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Effectiveness and performance of HACCP-based programs

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Abstract

Since the early 1990's, HACCP-based programs are being implemented as a means of preventing food hazards in fish and seafood products. From an engineering perspective, a system designed to control a manufacturing process is expected to result in final product that consistently meet requirements. Although audits are used to verify program implementation, there is a need for some product monitoring to measure the effectiveness and performance of the control systems. This paper discusses the need to monitor final product in seafood HACCP-based programs to measure effectiveness from a systems approach. Information time series of audits and inspections conducted are shown to be more indicative of program performance than snapshot inspections of the final product.

Keywords: HACCP; Performance; Effectiveness

1. Introduction

HACCP-based programs were implemented in the 1990's to enhance food safety and quality. Preventive measures in terms of adequate process controls accompanied by periodic verification and corrective actions were considered more effective than inspecting defects out of each lot of final product (Ropkins & Beck, 2000). Thus, seafood regulatory authorities and industry incorporated the HACCP principles in their programs and processes (Adams, 2002). In some cases, entire inspection services and quality control programs were totally redesigned replacing product and facility inspections with process and system audits (Lee & Hathaway, 2000; McEachern & Mountjoy, 1999). In seafood, HACCP-based programs are now based on a comprehensive set of procedures and controls that also adhere to good manufacturing practices (GMP) and good hygiene practices (GHP) (Ababouch, 2000; Huss, Ababouch, & Gram, 2003).

Comprehensive audits of program implementation and operation are considered as the primary tool of HACCP-based program verification (Sperber, 1998). Such audits are used by regulators and industry to ensure regulatory compliance, production performance and, even, equivalency between trading partners (Higuera-Ciapara & Noriega-Orozco, 2000; Lupin, 1999). Less emphasis is directed towards final product inspections given that HACCP-based programs are deemed to provide an appropriate level of protection via preventative control measures and corrective actions (Adams, 2002; Sperber, 1998). However, the need for final product monitoring to verify the effectiveness of these programs is also recognized (Allen, 2001; Brown et al., 2000; Ingham et al., 1997; Notermans, Nauta, Jansen, Jouve, & Mead, 1998). Final product monitoring is often conducted during audits as low level sampling or in response to market requirements (Robach, 1996; Silliker,

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1995). Upon finding a food hazard in the product, the HACCP-based system of procedures and controls is assumed to have failed. Subsequently, considerable efforts are devoted in recalling product and in implementing adequate corrective action deemed necessary to restore control (Struijk, 1996). Generally, little attention is given to the fact that a HACCP-based program can only minimize the probability or risk of food hazards from occurring (Struijk, 1996; Untermann, 1997; Untermann, Dura, & Stephan, 1997). This concept is well understood in manufacturing where any process is expected to have a normal failure rate (Tobias & Trindade, 1998).

Listeria monocytogenes is the pathogenic agent of Listeriosis, a foodborne illness, which can prove fatal in susceptible individuals (FAO, 1999). Studies show that *L. monocytogenes* is particularly difficult to eliminate from the processing environment and equipment stressing the need for relentless vigilance in employee hygiene and improvements in equipment design and cleaning agents (Chiasson, Cormier, Cormier, & Beaulieu, 1998; Miettinen, Aarnisalo, Salo, & Sjöberg, 2001; Valdimarsson, Einarsson, Godbjörnsdottir, & Magnusson, 1998). Facing zero tolerance requirements for *L. monocytogenes* from their major import markets, both Canadian and Icelandic seafood industries started implementing measures to control this pathogen in the 1990's. However, ready-to-eat (RTE) frozen lobster meat and shrimp have inherent preservation constraints given their susceptibility to heat treatment needed to eliminate this pathogen. The quality of such products in terms of texture and flavour are significantly altered when subjected to high temperatures.

Today, *L. monocytogenes* remains a challenge for the RTE seafood industry even after the implementation of focused hygiene and sanitation practices and HACCP-based programs (Gudbjörnsdóttir et al., 2004). Having consistently monitored these products in addition to implementing HACCP-based programs, the data collected from the Canadian and Icelandic analysis can be used to study the benefits of implementing HACCP in the manufacturing processes of these products. This paper discusses the feasibility of such time series in measuring the effectiveness and performance of HACCP-based programs. It also discusses the merits of final product monitoring as a paradigm shift from inspection of individual lots to monitoring of an entire program.

