



Crossover Food Businesses in Louisiana, United States: A Descriptive Study of Their Characteristics and Food Safety Training Needs From Public Health Inspectors' Perspective

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Objectives: Integrating retail and manufacturing enables limitless potential for food businesses, but also creates challenges for navigating within complex food safety regulations. From public health inspectors' (PHIs) perspective, this study aimed (1) to describe the characteristics of crossover businesses in Louisiana, and (2) to evaluate regulation awareness and food safety education needs for business owners and PHIs who inspect crossover businesses.

Methods: A self-administered questionnaire was administered to Louisiana Department of Health PHIs using Qualtrics[®]. A descriptive analysis was performed, focusing on the frequency of each item.

Results: In total, 1774 retailers were conducting or planned to conduct specialized processes, while 552 food manufacturers were performing or planned to perform retail functions. Reduced oxygen packaging, the use of additives such as vinegar as a method of preservation, and smoking food as a method of preservation were observed by 62%, 36%, and 35% of the PHIs, respectively. The PHIs perceived crossover businesses as "not aware" or "somewhat aware" of the food safety regulations. The current food safety training level for these businesses was reported to range from "no training" to "some training but not sufficient." When asked for a self-assessment, the majority of PHIs reported themselves as being "familiar" with the variance requirement for specialized processing. Their confidence in inspecting crossover businesses, however, leaned towards "not confident" or "somewhat confident."

Conclusions: To better guard public health, food safety training is needed for crossover food business owners, as well as PHIs, on regulations and conducting or inspecting specialized processes.

Key words: Crossover food businesses, Public health inspectors, Food safety, Inservice training

Received: January 8, 2022 Accepted: March 25, 2022

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INTRODUCTION

Food safety is a global public health problem, and it has been a major concern in the United States for decades [1]. The food industry is challenging to regulate because it is dynamic and flexible. A recent trend is for food businesses to cross over between retailing and manufacturing, blurring the lines between industries [2-5]. For example, a retail food establishment

may start focusing on selling food directly to consumers with a side revenue of selling to other businesses. Over time, the selling to other businesses portion might grow to the point that it exceeds direct sales to consumers, completely changing the primary function of the business. Conversely, it is not unusual to see a food manufacturer perform retail functions, where foods are sold directly to consumers. Engaging in manufacturing, retail, and/or food services enables limitless potential and growth of food businesses, but also makes it complicated for businesses to understand what regulations they need to follow.

Regulations on intrastate food businesses vary among states. Louisiana retail-food service businesses are regulated under the Louisiana Administrative Code Title 51 Part XXIII Retail Food Establishments [6]. The Louisiana Department of Health (LDH) Retail Food Program enforces regulations that protect the food supply and investigate foodborne illness outbreaks within the state. A total of 174 PHIs in Louisiana (at the time of the study), also administratively known as sanitarians, inspect nearly 34 000 food establishments that have permits in the state [7], including 16 747 restaurants, 7140 grocery stores, and 1077 meat markets. The LDH conducts 4 types of inspections of retail food establishments to determine compliance with the state's regulations, including pre-operational inspections, routine inspections, re-inspections, and complaint inspections. Routine inspections are conducted 1-4 times per year depending on the risk level of the establishment [8]. Many businesses that perform specialized processing methods, as described in the Federal Food Code §3-502.11 and §3-502.12, are required to have a Hazard Analysis Critical Control Points (HACCP) plan, and some may require a variance to be submitted to LDH [9].

Specialized processing is defined by the U.S. Food and Drug Administration (FDA) Food Code to mainly include the following processing categories: (1) smoking food as a method of food preservation rather than as a method of flavor enhancement; (2) curing food; (3) using food additives, such as vinegar, as a method of food preservation; (4) packaging time/temperature control for safety (TCS) foods using reduced oxygen packaging (ROP); (5) operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption; (6) custom-processing animals that are for personal use as food and not for sale or service in a food establishment; and (7) sprouting seeds or beans [9]. These specialized processes call for additional regulations because they have been associated with pathogens with public health concerns such as *Clostridium botulinum* [10] and *Listeria monocytogenes* [11].

