July 2002

Cost of Reformulating Foods and Cosmetics

Final Report

Prepared for

Edward Puro
DHHS/Food and Drug Administration
Center for Food Safety and Applied Nutrition
HFS-726
5100 Paint Branch Parkway
College Park, MD 20740-3835

Prepared by

William J. White
Erica Gledhill
Shawn Karns
Mary K. Muth
RTI
Center for Regulatory Economics and Policy Research
Research Triangle Park, NC 27709

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Research Triangle Park, NC 27709-2194

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1 Introduction

Food and cosmetic manufacturers choose bundles of product attributes to maximize their expected profits and may alter these attributes through product reformulation.

The food and cosmetic products purchased by households in the United States convey a variety of benefits that are valued by their consumers. In addition to caloric and nutrient content for sustenance, food products offer pleasing taste, aroma, texture, and appearance. Some may provide ease of preparation (microwave pizza), vitamin fortification (bread and cereal), increased feelings of status (some premium ice creams), or a wide variety of other tangible or perceived benefits. Cosmetic products, likewise, can impart to consumers a sense of well-being or status, in addition to their core functions of making the user more attractive or perhaps just more pleasant-smelling. In both of these product areas, buyers are willing to pay for all of these attributes in making their purchase decisions.

The firms that produce these food and cosmetic products choose a bundle of characteristics that will maximize their expected profits. Except in the case of most fresh produce and a few other very simple products, all firms in the industry modify their ingredients in some way to influence consumers' willingness to buy at the established price. We can think of (and model) purchasers as paying separately for each of the quality or performance attributes they choose (Lancaster, 1974). Over time, manufacturers will reformulate their products in response to changing consumer tastes or preferences, changes in cost or availability of raw materials, or governmental regulatory action.

The Food and Drug Administration (FDA) has the responsibility to ensure that foods and cosmetic products offered for sale in the

United States are safe and unadulterated. Some components of these products may be so harmful that they need to be eliminated from consumer products through a restriction or ban. In less drastic cases, there are potential economic and health benefits from requiring truthful revelation of health characteristics and risks; the reduction in consumers' uncertainty can reduce or eliminate the adverse selection problem.

Many of the food safety and nutrition regulations proposed by the FDA require reformulation of affected products or induce manufacturers to reformulate to avoid labeling changes. FDA is required by law to analyze the costs and benefits of proposed food and cosmetic regulations prior to implementation to make sure that the regulation will be socially beneficial. The Economics Team at FDA's Center for Food Safety and Applied Nutrition (CFSAN) must estimate the costs incurred in reformulation as part of its regulatory impact analyses (RIAs) for new food and cosmetic regulations.

1.1 PROJECT OBJECTIVES

The primary objective of this project is to develop an operational model to estimate the costs of product reformulation for food and cosmetic products regulated by FDA. Such a model will allow the Economics Team to obtain a range of cost estimates associated with the types of reformulation that manufacturers may undertake in response to regulations. The model is designed to be consistent in approach and concept to RTI's labeling cost model (Muth, Gledhill, and Karns, 2001).

1.2 OVERVIEW OF THE REPORT

This report is organized as follows. Section 2 provides an overview of the reformulation process including a description of the factors that affect the level of reformulation complexity. Section 3 describes the assumptions of the model, the cost estimates used in the model, and the equations for calculating the total costs of a reformulation. Finally, Section 4 provides instructions for using and updating the model.

The appendices contain additional supplementary information. Appendix A provides a table listing product categories by North American Industry Classification System (NAICS) codes. Appendix B includes the Stata program used to calculate the cost estimates and instructions for revising the Stata data files.

1.3 REFERENCES

Lancaster, K. 1974. *Introduction to Modern Microeconomics.* Second Edition. Chicago, IL: Rand McNally College Publishing Company.

Muth, M.K., E.C. Gledhill, and S.A. Karns. November 2001. "FDA Labeling Cost Model." Report prepared for U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition. Research Triangle Park, NC: RTI.

2 Reformulation Concepts and Process

Manufacturers may reformulate products as a direct or indirect result of a regulation.

The reformulation of food and cosmetic products is a form of technical change. It involves the search for a new recipe for combining the product ingredients that will preserve or even enhance consumers' perceptions of the product without negatively affecting producer profits. Such reformulation may be rather minor, and of low cost, as would be the case with qualification of a new supplier or the substitution of one colorant for another. On the other extreme, it may present significant technical and economic challenges to producers, as would the reduction of saturated fat or cholesterol in dairy products.

In this section, we present some general concepts related to determining the complexity and thus the level of costs associated with reformulation. Both the importance of the ingredient to the product formula and the likely response of manufacturers can affect the level of cost incurred. Following that discussion, we then provide an overview of the steps and testing involved in the reformulation process.

2.1 BASIC CONCEPTS IN REFORMULATION

Manufacturers continuously reformulate food and cosmetic products in response to changing consumer needs and to reposition themselves in the product space in response to the actual or anticipated actions of competitors (Kuntz, 1993). These reformulations require developing new knowledge and thus are

essentially a research and development (R&D) effort. The goal of these reformulations is generally to reduce production costs or change the product attributes in a manner that better meets consumer preferences. Because the development of new recipes is the uncertain outcome of R&D, firms must evaluate the probability of technical success; the probability, given technical success, that the reformulated product can be effectively commercialized; and the probability, given commercialization, that the expected return on investment in R&D (and potentially, in the production process itself) will meet or exceed the firm's hurdle rate or threshold for project acceptance (see Mansfield, 1961).

In the context of a response to government regulation, the goal of product reformulation is to meet the regulatory requirements without substantially affecting production costs or consumer acceptance of the product.

In contrast, in the context of a response to government regulation, the goal of product reformulation is to meet the regulatory requirements without substantially affecting production costs or consumer acceptance of the product. Whether this goal can be met depends on the complexity of the required change, the availability and quality of substitutes or suitable processing steps, and the time period allowed for making the change. If the expected costs of reformulation are greater than projected increases in revenue, and if complying with the regulatory requirement without reformulation is likely to create losses as well, then the firm's response will be to cease production.

When assessing reformulation costs, several key drivers cut across all product categories in food and cosmetics sectors:

- ➤ the importance of the ingredient or component to the affected product or product category
- ➤ the likely response of manufacturers to the proposed regulation
- ➤ the compliance period allowed

In the next three subsections, we discuss each of these cost drivers in detail.

2.1.1 Importance of Ingredient or Component

The importance of the component or ingredient in the product formula affects the complexity and, therefore, the costs of product reformulation. Table 2-1 lists categories of component importance with examples for food and cosmetic products. At one extreme, some minor components could be eliminated at nominal expense

Table 2-1. Categories of Component Importance with Examples for Food and Cosmetic Products

Importance Category	Examples
Noncritical minor ingredient—used at low levels with no functional performance effects	Dye/colorant Preservative Shampoo or lotion fragrance
Critical minor ingredient—used at low levels with either functional performance or safety effects	Perfume fragrance Aloe in a sun care product Preservative in product snack foods
Major ingredient—used at high levels and thus always has functional performance and safety effects	Peanut oil in potato chips Durum wheat flour in pasta Sodium lauryl sulfate in shampoo
Primary component or inherent characteristic of an ingredient—a naturally occurring component of an ingredient that would require a production process change to remove it	Saturated or trans fats in foods Cholesterol in animal products Trace metals or toxins in fruits

by, for example, small-scale testing of a new formula, changing the formula card, and analyzing a few product batches. In contrast, major components and those most important in forming the value proposition for the consumer may take months of R&D effort to replace. Manufacturers may not be able to develop a new formula that meets product performance, cost, and consumer acceptance criteria.

2.1.2 Likely Response of Manufacturers to Regulation

Potential reformulation responses include
- ➤ substituting for an ingredient and
- ➤ changing the production process.

Having decided to reformulate a product, a producer still must determine what specific actions to take. For ingredients, the most productive options are dictated by the role the ingredient plays in the food or cosmetic formula; the availability of good substitutes; and sensory concerns such as taste, texture, and fragrance. For inherent constituents of a product, including trace impurities, fatty-acid composition, and cholesterol, the optimal decision will depend on the processing steps necessary to remove the offending component. Potential responses include substituting for the ingredient and changing the production process. We describe each of these potential responses below.

Substituting for an Ingredient

Substituting one ingredient for another is probably the most commonly adopted type of reformulation. In some cases, manufacturers might substitute a similar ingredient purchased from a different supplier but in other cases, manufacturers might substitute a different type ingredient. By substituting a similar ingredient from a different supplier, manufacturers might obtain a higher-quality ingredient or one made from a different source or a different process. Thus, manufacturers may eliminate a potential health concern.

By substituting an entirely different ingredient, manufacturers might also eliminate a potential health concern. However, if one assumes that the manufacturer optimized the initial formula, then every ingredient has an intended function.[1] If one ingredient is eliminated to avoid a regulatory impact, a similar material must be found to perform its function(s).

A few examples of ingredient substitution are

- ➤ replacing a synthetic chemical with a naturally derived one (or possibly the reverse) to eliminate a trace impurity that would otherwise require a warning label,
- ➤ replacing a bleach or filtered vegetable oil with one that has been distilled or deodorized to remove cholesterol and other unhealthy components,
- ➤ replacing reconstituted orange juice with freshly squeezed orange juice to allow a "fresh" claim on a product label,
- ➤ replacing Red Dye #2 after FDA determined it was hazardous to consume and banned it,
- ➤ par-frying frozen potato products in vegetable oil rather than tallow to eliminate cholesterol, and
- ➤ replacing sucrose with a less caloric sweetener in response to a change in nutrition facts requirements.

Substitution of a new ingredient will typically require the manufacturer to conduct a full-scale reformulation effort. Because a new component is being added, safety, stability, and consumer acceptance tests will be required in some form, legal and marketing approvals will be needed, and the manufacturing and materials

[1] Some reformulations could potentially involve elimination of a noncritical minor ingredient without substitution. However, these types of reformulation appear to be infrequent. Furthermore, the types of activities required for removal of an ingredient are likely similar to those for substitution of an ingredient.

handling processes will be affected. The amount and cost of effort required in each of these areas will depend on other factors discussed in this section.

Changing the Production Process

The most complex and costly reformulation efforts occur if a change in processing conditions or a new production step is required. Such an undertaking is likely if the manufacturer must eliminate a bulk component or trace impurity, and cannot use a new source of supply to avoid the issue. The National Food Processors Association (NFPA) indicated this type of change might be needed to avoid labeling for trans-fatty acids (NFPA, 2001). Process change may even be required to support a substitution effort, as would be the case if a powdered ingredient were replaced with a liquid, for example. In this case, costs will include those listed for substitution, plus the cost of engineering, constructing, and starting up the new process.

If large-scale process changes are required to avoid a labeling mandate, the high costs may make it likely that many affected firms will choose to relabel rather than reformulate. In the extreme, as when a component ban or restriction was imposed and relabeling was not an option, the producers might choose to cease making the product rather than comply.

2.1.3 Effects of the Compliance Period

Short compliance periods will likely increase the costs of reformulation, but long compliance periods will not eliminate all reformulation costs.

In addition to the component importance and likely response, the compliance period will affect the cost of reformulation. If the time allowed is short, premium labor costs and/or contract manufacturing services might be required to keep store shelves stocked with a firm's product. More importantly, long-term purchase contracts may require payment for unneeded raw materials and packaging, and a finished product that sells slowly may need to be recovered and scrapped.

On the other hand, long compliance periods do not eliminate regulatory compliance costs. This would be the case if firms could coordinate regulatory reformulations with those already scheduled for cost reduction, product improvement, advertising claims support, or other corporate initiatives. In researching the labeling cost model, for instance, RTI found that labeling costs would be

negligible if a 3-year compliance period were allowed. In the present case, however, we found that routine reformulation occurs less frequently than relabeling. Low-volume products, especially those made by small companies, are less likely to be reformulated without a regulatory mandate.

Specific types of compliance period-dependent costs are the following:

- Overtime charges for accelerated product development, testing, and support activities. These charges would be unlikely with compliance periods of 2 years or more but would be certain if 6 months or less were allowed.
- Scrapping or resale of obsolete raw materials. Most firms keep only a few weeks of raw materials inventory on hand but may have purchase commitments of a year or more. For compliance periods longer than 1 year, the costs are likely to be borne as contract cancellation fees rather than scrapping or loss on resale.
- Scrapping of packaging materials. Unlike raw materials, packaging materials cannot typically be resold; they must be thrown away or recycled.
- Throwaway of processed material or finished product. This extremely costly situation would only occur if compliance periods were very short or if firms were not allowed to "sell through" existing inventories of finished products.
- Contract manufacturing. If additional processing steps were required or decontamination of existing production equipment indicated, firms might have to contract out production if short compliance periods were imposed.

2.2 THE PROCESS OF REFORMULATION

The steps followed in the reformulation process depend on the importance and function of the ingredient affected by the regulation.

In this section, we describe the process by which food and cosmetic products are developed. It is necessary to understand all of the steps in the reformulation process so that we can later estimate the cost of each step in the process. Even if the ingredient affected is a noncritical minor ingredient, almost all of the steps in the process will still have to be followed to some extent. Each step needs to be followed because the ingredients in a product exist in a delicate balance and every ingredient contributes some characteristic to the product. It is often difficult to determine if the formulation policy should involve replacing an ingredient or removing it. Although occasionally one method makes more sense than another, neither approach is as simple as it sounds (Kuntz,

1993). However, a reformulation can be more or less complex depending on the function the reformulated ingredient performs in the food or cosmetic product. In general, the more complex the reformulation, the more time and money are spent at each step in the process.

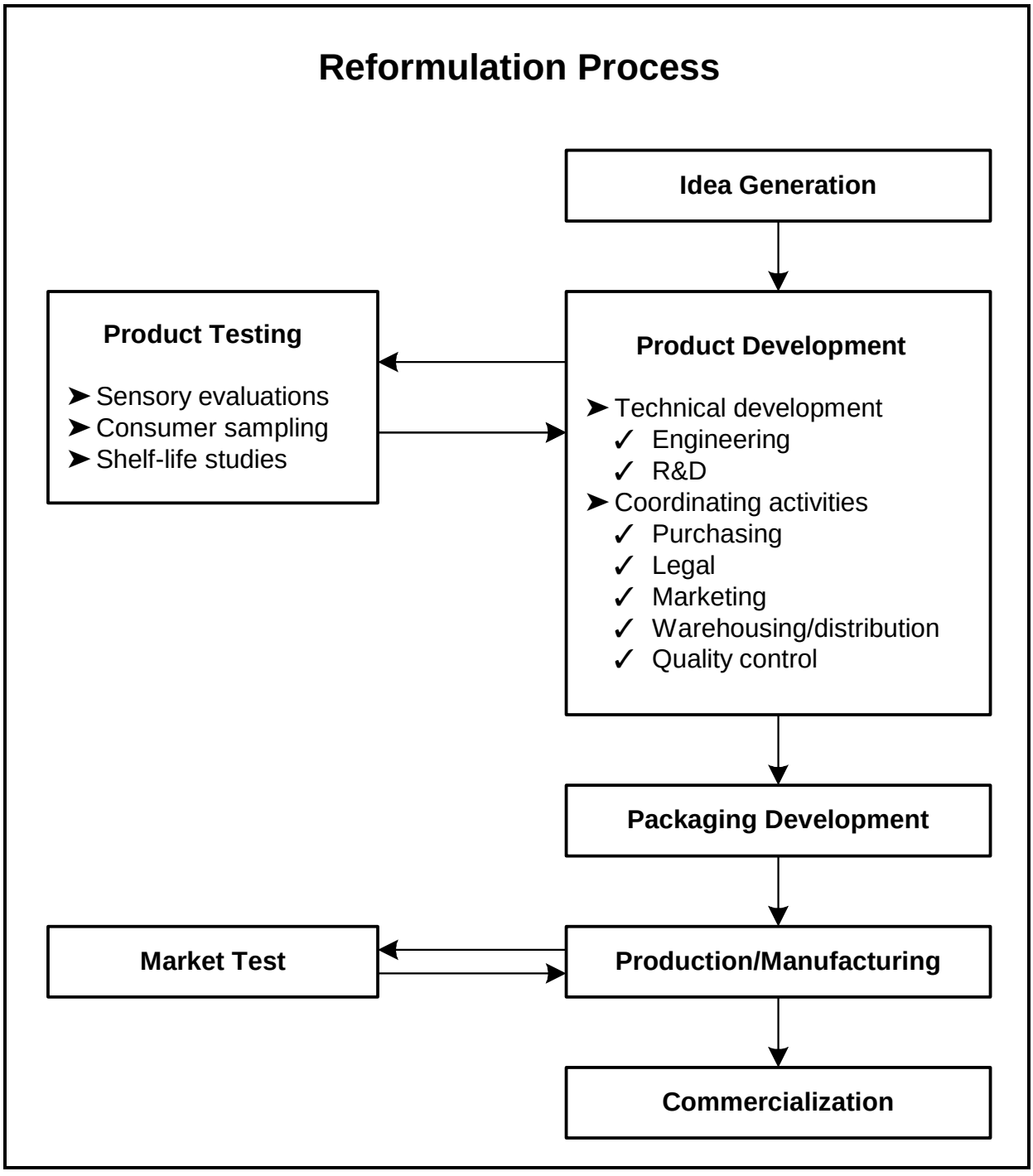
Once the manufacturer has decided to reformulate, it follows a number of steps to initiate the reformulation process. In general, the steps are as follows:

- idea generation
- development
- sensory evaluation
- consumer sampling (prior to marketing)
- shelf-life studies
- packaging
- production/manufacturing
- market testing (in a few cases)
- commercialization (in some cases) (Baker, Hahn, and Robbins, 1988)

These steps are outlined in Figure 2-1. Even though these steps are outlined linearly, many different departments are involved in the process of reformulating and work together in a product development team. Many of these steps run concurrently with each other, and the process is also iterative, so the results of one step may feed back into a previous step to allow for further refinements of the product. This occurs, for example, when product tests such as sensory evaluations, consumer sampling, and shelf-life studies are conducted at the same time the product is being developed. The results from these product tests cause the product to be further developed, and these refinements, in turn, necessitate more testing. The following departments are likely included in the product development team for a reformulation:

- R&D
- engineering
- production
- legal
- marketing
- purchasing

Figure 2-1. Overview of the Reformulation Process



- ➤ quality control
- ➤ management (Fuller, 1994)

R&D is involved in the more technical aspects of product development, while the other departments serve more supportive and coordinating roles. We describe each of the steps in more detail below.