2. Sampling and analytical methods

2.1. Canada

In light of the zero tolerance requirements of the United States market (Buchanan, 1991), quality control staff, at the processing establishment, collected weekly aseptic samples of lobster meat at the end of the production line or from frozen RTE lobster product. Upon arrival at the "Centre de recherche sur les aliments", each sample was kept frozen until analysis usually conducted within 1–3 days. It is noted that upon finding *L. monocytogenes*, the product was further pasteurized. A total of 2874 RTE Lobster samples were analyzed between 1991 and 2001 (Table 1).

Table 1
The number of RTE lobster samples found positive for *Listeria monocytogenes*

Year	Positive	Total
1991	2	41
1992	14	74
1993	12	78
1994	36	254
1995	67	247
1996	71	234
1997	13	239
1998	28	401
1999	9	397
2000	19	396
2001	16	513
Total	287	2874

From 1991 to 2001, *L. monocytogenes* analyses were conducted using standard Health Canada methods as listed in the "Compendium of Analytical Methods" (HC, 1998, HC, 2001a, 2001b; HWC, 1988; HWC, 1995). Although these methods are updated by the competent authority overtime, the method MFHPB-30 (HC, 2001b) was used consistently for the confirmation *L. monocytogenes*.

2.2. Iceland

From 1989 to 1999, analyses for *L. monocytogenes* were routinely made for ready-to-eat shrimp. The samples of cooked and peeled shrimp were taken as part of a regular quality assessment and sent to the Icelandic Fisheries Laboratories. Adhering to the principles of random sampling, all samples that were part of a targeted sampling regime are excluded from the data set of this analysis. A total of 7156 RTE Shrimp samples were analyzed between 1989 and 1999 (Table 2).

The method for *L. monocytogenes* consisted of a 25 g sample put into a 225 ml of UVM modified *Listeria*

Table 2
The number of RTE shrimp samples found positive for *Listeria monocytogenes*

Year	Positive	Total
1989	5	78
1990	72	447
1991	256	667
1992	48	977
1993	43	1001
1994	7	744
1995	13	937
1996	3	732
1997	6	521
1998	3	780
1999	2	272
Total	458	7156

enrichment broth (BBL). Incubation was in a Stomacher bag at 30 °C for 26 ± 2 h (Fraser broth: UVM modified Listeria enrichment broth (BBL) + LiCl (Merck) 3.0 g/l; acriflavin (Sigma) 0.012 g/l; ferric ammonium citrate (Sigma) 0.5 g/l). A loop full from the black Fraser broth was then streaked onto Oxford agar (LOX) (Oxoid) and the plates were incubated at 35 °C for up to 48 h. Confirmation tests were made on black colonies from LOX agar via Gram-staining/microscopic examination, motility (hanging drop) and catalase test. The KOH test (Gregersen, 1978) was in some cases used instead of Gram staining. Species identification was occasionally done. Haemolysis on blood agar and fermentation tests were used. Starting in 1995, the API Listeria kit (System for the Identification of Listeria, bioMérieux SA/France) has been used.

2.3. Binomial confidence limits calculations

The non-compliance rate is defined as the proportion of lots found to be non-compliant. Non-compliance rate confidence intervals were all calculated using the binomial distribution. The confidence interval is defined by a lower (L) and upper (U) non-compliance rate bound such that:

$$\Pr(X > x|L) = \sum_{j=1}^{x-1} \text{Binomial}\ (N \text{ trials}, j \text{ failures}, L) = \alpha/2 \tag{1}$$

$$\Pr(X \leqslant x|U) = \sum_{j=1}^{x} \text{Binomial}\ (N \text{ trials}, j \text{ failures}, U) = 1 - \alpha/2. \tag{2}$$

The values of L and U of Eqs. (1) and (2) are calculated using the total number of sampled lots (N) and the number of non-compliant lots (x). An $\alpha = 0.05$ provides a confidence interval at the 95% level.

Given that the binomial is a discreet distribution, the calculated confidence level may not match exactly the theoretical 95% level. Therefore, the L and U yielding the closest value $\alpha/2$ and $1 - \alpha/2$ are chosen. In cases where the non-compliance rate is zero ($x = 0$), only an upper bound can be calculated since a non-compliance rate cannot be lower than 0%. Given that non-compliance rates in this study are mostly between 0% and 10%, the normal approximation is not used to calculate confidence intervals to avoid biased estimates.