C. botulinum forms spores and is often associated with ROP due to its anaerobic characteristics. The toxin produced by *C. botulinum* is considered one of the most poisonous naturally occurring substances known [12]. *L. monocytogenes* is an environmental pathogen that is widely distributed and could be introduced into food establishments through raw ingredients, personnel, and/or equipment. *L. monocytogenes* is frequently associated with cold-stored ready-to-eat foods, including meat and poultry products, soft cheese, unpasteurized milk, vegetables, and seafood [11]. Even though listeriosis is rare, it is a serious illness, with a 20-30% mortality rate [13].

To reduce the risk of foodborne illnesses, food businesses must comply with food safety regulations. Yapp and Fairman [14] evaluated the factors affecting food safety compliance. A lack of knowledge and understanding was identified as a barrier preventing compliance with regulatory requirements. Considering the dynamic and uniqueness of crossover food businesses, this study aimed (1) to describe the characteristics of crossover businesses in Louisiana, and (2) to evaluate regulation awareness and food safety education needs for business owners and PHIs who inspect crossover businesses. This study approached the assessment from the perspective of PHIs, who inspect all food establishments within the state, because they are closest to the government agencies that enforce food safety regulations.

METHODS

Questionnaire Development

A descriptive questionnaire was designed to record information in 4 domains with 8 constructs (Table 1), including the number of crossover businesses a PHI inspected in the past 12 months, crossover businesses' awareness of food safety regulation, PHIs' awareness of the FDA Food Code variance requirements, the number and types of specialized processing observed by PHIs; crossover businesses' food safety education needs from PHIs' perspectives, crossover businesses' food regulation navigation needs from PHIs' perspectives, PHIs' confidence level when inspecting crossover businesses, and the demographic characteristics of the PHIs. The 12-month time frame was chosen because routine inspections by PHIs were planned and conducted on a yearly basis. A 3-point Likert scale was used to measure awareness, educational needs, regulation training needs, and confidence. For example, in the "crossover

Table 1. Questionnaire grouping and question categories completed by LDH PHIs on September 29, 2020

Domain	Category or categories
Participant characteristics	Demographics
Landscape of crossover businesses and specialized processing in Louisiana	No. of crossover businesses a PHI inspected in the past 12 mo No. and types of specialized processing observed by PHIs
Business owners' awareness of food safety regulations, food safety education needs, and regulation navigation needs	Crossover businesses' awareness towards food safety regulation Crossover businesses' food safety education needs Crossover businesses' food regulation navigation needs
PHIs' awareness, confidence, and challenges	PHIs' awareness of the FDA Food Code variance requirements PHIs' confidence level when inspecting crossover businesses

LDH, Louisiana Department of Health; PHI, public health inspector; FDA, U.S. Food and Drug Administration.

businesses' awareness of food safety regulation" category, one of the questions stated, "in your opinion, how aware are owners of businesses that they need to comply with different regulations if they cross the line between retail and manufacturing," and the options included "not aware at all," "somewhat aware," and "very aware". In the "PHIs' awareness of the FDA Food Code variance requirement" category, a question stated, "are you, as a sanitarian, familiar with the following FDA Food Code variance requirements," and the options included "not familiar at all," "familiar," and "very familiar."

The questionnaire was reviewed internally. Feedback was received from 3 colleagues within the university and the Chief Sanitarian Supervisor from LDH. The questionnaire wording was modified based on the feedback. The length of the questionnaire was deemed acceptable by reviewers.

Questionnaire Administration

The questionnaire was explained and administered to state PHIs via a Zoom meeting on September 29, 2020. The meeting was organized by the LDH Chief of Field Operation as a state-wide education session. A 15-minute presentation was given to explain the purpose and importance of the survey. At the end of the presentation, a Qualtrics® link was used to distribute the questionnaire. PHIs completed the survey while still connected to the meeting. Two authors facilitated the session. Questions were addressed when they were asked. The total number of responses (171) was compared with the total number of PHIs (174) and confirmed by the Chief. The average completion time was 7.9 minutes.

