Methods for Developing New Food Products

An Instructional Guide

Fadi Aramouni, Ph.D.
Professor of Food Science
Kansas State University

Kathryn Deschenes, M.S.
Food Science, Deschenes Consulting, LLC

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Preface

THE ideas in this text include and yet transcend the concepts normally offered in food science courses. They speak to practical and business issues, such as food marketing, product feasibility and industry expectations for oral and written communication. Much of the applied technology covered herein is derived from consultation with experts in areas such as these. While the book aspires to provide a review and overview of information required by a well-informed specialist in the food industry, no single volume can cover everything. Hence, the book is a stepping-stone and guide for the readers' own work and research.

The content and organization of this book were originally developed and delivered for a capstone course at Kansas State University. Students who participated in the course and applied its ideas have won many competitions and awards, including:

- First place four years in a row at the American Association of Cereal Chemists Product Development Competition
- First place in Danisco Ingredients R&D Competition
- Third place three times in the IFT's Student Division's Annual Product Development
- Grand Prize in the Disney Healthy Snack for Kids
- First place in the Almond Board of California Competition
- First place twice in the Cherry Marketing Institute's New Food Product Competition
- Dairy Management's Most Creative Product Award

- Finalists in Raisin Board of California Bread Competition three years in a row
- Finalists in Research Chefs of America Competition
- Finalists in Dairy Institute Competition

For students the book provides the framework for understanding and appreciating the complexity of food development projects. As the foregoing list attests, the book also forges tools for success in working individually or on teams to create or enhance food products and product lines.

This text also offers challenges and opportunities for instructors, not only in capstone but in other courses. Because product development is by its nature a broad and interdisciplinary set of tasks, the teacher is called upon to present information from specialties that are not his or her own. Just as the book encourages teamwork among students, it also lends itself to team teaching, with instructors from different departments. The book should help students consolidate what they know in a given area and also venture into new subject matter. In every instance the book invites readers to apply what they know to developing new products and at the same time learn from others what must yet be mastered. In this context, it is recommended that students have ready access to other texts, including ones covering the basics of food chemistry, statistics, sensory analysis and food processing, which are referenced in the pages that follow.

CHAPTER 1

Overview of Food Product Development

Learning Objectives

- Learn the steps involved in food product development.
- Know the definitions of acid, low-acid, and acidified foods along with examples of each.
- Know the feasibility barriers to product commercialization.

FOOD product development involves more than just creating the perfect recipe. Companies must plan extensively, work hard, and research for an extended period of time in order to produce new food products. Prior to starting a new development venture, it is imperative to develop specific objectives and timetables that integrate the future direction of the business. Companies engage in new product development with the hopes of gaining new customers, expanding into new geographic markets, increasing profits, elevating brand excitement, or increasing market shares.

Companies large and small introduce thousands and thousands of new food products each year. The time spent developing new food products ranges from 6 months to 5 years, depending on the degree of new technology and innovation. For example, line extension development that utilizes equipment that is already in place at a manufacturing facility usually takes less time to develop than a new product that needs a custom processing line. The failure rate of new products, which is defined as a product no longer on store shelves after five years, can be as high as 90% in some grocery categories.

Larger companies rely on a product development team that includes food scientists, food engineers, regulatory specialists, marketing experts, and purchasing gurus, while smaller companies may not even have a research and development department. Smaller companies may

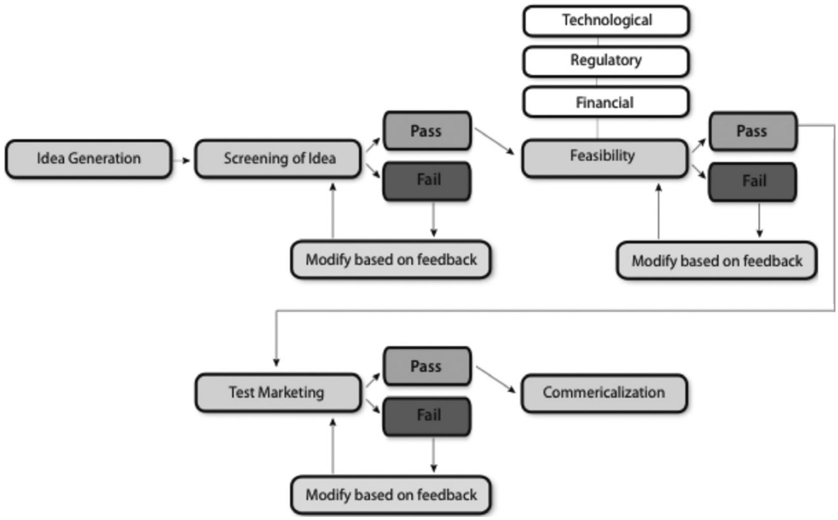

FIGURE 1.1. The process of product development.

rely heavily on outside resources, such as universities and independent laboratories in order to create successful products.

IDEA GENERATION

Companies use varying techniques to generate ideas for new products. Marketing teams may be charged with the central development of ideas with supplementation of researcher input. Ideas may also come from consumer input. Some companies may not need this step, especially if they thrive on regenerating competitor's products. An example of this is having a store brand product that is very similar to a name brand product that is offered. Ideation sessions using participants from all departments can also be a part of corporate idea generation. After idea generation, the major steps in developing a new food product may be divided into four phases: screening, feasibility, test marketing, and commercialization. Idea generation should be completed by gathering information about trending ingredients and consumer wants by attending trade shows, keeping up to date on new product releases by other companies, scanning research articles and trade publications, and monitoring grocery shelves.

SCREENING

After an idea has been created, the steps of product development begin. Screening is the most critical step in a product development project. Thorough testing of product concepts can assist a firm in deciding whether to invest time and money into a venture, or to abandon the efforts completely. Project ideas should be congruent with organizational goals. Project managers should screen ideas throughout the development project in order to gauge if the marketplace has shifted in its acceptability of the concept, ingredient availability, and regulatory factors. Smaller companies may call on outside firms to assist in market screening.

Questions for Screening Concepts

Companies can begin by asking a series of questions such as:

- Who will use the product?
- How will it be used?
- What preparation is necessary for the consumer?
- How will the consumer benefit from it?
- Does it have any other uses?
- Who is the competition? How is the product different?
- Where will the product be available?
- How will people find out about the product?
- What will the price be?

Collaboration of departments during the screening step helps to evaluate individual areas involved in product development including financial and legal considerations, process and equipment availability, purchasing power and ingredient accessibility, shifts in the marketplace, and consumer perceptions. Examining markets and conducting consumer research are vital to product screening.

Consumer testing is essential when screening products. Without consumer testing, companies have no way of knowing consumer needs, desires, and willingness to purchase. Initial screening may reveal useful information for later marketing schemes.

FEASIBILITY

Feasibility considerations for a business include regulations, technology, and finances. By setting up an interdepartmental team, the tools will be available to answer initial questions of attainability that may be introduced at any stage during the development process.

Regulations

At the start of a project, firms must be cognizant of the state and/or federal agencies that regulate a product. In general, products sold locally (which do not cross state lines) are regulated by state agencies. A product crossing state lines comes under the United States Food and Drug Administration (FDA) or the United States Department of Agriculture (USDA) jurisdiction depending on the type of food. Some states allow small food processing businesses to be conducted out of a person's home, but the processing area must be separated from the living quarters by solid walls, and there should be no direct entrance from the living quarters to the food processing area. Some local governments prohibit in-home commercial food processing, so awareness of local zoning laws is of utmost importance.

Food—as defined in 21 CFR 321 (f)—is "a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum." Standards of identity state the requirements of individual food products as defined in the code of federal regulations. An individual product must meet certain guidelines in order to use a specific name. "Applesauce", for example, has strict guidelines on ingredient inclusion in order for it to be labeled as such (21 CFR 145.110). "Applesauce" must have a soluble solids content (measured by a refractometer) of at least 9% if unsweetened and of 16.5% if sweeteners are added. Apples should be the primary ingredient of the product, but optional ingredients such as water, salt, apple juice, organic acids, nutritive carbohydrate sweeteners, spices, natural flavorings, and a color additive/color preserving agent can be added in distinct quantities. The FDA and USDA release publications that give the guiding principles of labeling products under their jurisdiction titled "Food Labeling Guide" and "The Food Policy and Labeling Guide" respectively.

Meat and poultry products that contain more than 3% fresh meat, or at least 2% cooked poultry, and that are intended for sale in interstate commerce are regulated by the USDA Food Safety Inspection Service (FSIS). The FDA regulates all other food products with the exception of seafood, which is regulated by the Department of Commerce and the FDA.

