

PRACTICAL EXPERIENCE IN FOOD SAFETY AND PRODUCT DEVELOPMENT:
A MASTER'S JOURNEY TOWARDS FOOD CONSULTANCY

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ABSTRACT

The present work encompasses two projects conducted as part of the master's program in Food Science in two different areas that are relevant to the food industry: food safety and product development. The first project involved developing a food safety plan for a local brewery's non-alcoholic carbonated drink production line. A hazard analysis was conducted by evaluating their process and preventive controls were identified to ensure the safety of the product and comply with food safety regulations. The second project was an internship at the Cornell Dairy Plant where a benchtop ice cream recipe was scaled up to a plant-scale standardized formula. This included adjusting ingredient proportions, sourcing approved ingredients, developing the product label, and conducting a successful production run. The scale-up process allowed for the effective launch of an ice cream that is now commercially available. Both projects conceded practical experience and application of food science principles in real-world settings.

BIOGRAPHICAL SKETCH

Ana Sofia Morales Rico was born in Saltillo, Mexico in 1994. She attended Instituto Tecnológico y de Estudios Superiores de Monterrey, one of the top universities in Mexico, where she earned her undergraduate degree in Biotechnology Engineering in 2017.

Sofia began her journey in the food industry as an R&D intern at PepsiCo. Afterward, she gained valuable experience by working at the Monterrey manufacturing plant for a few years. During her time there, she took on the responsibility of managing two biscuit production lines and overseeing a team of over 100 front-line employees. Her experience in the industry paved the way for her transition into consultancy. She initially worked with a Mexican company and later ventured into an independent career and collaborated with reputable consulting firms in both Mexico and the United States, participating in projects for clients that went from entrepreneurs to multinational companies.

In the fall of 2022, she started the program of Master's in Food Science at Cornell University. Her intention in seeking this degree was to solidify her technical knowledge and understanding of food science and gain practical experience to advance her career as a food consultant.

This work is dedicated to my mom, who taught me through her example to follow my dreams, even if they are scary. Mom, wherever you are, you are always in me.

ACKNOWLEDGMENTS

First and foremost, I would like to express my heartfelt gratitude to my advisor, Sam Alcaine. Sam, thank you for always listening to my wants and needs and for helping me find relevant projects that allowed me to achieve my goals. Your support, guidance, and mentorship have been key to my success in the Master of Food Science program.

I would also like to extend my sincere thanks to the local brewery personnel, particularly Andrew, for their trust, time, and generous hospitality. Their willingness to open their doors to their facility and allow me to contribute to the development of their food safety plan.

Special thanks to Deanna Simons and the Cornell Dairy personnel. As I wrote in my personal statement when applying to graduate school, one of the things that excited me the most about enrolling at Cornell was to study at a school with its own ice cream brand (I am a big ice cream lover). Not only did I get to study at such a school, but I also had the opportunity to get involved in the ice cream-making process, at Cornell's own dairy, which was truly a dream come true. I am forever grateful to Deanna for taking me in as her intern and teaching me so much during this process. Working on the development of an ice cream that was sold at the Cornell Dairy Bar is for sure one of the highlights of my master's program.

I would also like to thank to my classmates and lab mates, members of the Alcaine Research Group. Their advice and guidance have been extremely valuable and incredibly helpful throughout this program.

My deepest gratitude goes out to the friends I have made here, who have become my family. The moments we shared together throughout this year, and the memories and experiences we created, have been some of the most valuable things I have gained from my time at Cornell. Your presence has made this experience entirely different and infinitely better. I cannot thank you enough for your unwavering support, for always lending being there during difficult times, for every celebration, every party, every meal, and every conversation we shared. I am certain that the bond we have created here will last a lifetime.

Lastly, I would like to extend my sincerest appreciation to my family, friends, and boyfriend who are back home. Your belief in me has been a constant source of motivation throughout this journey. Despite being physically far away, I always felt your presence and support. This accomplishment is also yours, and I am forever grateful for having you in my life and for your encouragement to pursue my dreams.

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PREFACE

Food science is a fascinating and multidisciplinary field that combines principles from many different sciences and applied them to something all humans are familiar with: food. As I originally wrote in my personal statement when applying to Cornell “Creating innovative, sustainable, convenient, delicious, safe, healthy, and nutritious food and beverage goods that respond to the worlds and consumers’ desires and needs, is how I wish to keep putting in my tiny grain of sand in the world”, and I believe that I can achieve this through consultancy. I am a very active, curious, energetic, and dynamic person who loves working on different projects, and products, traveling to new places, learning new things, and meeting new people. This is why being a food consultant appealed to me, and my previous experiences have led me to pursue this career path.

Before coming to Cornell, I had started working as a food consultant. However, I knew that I could take my skills and knowledge to the next level by enrolling in the MFS program. I was confident that Cornell would provide me with the valuable tools I needed to achieve my dream. My intention for joining the program was clear: to learn things and gain experience that could be applicable to my career path. I desired to work on projects that addressed real-world situations faced by food consultants. This is how I came to be involved in the projects that I will be presenting in this paper.

Throughout the year, I worked on two projects with companies in the food and beverage industry in upstate New York. The experience was exciting and rewarding, and it reinforced my belief that I am on the right track to achieving my professional goals. I really enjoyed working on these projects and I hope you enjoy reading about them.

1. Carbonated Beverages Food Safety Plan

1.1 Introduction

The U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA), signed into law in 2011, requires processors to proactively manage food safety hazards associated with the manufacture and transport of FDA-regulated food products. With the introduction of FSMA, beer and other alcoholic beverages are considered FDA-regulated food products. FSMA specifically defines alcoholic beverages as food, and for the first time brings breweries, wineries, cider producers, and distilleries under direct FDA regulation, without affecting TTB authority. According to Title 21 of the Code of Federal Regulations Part 117.5 (21 CFR 117.5), these facilities are exempt from some portions of FSMA but need to comply with others, such as Good Manufacturing Practices (GMPs). Portions of FSMA that do not apply to breweries include 21 CFR 117 subpart C- Hazard Analysis and Risk-based preventive controls and 21 CFR 117 Subpart G- Supply Chain Management. However, 21 CFR 117.5 also stipulates that businesses that produce non-alcoholic beverages may additionally need to develop a food safety plan following the hazard analysis and risk-based preventive controls methodology for the non-alcoholic products.

An upstate New York brewery, which was founded in 1998 and still is a family – run operation, produces non-alcoholic carbonated beverages in addition to beer. The brewery’s facility operates with 6-8 employees in brewing and production and contains a state-of-the-art brew system with an annual production of 150,000 bbls of beer. In order to be FSMA compliant, this local brewery must attain to what is stipulated in subpart C of 21 CFR 117. Therefore a food safety plan under preventive controls is required for the non-alcoholic carbonated beverages they produce.