Idea Generation

Idea generation is the process of determining the type of reformulation actions to be taken.

During the idea generation phase of a project, the product development team, which comprises members from each department involved in the reformulation, decides how it is going to respond to the challenge (Baker, Hahn, and Robbins, 1988). They decide what type of actions they will take—whether it is eliminating an ingredient, substituting an ingredient, or changing the production process. Limits to what the production plant can and cannot physically do with respect to the reformulated product are also outlined (Fuller, 1994). Although the process of idea generation within manufacturing firms is quite complex and highly proprietary in general, we expect that the restricted degrees of freedom found in reformulation cause this step to be rather straightforward.

Product Development

Product development is responsible for developing the new formula and coordinating testing and support activities.

The development of a product continuously evolves based on advice given by each department involved in reformulation. The technical development of the product itself involves food or cosmetic technologists from the R&D department working in the laboratory and on computers to devise new formulas. Information from tests and supporting activities is constantly fed back to them, and they make refinements to the product based on this information. R&D works with the purchasing department to find sources of new raw materials, ingredients, and packaging. The legal department reviews the formulations for compliance with all legal requirements in terms of limiting liability issues and complying with regulatory requirements. The market research department provides information from consumer tests about product preference. The quality control department determines whether all processing, product, environmental, and worker safety standards have been adhered to and that the product has been

protected from public health hazards (Fuller, 1994). In the development process, a development team comprising different departments with many different skills turns the idea for a product reformulation into a reality.

Sensory Evaluation

In sensory evaluation, the organoleptic properties of the new formula are tested by experienced panels and nonexpert consumers.

Because of the importance of organoleptic properties in consumer acceptance of food and cosmetic products, sensory evaluation is perhaps the most critical activity in reformulation. Sensory evaluations run concurrently with development so that the food technologists can obtain the results and refine recipes and formulations accordingly. Ideally, food and cosmetic manufacturers use two panels to find information on a product: a trained panel and a consumer panel. The trained panel can more objectively distinguish between flavor, texture, tenderness, and juiciness, and, in the case of reformulation, can determine the difference between the reformulated product and the original product (Baker, Hahn, and Robbins, 1988). A consumer panel is used to determine preferences to help the manufacturer produce products that are popular with the public. In large firms, the consumer panel may be made up of company employees (Carpenter, Lyon, and Hasdell, 2000). Technologists in R&D are typically responsible for running and analyzing the experienced panels, and the market research department usually coordinates the consumer panels.

Manufacturers use these methods in reformulation because when some element of the manufacturing process is changed, they need to check the impact on the final product quality.

- **Discrimination studies** test the consumer's ability to detect and recognize differences in a product. These tests involve side-by-side comparative judgments and can be very sensitive and capable of detecting very small differences between products.
- **Descriptive tests** are designed to identify and quantify sensory characteristics. Descriptive tests are appropriate to use with a reformulation because they provide an objective measure of any quality changes caused by ingredient or process changes.
- **Preference and acceptability tests** establish whether the product differences are recognized by the consumer and are seen to improve liking or acceptability. These methods lie on the fringe between sensory analysis and consumer

research and require assessors that are representative of the target consumer population and have little or no sensory training (Carpenter, Lyon, and Hasdell, 2000).

Discrimination and descriptive tests are described as *analytical* sensory tests because highly trained assessors make the evaluations. Preference and acceptability tests are *affective* sensory tests because the assessors comprise large numbers of untrained panelists who represent a type of consumer (Baker, Hahn, and Robbins, 1988). Table 2-2 lists and describes specific types of tests within these general categories.

Consumer Sampling

Consumer sampling can be accomplished through
- ➤ focus groups,
- ➤ central location tests, and
- ➤ in-home tests.

Consumer sampling is not always practiced, but valuable information about the product may be obtained at a relatively low cost by testing the product with a small consumer population (Baker, Hahn, and Robbins, 1988). The three main methods of consumer sampling are the following:

- ➤ Focus group: A small number of panelists (usually 8 to 10) representative of the target population are questioned about their attitudes toward the product category and then asked to test the product, fill out a questionnaire on the product, and discuss the product.
- ➤ Central location test: The manufacturer takes the product to a central location where it conducts tests with a broad cross-section of individuals at locations such as malls or churches. The testers fill out a questionnaire about the product.
- ➤ In-home test: Preselected consumers are sent samples of a product to prepare at home. There is no control of the environment in which the test is carried out, but the manufacturer is able to find out valuable information such as how well the instructions were followed at home. Testers fill out and return a questionnaire or are interviewed over the telephone.

These consumer sampling tests are usually coordinated by the marketing department and may be conducted multiple times in different areas of the country (Fuller, 1994).

Table 2-2. Types of Sensory Evaluation Tests Used for Food and Cosmetic Products

Type of Test	Description of Tests
Discrimination Type Tests	➤ Paired comparison test: Panelists are asked to state if there is a difference between two samples.
	➤ Duo trio test: One sample is presented as a reference; then a pair of samples is presented, and the panelist is asked to identify which of the two matches the reference sample.
	➤ Triangle test: This is similar to the duo trio, except that none of the three materials is a reference material.
	➤ Rating difference/scalar difference: A control is identified with multiple coded samples, and the panelists use a scale to rate how different the sample is from the control.
	➤ Two-out-of-five test: This test is similar to the triangle test, but it involves five samples.
	➤ Ranking test: Panelists are asked to rank coded samples in order for a certain sensory characteristic (e.g., bitterness, spiciness).
	➤ Magnitude estimation: Panelists are presented a reference sample and it is assigned an arbitrary value for the attribute in question. Subsequent samples are then given higher or lower values according to the magnitude of the perceived difference.
Descriptive Tests	➤ Consensus profiling: Four to six highly trained assessors work together to achieve agreed-upon standards to define and then rank the odor, flavor, taste, and feeling of the product.
	➤ Descriptive profiling: Highly trained assessors define attributes collectively but assign ratings and scores individually.
	➤ Free choice profiling: Highly trained assessors define and assign ratings individually.
Preference and Acceptance Tests	➤ Paired comparison preference test: Panelists are presented with two samples and asked which one they prefer based on an attribute.
	➤ Repeat paired comparison preference test: Panelists are asked to make a preference judgment between two products on one occasion and then to repeat the test a second time—ideally, 24 hours later.
	➤ Ranking preference test: Three or more samples are ranked by panelists according to preference.

Sources: Carpenter, Roland P., David H. Lyon, and Terry A. Hasdell. 2000. *Guidelines for Sensory Analysis in Food Product Development and Quality Control*. Gaithersburg, MD: Aspen Publishers, Inc.

Baker, Robert C., Patricia Wong Hahn, and Kelly R. Robbins. 1988. *Fundamentals of New Food Product Development.* Amsterdam: Elsevier Science Publishers.

Shelf-Life Studies

The response of products to conditions experienced in handling and storage can be determined by

- static storage tests,
- accelerated aging tests, and
- use/abuse tests.

Shelf stability needs to be tested so that the manufacturer has an understanding of how long a product will keep under a variety of different temperatures and conditions. Many different chemical reactions can take place during the storage life of a product. Shelf-life studies are usually administered by product or packaging development personnel within the R&D organization. In addition, most companies have chemists and microbiologists to study any chemical or biological reactions that occur; smaller firms may contract out for these analyses (Baker, Hahn, and Robbins, 1988).

In reformulation, the manufacturer already has an understanding of the shelf life of the base product, but a new ingredient or change to the process may alter the stability and thus the acceptable shelf life of the reformulated product. Therefore, shelf-life stability needs to be studied in the case of a reformulation, although the tests may not have to be as extensive, depending on the complexity of the reformulation.

There are three kinds of shelf-life tests:

- Static tests: The product is stored under a given set of environmental conditions selected as most representative of distribution system and household storage conditions.
- Accelerated tests: The product is stored under a range of environmental variables (e.g., temperature, humidity, barometric pressure) more extreme than will be experienced in normal storage. These tests are only projectable if they have been calibrated against a normal stress condition.
- Use/abuse tests: The product is cycled through different levels of certain environmental conditions to identify how much abuse can be tolerated before product failure.

Static tests are the simplest to set up and operate. However, the long time period that it takes for noticeable changes to occur makes them time-consuming and resource-intensive for the producer. In addition, they do not provide information on the behavior of the product under unusual conditions or other stresses. Accelerated tests provide more timely information about the product and the kinetics of its deterioration and, for this reason, are usually preferred (Fuller, 1994).

Use/abuse tests are the only way to test for certain abnormal changes. For example, transportation at high altitudes (such as shipment to the West Coast from the East) may cause vacuum-

packed products to lose their seal, permitting deterioration and loss of flavor. A barometric pressure cycling test in the laboratory can simulate this type of stress and ensure that the proper vacuum conditions are maintained.

Packaging Development

Packaging development assesses compatibility of product and package and conformance of package and label to regulations.

Packaging is not only important to add attractiveness and convenience to a product, but it also protects the product. It is also important that packaging is easy to apply, lightweight, economical, and does not react with the product (Baker, Hahn, and Robbins, 1988). The package structure will usually not have to change because of a reformulation, unless the changed ingredient is a major ingredient or a primary component to the product. In that case, the engineering department may have to alter the packaging for the reformulated product.

However, even if the type of packaging does not need to change, a reformulation usually requires the manufacturer to change the label. Generally the marketing department handles the new label design and label copy, but the legal department must also sign off on the final label to make sure that it complies with all regulations.

Market Testing

Advertising or marketing personnel may conduct a market test if there is a significant risk of commercial failure with the reformulated product.

Manufacturers market test a product when they want to reduce the risk of having an expensive failure with a national introduction. The manufacturer selects a city to release the product where the population comprises many different ethnic groups with a broad spectrum of incomes (Baker, Hahn, and Robbins, 1988). Numerous models for market testing have been developed to present the new product to consumers in a relatively realistic setting. A market test is done to obtain more accurate information about the product's sales potential because the manufacturer is able to take direct consumer measures and forecast them to predict total trial and repeat purchases (Brody and Lord, 2000). If the product succeeds in sales and repeat purchases, the manufacturer can try a larger or national introduction. If the product fails, it can be dropped or examined to determine the reasons for failure. If the development team can correct the problem, the product can be placed in another test market to confirm its ability to succeed (Baker, Hahn, and Robbins, 1988).

In the case of a reformulated product, the manufacturer would only conduct a market test if the reformulation is a major one, and even then, it would probably only be carried out by large food or cosmetics companies. Most small companies that sell locally would not go to the expense of a market test.

Production/Manufacturing

The production department ensures the proper people, equipment, and logistics are in place to manufacture the reformulated product.

During the early stages of reformulation efforts, the R&D department must communicate with the production (or manufacturing) organization to ensure that the necessary skills, labor, and physical plant are or will be available to produce the new product within the cost constraints and quality parameters required. The production department works with engineers to modify the existing production process or evaluate alternative production processes. They also will determine any potential need to engage a co-packer for the product or the need to purchase equipment (Baker, Hahn, and Robbins, 1988). Usually, only small adjustments to the production process would need to be made for reformulations of minor ingredients, but reformulations of major ingredients or primary components of the product may require new production processes and equipment.

Once any necessary changes to the production line have been made and the production line has been set up, a plant trial is conducted to ensure that all of the production activities are feasible. Following the plant trial, production start-up can begin. As part of production start-up, verification activities are conducted to ensure that all the specifications of the production process and the product are being met. If a product is going to be market tested, full-scale production should not occur until after a successful market test. If a market test is not going to be performed, full-scale production should take place when all of the previous steps in the development process have been successfully completed.

Commercialization

Commercialization costs will be incurred if new advertising or promotion is associated with the reformulation.

The commercialization stage of product development involves advertising the new product (Baker, Hahn, and Robbins, 1988). In the case of reformulation, advertising would only be necessary if the marketing staff have decided to change the campaign based on the reformulation. They might do this if they wanted to emphasize the fact that the product no longer contains the ingredient that they eliminated from the formula or to simply state that the product is "new and improved." If new advertising were not part of the marketing plan, then the commercialization stage would not occur. The old advertisements would continue to run and the new reformulated products would simply fill the shelves without alerting the consumer that the formula had been changed. If the compliance period were sufficiently long, the cost of creating new advertising schemes would be irrelevant, because the marketing department would be able to incorporate the information about the reformulation into periodic planned advertising changes.

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3 Reformulation Cost Model Assumptions, Data, and Calculations

In this section, we describe the assumptions underlying the reformulation cost model, present the product category and cost data used in the model, and explain the formulas used to calculate reformulation costs. This information provides the background that a user of the model may need to select the model inputs (as described in Section 4) and interpret the outputs.

3.1 REFORMULATION COST MODEL ASSUMPTIONS

The reformulation cost model includes food, dietary supplement, and cosmetic products under FDA's jurisdiction.

The reformulation cost model provides estimates of the costs of reformulation for the range of food, dietary supplement, and cosmetic products under FDA's jurisdiction. The product categories that form the basis of the model were derived from disaggregated scanner data obtained from Information Resources, Inc. (IRI) for food and dietary supplement and from aggregated scanner data obtained from ACNielsen for cosmetic products. To be included in these sources, products must have scannable universal product codes (UPCs); therefore, products that do not have scannable UPCs are excluded from the model (e.g., food products produced only for foodservice and cosmetic products produced for sale in department stores).

Based on our review of the literature described in Section 2 and information collected during interviews with manufacturers, we developed the following key assumptions for the reformulation cost model:

- **The costs of reformulating food and cosmetic products are on a per-formula basis.** Manufacturers may produce and distribute several products (with different stock keeping units [SKUs]) that are essentially the same formula. When reformulating these products, they incur the costs of the reformulation process for each individual formula. They also incur the costs of analytical testing, sensory evaluation, and consumer sampling on a per-formula basis.
- **The costs related to the process of reformulating private label and branded food and cosmetic products are the same because the same types of activities would have to occur for both types of products.** We assume that the complexity of the formulas for both private label and branded foods are similar and that manufacturers would conduct the same level of effort in reformulating both types of products.
- **The costs of reformulating a product in 12 months versus longer time periods are higher because manufacturers may have to discard unused raw material and finished goods inventories.** We assume that for branded products, 2.5 percent of the annual volume of finished goods and 2.5 percent of the annual volume of raw materials would have to be discarded for a 12-month compliance period. For private label products, with slower sell-through and fewer opportunities to re-use unneeded raw materials, we assume that 5 percent of the annual volume of finished goods and 5 percent of the annual volume of raw materials would have to be discarded for a 1-year compliance period.
- **Depending on the compliance period, some manufacturers will be able to coordinate a reformulation required as a result of an FDA regulation with a scheduled reformulation.** If manufacturers can coordinate a required reformulation with a scheduled reformulation, we assume the costs associated with compliance are negligible. The default coordination assumptions, which the user can modify in the model, are the following:
  - ✓ 12 months—5 percent can coordinate
  - ✓ 24 months—20 percent can coordinate
  - ✓ 36 months—30 percent can coordinate
  - ✓ 48 months—40 percent can coordinate

Additional specific assumptions were required for particular data elements in the model. These assumptions are described in Sections 3.2 and 3.3.