Due to the potential hazard of botulism, special regulations apply for heat processed, low-acid canned foods, and acidified foods in *hermetically sealed containers* (Code of Federal Regulations CFR 108, 113 and

114). *Acid foods* are those that naturally have a pH below 4.6 and/or a water activity below 0.85. These regulations are based upon the microbiological activity of *Clostridium botulinum* and *Staphylococcus aureus*. *Low-acid canned foods* are defined as processed foods with a pH greater than 4.6 and a water activity greater than 0.85 with the exception of alcoholic beverages. *Water activity* (a_w) is a measure of the water available for microbial growth in a food. *Acidified foods* are low-acid foods to which acid(s) or acid food(s) are added to reduce the pH to 4.6 or below with an a_w greater than 0.85. All processors of these foods must take an FDA-approved course of study often referred to as the Better Process Control School. In addition, companies must also provide specific processing information for FDA approval. Products such as jams, jellies, and barbecue sauces usually have pH values low enough that they do not fall under these regulations. Most canned vegetables and pickled products are subject to low-acid food regulations.

Other regulated areas that require attention fall under two general categories: health safeguards and economic safeguards. Health safeguards protect against the issues of adulteration, natural toxicants, food additives, residues, and unsanitary processing or holding practices. Economic safeguards include the issues of labeling, especially with respect to misleading or false statements, and net contents. More information on these subjects will be covered in Chapter 10, Regulatory Considerations.

Technology

In order to launch a new food product, the necessary equipment, facilities, and processes needed to manufacture a product must be established. When products are found to not be technologically feasible, the project should be terminated.

Formulation

Varying ingredients, processing parameters, and packaging options will be utilized in order to find the best combination to create the desired product. Sound statistical analysis and good record keeping are critical at this step. After some initial trials, an experimental design will cut down on the number of prototypes to be developed which will save time and money. All formulas and experiments should be detailed in a laboratory notebook. Each entry should include all necessary details.

This is beneficial when projects are temporarily delayed, last for long periods of time, or may be passed to other developers at the organization.

Ingredients

Considerations when choosing ingredients include whether the commodity will be available for purchase year-round or seasonally. Product developers will generally consider more than one supplier of the same product to test quality and cost effectiveness. Larger companies may need to find more than one supplier of the same product to fulfill needs. If more than one supplier is used, tight product specifications must be followed by all suppliers.

Processing

If there is an existing facility, what equipment do you already have? Companies usually try to produce newly developed products on equipment that is already acquired if possible. New equipment is a big capital expense, so new product development projects are often based on expanding product lines using existing facilities and equipment. For this reason, product developers should be aware of what equipment is available in the location that the product will ultimately be produced. If the product will be produced in more than one plant, considerations should fall on what the differences are in the available equipment and how they can be reconciled to produce commercially similar products.

Facilities

The facility that is available for processing should be considered. If the company has acquired a new plant, the water supply and sewage systems will need to be inspected. The conditions inside the plant, such as temperature and relative humidity control, should be taken into account. Facilities in areas with high humidity and heat in the summer without controls for these conditions may have to modify operating conditions to produce quality foods.

Packaging

Packaging is an important part of a consumer's appeal for a product, especially with first time purchases. It is important to consider how consumers will view the packaging and if it will convey the product's quality goals, such as being a high quality premium product or a generic grade. Marketing, product developers, and packaging engineers should consider the types of packaging materials that are being used on competitors' products and how to set themselves apart.

Distribution

Products that require special distribution needs include frozen and refrigerated foods. Organizations should consider the cost of special distribution. Other distribution considerations include the radius in which the product will be available. Will the product have nationwide or regional distribution? The distribution radius can also influence the packaging needs.

Shelf Life

Shelf life is the determination of how long a product will hold its quality as perceived by customers. The shelf life of a product is important when considering distribution channels. Shelf life can be determined through the use of accelerated or real time testing. More information about shelf life and its testing will be given in Chapter 14.

Safety

New product developers should consider the safety risks of their products. History of outbreaks and published safety risks of certain product categories can help give clues on risk factors of which processors should be cognizant. For example, peanut butter producers must use controls to test for possible salmonella contamination after a large outbreak in early 2009 caused over 400 people to become ill and at least five deaths. Some products are susceptible to the growth of spoilage and pathogenic microorganisms. Allergens and physical contaminants, like metal shavings from processing equipment, can pose safety threats to consumers as well.

Finances

Before a food product is created for sale, an understanding of all production and marketing costs is required. A detailed cost analysis should be made prior to manufacture. The two types of costs to consider include fixed costs and variable costs. Annual *fixed costs* are those that will not change in any one year, regardless of the level of production. These costs include equipment, building, property taxes, and other items that do no fluctuate due to changes in production. Variable costs are expenditures that vary with the volume of production, such as hired labor, raw ingredients, packaging materials, fuel, electricity, utilities, and other items used during production. Variable costs should be carefully examined prior to test marketing and commercialization to implement a unit price in order for the new product to make a profit.

TEST MARKETING

Should your screening and feasibility tests indicate a product's potential for launch, the next logical step is development of the product and test marketing. Purchasing equipment at this stage is not advisable. The main cost should be packaging and labeling material, promotion, and ingredients. Large companies rely on pilot plants to manufacture smaller batches of new food products for test marketing. For start-up companies, pilot plants at several regional universities or community centers can be used at minimal charge. Alternatively, the test product could be manufactured at an approved food processing facility in your area with capable equipment.

Consumer tests at this stage are sometimes conducted as in-home use tests. Consumers assess the likes and dislikes of the product prior to the organization launching a larger marketing scheme. Market testing is most effective when planned well in advance with the help of an expert in the field. Ask for assistance from marketing specialists who can devise a plan and interpret the results of your test. Test marketing should address formulation, processing, and packaging.

At the time of test marketing, a final formula is no longer a "recipe" and should be expressed in a weight percent basis. Multiple sources for all ingredients should be located. These should be of high quality with very little variability between shipments.

The process should be adequate to deliver a high quality, safe product. Check for state or federal regulations on processing parameters, such as final internal temperature, for specific products. Packaging should be appealing to the consumer and, at the same time, provide protection from contamination. The use of code packaging can be helpful in keeping track of shelf life and distribution.

Documentation will be critical to assess the success or failure of your market test. Records should be kept for all processing steps and controls including quality and temperature of raw ingredients, final cooking temperature, weight of every ingredient used in the batch, chemical and physical tests performed on net content of containers, and the number of defective units.

For test marketing, it is best to limit the distribution area. The target market should be defined by now. Questionnaires should be provided for consumers to evaluate the quality of your product. Keep in touch with store managers selling your product, and take frequent trips to determine who is buying it and where it is displayed in the store. Keep a detailed record of the market test and ask for help in analyzing the data to determine whether you should take the next big step—commercialization.

COMMERCIALIZATION

Should your market test prove successful, the product will be ready to commercialize. The product can still be produced at an existing food processing plant; otherwise, the main concern at this step is to find a location to manufacture the product. To set up a processing facility, a firm must address issues that include finding a location, building, equipment, utilities, and personnel. Consumer concerns during test marketing should be taken into consideration, and a second test may be conducted if deemed necessary.

Product promotion should be an integral part of commercialization. Companies with the leverage to fund national marketing schemes may use many avenues to get their products noticed. Common methods of marketing new products include savings coupons, national television advertisements, internet advertisements, and product placement strategies. The promotion strategies are product- and target-market dependent.

Finally, product maintenance should be included in commercialization. It should concentrate on quality improvement and profit improvement. Quality factors are maintained by noting potential defects in the product as it is handled in processing, distribution, and display. Cutting your costs rather than raising the price of your product can achieve profit improvement without deterring potential consumers. Investigating ways to improve process efficiency, save on labor costs, and find alternate suppliers of ingredients is essential to boost profits. While the product is new, solicit consumer response to help identify alternative flavors and packaging.

PRODUCT LIFE CYCLES

Products go through cycles during the duration of their sales. During the introductory period when the product is first launched, companies heavily promote their products in order to attract customers. In-store demonstrations are sometimes used to attract customers that may not try the product otherwise. Discounts and coupons can help spike sales of a new product as well. In this introductory period, the costs on the company are high and the returns are minimal.

The next phase in the cycle is a strong growth period. At this time, repeat buyers may decide to purchase the product on a regular basis. Word of mouth from customers may begin to attract other new customers. Expansion to new markets may assist in growing sales. Costs continue to be high, but profits are improving.