3. Results and discussion

A HACCP-based program is basically a comprehensive set of requirements, procedures and controls to ensure the safety and quality of the final seafood product. Most programs include prerequisite requirements for the processing establishment, control measures at critical and non-critical steps of the processing line as well as management practices with a focus on record keeping and corrective actions. The effectiveness of such programs is considered as the capacity to achieve safety and quality objectives while the efficiency is related to costs of implementation and operation. The performance of a HACCP-based program is the measure of consistency, and thus reliability, in achieving safety and quality objectives successively from batch to batch or lot to lot during a production cycle or a season of operation. In this study, *L. monocytogenes* is used only as an example of a food safety hazard for which a HACCP-based program is implemented for its control.

3.1. Canadian context

In Canada, the quality management program (QMP) was implemented as a regulated program in 1992. The program was initially a comprehensive set of procedures and requirements dealing with processing plant equipment, operation, employee qualifications, sanitation, process control, recall procedures and included requirements for incoming fish, ingredients, packaging, labelling and the final product. Although the program resulted in a stable lot rejection rate for quality attributes of ≅4.5% after implementation (Cormier, 2002), *L. monocytogenes* in RTE frozen lobster continued to be of concern (Chiasson et al., 1998). In the early part of 1996, the QMP was re-engineered to realign the program with the principles of HACCP. The re-engineered version was implemented in 1997 with considerable training provided to inspection and industry staff (McEachern, Rideout, Bungay, Flohr, & Dillon, 1998).

3.2. Icelandic context

Between 1992 and 1994, major buyers were requesting that the shrimp processing industry establish their own standards resulting in the creation of quality handbooks. Requirements also included quality management practices internal to the processing plant with a focus on cleanliness and improved processing facilities. Over time, buyers demanded that analysis be conducted on the final product prior to signing a contract as a method of verifying that processing facilities were adhering to the quality systems. During this period, processing plant operations segregated the movement of equipment and employees as to prevent raw products from becoming in contact with cooked products. This was done with the implementation of enhanced plant layout and operational procedures. Concurrently, HACCP principles were being adhered to with the development of HACCP-based programs that were fully operational between 1993 and 1994.

3.3. Trend analysis

Both the RTE lobster (Fig. 1) and RTE shrimp (Fig. 2) data suggest that the implementation of HACCP-based programs had a net impact on their respective processes in terms of minimizing the probability of finding *L. monocytogenes* in their RTE seafood. After the implementation of the re-engineered QMP in 1997, the non-compliance rate

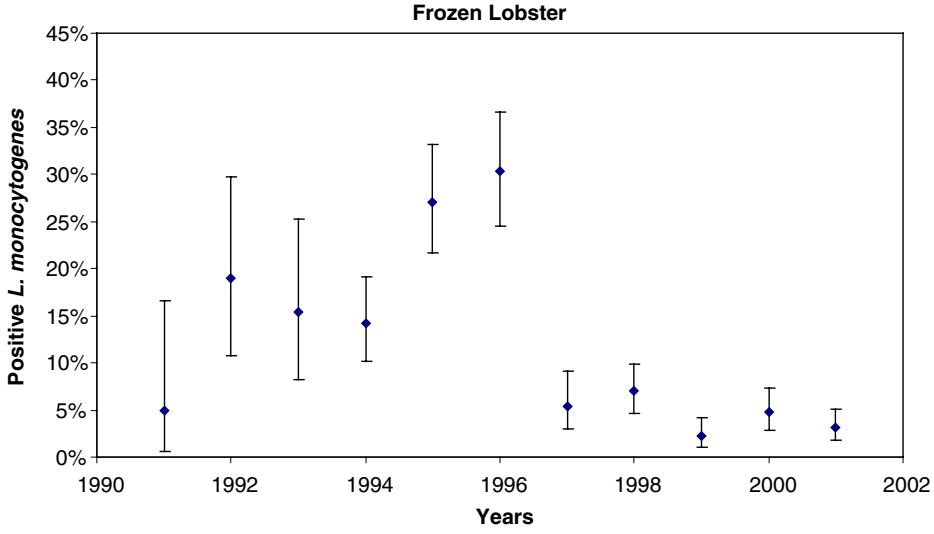

Fig. 1. Yearly non-compliance rates for the presence of *Listeria monocytogenes* in RTE lobster.