The scope of the present project is to conduct a hazard analysis of the soda manufacturing process at the local brewery and identify the process preventive controls as a base for the development of the entire food safety plan.

1.2 Product Characteristics

Soft drinks are defined as carbonated or non-carbonated beverages composed of about 90% water, which must comply with drinking water regulations. The rest of the ingredients that typically make up soft drinks include sweeteners, acidulants, flavorings, and preservatives. Soft drinks have markedly acidic pH (2.5–4.0), 1.5 to 4 volumes of carbon dioxide (CO₂), with a typical carbonation level of about 3 volumes (Azeredo et al., 2016).

In this case, the sodas manufactured by the local brewery are non-alcoholic carbonated beverages are produced in two flavors: ginger beer and root beer. They are composed of water, sugar, organic acids (phosphoric and citric), flavorings, juice, fresh ingredients (ginger and vanilla beans), dried ingredients (anise and juniper berries), and preservatives (sodium benzoate). They have a pH in the range between 3.0 and 4.0 and are carbonated with around 3.2 volumes of CO₂. They are packaged in amber glass bottles, which protect the drinks from the light, or kegs. The sodas are stable at ambient temperature and have a shelf life of one year.

1.3 Process Description

The manufacturing process of the non-alcoholic sodas at the local brewery is shown in Figure 1. This process starts with the reception of ingredients and packaging materials. Most of the raw materials are dry, but the facility also receives fresh ingredients under refrigeration conditions (fresh ginger and vanilla beans). The ingredients and packaging materials are stored in ambient or refrigerated conditions, according to the requirements of each of them. When sodas are

produced, filtered water, sugar, acidulants, and other ingredients such as ginger, vanilla beans, hops, anise, and dried berries are added to a kettle where they are heated to 98 °C. This temperature is held for 20 minutes and then the solution is transferred to a whirlpool, where sodium benzoate is added. After resting in the whirlpool for 15 minutes, the solution is pumped through a heat exchanger, where it is cooled down to 19°C, and a filter into a tank where flavoring is added. At this point, pH is checked using a pH meter and ensuring that pH is within specification (3.0-4.0). The solution is further cooled and carbonated at around 0°C to 3.2 volumes of CO₂. Then, the carbonated beverages are pumped to the filling line where they are packaged into glass bottles or kegs, which are rinsed and sanitized, respectively. Every bottle goes through a detection system to ensure proper filling. After bottling or kegging the product is appropriately labeled and sent into finished product storage.

1.4 Hazard Analysis and Process Preventive Controls

A hazard analysis was conducted by visiting the local brewery's facility and carefully observing the entire production process of the nonalcoholic carbonated sodas. In addition to the on-site inspection, relevant information was also collected from management to identify potential hazards and assess their associated risks. Table 1 shows the complete hazard analysis for the soda manufacturing process in the local brewery.

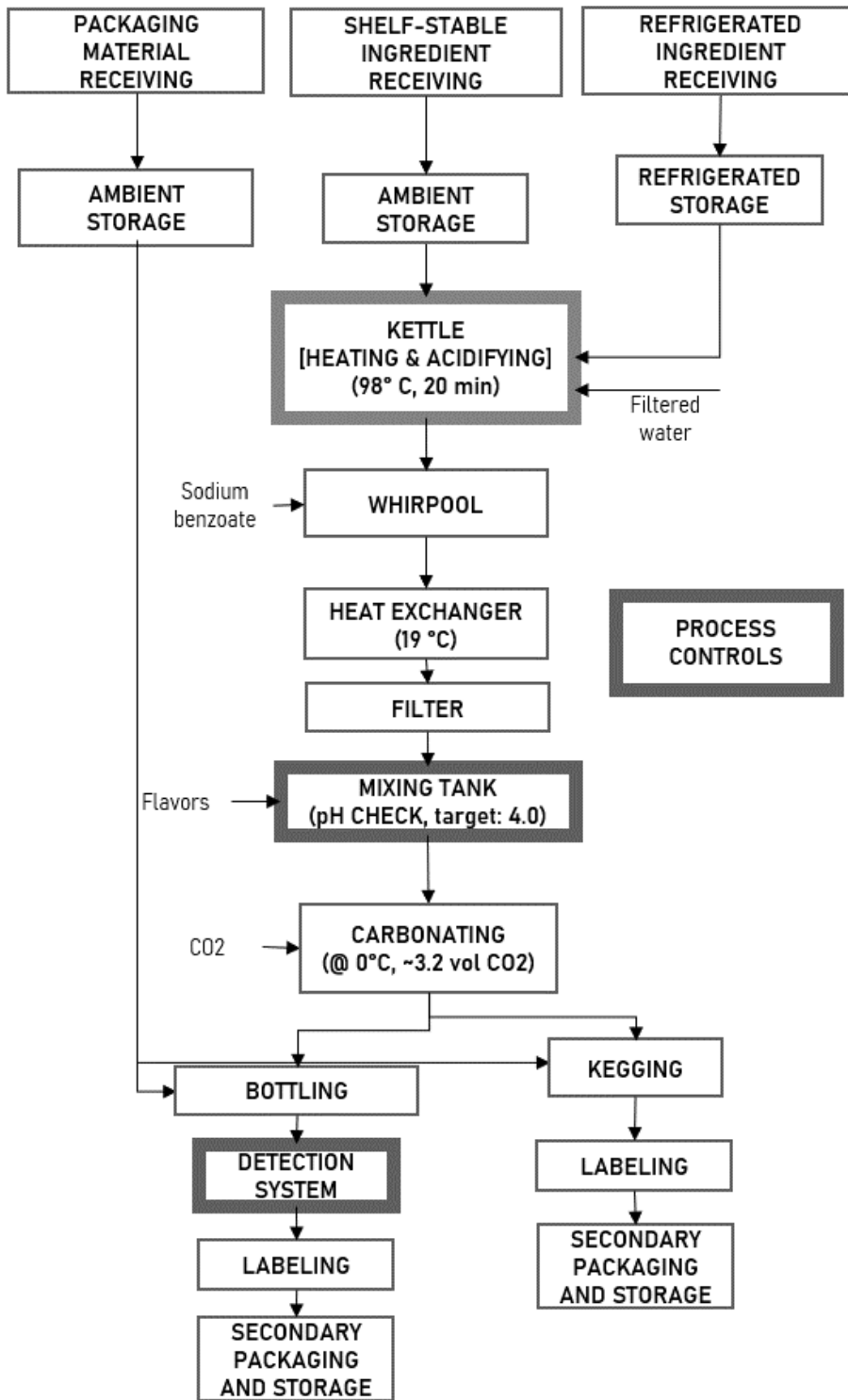


Figure 1. Soda manufacturing process at local brewery.