The next phase is a decline in the growth rate. Repeat buyers decline, new markets have been tapped out, the competition begins to grow, and there are new costs associated with trying to attract attention to the product. Profits are still good in this phase.

The stability period sees no growth in sales due to consumer fatigue. There is little excitement about the product, and sales stagnate. Costs and profits break even, but profits may begin to decline.

In the product decline phase, competitive products begin to beat out the product, and promotions are too costly to be beneficial. Sales of the product decline, and the product becomes costly to maintain. The product is unprofitable. At this point, companies must decide if it is necessary to cease manufacturing the product.

SUMMARY

Product success is dependent on many factors. Realistic goals for a product and sound financial analysis can make a product more apt to prosper. Collecting ample product research assists in creating products that fit consumer desires as well as ones that are competitive in the marketplace. A good business plan with adequate lists of all necessary tools is essential to building a realistic, profitable business/product. Product development also takes a bit of consumer acceptance, correct timing, and luck.

KEY WORDS

Acid foods—processed foods that naturally have a pH below 4.6 and/or a water activity below 0.85.

Acidified foods—low-acid foods to which acid(s) or acid food(s) are added to reduce the pH to 4.6 or below with a water activity greater than 0.85.

Food—as defined by the FDA in 21 CFR 321 (f), "a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum."

Hermetically sealed container—as defined by FDA in 21 CFR 113.3 (f), "a container that is designed and intended to be secure against the entry of microorganisms and thereby to maintain the commercial sterility of its contents after processing."

Low-acid canned foods—processed foods in hermetically sealed containers with a pH greater than 4.6 and a water activity greater than 0.85 with the exception of alcoholic beverages.

Shelf life—the determination of how long a product will hold its quality as perceived by customers.

Water activity (a_w)—the measure of the water available for microbial growth in a food.

COMPREHENSION QUESTIONS

1.1. What are the four steps in product development?

1.2. What three types of feasibility should product development teams be concerned about?

1.3. Find the standard of identity for ketchup from Title 21 CFR.

(*Hint: Go to FDA.gov and search for 21 CFR, then search within 21 CFR.*) Give the ingredients allowed and the allowable labeling of ketchup.

1.4. What must a producer do in order to make their product if it is considered a low-acid or acidified food and it has a pH greater than 4.6 and a water activity greater than 0.85?

EXERCISE 1.1: MARKET SCREENING

Market screening means distinguishing profitable ideas and market opportunities by assessing the saturation of a certain market. This is a tedious and time-consuming exercise, yet it is probably one of the most important steps in product development.

Step 1: Choose one of the following categories:

- reduced-fat, salty snacks
- ethnic condiments
- “gourmet” dessert items
- healthy beverages
- single-serve, shelf stable lunch foods
- home meal replacement entrees
- frozen side dishes (high in vitamin A, iron, or calcium)
- breakfast on the run items containing meat
- kids “gimmick” items
- soy-based foods

You may also come up with your own category that matches your interest

Step 2: Go to the grocery store where you usually do your shopping and prepare a simple sketch diagram of the store indicating location of food items by category.

Step 3: For the food category you chose, make a list of ALL products available. List suppliers, prices per unit and per serving, flavors, packaging sizes/options, national or regional brands, any distinct properties about the product, and the location in the store. Note that some product categories may be spread around the store including in front displays.

Step 4: Discuss all potential competing products not from the same category. For example, if you are screening gourmet items in the dessert section of the store, you may want to look also at dessert yogurt or pudding products in the refrigerated case. Indicate any consumer and market trends that you have observed in this category or that you have read about. Be sure to check professional magazines and trade journals for recent trends and include any such references in your report.

Step 5: Without trying any of the products in your category at the grocery store and based solely on first impression, separate them into one of three categories: *would definitely buy, may buy, would definitely not buy*.

Step 6: Choose your favorite and least favorite products and list the reasons why you chose each. Purchase these two items.

Step 7: Try your favorite and least favorite products being careful to follow the manufacturer's recommendations for preparing the foods. What two things do you like most and what two things do you dislike most about each? Which of the products would you buy again?

Step 8: Based on your market screening, come up with one or more ideas for a new product in this category. These may be new flavors, different packaging options, or completely new concepts. In thinking about new products, consider the list of ten questions discussed under "screening" at the beginning of the chapter and keep in mind current consumer trends.

REFERENCES

Fuller, G.W. 1994. *New Food Product Development: From Concept to Marketplace.* Boca Raton, FL: CRC Press.

KSU and Kansas Department of Commerce and Housing. 1998. *Reference Guide for Kansas Food Processors.*

Nelson-Stafford, B. 1991. *From Kitchen to Consumer: The Entrepreneur's Guide to Commercial Food Production.* San Diego, California: Academic Press.

Consumer Preferences, Market Trends, and Creativity

Learning Objectives

- Learn about influences of consumer preferences.
- Explore market trends.
- Become more familiar with activities that stimulate creativity and new idea generation.

THE involvement of food scientists in the creative process of new product development varies in the industry. No matter the direct involvement, it is important to be aware of trends in the market, consumer preferences, and how concepts are developed in an organization.

CONSUMER PREFERENCES

A myriad of influencers assist in the decisions of consumers to purchase or pass on a product. Consumers are influenced by religion, ethnicity, age, non-religious beliefs, and their experiences. Product developers should understand their target markets in order to devise a product that meets consumer standards. It is important to understand the restrictions of some diets prior to development.

Age

Age affects consumer preferences because of experiences or the scientific beliefs of that era. For example, if you grew up eating margarine and being told that it was a better alternative to butter, there is a chance that you may choose margarine in the grocery store rather than butter. In addition, age also brings unique food choices. Prunes are more readily consumed by aging consumers, while fruit snacks shaped like the latest children's movie hit are more likely to be eaten by a younger demographic. With the baby boomer generation aging, there is a push to create products strictly geared toward this group. With age also comes diet restrictions that correspond with illness, such as diabetes, heart disease, and high blood pressure.

Religion

Religious denominations can affect the preference of the foods consumed. Catholics and some Protestant sects may fast or abstain from eating meat on certain holidays. Traditionally, those who are Catholic may substitute fish items for meat on Fridays during the Lenten season, the 40 days before the Easter holiday.

Those who practice Islam may only consume foods that meet halal standards. Foods that are not permitted are referred to as "haram." Foods that are haram include any items containing alcohol, pork, animals not slaughtered according to standards, and items containing gelatin.

In the Jewish faith, those practicing eat according to kosher laws. Kosher law does not permit the consumption of pork products, crustaceans, animals not slaughtered according to standards, and items containing gelatin. In addition, there are guidelines for eating baked goods and eating meals with both meat and dairy in them.

Ethnicity

Ethnic background can affect food choice. For example, having a family with Hispanic roots would likely result in an affinity for different types of food than someone who is from India. The types of food that are consumed as a child help shape the foods that are craved as an adult.

Non-religious Beliefs

Have you ever asked a vegetarian why they practice vegetarianism? Common answers to this question include the belief that animals are mistreated, that it is healthier, or that excess farm animals contribute to the pollution of our earth. Those who devote their eating habits to local or organic foods may also have beliefs that contribute to their decision to live a certain way. Those who keep restrictive diets may think that this contributes to overall wellness.

Income

As customers begin to make more money, shopping behaviors generally change. Customers with lower incomes tend to shop at different stores than those with excess funds. Having extremely low income usually prohibits shoppers from being organic and local consumers explicitly, while higher income has consistently been linked with those who commonly purchase these types of foods (Zepeda and Nie 2012).

Community

Some cities have cultures that support different eating patterns. If you live in a city with a farmer's market on every other block, there is a higher likelihood of you purchasing your foods there. People who live in states that produce a lot of a certain type of food product usually consume a little more of that product. For example, those who live in Kansas would eat less fish than those who live in Maine.

MARKET TRENDS

Market trends stem from many sources—celebrity diets, the latest scientific research, or popular ingredient trends. Companies producing foods should try to be on the front end of trends so that new products come out with the newest trends. Diet-based trends can come and go quickly, but play on what consumers desire. It can be financially beneficial to produce products that align with the latest customer demands.

Hot trends in 2014 included, gluten free, ancient grains, and redesigning packaging to be more environmentally friendly. Consumers with purchasing power may decide to purchase one product over another merely for personal belief, the power to make a better world through earth-friendly purchases, or to purchase from companies that make efforts to give back. New product ideas that disregard the current consumer fixations are generally less successful than others unless they can gain market attention through low prices or catchy marketing.

