CHAPTER 12

PRODUCING RESEARCH DIETS

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FOOD PROCUREMENT AND STORAGE

Procuring food is a fundamental aspect of producing research diets—one that is more complex and challenging than it might appear. A major priority in food procurement is to ensure constancy of the nutrients of interest throughout the course of the study. It is common to purchase food items from single lots, in quantities sufficient for the entire study. In some tightly controlled studies this includes all food items except those that are highly perishable (eg, milk or fresh fruit). In studies requiring less control, fewer food items—perhaps only test foods—are purchased and used with this degree of control.

If a study is designed to feed all participants collectively (eg, 20 participants studied on an outpatient basis for 4 weeks), then a facility's ability to provide constancy of food items is typically limited by storage space. If the study is to be carried out in an intermittent or extended fashion (eg, 1 or 2 participants per month) constancy in food procurement is also limited by storage space, but it is further compounded by the need to guarantee food freshness and nutrient stability over time. Shelf-life, storage space, and freshness are critical considerations for most studies.

Purchasing According to Needs and Storage Capacity

Raw and Cooked Weight

When considering the quantity of food to be purchased, study designers must first be aware of whether the calculations for the nutrients of interest are based on the raw or cooked weight of the food items. When participants are studied individually, food may be prepared on a participant-by-participant basis. In this case, calculations may be based on raw weights, which simplifies the determination of quantity of food to be purchased. In larger facilities in which numerous participants are studied concurrently, however, foods may be cooked as a unit for multiple participants and then portioned prior to service. In addition, mixed dishes such as meat loaves, casseroles, soups, and sauces may be used if recipes are analyzed and scaled for the appropriate number of servings. If the cooked weight is known, then the appropriate calculations can be made to convert to raw weight after considering losses or gains during preparation and cooking.

Purchasing Sufficient Amounts of Food

In procuring food for research studies, it is prudent to err on the side of overpurchasing; running out of a food item can

American Dietetic Association

Source: "Well-Controlled Diet Studies in Humans, A Practical Guide to Design and Management", American Dietetic Association, © 1999.

be a crisis for a well-controlled feeding study. Dietitians typically make a ''best estimate'' of the amount of each food item needed for a study and then ensure adequate quantities by adding a ''safety'' (or caution) factor. The best estimate is based on edible portions of foods as purchased; for example, an 8-oz (227-g) can of green beans may only contain 180 g edible weight of green beans. Lean cuts of beef may be further trimmed in the research kitchen to yield smaller portions.

The safety factor must be adequate to cover any differences between estimated and actual food requirements; safety factors are not a substitute for making best estimates that are as accurate as possible. Typically, estimated food requirements are increased by 25% to guarantee that sufficient quantities are purchased. This safety factor should account for the number of diets to be used for composites, food spoilage, food that might be unexpectedly wasted during preparation, and food that might be wasted because of meal delays. The size of this safety factor may vary depending on the particular food item. For example, a smaller safety factor would be needed for dry goods such as pasta, rice, and beans, which generally have a long shelf-life, and a longer safety factor would be needed for poultry.

The safety factor may also vary with the number of participants to be fed. In this situation, the principle of *economy of scale* must be considered: when planning for 10 participants, a safety factor of 25% may be sufficient, but when planning for 1 or 2 participants, a safety factor of 50% may be necessary. For example, a 25% safety factor applied to the amount of food consumed by 30 participants would easily provide sufficient food for triplicate composites of foods from each of two dietary treatments, whereas a 50% safety factor applied to the food consumed by 1 participant may be necessary if triplicate composites are to be made.

Storage Capacity and Shelf-Life

The capacity of the storage facility is of vital importance in considering the amount of food that can be purchased at one time. The purchasing agent must also consider the form in which these items are to be stored; eg, does the food need refrigeration or freezing; will it be kept in cans or as dry bulk items? Other considerations are these:

- Most meats will be portioned prior to freezer storage, whereas canned items typically do not need to be portioned until just prior to serving.
- Items such as breads and meats will require adequate freezer space.
- Canned items may be easiest to store because they require the least accommodation.
- Dry goods such as cookies, cereals, sugar, dry milk powder, rice, and pasta will need space that is reliably cool, dry, well-ventilated, and protected against insect invasion.
- Food items that come individually packaged in portion-controlled servings may stay fresher for a longer period than those packaged in family-sized or institutional portions. However, items that come in portion-controlled servings may require reweighing prior to serving.

If storage capacity for all items is limited, then this factor may constrain the number of participants that can be studied at any one time. To minimize intraparticipant variability, it is essential that each participant eat exactly the same food over the course of his or her individual study. Although it is desirable for all participants in a research study to eat exactly the same food from a common lot regardless of when they are studied, this may not always be possible. Every effort, therefore, should be made to purchase the same brands of dairy products and staples and the same cuts of meat. If differing food lots are used for different participants throughout the course of a study, variance in nutrient intake among participants can be detected by assaying diet composites that have been collected over time.

The shelf-life of each food also must be considered when staff decide how much to purchase. Table 12-1 provides maximum storage times for foods typically stocked for research diets. In addition, many food items will have the ''out-date'' or last usable date stamped on the container, which provides additional information about expected storage times.

Dry goods and canned foods are subject to deterioration through the process of nonenzymatic browning. Nonenzymatic browning causes the formation of dark-colored pigments in foods as diverse as dry milk powder, canned fruit, fruit juice, corn syrup, and dehydrated meat. The Maillard condensation reaction between simple sugars and amino acids, reactions involving ascorbic acid, and caramelization reactions are examples of nonenzymatic browning. As a rule, browning is considered a distinct sign of deterioration in food and is an important factor limiting its shelf-life (1).

Maintaining Records of Food Sources

Detailed information about individual foods, including the manufacturer, exact food item, and lot number, should be included in participants' food records. Many food manufacturers can provide ''cut sheets'' detailing the nutrient composition of their food items. Cut sheets can be valuable sources of nutrient information, as well as excellent records of the exact food used. Even if nutrient composition is available from the manufacturer, however, it is usually recommended that essential items be chemically assayed for the main nutrients of interest. This information should then be a part of the permanent records of the research kitchen and added to the computer database.

Using the same food distributor over time can also help ensure consistency, especially for fresh meats, poultry, eggs, dairy products, vegetables, and fruits. The same distributor is more likely to be able to provide the same cultivar of broccoli from one study to the next, because it is possible to identify the grower from whom the broccoli was purchased in the past. In many institutional settings, however, pur-

TABLE 12-1

Recommended Storage Times

Food	Maximum Storage Time[1]
Canned Products	**12 months**
Dried Foods	
Cereals	6–9 months
Chips, cookies, crackers	12 months
Pasta, rice, beans	12 months
Powdered milk	3 months
Frozen Foods	
Bread	1–2 months
Butter, margarine	3–6 months
Fruits, vegetables	12 months
Beef, poultry	6–9 months
Ground meat, fish	1–3 months
Pork	3–6 months

Source: Adapted from West BB & Wood L. *Foodservice in Institutions.* 6th ed. New York: Macmillan; 1988.
[1]Storage times are based on foods stored in their original containers. If highly perishable products such as ground meat and fish are portioned prior to freezing, storage times should be decreased by half.

chasing from the same distributor is not always possible because of policies stipulating that food contracts be awarded to the lowest bidder. In that case, it may be helpful to meet with purchasing department personnel and storehouse managers to explain the unique needs of the research kitchen. Formal waivers from purchasing policies may be required.