Table 1. Hazard analysis for soda production at local brewery.

PLANT NAME: X Brewery		ISSUE DATE		PAGE			
ADDRESS:		SUPERSEDES		PRODUCT CODE			
Hazard Analysis for: Non-alcoholic carbonated beverages							
(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step <i>B = biological, C = chemical (including radiological) P = physical</i>	(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Packaging material receiving	B None						
	C None						
	P Glass fragments (7-25 mm)	X		Glass fragments from any broken bottles that may end up in the final product and can harm the consumer.	Process control- Heuft detection system		X
Shelf- stable ingredient receiving- Sugar	B None						
	C None						
	P None						
Shelf stable ingredient receiving- Phosphoric acid	B None						
	C None						
	P None						
Shelf stable ingredient receiving- Citric Acid	B None						
	C None						
	P None						
Shelf- stable ingredient receiving- Sodium benzoate	B None						
	C None						
	P None						
Shelf stable ingredient receiving- flavorings	B Vegetative cells of pathogens such as L. monocytogenes, E. coli, <i>Salmonella</i> , <i>S. aureus</i> .			Because the flavor is added after the kill step (kettle), any pathogens present will end up in the final product and reach the consumer.	Supply-chain control: Hazards are controlled by suppliers. COAs are received from approved suppliers.		
	C None						
	P None						

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step <i>B = biological, C = chemical (including radiological) P = physical</i>	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Refrigerated ingredient receiving- Lemon juice	B Vegetative cells of pathogens such as <i>L. monocytogenes, E. coli, Salmonella, S. aureus.</i> Spore- forming microorganisms	X		While lemon juice is a high acid product and most microbes don't grow under such acidic conditions, presence of vegetative cells of pathogens and spore formers is a potential hazard.	Process control- Heating (98°C) and acidifying (pH< 4.6) in Kettle step.		X
	C None						
	P None						
Refrigerated ingredient receiving- Ginger and vanilla beans	B Vegetative cells of pathogens such as <i>L. monocytogenes, E. coli, Salmonella, S. aureus.</i> Spore- forming microorganisms	X		Presence of vegetative cells of pathogens and spore formers is a potential hazard in raw produce.	Process control- Heating (98°C) and acidifying (pH< 4.6) in Kettle step.		X
	C None						
	P None						
Ambient Storage- packaging materials	B None						
	C None						
	P Glass fragments (7-25 mm)	X		Glass fragments from any broken bottles that may end up in the final product and can harm the consumer.	Process control- Heuft Detection system		X
Ambient storage- Ingredients	B None						
	C None						
	P None						

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step <i>B = biological, C = chemical (including radiological) P = physical</i>	(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Refrigerated storage- ginger, vanilla beans, lemon juice	B Vegetative cells of pathogens such as <i>L. monocytogenes, E. coli, Salmonella, S. aureus</i> Spore- forming microorganisms	X		If any vegetative cells of pathogens or spore-formers are present in ingredients they will be maintained at refrigeration temperatures, even though their growth will be slowed down.	Process control- Heating (98°C) and acidifying (pH< 4.6) in Kettle step		X
	C None						
	P None						
Kettle- heating and acidifying	B Vegetative cells of pathogens such as <i>L. monocytogenes, E. coli, Salmonella, S. aureus</i> Spore- forming microorganisms	X		Pathogens can cause food poisoning if they reach the final product and are ingested by the consumer.	Process control- Heating: raising the temperature to 98°C and maintaining it for 20 minutes will kill any vegetative cells of pathogens present. Acidifying: adding acid and lowering the pH below 4.6 will control for spore-formers	X	
	C Allergen- wheat	X		There are no allergens in the product. However, other products made in this equipment contain wheat. There could be cross- contamination.	Sanitation control- prevent allergen cross contact		
	P None						
Preservative blending- sodium benzoate	B None						
	C Exceeding concentration of sodium benzoate		X	Sodium benzoate is safe to use in foods and beverages at a maximum level of 0.1%. The FDA has not determined if use at different conditions would be GRAS (21 CFR 184. 1733). Historically, there hasn't been an issue in the company with the measurement and addition of sodium benzoate, so this is not considered a hazard that needs a control step.			
	P None						

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step <i>B = biological, C = chemical (including radiological) P = physical</i>	(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Whirlpool	B Vegetative cells of pathogens such as <i>L. monocytogenes, E. coli, Salmonella, S. aureus</i>	X		Because this is after the kill step, any presence of microorganisms on the equipment will recontaminate the product and reach the consumer.	Sanitation control- prevent recontamination		X
	C Allergen- wheat	X		There are no allergens in the product. However, other products made in this equipment contain wheat. There could be cross- contamination.	Sanitation control- prevent allergen cross-contact		X
	P None						
Heat exchanger-cooling	B Vegetative cells of pathogens such as <i>L. monocytogenes, E. coli, Salmonella, S. aureus</i>	X		Because this is after the kill step, any presence of microorganisms on the equipment will recontaminate the product and reach the consumer.	Sanitation control- heat sterilization of heat exchanger to prevent recontamination		X
	C Allergen- wheat	X			Sanitation control- prevent allergen cross-contact		X
	P None						
Filter	B Vegetative cells of pathogens such as <i>L. monocytogenes, E. coli, Salmonella, S. aureus</i>				Sanitation control – heat sterilization of filter to prevent recontamination		
	C Allergen- wheat				Sanitation control- prevent allergen cross-contact		
	P None						
Mixing tank-	B Vegetative cells of pathogens such as <i>L. monocytogenes, E. coli, Salmonella, S. aureus</i> . Spore formers	X		Because the flavor is added after the kill step (kettle), any pathogens present will end up in the final product and reach the consumer. If pH is not at the target level (3.0) and is above 4.6, some microorganisms may be able to grow.	Supply-chain control: checking COAs from approved supplier at receiving stage. pH check- pH < 4.6 will control for spore formers. Sanitation control- of tank to prevent recontamination	X	X
	C Allergen- wheat				Sanitation control- prevent allergen cross-contact		X
	P None						
Carbonating	B None						
	C None						
	P None						
Packaging-Bottling	B None						

