ERG

Final

Model for Estimating the Impacts of Regulatory Costs on the Survival of Small Businesses and its Application to Four FDA-Regulated Industries

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Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

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EXECUTIVE SUMMARY

The Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires agencies to analyze how their regulations will affect small entities. Small entities have fewer resources to devote to regulatory compliance and, therefore, may be unduly burdened by regulatory-related costs. The RFA encourages agencies to tailor regulatory and informational requirements to the size of entities. The goal is to develop regulations so as to avoid unduly burdening small entities while remaining consistent with the objectives of the regulation and applicable statutes.

The Small Business Association's Office of Advocacy (SBA) and Office of Management and Budget (OMB) oversee the administration of the RFA and SBREFA. The RFA and SBREFA apply to proposed and final rules that are subject to notice and comment requirements, as well as any rule issued under the Administrative Procedure Act (APA). If impacts on small entities are found to be substantial, then federal agencies are required to assess alternative formulations of the regulation and develop compliance assistance mechanisms for small businesses in order to minimize impacts on them. Therefore, it is crucial that a regulatory agency first be able to project potential regulatory impacts incurred by small businesses, and second, to be able to assess potentially mitigating actions.

Under contract to the U.S. Food and Drug Administration (FDA), Eastern Research Group (ERG) developed a model framework for estimating regulatory impacts on small businesses. The preliminary model framework is designed to accommodate a wide variety of potential regulatory activities, ranging from Hazard Analysis Critical Control Point (HACCP) to product labeling, and is tailored to measure impacts on the following four FDA-regulated industries:

- Dietary supplements (DS) industry,
- Candy manufacturing,
- Cosmetics manufacturing, and

- Ready-to-eat (RTE) foods manufacturing.

Using the *1997 Economic Census* and other readily available data, the model estimates the cash flows of representative establishments, called model facilities, of varying size classes for each industry. Using these mean estimates of pre-regulation cash flow, the model estimates a distribution of income for each model facility. Next, based on post-regulation cash flow and distribution of income for each model facility, the model generates the percentage of facilities in each model class that are vulnerable to closure. Although not as robust, revenues and EBIT are provided as alternative income measures to cash flow to measure impacts.

The model framework allows the Agency to (1) predict the probability and frequency of small business failure as a result of FDA regulations and (2) estimate the effects of various forms of regulatory relief on the survival of small businesses, on a per-establishment basis. While regulatory impacts are typically assessed at the company-level, the company is usually a single-establishment firm in the case of small businesses. Therefore, in the analysis of small business impacts, the company and the establishment are identical and reporting impacts on a per-establishment basis is largely equivalent to reporting impacts at the company-level.

SECTION ONE

MODEL FOR ESTIMATING THE EFFECTS OF REGULATORY COSTS ON THE SURVIVAL OF SMALL BUSINESSES

This section describes the basic model framework developed for estimating small business impacts of FDA regulations. There are a number of overarching themes in (ERG)'s approach to developing this model framework. First, the model focuses on measures of net facility income. More specifically, it estimates the revenue and cost structure of a series of representative small establishments of varying size classes. These are referred to as model facilities hereafter. By focusing on production costs and revenues instead of just revenues, the Agency can better assess the ability of small businesses to bear regulatory burdens. Second, the model estimates a distribution of income for each model class within each industry. Estimating the *distribution* of income within a model class is necessary for projecting the percentage of facilities in each model class that are vulnerable to a given level of regulatory costs. Third, by modeling a number of model facility classes within each industry, the model provides flexibility for examining impacts among different size classes of small facilities.

Section 1.1 presents an intuitive overview of the basic model framework. Section 1.2 discusses the primary data sources utilized in creating model facilities and their respective income measures. Section 1.3 provides a detailed description of the basic model framework, including the development of model facility income measures, the estimation of the frequency distribution of different income measures, and the estimation of impacts on small businesses.

1.1 Model Overview

1.1.1 Modeling Strategy

The ERG small business model framework is primarily based on two basic concepts:

(1) Negative accounting cash flow is analogous to a short-run average variable costs exceeding average revenues

(2) Size affects an establishment's ability to absorb regulatory costs.