3.2 REFORMULATION COST MODEL DATA

In this section, we present the data that underlie the cost calculations for the model. These include the product category definitions and the costs associated with each reformulation activity. These activity-based costs were collected in interviews with food and cosmetics manufacturers, industry trade association representatives, and food industry consultants and laboratories.

3.2.1 Product Categories

As noted above, the product categories for the reformulation cost model were derived from two sources. For food and dietary supplement products, we derived the categories from disaggregated IRI scanner data, and for cosmetics, we derived the categories from aggregated ACNielsen scanner data. We describe the data associated with these product categories below.

Food and Dietary Supplement Product Categories

The process we followed for defining the food products categories was described in the labeling cost model report (Muth, Gledhill, and Karns, 2001). Table 3-1 lists the product categories, estimated number of formulas, number of SKUs, and annual units sold for food products included in the model. These product categories include approximately 220,000 formulas, 350,000 SKUs, and $192.5 billion in sales in grocery stores, drug stores, and mass merchandise stores.

To derive the counts of the number of unique formulas for food products, we used information in the product name field from the IRI data set. First, we eliminated the size of the package from the product name, and then we grouped products with the same product name. For each product category, we counted each set of grouped products as a unique formula. Because we believe the counting process may have overstated the number of unique formulas, we adjusted the final number of formulas downward by multiplying by 0.94. We derived the adjustment factor by reviewing in detail a sample of product categories. This factor combines an adjustment for mid-year manufacturer name changes for the same branded product (approximately 1.3 percent of

Table 3-1. Food Product Categories Included in the Reformulation Cost Model

Product Category	Number of Formulas		Number of SKUs		SKUs per Formula		Annual Units Sold (millions)	
	Branded	Private[a]	Branded	Private[b]	Branded	Private	Branded	Private
Baked Goods								
Bakery Snacks—Non-Rfg	4,162	1,698	4,988	2,817	1.2	1.7	1,098.4	172.9
Bakery Snacks—Rfg	39	49	43	65	1.1	1.3	1.3	1.2
Bread/Rolls—Non-Rfg	7,373	4,998	13,822	9,245	1.9	1.8	3,076.0	2,057.3
Bread/Rolls—Rfg & Fz	807	96	1,236	198	1.5	2.1	354.9	47.9
Breadcrumbs/Batters/ Croutons	816	87	1,013	147	1.2	1.7	204.5	29.7
Cookies	5,055	664	7,383	1,415	1.5	2.1	2,148.2	348.0
Crackers	2,395	381	2,898	622	1.2	1.6	1,676.9	210.4
Snack & Granola Bars	898	80	1,184	109	1.3	1.4	600.8	34.9
Baking Ingredients								
Baking Ingredients	973	194	1,495	303	1.5	1.6	613.3	121.4
Baking Ingredients—Powders	124	13	149	24	1.2	1.8	151.8	17.9
Baking Mixes	1,324	181	1,612	313	1.2	1.7	1,115.1	55.5
Dough—Rfg & Fz	359	111	507	220	1.4	2.0	777.3	230.4
Flour/Meal	961	147	1,468	278	1.5	1.9	330.9	62.6
Nuts—Baking nuts	779	87	1,113	228	1.4	2.6	109.5	22.4
Pizza—Crust/Dough	112	22	132	40	1.2	1.9	38.5	6.4
Beverages								
Bottled Water	1,956	545	2,850	1,465	1.5	2.7	1,095.5	563.1
Carbonated Beverages—Regular	2,320	381	3,821	769	1.6	2.0	5,602.0	831.5
Carbonated Beverages—Sugar substitute	493	136	880	207	1.8	1.5	2,155.5	191.6
Carbonated Beverages—Water/Club Soda	875	542	1,083	720	1.2	1.3	360.5	239.8

(continued)

Table 3-1. Food Product Categories Included in the Reformulation Cost Model (continued)

Product Category	Number of Formulas		Number of SKUs		SKUs per Formula		Annual Units Sold (millions)	
	Branded	Private[a]	Branded	Private[b]	Branded	Private	Branded	Private
Coffee—Ground	1,622	187	2,183	338	1.3	1.8	567.7	63.7
Coffee—Instant	389	86	486	139	1.2	1.6	189.8	14.7
Coffee—Whole	1,262	169	1,460	276	1.2	1.6	43.5	7.0
Creamer/Coffee Additives—Non-Rfg	343	194	487	360	1.4	1.9	90.9	67.2
Creamer—Rfg & Fz	644	257	989	492	1.5	1.9	455.0	226.2
Drink Mixes—Cocktail Mixes	442	16	561	19	1.3	1.2	32.3	0.8
Drink Mixes—Milk/Cocoa Dry Mixes	317	82	449	165	1.4	2.0	164.4	27.3
Drink Mixes—Other	327	132	439	186	1.3	1.4	1,188.1	56.3
Isotonic Drinks	485	43	811	71	1.7	1.6	517.9	12.7
Juices—Aseptic	444	42	579	48	1.3	1.1	379.4	13.6
Juices—Bottled	3,231	531	4,837	1,169	1.5	2.2	1,791.2	432.8
Juices—Canned	768	136	962	203	1.3	1.5	469.8	99.2
Juices—Concentrate, Rfg & Fz	346	200	469	283	1.4	1.4	531.2	320.6
Juices—Rfg	1,910	475	3,303	825	1.7	1.7	1,409.6	352.2
Milk—Condensed	68	55	91	78	1.3	1.4	200.2	172.4
Milk—Flavored/Substitutes	1,294	318	2,239	633	1.7	2.0	312.9	88.4
Milk—Powdered	38	25	61	68	1.6	2.7	6.6	7.3
Milk—Rfg	1,811	2,234	3,855	6,902	2.1	3.1	1,529.3	2,738.0
Non-Fruit Drinks	292	3	433	4	1.5	1.4	150.6	1.2
Tea—Canned/Bottled	679	42	1,099	85	1.6	2.0	429.7	20.9
Tea—Instant	132	81	169	191	1.3	2.4	63.0	22.5
Tea—Loose	1,849	124	2,226	248	1.2	2.0	269.2	30.0

(continued)

Table 3-1. Food Product Categories Included in the Reformulation Cost Model (continued)

Product Category	Number of Formulas		Number of SKUs		SKUs per Formula		Annual Units Sold (millions)	
	Branded	Private[a]	Branded	Private[b]	Branded	Private	Branded	Private
Breakfast Foods								
Breakfast Food—Frozen	227	30	437	78	1.9	2.6	413.2	34.9
Breakfast Food—Instant	41	11	57	32	1.4	2.8	30.4	1.9
Breakfast Food—Ready to Eat	126	46	197	94	1.6	2.0	259.0	64.3
Cereal	1,345	528	1,773	961	1.3	1.8	2,657.1	343.7
Candy & Gum								
Chocolate Candy—Single Serve	838	26	1,100	29	1.3	1.1	1,712.7	0.3
Chocolate Candy—Snack	1,818	161	2,338	217	1.3	1.4	1,193.4	6.0
Gum—Regular Gum	669	17	910	68	1.4	4.0	743.6	3.2
Gum—Sugarless Gum	103	1	156	1	1.5	1.1	528.0	0.0
Nonchocolate Candy—Diet	439	54	559	97	1.3	1.8	46.4	5.0
Nonchocolate Candy—Kits	161	22	219	24	1.4	1.1	31.4	1.4
Nonchocolate Candy—Pkg & Roll	1,653	132	2,618	535	1.6	4.1	895.2	28.0
Nonchocolate Candy—Single Serve	2,340	157	3,306	420	1.4	2.7	750.0	12.2
Nonchocolate Candy—Snack	2,098	252	3,122	837	1.5	3.3	562.5	90.5
Seasonal Candy	2,451	118	5,491	383	2.2	3.2	1,257.6	19.3
Condiments/Dips/ Spreads								
Condiments—Non-Rfg	1,018	155	1,345	383	1.3	2.5	439.7	125.2
Condiments—Rfg	444	22	584	33	1.3	1.5	25.8	0.9
Dips—Dry Mixes	128	19	147	37	1.1	2.0	36.2	2.6
Dips—Rfg & Fz	825	168	1,188	317	1.4	1.9	155.9	41.6
Dips—Shelf Stable	360	25	397	40	1.1	1.6	81.3	3.4

(continued)

Table 3-1. Food Product Categories Included in the Reformulation Cost Model (continued)

Product Category	Number of Formulas		Number of SKUs		SKUs per Formula		Annual Units Sold (millions)	
	Branded	Private[a]	Branded	Private[b]	Branded	Private	Branded	Private
Jams/Jellies/Preserves	2,812	797	4,106	1,581	1.5	2.0	291.0	112.0
Mayonnaise	215	58	314	95	1.5	1.6	461.5	63.4
Peanut Butter	267	44	455	118	1.7	2.7	289.3	75.0
Pickles/Relish/Olives	4,289	1,441	6,742	2,789	1.6	1.9	702.2	290.4
Salad Toppings	140	15	165	42	1.2	2.8	90.4	3.0
Salt/Salt Substitutes	565	105	668	209	1.2	2.0	197.1	61.7
Spices/Seasonings	8,552	1,145	10,122	2,021	1.2	1.8	570.8	113.9
Dairy Foods								
Butter	284	217	355	315	1.3	1.5	235.8	208.9
Cheese—Grated	237	74	331	176	1.4	2.4	72.5	38.5
Cheese—Imitation	120	17	154	25	1.3	1.5	19.9	3.2
Cheese—Natural Cheese	1,807	841	3,029	1,863	1.7	2.2	558.3	343.3
Cheese—Processed Cheese	823	244	1,577	547	1.9	2.2	647.0	224.3
Cheese—Ricotta/Cream/ Cottage	1,049	468	1,600	907	1.5	1.9	597.9	339.0
Cheese—Shredded	448	283	749	519	1.7	1.8	367.3	254.3
Frozen Novelties	3,574	782	5,704	1,434	1.6	1.8	686.0	172.4
Ice Cream & Ice Milk	5,642	2,347	7,927	3,009	1.4	1.3	864.0	327.9
Sour Cream	384	161	577	320	1.5	2.0	273.6	151.7
Yogurt	1,867	442	2,160	554	1.2	1.3	1,884.7	483.8
Desserts								
Desserts—Toppings	331	68	407	115	1.2	1.7	280.4	79.2
Gelatin/Pudding— Mixes	474	191	554	336	1.2	1.8	623.4	68.1
Gelatin/Pudding— Regular	755	154	1,007	245	1.3	1.6	450.1	18.7

(continued)

Table 3-1. Food Product Categories Included in the Reformulation Cost Model (continued)

Product Category	Number of Formulas		Number of SKUs		SKUs per Formula		Annual Units Sold (millions)	
	Branded	Private[a]	Branded	Private[b]	Branded	Private	Branded	Private
Pies & Cakes—Non-Rfg	2,152	1,670	2,353	3,681	1.1	2.2	96.0	80.7
Pies & Cakes—Rfg & Fz	964	433	1,201	760	1.2	1.8	248.6	10.3
Dietary Supplements								
Dietary Supplements—Liquid	376	23	1,642	102	4.4	4.4	20.3	1.3
Dietary Supplements—Pills	6,536	2,833	17,874	9,896	2.7	3.5	599.8	332.0
Dressings & Sauces								
Gravy/Sauce—Canned/Bottled	5,880	411	7,344	673	1.2	1.6	1,312.6	120.3
Gravy/Sauce—Mixes	1,441	198	1,666	357	1.2	1.8	565.6	121.1
Gravy/Sauce—Rfg & Fz	685	78	865	106	1.3	1.4	40.0	4.2
Salad Dressing—Bottled, non-rfg	1,798	233	2,206	372	1.2	1.6	624.7	52.0
Salad Dressing—Dry Mix	74	11	87	15	1.2	1.3	58.6	1.2
Salad Dressing—Rfg	416	38	504	50	1.2	1.3	57.6	1.4
Vinegar	817	404	1,134	975	1.4	2.4	78.4	67.4
Eggs								
Processed Eggs	25	3	42	8	1.7	2.8	51.1	8.1
Shell Eggs	758	1,041	1,294	4,431	1.7	4.3	391.8	1,341.7
Entrees								
Entrées—Fz	3,323	412	3,949	596	1.2	1.4	2,686.0	63.1
Entrées—Rfg	1,137	446	1,361	680	1.2	1.5	154.7	39.2
Entrées—Shelf Stable	826	233	1,051	290	1.3	1.2	1,030.8	108.5
Lunches—Rfg	81	26	147	90	1.8	3.4	325.0	16.9
Pizza—Pizza/Kits/Mixes, Rfg & Fz	1,215	212	1,555	591	1.3	2.8	819.8	67.8

(continued)

Table 3-1. Food Product Categories Included in the Reformulation Cost Model (continued)

Product Category	Number of Formulas		Number of SKUs		SKUs per Formula		Annual Units Sold (millions)	
	Branded	Private[a]	Branded	Private[b]	Branded	Private	Branded	Private
Fats & Oils								
Lard/Shortening	101	23	152	36	1.5	1.6	76.3	18.2
Margarine	241	63	332	87	1.4	1.4	924.6	123.1
Oil	1,129	354	1,686	768	1.5	2.2	358.0	163.0
Fruits & Vegetables								
Beans—Canned	300	48	477	102	1.6	2.1	705.5	75.4
Fruit—Canned/Bottled	997	378	1,247	761	1.3	2.0	1,127.8	403.6
Fruit—Dried	1,360	218	1,724	313	1.3	1.4	203.5	36.9
Fruit—Dry Fruit Snacks	249	28	303	34	1.2	1.2	244.2	17.8
Fruit—Fz	310	502	364	761	1.2	1.5	32.6	68.1
Fruit—Sauce	306	70	420	177	1.4	2.5	189.9	79.9
Tomato Products—Canned/Bottled	469	166	645	343	1.4	2.1	412.9	219.7
Tomato Products—Sauce	1,590	1,113	1,911	1,806	1.2	1.6	431.3	407.5
Vegetables—Canned/Bottled	2,523	768	3,438	2,023	1.4	2.6	2,386.5	1,404.3
Vegetables—Dried	1,428	1,191	1,944	2,299	1.4	1.9	103.6	122.5
Vegetables—Fresh Cut Salad	265	82	319	145	1.2	1.8	563.6	63.4
Vegetables—Frozen	1,599	894	2,071	1,507	1.3	1.7	1,003.9	730.5
Infant Foods								
Baby Food	609	1	684	1	1.1	1.1	1,404.9	0.0
Baby Formula—Liq Concentrate	28	0	41	0	1.5	0.0	309.6	0.0
Baby Formula—Powder	55	8	91	10	1.7	1.3	141.4	0.8
Baby Formula—Ready to Drink	72	14	109	30	1.5	2.1	109.0	6.4
Baby Juice	94	0	121	0	1.3	0.0	136.4	0.0

(continued)

Table 3-1. Food Product Categories Included in the Reformulation Cost Model (continued)

Product Category	Number of Formulas		Number of SKUs		SKUs per Formula		Annual Units Sold (millions)	
	Branded	Private[a]	Branded	Private[b]	Branded	Private	Branded	Private
Seafood								
Seafood—Canned	1,356	117	2,279	273	1.7	2.3	1,429.2	171.3
Seafood—Fz	1,833	277	2,606	474	1.4	1.7	191.8	33.2
Seafood—Rfg	607	55	1,062	125	1.7	2.3	51.2	6.0
Side Dishes & Starches								
Instant Potatoes	220	64	285	110	1.3	1.7	195.0	30.1
Pasta—Dry	4,257	792	4,984	1,252	1.2	1.6	1,057.2	265.7
Pasta—Rfg & Fz	1,002	192	1,239	271	1.2	1.4	144.2	13.5
Rice	1,301	219	1,875	361	1.4	1.6	625.1	120.4
Side Dishes—Fz	1,344	215	1,576	266	1.2	1.2	347.4	12.1
Side Dishes—Kits/Mixes	1,229	219	2,150	478	1.7	2.2	1,576.1	282.9
Side Dishes—Rfg	1,067	361	1,659	683	1.6	1.9	154.4	63.6
Side Dishes—Shelf Stable	363	41	429	51	1.2	1.2	64.3	7.7
Stuffing	212	57	244	87	1.2	1.5	146.9	24.5
Snack Foods								
Nuts—Snack nuts	2,095	358	3,003	864	1.4	2.4	337.7	97.2
Salty Snacks—Bagged	4,299	289	8,333	857	1.9	3.0	3,575.7	320.3
Salty Snacks—Other	1,842	118	2,949	205	1.6	1.7	934.0	17.0
Salty Snacks—Unpopped Popcorn	331	73	593	166	1.8	2.3	303.7	77.3
Seeds—Snack	531	46	696	95	1.3	2.1	80.1	7.5
Soups								
Soup—Canned	1,113	126	1,388	215	1.2	1.7	2,496.5	340.3
Soup—Dry	1,183	97	1,463	179	1.2	1.8	285.6	28.6
Soup—Ramen	294	23	390	40	1.3	1.8	1,368.9	49.8

(continued)

Table 3-1. Food Product Categories Included in the Reformulation Cost Model (continued)

Product Category	Number of Formulas		Number of SKUs		SKUs per Formula		Annual Units Sold (millions)	
	Branded	Private[a]	Branded	Private[b]	Branded	Private	Branded	Private
Sweeteners								
Sugar	203	161	321	371	1.6	2.3	356.9	412.2
Sugar Substitutes	86	17	152	47	1.8	2.8	86.6	12.5
Syrup/Molasses	979	232	1,226	373	1.3	1.6	189.7	57.7
Weight Control Foods								
Weight Control Liq/Powder	648	42	1,203	65	1.9	1.5	230.2	12.4

[a]Private label formulas are estimated based on the number of formulas for branded products.