	C	None						
	P	Glass fragments (7-25 mm)				Process control- Heuft Detection system		X
Detection system	B	None						
	C	None						
	P	Glass fragments (7-25 mm)	X		Glass fragments from any broken bottles that may end up in the final product and can harm the consumer.	Process control- Heuft Detection system- reject any broken bottles	X	
Labelling	B	None						
	C	Allergen- (potential)		X	Currently there are no allergens in any of the sodas. If one was introduced it'd have to be declared on the label.			
	P	None						
Packaging- Kegging	B	Vegetative cells of pathogens such as <i>L. monocytogenes</i> , <i>E. coli</i> , <i>Salmonella</i> , <i>S. aureus</i>	X		Because kegs are reused (have been exposed t the environment), recontamination of the product is a possibility.	Sanitation control- prevent recontamination	X	
	C	Residues of cleaning chemicals	X		Because kegs are reused the are sanitized. Improper sanitation can leave residues of cleaning solutions that can reach the consumer.	Sanitation control- proper washing and rinsing of kegs	X	
	P	None						

Non-alcoholic carbonated beverages are typically perceived as safe beverages with no significant associated food-borne illnesses. However, hazard that pose a risk to human health cannot entirely be ruled out (Juvonen et al., 2011). Because of their low pH and CO₂ content, sodas are typically microbiologically safe. The low pH and carbonation are barriers that prevent microbial growth in soft beverages such as sodas (Azeredo et al., 2016). Food-borne pathogens do not generally grow at pH 4.6 or below, therefore, because the pH of the sodas in question is between 3.0 and 4.0, microbial pathogen growth should be inhibited. Nevertheless, some studies have shown that pathogenic bacteria, such as such as *E. coli*, *Salmonella*, *L. monocytogenes*, and *S.aureus* , can survive in acidic and carbonated beverages, even if they are not able to grow during storage, and remain viable for extended periods of time (Juvonen et al., 2011).

Water is a potential source of microbial contamination in soft beverages, as pathogens like *Salmonella* and *E. coli* are often transmitted through it. If the water used in the production of carbonated beverages has poor microbiological quality and high initial loads of such pathogens, there is a risk of contamination in the final product. At the local brewery, water is treated to ensure that it is safe for consumption. Another potential cause of bacterial contamination in these sodas is the inclusion of natural ingredients, particularly those that are fresh. However, during the kettle step of the soda manufacturing process, the temperature is raised to 98°C and held for 20 minutes to effectively eliminate any microbial pathogens that may have been introduced with these ingredients or water.

Spore-forming bacteria of the genera *Bacillus* and *Clostridium* are usually inhibited in soft drinks due to low pH, however, spores may remain viable in these products (Jovonen et al., 2011). Ensuring that the pH of the beverages is below 4.6 is critical to prevent the growth of spore-formers and therefore the presence of spores in the drinks.

For the flavorings, microbial contamination is very critical because they are added after the kettle and there will be no further killing treatments. In this case, hazards introduced by these ingredients controlled by the supplier and managed in the local brewery through a supply chain program. Microbial contamination can also originate from the factory environment. This is why ensuring compliance with GMPs and proper cleaning and sanitation procedures is critical for the safety of the beverages.

There are some bacteria, such as *Alicyclobacillus*, that possess acidophilic and thermophilic characteristics and thrive in environments of low pH and high temperatures. However, while this bacterium can negatively impact the quality of the product, it is not considered a human pathogen (Azeredo et al., 2016), and thus is considered a spoilage issue and not a safety one. According to

Azeredo et al. (2016), treatment at 95°C for more than 8 minutes can effectively kill 90% of *Alycyclobacillus* spores. At the local brewery, the soda manufacturing process uses even higher temperatures and longer treatment times, which are more than adequate to eliminate any potential risk of spoilage.

Table 2. Process preventive controls for soda production at local brewery.

Process Preventive Controls									
Process Control Step	Hazard(s)	Parameter, values, or critical limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Kettle	Vegetative cells of pathogens such as <i>L. monocytogenes</i> , <i>E. coli</i> , <i>Salmonella</i> , <i>S. aureus</i> .	Temperature: 98°C	Temperature of the water/ solution in the kettle	Sensor in kettle automatically measures temperature. Additionally, temperature is measured using a manual digital thermometer.	Every batch	Production employee	Hold product and raise temperature again until it reaches 98°C and hold for 20 minutes.	Accuracy check for thermometer. Calibration of thermometer	Soda worksheet in which temperature is recorded. Accuracy check records and Calibration records.
Mixing tank (pH check)	Spore-forming microorganisms	pH: < 4.6	pH of the solution in the mixing tank	Using a pH meter	Every batch	Production employee	Hold product and add more acid until pH level is right	Accuracy check for pH meter Calibration for pH meter	Soda worksheet in which pH is recorded. Accuracy check records and Calibration records.
Bottling-Heuft detection system	Broken glass pieces	No glass fragments in finished product.	Every bottle goes through an operating cleaning process and through the system that detects fill height and crowns.	Visual examination that the detection system is on every time soda is being bottled	Before the beginning of the bottling process	Production employee	If a bottle breaks or a fault is detected the line goes into wash-down mode. The bottles will not be crowned and therefore rejected.	Calibration of equipment	Detection system log Calibration records

Product Name: Ginger Beer and Root beer	PLANT NAME: X Brewery
	ADDRESS
	ISSUE
SUPERSEDE	ISSUE
	PAGE
	PRODUCT CODE

The only chemical hazard that was identified is wheat, which is a major allergen and is used as an ingredient in some beers produced at the brewery. No other major allergens are handled in the facility and the sodas themselves are allergen-free. To prevent allergen cross contact, GMPs such as the proper storage and identification of raw materials and scheduling production are done.

The sodas are typically run on Mondays, so it is the first product that is run after the line is cleaned and sanitized when the production of beer is finished on Friday.

The presence of glass fragments in the product is the only physical hazard in the soda manufacturing process. Glass inclusion can occur whenever processing involves the use of glass containers, which is the case of sodas at the local brewery, since handling and packaging methods can result in breakage. The presence of glass fragments can be managed through the visual examination of glass containers before or after the filling process. Additionally, glass containers can be cleaned with water or compressed air and inverted to remove any loose glass fragments. Another approach to managing the hazard of glass inclusion is to conduct routine inspections of the processing areas and equipment for any signs of glass breakage. While this measure may not entirely eliminate the risk of glass fragments being introduced into the product, it can enable the separation of products that may have been exposed to such fragments (FDA, 2011).