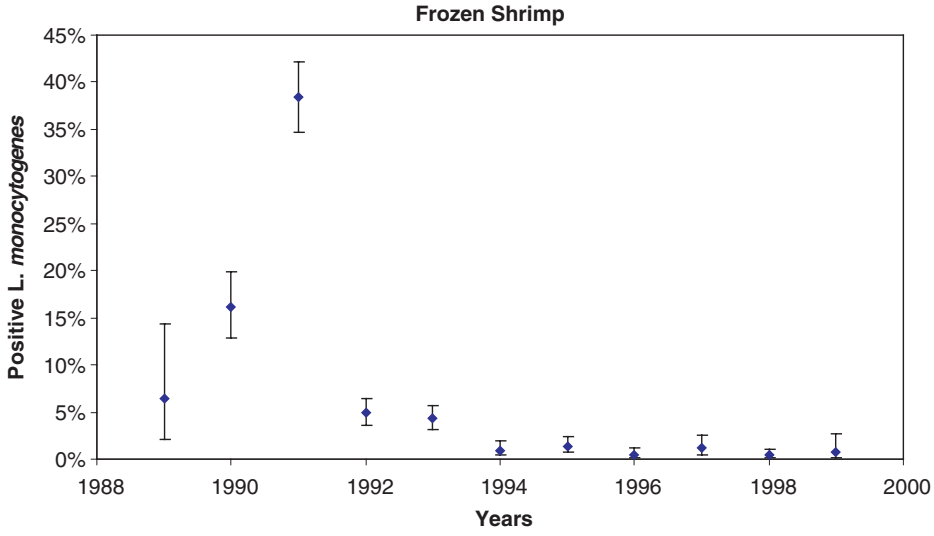

Fig. 2. Yearly non-compliance rates for the presence of *Listeria monocytogenes* in RTE shrimp.

for *L. monocytogenes* in RTE lobster dropped to ≅5%. A similar trend is observed for RTE shrimp from Iceland where the non-compliance rate for *L. monocytogenes* dropped to ≅0.1% after the implementation of enhanced sanitation and HACCP-based programs in 1994.

As with HACCP-based programs, process control or quality management systems are designed to reduce or eliminate the known causes of process variation that may impact product specifications (Kear, 1998). These systems are expected to manufacture product that meet specifications consistently. HACCP-based programs are also expected to produce food that meet a given set of food safety and quality specifications consistently. The data corroborate this concept showing that the HACCP-based programs in both countries are effective at minimizing the occurrence of *L. monocytogenes* in their respective RTE seafood. From a consistency perspective, both sets of data show that the yearly non-compliance rates have remained unchanged and stable with no significant differences ($\alpha = 0.05$) from year to year. The data also show that with state of the art processing methods and facilities, the prevalence of *L. monocytogenes* is such that, under zero tolerance import regimes, shipments will be rejected.

Manufacturing control and management systems also have inherent failure rates due to unavoidable and inherent process variation for which no specific causes can be identified (Kear, 1998). Such failure rates are closely related to process design which includes the controls and management practices. As such, fundamental redesign is most often needed when a failure rate is deemed unacceptable. This study suggests that processes, managed by HACCP-based programs, also have an inherent non-compliance rate similar, in concept, to a manufacturing failure rate. The data also show that the non-compliance rate is specific to the

type of process and product. RTE shrimp processes are much more mechanized than RTE lobster processes resulting in a lower normal non-compliance rate for introduced pathogens such as *L. monocytogenes*.

In the past, product inspections were aimed at finding non-compliant lots and eliminating them from the food supply. Upon failing inspection, the non-compliant or rejected lot was destroyed, culled or re-worked. With the advent of HACCP-based programs, inspection efforts shifted towards audits of a system of controls and management practices designed to prevent non-compliance. Based on the best available scientific and technical information, critical control points (CCP's) are sometimes assumed to be effective and even fool proof at controlling hazards resulting in expectations of zero risk (Anklam & Battaglia, 2001). However, the reliability of a system and the assurance that the resulting product meets expected specifications is dependent upon the cumulative effectiveness of the controls and management practices of the entire system (Joppen, 2004; Tobias & Trindade, 1998). Program effectiveness should not be confused with efficiency that are mostly issues related to human resource and operational costs. In a HACCP-based program, it is the entire system of CCP's, processes, handling practices, sanitation cycles, monitoring procedures, corrective actions and even employees abilities and attitudes that have to operate flawlessly to ensure that the product is compliant from batch to batch or manufacturing cycles (Adams, 2002; Mortimore, 2001). The data clearly show that final product monitoring can provide valuable insight as to the effectiveness and performance of any given HACCP-based program (Baird-Parker, 1995; van der Spiegel, Luning, Ziggers, & Jongen, 2003). In recognizing that such programs have inherent non-compliance rates, a process, managed by such a program, cannot be considered "out of control" when an individual lot of product is found non-compliant, even though product action is required to remove the problem lot from market. It is only when the non-compliance rate varies from batch to batch or continues to increase over time that a process can be deemed "out of control". From a before and after perspective, such data can also measure the impact of program changes or redesign as well as provide industry performance benchmarks. However, product monitoring schemes must be based on sound random stratified sampling strategies where inspection needs to shift from looking for problems in a specific lot to monitoring the performance of entire system controlled by HACCP-based programs.