First, economic theory states that a profit-maximizing firm will shut down where short-run average variable costs (AVC) exceed average revenues (AR). In modern corporate finance, accounting cash flow (i.e., net income plus depreciation) is roughly analogous to the comparison of short-run variable costs and revenues. Accounting cash flow, which excludes depreciation (the accounting charge for the utilization of previously purchased capital equipment), essentially measures the current operating revenues net of operating costs of an establishment. Thus, if an establishment's cash flow turns negative after regulatory costs are subtracted from its pre-regulatory cash flow, then it is equivalent to the theoretical microeconomic firm that shuts down due to short-run AVC exceeding AR.

Second, differences in establishment size typically result in differences in relative earnings (e.g., net income as a percent of operating costs, or per employee). Additionally, regulatory cost burdens tend to vary across different-sized establishments. Hence, establishment size is an important determinant of regulatory impacts.

Using these assumptions as the starting point, the application of the small business model framework to a specific industry requires the (1) characterization of a series of different-sized model establishments and (2) estimation of cash flow and its distribution for each of the model establishments.[1] Accounting for the distribution of cash flow for all establishments represented by each model establishment is essential because each model establishment reflects the average of a group of establishments, not a group of identical establishments. Hence, a simple comparison of average regulatory costs with a model establishment's cash flow will generate an all-or-nothing result (i.e., all facilities represented by a particular model incur impacts identical to those of the model facility) leading to impact estimation errors.

[1] The model framework also evaluates impacts utilizing two additional income measures, mainly revenues and earnings before interest and taxes (EBIT). Although cash flow is the best predictor of facility survival, the additional income measures provide a sensitivity analysis to check for consistency in model results.

The model uses the following information to estimate the distribution of cash flow for establishments represented by each model establishment:

- Mean of the distribution,
- Variance of the distribution, and
- Type of distribution.

In the context of the model framework, the mean of each distribution is equal to the model establishment's cash flow. Similarly, the variance of each distribution is equal to the variance of the model establishment's cash flow (derived from Census Bureau data obtained by special request). Section 1.2 presents the data sources for the estimation of model establishment mean cash flow and its variance in detail. For the type of distribution, ERG assumed that within each model establishment class, cash flow is normally distributed around the model establishment mean.[2] Hence, given the mean and variance of cash flow for each class of model establishments, and assuming that cash flow for each class is normally distributed, ERG was able to estimate the distribution of cash flow for each model class. Section 1.3.2 describes how the distribution of cash flow is estimated in further detail.