At the local brewery, there are several measures in place to prevent glass fragments from contaminating the bottled beverages. Before filling, bottles are rinsed and inverted and after filling the crown applied, all by automated equipment. The brewery also has a Heuft detection system in line after filling that detects the fill level and crown, preventing broken bottles from proceeding through the filler and crowner. This system ensures that a broken bottle is not crowned, stopping the machine and requiring human intervention. If a bottle breaks during the filling sequence, the line goes into wash-down mode. During the wash down, all bottles on the filler at that time pass through and are not crowned. The crown detection equipment then rejects them, immediately following the crowner and before any labeling process. Additionally, at the manned drop-packer station, every case is monitored for errors, and any case with broken glass is pulled from the line. Random closure inspections are also conducted to ensure the crowner is operating correctly.

The determination of the appropriate process preventive control for the glass fragment hazard underwent thorough discussion and careful consideration. While several measures were already in place to minimize the risk of glass fragments in the final product, the detection system emerged as the optimal process control. This is because it serves as the final step in the process where the hazard could be eliminated, with all bottles passing through it. Furthermore, reliance on visual inspection by personnel could prove less reliable due to the possibility of missing faulty bottles or undetected glass fragments within bottles.

1.5 Next steps and recommendations

The local brewery appears to have an adequate implementation of process controls, and observations during the facility visit indicate compliance with Good Manufacturing Practices. However, there are areas that require further work, such as the need to develop written procedures for verification activities, including accuracy checks and calibration of devices and equipment like pH meters and the Heuft detection system. The brewery must also maintain rigorous record-keeping to comply with FSMA regulations. Although supply chain controls are in place for ingredients added after the kettle, such as flavors, these measures should be documented in writing. The plant's allergen cross-contamination prevention through sanitation should also be documented. Additional verification procedures could be developed and implemented.

A recommendation for the local brewery to ensure food safety in the long term, and in an alternative way to which they are doing it now, would be to invest in a pasteurization tunnel. This technology would enable heat treatment of the finished, bottled product, ensuring its safety and stability.

1.6 Conclusion

Even though breweries are exempt from having a food safety plan under FSMA, carbonated non-alcoholic beverages are subject to Preventive Controls for Human Food, which requires a food safety plan for this product line. The hazard analysis conducted during the project identified potential hazards associated with the production of non-alcoholic carbonated drinks at a local brewery, and preventive controls were established to ensure compliance with the Food Safety Modernization Act. While the project did not include the development of a complete food safety plan, the hazard analysis serves as a starting point and foundation for the brewery to continue its efforts in implementing a comprehensive food safety plan. To complete the food safety plan, some action still needs to be taken by the company such as writing certain procedures and establishing additional verification activities, as well as consolidating recordkeeping.

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2. From bench-top to commercial level: Ice cream scale-up process

2.1 Introduction

Product development is a critical aspect of the food industry, as it enables companies to stay competitive and meet the ever-evolving demands and needs of consumers. In a highly dynamic market, companies must continuously launch new products or reinvent existing ones to stay profitable and relevant. Within product development, there are different strategies that companies can implement, including introducing a completely new product, repositioning an existing one, reformulating a product, creating a new form of an existing product, or extending a product line. A line extension is a product development strategy in which a new variation of an existing product line is introduced. This approach offers several benefits versus other product development strategies, including shorter development time and less research, no significant changes to manufacturing processes or equipment purchases, minimal or no changes to the marketing strategy, and no new storage or handling techniques for raw materials or finished products. This project involves a line extension example, specifically, the introduction of a new flavor to an existing ice cream line.

The product development process in the food industry is comprised of several steps that include concept generation and evaluation, laboratory or bench-top formulation, sensory evaluation, scale-up, pilot testing, and commercialization, among others. In product development, scale-up is the collection of changes that occur between the smaller laboratory or kitchen prototype and full-scale manufacturing (Brody and Lord, 2007). Many new food products start out as recipes created in a kitchen. However, to produce these recipes on a commercial level, it is essential for them to be transformed into a standardized formula. Scaling up a recipe to make it commercially viable involves more than just using bigger equipment and making larger batches. Factors such as

ingredient sourcing, formulation adjustments, and process characteristics need to be considered. To ensure successful scale-up, it is critical to have a well-structured and organized process guided by clear objectives.

FDSC 1101 Science and Technology of Foods is an esteemed undergraduate course offered by Cornell University every fall. This course provides an introduction to the application of science and technology to foods, while also exploring the various disciplines within the field of food science, using ice cream as a model system. During this course, students collaborate in groups to create a novel ice cream flavor based on a specific theme. A panel of judges then selects the winning flavor from the assortment of creations. The winning flavor is subsequently scaled up for production at the Cornell Dairy plant and is commercially available on campus. The present project focuses on scaling up the bench-top recipe of the winning flavor to an industrial-scale formula for commercial production at the Cornell Dairy plant.

Cornell Dairy is a highly regarded hyper-local food processor that makes a wide range of dairy products for the campus and Ithaca communities. The Dairy is well known for its commitment to sourcing fresh milk from the Cornell Veterinary College Dairy Teaching Barn located only one-half mile away from the fully licensed and Kosher certified Dairy plant. The Dairy prides itself on delivering fresh milk to campus dining and retail units within two-to-seven days of processing and bottling. In addition to milk, the Dairy produces fresh butter, yogurt, and ice cream on a weekly basis, which includes 18 ice cream base flavors and seasonal varieties. In addition, the Dairy creates specialty ice cream flavors for Cornell Dignitaries. Utilizing 100% of the milk from the Teaching Barn, the Dairy has little to no waste. Established in 1880, the current facility was commissioned in 2012 and is staffed by 8 full-time employees. Taking the kitchen-top ice cream recipe to successful production at this facility was the primary objective of this project.

This involved careful evaluation of ingredient sourcing, recipe formulation, and production processes to ensure that the resulting ice cream would meet the quality standards of Cornell Dairy while also staying truthful to the essence of the new flavor developed by the students.

2.2 Formula Optimization

Scaling up a recipe that started in a kitchen to a commercial-scale formula is an essential step in successfully making new food products and launching them into the market. Several differences exist between a kitchen recipe and a standardized commercial formula, a major one being the units of measurement for the ingredients. When developing a recipe in a kitchen, ingredients are often measured using “home-cooking” non-standard units such as cups, tablespoons, and pinches. This can lead to inconsistencies and impracticalities when producing at a commercial level. In contrast, a standardized commercial formula specifies all ingredients in consistent units, usually weight or volume, and expresses each raw material as a percentage of the composition of the final product, allowing for easier calculation of ingredient amounts and scalability. Additionally, having all the ingredients measured in the same units and by weight is important for regulatory compliance. According to food labeling regulations by the FDA in the United States, contained in section 101.4 of title 21 of the Code of Federal Regulations ingredients are required to be declared on the label of a food and shall be listed in descending order of predominance by weight (21 CFR 101.4). Table 3 presents the original recipe for “Pure Honey” ice cream, created by the winning group in FSDC 1101 class, which uses a variety of non-standard units for ingredient measurement. This recipe was the starting point for the scale-up process of what is now Honey Crunch ice cream.