Statistical Analysis

Descriptive statistical analyses were conducted in Microsoft Excel version 2016 (Microsoft Corp., Redmond, WA, USA). To

access the characteristics of the crossover businesses in Louisiana, the total number of businesses crossing from retailing to manufacturing and from manufacturing to retailing was calculated by totaling the numbers reported by each PHI. Percentages were used to describe the specialized processes conducted at retail businesses, through which we identified the top 3 specialized processes conducted by food establishments in Louisiana. Business owners' awareness of food safety regulation and their food safety education needs from PHIs' perspective, as well as PHIs' awareness and confidence data, were collected on a 3-point Likert scale (not aware at all, somewhat aware, very aware). Percentages were calculated based on the total responses for each specialized process, regulation, or food safety training program.

Ethics Statement

The study was approved by the Institutional Review Board of Louisiana State University AgCenter (HE19-13) prior to administration.

RESULTS

Characteristics of Respondents

In total, 171 completed questionnaires were collected. Thanks to the collaborative efforts of the LDH, the response rate was 98%, which provided us a relatively complete picture of the food businesses in the state of Louisiana from PHIs' perspective. Among all the participants, retail business inspectors accounted for 87.6%. Other participants included Specialty Operations (non-seafood, 8.0%) and Specialty Operations PHIs (seafood, 4.4%). When asked how many parishes (counties) they covered, 64% of PHIs stated that they only covered 1 parish. PHIs' working experience ranged from 1 month to 35 years.

Responses from regional and statewide supervisors, as well as central office staff (29 total), were excluded because they contributed to the duplication of the results. Supervisors and central office staff reported the total numbers within their supervision area, which had already been reported individually by parish PHIs. After this exclusion, 142 responses were used for further analysis.

Characteristics of Crossover Businesses and Specialized Processing in Louisiana

The results showed that 12 months before the time of this study, 2326 food establishments either were or were planning to become crossover businesses. PHIs collectively inspected 1774 retailers who were conducting specialized processing (72%) or were planning to package foods for sale (28%), compared to a much lower number of manufacturers (a total of 552) that had retail stores (75%) or were planning to open retail stores (25%).

Sixty-two percent of the PHIs reported inspecting food establishments that conducted ROP. Smoking food and the use of additives as a method of preservation were reported by 35% and 36% of the PHIs, respectively. Curing food and shellfish life support systems were not as popular. Curing food was observed by 14% of the PHIs, while shellfish life support systems were observed by 13% of the PHIs.

Among the PHIs who reported ROP processes, 85% reported inspecting ROP of a raw single ingredient (such as vacuum-packed pork chops). Seventy-six percent of these PHIs reported inspecting ROP of a seasoned raw product (such as vacuum-packed seasoned chicken breast). Seventy-two percent of these PHIs reported inspecting observed ROP of raw multi-ingredients (such as vacuum-packed stuffed chicken). ROP of a cook-chilled product (such as vacuum-packed soup, stocks, and prepared foods) was observed by 63% of the PHIs who inspected ROP process. Sous vide preparation was only observed by 32% of these PHIs. Thirty-six percent of the PHIs reported inspecting food establishments that used food additives such as vinegar as a method of preservation. Among these PHIs, 57% reported inspecting sushi rice. The same proportion of PHIs (57%) also reported inspecting pickled vegetables. Thirty-five percent of the PHIs observed smoking being conducted at food establishments as a method for preservation. Among these PHIs, 92% reported inspecting hot smoking processes, while only 8% reported inspecting cold smoking processes.

Regulation Awareness and Food Safety Training Level of Crossover Business Owners

Even though the definitions of retailers and manufacturers are clear in 21CFR1.327 and 21CFR1.227, in reality, crossover businesses struggle to understand regulatory compliance for different types of businesses. The PHIs perceived that 41% of the retailers crossing over to manufacturers were not aware of the regulations at all, while 56% of them were somewhat aware. Only 3% of retailers were very aware of the differences in regulations. For businesses transitioning from manufacturers to retailers, the PHIs reported that crossover businesses demonstrated better awareness with only 27% being “not aware at all” and 8% classified as “very aware,” whereas the majority (73%) were categorized as “somewhat aware.”