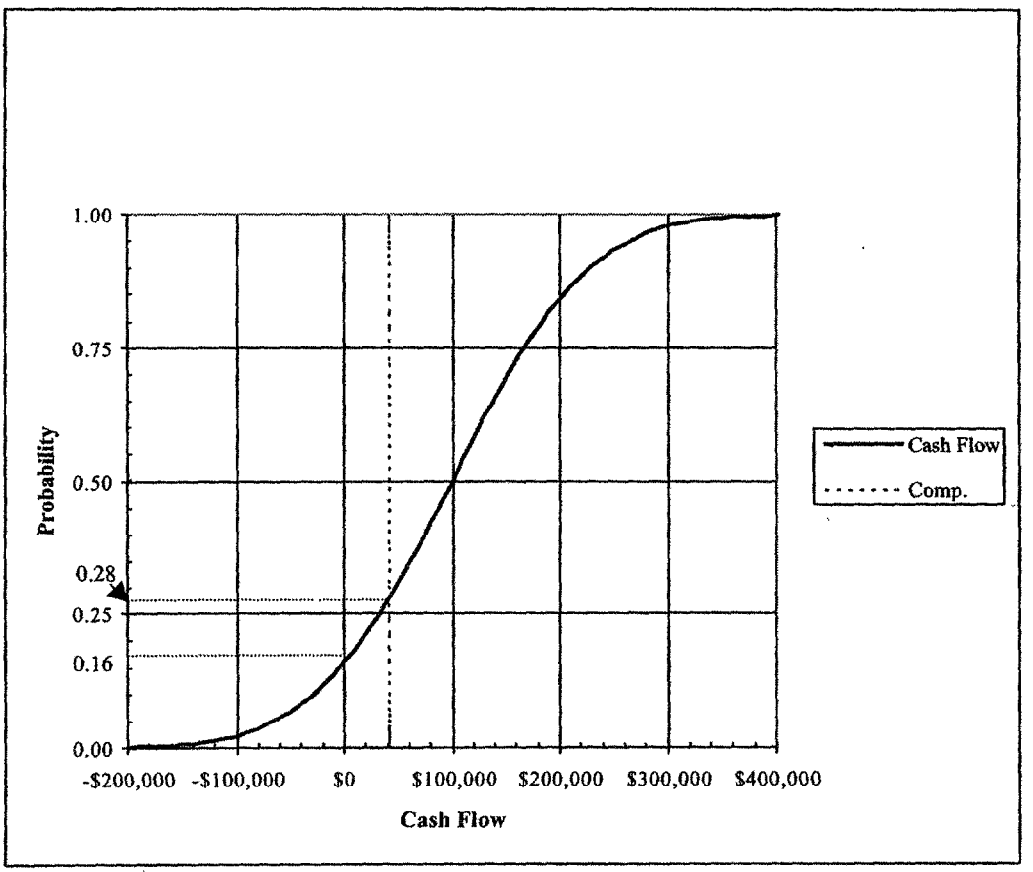
Example: Figure 1-1 illustrates a sample cash flow distribution for a given model establishment class. For the purposes of illustration, the mean cash flow for this model establishment class is set at $100,000 and variance at $100,000. With this mean and variance, approximately 16 percent of establishments in this class are projected to earn negative cash flow (the point where the distribution function crosses the $0 value).

To demonstrate the use of the model framework to project impacts of a potential regulation, suppose, for example, annual compliance costs are estimated at $40,000 for the model establishment. Under this scenario, any establishment in the model class with cash flow less than $40,000 per year would be projected to close. In Figure 1-1, the vertical line marking the estimated annual compliance costs of $40,000 is used to determine the probability of closure.

[2] ERG also examined alternative distributional assumptions to provide analysis of the sensitivity of model impacts to the normality assumption.

Figure 1-1

Baseline Distribution Function for Model Establishment Cash Flow



Reading from the point on the graph where the distribution function intersects the compliance cost marker, the probability that a facility earns cash flow that is less than $40,000 per year is about 28 percent. Therefore, the *incremental* probability that an establishment in this model class will close due to the regulation is around 12 percent (28 percent minus 16 percent). [3]

The number of establishments projected to close due to regulation is then calculated by multiplying the incremental probability of closure by the number of establishments in the model class. Further, multiplying the projected number of closures by the average number of employees per establishment in the model class yields an estimate of employment impacts. Establishments that are not projected to close continue to operate with a lower level of profitability and a lower probability of survival. The extent of these impacts may be characterized by using the model to examine the number and percentage of establishments that incur costs exceeding some specified percentage of establishment cash flow. For example, the model can be used to estimate the number of establishments that incur costs exceeding 1 percent or 3 percent of cash flow. There is, however, no necessary and sufficient relationship beyond that used to project closure that can be used to determine further impacts on the industry.