[b]Private label SKUs are estimated based on the number of SKUs for branded products.

Source: Based on scanner data obtained from IRI for calendar year 1999.

formulas) and for multiproduct packaging bundles (approximately 4.7 percent of formulas).[2]

IRI scanner data aggregate into a single record all private-label SKUs for similar sizes and flavors. Therefore, we adjusted our initial private label SKU and formula counts to account for this. For the SKU adjustment, the process we followed is based on the relationship between unit sales and number of SKUs for branded products and is the same as in the labeling cost model (Muth, Gledhill, and Karns, 2001). Within each of the product categories, we subdivided the SKUs and calculated the annual units sold for private label and branded products. We then calculated the ratio of SKUs to annual units sold for branded products (B) and multiplied the ratio by the annual units sold for private label products (PL) as follows:

$$\text{Estimated SKUs}_{PL} = (\text{SKUs}_B / \text{Units}_B) * (\text{Units}_{PL})$$

For categories in which a large proportion of the products sold are branded (e.g., aseptic juices, baby formula, and candy), this

[2]Another factor that may cause our counting process to overstate the true number of formulas is that manufacturers may package essentially the same formula under different brand names. However, we are unable to estimate an adjustment factor for these occurrences using scanner data.

calculation results in a lower estimate of the number of SKUs than simply using the number of private label SKU-level records in the IRI dataset. In these cases, we used the number of private label SKU-level records as the estimate instead of using the calculation described above.

Once we derived a final estimate of the number of private label SKUs, we then adjusted the initial count of private label formulas as follows:

$$\text{Estimated Formulas}_{PL} = \left(\frac{\text{Estimated SKUs}_{PL}}{\text{Counted SKU}_{PL}}\right) * \text{Counted Formulas}_{PL}$$

As in the labeling cost model, we made an adjustment to the dietary supplement SKU counts because IRI tracks only vitamins and minerals and not other types of dietary supplements. Based on data published in *Nutrition Business Journal* (2000), we calculated that approximately half of all dietary supplements sold in 1999 were vitamin and mineral products. Thus, we scaled up the number of formulas, SKUs, and units sold for vitamins and minerals in the IRI dataset by doubling both numbers.

Cosmetic Product Categories

Table 3-2 lists the product categories, number of formulas, number of SKUs, and annual units sold for cosmetic products included in the model. Because ACNielsen does not differentiate branded and private label cosmetic products, the data presented in Table 3-2 combine both.[3] These product categories account for an estimated 48,000 formulas and $43.1 billion in sales in grocery stores, drug stores, and mass merchandise stores.

To derive the counts of the number of unique formulas for cosmetic products, we relied on information derived from the disaggregated data for food products. For food products, each formula had a median retail dollar sales volume of $900,000, and each formula had a median 1.55 SKUs. Thus, for cosmetic products we calculated the number of formulas as total dollar sales volume divided by $900,000, and the number of SKUs as the number of formulas times 1.55.

[3] In general, substantially fewer cosmetic products are sold as private label, and the costs of reformulation are likely similar.

Table 3-2. Cosmetic Products Included in Reformulation Cost Model

Product Category	Number of Formulas[a]	Number of SKUs[b]	Annual Units Sold
Hair Care			
Shampoo	2,010	3110	671.1
Conditioner	960	1480	339.9
Hair Coloring	1,570	2430	235.3
Wave-Setting	740	1140	270.0
Women's Hair Spray	480	740	229.3
Hair Growth	140	210	4.5
Ethnic Hair Preparations	210	320	52.8
Other Hair Care	1,620	2510	586.7
Oral Hygiene			
Toothpaste	1,920	2970	748.9
Antiseptics/Rinses	840	1300	246.6
Other Oral Hygiene	790	1220	228.6
Facial Products			
Facial Make-up	1,250	1930	194.3
Eye Make-up	1,070	1650	244.8
Lipstick & Lip Remedies	1,230	1900	391.1
Other Facial Products	170	260	39.0
Nail Products	820	1270	308.0
Skin Care Preparations			
Lotions	2,400	3720	477.7
Talc & Dusting Powder	70	100	21.6
Suntan Preparations	570	880	78.6
Other Skin Care	970	1500	196.6
Hair Removal			
Shaving Cream	440	680	219.0
Depilatories	110	170	20.4
Deodorant			
Stick/Solid Deodorant	1,220	1890	507.3
Roll-on Deodorant	170	260	50.7
Aerosol Deodorant	250	380	76.0
Cologne & Other Deodorants	290	440	118.6

(continued)

Table 3-2. Cosmetic Products Included in Reformulation Cost Model (continued)

Product Category	Number of Formulas[a]	Number of SKUs[b]	Annual Units Sold
Baby Care			
Baby Oils, Ointments, Lotions	210	320	69.2
Baby Powder	90	130	41.4
Baby Bath Soap	70	100	27.6
Fragrances			
Fragrances	1,110	1720	127.6

[a]Number of formulas are estimated based on dollar sales.

[b]Number of SKUs are estimated based on formulas.

Source: Based on aggregated scanner data obtained from ACNielsen for calendar year 1999.

3.2.2 Cost Estimates Used in the Reformulation Model

As described in Section 2, the reformulation process varies depending on the importance of an ingredient in the product, the likely response of manufacturers, and the compliance period. After conducting data collection interviews, we modified our preliminary hypotheses regarding the correspondence between the type of reformulation and the steps involved in a typical reformulation process. The final correspondences are indicated in Table 3-3. A bullet in a cell indicates that the cost associated with that step in the reformulation process is included in the cost estimate calculation in the model. Other costs that may be included as user selections within the model are analytical tests, sensory evaluation tests, and consumer sampling tests.

The cost estimates include the following:

- ➤ The activities associated with the actual reformulation process, which may include
  - ✓ idea generation,
  - ✓ product research and development,
  - ✓ coordinating activities (purchasing, legal, marketing, and quality control),
  - ✓ product performance testing (shelf-life studies and safety studies),
  - ✓ packaging development,
  - ✓ market testing, and

Table 3-3. Correspondence Between Type of Reformulation, Ingredient Importance, and Steps in the Reformulation Process

Cost	Ingredient Substitution				Processing Change
	Non-critical Minor Ingredient	Critical Minor Ingredient with Functional Effects	Critical Minor Ingredient with Safety Effects	Major Ingredient	
Idea generation	●	●	●	●	●
Product development					
Product research	●	●	●	●	●
Process development	●	●	●	●	●
Coordinating activities[a]	●	●	●	●	●
Product testing					
Shelf-life studies	●	●	●	●	●
Safety studies			●	●	●
Packaging development			●	●	●
Market testing				●	●
Production/manufacturing					
Change process					●
Plant trial		●	●	●	●
Start-up and verification	●	●	●	●	●
Discarded inventory					
Finished product	●	●	●	●	●
Raw materials	●	●	●	●	●

[a]Coordinating activities include activities conducted by the purchasing, legal, marketing, and quality control departments.

- ✓ production or manufacturing adjustments (changing the process, running a plant trial, and conducting start-up and verification).

➤ The costs associated with additional testing activities, which may include

- ✓ analytical testing,
- ✓ sensory evaluation, and
- ✓ consumer sampling.

- ➤ The costs associated with discarding unused inventory, which may include
  - ✓ raw materials and
  - ✓ finished products.

Reformulation Process Costs

Tables 3-4a and 3-4b present the low, medium, and high per-formula cost estimates for the types of activities involved in the reformulation process based on the level of importance of the ingredient and the likely response of manufacturers. We developed the cost estimates for each of the steps from respondents' estimates of the number of workers' effort hours required multiplied by appropriate wage rates (including fringe benefits) plus the cost of purchased materials. If the activity was typically contracted out, we requested an estimate of the total price paid.

Across the manufacturers we interviewed, there was a wide range of cost estimates for each reformulation activity. Several respondents informed us that some reformulations prove to be quite difficult, requiring a large number of candidate formulas before a suitable one is found. These difficult reformulations, which cannot be fully anticipated, may cost several times as much as the easiest ones of the same type.

Additional Testing Activities

The reformulation cost model includes three additional types of testing—analytical testing, sensory evaluation, and consumer sampling. Depending on the level of importance of the ingredient and likely response of manufacturers, the model displays default test assumptions. The user may accept these default assumptions or alter them based on other information sources.

The analytical testing cost estimates are an augmented version of the labeling cost model cost information, while the sensory evaluation and consumer sampling cost estimates were derived separately. We developed these estimates using published price and service lists available on the Internet from several testing laboratories.

Table 3-4a. Cost Estimates for Steps in the Reformulation Process: Substitution for Minor Ingredients

	Noncritical Minor			Critical Minor with Functional Effects			Critical Minor with Safety Effects		
	Low	Med	High	Low	Med	High	Low	Med	High
Idea generation	$421	$2,105	$5,052	$842	$4,210	$10,104	$842	$4,210	$10,104
Product development									
Product research	$1,303	$13,025	$26,050	$2,605	$26,050	$52,100	$2,605	$26,050	$52,100
Process development	$3,553	$10,065	$21,840	$7,105	$20,130	$43,680	$7,105	$20,130	$43,680
Coordinating activities (purchasing, legal, marketing, quality control)	$2,271	$6,812	$11,353	$4,541	$13,623	$22,705	$4,541	$13,623	$22,705
Product testing									
Safety studies	$0	$0	$0	$0	$0	$0	$1,000	$2,850	$10,500
Shelf-life studies	$643	$2,213	$5,351	$1,285	$4,426	$10,702	$1,285	$4,426	$10,702
Packaging development	$0	$0	$0	$0	$0	$0	$3,105	$8,263	$15,525
Market testing	$0	$0	$0	$0	$0	$0	$0	$0	$0
Production/manufacturing									
Change process	$0	$0	$0	$0	$0	$0	$0	$0	$0
Plant trial	$0	$0	$0	$1,684	$6,140	$22,281	$1,684	$6,140	$22,281
Start-up and verification	$1,114	$5,570	$12,281	$2,228	$11,140	$44,562	$2,228	$11,140	$44,562
Total costs per formula	$9,305	$39,790	$81,927	$20,290	$85,719	$206,134	$24,395	$96,832	$232,159

Table 3-4b. Cost Estimates for Steps in the Reformulation Process: Major Ingredients, Process Changes, and Unknown

	Noncritical Minor			Critical Minor with Functional Effects			Critical Minor with Safety Effects		
	Low	Med	High	Low	Med	High	Low	Med	High
Idea generation	$1,684	$8,420	$20,208	$1,684	$8,420	$20,208	$421	$4,210	$20,208
Product development									
Product research	$5,210	$52,100	$104,200	$5,210	$52,100	$104,200	$1,303	$26,050	$104,200
Process development	$14,210	$40,260	$87,360	$14,210	$40,260	$87,360	$3,553	$20,130	$87,360
Coordinating activities (purchasing, legal, marketing, quality control)	$9,082	$27,246	$45,410	$9,082	$27,246	$45,410	$2,271	$13,623	$45,410
Product testing									
Safety studies	$2,000	$5,700	$21,000	$2,000	$5,700	$21,000	$0	$5,700	$21,000
Shelf-life studies	$2,570	$8,851	$21,404	$2,570	$8,851	$21,404	$643	$4,426	$21,404
Packaging development	$6,210	$16,525	$31,050	$6,210	$16,525	$31,050	$0	$8,263	$31,050
Market testing	$40,000	$70,000	$115,000	$40,000	$70,000	$115,000	$0	$40,000	$115,000
Production/manufacturing									
Change process	$0	$0	$0	$2,363	$7,816	$17,266	$0	$7,816	$17,266
Plant trial	$3,368	$12,281	$104,562	$3,368	$12,281	$104,562	$0	$6,140	$104,562
Start-up and verification	$4,456	$22,281	$109,123	$4,456	$22,281	$109,123	$1,114	$11,140	$109,123
Total costs per formula	$88,790	$263,664	$659,317	$91,153	$271,480	$676,583	$9,305	$147,498	$676,583

Analytical Testing Costs. In the reformulation cost model, the user chooses which analytical tests to include in the cost estimates. For each formula, the total analytical test cost calculation includes

- ➤ the cost of testing two samples,
- ➤ 1 hour of labor to prepare and package the samples ($14.73), and
- ➤ delivery charges for one 2-pound package delivered overnight ($26.30).

Table 3-5 provides low, medium, and high cost estimates for the set of analytical tests included as options in the model. The labor cost estimate was based on average total compensation (wages and benefits) for "handlers, equipment cleaners, helpers, and laborers" in manufacturing industries (U.S. Department of Labor, 2001). The delivery charge estimate was based on the average charge for delivery of a 2-pound package overnight by FedEx (FedEx, 2001).

Sensory Evaluation Test Costs. In the reformulation cost model, the user chooses which sensory evaluation tests to include in the cost estimates. For each test the user selects, we assume that manufacturers perform at least two sensory evaluation tests—one with an experienced panel and one with a consumer panel. Table 3-6 provides the low, medium, and high cost estimates for the set of sensory evaluation tests included as options in the model.

Consumer Sampling Test Costs. In the reformulation cost model, the user chooses which consumer sampling tests to include in the cost estimates. For each test the user selects, we assume that manufacturers perform a number of specified tests. Table 3-7 provides the low, medium, and high cost estimates for the set of consumer sampling tests included as options in the model.

Discarded Inventory Costs

For short compliance periods, manufacturers may need to discard finished goods that cannot be sold prior to the effective date of the regulation. In addition, long-term contracts for raw materials often require purchase of specified quantities; if the ingredient in question is eliminated from the new formula, the manufacturer may still be obligated to pay for the material. In most cases, producers will have sufficient time to sell through existing inventories and

Table 3-5. Analytical Testing Cost Estimates (Selected by the Model User)
In the model, these costs are multiplied by two tests, and labor and shipping costs are added.

Type of Test	Low	Medium	High
NLEA panel	$485	$560	$650
Fatty acid profile	$75	$125	$275
Trans fatty acids	$110	$125	$165
Sugar profile	$50	$73	$300
Peroxide	$20	$33	$46
Soluble fiber	$80	$133	$190
Insoluble fiber	$80	$100	$185
Vitamins	$32	$72	$260
Minerals	$12	$33	$85
Iodine	$45	$60	$90
Acidity (pH)	$15	$19	$23
Microbiological screen	$55	$64	$73
Iodine value (IV)	$30	$48	$65
Pathogens	$8	$26	$85
Bioengineered—PCR test	$245	$300	$355
Bioengineered—ELISA lab test	$50	$60	$70
Bioengineered—ELISA strip test	$5	$7.50	$10
Caffeine	$65	$103	$110
Allergens	$70	$85	$100
Dietary supplement—vitamins	$32	$72	$260
Dietary supplement—minerals	$12	$33	$85
Dietary supplement—amino acids	$100	$160	$260
Dietary supplement—botanicals	$110	$205	$400
Dietary supplement—other ingredients	$125	$225	$450

Table 3-6. Sensory Evaluation Test Cost Estimates (Selected by the Model User)

Type of Test	Low	Medium	High
Descriptive test	$480	$960	$1,440
Discrimination test	$690	$1,380	$2,070
Preference and acceptability test	$1,640	$3,280	$4,920

Table 3-7. Consumer Sampling Test Cost Estimates (Selected by the Model User)

Type of Test	Low	Medium	High
Focus groups	$8,000	$20,000	$30,000
In-home tests	$15,000	$50,000	$60,000
Central location tests	$8,000	$15,000	$20,000

fulfill contract conditions. We assume that this is the case for 24-, 36-, and 48-month compliance periods.