Control of Food Variability Over Time

Although purchasing from single lots is common for research facilities, it is rare in general foodservice, so vendors may not appreciate the importance of providing foods from single lots. For single-lot purchases, it is imperative to clearly communicate to the vendor that a single-lot purchase is required. Upon delivery, single-lot purchases must be verified by checking each carton, package, and can. Lot numbers are imprinted on individual cans and packages and also indicated on the outside of the carton. Although it is best to purchase sufficient food of a single lot for an entire study, this may not be possible if storage space is limited. As a result, food items for all participants in an entire study may not be from the same lot. However, as mentioned earlier, it is essential that all the food of each type eaten by a given participant come from a single lot.

It is necessary to establish and maintain written specifications for each food item used in the research kitchen. Adherence to these written standards from one participant to the next will minimize variability among participants' diets. Written specifications for beef, for example, should indicate the grade, cut, percent fat, or trim standards. Specifications for chicken should indicate class, grade, cut, and weight. It is advisable to purchase chicken parts that are boneless and skinless to minimize processing in the research kitchen. Specifications for vegetables and fruits should indicate product, supplier or manufacturer, style, and can size. Specifications for packaged dry goods should indicate product, manufacturer, and weight as purchased.

Use of a single-source supplier is also desirable. For example, it is preferable to purchase ground beef from the same breed of animal raised by the same rancher. However, given today's US food distribution system, this is seldom possible; and, for many studies, it may also be unnecessary. If protein is the nutrient of interest, for example, ensuring that the cut, percent fat, and nitrogen analysis of the meat is the same from participant to participant (and verifying this by periodic composite assay) may be sufficient. If selenium is the nutrient of interest, however, the meat must come from animals raised by one rancher because the amount of selenium in beef is a reflection of the forage that the animals eat (2).

Seasonal food items can add variety and freshness to a repetitive meal plan. There may be considerable variability in the micronutrient composition of fresh foods (eg, the amount of vitamin C in fresh broccoli may vary with cultivar, soil conditions, time of harvest, transport time to distribution center, and amount of time prior to sale) (3). Thus, it is imperative in many studies that seasonal food items be purchased in quantities sufficient to last for an entire study. But food quality and nutrient stability may be of concern if too great a quantity of fresh food is purchased and expected to last over a long period of time. A useful example is that of broccoli used in a study of antioxidant vitamins: the amount of vitamin C in the broccoli would be expected to decrease as a function of storage time after purchase (3).

Procurement of sufficient broccoli for use during 1 week of a study may be acceptable, whereas purchasing sufficient fresh broccoli for use over 3 weeks would not be. As a result, weekly purchases would necessitate chemical assay of the vitamin C levels in each batch of broccoli and adjustment of quantities served on the basis of the analyzed values. If this process is too cumbersome, the investigator may find that a better alternative is to use a canned or frozen product that can be purchased in a single lot.

Fresh potatoes may be used for short-term, constant or metabolic diets if the potatoes are purchased in 50-lb or larger bags. The reason for this is that when potatoes are pulled from the ground, all the potatoes in a specific area of the field go into one 50- or 100-lb bag. Therefore, the composition of the potatoes from that bag should be comparable. However, sufficient storage space is vital if fresh, rather than instant, potatoes are used. For long studies, compositional changes that occur with storage must be considered.

Preparation Techniques for Conventional Food Diets

Whether conventional food or liquid formula diets are used, it is important to develop a procedure manual detailing food preparation techniques and recipes. The procedures are essential documents that represent the standards of operation of the research kitchen. Special procedures may be designed for individual studies, if necessary.

Weighing and Measuring

All research kitchens should have electronic analytical balances that are accurate to at least 0.1 g. If small amounts of substances such as vitamins and mineral supplements, stable isotopes, spices, herbs, and other similar items are to be weighed, then the balance must be accurate to 0.01 g. These balances must undergo weekly calibration checks, periodic inspection, and maintenance to confirm their accuracy. Typically, every food item should be weighed as accurately as possible prior to service, including liquids. Exceptions in some macronutrient studies may include foods such as broth, lettuce, celery, onion, and carrot sticks. Table 12-2 lists the weights of common serving sizes of various foods.

It is generally preferable to weigh rather than measure most food items because there may be considerable variability in the weight of fluid volumes. However, when micronutrient intakes are not of prime concern (eg, in a study comparing different dietary fats), a decision may be made to measure fluids in graduated cylinders. A graduated cylinder must first be placed on a level platform so that the graduations are at eye level. The bottom of the meniscus (the lowest point of the fluid level) is the point that should be read. Sometimes a small piece of white paper placed behind the cylinder can aid in detecting the meniscus.

Portion-controlled foods should not be considered accurately weighed unless frequent spot checks reveal that, in fact, a precise quantity is consistently delivered. The reported weight of portion-controlled foods—especially dry goods such as crackers and cookies, and condiments such as salt and pepper—is generally not sufficiently accurate for most research diet studies. For example, cereal boxes claiming to contain 21 g have been found to contain as much as 28 g of cereal; 4 cookies allegedly weighing 28 g weighed only 22 g; pepper packets weighed from 2 g to 4 g each. The degree of accuracy necessary for food weights will depend on the nutrient under consideration. For example, portion-controlled boxes containing $\pm$ 5 g of a fat-free, fortified breakfast cereal may be acceptable for a study controlling lipid intake, but this degree of accuracy would not be sufficient for a study of iron balance.

The water and fat content of foods can change during cooking, as can the content of some other nutrients. (Also see Chapter 11, "Designing Research Diets.") Thus, the kitchen staff must be careful to portion foods for participants in the same form (ie, raw or cooked) used to calculate the diets. For example, if the raw food was used to calculate nutrient content of a chicken breast, then this item must be portioned prior to food preparation.

Cooking Techniques

A major goal in food preparation for controlled feeding studies is to minimize variability among individual servings. Microwave cooking and oven roasting or baking in closed containers are methods that yield minimal losses and greatest reproducibility.

In large-scale studies, in which diets are planned for multiple participants at stepwise calorie levels, food may be purchased fresh or frozen, prepared, and then weighed out according to desired calorie level. In this setting, care must be taken to minimize losses during cooking and to ensure accuracy during portioning. Standardizing cooking times and temperatures will help to control batch-to-batch variability.

In small-scale studies, diets may be individually planned for each participant, with control exercised for calories as well as macro- and micronutrients. Food is often weighed first, frozen, thawed, and then prepared. Many facilities seek to avoid transferring food from one container to another after it has been weighed, and from the cooking vessel to the serving plate after the food has been cooked. A variety of dishes and containers, available from restaurant wholesalers, are suitable for food storage as well as cooking and serving. Many glass and ceramic products, for example, are freezer-, oven-, and microwave-safe. In addition, these containers make an attractive place setting.

Meat, Poultry, and Fish

Ground beef of a specified cut and percent fat content is a simple product to weigh in advance and store in a freezer.