As a new product developer, it is important to be cognizant of the ever-changing trends in the food industry, to constantly ask how a new product will fit into the current scheme of products, and to know that assessing market needs is important.

CREATIVITY

Unfortunately, not every person is born with innate creativity. Companies can facilitate creativity in their employees by encouraging it. A certain amount of creativity can be "taught" through short courses that introduce techniques for brainstorming. The best ideas are sometimes found by accident or with a team putting their heads together. The most important piece of brainstorming for a new product is to not discourage any ideas that seem out of touch or not so great to others. Ideation sessions should include a "no putting down" rule to help facilitate an open environment. When you have a great idea, hammer out possible details of how the product would be packaged and how it would be marketed to the public.

COMPREHENSION QUESTIONS

2.1. Give two examples of current hot market trends. Give a product that you would create to fit in these trends.

2.2. What is the best way for you to think creatively? Are you an innately creative person?

REFERENCE

Zepeda, L. and Nie, C. 2012. What are the odds of being an organic or local food shopper? Multivariate analysis of U.S. food shopper lifestyle segments. *Agriculture and Human Values, 29*(4), 467–480.

Experimental Design in Food Product Development

Learning Objectives

- How to use the appropriate statistical design to get meaningful results from your product development experiments.
- To reduce time and cost involved in testing new formulations, ingredients, or treatments by using reliable statistics.

ELEMENTARY CONCEPTS IN STATISTICS

IT is beyond the scope of this chapter to teach statistics, a subject that is covered by numerous classes on most campuses. The information provided below assumes that the reader is familiar with the subject, and the following will address the issue of how to use this knowledge in product development. Experiments in the product development process, as in most processes, involve the gathering of data, which is used to make inferences about a certain variable or its effects. It is generally hoped that data gathered follows the normal distribution, i.e., the classic "bell-shaped" curve. The total area under the normal distribution is equal to 1 with the center being the mean of the distribution. A standard normal distribution will have a mean of 0 with a standard deviation of 1. The empirical rule regarding the standard deviation from the normal distribution is that:

- Area in $\mu < \sigma = 0.6826$
- Area in $\mu < 2\sigma = 0.9544$
- Area in $\mu < 3\sigma = 0.9974$

As an example, what this refers to is that the probability that a value falling within 1, 2, or standard deviations of the mean is 68.26%, 95.44%, and 99.74% respectively.

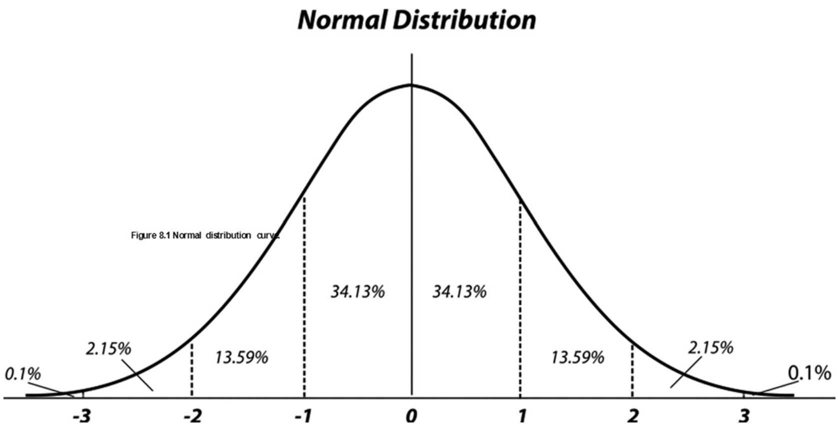

FIGURE 8.1. Normal distribution curve.

Inferences for Normal Distributions

The above figure is used to define the value α called the confidence level. Therefore, in a set of data where $\alpha = 0.05$, the probability that the interval of values obtained experimentally covers the true value of the parameter is 95%.

Hypothesis Test

When running an experiment in product development, you are often trying to test a certain hypothesis, such as: if for cost reasons you want to replace sugar with corn syrup in your cake formulation, will it affect cake volume? Therefore, the hypothesis test is the procedure to help you draw a conclusion about a certain parameter:

A hypothesis test consists of 5 steps:

1. Null Hypothesis, H_o

   H_o, $\mu = \mu_o$, in this case, the volumes of the cakes will be the same

2. Alternative Hypothesis, H_a

   H_a: $\mu < \mu_o$ and $\mu > \mu_o$ (one-tailed test); the volume of the cake with corn syrup will be greater or smaller than the cake made with sugar

   $\mu \neq \mu_o$ (two-tailed test); the volumes of the cakes will be different

Practically, you make three cakes with sugar and three with corn syrup, keeping all other factors the same, and measure the volumes of the cakes. You will then run an analysis of the means of the two treatments, and go to the third step.

3. Test statistic (*t* or *z*-value): you test whether these means are the same using an appropriate statistical tool such as a student t-test. The results will tell you if the null hypothesis is correct: i.e., there is no difference in cake volume, or if it is to be rejected: i.e., there is a difference (step 4).
4. Rejection Region: You can also tell from the *t*-test whether the volume of the cake with the syrup is significantly larger or smaller than the control.

$$t > t_\alpha$$

$$t < -t_\alpha$$

$$|t| > t_\alpha/2$$

5. Draw your conclusion.

Special Notes on Inferences

- Rejection region depends on specification of desired α (Type I error), most commonly α will be either 0.05 or 0.01.
- Alternatively, we can compute a *p*-value for the test statistic.
  —The *p*-value is the probability of observing a test statistic value as extreme as the observed value, assuming that H_o is true.
  —A small *p*-value therefore indicates that such an extreme test statistic is unlikely to occur when H_o is true, leading us to believe that H_o is wrong.
- Failing to reject a null hypothesis does not mean the H_o is necessarily true. Remember it is just a question of probability.

Logarithmic Scales

Special consideration must be given to pH and microbiological counts as they are based on logarithmic scales. Differences may be under or over significantly. Changes in microbial counts can multiply very quickly. For example, if you are testing the effect of two acidifying ingredients on the pH of a salsa and your statistical analysis indicates no significant differences with the two means: 4.55 and 4.66. That may be true mathematically, but it makes a very big difference in the safety of the salsa and its regulation. The salsa with a pH of 4.55 will be considered acid or acidified and does not support the growth of botulism while the salsa with a pH of 4.66 will be considered a low-acid food.

In the case of microbial growth, any differences less than 1 log are considered insignificant due to the nature of microbial growth.

Statistics Basics

- *Random sample*—random implies that each sample in the population has an *equal chance* of being selected.
- *Sample mean*—a measure of the "central tendency" of the sample. It is the sum of a set of measurements divided by their number.
- *Sample variance (s^2) and standard deviation (s)*—measure the "spread of the sample." The standard deviation is commonly considered the more useful of these, because its units are the same as those for the sample.
- *Estimation*—the process of using a quantity computed on a sample to provide information regarding the corresponding population quantity. We often use the sample mean to estimate the population mean and the sample variance to estimate the population variance.

Experimental Designs

The design of experiments is essential in successful food product development projects. Well-designed studies save money and are easier to analyze. The statistical design of experiments provides confidence that the information you collect is reliable. Experimental design is used mostly in formulating product, process development, sensory testing, and test market analysis.

Completely Randomized Design (CR)

Completely randomized design (CR) is an experimental design in which the analyst randomly assigns the samples to different procedures. For example, if you are trying to find the best chocolate chip out of four samples that will produce the best taste for a cookie recipe, you could make three cookies with each of the four chocolates, and assign the 12 cookies randomly to four judges to score them on chocolate flavor.

Randomized Complete Block Design (RCB)

A randomized complete block design (RCB) is a restricted randomization of treatments in which the units are sorted into blocks, and the treatments are randomly assigned to units within each block. The block design is considered complete if each treatment is assigned to at least one unit in each block. Otherwise the block design is incomplete. In general, we have *t* treatments, *b* blocks, so in a RCB we have $t \times b$ experimental units.

In the previous example, you will use a panel of four judges to test four cookies; each made with a different chocolate, and with all other ingredients maintained the same. Each judge is going to test every cookie three times, randomly assigned, and scores them. Scores are tabulated and data is analyzed for differences among the means.

The advantages of RCB over CR are that these tests reduce variability of treatment comparisons by allowing them to be made on more similar units within a block. Variability in experimental units can be introduced deliberately by including a wide variety of blocks, thus broadening the population about which inferences can be made. RCB tests are easy to construct and easy to analyze. This type of design is also flexible to the number of treatments and blocks. If the number of treatments is large, you may not be able to find enough similar units to call a block, therefore making other tests a better choice.

