

Small Business CFSAN Models

Client: U.S. Department of Health and Human Services, Food and Drug Administration

Project Overview

The purpose of this project was to develop and update 4 independent models for the Food and Drug Administration’s (FDA) Center for Food Safety and Applied Nutrition (CFSAN). The models were designed to investigate the impacts of FDA regulations on small entities, in compliance with the Regulatory Flexibility Act (RFA). These small business entities have fewer resources to devote to regulatory compliance and may be burdened unduly by regulatory-related costs.

The 4 models corresponded to 4 FDA-regulated industries:

1. The candy manufacturing industry
2. The cosmetics industry
3. The ready-to-eat food manufacturing industry
4. The dietary supplements manufacturing industry

Model	List of 6-Digit NAICS Codes Comprising the Industry				
1. Candy	311320				
	311330				
	311340				
2. Cosmetics	325611				
	325620				
3. Dietary Supplements	311222				
	311920				
	325188				
	325199				
	325411				
4. Ready to Eat Manufacturing	311111	311411	311513	311821	311991
	311119	311421	311514	311830	311999
	311225	311422	311520	311911	312111
	311230	311423	311711	311919	312112
	311312	311511	311811	311941	312113
	311313	311512	311812	311942	312120

Data for the models was derived largely from the U.S. Census Bureau’s Economic Census—Manufacturing Industry Series and Manufacturing Subject Series, Statistics of U.S. Businesses: Dynamic Data, and the Annual Survey of Manufacturers (ASM). These 3 principal sources were augmented by data from Harris Interactive; the Federal Reserve Board; the Internal Revenue Service; the Federation of Tax Administrators Web site; the “Candy Buyers’ Directory;” and CCH’s “2006 State Tax Handbook.”



The models were developed in Excel using approximately 12 spreadsheets per model to house the data. Insight identified, acquired, and edited/cleaned the data; constructed data tables in a format that could be utilized by the CFSAN models; and evaluated results. All data were subjected to a thorough quality assurance process that involved an independent review of every data element. In addition, the models were invoked repeatedly using varying data assumptions to test both their stability and the generated results. Additionally, Insight wrote a guide to updating and using the models detailing 1) the data sources used in the CFSAN models, 2) the data elements used from each data source, 3) the process used for acquiring and preparing data for the models, and 4) the results/impacts of the updated models.

Core Activities

Literature Reviews and Environmental Scans; Secondary Data Analysis and Simulations; Database Development; Report Development and Presentation

Products

- Electronic models
- A final report entitled “Updating CFSAN Small Business Models for Four FDA-Regulated Industries” (March 2008)

