



Modeling the Decision to Reformulate Foods and Cosmetics

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Presented by

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Overview of Presentation

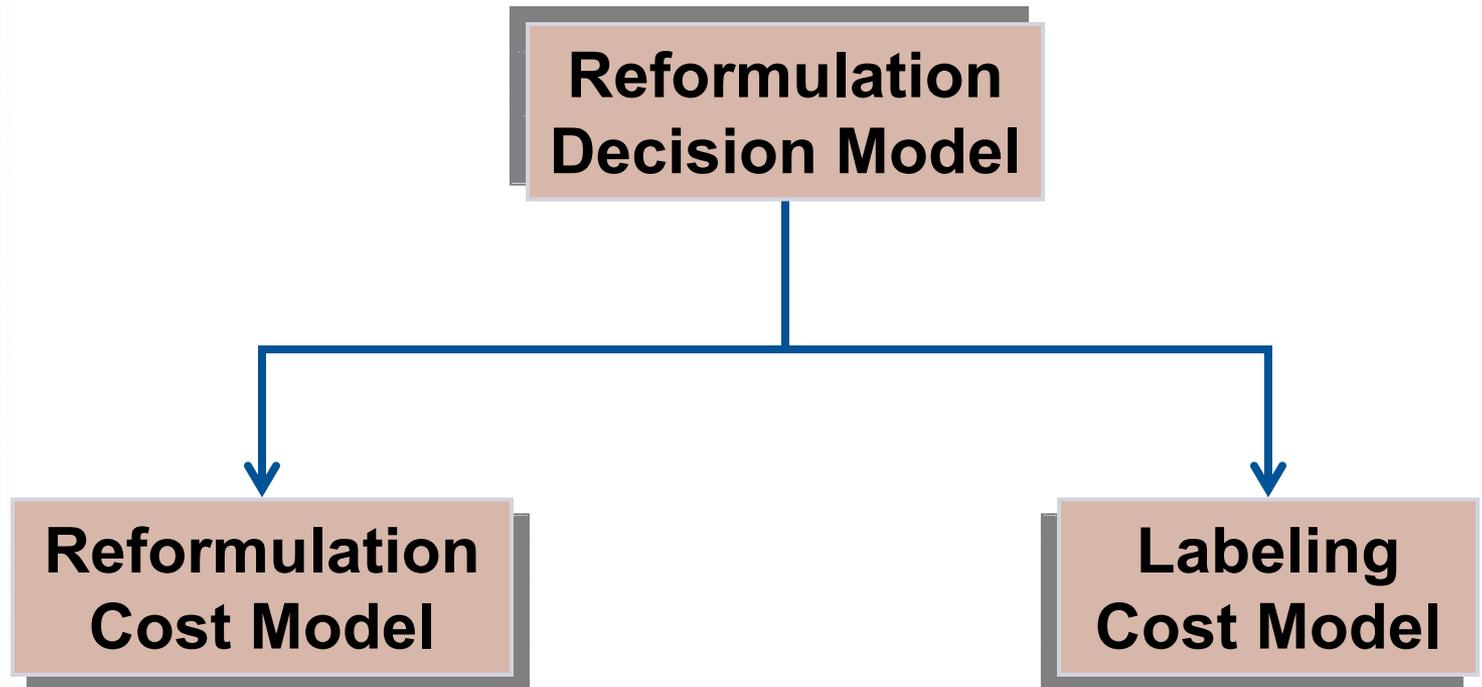
- Project objectives
- Challenges in modeling the decision to reformulate products
- Overview of the reformulation decision model
- Data collection process
- Model validation process
- Key model concepts and conclusions
- Operational model interface



Project Objectives

- To develop an operational model for estimating the probability of product reformulation in response to regulation by manufacturers of
 - foods under FDA's jurisdiction
 - dietary supplements
 - cosmetics (non-OTC)
- Outputs of the model can be used to
 - estimate the costs of compliance with a regulation
 - estimate the benefits of a regulation