Factorial Design: Handling Many Factors Simultaneously

Usually a set of "alphabetic" factor notation will be used to talk about any kind of factorial structure in general (Table 8.1).

Factor A has *a* levels, Factor B has *b* levels, and so on. When we refer to a factorial structure, we refer to it generically by its level. If we have 3 levels of Factor A and 4 levels of Factor B we call this a 3×4 factorial structure.

The number of treatment combinations is just the product of the lev-

TABLE 8.1. Factorial Design Set Up.

Factor Name	Number of Levels	Subscript on y or μ
A	a	i
B	b	j
C	c	k

els of the factors: $t = a \times b \times c$. Factorial designs can be run in any of the following types:

1. Full factorial design
2. Fractional factorial design
3. Response surface design: very commonly used in product development
4. Mixture designs

Questions to Consider in Factorial Design

- Questions you might want to answer:
  —Is there a Factor A effect?
  —Is there a Factor B effect?
  —Is there any interaction between the different factors?
- *Example:* you are working on developing a new cherry pie and you want to test the following:
  —3 levels of sugar (high/low)
  —2 suppliers of cherries
  —Butter (B) or margarine (M)
  —You can have a 3 × 2 × 2 full factorial design, resulting in 12 different treatments.

SUMMARY

Experimental design in new product development can save companies time and money. By starting with an experimental plan, the product development team can develop a schedule to test each variable in the experiment. Taking detailed notes during all experiments is necessary in case the project is temporarily put on hold or team members are not able to fulfill the entire project.

KEY WORDS

Estimation—the process of using a quantity computed on a sample to provide information regarding the corresponding population quantity. We often use the sample mean to estimate the population mean and the sample variance to estimate the population variance.

Random sample—random implies that each sample in the population has an equal chance of being selected.

Sample mean—a measure of the "central tendency" of the sample. It is the sum of a set of measurements divided by their number.

Standard deviation (*s*)—the standard deviation is commonly considered the more useful of these, because its units are the same as those for the sample.

COMPREHENSION QUESTIONS

8.1. Give two advantages of the RCB over the CR design.

8.2. Design a study to correspond to a certain variable you are testing in your own product. Explain why you chose the design you did.

REFERENCE

Hubbard, M.R. 1990. *Statistical quality control for the food industry.* New York: Van Nostrand Reinhold.

or outer wrapper. The plastic tray or bag is referred to as the primary packaging, while the outer box or wrapper is referred to as the secondary packaging. Primary and secondary packaging are both seen by the consumers at their retail provider. When the products are delivered to a store, they are usually packed in bigger boxes (distribution/tertiary packaging). These corrugated boxes are usually packed full to protect the product and to allow ease of handling to and at the store. At plants, these tertiary/distribution packages may be packed on a pallet. The pallet is referred to as the unit load/quaternary package. Figure 11.1 demonstrates how this might work with a cookie product that is packed in a plastic tray and has an outer wrapper that was packed in a bigger box.

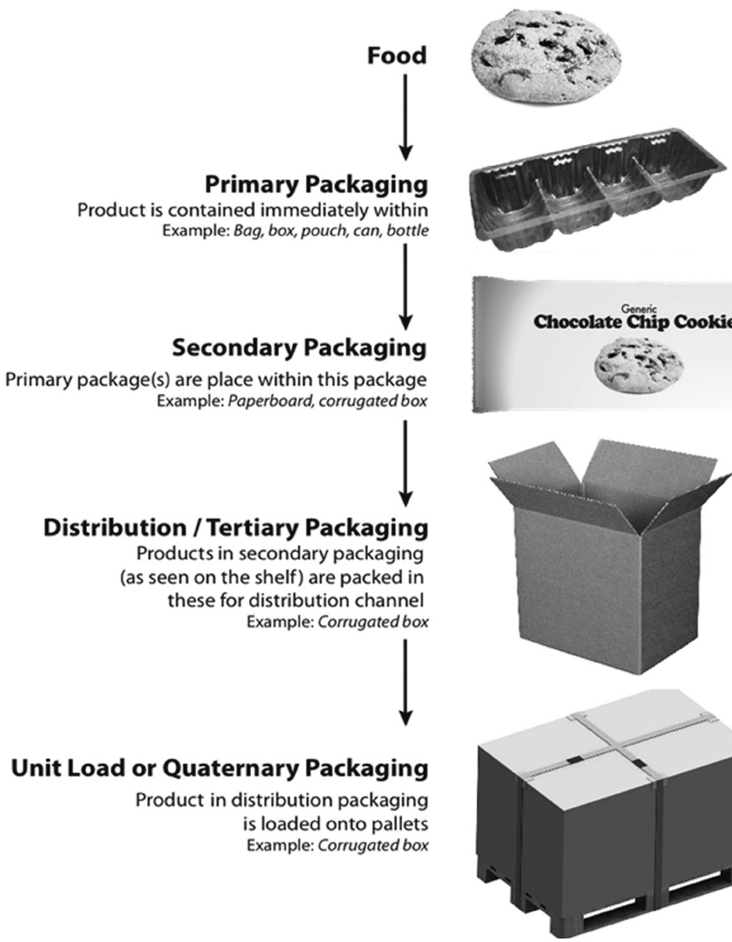

FIGURE 11.1. *Demonstration of the levels of packaging for a cookie product.*

STEPS TO DETERMINING PACKAGING

Step 1: Define Food Properties

In order to determine what packaging should be used, first consider the type of product that you are producing. Are you making snack crackers, cereal, beef jerky, candies, or eggs? It is important to establish what sort of product it will be, and what the regulations are for this particular product.

Is the product a solid, liquid, or gas? Is the liquid thin and have good flow properties, or thick? Is it a powder? How big is it? The type of packaging will most likely differ for products with changing flow properties and physical form. If the product is meant to be distributed frozen, how will the packaging be different? Is the product's shelf-life short? Does the product mold easily? Is the product highly acidic? Taking all of the product considerations into play is important to determine the packaging material that is most appropriate. FDA has specific "Definitions of Food Types and Conditions of Use for Food Contact Substances." These are divided into 2 groups: the first deals with food type (Table 11.1), and the second with the use conditions (Table 11.2).

Step 2: Define Package Technical and Functional Requirements

Prior to choosing packaging, it is important to consider all product attributes and the traits that you would like a package to have. Another important consideration is the radius of distribution. A product susceptible to breakage by vibration or drops will incur significantly less damage when distributed in a 100 mile radius than it will with nationwide distribution. The way that individual packages are boxed and palletized can help eliminate some damage.

Step 3. Define Package Marketing and Design Requirements

Packaging is a form of marketing to consumers. More sophisticated designs may take special packaging materials; therefore packaging engineers should be involved in discussing design, shape, and any special functions that are desired for the product. Another important consideration that is important is the shelf display requirements for grocers. Will the package be displayed by a hanger as some candies are displayed? Will the product's package contain any features? Features include easy

TABLE 11.1. Types of Raw and Processed Foods.

Categories of Foods for packaging
Non-acid, aqueous products; may contain salt, sugar, or both (pH above 5.0)
Acid, aqueous products; may contain salt, sugar, or both, and include oil-in-water emulsions of low- or high-fat content
Dairy products and modifications: Water-in-oil emulsions, high- or low-fat Oil-in-water emulsions, high- or low-fat
Nonacid, aqueous products; may contain salt, sugar, or both (pH above 5.0)
Aqueous, acid or non-acid products containing free oil or fat; may contain salt and include water-in-oil emulsions of low- or high-fat content
Low-moisture fats and oil
Beverages: Containing up to 8% alcohol Non-alcoholic Containing more than 8% alcohol
Bakery products: Moist bakery products with surface containing free fat or oil Moist bakery products with surface containing no free fat or oil
Dry solids with the surface containing no free fat or oil (no end test required)
Dry solids with the surface containing free fat or oil

Source: http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm109358.htm.

open bags or resealable packaging. It may also be important to consider the ease of recycling some products, as consumers are becoming more environmentally conscious. Packaging is a marketing tool.

Step 4: Identify Legal and Regulatory Requirements

Legal restrictions can include regulations for the use of certain packaging materials or infringing on patented technologies. All packaging materials are given approval by the FDA, just like food additives. Other considerations are religious restrictions, such as the kosher packaging stipulations for Jewish customers.

