



# An Operational Model of Food Reformulation in Response to Regulation

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## 1. Introduction and Purpose

Regulations that affect food labeling or food production processes may cause manufacturers to reformulate foods. In some cases, regulations are mandatory, such as a limit on a particular ingredient, or are voluntary, such as a health claim that would be allowed if the product contains certain ingredients. A few previous studies have analyzed changes in product formulation and labeling in response to greater freedom to include voluntary health claims on products in the 1980s and in response to the Nutrition Labeling and Education Act of 1990. However, for conducting regulatory impact analyses of proposed regulations, the U.S. Food and Drug Administration (FDA) needed a method to estimate *ex ante* what proportion of affected foods would be reformulated and/or relabeled in response to regulation.

This poster presents a model developed for FDA to estimate the proportion of products that will be reformulated, relabeled, both reformulated and relabeled, neither reformulated nor relabeled, or discontinued in response to five general classes of regulations. The outputs of the model can be used in estimating the costs of compliance with a regulation or the public health benefits of a regulation.

## 2. Structure of the Model

The basic structure of the model relates the context of a regulation to predictions regarding manufacturer responses as shown in Figure 1.

The context of the regulation has three dimensions:

### 1. Broad Product Segment

- Baked goods
- Baking ingredients
- Beverages
- Breakfast foods
- Candy and gum
- Condiments/dips/spreads
- Dairy foods
- Desserts
- Dressings and sauces
- Eggs
- Entrees
- Fats and oils
- Fruits and vegetables
- Infant foods
- Seafood
- Side dishes and starches
- Snack foods
- Soups
- Sweeteners
- Weight control foods

### 2. Type of Regulation

- Positive labeling — positive information, such as a health claim, is allowed anywhere on the product package
- Negative principal display panel (PDP) labeling — negative information, such as a caution statement, is required on the principal display panel (front of the package)
- Negative information panel (IP) labeling — negative information is required on the information panel (back of the package)
- Ingredient limit — the amount of a specific ingredient is limited or banned
- Processing conditions — specific processing conditions must be met

### 3. Type of Reformulation that Would Comply with a Regulation

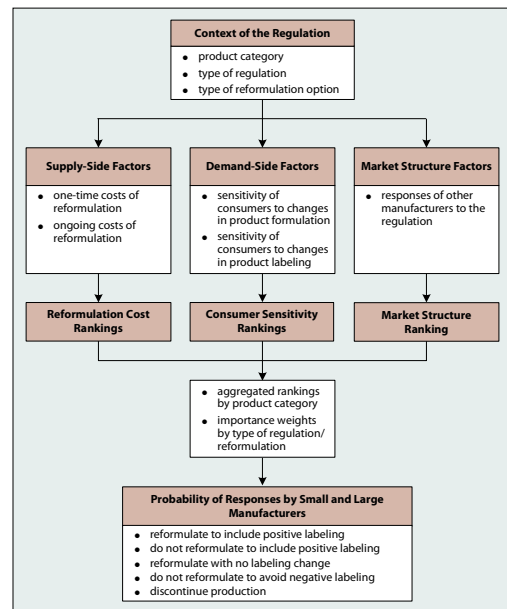
- Substitution of a noncritical minor ingredient (an ingredient used at low levels with no functional performance effects)
- Substitution of a critical minor ingredient (an ingredient with functional or food safety effects)
- Substitution of a major ingredient (an ingredient used at high levels in the product and that would likely also require a processing change)
- Change in the production process

Given the context of the regulation, food manufacturers choose a response to the regulation based on the expected discounted present value of changes in profits under alternative reformulation and relabeling scenarios. The factors that affect their decisions include the following:

- One-time costs of reformulating the product
- On-going costs associated with the reformulation
- Consumer sensitivity to changes in the product formulation
- For labeling regulations, consumer sensitivity to changes in labeling:
  - Positive label information anywhere on the package
  - Negative PDP label information
  - Negative IP label information
- Importance of competitor activities

The level of importance of these reformulation factors varies by product segment. The relative importance of these reformulation factors varies by the type of regulation, the type of reformulation required, and the size of the business that produces the affected product.