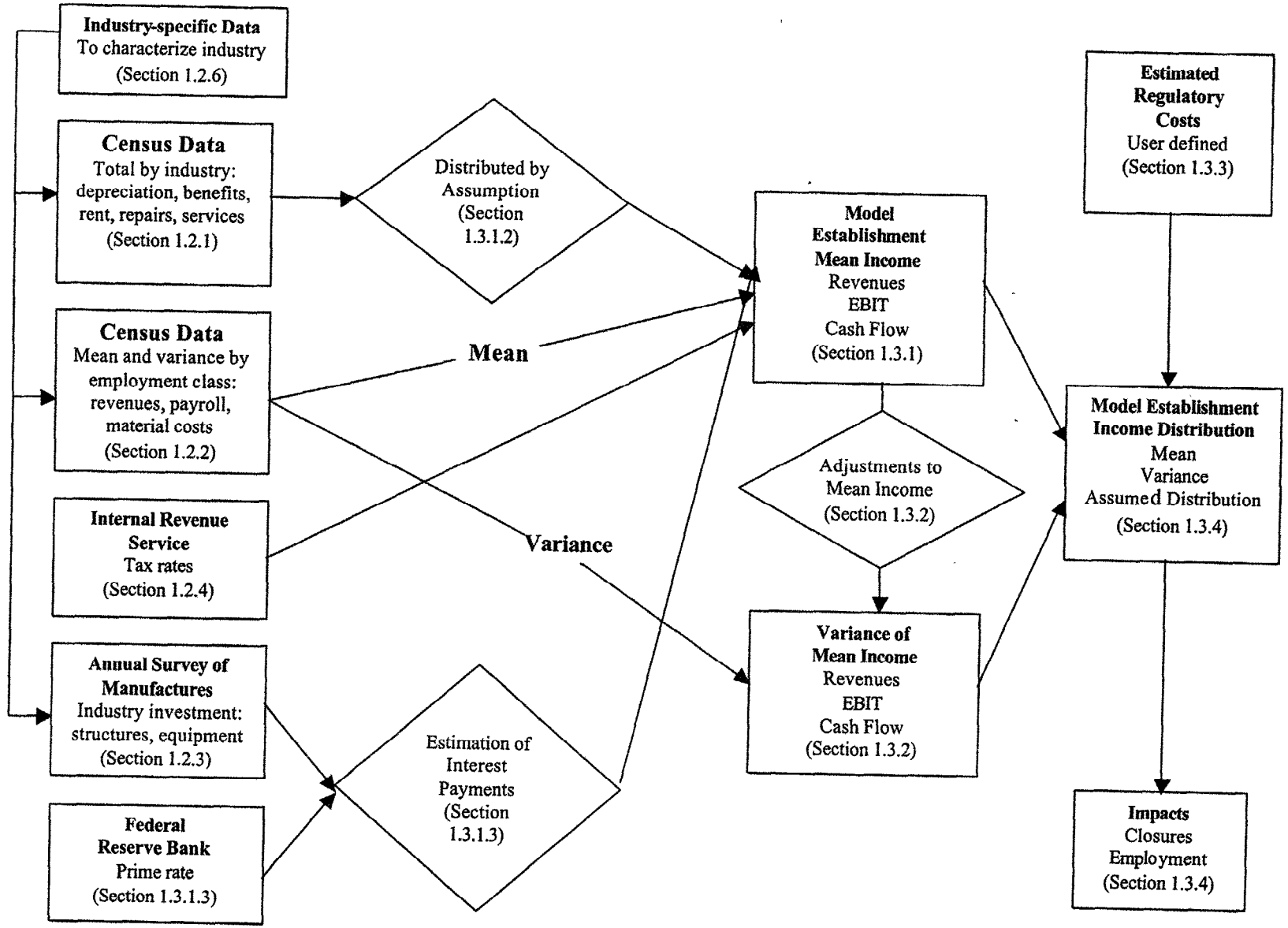
1.1.2 Organization of Model Presentation

Because the actual calculation of the mean and variance of establishment income involves a wide variety of sources, and a number of calculation steps, this section provides a roadmap through the detailed explanation to follow in Sections 1.2 and 1.3. Figure 1-2 is a flow diagram presenting the key data sources, how those data sources enter the model, the

[3] The effect of the regulation on facilities with negative cash flow in the baseline ("baseline closures") cannot be evaluated. The basis for determining the impact of a potential regulation on an establishment is that the establishment must have positive earnings prior to the regulation and negative earnings after regulation. If an establishment has negative earnings prior to the regulation, then it may very well close even if the regulation is never promulgated. Thus, closure of such an establishment should not be considered an impact of the regulation.

Figure 1-2

Flow Diagram for Model Framework



interrelationship between the two primary components of the model, and how those components interact with user-defined regulatory cost estimates to project regulatory impacts.