Food additives that come into contact with food as part of packaging are considered as Indirect Food Additives. They are regulated as mentioned in 21CFR and include adhesives and components of coatings (Part 175), paper and paperboard components (Part 176), polymers (Part 177), and adjuvants and production aids (Part 178). Additional indirect food additives are authorized through the food contact notification program and some may be authorized through 21 CFR 170.39. The FDA also maintains an "Inventory of Effective Food Contact Substance

Case Study: Package Size

When companies are thinking about what package sizes they should distribute, they must consider who potential customers will be. How often do you see family size bags of prunes? Probably not very often, as prunes are generally thought to be sold to the older demographic. In addition, family sizes in the United States have been shrinking so companies must also consider that. Families maybe don't need that mega jumbo sized jar of jam for their family. Due to these reasons, and living in the age of convenience, package sizes are moving toward smaller or individual packaging schemes or limited calorie packages.

(FCS) Notifications." "The database lists effective premarket notifications for food contact substances that have been demonstrated to be safe for their intended use. The list includes the food contact substance (FCS), the notifier, the manufacturer of the FCS, the intended use, the limitations on the conditions of use for the FCS and its specifications, the effective date, and its environmental decision." (http://www.fda.gov/Food/FoodIngredientsPackaging/ucm112642.htm.)

Step 5: Select Potential Package Design and Materials

Potential designs should meet all marketing, design, safety, and functional requirements. Estimated costs will be considered in this step.

TABLE 11.2. Parameters that Affect the Packaging Materials Used.

Condition of Use for Packaging
Boiling water sterilized
Hot filled or pasteurized above 150°F
Hot filled or pasteurized below 150°F
Room temperature filled and stored (no thermal treatment in the container)
Refrigerated storage (no thermal treatment in the container)
Frozen storage (no thermal treatment in the container)
Frozen or refrigerated storage:
Ready-prepared foods intended to be reheated in container at time of use:
Aqueous or oil-in-water emulsion of high- or low-fat
Aqueous, high- or low-free oil or fat
Irradiation
Cooking at temperatures exceeding 250°F

Source: http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm109358.html.

Mock-ups can be made at this point and consumer preference may be measured.

Step 6: Establish Feasibility of Packaging with Equipment and Material

The packaging engineer should obtain some packaging materials to determine whether the packaging material will function on the equipment in place. In these tests it is beneficial to subject the food to the packaging material to determine how the packaging will change the food, or if it will provide for the minimum shelf-life requirements.

Step 7: Estimate Time and Cost Constraints

Will the cost of this packaging be recouped by product purchases? Can the cost be cut down? Important factors in this phase are to determine when the packaging materials will be needed and when they can be provided. Cost is an important factor in organization's decisions.

Step 8: Shelf-Life Testing and Market Testing

In products with extended shelf-life, it will be very important to determine the weaknesses of the packaging, and if it will hold up for the product's entire life. Consumers input may be important to establish their preference prior to moving forward with a certain design. The shelf-life and safety of the product should be determined prior to consumer exposure. When the product design is well-accepted by consumers and meets company specifications, the packaging and product can go into full production.

PACKAGING MATERIAL

Paper and Paperboard

Paper and paperboard are widely used for packaging. Paper and paperboard products include corrugated boxes and shipping boxes. Flour and sugar are sometimes packaged in just a paper wrapping. Benefits of using paper are that it has low cost and is lightweight (Mauer and Ozen 2004). Ready to eat cereals, many snack products, cake mixes, and other foods are packaged in paperboard boxes. Because paper does not have very many protective qualities, many foods are packed in a sealed plastic bag inside a paper box. Paper can also be used for pouches of product that is not excessively moist.

Disadvantages of using paper include that it lacks the resistance of pests and is poor at blocking moisture and gas (Mauer and Ozen 2004). Paper expands and contracts with its environment and is easily distorted. Uncoated paperboard can absorb grease and moisture, and therefore should not be used for products with these attributes.

Metal

Metal is commonly used in canned foods, drinks, and in metalized films for lining plastic. The four types of metals used in the food industry are: steel, aluminum, tin, and chromium.

When using tin and steel, a layer of oil is usually added to reduce the risks of corrosion (Mauer and Ozen 2004). Steel is generally cheaper than tin.

The most common types of metal food packaging include three piece cans, two piece cans, and foil pouches. Three piece cans are formed out of a tinplate or steel cylinder (with a side seam) and two end pieces. The end pieces are curled and welded together to create a uniform container.

FIGURE 11.2. *Example of a 3 piece can.*

FIGURE 11.3. *Example of a 3 piece can.*

Usually the body of the can has ridges to help increase the strength and reduce collapsing with any shock (Mauer and Ozen 2004).

Two piece cans are made from aluminum or steel with one end piece. These cans are most familiar as can used for carbonated beverages. The advantage of aluminum is that it can be rolled very thin.

Aseptic boxes (used for juice boxes) and pouches (used for a variety of applications) use metallic foils on the inside to protect the product. Metal foils provide a moisture, gas, and light barrier. Metalized films are used in the packaging of snack products, such as granola bars, chips, and coffee. These have the option to be vacuum sealed (as commonly seen in coffee applications).

Metal is stable under thermal heating conditions, as well as having great barrier properties to light, gas, and moisture. Metal is also recyclable and has high consumer acceptance. Generally, the insides of metal cans are coated to prevent corrosion. This is sometimes done with bisphenol A (BPA).

Products that most commonly utilize metal packaging are soups, canned fruits and vegetables, and canned meats—thermally processed shelf stable foods (Mauer and Ozen 2004).

Glass

Glass is a good packaging medium because it is non-reactive, meaning it does not leech chemicals like other materials do. Glass is also beneficial because it allows the customer to see the product. Colored glass can be used for products that are light sensitive. Soda-lime glass is the most commonly used glass for food packaging (Mauer and Ozen 2004). Disadvantages to using glass include the risk of breakage and the fact that it can be heavy, which contributes to higher distribution costs.

Plastics

Plastics are very attractive packaging material due to their combination of properties. Plastics do not weigh very much, making them more attractive for distribution costs. Plastics also do not break easily like glass. Plastic packages can be made with convenient attributes for consumers such as resealability and flexibility. Flexible packaging is important for squeeze bottles such as the ones that ketchup and mustard use for packaging. Some plastics are opaque, which can help reduce the deterioration in some foods caused by light. The food industry has come to depend on plastics to package many products on the shelves. Product developers looking to pack a food in plastic should be familiar with the properties of the materials and the technical terms used to qualify these properties. In terms of potential uses, the important properties of plastic resins that should be checked or made available by the packaging supplier are:

- Oxygen permeability (cc/100 $in^2 \times$ day $\times$ atm)
- Water vapor permability (g/100 $in^2 \times$ day)
- Resistance to acids, alkalis, and solvents
- Yield/thickness (m^2/kg: 1 mil)
- Tensile strength (kpsi)
- Elongation at break (%)
- Tear strength (gm/mil)
- Light transmission (%)
- Heat seal temperature and service temperature

Polyethylene

Polyethylene (PET) is the most-used plastic for packaging. Densities range from 0.89 g/cc to 0.96 g/cc. PET is most commonly used due to its light weight; it is inexpensive, impact resistant, and relatively easily fabricated. It also has excellent water vapor and liquid containment properties, but is not a good gas barrier and is not transparent.

Polypropylene

Polypropylene is better as a barrier against water vapor than PET, as well as being more transparent and having more stiffness. This plastic is more difficult to fabricate than PET. Polypropylene is most commonly used for making pouches and candy wrappers. It is heat resistant up to 133ºC and can be used in a microwave oven.

Other Packaging Types

Aseptic Processing

Aseptic packaging has become a popular way to package soups, juices, and other liquid products. Aseptic processing produces a sterile product that is then filled into a sterile container in an enclosed and controlled environment. The processing temperatures for aseptic processing are usually very high—at ultra-high temperature process (UHT) or high temperature short time (HTST). Packaging materials and the product are sterilized separately. Aseptic processing reduces the effect of heat on the sensory properties of the product because of the short time it is exposed to elevated temperatures. Packaging is sterilized through heat, chemical treatments, or irradiation. Aseptic containers can be found in molded PET plastic or boxes made from paper/paperboard, PET, and a metalized foil.

Modified and Controlled Atmosphere Packaging

Modified atmosphere packaging (MAP) and controlled atmosphere packaging (CAP) change the atmosphere in which the food is exposed to during its shelf-life. In MAP, the atmosphere is modified only at the time of packaging. In products with MAP, the gases inside the package are flushed out and replaces with a mixture of carbon dioxide, oxygen, and nitrogen. Vacuum packaging is used to reduce the amount of air in a packaging, also extending sensory properties and shelf-life of products like coffee. CAP is mostly used for fresh produce. The storage atmosphere is controlled throughout transport by automatic releaser of certain compounds to keep the atmosphere at the controlled concentrations. The optimum concentrations of gases depend on the product being produced.