TABLE 12-2

Approximate Weights of Common Serving Sizes of Various Foods[1]

Food	Serving Size	Weight[2]
Meat		
Chicken, breast, raw, ½ breast	1 piece	118 g
Chicken, breast, roasted, ½ breast	1 piece	86 g
Chicken, thigh, raw	1 piece	69 g
Chicken, thigh, roasted	1 piece	52 g
Chicken, drumstick, raw	1 piece	62 g
Chicken, drumstick, roasted	1 piece	52 g
Beef, chuck, pot-roasted, lean	1 slice	85 g
Beef, round steak, lean	1 slice	85 g
Beef, ground, 17% fat	1 patty	113 g
Frankfurter, beef and pork	1 link	57 g
Fruit		
Apple, raw with peel, 2.75″ diameter	1 whole	138 g
Apple, raw with peel, 3.25″ diameter	1 whole	212 g
Applesauce	½ cup	122 g
Pear, raw, Bartlett, medium	1 whole	166 g
Pear, raw, Bosc, small	1 whole	139 g
Pear, canned	1 half	79 g
Orange, California navel, peeled	1 whole	140 g
Orange, Valencia, peeled	1 whole	121 g
Peach, canned	1 half	98 g
Pineapple, canned	1 slice	47 g
Vegetables		
Green beans, canned	½ cup	68 g
Peas, canned	½ cup	85 g
Corn, canned	½ cup	82 g
Carrots, canned	½ cup	73 g
Spinach, canned	½ cup	107 g
Potatoes, mashed	½ cup	105 g
Potato, with skin, baked	1 whole	156 g
Potato, peeled, boiled	1 whole	135 g
Rice and Pasta		
Rice, white, cooked	½ cup	103 g
Rice, brown, cooked	½ cup	98 g
Rice, white or brown, uncooked	½ cup	93 g
Spaghetti, cooked firm	½ cup	70 g
Spaghetti, cooked tender	½ cup	70 g
Baked Goods		
Bread, white or whole wheat	1 slice	28 g
Saltine crackers	4 crackers	12 g
Hamburger bun	1 whole	43 g
Hot dog bun	1 whole	43 g
English muffin	1 whole	57 g
Bagel, 3.5″ diameter	1 whole	71 g
Blueberry muffin	1 whole	57 g
Cookies, chocolate chip	4 cookies	40 g
Cookies, sandwich type	4 cookies	40 g
Pound cake	1 slice, ½″ thick	28 g

continued

TABLE 12-2

Continued

Food	Serving Size	Weight[2]
Beverages		
Milk, whole	1 cup	244 g
Milk, skim	1 cup	245 g
Apple juice	1 cup	248 g
Orange juice	1 cup	249 g
Cranberry juice cocktail	1 cup	253 g
Spreads and Condiments		
Butter and margarine	1 tsp	5 g
	1 pat	5 g
	1 tbsp	14 g
Jam and preserves	1 packet	14 g
Peanut butter	1 tbsp	16 g
Sugar, white	1 packet	6 g
Coffee, instant dry powder	1½ tsp	2 g

[1]Adapted from *USDA Nutrient Database for Standard Reference Release 12,* Agricultural Research Service, Beltsville, Md (1998).
[2]Weights given are typical but approximate. For greatest accuracy, each item should be weighed prior to use.

Typical serving sizes range from 50 g to 120 g (Table 12-2). When meat is thawed prior to service, care should be taken to transfer all juices from the wrapper to the cooking dish. If the meat is to be grilled or fried, a portion of the participant's allotted butter for the day can be used to grease the grill or frying pan. Care should be taken that the fat does not splatter by cooking with low heat and/or covering the meat pan with a lid.

After the meat has been cooked to the desired doneness and removed to the dinner plate, a spatula should be used to remove all meat particles from the cooking surface. A small amount of deionized water—eg, 5 mL to 10 mL applied three times—can be used with a spatula to clean the cooking surface. This water (now ''gravy'') should then be poured over the meat. Meat cuts requiring individual preparation are seldom used in large-scale studies; instead, meats that can be cooked as one unit then portioned (eg, roasts and meat loaf) or that lend themselves to casserole preparations are typically preferred.

Chicken breasts from specific classes and grades (eg, fryers or roasters) should be purchased skinless and boneless to minimize waste and preparation time. The dietary staff should then trim all visible fat from, rinse, and dry the meat prior to weighing. Typical serving sizes range from 50 g to 120 g (Table 12-2). Chicken breasts can be prepared in the same manner as beef patties, using the same precautions. Condiments or sauces are often applied to the meat during the latter stage of cooking. If needed, chicken with sauce can be warmed in a microwave oven just prior to serving.

Fish fillets can be purchased flash-frozen in specified weights. These should be weighed into individual portions after thawing. They can be cooked directly in the microwave oven on the serving plate or grilled or fried following the same steps as for meats described earlier. Liquids remaining in the serving dish after the fish has been cooked should be consumed by the participant. Canned fish such as tuna should be drained in a colander for a specified time prior to weighing. Tuna packed in water without added salt should be used if sodium is the nutrient under investigation.

Vegetables and Fruits

Canned and frozen fruits and vegetables offer the most consistency in nutrient composition. They can be purchased in single lots in quantities sufficient for an entire study. For the best consistency, canned fruits should be packed in their own juices with no added sugar; vegetables should be canned in water with no added salt or sugar. Canned fruits and vegetables should be drained for a specified length of time and blotted dry prior to weighing. To preserve palatability, it is recommended that portioning of canned fruits and vegetables should take place no more than 1 day prior to serving. Typical serving sizes range from 60 g to 220 g (Table 12-2). Fruits should be weighed into serving dishes. Vegetables should be weighed into containers that can be used for microwave cooking and subsequent serving. Butter or margarine from the participant's allotment can be melted on the vegetables during microwave cooking. Salt or spices, if used, should be added by dietary personnel or the participant and thoroughly mixed into the vegetables prior to consumption.

Frozen fruits and vegetables are a good alternative to canned products because they too can be purchased in single lots to ensure nutrient consistency. However, frozen foods must be thawed and drained in a consistent manner prior to weighing in order to ensure an accurate weight. When sodium is the nutrient under investigation, frozen vegetables may contribute more than an acceptable level of sodium to the diet. In addition, there may be variability in the amount of sodium present, for example, in a given spear of frozen broccoli, depending on the number of cut surfaces exposed on that spear.

Fresh fruits and vegetables are acceptable for use in studies investigating macro- but not micronutrients. Micronutrient variability can be considerable in fresh fruits and vegetables, and it may be preferable to use canned or frozen products unless the investigator is willing to assay aliquots of each purchased batch of food prior to use. If fresh fruits and vegetables are used, the most accurate form of delivery entails weighing them in their trimmed, cored, and/or peeled state just prior to serving. However, for some studies it is sufficient to weigh fruits with peels or cores after applying a refuse factor (Table 12-3). If researchers are using potatoes and basing nutrient intake on the peeled weight, potatoes should be peeled prior to weighing and cooked in the microwave or boiled prior to serving.

Some participants object to the taste of reducing compounds such as ascorbic acid or lemon juice used to prevent oxidation of cut apples. Unlike most varieties of apples, which turn brown when cut, Cortland apples do not oxidize. This cultivar is grown in the northeastern United States and may be regionally limited in distribution. Cortland apples can be used fresh but also have good baking properties. The Golden Delicious variety does oxidize but much more slowly than most varieties. Golden Delicious apples are sweeter than Cortland apples and are available nationally.