However, for the 12-month compliance period, the model calculates rough estimates of the value of discarded inventory based on the dollar sales volume for the product category. The assumptions used in these calculations are included in Table 3-8. Using these assumptions, the total costs of discarded inventory are (annual proportion of inventory remaining) * (ratio of item cost to retail price) * (total dollar sales volume for the product category). The estimates for raw materials and finished goods are then added together to determine the total estimated discarded inventory costs.

Table 3-8. Discarded Inventory Calculation Assumptions

Inventory Item	Annual Proportion Remaining (Private Label)	Annual Proportion Remaining (Branded)	Ratio of Item Cost to Retail Price
Raw Materials	0.05	0.025	0.2
Finished Goods	0.05	0.025	0.5

3.3 REFORMULATION COST MODEL CALCULATIONS

Using the data tables described in Section 3.2, the model calculates the costs of reformulating a food or cosmetic product. Table 3-9 describes the variables used in the model calculations. The user makes the following selections in the model:

- ➤ affected product category, PC;
- ➤ the proportion of the product category that is affected, a;

Table 3-9. Descriptions of Variables Used in the Reformulation Cost Model Calculations
These variables are used to calculate the costs of reformulating food, dietary supplement, and cosmetic products.

Variable	Description
PC	Affected product category
x	Total number of *affected* formulas for a product category
y	Total number of formulas for a product category
a	Proportion of a product category that is affected by a regulation
c	Proportion of a product category that could be coordinated with a scheduled change
i	Ingredient importance (minor, minor with functional effects, minor with safety effects, major)
r	Response of manufacturers (substitute ingredient, change production process)
d	Discount rate or inflation factor
b	Cost adjustment factor for 12-month compliance period (assumed 0.1)
IDE	Idea generation costs
RES	Product research costs
DEV	Process development costs
COR	Coordinating activity costs—legal, purchasing, marketing, quality control
PKG	Package development costs
MAR	Market testing costs
SHL	Shelf-life testing costs
SAF	Safety testing costs
PRO	Production process change costs
TRI	Plant trial costs
STP	Start-up and verification costs
ANT	Analytical testing costs
SEN	Sensory evaluation test costs
CON	Consumer sampling test costs

- the proportion of products that could be coordinated with a scheduled reformulation, c;
- importance of the affected ingredient, i;
- likely response of the manufacturer, r;
- types of analytical testing (optional), ANT;
- types of sensory evaluation testing (optional), SEN;
- types of consumer sampling testing (optional), CON; and
- an inflation or discounting factor, d.

For each affected product *category*, the number of affected product *formulas* is calculated as follows:

$$x = a * (1-c) * y$$

where y is the total number of product formulas for the product category. Thus, the number of affected product formulas is adjusted for the proportion of the category that is affected by the regulation and the proportion of the products that could coordinate a required reformulation with a required reformulation.

The low, medium, and high cost estimates for the reformulation process for each product category, PC, are calculated as follows:

$$COST_{PC,i,r} = (1 + b) * (IDE_{i,r} + RES_{i,r} + DEV_{i,r} + COR_{i,r} + PKG_{i,r} + MAR_{i,r} + SHL_{i,r} + SAF_{i,r} + PRO_{i,r} + TRI_{i,r} + STP_{i,r})$$

In other words, the cost of the reformulation process depends on the affected ingredient, i, and the likely response of manufacturers, r.

We then add the costs of the user selected test options as follows:

$$TEST_{PC} = \sum_j ANT_j + \sum_k SEN_k + \sum_l CON_l.$$

where j indexes the types of analytical test, k indexes the types of sensory evaluation test, and l indexes the types of consumer sampling tests.

Finally, the total cost of the reformulation is

$$(1+d) * (COST_{PC,I,r} + TEST_{PC}) * x.$$

As discussed previously, for the 1-year compliance period, we also assume that manufacturers must discard some proportion of their raw materials and finished products. The formula used to calculate

discarded inventory costs is described in Section 3.2. For longer compliance periods, we assume that manufacturers would have sufficient time to deplete their inventories.

3.4 CONSIDERATIONS BEYOND THE MODEL

As we constructed the model and conducted interviews with manufacturers, we identified several considerations that could not be addressed in the current modeling framework. FDA may wish to consider addressing these issues in future data collection efforts. These include the following:

- **The current modeling framework includes the one-time costs for reformulating products, but manufacturers may incur ongoing costs associated with the regulation.** Ongoing costs may include higher cost ingredients, additional processing steps, and changes in yield of the product. These costs are difficult to estimate and generalize because they vary substantially from product to product and by type and complexity of the reformulation.
- **The current modeling framework includes the costs of reformulation on a per-formula basis, but manufacturers may potentially achieve cost savings by reformulating multiple product formulas simultaneously.** In our interviews with manufacturers, they reported that they frequently reformulate several product versions at one time. It is certainly reasonable to expect that there may be "economies of scope" associated with reformulation activities. Making an adjustment to account for this potential would require detailed information about the typical number of similar products produced by a manufacturer.
- **Under some situations, a manufacturer may choose to stop producing a product rather than reformulate to comply with a regulation.** We received information in our interviews that small firms would be more likely than large firms to stop production if their reformulation costs were large. Large firms reported they would likely bear even very high costs, as long as their competitors were similarly affected.

3.5 REFERENCES

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4 Instructions for Using the Reformulation Cost Model

In this section, we describe the procedures for obtaining cost estimates using the reformulation cost model. The data sets that form the core of the model are in Stata for Windows, and the interface is in Microsoft Excel. Once the user chooses the options for running the model, the program executes in Stata for Windows and returns the results in an Excel spreadsheet. The advantage to maintaining the data sets in Stata for Windows is that the user can conduct any additional types of desired analyses within Stata for Windows without converting the data sets from another format. While running the model, the user will not work directly in the Stata for Windows environment.

4.1 PREPARING TO RUN THE MODEL

Prior to running the reformulation cost model, you must install the program files on your personal computer. To install the program files, you will need to do the following:

1. Create a folder on your hard disk called **C:\Reformulation**.
2. Copy the following files into the **C:\Reformulation** folder:
   - ✓ the Excel interface file: **reformulation model.xls**
   - ✓ the Stata data files: **analytical.dta, consumer.dta, inventory.dta, product.dta, response.dta, and sensory.dta.**
   - ✓ the Stata program file: **reform.do**

In Section 4.2, we provide instructions for running the model. However, prior to running the model, it may be useful to review the process by which the model runs. The process is as follows:

- ➤ Open the Excel interface (**reformulation model.xls**) and choose the model inputs.
- ➤ The Excel interface outputs the model inputs into a text file in the **C:\Reformulation** folder, calls up the Stata for Windows program, and waits for an output file.
- ➤ The Stata for Windows program (**reform.do**) reads the text file of user inputs, calculates the reformulation cost estimates, and outputs a tab-delimited text file called **reformcost.out** into the **C:\Reformulation** folder.
- ➤ The Excel interface program opens the **reformcost.out** file and dumps the cost estimates into the **Data** and **Aggregate Data** sheets and dumps the user inputs into the **Inputs** sheet.
- ➤ The Excel program creates the following two pivot tables (each on a separate sheet):
  - ✓ **Aggregate Costs**, which displays the total low, medium, and high cost estimates by product category;
  - ✓ **All Costs**, which displays the detailed low, medium, and high cost estimates for each product category; and
  - ✓ **Totals by Cost Type**, which displays the total low, medium, and high cost estimates by type of cost for all product categories combined.

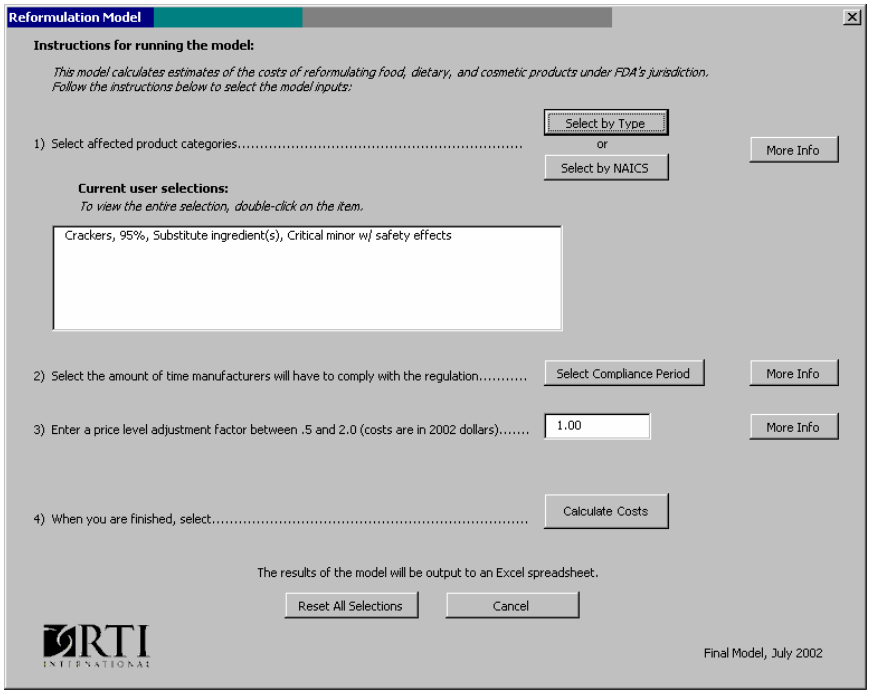
4.2 SELECTING MODEL INPUTS

Step 1: Open the file **reformulation model.xls** by double-clicking on the file name.

To select the inputs for running the labeling cost model, open the Excel file **reformulation model.xls**. Once the model has opened, click [**Start Reformulation Model**] and the Main Menu screen will appear (see Figure 4-1). This menu will guide you through the process of choosing the inputs for the model.

You may click [**Cancel**] on the Main Menu to exit the model at any time, and you may click [**Reset All Selections**] on the Main Menu to clear all of your selections on every menu. Click [**Reset Selections**] at the bottom of the other menus to clear your selections on that particular menu. To learn more about any of the model inputs, you may click the [**More Info**] buttons on the right side of the Main Menu or at the bottom of each input menu.

Figure 4-1. The Main Menu Screen for the Reformulation Cost Model
Follow the steps on the Main Menu screen to select the model inputs.



Step 2: Choose affected product categories sorted by either:

- ➤ product types or
- ➤ NAICS codes.

You may select product categories sorted by Product Type OR by NAICS code. You may also select an entire Product Type OR and entire NAICS code. Although you may select more than one category, type, or NAICS code to include in a cost estimation, they must be chosen individually because of several assumptions that are linked with each selection. Having these assumptions linked to individual product categories, types, or NAICS codes allows you to vary the assumptions by selection rather than assume that they are the same across all selected categories, types, and/or NAICS codes. These assumptions include the percentage of the formulas in the category that would be affected by the regulation, the response of manufacturers within that product category to the regulation, and the level of importance the regulated ingredient has in that product category.

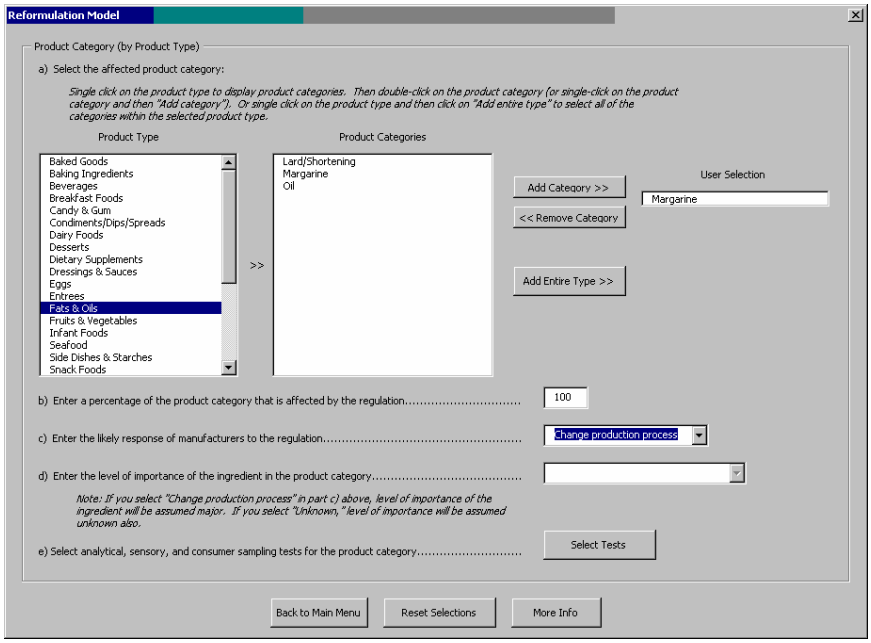
To select product categories by IRI-based product types, begin here.

To choose the affected product categories sorted by Product Type or an entire product type:

➤ Click [**Select by Type**].

When you click [**Select by Type**], a new menu will open (see Figure 4-2). On this menu, you may choose an individual product

Figure 4-2. The Product Selection Screen for Choosing Product Categories by IRI-Based Product Types
You may choose product categories by product type or by NAICS codes (see Figure 4-3).



category to include in the model. To select an individual product category:

- ➤ Click on a product type from the "Product Type" list on the far left of the menu. Once a product type is highlighted, all of the product categories within the type will display in the "Product Categories" list immediately to the right.
- ➤ Double-click on the desired product category in the "Product Categories" list and it will display in the "User Selection" box.

OR:

- ➤ Click on the desired product category in the "Product Categories" list. Click [**Add Category**]. The selected category will then display in the "User Selection" box.

To select an entire product type:

- ➤ Click on a product type from the "Product Type" list at the far left of the menu.
- ➤ Click [**Add Entire Type**].

To remove the selected product category or type from the "User Selection" box:

- ➤ Double-click on the product category or product type in the "User Selection" box.

OR:

➤ Click on the category or product type in the "User Selection" box and then click [**Remove Category**].

To select the percentage of the product category or type that is affected by the regulation:

➤ Click on the percentage affected text box and enter a value between 0 and 100.

To select the likely response of manufacturers to the regulation:

➤ Click on the arrow in the manufacturer's response drop-down box and select **Substitute ingredient(s), Change production process,** or **Unknown.**

Once the manufacturer response has been chosen, the ingredient importance must be chosen. If you select **Change production process** as the manufacturer response, then the model assumes the ingredient importance to be major, and the ingredient importance drop-down box is deactivated. Similarly, if you selected **Unknown** as the manufacturer response, then the model assumes the ingredient importance to be unknown and the ingredient importance drop-down box is also deactivated. To select the level of importance of the ingredient in the product category:

➤ Click on the arrow in the ingredient importance drop-down box and select **Noncritical minor**, **Critical minor w/ functional effects**, **Critical minor w/ safety effects**, or **Major**.

➤ If you would like to clear your selections on this screen only, click [**Reset Selections**].

The selected manufacturer response and the ingredient importance level determine default tests to be assumed by the model. If you would like to select additional tests, or alter the defaults,

➤ Click [**Select Tests**]

OR:

If you would like to retain the default tests,

➤ Click [**Back to Main Menu**]

A message box will appear to confirm that you accept the assumed default tests. If you would like to retain the defaults, click [**Yes**] and you will be returned to the Main Menu. If you would like to alter the selected tests, click [**No**] and the Test Menu will open.

To select product categories by NAICS code, begin here.