Figure 1. General Concept for the Reformulation Decision Model



## 3. Reduced-Form Equations in the Model

In deciding how to respond to each type of regulation, food manufacturers evaluate the expected direction and size of the supply and demand shifts under alternative scenarios. Based on the factors that typically affect food manufacturers' responses, we developed a set of reduced-form equations to estimate the proportions of products that will be reformulated and/or relabeled in response to regulation. The reduced-form equations are based on economic reasoning in that some factors, such as the level of costs of reformulation, are associated *ceteris paribus* with a lower probability of reformulation, while other factors, such as how sensitive consumers are to labeling changes, are associated *ceteris paribus* with a higher probability of reformulation. The reduced-form equations in the model provide a method of combining data on the factors affecting the regulatory response decision.

The notation used in the model equations is as follows:

Decision Factor	Product Ranking (1=low...9=high)	Importance Weights <sup>a</sup>	
		Small Businesses	Large Businesses
(1) One-time costs of reformulation	$R_{1i}$	$W_{1,f}^S$	$W_{1,f}^L$
(2) Ongoing costs of reformulation	$R_{2i}$	$W_{2,f}^S$	$W_{2,f}^L$
(3) Consumer sensitivity to reformulation	$R_{3i}$	$W_{3,f}^S$	$W_{3,f}^L$
(4) Consumer sensitivity to positive labeling	$R_{4i}$	$W_{4,f}^S$	$W_{4,f}^L$
(5) Consumer sensitivity to negative PDP labeling	$R_{5i}$	$W_{5,f}^S$	$W_{5,f}^L$
(6) Consumer sensitivity to negative IP labeling	$R_{6i}$	$W_{6,f}^S$	$W_{6,f}^L$
(7) Importance of competitor activities	$R_{7i}$	$W_{7,f}^S$	$W_{7,f}^L$

<sup>a</sup>Subscript  $i$  denotes product segment,  $r$  denotes regulation type, and  $f$  denotes reformulation type. Superscript  $S$  denotes small businesses and  $L$  denotes large businesses.

<sup>b</sup>The weights are calculated such that the sum of the weights for the factors relevant for a particular type of regulation are less than or equal to one.

In the model equations listed below, superscripts for small and large businesses on the importance weights are suppressed. Note that factors with negative signs decrease the probability of reformulation, and factors with positive signs increase the probability of reformulation in response to a regulation.

Regulation type 1 ( $r = 1$ ) allows positive information on the product label if a manufacturer reformulates. Possible manufacturer responses: • reformulate to include positive labeling • do not reformulate to include positive labeling • discontinue product	The proportion of products that will be reformulated to include positive labeling is estimated as $P_{1,i} = \max(0, [9 - (R_{1,i}W_{1,i} + R_{2,i}W_{2,i} + R_{3,i}W_{3,i} - R_{4,i}W_{4,i} - R_{5,i}W_{5,i})]/9)$ The remaining proportion of the products, $1 - P_{1,i}$ , will either (1) not be reformulated to include positive labeling or (2) be discontinued. The proportion of products that will be discontinued is estimated as $D_{1,i} = [(R_{1,i}W_{1,i} + R_{2,i}W_{2,i})/9] * (1 - P_{1,i})$
Regulation type 2 ( $r = 2$ ) requires negative information on the PDP if a manufacturer does not reformulate a product. Possible manufacturer responses: • reformulate to avoid negative labeling • do not reformulate to avoid negative labeling • discontinue product	The proportion of products that will be reformulated to avoid negative PDP labeling is estimated as $P_{2,i} = \max(0, [9 - (R_{1,i}W_{1,i} + R_{2,i}W_{2,i} + R_{3,i}W_{3,i} - R_{4,i}W_{4,i} - R_{5,i}W_{5,i})]/9)$ The remaining proportion of the products, $1 - P_{2,i}$ , will either (1) not be reformulated to avoid the required negative statement or (2) be discontinued. The proportion of products that will be discontinued is estimated as $D_{2,i} = [(R_{1,i}W_{1,i} + R_{2,i}W_{2,i})/9] * (1 - P_{2,i})$
Regulation type 3 ( $r = 3$ ) requires negative information on the IP if a manufacturer does not reformulate a product. Possible manufacturer responses: • reformulate to avoid negative labeling • do not reformulate to avoid negative labeling • discontinue product	The proportion of products that will be reformulated to avoid negative IP labeling is estimated as $P_{3,i} = \max(0, [9 - (R_{1,i}W_{1,i} + R_{2,i}W_{2,i} + R_{3,i}W_{3,i} - R_{4,i}W_{4,i} - R_{5,i}W_{5,i})]/9)$ The remaining proportion of the products, $1 - P_{3,i}$ , will either (1) not be reformulated to avoid the required negative statement or (2) be discontinued. The proportion of products that will be discontinued is estimated as $D_{3,i} = [(R_{1,i}W_{1,i} + R_{2,i}W_{2,i})/9] * (1 - P_{3,i})$
Regulation type 4 ( $r = 4$ ) requires products to be reformulated to comply with an ingredient limit. Possible manufacturer responses: • reformulate (without relabeling) or • discontinue product	For a regulation that requires ingredient limits ( $r = 4$ ), the proportion of products that will be reformulated is estimated as $P_{4,i} = \max(0, [9 - (R_{1,i}W_{1,i} + R_{2,i}W_{2,i} + R_{3,i}W_{3,i})]/9)$ The remaining proportion of the products, $1 - P_{4,i}$ , will be discontinued because manufacturers have no other compliance option.
Regulation type 5 ( $r = 5$ ) require products to be reformulated to comply with processing condition requirements. Possible manufacturer responses: • reformulate (without relabeling) or • discontinue product	For a regulation that requires specific processing conditions to be met ( $r = 5$ ), the proportion of products that will be reformulated is estimated as $P_{5,i} = \max(0, [9 - (R_{1,i}W_{1,i} + R_{2,i}W_{2,i} + R_{3,i}W_{3,i})]/9)$ The remaining proportion of the products, $1 - P_{5,i}$ , will be discontinued because manufacturers have no other compliance option.