Baked Goods

Baked goods are typically purchased in single lots and kept in frozen storage until needed. Desired quantities should be thawed and weighed prior to serving. For most research diet studies, bread may be toasted without significantly altering the nutrient composition of the food. However, losses may occur if the bread is crumbly and falls apart during toasting.

Dry Goods

Dry goods such as rice, pasta, instant potatoes, cereal, cookies, and snack food items should be purchased in single lots. Rice and pasta should be cooked in deionized water if minerals are under consideration in the study. Individual portions of preweighed dry material may be cooked in individual serving dishes. However, larger quantities may be cooked and portioned after cooking if care is taken to guarantee that the same recipe is always used (eg, 400 g dry macaroni to 12 L deionized water, cooked at a rolling boil for 10 minutes; weigh entire cooked product and divide by 8; weigh out 8 equal servings, each equivalent to 50 g dry macaroni). Mashed potatoes made from instant potatoes, deionized water, milk, and margarine should be weighed and mixed in the serving dish according to a predetermined recipe. Dry cereal should be weighed into the serving bowl. Cooked cereal should be weighed, dry mixed with deionized water, and cooked in the microwave oven in the serving bowl. Cookies and snack food items should be weighed prior to serving even if they are purchased in portion-controlled packages. Table 12-2 shows typical serving sizes for commonly used dry goods.

TABLE 12-3

Refuse Values for Selected Raw Fruits[1]

Fruit	Inedible Material	Percent[2]
Apples, with skin	Core and stem	8
Bananas	Skin	35
Blueberries	Stems and spoiled berries	2
Cherries, sour, red	Pits and stems	10
Grapes, American style	Total refuse	42
(slip skin)	Seeds	6
	Skin	34
	Stems	2
Grapes, European style		
(adherent skin)	Stems	4
Oranges, California		
Navels	Peel and navel	32
Valencias	Peel and seeds	25
Oranges, Florida	Peel and seeds	26
Pears, with skin	Core and stem	8
Plums, with skin	Pits	6
Strawberries	Caps and stems	6
Tangerines	Peel and seeds	28

[1]Adapted from *USDA Nutrient Database for Standard Reference Release 12,* Agricultural Research Service, Beltsville, Md (1998).
[2]Percent of total weight of the fruit, as purchased.

Condiments and Spices

Condiments and spreads such as butter, margarine, peanut butter, jams, jellies, mayonnaise, mustard, catsup, and salad dressings should be purchased in single lots and weighed prior to serving. Portion-controlled items should be reweighed to maintain accuracy. There are a number of nutrient-controlled condiments on the market, and because these items can add variety and palatability to a research menu, the nutrition coordinator is encouraged to investigate their availability.

Salt, sugar, and spices are also an important part of an appetizing diet. These items, each purchased from a single lot, can be used by the dietary staff and the participants to enhance the flavor of the diet. In most cases, one or more condiments can be preweighed for an entire day's service. Care should be taken that the condiment is not lost in transfer from the portion container to the food. In addition, investigators should be aware that spices and sauces can be hidden sources of nutrients. Paprika contains carotenoids; Worcestershire sauce, which contains anchovies, provides small amounts of omega-3 fatty acids.

Beverages

Deionized water should be used in research diet studies if essential minerals are under investigation. For these tightly controlled studies, instant coffee and tea are reconstituted with a measured amount of boiled, deionized water. Brewed coffee is made in an electric coffeemaker using a weighed amount of coffee and deionized water. After the coffee is brewed for a timed period, individually weighed portions are served. Beverages such as canned soda may be used if purchased from the same lot. Portion-controlled milk, cream, and juices may be used, but many studies require that they be remeasured prior to being served. (See Chapter 15, ''Meeting Requirements for Fluids.'')

Mixed Dishes

Mixed dishes can provide much-needed variety during long menu cycles. However, unless the dish is prepared in-house, it is more difficult to minimize nutrient variability in mixed dishes. Some commercially prepared products such as frozen waffles, French toast, and pancakes may be acceptable breakfast alternatives if purchased in single lots for an entire study. For other mixed dishes, such as stews, casseroles, or soups, it may difficult to guarantee nutrient accuracy if the entire portion is not served. Homogeneous mixtures such as spaghetti sauce can often be used if the accompanying pasta and meat are weighed separately. Macaroni and cheese, chicken à la king, chicken salad, and similar dishes can also be prepared in ''steps'' with each ingredient weighed separately. However, this stepwise process will require additional time and staffing devoted to preparation.

An alternative to either conventional solid food diets or formula diets is the frozen diet (4). The frozen diet comprises standard meals that are created at defined calorie levels and then flash-frozen. These ''TV-dinner'' frozen meals can simplify food delivery, especially for short-term and outpatient studies. Special serving dishes such as partitioned aluminum foil or plastic containers that are microwave-safe should be used.

Although the planning and preparation needed to create these frozen diets is considerable, frozen meals may reduce the need for inpatient admissions. In addition to the preparation, however, careful instructions and participant monitoring in the outpatient setting are essential for a successful study.

TRACKING THE PRODUCTION PROCESS

Food Labels

When portioning the product for serving, the foodservice worker weighs the gram amounts indicated on the production sheet (see Chapter 13, ''Delivering Research Diets,'' and Chapter 18, ''Documentation, Record Keeping, and Recipes'') for each participant at his or her designated calorie level. As the food is portioned and wrapped, a label bearing the code number for that food item is applied to each serving. If the study is masked, the label (Figure 12-1) on a participant's serving of food will show the generic description and code (ie, spice cake, 420) rather than a full description (spice cake with moderate *trans* margarine). The participant's calorie level (2,800), masked dietary treatment (blue), and menu number are also displayed.

Visually striking, clearly worded labels become particularly important when a facility is engaged in multiple concurrent protocols. (Also see Chapter 20, ''Staffing Needs for Research Diet Studies.'')

Individual food labels can be computer generated—a great savings of time compared with making labels by hand—and color coded as appropriate. Alternatively, foods can be labeled with bar codes. This facilitates blinding participants to their assigned diets. Data encoded in the bar code is matched to information contained on the menu in the database. Thus, any error in treatment or calorie level and any missing or duplicated food item will be promptly spotted when the bar codes on a participant's tray are scanned. Bar codes can be generated directly from a database; for example, a database of daily menu items containing gram amounts served at each calorie level. Selected data file fields are incorporated into a label-generating facility of the preferred database software, then printed onto adhesive labels. Office supply stores carry labels in a variety of sizes and colors that are suitable for computer printing on tractor feed or laser printers. (See Chapter 3, ''Computer Applications in Controlled Diet Studies.'')