Table 3. "Pure Honey" original ice cream recipe.

Ingredient Name	Source	Quantity
White base mix	Cornell Dairy	5 gal
Bourbon Vanilla	Star Kay White	100 ml
Honeycomb crunch	Snooks Candy	850 g
Salty Caramel Variegate	Smuckers	680 ml

Another major difference when scaling up a from a bench-top recipe to a formula for commercial production is the sourcing of the ingredients. While it's feasible to buy ingredients from retail at a local grocery store, such as Smuckers, or from small businesses, such as Snooks Candy, when working at the kitchen or bench-top level, it is not practical at an industrial level. This is why it is essential to source ingredients from approved suppliers who can guarantee consistent quality, availability, and cost-effectiveness in meeting the requirements of the standardized commercial formula. This ensures that the product manufactured on an industrial scale is consistent and meets the necessary regulatory and quality standards. To create a standardized formula out of the initial recipe, it was necessary to optimize it through the adjustment of the amount of each ingredient, replacement of certain ingredients and introduction of new ones, the sourcing of raw materials from adequate, and the conversion of all ingredients to standardized units.

A. Ice Cream Mix

Ice cream is a regulated food product with a standard of identity established by the United States Food and Drug Administration (FDA). According to the FDA, ice cream is produced by freezing, while stirring, a pasteurized mix consisting of one or more dairy ingredients stipulated in part 135 of title 21 of the Code of Federal Regulations (21 CFR 135). Ice cream must meet certain

specifications, such as a minimum weight and fat and total solids content, to meet the FDA's standard of identity and be called that.

The ice cream mix is the most crucial element in ice cream as it is the foundation of the final product. It contains essential ingredients such as dairy (fat and nonfat), sweeteners, stabilizers, and emulsifiers, which give ice cream its desired texture, flavor, and mouthfeel. The quality and consistency of the ice cream mix directly impact the final product's properties, including overrun (the amount of air incorporated), melting rate, and shelf life. Therefore, achieving a high-quality ice cream with desirable properties requires a carefully formulated ice cream mix. The percentage and source of ingredients play a crucial role in determining the quality of the ice cream mix.

One of the main components of ice cream is fat, which comes from dairy ingredients, typically cream, butter, or butter oil, but nondairy ingredients such as coconut, palm, or vegetable oil can also be used. Cream is the highest quality ingredient that can be used in ice cream as a fat source. Fat has a critical role in ice cream providing texture and structure and increasing the richness of flavor. Fat affects the viscosity of the mix and is also a good carrier for added flavors. The legal minimum amount of fat required in ice cream is 10%. However, fat content varies with the quality of the ice cream. Generally, the higher the fat content, the more premium the ice cream (Table 4). However, too much fat can mask flavors and impact flavor release, so it is important to strike a balance between the fat content and other ingredients to ensure that the ice cream's flavor profile is not affected and that it has the desired texture, body, and melting properties.

Table 4. Ice cream quality and fat content.

Ice cream	Fat content
Standard	10-12%
Premium	12-15%
Super premium	15-18%

The next component of the ice cream mix is the milk solids non-fat, which encompass lactose, casein, and whey proteins naturally present in milk. Concentrated milk, milk powder, and whey products are common sources of these elements. The milk solids non-fat affect both the texture and flavor of the final product and contribute to its structural integrity by providing emulsification, whipping, and foam formation properties, as well as water-holding capacity and freezing point depression. Balancing ingredients, such as water, skim milk, or whole milk, are also included in the ice cream as water sources to round up the formula.

Sweeteners are a key ingredient in the formulation of ice cream mix. In addition to their primary function of providing sweetness, they play an essential role in enhancing flavor, improving palatability, reducing the freezing point of the mix, increasing total solids, and improving body and scoopability. Nutritive sweeteners such as cane sugar, corn syrup solids, high fructose corn syrup, and invert sugar are commonly used in ice cream production. Other sweeteners such as sugar alcohols and natural and synthetic non-nutritive sweeteners are also utilized, often in small quantities due to their high intensity. The selection of sweeteners is influenced by several factors, including total solids desired, cost, freezing point depression, nutritional value, and flavor profile.

Stabilizers, which are typically polysaccharides, are added to ice cream to increase viscosity, stabilize the mix, prevent syneresis, aid in the suspension of flavoring particles, retard lactose and ice crystal growth during storage, slow moisture migration, provide uniformity and resistance to melting, and produce a smooth texture. Some commonly used stabilizers in ice cream production include locust bean gum, cellulose gum, and carrageenan. Emulsifiers, which are usually added in combination with stabilizers, are essential for ice cream production. Most ice cream manufacturers use stabilizer/emulsifier blends formulated by specialized suppliers. The functions of emulsifiers include promoting nucleation of fat during aging, reducing aging time,

improving the whipping quality of the mix, interacting at the air interface, aiding in the homogeneous distribution of air in the ice cream, enhancing fat destabilization, producing drier ice cream, aiding in molding and extrusion, increasing resistance to shrinkage and rapid meltdown, and inhibiting the development of a coarse or icy texture. Some commonly used emulsifiers in ice cream manufacturing are mono/diglycerides and polysorbate.

Cornell Dairy is a hyper-local producer that sources milk from within one mile of its facility which translates to the highest quality products. Cornell Dairy produces two base mixes that are used to make all their ice cream flavors. The production of all their ice cream flavors begins with two base mixes, either white or chocolate. The white base is a 16% fat ice cream mix used in the Honey Crunch flavor. This base mix comprises milk, cream, sugar, corn syrup solids, skim milk, stabilizers, and emulsifiers. Given the quality and standardization of this base mix, which already produces premium ice cream, there was no need for optimization or adjustment in this project. Instead, the project focused on a line extension by developing a new flavor using an already established premium ice cream base, optimizing only for the rest of the components: flavoring, inclusion, and variegate.

B. Base Flavor

Optimizing the flavor profile of ice cream is crucial to create a formulation of an overall good product. To impart flavor to the base ice cream, flavorings or extracts can be added directly to the mix before it is frozen. One of the key considerations is determining the appropriate amount of flavoring to add. Typically, a recommended usage level is specified by the supplier, which generally falls in the range of 0.2-0.4%. However, it's important to note that the amount of flavoring needed can also depend on the fat content of the mix. As a general rule, the higher the

fat content, the more flavoring is required to achieve the same flavor intensity because a higher fat content leads to a slower flavor release (Frost et al., 2005).