To choose the affected product categories sorted by NAICS code or an entire NAICS code:

➤ Click [**Select by NAICS**]

When you click [**Select by NAICS**], a new menu will open (see Figure 4-3). On this menu, you may choose an individual product category or an entire NAICS code to include in the model. To choose an individual product category:

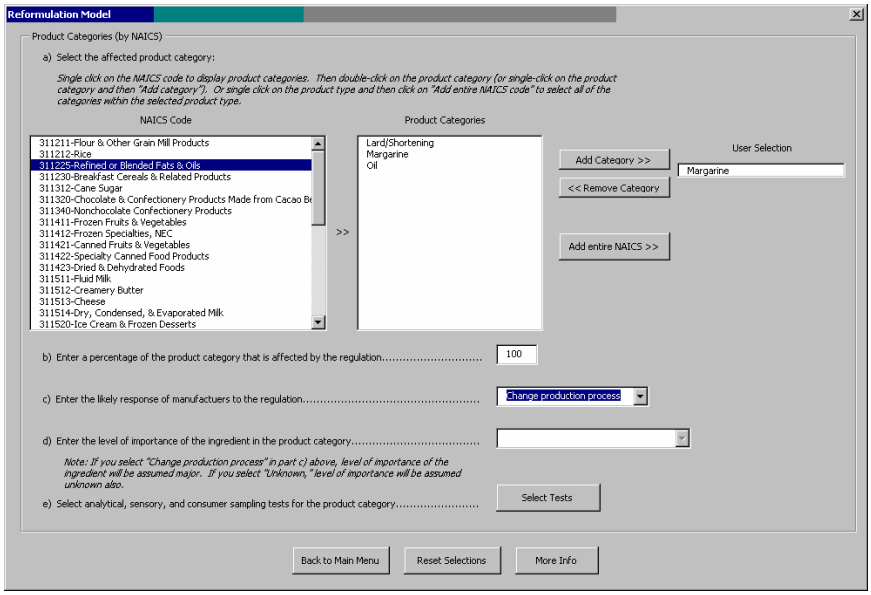
➤ Click on a product type from the "NAICS Code" list on the far left of the menu. Once a product type is highlighted, all of the product categories within the type will display in the "Product Categories" list immediately to the right.

➤ Double-click on the desired product category in the "Product Categories" list and it will display in the "User Selection" box.

OR:

➤ Click on the desired product category in the "Product Categories" list. Click [**Add Category**]. The selected category will then display in the "User Selection" box.

Figure 4-3. The Product Selection Screen for Choosing Product Categories by NAICS Codes
You may choose product categories by NAICS codes or by product types (see Figure 4-2).



To select an entire NAICS code:

➤ Click on a NAICS code from the "NAICS Code" list on the left of the menu.

➤ Click [**Add Entire NAICS**]

To remove the selected product category or entire NAICS code from the "User Selection" box:

➤ Double-click on the product category or NAICS code in the "User Selection" box.

OR:

➤ Click on the product category or NAICS code in the "User Selection" box and then click [**Remove Category**].

To select the percentage of the product category or NAICS code that is affected by the regulation:

➤ Click on the percentage affected text box and enter a value between 0 and 100.

To select the likely response of manufacturers to the regulation:

➤ Click on the arrow in the manufacturer's response drop-down box and select **Substitute ingredient(s), Change production process,** or **Unknown**.

Once the manufacturer response has been chosen, the ingredient importance must be chosen. If you selected **Change production process** above, then the model assumes the ingredient importance to be major, and the ingredient importance drop-down box is deactivated. Similarly, if you selected **Unknown** as the manufacturer response, then the model assumes the ingredient importance to be unknown and the ingredient importance drop-down box is also deactivated. To select the level of importance of the ingredient in the product category:

➤ Click on the arrow in the ingredient importance drop-down box and select **Noncritical minor**, **Critical minor w/ functional effects**, **Critical minor w/ safety effects**, or **Major**.

➤ If you would like to clear your selections on this screen only, click [**Reset Selections**].

The selected manufacturer response and the ingredient importance level determine default tests to be assumed by the model. If you would like to select additional tests, or alter the defaults,

➤ Click [**Select Tests**]

OR:

If you would like to retain the default tests,

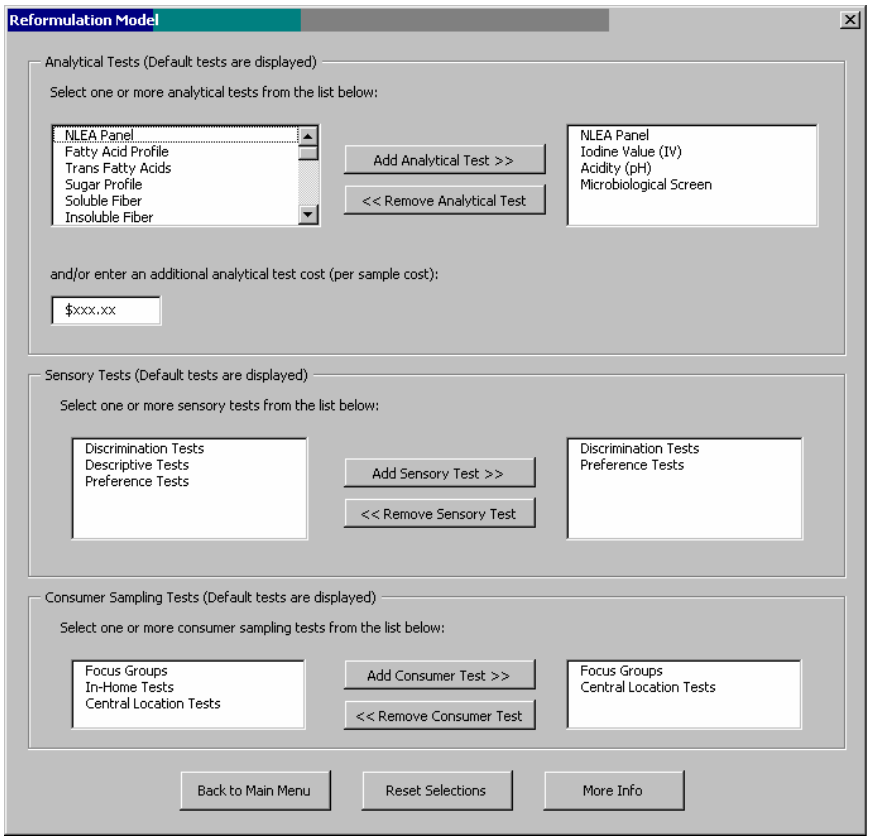
➤ Click [**Back to Main Menu**]

A message box will appear to confirm that you accept the assumed default tests. If you would like to retain the defaults, click [**Yes**] and you will be returned to the Main Menu. If you would like to alter the selected tests, click [**No**] and the Test Menu will open.

Step 3: Choose analytical, sensory, and consumer tests (optional).

If you choose to alter the default tests, the Test Menu will display (see Figure 4-4). The default tests will already appear in the lists on the right of the menu.

Figure 4-4. The Test Screen
You may choose analytical, sensory, and/or consumer tests for each product category.



To include additional analytical tests:

➤ Double-click on the desired test from the list of analytical tests located at the top-left of the Test Menu.

OR:

➤ Click on the desired test from the list of analytical tests located at the top-left of the Test Menu and then click [**Add Analytical Test**].

To remove analytical tests:

➤ Double-click on the test to be removed from the list of selected analytical tests located at the top right of the Test Menu.

OR:

➤ Click on the test to be removed from the list of selected analytical tests located at the top right of the Test Menu and then click [**Remove Analytical Test**].

To add analytical tests for a type of test not listed:

➤ Click on the additional test cost box and enter in a total cost per sample.

To include additional sensory tests:

➤ Double-click on the desired test from the list of sensory tests located at the center-left of the Test Menu.

OR:

➤ Click on the desired test from the list of sensory tests located at the center-left of the Test Menu and then click [**Add Sensory Test**].

To remove sensory tests:

➤ Double-click on the test to be removed from the list of selected sensory tests located at the center-right of the Test Menu.

OR:

➤ Click on the test to be removed from the list of selected sensory tests located at the center-right of the Test Menu and then click [**Remove Sensory Test**].

To include additional consumer tests:

➤ Double-click on the desired test from the list of consumer tests located at the bottom-left of the Test Menu.

OR:

➤ Click on the desired test from the list of consumer tests located at the bottom-left of the Test Menu and then click [**Add Consumer Test**].

To remove consumer tests:

➤ Double-click on the test to be removed from the list of selected consumer tests located at the bottom-right of the Test Menu.

OR:

➤ Click on the test to be removed from the list of selected consumer tests located at the bottom-right of the Test Menu and then click [**Remove Consumer Test**].

- ➤ If you would like to clear your selections on this screen only, click [**Reset Selections**].
- ➤ Once you have selected analytical, sensory, and consumer tests, click [**Back to Main Menu**].

Once you have clicked [**Back to Main Menu**] from either the product screen or the test screen you will return to the Main Menu and must choose a compliance period.

Step 4: Choose a compliance period and coordination assumptions.

To choose a compliance period:

- ➤ Click [Select Compliance Period].

When you click [**Select Compliance Period**] a new menu will open (see Figure 4-5). On this menu, you must select the time period that manufacturers have to comply with the regulation. You may also change the model's assumption about the percentage of products that can coordinate a regulated reformulation with a scheduled reformulation.

- ➤ To select a compliance period, choose **12 months**, **24 months**, **36 months**, or **48 months** from the drop-down box.
- ➤ The coordination assumptions for the selected compliance period will then display in the box below. To change those assumptions click on the box and enter a new percentage.
- ➤ If you would like to clear your selections on this screen only, click [**Reset Selections**].
- ➤ Once you have selected the compliance period, click [**Back to Main Menu**].

Step 5: Enter a price adjustment factor (optional).

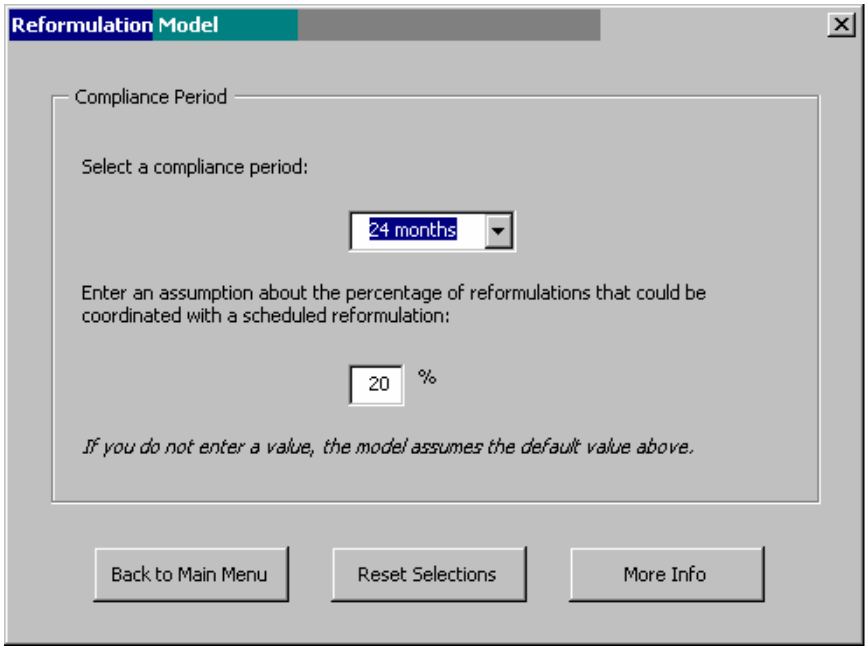
You will again be returned to the Main Menu and may now select a price adjustment factor. If you are running the model to estimate costs in a year beyond 2002, you may wish to enter an inflation factor. To enter an inflation factor:

- ➤ Click on the price adjustment factor box and enter 1.xx where xx represents the total inflation factor beyond 2002. (By default, the inflation factor is set to 1.00.)

You may also wish to use the price adjustment factor to discount future changes back to the present. To enter a discount factor:

- ➤ Click on the price adjustment factor box and enter a value between 0.5 and 1.0.

Figure 4-5. The Compliance Period Screen
Once you select a compliance period, the assumption about the proportion of reformulations that could be coordinated with a scheduled reformulation will display.



You may view your final selections prior to running the model.

While at the Main Menu, you can also view all of the selections you have made for each product category. To do so:

➤ Double-click on the desired product category within the "Current user selections" box on the Main Menu. A message box will then display all of the selections you have made for that product category (see Figure 4-6).

Step 6: Calculate costs

Finally, once you have made all of your selections:

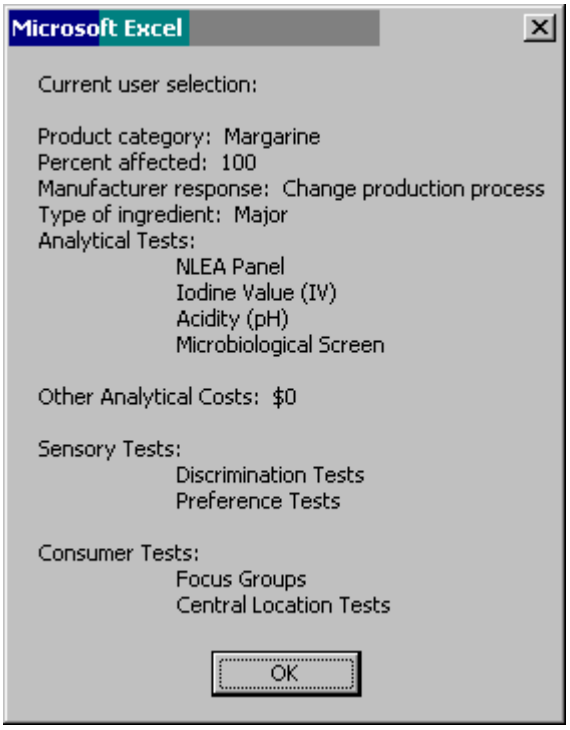
➤ Click [**Calculate Costs**] at the bottom of the Main Menu.

The model will then calculate the cost estimates in Stata for Windows and return the output as described below.

4.3 OUTPUTS OF THE MODEL

Once you have run the reformulation cost model, it generates four separate sheets in the file **reformcost.out**. We describe each of these sheets below.

Figure 4-6. The Display Selection Message Box
Once you click on a selection in the "Current user selections" box, then all of the choices the user has made for that selection will display.



The **Inputs** sheet displays the user's choices that were used to generate the reformulation cost estimates.

The **Inputs** sheet displays your choices in running the model. These inputs, described in Section 4.2, include the following (see Figure 4-7):

- product categories
- the percentage affected, the manufacturer response, the ingredient importance, and tests for each of the product categories selected
- compliance period and the proportion of products that can coordinate a reformulation change with a scheduled change
- the price adjustment factor

Figure 4-7. The Inputs Sheet of the Reformulation Cost Model Output
The Inputs sheet displays the user's selections and provides information on the representative products.

Reformulation Cost Model
User Inputs - 7/25/2002

Product 1 Selections		**Overall Selections**	
Product Category:	Crackers	Compliance Period:	24 months
Percent of Category Affected:	95	Percent Coordination:	20
Manufacturer Response:	Substitute ingredient(s)	Price Adjustment Factor:	1
Ingredient Importance:	Critical minor w/ safety effects		
Analytical Tests:	NLEA Panel		
	Iodine Value (IV)		
	Acidity (pH)		
	Microbiological Screen		
Other Analytical Test Costs:	0		
Sensory Tests:	Discrimination Tests		
Consumer Tests:	Focus Groups		

Product 2 Selections	
Product Category:	Margarine
Percent of Category Affected:	100
Manufacturer Response:	Change production process
Ingredient Importance:	Major
Analytical Tests:	NLEA Panel
	Iodine Value (IV)
	Acidity (pH)
	Microbiological Screen
Other Analytical Test Costs:	0
Sensory Tests:	Discrimination Tests
	Preference Tests
Consumer Tests:	Focus Groups
	Central Location Tests

The **Aggregate Costs** sheet displays the low, medium, and high cost estimates for private label and branded products within each product category.

The **Aggregate Costs** sheet displays the following results of the reformulation cost model (see Figure 4-8):

- product types and categories
- NAICS codes and NAICS descriptions
- number of affected SKUs for each of the selected categories for private, branded, and cosmetic products
- number of affected formulas in the selected categories for private and branded products
- total low, medium, and high cost estimates for private and branded products

Figure 4-8. The Aggregate Cost Sheet of the Reformulation Cost Model Output
The Aggregate Costs sheet lists total low, medium, and high cost estimates for each product category. The product categories are displayed by product type (as shown) or by NAICS codes depending on how the user selected the product categories.