When asked whether crossover businesses had training on specialized processing, the PHIs predominantly reported “no training” or “some training but not sufficient” for all 5 specialized processing methods. Within the top 3 most observed specialized processing methods (ROP, smoking food as a method of preservation, and the use of additives such as vinegar as a method of preservation), only 23% of the PHIs considered businesses that conducted ROP as having sufficient training. The number dropped to 17% for smoking food and 14% for the use of additives as a method of preservation.

When asked whether the crossover businesses had regulation training for retailers that conducted specialized processing to help them navigate the differences in regulations, ServSafe[®] training was considered sufficient by 47% of the PHIs, while Good Manufacture Practices (GMPs), Seafood HACCP, Meat and Poultry HACCP, and Preventive Controls for Human Foods had evaluations ranging from “no training” to “some training but not sufficient.” PHIs reported that manufacturers with retail stores demonstrated a similar pattern, even though the GMPs, HACCPs, and Preventive Controls for Human Foods should be the main regulations that govern the manufacturing process.

Regulation Awareness and Confidence of Public Health Inspectors When Inspecting Crossover Businesses

Considering the complexity of the FDA variance requirements for specialized processing and the dynamic nature of the industry, we asked whether PHIs were themselves familiar with the variance requirements. The majority of PHIs reported they were “familiar” with ROP (71%), smoking food as a method of preservation (59%) and use of additives such as vinegar

Table 2. LDH PHIs' confidence level when inspecting businesses that conduct specialized processing

Specialized processing methods and the most popular product(s)	PHIs' confidence			
	Not confident	Somewhat confident	Very confident	Currently, I do not inspect such businesses
Reduced oxygen packaging				
Raw single ingredient (n=127)	21	47	17	15
Raw multi-ingredients (n=125)	28	42	12	18
Seasoned raw product (n=126)	25	44	13	18
Smoking food as a method of preservation				
Hot smoke (n=124)	37	27	11	25
Use of additives such as vinegar as a method of preservation				
Sushi (n=122)	28	37	13	22
Pickled vegetables (n=124)	34	25	9	32

Values are presented as percentage.
LDH, Louisiana Department of Health; PHI, public health inspector.

as a method of preservation (55%). A small percentage of the PHIs reported being "not familiar at all" with these 3 specialized processing methods: 12% for ROP, 33% for smoking food as a method of preservation, and 35% for the use of additives such as vinegar as a method of preservation.

The confidence of the PHIs was analyzed for each individual specialized processing method. Table 2 shows PHIs' confidence levels when inspecting businesses that conduct the most widely used specialized processing methods (ROP, smoking, and use of additives) and most popular products within these methods (as identified in characteristics of crossover businesses and specialized processing in Louisiana). In the most popular products within the most widely used specialized processing method, PHIs' self-reported confidence leaned towards "not confident" and "somewhat confident." Twenty-one percent of PHIs reported being "not confident" when inspecting the ROP of raw single-ingredient products, and 47% of them reported being "somewhat confident." When inspecting hot smoking products, the percentages of PHIs who reported being "not confident" and "somewhat confident" reached 37% and 27%, respectively. When inspecting sushi, 28% PHIs reported being "not confident," while 37% of them reported being "somewhat confident."

DISCUSSION

Unlike healthcare or the pharmaceutical industry, the food industry is dynamic and flexible. Innovations in culinary art in particular lead to challenges in regulatory compliance in retail food establishments. Over the past decade, retail segment op-