The column of boxes at the left-hand margin of Figure 1-2 represents the data sources. First, a variety of industry-specific data sources are used to characterize an industry to determine what Census data (i.e., which NAICS codes) are most appropriate to model a given industry. After using these data sources to map the industry onto Census data, the remaining specified data sources are used to model it. All data are used to develop estimates of model facility income (i.e., revenues, EBIT, and cash flow) and its distribution, albeit some data are used indirectly in the form of intermediate calculations. For example, investment data obtained from the *Annual Survey of Manufactures* are combined with interest rate data from the Federal Reserve to estimate industry interest payments, which are ultimately used in the model facility income calculations.

The key data source is from the U.S. Census of Manufactures. Two types of Census data are used: industry-level data and employment-class data. Various components utilized in generating the income measures are only reported at the industry-level. These data are then distributed among the various employment classes to generate the various income measures. Model establishment classes are defined by employment size; Census provides key components such as revenues, payroll, and material costs at the employment class level. Calculated as means for each employment class, these data are the most important components of model establishment income. Furthermore, ERG obtained from Census the variances and covariances of these components used to estimate the variance of model establishment class income.

Mean revenues, payroll and material costs are the primary components of model facility income, and the variances and covariances of revenues, payroll and material costs are the primary components of the variance of model facility income. Model facility income is, however, modified by the inclusion of other components (e.g., interest payments, taxes, and other operating costs). These components, in all likelihood, affect estimated variance as well as income. Because direct information on the variance of these individual components is not

available, the model estimates their impact on the variance of income. Hence, there is a link between the two primary components of the model: income, and the variance of that income.

Given estimated model facility income, and the estimated variance of that income, the cumulative distribution function for the entire class of establishments represented by that model can be estimated. Combining this income distribution with user-specified estimates of compliance costs, the model computes the percentage and number of establishments that incur costs exceeding an income measure and the number of workers employed in those establishments.

1.2 Data Sources

The primary data sources utilized in the base model include:

- *1997 Economic Census: Manufacturing – Industry Series*,
- 1997 Economic Census customized tabulation,
- *Annual Survey of Manufactures (ASM)*, 1958-1997,
- 2000 Federal and state corporate tax rates,
- *1998-1999 Statistics of U.S. Businesses: Dynamic Data*, and
- Industry specific data sources, where applicable.

The following sections briefly discuss each data source and its utilization in the model framework.

1.2.1 1997 Economic Census: Manufacturing – Industry Series

The U.S. Census Bureau's *1997 Economic Census* for manufacturing industries constitutes the primary data source for the model. ERG created an estimated income statement for each model facility from the Census' establishment level data. Census data are the only high

quality source of consistent, systematically collected revenue and cost data for most industries. It is these qualities that ensure that model facilities and their estimated income are representative of the industry. The relevant data fields available from the Census include the following:

- At the employment class level: Number of establishments, number of employees, value of shipments, payroll, value-added, cost of materials, and capital expenditures, and
- At the North American Industry Classification System (NAICS) industry level: Employment benefits, depreciation, rent payments, building repairs, equipment repairs, communications, legal services, accounting services, data processing advertising services, and refuse removal services.

Other data sources, such as market analyses, studies, and profiles generated by private research firms or by trade associations, have two primary drawbacks for building this type of model. First, the information is not systematically collected, and therefore may not be entirely representative of the industry as a whole. These studies tend to be based on conversations with representatives of firms operating in the industry, the expert opinion of industry observers, or voluntary surveys. Second, market studies frequently provide information on revenues, but rarely provide information on production costs. While these data sources are important, the model relies on Census data as its primary data source for building the basic small business impact model. These additional data sources are then used to (1) map the four FDA-regulated industries to be analyzed (dietary supplements manufacturing, candy manufacturing, cosmetics manufacturing, and ready-to-eat foods manufacturing) onto the Census NAICS industries and (2) overcome any prospective data deficiencies in the Census data.