					Data				
Product Type	Product Category	NAICS Code	NAICS Description	Brand Type	SKUs	Formulas	Low Cost	Med Cost	High Cost
Baked Goods	Crackers	311821	Cookies & Crackers	Branded	2,202	1,820	$63,606,930	$220,195,096	$487,669,845
				Private	473	290	$10,118,715	$35,028,983	$77,579,246
	Crackers Total				2,675	2,110	$73,725,645	$255,224,079	$565,249,091
Baked Goods Total					2,675	2,110	$73,725,645	$255,224,079	$565,249,091
Fats & Oils	Margarine	311225	Refined or Blended Fats & Oils	Branded	266	193	$25,992,028	$69,963,732	$155,741,416
				Private	70	50	$6,794,657	$18,289,335	$40,712,547
	Margarine Total				335	243	$32,786,686	$88,253,067	$196,453,963
Fats & Oils Total					335	243	$32,786,686	$88,253,067	$196,453,963
Grand Total					3,010	2,353	$106,512,331	$343,477,145	$761,703,054

The **All Costs** sheet displays the disaggregated cost items within each product category.

The **All Costs** sheet displays the following disaggregated results of the reformulation cost model (see Figure 4-9):

- ➤ product types
- ➤ product categories
- ➤ NAICS code
- ➤ low, medium, and high cost estimates disaggregated by type of costs (idea generation, product research, process development, coordinating activities, analytical testing, sensory testing, consumer testing, safety studies, shelf-life studies, packaging development, process change, market test, plant trial, start-up, and inventory)

The **Totals by Cost Type** sheet displays the total costs for all product categories combined by type of cost.

The **Totals by Cost Type** sheet displays the following results (see Figure 4-10):

- ➤ total low, medium, and high cost estimates for all product categories combined disaggregated by type of costs (idea generation, product research, process development, coordinating activities, analytical testing, sensory testing, consumer testing, safety studies, shelf-life studies, packaging development, process change, market test, plant trial, start-up, and inventory)

The **Data** and **Aggregate Data** sheets contain the raw data used to generate the summary cost tables.

Finally, the **Data** sheet includes the raw cost data generated by the Stata for Windows program. The pivot tables in the **All Costs** and **Totals by Cost Type** sheets are generated using the **Data** sheet. The **Aggregate Data** sheet includes the affected formulas, affected SKUs, and total cost data generated by the Stata for Windows program. The pivot table in the **Aggregate Costs** sheet is generated using the **Aggregate Data** sheet. You should not need to alter any of the information on these data sheets.

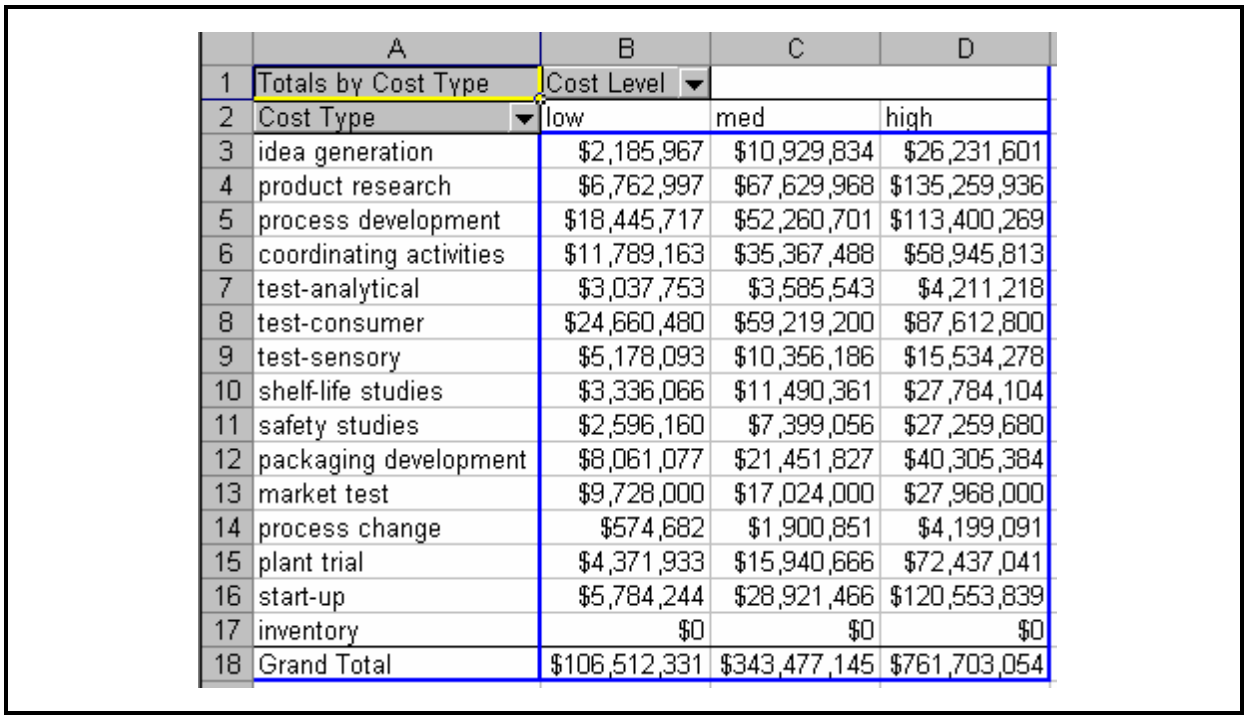
Figure 4-9. The All Costs Sheet of the Reformulation Cost Model Output
The All Costs Sheet lists disaggregated low, medium, and high cost estimates for each product category.

All Costs				Cost Level		
Product Type	Product Category	NAICS Code	Cost Type	low	med	high
Baked Goods	Crackers	311821	idea generation	$1,776,418	$8,882,090	$21,317,015
			product research	$5,495,925	$54,959,248	$109,918,496
			process development	$14,989,845	$42,469,469	$92,154,317
			coordinating activities	$9,580,420	$28,741,260	$47,902,101
			test-analytical	$2,468,501	$2,913,661	$3,422,113
			test-consumer	$16,878,080	$42,195,200	$63,292,800
			test-sensory	$2,911,469	$5,822,938	$8,734,406
			shelf-life studies	$2,711,042	$9,337,798	$22,578,652
			safety studies	$2,109,760	$6,012,816	$22,152,480
			packaging development	$6,550,805	$17,432,947	$32,754,024
			market test	$0	$0	$0
			process change	$0	$0	$0
			plant trial	$3,552,836	$12,953,926	$47,007,563
			start-up	$4,700,545	$23,502,726	$94,015,125
			inventory	$0	$0	$0
		311821 Total		$73,725,645	$255,224,079	$565,249,091
	Crackers Total			$73,725,645	$255,224,079	$565,249,091
Baked Goods Total				$73,725,645	$255,224,079	$565,249,091
Fats & Oils	Margarine	311225	idea generation	$409,549	$2,047,744	$4,914,586
			product research	$1,267,072	$12,670,720	$25,341,440
			process development	$3,455,872	$9,791,232	$21,245,952
			coordinating activities	$2,208,742	$6,626,227	$11,043,712
			test-analytical	$569,252	$671,883	$789,105
			test-consumer	$7,782,400	$17,024,000	$24,320,000
			test-sensory	$2,266,624	$4,533,248	$6,799,872
			shelf-life studies	$625,024	$2,152,563	$5,205,453
			safety studies	$486,400	$1,386,240	$5,107,200
			packaging development	$1,510,272	$4,018,880	$7,551,360
			market test	$9,728,000	$17,024,000	$27,968,000
			process change	$574,682	$1,900,851	$4,199,091
			plant trial	$819,098	$2,986,739	$25,429,478
			start-up	$1,083,699	$5,418,739	$26,538,714
			inventory	$0	$0	$0
		311225 Total		$32,786,686	$88,253,067	$196,453,963
	Margarine Total			$32,786,686	$88,253,067	$196,453,963
Fats & Oils Total				$32,786,686	$88,253,067	$196,453,963
Grand Total				$106,512,331	$343,477,145	$761,703,054

Remember to save the output file if you will be rerunning the model.

If you will be running additional cost estimate scenarios using the reformulation cost model, you must first close the **reformcost.out** file. If you would like to save your results, save the file under a different name or the program will overwrite the file when you run the model again.

Figure 4-10. Totals by Cost Type Sheet of the Reformulation Cost Model Output
The Totals by Cost Type sheet lists low, medium, and high cost estimates by type of cost for all product categories combined.



	A	B	C	D
1	Totals by Cost Type	Cost Level		
2	Cost Type	low	med	high
3	idea generation	$2,185,967	$10,929,834	$26,231,601
4	product research	$6,762,997	$67,629,968	$135,259,936
5	process development	$18,445,717	$52,260,701	$113,400,269
6	coordinating activities	$11,789,163	$35,367,488	$58,945,813
7	test-analytical	$3,037,753	$3,585,543	$4,211,218
8	test-consumer	$24,660,480	$59,219,200	$87,612,800
9	test-sensory	$5,178,093	$10,356,186	$15,534,278
10	shelf-life studies	$3,336,066	$11,490,361	$27,784,104
11	safety studies	$2,596,160	$7,399,056	$27,259,680
12	packaging development	$8,061,077	$21,451,827	$40,305,384
13	market test	$9,728,000	$17,024,000	$27,968,000
14	process change	$574,682	$1,900,851	$4,199,091
15	plant trial	$4,371,933	$15,940,666	$72,437,041
16	start-up	$5,784,244	$28,921,466	$120,553,839
17	inventory	$0	$0	$0
18	Grand Total	$106,512,331	$343,477,145	$761,703,054

Appendix A: Products in the Reformulation Cost Model for Each NAICS Code

Table A-1. Products in the Reformulation Cost Model for Each NAICS Code

NAICS Code	NAICS Description	Product Type	Product Category	SBA Size[a]
311211	***Flour & Other Grain Mill Products***	Baking Ingredients	Flour/Meal	500
311212	***Rice***	Side Dishes & Starches	Rice	500
311225	***Refined or Blended Fats & Oils***	Fats & Oils	Lard/Shortening	1,000
			Margarine	1,000
			Oil	1,000
311230	***Breakfast Cereals & Related Products***	Breakfast Foods	Breakfast Food—Frozen	1,000
			Breakfast Food—Instant	1,000
			Breakfast Food—Ready to Eat	1,000
			Cereal	1,000
311312	***Cane Sugar***	Sweeteners	Sugar	750
311320	***Chocolate & Confectionery Products Made from Cacao Beans***	Candy & Gum	Chocolate Candy—Single Serve	500
			Chocolate Candy—Snack	500
			Seasonal Candy	500
311340	***Nonchocolate Confectionery Products***	Candy & Gum	Gum—Regular Gum	500
			Gum—Sugarless Gum	500
			Nonchocolate Candy—Diet	500
			Nonchocolate Candy—Kits	500
			Nonchocolate Candy—Pkg & Roll	500
			Nonchocolate Candy—Single Serve	500
			Nonchocolate Candy—Snack	500

(continued)

Table A-1. Products in the Reformulation Cost Model for Each NAICS Code (continued)

NAICS Code	NAICS Description	Product Type	Product Category	SBA Size[a]
311411	***Frozen Fruits & Vegetables***	Beverages	Juices—Concentrate, Rfg & Fz	500
		Fruits & Vegetables	Fruit—Fz	500
			Vegetables—Frozen	500
311412	***Frozen Specialties, NEC***	Entrees	Entrées—Fz	500
			Pizza—Pizza/Kits/Mixes, Rfg & Fz	500
		Side Dishes & Starches	Side Dishes—Fz	500
311421	***Canned Fruits & Vegetables***	Beverages	Juices—Rfg	500
			Juices—Aseptic	500
			Juices—Bottled	500
			Juices—Canned	500
		Condiments/Dips/Spreads	Jams/Jellies/Preserves	500
			Pickles/Relish/Olives	500
		Fruits & Vegetables	Beans—Canned	500
			Fruit—Canned/Bottled	500
			Fruit—Sauce	500
			Tomato Products—Canned/Bottled	500
			Tomato Products—Sauce	500
			Vegetables—Canned/Bottled	500
		Infant Foods	Baby Juice	500

(continued)

Table A-1. Products in the Reformulation Cost Model for Each NAICS Code (continued)

NAICS Code	NAICS Description	Product Type	Product Category	SBA Size[a]
311422	***Specialty Canned Food Products***	Entrees	Entrées—Shelf Stable	1,000
		Infant Foods	Baby Food	1,000
		Side Dishes & Starches	Side Dishes—Shelf Stable	1,000
		Soups	Soup—Canned	1,000
311423	***Dried & Dehydrated Foods***	Fruits & Vegetables	Fruit—Dried	500
			Fruit—Dry Fruit Snacks	500
			Vegetables—Dried	500
		Soups	Soup—Dry	500
			Soup—Ramen	500
311511	***Fluid Milk***	Beverages	Milk—Rfg	500
			Milk—Flavored/Substitutes	500
			Creamer—Rfg & Fz	500
		Dairy Foods	Sour Cream	500
			Yogurt	500
311512	***Creamery Butter***	Dairy Foods	Butter	500
311513	***Cheese***	Dairy Foods	Cheese—Grated	500
			Cheese—Imitation	500
			Cheese—Natural Cheese	500
			Cheese—Processed Cheese	500
			Cheese—Ricotta/Cream/Cottage	500
			Cheese—Shredded	500

(continued)

Table A-1. Products in the Reformulation Cost Model for Each NAICS Code (continued)

NAICS Code	NAICS Description	Product Type	Product Category	SBA Size[a]
311514	***Dry, Condensed, & Evaporated Milk***	Beverages	Drink Mixes—Milk/Cocoa Dry Mixes	500
			Milk—Condensed	500
			Milk—Powdered	500
			Creamer/Coffee Additives—Non-Rfg	500
		Infant Foods	Baby Formula—Liq Concentrate	500
			Baby Formula—Powder	500
			Baby Formula—Ready to Drink	500
		Weight Control Foods	Weight Control Liq/Powder	500
311520	***Ice Cream & Frozen Desserts***	Dairy Foods	Frozen Novelties	500
			Ice Cream & Ice Milk	500
311711	***Seafood Canning Products***	Seafood	Seafood—Canned	500
311712	***Fresh & Frozen Seafood***	Seafood	Seafood—Fz	500
			Seafood—Rfg	500
311812	***Commercial Bakery Products***	Baked Goods	Bakery Snacks—Non-Rfg	500
			Bakery Snacks—Rfg	500
			Bread/Rolls—Non-Rfg	500
			Bread/Rolls—Rfg & Fz	500
			Breadcrumbs/Batters/Croutons	500
			Snack & Granola Bars	500
		Desserts	Pies & Cakes—Non-rfg	500
311813	***Frozen Bakery Products***	Desserts	Pies & Cakes—Rfg & Fz	500

(continued)

Table A-1. Products in the Reformulation Cost Model for Each NAICS Code (continued)

NAICS Code	NAICS Description	Product Type	Product Category	SBA Size[a]
311821	***Cookies & Crackers***	Baked Goods	Cookies	750
			Crackers	750
311822	***Flour Mixes & Dough Made From Purchased Powder***	Baking Ingredients	Baking Mixes	500
			Dough—Rfg & Fz	500
			Pizza—Crust/Dough	500
311823	***Dry Pasta Manufacturing***	Side Dishes & Starches	Pasta—Dry	500
311911	***Roasted Nuts or Seeds & Peanut Butter***	Baking Ingredients	Nuts—Baking Nuts	500
		Condiments/Dips/Spreads	Peanut Butter	500
		Snack Foods	Nuts—Snack Nuts	500
			Seeds—Snack	500
311919	***Other Snack Foods***	Snack Foods	Salty Snacks—Bagged	500
			Salty Snacks—Other	500
			Salty Snacks—Unpopped Popcorn	500
311920	***Coffee & Tea Products***	Beverages	Coffee—Ground	500
			Coffee—Instant	500
			Coffee—Whole	500
			Tea—Instant	500
			Tea—Loose	500

(continued)

Table A-1. Products in the Reformulation Cost Model for Each NAICS Code (continued)

NAICS Code	NAICS Description	Product Type	Product Category	SBA Size[a]
311941	***Mayonnaise, Dressings, & Other Prepared Sauces***	Condiments/Dips/Spreads	Condiments—Non-Rfg	500
			Condiments—Rfg	500
			Dips—Shelf Stable	500
			Dips—Rfg & Fz	500
			Mayonnaise	500
		Dressings & Sauces	Gravy/Sauce—Canned/Bottled	500
			Gravy/Sauce—Rfg & Fz	500
			Salad Dressing—Bottled, non-rfg	500
			Salad Dressing—Rfg	500
			Vinegar	500
311942	***Spices & Extracts***	Condiments/Dips/Spreads	Dips—Dry Mixes	500
			Salt/Salt Substitutes	500
			Spices/Seasonings	500
		Dressings & Sauces	Gravy/Sauce—Mixes	500
			Salad Dressing—Dry Mix	500
311991	***Perishable Prepared Food Manufacturing***	Entrees	Entrées—Rfg	500
			Lunches—Rfg	500
		Fruits & Vegetables	Vegetables—Fresh Cut Salad	500
		Side Dishes & Starches	Pasta—Rfg & Fz	500
			Side Dishes—Rfg	500