Three Interrelated Models

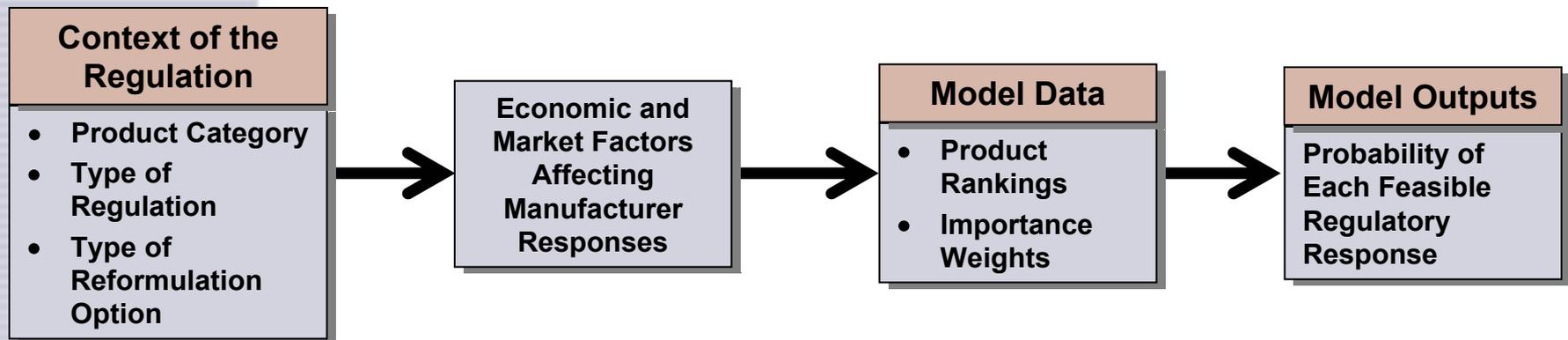




Challenges in Modeling the Decision to Reformulate Products

- Reducing the dimensions of the problem:
 - Range of products under FDA's jurisdiction
 - Types of regulations that may be implemented
 - Types of product reformulations that may occur in response to regulation
 - Key factors that affect manufacturers' decisions to reformulate or relabel products
- Developing a method to collect data to inform the model; no secondary data sources are available

Basic Structure of the Model



Product Categories Included in the Model

- Food products—20 categories
 - Uses same general categories as the Labeling Cost Model and the Reformulation Cost Model
- Dietary supplement products—1 category
- Cosmetics—24 categories
 - Uses categories based on AC Nielsen data, augmented by expert elicitation participants' input



Types of Regulations

- Positive information (e.g., health claim) is allowed anywhere on the package
- Negative information (e.g., warning statement) is required on the PDP
- Negative information is required on the IP
- The amount of a specific ingredient is limited
- Specific processing conditions must be met



Types of Reformulation

- Substitution of a noncritical minor ingredient
- Substitution of a critical minor ingredient (has functional or food safety effects)
- Substitution of a major ingredient (also likely requires a change in the production process)
- Change in the production process

Note: Types of reformulation correspond to those in the Reformulation Cost Model.

Possible Responses to the Regulation

- Reformulate to include positive labeling
- Do not reformulate to include positive labeling
- Reformulate with no labeling change (to avoid negative labeling or to comply with ingredient limits or processing condition requirement)
- Do not reformulate to avoid negative labeling
- Discontinue production of the product

Note: Determining which responses are feasible depends on the requirements of the regulation.

Factors Affecting Reformulation Decisions in Response to Regulation

- One-time costs of reformulation
- Ongoing costs of reformulation
- Consumer sensitivity to changes in formulation
- Consumer sensitivity to changes in labeling
 - Positive label information
 - Negative information on the PDP
 - Negative information on the IP
- Importance of competitor activities

Data Needed to Populate the Operational Model

- **Product rankings** for each factor that affects decisions to reformulate
 - Vary by product category
- **Importance weights** for combining the set of factors that affect decisions to reformulate
 - Vary by regulation type and reformulation type
- Product rankings and importance weights are combined using a set of reduced-form equations to calculate the estimated manufacturer responses

Expert Elicitation for Obtaining Data (I)