Food Codes

Foods are frequently identified by code number as well as description. These codes usually are food database numbers or other codes assigned by the research kitchen staff. (Also

SPICE CAKE 420 Menu 12
2.800 kcal Friday
Blue Dinner
50 grams

FIGURE 12-1. Label on food item served to a participant eating 2,800-kcal diet in a masked study.

see Chapter 13, ''Delivering Research Diets.'') Code numbers can serve as a convenient shortcut for the staff, lightening the work of writing or printing labels. The codes also can be an important part of the protocol, however, by preserving the masking of foods in a blinded study. For example, in a masked study comparing three test fats, the kitchen might prepare various baked goods as carriers of the test fats. The test margarines (no *trans* [ZERO], moderate *trans* [MOD], and high *trans* [HIGH] margarines) might be assigned the codes 10, 20, and 30, respectively. Spice cake, one of the vehicles for delivering these test fats, would be prepared with each type of margarine. Spice cake would be assigned the general code of 400, and the spice cakes made with the three test fats would be coded 410, 420, and 430, respectively. In the kitchen, both the code and full description (eg, 420, MOD spice cake) would be associated with the product.

During production and storage, foods are tagged with both codes and full descriptions. For example, a baker preparing spice cakes adds moderate *trans* margarine to the mixer, tags the mixer with the test fat code (ie, 20), and labels the baking pan with the appropriate code number and the full description of the product (ie, 420, spice cake w/MOD *trans* margarine). This prevents a possible mixup among cakes at the point of production. The code and description stay with the product as it is baked and during frozen storage. At temperatures normally used for baking and freezing foods, masking tape labels are stable and adhere well to aluminum baking pans. (The staff must take care to ensure that these production codes and labels are not seen by study participants.)

Chain of Custody

Proper use of production forms (see Chapter 18, ''Documentation, Record Keeping, and Recipes''), codes, and labels will establish an effective ''chain of custody'' for all foods produced in the research kitchen. The chain of custody concept also is highly applicable to test materials used for research menus. This involves ''logging in'' test foods as they are received and used.

For example, in a research kitchen using three test fats, the amount and type of each fat is recorded in a log as it is received and the code number and full description are written on each container of fat. Direct access to the test materials can be limited to key personnel who serve as ''gatekeepers,'' distributing the fats to foodservice workers as they are needed. This control point ensures that the foodservice worker uses the correct test fat. It also allows for efficient record keeping, because the gatekeeper records the date and amount of test material used at the time it is passed into the custody of the foodservice worker. Any fat that is discarded (eg, a burned cake) is also noted in the log book. After the study, if questions arise about use of test materials, complete records will be available for review. (Chain of custody procedures are also used for quality control in handling and analysis of biological samples and food composites.)

SAFETY AND SANITATION

The safety and sanitation standards for research diets are the same standards that apply to all foodservice operations. Standards that have been established by such agencies as local and state health departments, the Joint Commission on Accreditation of Healthcare Organizations, and the Occupational Safety and Health Administration are the commonly used ones that should be followed in the research kitchen. These standards are extremely important in research diet preparation, particularly so because food for research diets is often handled many times prior to service and this may increase the risk of foodborne illness.

The Hazard Analysis Critical Control Point concept (HACCP), a system of continuous quality improvement in food safety, provides a model for integrating safety and sanitation measures into the preparation and production processes of research diets (5, 6). HACCP suggests identifying: (1) sensitive ingredients, (2) sensitive areas in food processing, and (3) sensitive points of personnel health and hygiene. Once these areas have been identified, critical control points are then categorized according to: (1) the potential for microbiological contamination, (2) sanitation requirements, (3) time-temperature constraints, and (4) employee hygiene.

Several examples, outlined here, demonstrate effective application of the HACCP model in the production of research diets. (Also see Chapter 21, ''Performance Improvement for the Research Kitchen,'' for further discussion of the HACCP model.) The preparation of fresh boneless and skinless chicken breasts provides one such example. Chicken breasts are generally purchased fresh, trimmed, portioned into serving sizes, frozen for long periods of time, thawed, prepared, and finally served to the participant. Poultry is potentially hazardous because, as a protein source with a neutral pH, its risk of microbial growth is high. Poultry also is known to have a high rate of intrinsic salmonella contamination. Caution must therefore be taken that this meat is properly handled at every step in the process to avoid contamination and spoilage:

1. Employees should always wash their hands thoroughly prior to food handling.
2. Personnel should not have open cuts or sores on their hands and should not put their hands to their faces during the food production process.
3. Raw poultry should not be held in the temperature danger zone (7°C to 60°C, 45°F to 140°F) for more than 2 hours.
4. To avoid cross contamination, raw poultry should be cut on a sanitized cutting board. The board should not be used for ingredients other than raw meats. Cutting boards should be sanitized daily.
5. Poultry should be quickly washed, drained, dried, and packed into air-tight containers for freezing.
6. Freezer and refrigerator temperatures must be checked at least daily to guarantee that equipment integrity is maintained.
7. All frozen meats should be thawed in the refrigerator.
8. Poultry must be thoroughly cooked to a minimum of 74°C (165°F) for 15 seconds. A thermometer should be used to monitor quality assurance.

Exhibit 12–1 is an example of HACCP applied to this model. Following the principles of HACCP can help maintain food safety and sanitation standards in the food preparation process.

Another example of the HACCP concept is examining the way in which meals are prepared in large-scale foodservice systems. Frequently, meals are prepared in advance, with full cooking and food preparation taking place a day or two prior to service. Prepared meals are quickly chilled and held under refrigeration until they are reheated, often using a microwave oven, just prior to serving. A hazard analysis of this cook/chill process would identify potentially sensitive ingredients and critical time-temperature constraints in the system to minimize bacterial growth. The hazard analysis would include such points as:

- Foods must be cooked sufficiently and chilled quickly.
- Reheating must be thorough enough to destroy bacteria that may be present.
- Plastic disposable gloves should be worn when food handlers are preparing fresh foods such as salads or sandwiches that will not undergo heating prior to service.

Formulas that are prepared for research diets often do not have any heat treatment. A hazard analysis of this process must identify not only preparation control points but also safe sources of ingredients, especially for potentially sensitive protein components. When the formula is prepared in large batches, careful attention must be paid to the total time the mixture is held in the danger zone. The total holding time must include preparation time, freezing time, storage time, the time it takes to weigh the formula prior to service, and the time between service and participant consumption.

As with other potentially hazardous foods, formulas should be cooled according to published government guidelines (Food and Drug Administration, Food Code, US Public Health Service, US Department of Health and Human Services, Washington DC, 1997). Formulas that are heated must first be cooled within 2 hours from 60°C (140°F) to 21°C (70°F), and then further cooled within 4 hours from 21°C (70°F) down to 5°C (41°F) or lower. Formulas that are prepared at room temperature should be cooled from 21°C (70°F) to 5°C (41°F) or lower. Frozen formula should be thawed under refrigeration that maintains the mixture at tem-

EXHIBIT 12-1

The HACCP Checklist for Chicken Breast Preparation

Ingredient: Chicken Breast
Hazard Status: Potential for microbial contamination is *high*
Food Processing Requirements:

- Do not keep raw poultry in the danger zone (45°F to 140°F) for longer than 2 hours.
- Cutting board should be dedicated and marked ''FOR POULTRY ONLY.''
- Sanitize cutting board daily.
- Use airtight containers for packaging.
- Check freezer and refrigerator temperatures at least daily.
- Thaw frozen poultry in the refrigerator.
- Cook poultry to a minimum of 165°F—use a thermometer!