To achieve the best flavor profile for the Honey Crunch ice cream, it was important to have a strong and distinct base flavor that could hold up against the added inclusions. The original recipe used 0.5% pure vanilla extract to flavor the base, but upon sensory testing, it was found to be insufficient. In order to improve the flavor, several laboratory-scale trials were conducted where different levels of vanilla extract were added to the white ice cream mix. To do this, the ice cream was made by adding different amounts of vanilla extract into the mix and then freezing it in a kitchen ice cream maker machine (Cuisinart). After at least 24 hours of hardening, internal sensory evaluations were conducted where Cornell Dairy personnel participated to determine the optimal dosage of vanilla extract for the best flavor. As a result of these trials, the final dose of vanilla extract was increased from 0.5% to 0.9%.

C. Inclusion Piece

Inclusions in ice cream are any solid ingredients that are added to the ice cream base during production, such as pieces of fruit, nuts, candy, cookie dough, or chocolate chips. These inclusions make the ice cream more interesting and appealing to consumers by adding flavor and texture to it. Adding inclusions at 5 to 8% by weight is common for candy and confection pieces. The ideal scenario is for consumers to find a piece in every bite or at least several per scoop.

Several factors must be considered when adjusting the kind and amount of inclusions, including appearance, flavor, and texture. Inclusions should be visible to promote a value-added image, and their flavor should complement the rest of the ingredients to create a desired flavor profile. Texture is a critical consideration, and inclusions must maintain an acceptable texture

under frozen conditions and during extended storage. For instance, candies are often very high in solids and low in moisture, and this doesn't necessarily translate well in ice cream. If not properly formulated, the candy may become too hard to chew through when frozen. Chocolate chips used in ice cream, for example, typically must be specifically formulated for that purpose. It's worth noting that while some small-scale or artisanal ice cream makers make their own inclusions (such as baked goods like cookie or brownie pieces), most commercial ice cream producers rely on specialized suppliers for these raw materials. These suppliers have the expertise and resources to develop inclusions that meet the specific needs of ice cream production, ensuring optimal stability, texture, and flavor.

Besides sensory attributes, the manufacturing process also puts constraints on the inclusion characteristics. In the original Pure Honey Ice cream recipe, a honeycomb candy piece was added to the base ice cream as an inclusion. This piece was made by the students on a kitchen scale by combining water, sugar, and honey and heating the mixture up, followed by the addition of baking soda which caused it to become a foam. The foam was then spread on a sheet and allowed to cool down and then broken down into smaller pieces. This process was time intensive and had to be repeated several times in order to get enough of the candy piece to use in a pilot plant trial.

During the scale-up process for this ice cream, making the honeycomb piece as it was made in the kitchen was not feasible, thus, an ingredient supplier that met the facilities requirements was sought to provide the honeycomb candy. Cornell Dairy is certified Kosher and therefore all the raw materials used in the manufacturing of its products must be certified as well. A supplier that met this criterion was found, and the piece was ordered from them to do some trials.

Finding the right inclusion piece for this ice cream was a challenge as size was a limiting factor. The honeycomb piece from the manufacturer was too large to add to the ice cream and required

additional processing to break it down into smaller pieces. This would have required additional equipment and labor, making it an impractical solution. In addition, the honeycomb piece was too hard and did not contribute to the overall eating experience of the ice cream in a pleasant way.

To solve these issues, the Heath Bar piece was chosen as an alternative inclusion. It delivered in all aspects, including appearance, flavor, and texture. The Heath Bar piece was sourced from a supplier that met all the requirements and came in small bits that were ready to be incorporated and distributed in the ice cream in such a way that several pieces could be found in every bite. Furthermore, it complemented the flavor of the ice cream very well. It was a practical and cost-effective solution to ensure a high-quality product for consumers.

D. Variegate

Variegates are sauce- or syrup-like ingredients, such as fruit puree, caramel, or fudge, that are added to the ice cream mix to create a ribbon-like or swirled effect. This effect is achieved by swirling or injecting the sauce-like ingredient through the ice cream while it is still semisoft, but before it is hardened. Variegates add both flavor and visual appeal to ice cream and can be customized to create a wide variety of different flavor combinations.

As previously mentioned, adding ingredients to ice cream is more complex than just mixing them in, as the freezing process can alter the ingredient and affect the final product. Therefore, as with inclusions, the use of variegates that are specifically formulated for ice cream is important. Key physicochemical properties that must be considered in an ice cream variegate are sugar content, viscosity, and density. Sugar content of syrup or sauce directly impacts freezing point depression. Therefore, it should be formulated with enough sugar to remain unfrozen at temperatures below the freezing curve of ice cream. However, if the sugar content is too high

crystallization may occur. Viscosity is also critical, and it should be adjusted to ensure that it pumps properly through the equipment without smearing or diffusing into the ice cream, so the swirling effect can be maintained (Goff, 2013). Additionally, the density of the variegate is crucial, as it affects its incorporation into the ice cream. If the variegate has a higher density than the ice cream mix, it may sink to the bottom of the container during storage. On the other hand, if the variegate has a lower density it may float to the top. In both cases, the variegate would not be evenly distributed throughout the ice cream. To overcome these issues, manufacturers often adjust the density of the variegate to ensure that it is similar to the density of the ice cream mix, making it easier to incorporate it evenly.

In the original ice cream recipe, honey was incorporated into the product as one of the components of the honeycomb inclusion. However, following the substitution of the honeycomb candy with Heath Bar pieces, the use of honey as an ingredient was excluded from the recipe. Given the centrality of honey to the product's identity, the idea of incorporating honey as a variegate was raised during the scale-up process.

Honey is a supersaturated mixture of several sugars (glucose, fructose, sucrose, maltose, etc.) in a water system with high viscosity at low temperatures. Sugars constitute approximately 80% of honey's composition, with glucose and fructose being the predominant ones, while water makes up the remaining 20%. Crystallization is a process that occurs naturally and spontaneously in honey due to the lower solubility of glucose in a supersaturated state, leading to an increase in the water content of the liquid phase (Ahmed and Basu, 2017). Crystallization is a characteristic of pure and natural honey, and it does not negatively impact its quality.