Product monitoring schemes must be designed to statistically measure the effectiveness of HACCP-based programs and the performance of their implemented system. These schemes need to take into account the type of process and the safety and quality compliance requirements including the number and frequency of sampled batches or lots over time. Each type of process has a specific profile of safety and quality issues for which the HACCP-based program was designed to control such as *L. monocytogenes*. Instead of targeting inspection towards suspect product and problems, such monitoring should evaluate systematically the entire set of specification to establish base-line data for each of the specific hazards or issues controlled by the HACCP-based program. The frequency of the sampling effort should cover the start-up, operational and shut-down phase of the seafood processing cycle or season. Finally, the number of batches or lots sampled must be sufficient to allow for statistical comparison of HACCP-based performance from year to year or sector to sector. Low levels of sampled lots will result in very large confidence interval rendering comparison useless. In this study, simple binomial confidence intervals ($\alpha = 0.05$) calculated for each yearly non-compliance rate provided for adequate statistical comparison. Using a non-compliance rate of 5%, as an example, 80–100 batches or lots would be needed to reduce the confidence limit range to ≅10% (Table 3).

Table 3
Binomial confidence limit ($\alpha = 0.05$) ranges for a non-compliance rate of 5%

Lots tested	Lots failed	Lower bound (%)	Upper bound (%)	Confidence range (%)
20	1.0	0.13	24.87	24.74
40	2.0	0.61	16.91	16.30
60	3.0	1.04	13.92	12.88
80	**4.0**	**1.38**	**12.30**	**10.93**
100	**5.0**	**1.64**	**11.28**	**9.64**
200	10.0	2.42	9.00	6.58
300	15.0	2.82	8.11	5.28
400	20.0	3.08	7.61	4.53
500	25.0	3.26	7.29	4.03
600	30.0	3.39	7.06	3.66
800	40.0	3.59	6.74	3.15
1000	50.0	3.73	6.53	2.80
2000	100.0	4.08	6.04	1.96

4. Conclusion

Proponents of the former "inspect as you go" approach argue that some form of product monitoring is still required to verify the implementation of HACCP-based programs (Allen, 2001; Kvenberg & Schwalm, 2000). Audits which include a visit to the facility and review of records can only confirm that the procedures and processes of the manufacturing system are being implemented as planned. The data presented in this paper highlights the value of product monitoring time series as a means of measuring the effectiveness and performance of HACCP-based programs. A time series can provide valuable feedback in tracking impacts of changes made to the design of a program or the performance of its implementation over time. However, the number of examined lots or shipments must be sufficient to ensure comparisons from year to year that can bear statistical scrutiny. However, these time series must be maintained for extensive periods of time. The data in this study covered a period of over 11 years. Such maintenance include proper documentation of the data in terms of type of product, types of methods used, data interpretation

and safeguards in terms of record keeping in paper or electronic forms. With the proliferation of personal computers and databases, this has been particularly problematic (Cormier, 2004).

Still, HACCP-based program implementation is not yet homogeneous between trading partners (Ababouch, 2000; Higuera-Ciapara & Noriega-Orozco, 2000). In addition to hampering equivalency negotiations, some exporting countries have to maintain several HACCP plans in order to meet the requirements of each export market even though they only have one process and product (Panisello & Quantick, 2001). The Sanitary and Phytosanitary Agreement (SPS Agreement) of the World Trade Organization (WTO) stipulates that control measures should be based on sound scientific evidence. In addition, a member country of the WTO shall accept the other member country measures as equivalent if final results are the same. Equivalence in food safety systems should focus on achieving similar levels of protection against fish-borne health hazards and quality defects by whatever means of control and management processes (Stewart, Tompkin, & Martin, 2002; Valdimarsson, Cormier, & Ababouch, 2004). A compliance criterion is the expected level of protection while a non-compliance rate is a measure of program effectiveness. Such base line data is much more valuable in providing a measure of program performance which is the ability of a given program to produce food that meets the compliance requirements consistently between shipments. This type of data can be an excellent indicator of system control. Finally, such data can greatly facilitate equivalency negotiations given the transparency principles of the SPS Agreement. In addition to leaving the notions of zero tolerance a fallacy, one would be hard pressed to refuse entry of a given food when the imported product has an equivalent or better non-compliance rate performance.

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