Personnel Requirements:

- Wash hands thoroughly prior to food handling.
- Check hands for open cuts or sores.
- Keep hands away from faces during the food production process.

peratures of 5°C (41°F) or less. (Also see Chapter 14, ''Planning and Producing Formula Diets.'')

Temperature-sensitive labels are available that can help to monitor time and temperature conditions. These labels use liquid crystal technology to identify products that have been exposed to adverse conditions and thus help to guarantee the safety of sensitive foods (sources include Monitor Mark Brand Product Exposure Indicators, 3M Packaging Systems Division, St Paul, Minn, also LifeLines Technology, Inc, Morris Plains, NJ).

Research diets prepared for outpatient studies present another potentially hazardous food safety situation. Possible problem areas include improper packaging and/or subsequent participant mishandling. Study participants should be instructed in proper food-handling techniques, food storage, and food preparation. Strict adherence to limiting the time that food remains in the danger zone to a 2-hour to 4-hour maximum is critical for food safety. Yet, depending on the amount and type of initial contamination, the growth medium, and the temperature, even a maximum of 2 hours in the danger zone cannot guarantee food safety. Willingness to follow safe food-handling procedures is a key characteristic of a compliant participant; screening materials, informed consent documents, and protocol instructions all must address the issue of food safety.

The ultimate responsibility and liability for safety and sanitation standards as they apply to research diets lies with the investigator in charge of the study. It is the chief dietitian's responsibility to ensure that food safety and sanitation standards are firmly established and documented in the facility. In addition, dietary staff must be formally trained and periodically retrained through in-service education sessions to ensure that the proper standards are maintained. The HACCP concept provides a model for monitoring food safety that is especially appropriate for the research kitchen.

Use of Modified Foods and Experimental Foods

At times the diet design targets of the protocol cannot be achieved with the use of standard foodstuffs. For these cases, investigators may wish to consider using modified foods that differ from their traditional counterparts with respect to one or more nutrients or dietary compounds. These modified foods can be useful tools for changing levels of various nutrients in experimental diets. Some can be substituted for the traditional product with little or no devaluation of sensory properties. Others have altered cooking properties or palatability, reducing their acceptability.

The modified foods discussed in this section do not represent a comprehensive listing; rather, the intent is to give examples of experimental foodstuffs that have been used in controlled diet studies and to address issues relevant to feeding experimental foodstuffs to study participants. Additionally, the investigator will want to inquire about the safety of experimental foodstuffs for human consumption. At this writing, some of the foods mentioned here have not been approved for human consumption by the Food and Drug Administration, and some have been approved only for limited use.

Modified or experimental foods usually are far more expensive than standard items, often by more than a factor of 10. These costs must be considered when researchers plan the study's budget. In some cases costs of such foods may be prohibitive and a revised protocol is in order. At other times an experimental food product provides a key element of dietary control.

Plant Foods with Isotopic Labels or Altered Composition

The use of stable isotopes to label plant foods for human nutrition studies was recently reviewed by Grusak (7). Stable isotopes in general are considered inherently safer than radioactive isotopes, and their use is expanding to studies of nearly every category of nutrient, from macronutrients to vitamins, minerals, and water. Elements lending themselves to such studies include hydrogen, carbon, nitrogen, magnesium, calcium, iron, copper, and zinc. (Also see Chapter 16, ''Compartmental Modeling and Balance Studies.'')

Clinical investigators interested in using isotopically labeled plant products for controlled feeding studies should undertake product development through close collaboration with knowledgeable plant physiologists. For example, if labeled seeds are needed, it is best to select a cultivar (variety) whose seeds tend to mature at a fixed time rather than sequentially over an indeterminate time frame (7). In addition, depending on the nutrient and the means of administration, the tracer may preferentially concentrate in certain plant tissues (eg, stems, roots, leaves, or seeds). Stable isotopes can be incorporated into plant tissues as they grow (''intrinsic labeling'') by culturing plants in labeled hydroponic medium, injecting isotopes into plant stems, or growing the plants in labeled gaseous atmosphere (a method used primarily for carbon-13 studies) (7). Although many varieties of plants lend themselves to labeling treatment, their growing habits or metabolic characteristics can affect how suitable they are for a particular protocol.

The stable isotope of carbon, ^{13}C, is naturally concentrated above background environmental levels (ie, in CO_2 from air) by certain plants, particularly corn and sugar cane. (Also see Chapter 14, ''Planning and Producing Formula Diets.'') ^{13}C can also be added to hydroponic cultures to produce isotopically labeled plant metabolites. Kale containing ^{13}C-labeled carotenoids have been grown in this way for studies of carotenoid absorption and metabolism (8).

Radioactive isotopes also are used to label foods when scientifically appropriate and are judged safe for subjects. For example, radiolabeled calcium chloride, incorporated into foods, has been fed to humans to assess relative absorbability of calcium from food sources (9). The tracer was added directly to milk (ie, *extrinsic* labeling) or incorporated into kale as it was grown hydroponically (ie, *intrinsic* labeling). Tissues of intrinsically labeled kale have a uniform distribution of the ^{65}Ca tracer.

Another way to test the effect of diets high or low in calcium is through supplementation of calcium in foods or use of low-calcium or calcium-substitute foods. Foods that have been supplemented with calcium include juices, dairy products, flours, and baked goods. In some food products, such as juices, participants can detect a difference in taste between the traditional and the calcium-supplemented product. Comparison diets that are low in calcium typically include few milk products; thus, soy milk (eg, Vita Soy®) can be useful as a low-calcium milk substitute.

Known geographical differences in the mineral content of local soils have been used to advantage in obtaining foods of specific composition. Wheat that is high in selenium has been grown in an area of South Dakota where the soil has a high selenium content. This high-selenium wheat and a low-selenium counterpart were incorporated into bread products and fed to men with low selenium status (10). The low- and high-selenium products were compared to each other and to other selenium supplements to assess the relative bioavailability of selenium. There was no difference in flavor or acceptability of the two wheat products in this study.

Wheat bran is a good source of dietary trace minerals, but it contains phytic acid that can form complexes with cations. Phytic acid has been implicated in reducing mineral bioavailability by binding several nutritionally important minerals including iron, zinc, calcium, and magnesium, thus making them unavailable for absorption. A modified product, dephytinized wheat bran from which phytic acid has been removed by promoting natural phytase activity, has been useful as an experimental food in evaluating the effect of phytic acid on apparent mineral absorption (11). The modified and traditional wheat brans were incorporated into muffins with no detectable differences in baking or sensory properties.

Foods Used to Reduce or Replace Dietary Fat

Many low-fat or fat-modified products are available commercially. Some products have reduced-fat content resulting from fat removal (eg, skimmed or low-fat rather than whole milk). In others, the fat is diluted, as when water replaces some of the fat in low-fat margarines, or air is incorporated into margarine and cream cheese to provide less fat for a given volume of product. In some products the type rather than the amount of fat is altered. In filled milk products, for example, vegetable oils are substituted for animal fats to retain properties of the original food (eg, milk that has the milk fat replaced with sunflower oil). However, filled milk products are not generally low in fat.