(continued)

Table A-1. Products in the Reformulation Cost Model for Each NAICS Code (continued)

NAICS Code	NAICS Description	Product Type	Product Category	SBA Size[a]
311999	***All Other Miscellaneous Food Preparations***	Baking Ingredients	Baking Ingredients	500
			Baking Ingredients—Powders	500
		Beverages	Drink Mixes—Cocktail Mixes	500
			Drink Mixes—Other	500
		Condiments/Dips/Spreads	Salad Toppings	500
		Desserts	Desserts—Toppings	500
			Gelatin/Pudding—Mixes	500
			Gelatin/Pudding—Regular	500
		Eggs	Processed Eggs	500
			Shell Eggs	500
		Side Dishes & Starches	Instant Potatoes	500
			Side Dishes—Kits/Mixes	500
			Stuffing	500
		Sweeteners	Syrup/Molasses	500
312111	***Soft Drinks***	Beverages	Carbonated Beverages—Regular	500
			Carbonated Beverages—Sugar Substitute	500
			Carbonated Beverages—Water/Club Soda	500
			Isotonic Drinks	500
			Non-Fruit Drinks	500
			Tea—Canned/Bottled	500

(continued)

Table A-1. Products in the Reformulation Cost Model for Each NAICS Code (continued)

NAICS Code	NAICS Description	Product Type	Product Category	SBA Size[a]
312112	***Bottled Water***	Beverages	Bottled Water	500
325199	***All Other Basic Organic Chemical Manufacturing***	Sweeteners	Sugar Substitutes	1,000
325412	***Pharmaceutical Preparations***	Dietary Supplements	Dietary Supplements—Liquid	750
			Dietary Supplements—Pills	750
325611	***Soaps and Other Detergents***	Oral Hygiene	Toothpaste	750
		Baby Care	Baby Bath Soap	750
325620	***Toilet Preparations***	Hair Care	Shampoo	500
			Conditioner	500
			Hair Coloring	500
			Wave-Setting	500
			Women's Hair Spray	500
			Hair Growth	500
			Ethnic Hair Preparations	500
			Other Hair Care	500
		Oral Hygiene	Antiseptics/Rinses	500
			Other Oral Hygiene	500
		Facial Products	Facial Make-up	500
			Eye Make-up	500
			Lipstick & Lip Remedies	500
			Other Facial Products	500
		Nail Products	Nail Products	500

(continued)

Table A-1. Products in the Reformulation Cost Model for Each NAICS Code (continued)

NAICS Code	NAICS Description	Product Type	Product Category	SBA Size[a]
	Toilet Preparations (continued)	Skin Care Preparations	Lotions	500
			Talc & Dusting Powder	500
			Suntan Preparations	500
			Other Skin Care	500
		Hair Removal	Shaving Cream	500
			Depilatories	500
		Deodorant	Stick/Solid Deodorant	500
			Roll-on Deodorant	500
			Aerosol Deodorant	500
			Cologne & Other Deodorants	500
		Baby Care	Baby Oils, Ointments, Lotions	500
			Baby Powder	500
		Fragrances	Fragrances	500

[a]Small Business Administration size designation for the NAICS code (# of employees).

Appendix B: Stata Data Sets and Programming Code

In this appendix, we describe the contents of the data sets for the reformulation cost model and provide instructions for viewing and editing the data. We also provide the Stata programming code that calculates the costs of product reformulation.

B.1 STATA FOR WINDOWS DATA SETS

The reformulation cost model comprises six separate data sets. In this appendix, we list the data sets, indicate the relationships among them, and provide the format for each. Information on how the data sets were compiled and used in the model was described in Section 3.

The six data sets in the Stata for Windows model are

- ➤ product.dta,
- ➤ response.dta,
- ➤ inventory.dta,
- ➤ analytical.dta,
- ➤ consumer.dta, and
- ➤ sensory.dta.

Tables B-1 through B-6 lists the variable names, variable formats, and relationships for each data set. The tables also indicate which variables are used by the Excel interface.

B.2 EDITING AND VIEWING DATA SETS

Stata for Windows provides a **Data Editor** to conveniently edit or view data sets. The Data Editor is a spreadsheet-style data editor for editing existing data. The Data Editor also has a browse mode that lets you view the data sets without the possibility of accidentally changing the data.

Before editing a data set, please familiarize yourself with the format and relationships of each table. If changes are made to fields that link to other tables, the Stata model will not work. Also, if changes are made to fields linked to the Excel interface, then the Excel interface will not work.

To **browse** data with the Data Editor:

- ➤ Load the data set that you wish to view:

- ✓ Pull down **File** and choose **Open**. Then select the data set by double-clicking on the filename.

➤ Click on the **Data Browser** icon or type **browse** in the Command Window.

To **edit** data with the Data Editor:

➤ Load the data set that you wish to edit:

- ✓ Pull down **File** and choose **Open**. Then select the data set by double-clicking on the filename.

➤ Click on the **Data Editor** icon or type **edit** in the Command Window.

➤ Click on the cell that you would like to change.

➤ Type the new value into the cell, then press **Tab** or **Enter**.

➤ When you exit the editor, a dialog box will ask you to confirm your changes.

- ✓ To permanently save changes to the data set, click the **Save** button or pull down **File** and choose **Save**.

Please note that the changes are not permanent unless you save the file.

B.3 STATA PROGRAMMING CODE

The programming code for calculating the costs of reformulation changes is provided in Exhibit B-1.

Table B-1. Product Data Set

Variable Name	Variable Type	Variable Length	Description	Linked To:
prodtype	Char	24	Product type	
prodcat	Char	38	Product category	Excel interface
naiccode	Num	8	NAICS code	Excel interface
naicdes	Char	56	NAICS description	
sbasize	Num	8	NAICS SBA size	
pribrand	Char	2	Private or brand or cosmetic label indicator	inventory.dta
units	Num	8	Number of units sold	
dollars	Num	8	Dollar sales	
formulas	Num	8	Number of formulas	
skus	Num	8	Number of SKUs	

Table B-2. Response Data Set

Variable Name	Variable Type	Variable Length	Description	Linked To:
response	Char	10	Manufacturer response	Excel interface
ingredlev	Char	10	Ingredient importance	Excel interface
costlev	Char	12	Cost level (low, mid, high)	
costtype	Char	12	Cost type (idea, coord, mkttest, package, procchange, procdevel, research, safety, shelflife, startup, trial)	
cost	Num	8	Cost	

Table B-3. Inventory Data Set

Variable Name	Variable Type	Variable Length	Description	Linked To:
costtype	Char	12	Cost type (inventory)	
pribrand	Char	12	Private or brand or cosmetic label indicator	product.dta
compperd	Char	10	Compliance period	Excel interface
amtinv	Num	8	Percent remaining inventory	

Table B-4. Analytical Data Set

Variable Name	Variable Type	Variable Length	Description	Linked To:
analtest	Char	36	Analytical test	Excel interface
costtype	Char	10	Cost type (analytical)	product.dta
costlev	Char	10	Cost level (low, mid, high)	
cost	Num	8	Cost	

Table B-5. Consumer Data Set

Variable Name	Variable Type	Variable Length	Description	Linked To:
consumtest	Char	22	Consumer test	Excel interface
costtype	Char	12	Cost type (consumer)	product.dta
costlev	Char	12	Cost level (low, mid, high)	
cost	Num	8	Cost	

Table B-6. Sensory Data Set

Variable Name	Variable Type	Variable Length	Description	Linked To:
senstest	Char	34	Sensory test	Excel interface
costtype	Char	12	Cost type (sensory)	product.dta
costlev	Char	12	Cost level (low, mid, high)	
cost	Num	8	Cost	

Exhibit B-1. Stata Programming Code for the Reformulation Cost Model

```
*******************************
*Reformulation Model           *
*March 13, 2002                *
*Revised: July 23, 2002        *
*RTI                           *
*Stata version 7.0             *
*******************************

capture program drop formulate
program define formulate

set more off
set trace off
tempfile prod resp results crprod anal sense consume comp finish raw

***Product Choices*********************************************
/*Shift through product choices one at a time.                */
/*Create a temporary product file based on User's choices.    */
/*This temporary file will be used to build the results files.*/

  use "C:\Reformulation\product.dta", clear
    preserve
    global pcount=1

    while `""`1'"' ~= "" {
      restore, preserve
      keep if prodcat== "`1'"

    /*Generate affected formulas, skus, dollars and units by  */
    /*1) % of industry that can coordinate change and         */
    /*2) % of product category affected.                      */

      replace formulas=(1-$Coord)*${Affect$pcount}*formulas
      replace skus=(1-$Coord)*${Affect$pcount}*skus
      replace dollars=(1-$Coord)*${Affect$pcount}*dollars
      replace units=(1-$Coord)*${Affect$pcount}*units

      recast int skus formulas, force

      save "`prod'", replace

***Response Costs**********************************************
/*Keep records based on User's response and ingredient choices.*/
/*Save results as temp file                                    */

    use "C:\Reformulation\response.dta", clear
      keep if ${Response$pcount}
      keep if ${Ingredient$pcount}

      global Amult=1
      global Smult=2
      global Cmult=1
```

```
    /*Determine Test Multipliers                  */

      local mino : subinstr global Ingredient$pcount "minornc" "sub", all
count(local n1)
      local maj : subinstr global Ingredient$pcount "major" "sub", all
count(local n2)
      local pro : subinstr global Ingredient$pcount "process" "sub", all
count(local n3)

      if ‘n1’>0 {
       global Smult=$Smult-1}
      else if ‘n2’>0 {
       global Amult=$Amult+1}
      else if ‘n3’>0 {
       global Amult=$Amult+1
       global Smult=$Smult+2
       global Cmult=$Cmult+1}

      save "‘resp’", replace

    /*Merge onto temp product file.*/

      use "‘prod’", clear
        cross using "‘resp’"

    /*Scale up costs using                        */
    /*1) number of affected formulas and          */
    /*2) price adjustment factor.                 */

        replace cost=cost*formulas*$Inflate*$Adj
        drop response ingredlev

    /*Save results as temp file, append onto results table.*/

        if $pcount==1 {
          save "‘results’", replace}
        else {
          save "‘crprod’", replace
          use "‘results’", clear
          append using "‘crprod’"
          save "‘results’", replace}

***Analytical Costs (Optional)***********************************
/*Check for empty string if no error then  */
/*Get User’s analytical choices.           */
/*Collapse (sum) the costs into one cost.  */
/*Add User additional test costs           */
/*Save results as temp file                */

    use "C:\Reformulation\analytical.dta", clear
      capture local ifa=${Analysis$pcount}

      if _rc==0 {
        keep if ${Analysis$pcount}
        qui collapse (sum) cost, by(costtype costlev)
        replace cost=cost + ${Addtest$pcount}
        save "‘anal’", replace
```

```
    /*Merge onto temp product file.*/

        use "‘prod’", clear
          cross using "‘anal’"

    /*Scale up costs same as Response Costs plus        */
    /*5) 2 tests per product,                           */
    /*6) multiplier based on ingredient level, and      */
    /*7) additional shipping and handling costs (41.03).*/

          replace cost=formulas*$Inflate*$Amult*((cost*2)+41.03)

    /*Save results as temp file, append onto results table.*/

          save "‘anal’", replace
          use "‘results’", clear
          append using "‘anal’"
          save "‘results’", replace}

***Sensory Costs (Optional)************************************
/*Check for empty string if no error then  */
/*Get User’s sensory test choices.         */
/*Collapse (sum) the costs into one cost.  */
/*Save results as temp file                */

    use "C:\Reformulation\sensory.dta", clear
      capture local ifs=${Sensory$pcount}
      if _rc==0 {
         keep if ${Sensory$pcount}
         qui collapse (sum) cost, by(costtype costlev)
         save "‘sense’", replace

    /*Merge onto temp product file.*/

         use "‘prod’", clear
           cross using "‘sense’"

    /*Scale up costs same as Response Costs plus    */
    /*5) multiplier based on ingredient level.      */

           replace cost=cost*formulas*$Inflate*$Smult

    /*Save results as temp file, append onto results table.*/

           save "‘sense’", replace
           use "‘results’", clear
           append using "‘sense’"
           save "‘results’", replace}

***Consumer Costs (Optional)***********************************
/*Check for empty string if no error then  */
/*Get User’s consumer test choices.        */
/*Collapse (sum) the costs into one cost.  */
/*Save results as temp file                */
```

```
    use "C:\Reformulation\consumer.dta", clear
      capture local ifc=${Consumer$pcount}
      if _rc==0 {
        keep if ${Consumer$pcount}
        qui collapse (sum) cost, by(costtype costlev)
        save "‘consume’", replace

    /*Merge onto temp product file.*/

        use "‘prod’", clear
          cross using "‘consume’"

    /*Scale up costs same as Response Costs plus    */
    /*5) multiplier based on ingredient level.      */

          replace cost=cost*formulas*$Inflate*$Cmult

    /*Save results as temp file, append onto results table.*/

          save "‘consume’", replace
          use "‘results’", clear
          append using "‘consume’"
          save "‘results’", replace}

***Inventory Costs*********************************************
/*Keep records based on User’s compliance period choice. */
/*Save results as temp file                              */

    use "C:\Reformulation\inventory.dta", clear
      keep if $Comply
      sort pribrand
      save "‘comp’", replace

  /***Parse out Finished Materials***/

      keep if costtype=="finished"
      save "‘finish’", replace

    /*Merge onto temp product file (join=pribrand).*/

      use "‘prod’", clear
        sort pribrand
        joinby pribrand using "‘finish’"

    /*Scale up costs using                              */
    /*1) % of inventory remaining,                      */
    /*2) ratio of wholesale to retail price (0.5), and  */
    /*3) affected retail sales of product category.     */

        gen cost=amtinv*0.5*dollars*$Inflate
        replace costtype="inventory"
        save "‘finish’", replace

  /***Parse out Raw Materials***/
```

```
      use "‘comp’", clear
        keep if costtype=="raw"
        save "‘raw’", replace

    /*Merge onto temp product file (join=pribrand).*/

      use "‘prod’", clear
        sort pribrand
        joinby pribrand using "‘raw’"

    /*Scale up costs same as Finished except price ratios (#4) */
    /*4) ratio of raw materials costs to retail price (0.2).   */

        gen cost=amtinv*0.2*dollars*$Inflate
        replace costtype="inventory"
        save "‘raw’", replace

  /***Combine Finished and Raw Materials Temp Files***/
        append using "‘finish’"
        sort prodtype prodcat pribrand costtype
        save "‘comp’", replace

    /*Collapse (sum) the costs into one cost.  */

      qui collapse (sum) cost, by(prodtype prodcat pribrand costtype)

    /*Create 3 cost levels using collapsed costs */

        expand 3
        sort prodtype prodcat pribrand costtype
        by prodtype prodcat pribrand costtype: gen long tcount=_n
        gen str4 costlev="low"
        replace costlev="med" if tcount==2
        replace costlev="high" if tcount==3
        sort prodtype prodcat pribrand

    /*Save results as temp file, Merge onto temp product file.*/

        save "‘comp’", replace
        use "‘prod’", clear
        sort prodtype prodcat pribrand
        joinby prodtype prodcat pribrand using "‘comp’"
        drop tcount

    /*Save results as temp file, append onto results table.*/

        save "‘comp’", replace
        use "‘results’", clear
        append using "‘comp’"
        save "‘results’", replace

  /***Adjust product counter by 1***/
  /***Shift to Next Product Choice***/

     global pcount=$pcount + 1
     macro shift
   }
```

```
  format cost %20.0g
  sort prodtype prodcat pribrand costtype costlev
  save "C:\Reformulation\reformcost.dta", replace
  outsheet using "C:\Reformulation\reformcost.out", replace

  /***Create Aggregate Cost File***/

  use "C:\Reformulation\reformcost.dta", clear
  sort prodtype prodcat naiccode naicdes pribrand units dollars formulas skus
costlev
  collapse (sum) cost, by(prodtype prodcat naiccode naicdes pribrand units
dollars formulas skus costlev)

  reshape wide cost, i(prodtype prodcat pribrand) j(costlev) string

  save "C:\Reformulation\reformcostag.dta", replace
  outsheet using "C:\Reformulation\reformcostag.out", replace
end
```