erators have expanded into food manufacturing/processing-type operations [9], which has resulted in businesses crossing over industry boundaries with more complex food safety regulations. Mapping out the characteristics of crossover businesses in Louisiana and the specialized processing they are conducting will guide us to better understand potential challenges in regulatory compliance. Among the most inspected specialized processes, ROP reduces the amount of oxygen in the package to below the level normally found in atmospheric air; this category includes vacuum packaging, modified atmosphere packaging, and controlled atmosphere packaging [15]. To reduce the public health concern of botulism, ROP products require a HACCP for proper labeling and cold storage. Sushi, as a popular Asian food, can be held at room temperature for up to 8 hours, which deviates from the Food Code [9], according to which cooked rice falls under TCS food and should be refrigerated. Therefore, the sushi rice process needs a variance approval from LDH to prove that acidification is done properly, which indicates that there would be no differences in bacterial counts between rice stored at room temperature or refrigeration [16]. Smoked fish products have been associated with *L. monocytogenes* [17]. Fish products are normally cold smoked, where the temperature in the smoking chamber should not exceed 40°C. Cold-smoked fish has a delicate aroma of smoke, and it has a longer shelf life than hot-smoked fish because it contains significantly less water and more salt [18]. Hot smoking requires the smoking chamber to be kept above 80°C, because it is essentially smoking while cooking the food simultaneously. Hot smoking has been widely used in meat and poultry products such as sausages. Understanding the processes

and products associated with potential public health concerns helped PHIs to differentiate them from processes governed by current regulations and request additional food safety documentation.

When assessing crossover business owners' perceived awareness of the food safety regulations, the results were alarming. The lack of such awareness coupled with insufficient food safety training not only posed public health concerns, but also indicated strong educational needs to raise the awareness of this targeted group. Our findings agree with a variety of self-reporting, focus groups, and observation studies on food handlers or establishment operators [19,20], which likewise revealed the need for food safety education specific to these specialized processes.

The low confidence of PHIs when inspecting crossover businesses revealed by this study echoed the complexity of the food safety regulations for food businesses spanning retail, manufacturing, and food service. Similar to our approach, Pham et al. [21] investigated food safety issues and information resources from the perspective of PHIs in the province of Ontario, Canada. Most of the PHIs in the study of Pham et al. [21] reported that they were confident in their knowledge of food safety issues and foodborne pathogens. However, confidence in the knowledge of general food safety issues cannot be directly translated into confidence when inspecting complex crossover businesses. It is safe to conclude from our study that food safety education is needed for both crossover businesses and PHIs, which is supported by Pham et al. [21]. In addition, a study published by Kettunen et al. [22] surveyed Finnish local food control officials' opinions about the use and challenges of administrative enforcement measures to ensure food safety. Their results indicated that the development of operating procedures and provision of specific training on administrative procedures with a practical approach play a key role in strengthening officials' expertise and confidence in using enforcement measures. The low confidence of PHIs may also influence their perceptions of the business owners' awareness levels.

This study assessed crossover business owners' awareness of food safety regulation and food safety training needs from PHIs' perspective, which provided us with a unique angle but also had some limitations. Non-compliance could be interpreted as a lack of knowledge or awareness of regulation or basic food safety, which may not be accurate. A study published by Brough et al. [23] revealed that food businesses classified as "non-compliant" did not have poor awareness, knowl-

edge, or motivation. In contrast, they demonstrated a strong belief in the importance of food safety and a desire to comply with the regulations. In addition, differences in perspectives between inspectors and food business owners on food safety-related issues have been documented. Eyck et al. [4] revealed that inspectors' views on HACCP implementation were not in accordance with those of many of the apple cider processors in Michigan.

In conclusion, retailers crossing regulatory boundaries to become manufacturers have become popular in Louisiana. Conducting specialized processing was commonly observed in these crossover businesses. ROP, smoking food as a method of preservation, and using food additives such as vinegar as a method of preservation were identified as the most widely used specialized processing methods. PHIs' perceptions of crossover business owners' lack of awareness of food safety regulation differences and elevated needs for food safety education and regulation navigation called for specific education resources for this targeted group. PHIs' awareness of variance requirements and confidence when inspecting crossover businesses revealed educational needs for PHIs as well.

CONFLICT OF INTEREST

The authors have no conflicts of interest associated with the material presented in this paper.

FUNDING

This project was funded through the Food Safety Outreach Program of the United States Department of Agriculture-National Institute of Food and Agriculture (USDA-NIFA) Award No: 2019-70020-30353.

ACKNOWLEDGEMENTS

We thank all PHIs from the Louisiana Department of Health (LDH) for participating in the study. We also thank Carol Neusetzer from the LDH for coordinating the study.

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