## 4. Data Contained in the Model and Data Collection Process

We obtained the data for use in the model through an expert elicitation process. Seven food industry experts participated in a full-day exercise to rank products by each of the decision factors and assign importance weights to each of the decision factors for each regulation type. Five of the experts are former heads of research and development divisions of major food companies. Two of the experts are presidents of market research and strategic brand development companies.

Following discussions of each of the factors affecting the reformulation decision process and the relative importance of each factor in the decision process, we asked the experts to do the following:

- For each factor in the reformulation decision process, rank each individual product segment using a likert scale format (e.g., from 1=lowest consumer sensitivity to labeling changes to 9=highest consumer sensitivity to labeling changes).
- For each combination of regulation type, reformulation type, and business size, assign an importance weight to each factor in the decision process.

We aggregated their responses to create average product rankings for each product segment and average importance weights for each combination of regulation type and reformulation type. The model also allows users to modify the default product rankings and importance weights for more specific analyses.

## 5. Operation of the Model

The model is programmed in Microsoft Excel with Visual Basic components for user friendliness. In running the model, the user first selects the Input Screen button as shown in Figure 2.

From the display screen shown in Figure 3, the user follows the following steps:

- Choose an input preference (by product segment or by North American Industry Classification System (NAICS) code).
  - If selecting by NAICS code, then select the desired NAICS code.
- Select the affected product segment.
- Select the type of regulation.
- Select the type of reformulation that would allow for compliance with the regulation.
- Modify the default rankings and weights (optional).
- View the results of the model.