The Census data are also provided by establishment employment class. The Small Business Administration (SBA) standards for classifying firms as small are typically expressed in terms of entity employment level. All food processing industry SBA standards are defined by employment. Furthermore, all but four of 47 NAICS food-processing industries have SBA standards defined by employment thresholds that match Census employment classes (either 500 or 1,000 employees). Other NAICS industries of interest to FDA, such as NAICS 32560, Toilet Preparation Manufacturing (which includes cosmetics), also have size standards that match

Census employment class data. Therefore, it is straightforward to utilize the model to evaluate impacts using the NAICS-based SBA definitions.[6]

In the model, the model facility income measures are based on establishment-level data, while SBA size standards are determined by company-level employment. Where the company is a single-establishment firm, as most small businesses are, the company and the establishment are identical. SBA's Office of Advocacy provides a special compilation of Census data comparing the number of establishments with the number of firms, by employment level. For most food processing industries, the ratio of companies to establishments by employment class is close to 1.0 for establishments with fewer than 20 employees, and greater than 0.9 for establishments with fewer than 500 employees. Thus, the model assumption that the establishment is equivalent to the company should not significantly affect the analysis.

1.2.2 Customized Tabulation From the 1997 Economic Census

In addition to the published Census statistics above, ERG also requested a customized tabulation of the *1997 Economic Census* from the Census Bureau. The additional data fields obtained for each employment size class in a given NAICS included:

- Variance estimates for value of shipments, payroll, and cost of materials,
- Covariance estimates for value of shipments and payroll; value of shipments and cost of materials; and payroll and cost of materials, and
- Correlation coefficients of value of shipments and payroll; value of shipments and cost of materials; and payroll and cost of materials.

ERG used these statistics to estimate the frequency distribution of income measures for each employment class in the model (see Section 1.3.2).

[6] Upon FDA's request, the current version of the model summarizes impacts by three establishment size classes: establishments with less than 20 employees, with 20 to 499 employees, and with 500 or more employees.

1.2.3 Annual Survey of Manufactures (ASM), 1958-1997

Every five years, the Census Bureau surveys around 60,000 manufacturing establishments for the *Annual Survey of Manufactures (ASM)*. The survey sample for the ASM is drawn from the Census of Manufactures database of all manufacturing establishments in the country. The model utilizes time series data (1958 through 1997) from the ASM to compute interest payments for model facilities in each NAICS code.[7] The ASM data fields utilized in the model include

- Investment in capital equipment, and
- Investment in buildings

both of which are denoted in nominal dollars. The interest payment computations in the model must be updated as new annual data becomes available.

1.2.4 2000 Federal and State Corporate Tax Rates

The Internal Revenue Service (IRS) and the state governments provide the applicable Federal and state corporate tax rates in *Instructions for Forms 1120 and 1120-A* and *State Tax Handbook* publications, respectively. The tax rates utilized in the computation of tax payments in the model are provided in Table 1-1.

Table 1-1

2000 Federal and State Tax Rates

Taxable Income	Standard Tax	Taxable Income	Average Effective Tax Rate
$ -	$ -	$ -	15%
$50,000	$8,000	$50,000	25%
$75,000	$14,000	$75,000	34%
$100,000	$22,000	$100,000	39%
$335,000	$114,000	$335,000	34%
$10,000,000	$3,400,000	$10,000,000	35%
$15,000,000	$5,150,000	$15,000,000	38%
$18,333,000	$ -	$18,333,000	35%
Average state tax rate			6.6%