- Food and Dietary Supplement Panelists
 - Dr. A.S. Clausi—formerly with General Foods
 - Dr. James Kirk—formerly with Campbell's
 - Dr. Howard Moskowitz—president of brand development company
 - Dr. Nancy Nagle—formerly with Dole
 - Dr. Bob Smith—formerly with Nabisco
 - Dr. Michael Richmond—packaging consultant
 - Dr. Herbert Stone—president of market research and consulting company



Expert Elicitation for Obtaining Data (II)

- Cosmetic Panelists
 - Mr. Carl Geffken—formerly with Vaseline, Pond's, Aziza, Chanel, and Beiersdorf
 - Dr. Maurice Siegel—formerly with Faberge



Model Validation Questions

- Do the available **input selections** correspond to those that would be selected for these real examples?
- Did we include all of the **factors** that the manufacturers thought would be relevant for the decision process?
- Do the default **importance weights** for each of the factors correspond to those assigned by the manufacturers?
- Do the **product categories** for regulatory responses in the model correspond to those that occurred for these real examples?
- Do the **model predictions** correspond to the actual regulatory responses of the manufacturers?

Results of Model Validation

- Examples provided by nine manufacturers:
 - Trans fatty acid labeling for side dishes and starches, fats and oils, and snack foods
 - Processing requirements for allergen control in snacks
 - Limits on vitamin fortification in drink mix
 - Possible restrictions/limits on use of kava, ephedra, and vitamin A as dietary supplement ingredients
 - Sunburn alerts on lotion products containing alpha hydroxy acid
- Based on the validation findings, modified terminology used and added additional flexibility in the model.

Key Conclusions: Effects of Reformulation Type and Costs

- Almost all **manufacturers**, both small and large, will reformulate products (in contrast to other methods of compliance) if they can comply with a “simple” type of reformulation.
- **Product categories** with lower costs of reformulation are more likely to be reformulated for any type of regulation.
 - Lower costs: condiments/dips/spreads, sweeteners, side dishes and starches, packaged/canned fruits and vegetables
 - Higher costs: baked goods, baking ingredients, infant foods, weight control foods, dairy foods

Key Conclusions: Consumer Sensitivity to Formulation and Labeling

- Product categories for which consumers are more sensitive to **formulation changes** are much less likely to be reformulated in response to any type of regulation.
 - Beverages, candy and gum, snack foods
- Product categories for which consumers are more sensitive to **labeling changes** are more likely to be reformulated in response to a labeling type regulation.
 - Breakfast foods, weight control foods, dairy foods, eggs, infant foods

Key Conclusions: Competitor Activities and Business Size

- Product categories for which **competitor activities** are particularly important are more likely to be reformulated in response to labeling type regulations.
 - Breakfast foods, snack foods, beverages
- **Small businesses'** reactions to regulations:
 - Cost of reformulation matters more for their responses
 - Less likely to reformulate to avoid negative labeling statements
 - More likely to reformulate to include positive labeling statements
 - Less likely to be influenced by competitor activities

Key Conclusions: Labeling Versus Reformulation Regulations

- All regulations are labeling regulations
 - Even if a regulation does not require specific labeling changes, manufacturers may anticipate that most of the effects will occur through incidental labeling changes
 - For example—an ingredient ban that requires food manufacturers to change their labeling (nutrient content claim, health claim, Nutrition Facts panel) will cause manufacturers to consider the effect of the labeling change in their reformulation decision

A B C D E F G H I J K

1 MODELING THE DECISION TO REFORMULATE

2 FOODS AND COSMETICS

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4 This model provides estimates of the proportion of products that will be reformulated and/or relabeled in response to regulation.

5 Products include foods, dietary supplements, and cosmetic products under FDA's jurisdiction.

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8 Go to Model Input..... Input Screen

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10 View Product Rankings..... Product Rankings

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12 View Small Business Importance Weights..... Small Business Weights

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14 View Large Business Importance Weights..... Large Business Weights

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17 Prepared by:

18  RTI International

19 Version 1.2 Final

20 Version Date: October 2003

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Model Demonstration