Figure 2. Main Menu Screen for the Reformulation Decision Model

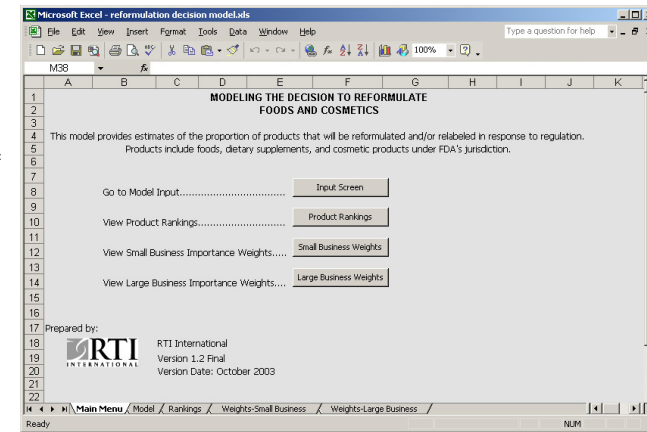
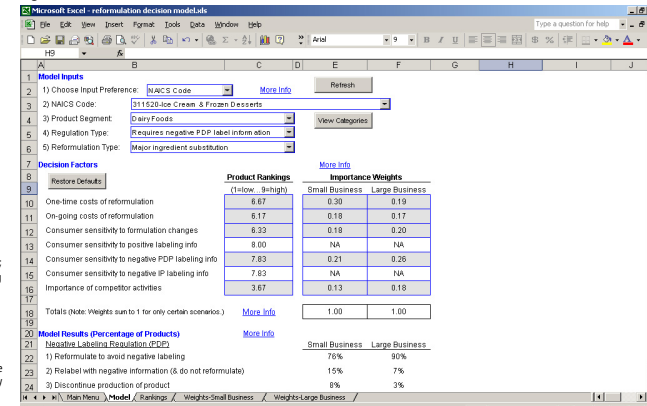


Figure 3. Reformulation Decision Model Worksheet



Note: (1) PDP = principal display panel; IP = information panel. Relabeling refers to changes that consumers would perceive as positive or negative and excludes incidental changes to the Nutrition Facts panel or ingredient list.  
(2) Percentages of products are relative to those that do not already comply with the requirements of the regulation

## 6. Validation of the Model

After constructing the model, we tested it using real examples provided by five manufacturers interviewed over the telephone. We asked each of the manufacturers to choose an example of a product for which the manufacturer had to decide whether to reformulate or relabel a product in response to a regulation. Three of the manufacturers selected examples related to trans fatty acid labeling requirements (negative IP labeling), one selected an example of a processing condition requirement to avoid cross-contamination with allergens in snack foods, and one selected an example of an ingredient limit in a beverage product.

In conducting the validation, we asked each manufacturer the following:

- the type of regulation that caused the manufacturer to consider reformulating or relabeling a product,
- the type of reformulation that allowed the product to comply with the requirements of the regulation,
- which factors affected the manufacturer's response and the weights the respondent would assign to each of the factors,
- what the manufacturer's actual response was,
- how similar the manufacturer believes his response was to other manufacturers' responses, and
- whether the manufacturer believes that some manufacturers stopped producing the affected product rather than reformulate and/or relabel it.

Based on their responses, we confirmed that the examples they provided could be classified into the regulation types defined in the model, that we included the most relevant factors in the decision process, and that our model outputs were generally within the range of responses that they predicted. As a result of the validation process, we clarified the terminology used throughout the report and provided additional clarification regarding the appropriate interpretation of the model outputs in the model documentation.

## 7. General Conclusions from the Data Collection and Modeling Exercises

Key conclusions that can be drawn from the data collection and modeling exercises are as follows:

- Almost all manufacturers, regardless of type of food produced, will reformulate products to comply with a regulation (rather than relabeling or discontinuing production) if they can comply by conducting a relatively simple type of reformulation.
- Foods with lower costs of reformulation in general are more likely to be reformulated (instead of being relabeled or discontinued) for any type of regulation.
- For some types of foods, consumers are very sensitive to formulation changes; these products are much less likely to be reformulated in response to any type of regulation.
- For some types of foods, consumers are more likely to respond to changes in product labeling (regardless of whether it conveys positive or negative information); these products are much more likely to be reformulated in response to labeling regulations.
- Foods for which competitor activities are particularly important factors in the decision-making process are more likely to be reformulated in response to labeling changes.
- The cost of reformulation matters more for small businesses than for large businesses, but small businesses are less likely to reformulate to avoid negative labeling requirements and are more likely to reformulate to allow positive labeling statements.
- Even for regulations that do not require specific labeling changes, food manufacturers may perceive that most of the effects of the regulation occur through incidental labeling changes that might be required as a result of reformulating the product.

The specific outputs of the model provide preliminary estimates of industry responses that can be used for conducting regulatory impact analyses.

### For More Information

For additional details on the model and data collection process, see Muth, M.K., S.A. Karns, D.W. Anderson, M.C. Cogliati, and M.S. Fanijoy, October 2003, "Modeling the Decision to Reformulate Foods and Cosmetics." Report prepared by RTI International, Research Triangle Park, NC, for David Zorn, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD.

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