At room temperature, honey has an average density of 1.4 kg/L, which is higher than the density of a typical 10% milk fat ice cream mix which is around 1.1 kg/L. However, the density

of an ice cream mix decreases with an increase in fat content (Goff, 2013). In the case of Cornell Dairy's white ice cream mix, which has a higher fat content of 16%, the density would be even lower. Due to this density difference, when honey is used as a variegate in ice cream, it tends to sink to the bottom of the container and distribute poorly throughout the ice cream. Additionally, incorporating honey into the ice cream mix can pose freezing and hardening challenges as it causes freezing point depression. However, mixing honey with dextrose equivalent corn syrup solids (DE CSS) can alleviate these issues and allow for a greater percentage of honey to be used (Goff, 2013). Although this technique was initially meant for sweetening the ice cream base, this approach was tested in the variegate of the Honey Crunch ice cream by mixing honey with caramel sauce. Different ratios of the caramel sauce and the honey were tested (Table 5).

Table 5. Different caramel sauce and honey ratios tested for the ice cream variegate formulation.

Sample	Caramel Sauce (%)	Honey (%)
A	75	25
B	90	10
C	60	40

The honey was locally sourced from the Cornell Dyce Lab for Honeybee Studies, which supplied both liquid and crystallized honey. A mixture of 50% liquid honey and 50% crystallized honey was created under the hypothesis that this would improve its performance as a variegate in the ice cream. The caramel sauce is a standard ingredient at Cornell Dairy, sourced from an approved supplier and already used in other ice cream flavors. Incorporating existing raw materials that have a proven track record and are readily available is a convenient and effective approach for line extensions in the food industry. Through internal sensory evaluation, the best blend was

chosen, resulting in a successful swirl that delivered in terms of flavor, distribution, and stability within the ice cream.

E. Final Formula

After the optimization of each of the individual ingredients, the whole ice cream was assembled. For confidentiality reasons, the final formula is not presented, however the ingredient list of Honey Crunch ice cream is. For confidentiality reasons, final formula and ingredient suppliers are not disclosed. Final ingredient statement for Honey crunch ice cream is:

Ingredients: Milk, Cream, Sugar, Caramel Sauce [sugar, water, corn syrup, high fructose corn syrup, nonfat dry milk, tapioca starch, butter (cream, salt), contains 2% or less of salt, molasses, soy lecithin, sodium citrate, natural flavor, and potassium sorbate], Heath Crunch Piece [sugar, palm oil, dairy butter (milk), almonds (roasted in cocoa butter and/or sunflower oil), salt, artificial flavor, and soy lecithin], Honey (locally sourced from the Cornell Dyce Lab for Honey Bee Studies), Corn Syrup solids, Skim milk, Stabilizer (Microcrystalline cellulose, Mono- and Di-glycerides, Cellulose gum, Carrageenan, Maltodextrin), Pure Vanilla extract (water, alcohol, sugar).

2.3 Processing

When scaling up a food product from kitchen to industrial scale, the manufacturing process undergoes significant changes. At a benchtop level, students received the base mix from Cornell Dairy and added other ingredients such as flavors, inclusions, and variegates to develop the ice cream. Honeycomb candy was made in the kitchen in small batches to add as an inclusion. Additionally, vanilla extract was added to the white base mix, and the ice cream was made using a kitchen ice cream maker. Once the ice cream was frozen, inclusion pieces and variegate were manually added, and the entire ice cream was assembled and placed in a freezer to harden.

The industrial process is considerably different, and it starts with the preparation of the base mix on. Cornell Dairy sources raw milk from Cornell's Veterinary School, which is then separated into cream and skim milk. The cream is then mixed with the other weighed or metered ingredients in a high-speed blender, after which the mix is pasteurized for safe consumption using a plate heat exchanger on Mondays. The mix is then aged for approximately 72 hours to allow for recrystallization of the fat crystals, completion of the hydration process by the gums and stabilizers, and the adsorption process by the proteins at the fat/water interface. Aging the mix for a longer period results in a higher-quality product. On Thursdays, the mix is flavored in flavor vats and then frozen using a continuous freezer, which is a scraped surface heat exchanger. During the dynamic freezing process, air is incorporated into the mix, and ice cream is created. The amount of air that is incorporated is known as overrun. Then, the inclusion pieces are added in a fruit feeder. The crystallized and liquid honey and the caramel sauce are mixed manually and then a variegate pump or swirler incorporates the mix into the ice cream. The speed of both the fruit feeder and the swirler can be adjusted to control the amount of inclusions and variegate added to the ice cream. Because inclusion pieces and variegates are added post-pasteurization, it is critical to source safe ingredients from approved suppliers and have impeccable Good Manufacturing Practices to avoid product recontamination. The ice cream is finally pumped to the filler and packaged into tubs, labeled, and then frozen rapidly in a blast freezer to -40°C for hardening.

The primary contrast between the bench-top and industrial processes is the use of specialized equipment and the almost fully automated nature of the latter. Since this project involved creating a new flavor of an already established product, ice cream, there was no need to adjust operating parameters such as speed and temperature. However, in the case of a scale-up

process for a completely new product, determining and optimizing these parameters is critical for the success of the project.

2.4 Other considerations

Scaling up a food product involves more than just ingredients, formulation, and processing. There are several other important considerations to keep in mind before launching a product on the market. One key aspect is the naming of the product. A good name should be appealing to consumers, memorable, distinct, and reflect the essence of the product. In this project, the name of the ice cream changed from “Pure Honey” to meet these criteria.

Correctly costing the product is also critical in scale-up, as all aspects such as ingredients, labor, energy, packaging, and more need to be considered in the cost analysis to ensure that the product is profitable. Additionally, it is essential to ensure that everything needed to launch the product to the market is in place. This includes well-established specifications, a label that complies with regulations, packaging, costs, supply chain, and logistics, among other aspects. Failing to address any of these critical considerations could result in costly delays or potential failure of the new product in the market.

2.5 Conclusion

Scaling up a food product from kitchen to industrial scale is critical in the development and commercialization of a food product. This process goes beyond increasing batch size and involves various steps such as adjustment and standardization of the formula, sourcing of the ingredients, conducting tests, and adjusting processing parameters. The optimization of a formula is the link between R&D and commercial production of a food product.

Increasing efficiency, reducing costs, enhancing sensory attributes, and complying with regulations are all objectives of the scale-up process. The transformation of Pure Honey ice cream to Honey Crunch ice cream in this project was successful due to the proper execution of the scaling process, which adapted the ice cream to production on a plant scale. 50 gallons of Honey Crunch ice cream was produced at the Cornell Dairy and is now available for sale at the Cornell Dairy Bar. Effectively implementing the scale-up process is crucial to delivering high-quality, consistent, and profitable food products to the market that meet consumer demands and expectations.

2.6 References

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