirements. (b) Model predicts growth of *C. perfringens* will exceed one log during cooling process.

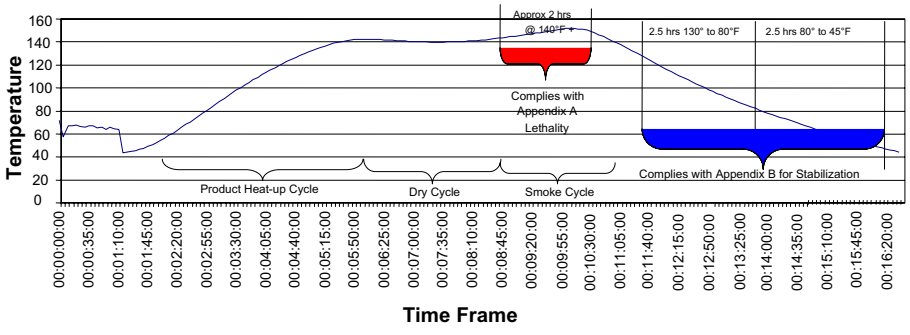

Fig. 2. Validation of smoking and cooling processes for a cured product.

the smoking and cooling cycle for a cured product. The smoking process of 60 °C for approximately 2 h exceeds the lethality guidance (60 °C for 12 min); the cooling process of 54.4 to 26.7 °C in 2.5 h and 26.7 to 4.4 °C in 2.5 h is in compliance with the cooling guidance for cured products (Option 3, Table 1).

A company that produces pasteurized, refrigerated meat and poultry products for which USDA does not currently specify lethality performance standards decided to target *L. monocytogenes* for heat treatments because the organism tends to have higher heat resistance than other meat and poultry pathogens. Based on literature data and other considerations, the company decided the process should be designed to inactivate 5 logs of the organism. As part of their process validation, they conducted thermal death time studies for *L. monocytogenes* in a variety of products, heat penetration studies on the products and temperature distribution studies on the processing equipment (smokers, continuous cookers, etc.).

FSIS has expressed concerns about the efficacy of re-cooking when there have been cooking deviations; concerns were based on the hypothesis that survivors may have enhanced heat resistance. NFPA conducted laboratory studies with *Salmonella* to validate that re-cooking such products to an internal temperature of 71.1 °C is adequate (Oyarzábel, Scott, & Gombas, 2002). These data have been used by food processors as their validation for their corrective action of re-cooking when poultry has been underprocessed.

When the US Food and Drug Administration decided to implement HACCP for juices, along with a performance standard for a 5-log reduction of pathogens, there were no literature data on the heat resistance of microbial pathogens in juices. NFPA conducted studies in various juices (apple, orange, white grape) with *E. coli* O157:H7, *Salmonella* and *L. monocytogenes* and established a general process of 71.1 °C for 3 s for juices with pH 4.0 and below (Mazzotta, 2001). This process is considered to be valid for juices except apple juice, where a 6 s process is required by FDA to inactivate *Cryptosporidium* (although this process is not fully validated).

3.3. Additives

Challenge studies are frequently conducted to validate that additives used as ingredients in formulations achieve their intended effect. This may involve initial laboratory studies to determine appropriate concentrations and evaluate the effects of temperature, pathogen load, etc. Formulations may then be prepared and product evaluated at refrigeration and abuse temperatures for the intended shelf life. Oscar Mayer Foods, working with Purac, has developed a scientific model to predict the growth of *L. monocytogenes* in cured ready-to-eat products with added lactate and diacetate that has been used as a component of validation studies for these products (Seman, Borger, Meyer, Hall, & Milkowski, 2002). The model (Opti.Form) has been incorporated into a spreadsheet available on CD-ROM from Purac. An example from the program is shown in Fig. 3.

3.4. Carcass treatments

For carcass treatments such as organic acid washes and hot water pasteurization, industry has used scientific publications along with on-site documentation that the units are set up according to manufacturers' specifications. This has been combined with "before" and "after" microbiological data for validation. In some cases, this information is being supplemented with challenge studies using non-pathogenic microorganisms that have been "calibrated" with respect to resistance in comparison with *Salmonella* and *E. coli* O157:H7.

Level of use		**3.3**	**2.5**	**2**	
	Control	**% OptiForm 4**	**OptiForm 6**	**%OptiForm 8**	**your own blend**
Product Ingredients	% of Finished Product	% of Finished Product	% of Finished Product	% of Finished Product	% of Finished Product
Salt (%) =	2.50	2.50	2.50	2.50	2.50
Sodium Diacetate (%) =	0.00	0.13	0.15	0.16	0.12
Potassium Lactate (%) =	0.00	1.85	1.35	1.04	1.00
Finished Product Moisture (%) =	55.00	55.00	55.00	55.00	69.00
Calculated 60% lactate solution used in your own blend:		3.08	2.25	1.73	1.67