Producing fat-modified and low-fat cheeses has proven to be a technological challenge. The texture, body, and flavor of cheeses are largely dependent on the type and amount of fat as are their functional properties. Storage conditions can affect fat-modified foods as well as their traditional counterparts. For example, in contrast to full-fat mozzarella cheese, low-fat mozzarella is hard and less meltable (12). However, following refrigerated storage for 6 weeks, the texture and melting characteristics are more desirable. Frozen storage also affects sensory characteristics of cheeses.

Low-fat and skimmed milk, and cheeses made with these milks, have an obvious role in reducing the saturated fat content of diets. Conversely, traditional, full-fat products can be used as vehicles for delivering fat in diets designed to be higher in fat. Although participants are likely to object to the use of visible fats, such as butter, in higher-fat diets, they typically accept whole milk or cheese without complaint.

Protein-based fat substitutes include Simplesse® (Monsanto Corp, Chicago, Ill), Trail Blazer® (Kraft General Foods, Glenview, Ill), Lita® (Opta Food Ingredients, Louisville, Ken), and Dairy-Lo® (Pfizer Inc, Milwaukee, Wisc). Additionally, soy products including flour, grits, and protein concentrates are used in comminuted meat products (frankfurters, meat loaves) resulting in products with reduced proportions of animal fat. Meat analogs made of soy resemble meat in texture and flavor and have similar reduced-fat characteristics. Soy has a distinct taste but works well as a meat substitute in chili and other spicy foods. Recipes for use of protein-based meat substitutes are available (13).

Among the protein-based fat substitutes, Simplesse is one of the better known. This product, composed primarily of egg and milk proteins, has a fat-like texture that is due to the small size of its microparticles (0.1 to 3 micron spheres) (14). Protein particles of this size have a smooth mouth feel in contrast to larger particles, which feel gritty. The product is well suited for frozen desserts and salad dressings. Because the microparticles break down when heated, the product is not suitable for use in foods that must be cooked. Individuals who are allergic to egg or milk proteins may have reactions to Simplesse (15).

Carbohydrate-based fat substitutes include cellulose, gums, and the maltodextrins including Oatrim® (ConAgra, Omaha, Neb), Z-trim® (USDA, recent patent), Ricetrin® (Zumbro Inc, Faribault, Minn), and Paselli-SA2® (Avebe America Inc, Princeton, NJ). For example, Oatrim can be incorporated into products without affecting taste or texture. It is suitable for use in dairy products and salad dressings and can be used in baked goods because of its stability at high temperatures. The product is used as a meat extender because it enhances the water-holding capacity of products such as ground beef, promoting juiciness that is normally associated with fat content. The product is also a good source of soluble fiber.

Fat-based fat substitutes include Olestra® (Proctor and Gamble, Cincinnati, Ohio), Veri-Lo® (Pfizer Inc, Milwaukee, Wisc), and Dur-Lo® (Loders-Croklaan Inc, Glen Ellyn, Ill). The best known of these, Olestra, is a sucrose polyester; that is, a mixture of hexa-, hepta-, and octaesters formed from sucrose and long-chain fatty acids (16). Olestra provides no calories because it is not hydrolyzed by gastric lipases and is not absorbed. Olestra can be tailored to meet desired functional and sensory characteristics by varying the fatty acid composition, and, like conventional fats, can be used for cooking. The product is suitable for blinded studies because Olestra has the taste and consistency of fat. Study participants are unable to distinguish between Olestra and conventional dietary fat, and many participants can consume fairly high levels of Olestra without experiencing gastrointestinal side effects (17). However, sucrose polyesters appear to reduce absorption of dietary carotenoids (18).

The use of synthetic triglycerides—those created to contain specific fatty acids—is an option when the goal is to control the type of dietary fat. In contrast to natural fats, which contain an array of fatty acids, synthetic triglycerides can be tailored to provide a desired number and distribution of fatty acids. Synthetic fats have been useful in experimental diets designed to investigate the effects of specific fatty acids on blood lipids (19). However, it should be noted that in some synthetic fats, a large proportion of the triglyceride contains a saturated fatty acid in the middle position of the glycerol. (This is also true of natural fats that have been randomly reesterified—that is, the fatty acids removed from the glycerol and reesterified.) In nature that position on the glycerol molecule is, for the most part, reserved for polyunsaturated fatty acids. This difference in triglyceride configuration can influence lipid absorption and metabolism (20).

Foods Modified to Reduce Cholesterol Content

There are a number of ways to reduce the cholesterol content of eggs (21). Perhaps the most common methods involve removing the yolk and replacing it with either vegetable oils or nonoil ingredients. For most baked products, egg substitutes can successfully replace whole eggs. However, some recipes require egg yolk for their emulsifying properties (mayonnaise) or fat content (Hollandaise sauce). Egg substitutes that contain vegetable oils are not satisfactory replacements in recipes that require egg whites for foam-forming functions (angel food cake, meringues).

Because of their high cholesterol content and the localization of cholesterol in the yolk, eggs have been the major food targeted for cholesterol reduction. In addition, methods are under development for removal of cholesterol from butterfat (22, 23), so more cholesterol-modified foods may soon be available for experimental diets.

Experimental Foods Used to Increase Fiber Content of Diets

Dietary fibers are used in controlled feeding studies both as conventional foods and as experimental foodstuffs. As a rule, the insoluble fibers add bulk to the diet, enhancing fecal bulking and laxation, but they do not lower blood cholesterol levels as some soluble fibers do. Soluble fibers are widely studied; but, as experimental foodstuffs, they are frequently a challenge to successfully incorporate into recipes.

Gums in soluble fibers (for example, beta-glucan in oat fiber) can produce stiff gels in doughs and batters during the mixing process, making the product sticky and difficult to handle; the stickiness increases yet further with longer mixing times. Another problem associated with gums and gel formation is decreased volume in baked goods. For example, the volume of baked goods can be reduced by one-third to one-half when carboxymethyl cellulose, a particularly sticky gum, is incorporated into the recipe. On the other hand, volume is unchanged with other fibers, such as locust bean gum. To minimize gum development in food preparation, it is prudent to add the soluble fiber as the last ingredient in a recipe and to mix as little as possible after its addition. Leavening agents are commonly increased in recipes to counteract the decrease in volume associated with using gums.

Some fibers are better tolerated by study participants than others, and individuals vary in their ability to tolerate a given type and amount of fiber. Adverse reactions such as bloating, belching, and flatulence are common during the first week of a high-fiber diet, but these symptoms generally ameliorate during the second week as the activity of colonic bacteria that ferment polysaccharides changes in response to the higher-fiber diet (24).

Pilot Plant Production of Experimental Foods

Researchers often need to collaborate with colleagues in universities or in the food industry to produce experimental foods in forms that are needed for human feeding studies. Trade organizations (Exhibit 12–2) can provide information and assist in making contacts with food scientists who produce specialized products. Many universities, particularly land grant universities, have pilot plant facilities that may be suitable for producing specialized experimental foods. Professional societies for food scientists and some of the many trade and professional journals for food science and technology are listed in Exhibits 12–3 and 12–4, respectively.

Food Safety and Experimental Foods

The investigator must ensure that any experimental food fed to humans meets high standards of sanitation and safety. As with all foods, the experimental food must be processed in sanitary facilities using good manufacturing practices. The food must be safe from pathogens, hazardous chemicals, and other potentially harmful agents, and free of repulsive or offensive matter that is considered filth (25).