Active Packaging

Active packaging uses inserts in packages to help control the environmental composition inside the packaging material. Inserts include oxygen scavengers, ethylene scavengers, moisture regulators, and antimicrobial agents (Mauer and Ozen 2004). Oxygen scavengers absorb oxygen in packages to prevent product deterioration due to the oxidation of lipids. Ethylene, a chemical that accelerates the ripening of fruit, can also be absorbed through scavengers. Ethylene scavengers are usually made from potassium permanganate, which creates acetate and ethanol through the oxidation of ethylene (Mauer and Ozen 2004). Moisture regulators are used to reduce moisture in dry packages or packages of fresh products to reduce spoilage. Antimicrobial agents used in packaging materials that are released from the packaging over time. Antimicrobials used in this type of packaging application include sorbates, benzoates, ethanol, and bacteriocins (Mauer and Ozen 2004).

ISSUES AND CONCERNS

When launching a new food product, food scientists should be aware of all consumer trends and concerns with respect to packaging. These may include size of package, portability, ease of opening, color, environmental issues, migration of chemicals over time or due to microwaving, and recyclability.

Recyclable Materials

Some packaging materials such as glass and aluminum have already been established as highly recyclable, while plastic materials continue to make progress in that area. If recycled plastics are to be used to package a new food product, food scientists should check the "list of submissions for which FDA issued a favorable opinion on the suitability of a specific process for producing post-consumer recycled (PCR) plastic to be used in the manufacturing of food-contact articles." The list includes the date of a no objection letter (NOL) from the FDA, the company that made the request, the plastic material approved with the limitations on the conditions of use.

> **Case Study: Biodegradable Packaging Makes Noise**
>
> In an effort to cut down on waste in landfills, Frito Lay—the maker of SunChips—spent 3 years developing packaging that was biodegradable (Fournier and Avery 2011) The chip bags, though environmentally friendly, were very loud. The movement of the bag produced undesirable racket for the consumer; therefore the complaints rolled into the company. Because of these complaints, the company is back at the drawing board for biodegradable packaging and the product is back in less audible SunChip bags.

SUMMARY

Packaging is a very important factor in food processing that contributes to the shelf-life, quality, and appeal of products. Packaging materials can add or eliminate costs, demonstrate to consumers the quality standard of your product, and renew the product's image. Packaging, therefore, should be chosen with much contemplation.

COMPREHENSION QUESTIONS

11.1. What are three roles of packaging?

11.2. *Match the following foods to the packaging system used.*

a. Pringles		_____ Aseptic
b. Juice box		_____ Vacuum
c. Hot dogs		_____ MAP

11.3. Describe the packaging for your product in terms of primary, secondary, and tertiary packaging.

11.4. Why would one not want to describe a package as "just plastic"?

11.5. Define Controlled Atmosphere (CA) storage. What are common oxygen and carbon concentrations for both fruits and vegetables?

Safety Concerns for New Food Products

Learning Objectives

- How companies ensure safety in their new products.
- The most prominent pathogenic microorganisms.
- How to prevent food safety breeches.

FOOD safety concerns emerge everyday with the news that someone found metal or a mouse in a food product, a nationwide outbreak of foodborne illness is causing death, or the findings that high levels of arsenic are present in the apple juice or rice. Food safety issues that threaten a new food product include microbial contamination or physical contamination by means of extraneous matter, product tampering, pesticide residues, and natural toxicants.

MICROBIAL CONTAMINATION

Microorganisms are tiny living creatures, much too small to see with the naked eye. In recent years, a number of widely reported outbreaks of food-borne illnesses caused by microbial contamination have increased public awareness and concern about the safety of food. The CDC estimates that 1 in 6 Americans get sick as the result of a food-borne illness—this adds up to 48 million people just in the United States (Estimates of foodborne illness in the United States 2012).

Microorganisms are everywhere in nature and in human environments. They need food just as humans do, so they compete with us for our food sources. Food can supply nutrients that support the growth of microorganisms. Under the right conditions, some of those microorganisms can cause human illness; others can cause the food to spoil.

The Problem of Food-borne Illnesses

Food-borne illnesses generally cause temporary disorders of the digestive tract, however, they can also lead to more serious consequences. Precise costs of food-borne illnesses are unknown, but recent estimates range from $4.4 billion to more than $33 billion annually from the 14 most common illnesses, which account for 95% of illnesses and 98% of deaths from foodborne illness (Hoffman *et al.* 2012). Because of ineffective and under-resourced monitoring procedures and widely variable costs of illness, data on actual cases and outbreaks of food-borne illness are inaccurate and greatly under represent the actual incidence and cost of illness.

The majority of cases of food-borne illnesses are not reported because the initial symptoms of most food-borne illnesses are not severe enough to require medical attention, the medical facility or state does not report such cases, or the illness is not recognized as food-borne. It is estimated, however, that about 9.4 million episodes of food-borne illness occurs, about 55,961 people are hospitalized, and about 1,351 deaths occur each year by the 31 major pathogens in the United States (Scallan *et al.* 2011). Bacterial pathogens are the most commonly identified cause of food-borne illnesses. They are easily transmitted and can multiply rapidly in food, making them difficult to control.

The Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, has targeted four pathogens (*E. coli* 0157:H7, *Salmonella enteritidis*, *Listeria monocytogenes*, and *Campylobacter jejuni*) as those of greatest concern. The CDC also is concerned about other bacterial pathogens, such as *Vibrio vulnificus* and *Yersinia enterocolitica* that can cause serious illnesses, and *Clostridium perfringens* and *Staphylococcus aureus* that cause less serious illnesses but are very common.

Viral pathogens are often transmitted by infected food handlers or through contact with sewage. Hepatitis A and Norwalk viruses are proven to cause food-borne illnesses.

Public health officials believe that the risk of food-borne illnesses is increasing. Because of our large-scale food production and distribution system, products that may be contaminated can reach a greater number of people. In addition, new and more virulent strains of previously identified harmful bacteria have appeared in the past several decades. Some of these organisms are resistant to usual controls, such as refrigeration.

Employee turnover, the need for constant training and supervision, and other factors in the foodservice industry can increase the risk of foodborne illness. Mishandling or improper preparation at any step in the food system, including the home, can be the culprit for causing serious illness.

In general, animal foods such as beef, pork, poultry, seafood, milk, and eggs are more frequently identified as the source of outbreaks in the United States than non-animal foods. Increasingly, however, produce such as apples, lettuce, potatoes, onions, garlic, sprouts, berries, melons, and tomatoes have been associated with food-borne illnesses.

Not Just the Flu

Many food-borne illnesses are brief and cause flu-like symptoms: nausea, vomiting, and minor aches and pains. In a small percentage of cases, more serious illness and death can result. Food-borne infections can spread through the bloodstream to other organs. Complications also result when diarrhetic infections act as trigger mechanisms in certain individuals, causing an illness such as reactive arthritis to flare up. In other cases, no immediate symptoms appear, but serious consequences eventually develop. About 2–3% of all cases of food-borne illness lead to serious consequences.

Salmonella enteritidis can lead to reactive arthritis, serious infections, and deaths. In recent years, outbreaks have been caused by the consumption of many different foods of animal origin, including beef, poultry, eggs, milk and dairy products, pork, and peanut butter. The largest outbreak occurred in the Chicago area in 1985 and involved more than 16,000 laboratory-confirmed cases and an estimated 200,000 total cases. Some of these cases resulted in reactive arthritis. One institution that treated 565 patients from this outbreak confirmed that 13 patients developed reactive arthritis after consuming contaminated milk. In addition, 14 deaths may have been associated with the outbreak. More recent outbreaks include a peanut outbreak in late 2008 that involved

Case Study: Jack-in-the-Box Outbreak of 1994

An outbreak in 1993 at the Jack-in-the-Box fast food chain affected more than 700 people. Fifty-five patients, including four children who died, developed hemolytic uremic syndrome, which is characterized by kidney failure. The culprit in this incident was *E. coli* 0157:H7, most commonly transmitted to humans through eating undercooked ground beef. *E. coli* 0157:H7 can cause kidney failure in young children and infants.

529 illnesses, 116 hospitalizations, and possibly 8 deaths. The peanut butter was used by many national and multinational companies, resulting in many recalls. A huge *Salmonella enteritidis* outbreak occurred in late 2010 involving shell eggs. The outbreak resulted in approximately 1,939 illnesses from two producers of eggs in Iowa.