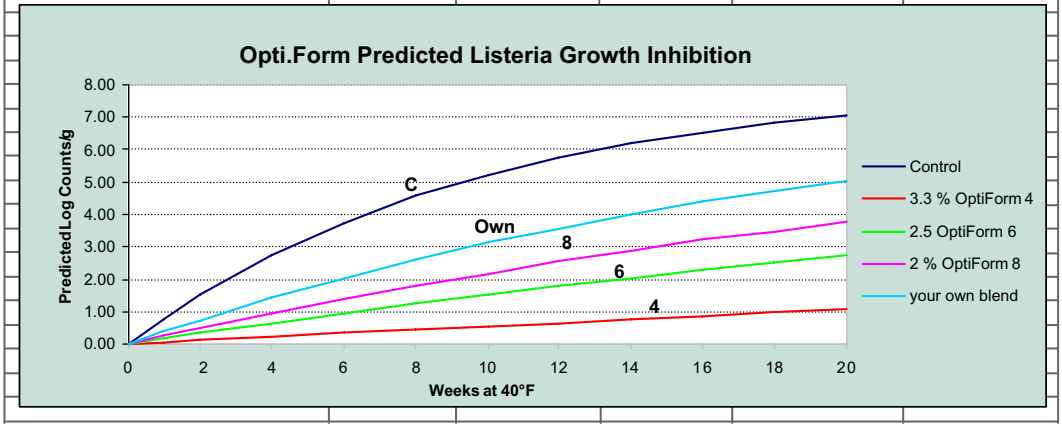

Fig. 3. Example of predicted growth of *L. monocytogenes* from Opti.Form model for ready-to-eat meat product containing sodium diacetate and potassium lactate.

3.5. Other validations

In response to FSIS concerns, one company found it necessary to determine whether, when undercooked product was produced on the line (i.e., product that did not meet the critical limit specified in the HACCP plan), it was necessary to stop the line and re-sanitize. The company argued that the surface of product would be adequately processed, however FSIS wanted to see validation data to demonstrate that undercooked product would not result in contaminated food contact surfaces. The company contracted with a laboratory to conduct studies with a surrogate; *Enterobacter faecalis* was used to inoculate product, and food contact surfaces were tested to see if the organism could be recovered under various cooking conditions. The study validated that sanitation was not necessary when there were cooking temperature deviations down to 68.3 °C and the undercooked product was intact (i.e., food contact surfaces were not exposed to the undercooked portion).

Companies are frequently asked to validate the number of sample units monitored at critical control points for pH or for temperature during cooking and cooling or for verification of compliance with the HACCP plan. Validation has been done by sampling a large number of units, looking at the variation and determining the number that would be representative of the batch, smokehouse, cooker, chiller, etc. Heat penetration and heat distribution tests have frequently been used to determine where in the product and where in the cooker or chiller temperatures should be measured to ensure that the monitoring location is appropriate.

4. Who conducts validation

Validation studies may be conducted by contract laboratories, by universities, by equipment or ingredient manufacturers, or in-house. Some components of validation may be conducted by personnel at the corporate office, others by plant personnel. Corporate personnel often become involved for validation of processes that will apply to multiple facilities belonging to the company. Trade associations may develop validation protocols that can be used by industry segments. Many validation studies are partnerships between companies and trade associations, companies and universities, or companies and suppliers. Partnerships are particularly useful when validation studies are being conducted for an industry segment rather than an individual company.

One unique partnership of Alkar-RapidPak, Kraft, and USDA is looking at integrating a steam surface pasteurization chamber into a hot dog packaging machine to provide a kill step prior to package sealing (Fig. 4). Inoculated pack tests (Table 2) have demonstrated that low levels of *L. monocytogenes* (10^2 per package) can be eliminated in single layer packages. Additional development work will be necessary for double layer packages and for other product types. The equipment

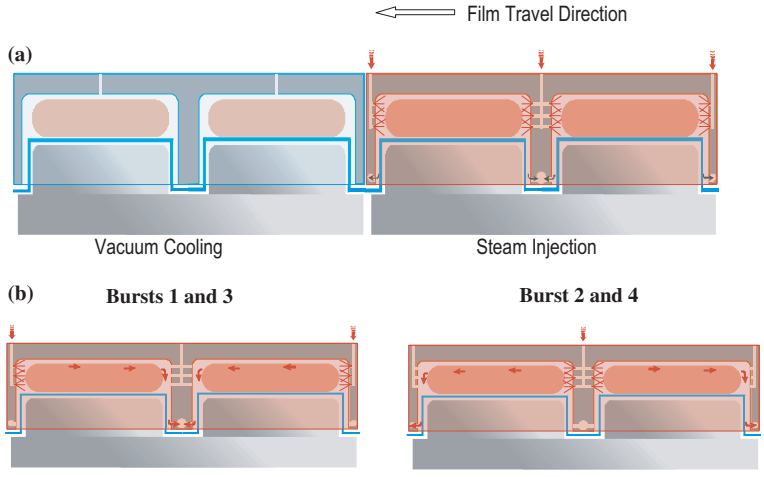

Fig. 4. Steam surface pasteurization. (a) Injection of high pressure steam and venting of condensate. (b) For each 1.5 s cycle there are four bursts, with alternating direction.

Table 2
Steam surface pasteurization (SSP) of hot dogs

Product	100 *L. monocytogenes* per package	1000 *L. monocytogenes* per package
Single layer SSP (6 hot dogs per package)	0% positive	36% positive
Double layer SSP (8 hot dogs per package)	60% positive	75% positive

manufacturer will conduct validation tests for its customers.

5. Reassessment and revalidation

The terms reassessment and revalidation are sometimes used interchangeably, which can cause confusion. Reassessment is a process where all the assumptions and conclusions are reviewed to see if they are still valid and if the HACCP plans is still adequate; it should occur annually. Revalidation may be required as a result of reassessment. Revalidation may be conducted to confirm earlier results, especially if data were limited and to assess the validity of less conservative parameters. Revalidation is required when there are failures, when new information becomes available that suggests the HACCP plan may be inadequate, or when significant changes occur in an operation.

6. Keys to validation

The keys to validation are to know the food safety purpose of what is being validated; develop scientific documentation for the process being validated; document delivery of the control measure; and document the functionality of the control measure, e.g., by conducting microbiological testing to determine the absence of the pathogen of concern. After the initial validation process, documenting delivery and functionality of the control measure become components of verification.

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