The investigator should be certain that the experimental food in question can legally be fed to humans. US regula-

EXHIBIT 12-2

Food-Related Trade Organizations

American Egg Board, Park Ridge, Ill. Promotes egg industry and demand for egg products. (847) 296–7043, http://www.aeb.org

American Frozen Food Institute (AFFI), McLean, Va. AFFI's Foundation for Frozen Food Research develops and coordinates scientific research in industry-wide, noncompetitive areas to increase understanding of the storing and thawing process of frozen food production. (703) 821–0770, http://www.affi.com

American Institute of Baking (ABA), Manhattan, Kan. Promotes education and research in the science and art of baking, bakery management, allied sciences, food processing sanitation, and safety for the benefit of all people. (785) 537–4750, http://www.aibonline.org

Food Marketing Institute (FMI), Washington, DC. Conducts programs in research, education, industry relations, and public affairs on behalf of its 1,500 members—food retailers and wholesalers and their customers in the United States and around the world. (202) 452–8444, http://www.fmi.org

Grocery Manufacturers of America (GMA), Washington, DC. GMA's member companies manufacture about 85% of supermarket goods. (202) 337–9400, http://www.gmabrands.com

Institute of Shortening and Edible Oils (ISEO), Washington, DC. Represents refiners of edible fats and oils. ISEO's 26 members represent approximately 90% to 95% of the edible fats processed domestically. (202) 783–7960, http://www.iseo.org

International Food Information Council (IFIC), Washington, DC. A nonprofit organization that communicates sound, science-based information on food safety and nutrition to health professionals, educators, government officials, journalists, and consumers. (202) 296–6540, http://www.ificinfo.health.org

National Cattlemen's Beef Association (NCBA), Chicago, Ill. Represents livestock marketers, growers, meat packers, food retailers, and food service firms. Conducts program of promotion, education, and information about beef, veal, pork, lamb, and associated meat products. (312) 670–9213, http://www.beef.org

National Fisheries Institute (NFI), Arlington, Va. The objective of NFI is to strengthen the US fish and seafood industry in its mission of supplying more and greater variety of high-quality fish and seafood products to the nation's consumers. (703) 524–8880, http://www.nfi.org

National Food Processors Association (NFPA), Washington, DC. Represents the scientific and technical interests of approximately 500 member companies that manufacture processed or packaged fruits and vegetables, meats, seafoods, juices, beverages, and specialty products. (202) 639–5900, http://www.nfpa-food.org

Refrigerated Foods Association (RFA), Atlanta, Ga. The RFA is an international association of manufacturers and suppliers of refrigerated foods. (770) 452–0660

Snack Food Association (SFA), Alexandria, Va. Represents manufacturers, distributors, and suppliers of snack foods. (703) 836–4500, http://www.sfa.org

United Fresh Fruits and Vegetables Association, Alexandria, Va. Provides a meeting place for members, customers, suppliers, and groups to exchange ideas and to associate; promotes the interests of its members; educates the public by promoting the benefits of increased consumption of fresh fruits and vegetables; and assists members and their employees in their professional development. (703) 836–3410

United Soybean Board (USB), Chesterfield, Mo. A team of approximately 60 farmer-members, working voluntarily in the areas of domestic marketing, production, new uses, and international marketing of soybeans. (800) 989–8721, http://www.unitedsoybean.com

tions regarding foods for human consumption are detailed in the Code of Federal Regulations (CFR) (25), which is revised at least once a year. To ensure that information is up to date, the latest issue of the CFR must be used in conjunction with subsequent amendments. The latest amendments can be traced through the ''List of Code of Federal Regulations Sections Affected,'' which is issued monthly, and the ''Cumulative List of Parts Affected,'' which appears in the Reader Aids section of the daily *Federal Register.* A summary of the principal laws and regulations that are enforced by the Food and Drug Administration (FDA) is available in nonlegal language (26).

The CFR describes conditions for safe use of food additives. A food additive is any substance that may be reasonably expected to become a component of food or affect the characteristics of food. US law requires that the safety

EXHIBIT 12-3

Professional Societies Concerned with Food Science and Experimental Foods

American Association of Cereal Chemists (AACC), St Paul, Minn. (612) 454–7250, http://www.scisoc.org/aacc
American Dairy Association, Rosemont, Ill. (847) 803–2000, http://www.dairyinfo.com
American Dietetic Association (ADA), Chicago, Ill. (800) 877–1600, http://www.eatright.org
American Meat Science Association, Kansas City, Mo. (816) 444–3500, http://www.meatscience.org
American Oil Chemists' Society (AOCS), Champaign, Ill. (217) 359–2344, http://www.aocs.org
AOAC International, Gaithersburg, Md. (703) 522–3032, http://www.aoas.org
American Society for Clinical Nutrition (ASCN), Bethesda, Md. (301) 530–7110, http://www.faseb.org/ascn
American Society for Nutritional Sciences (ASNS), Bethesda, Md. (301) 530–7050, http://www.nutrition.org
Institute of Food Technologists (IFT), Chicago, Ill. (312) 782–8424, http://www.ift.org
Poultry Science Association, Champaign, Ill. (217) 356–3182, http://www.psa.uiuc.edu

EXHIBIT 12-4

Trade and Professional Journals Concerned with Food Science and Experimental Foods

Cereal Chemistry
Cereal Foods World
Food Chemistry
Food and Nutrition Bulletin
Food Technology
International Journal of Food Science and Nutrition
International News on Fats, Oils, and Related Materials (INFORM)
Journal of Agricultural and Food Chemistry
Journal of The American Dietetic Association
Journal of the American Oil Chemists' Society
Journal of Applied Spectroscopy
Journal of the Association of Official Analytical Chemists International
Journal of Food Composition and Analysis
Journal of Food Science

of a food additive must be determined by the FDA before the additive may be used in food either indirectly (eg, as a result of processing or packaging) or directly. This law exempts from the definition of food additives those substances that are generally recognized as safe (GRAS) by qualified experts for the intended use in food.

Title 21, part 172 of the CFR contains a list of food additives permitted for direct addition to foods that are intended for human consumption. Title 21, part 182 of the CFR, identifies substances that are generally recognized as safe for human consumption. However, many unlisted substances may also be safe. If there is any question concerning the safety of an experimental food for human consumption, the investigator should seek an opinion from the FDA. Title 21, part 170 contains instructions for submitting a petition for affirmation of GRAS status, and Title 21, part 171 contains instructions for preparing a petition for approval of a food additive.

Some experimental foodstuffs may have characteristics that make them similar to pharmaceutical products. Investigators in these cases should inquire about whether it is necessary to develop a New Drug Application, which is handled by the FDA. Sufficient time in the study schedule must then be allotted for the approval process.

CONCLUSION

Many creative research diets have been designed using experimental foods. However, no matter how creative the study design, implementation is key to a successful research study. It is clear that accurately producing research diets requires considerable attention not only from the foodservice workers who "produce" meals but also from the principal investigator, the study coordinator, and from dietitians and lead cooks. Accurately and safely producing research diets requires unyielding attention to the details of food purchasing and storage, to weighing and cooking techniques, and dedication to uncompromised food safety and sanitation procedures.

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