Listeria can cause meningitis and stillbirths and has a fatality rate of 20–40%. All foods may contain these organisms, particularly raw poultry and unpasteurized dairy products. The largest outbreak occurred in 1985 in Los Angeles, largely in pregnant women and their fetuses. More than 140 cases of illness were reported, including at least 13 cases of meningitis. At least 48 deaths, including 20 stillbirths or miscarriages, were attributed to the outbreak. Soft cheese produced in a contaminated factory environment was confirmed as the source. A more recent outbreak occurred in the summer of 2012 involving cantaloupe grown in Colorado that was responsible for 147 illnesses and 33 deaths.

Campylobacter may be the most common factor for Guillain-Barre syndrome, which is now one of the leading causes of paralysis from disease in the United States. *Campylobacter* infections occur in all age groups, with the greatest incidence in children under 1 year of age. Most cases occur individually, primarily from poultry, not during large outbreaks. About 4,250 cases of Guillain-Barre syndrome occur each year and about 425 to 1,275 cases are preceded by *Campylobacter* infections.

Growth and Prevention of Microorganisms

Microorganisms are everywhere. When fruits, vegetables, and other crops are harvested and when livestock are slaughtered or milk is taken from cows, microorganisms are present. Further contamination occurs as commodities move through the food system.

Microorganisms grow rapidly. A single microorganism can quickly grow into a large load—1 becomes 2, 2 become 4, 4 become 8, 8 becomes 16, and so on. This is called logarithmic growth. The time it takes a bacterial cell to reproduce is called the generation time.

If we start with the 20th generation containing 524,288 bacteria, it takes only one generation to reach 1,000,000 bacteria, which is a large enough population to cause spoilage to begin in food products. If the equipment, personnel, and product are clean, the initial numbers of bacteria will be lower and we may begin with the 15th generation of 16,384. In this instance, the shelf-life will be five times longer than before.

There are four distinct phases that occur in the growth curve: lag, log or growth phase, stationary or resting phase, and death phase. Bacteria need about 4 hours to adapt to a new environment before they begin rapid growth. In handling food, this means we have less than 4 hours to make a decision to cool the food, heat it, or eat it. For example, when chickens arrive at the dock of a fast food outlet, at a restaurant, or at your home, you must decide whether to heat and eat them, to refrigerate them at a low temperature (chickens freeze at 28°F) for a short period of time, or to wrap and freeze the chicken for longer storage. If you don't decide, the bacteria will enter the log phase of growth, multiplying rapidly, causing food to spoil or creating an opportunity for food-borne illnesses.

Spoilage bacteria produce the slime, toxins, off-colors, and odors associated with food spoilage in the log phase of growth. Pathogenic bacteria can grow and produce large numbers of toxic compounds, and these are usually not detected by off odors, flavors, etc. Remember, the 4 hours bacteria remain in the log phase is approximate and cumulative.

As microorganisms grow, they tend to form colonies of millions of individual cells. Once a colony forms, the food available to each cell is limited and excretions from these millions of cells become toxic to a microbe. This is the stationary phase. Some of the cells now begin to die. If we can control bacterial growth, we can control the major cause of food spoilage and food-borne illness.

Keeping initial bacteria levels low is important. A food product that starts with 100 microorganisms per gram may have a shelf-life of 12 days before it develops off odors, slime, and spoilage. When the initial number is 5,000 per gram, the shelf-life of that same foodstuff may be shortened to 7 days. Because so much depends on the initial number of bacteria, temperatures, and handling practices, a specific shelf-life for a category of food products is difficult to determine.

Good personal hygiene, sanitizing equipment, controlling temperature, and using chlorinated water where possible are all practices that help keep initial numbers low. Different microorganisms require different combinations of the factors listed in Table 18.1.

Nutrients

Like all living things, bacteria require food to live, but they need only very small quantities. Some protein or fat left on the wall of a

TABLE 18.1. Requirements for the Support of Microorganisms.

Requirements for Microorganism Growth (FAT TOM)	
F	Food to meet growth requirements
A	Acid conditions to support growth. Acidity level favors certain organisms over others
T	Time at conditions to allow growth
T	Temperatures that support growth
O	Oxygen (or no oxygen) depending on organism
M	Moisture

processing plant, grease on the blade of a knife, or food residues on the wheel of a can opener or on a cutting board are a feast for microorganisms as well as for larger pests.

Acidic/Basic Conditions

Every microorganism has an optimal pH (acid) concentration for growth. Yeasts and molds favor more acidic conditions than bacteria.

Time

Some organisms grow faster than others. Under ideal conditions, certain bacterial populations can double in as short as 9 minutes; others require hours. Bacteria that reproduce most quickly will dominate.

Temperature

Temperature is probably the single most important factor in preventing microbial food spoilage. Generally speaking, the cooler the food is kept, the longer shelf-life it will have. A thermometer in the refrigerator is a necessity. Maintain the temperature at 35–40°F. Remember, however, that some foods, such as tomatoes and lettuce, will freeze or be damaged at 32–33°F.

Different bacteria require different temperatures for maximum growth. Some bacteria will grow at refrigerated temperatures. Others will only grow at moderate temperatures. Warm-loving bacteria grow at temperatures above 140°F. At temperatures above and below the optimum, they grow and reproduce at a slower rate. Food spoilage bacteria grow best at environmental temperatures of 70–100°F. A good "rule of thumb" is to double the shelf-life of a food that needs refrigeration, lower the temperature 18°F. That is, for every 18°F decrease in storage temperature, food will last twice as long.

Oxygen Use

Microorganisms are considered aerobic if they can use oxygen, anaerobic if they grow best without oxygen, and facultative if they can grow well with or without oxygen.

Moisture

All living things require moisture, and bacteria are no exception. Perishable foods requiring refrigeration usually have very high moisture contents. Moist food left over for long periods of time provides adequate moisture for bacterial growth. Bacteria need water because their only means of obtaining food is by absorption similar to that of a sponge. This process cannot be accomplished without moisture, which explains why foods such as dried milk, dried soups, and cereals do not spoil microbiologically. The organisms are there, but they can't eat.

Companies should perform challenge studies when producing processing parameters and periodically throughout the life of a product. Challenge studies are studies where the product is inoculated with a bacteria prior to processing, then allowed to go through the processing procedure in order to determine the success that the processing technique has on eliminating the bacteria. The bacteria chosen for the study should be similar to those that would be expected to thrive in the product.

BACTERIAL CAUSES OF FOOD-BORNE ILLNESS

Bacillus cereus

The disease: Two distinct syndromes may occur. In one, the toxin produced results in diarrhea, and in the other, the toxin causes vomiting. Generally, the diarrheal toxin is associated with consumption of puddings, starchy sauces, or vegetables such as mashed potatoes. The emetic syndrome is most frequently associated with cooked rice.

The organism: *Bacillus cereus* forms heat-resistant spores so it can survive the initial cooking of starch-based products. The spore can then

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About the Authors and Managing Editor

DR. FADI ARAMOUNI was born and raised in Beirut, Lebanon. He received his BS in Biochemistry in 1977 and his MS in Food Technology in 1980 from the American University of Beirut. Dr. Aramouni earned his PhD in Food Science in 1986 from Louisiana State University. He joined Kansas State University in 1989 where is currently a professor of food science. His responsibilities have been primarily to develop and maintain a value added extension program supporting the food processing industries in Kansas. In that role, he has helped Kansas companies develop test and launch hundred of food products. He has taught courses in Research and Development of Food Products, Principles of HACCP, Advanced HACCP Principles, and Fundamentals of Food Processing. His honors from the College of Agriculture include the Graduate Teaching Award, Builder Award, Faculty Member of the Semester.

KATHRYN GODDARD DESCHENES is from Ellsworth, Kansas. She received her BS in Food Science in 2011 and received her MS in Food Science in 2012 from Kansas State University. She has won several national awards in Food Product Development competitions, including first prize in the 2008 Almonds Board of California "Game Day Snacks for Men" and the grand prize at Disney's Healthy Snack for Children in 2009. Kathryn has managed activities at the Kansas Value Added Foods Lab from 2009 to 2013 as well as provided technical assistance to food companies in product development, ingredients and packaging, regulatory compliance, and packaging technologies. Kathryn also did an internship at Kellogg's in Battle Creek, Michigan. Kathryn is currently a regulatory compliance manager for a major food company in Idaho where she resides with her husband, Joshua.

Katie Altstadt has a BA in Fiction Writing from Columbia College Chicago. She has edited and published an online newsletter, the Scoop, targeting food processors in the state of Kansas.