Source: IRS, 2000 and State Tax Handbook, 1999

1.2.5 1997-1998 Statistics of U.S. Businesses: Dynamic Data

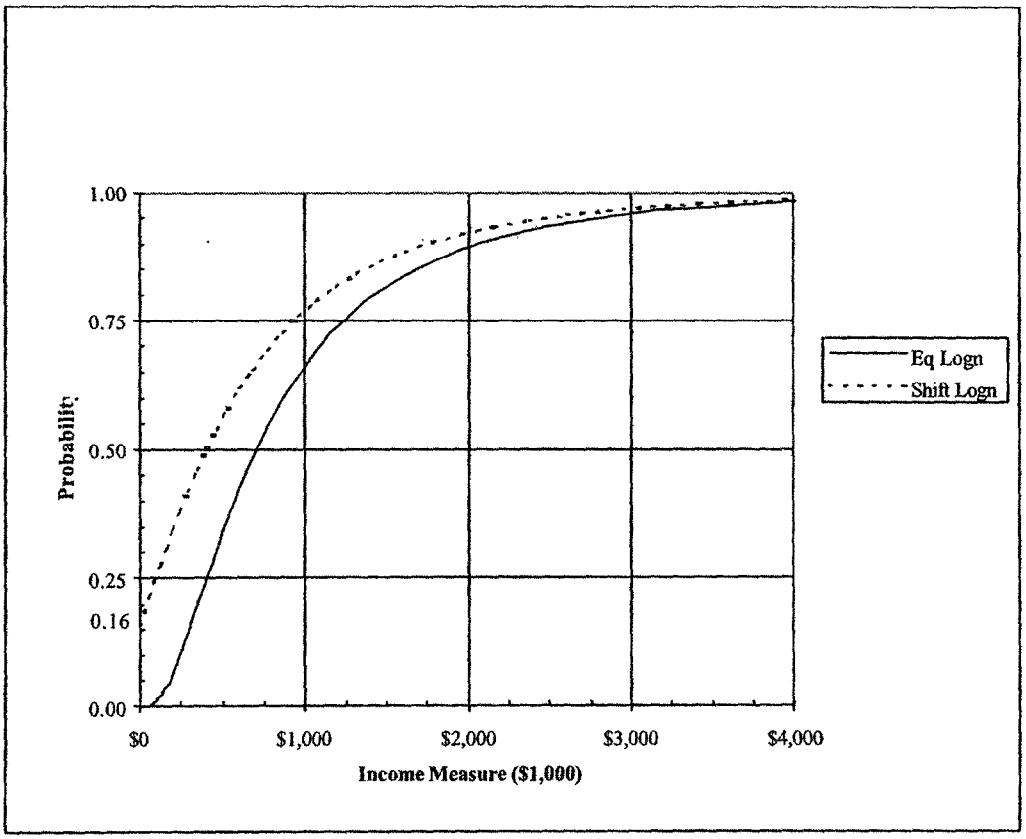
The U.S. Census Bureau collects and publishes statistics on the birth and death rate of firms by 4-digit NAICS industry, employment size, and state. The reported death rates correspond to establishments that were in business during the initial year but were out of business in the subsequent year for the 4-digit NAICS. The model uses the firm-death rate data to scale the cumulative frequency distributions of the three income measures under the lognormal distributional assumption (see Section 1.3.2 for further discussion).

Because the domain for the lognormal function is $(0, \infty)$, the lognormal distributional assumption cannot by definition incorporate the notion of baseline facility closures (i.e., facilities earning negative income regardless of any FDA regulation). To overcome this limitation, ERG used the reported firm-death rate figures as a proxy for the probability of baseline facility closure. Thus, the cumulative lognormal distribution was shifted up by the reported death-rate, such that at $0 income the cumulative probability was equivalent to the reported firm-death rate for the employment size class. This is depicted in Figure 1-3. Reading the point where the shifted

[7] At present, the ASM time series data are available on a Standard Industrial Classification (SIC) basis rather than the NAICS basis utilized in the model. Thus, ERG transformed the SIC-based investment data into NAICS basis using the SIC to NAICS bridge tables provided by the Census Bureau (see Section 1.3.2.2 for further discussion).

Figure 1-3

Lognormal Distribution Function of Income



lognormal curve intersects the y-axis, the probability of baseline closure for the employment size class is around 16 percent in the figure.

The current model uses the 1998-1999 death rate data. The Census Bureau releases these data annually. Hence, computations in the model need to be updated as new data become available.

1.2.6 Industry Specific Data Sources

Among the four industries under consideration, some do not closely match the NAICS industry definition. For example, dietary supplements (DS) industry establishments are distributed over four NAICS industries, but only comprise just a fraction of establishments in some of those industries. Therefore, for the DS industry, ERG also relied on FDA's database of DS establishments, which fully characterize the types of facilities (i.e., manufacturing, input supplier, etc.), employment size and product types (i.e., vitamins and minerals, herbal extracts, etc.) of those facilities, and the NAICS industries within which these facilities are classified.[2] The database enabled ERG to map the whole DS industry onto the Census NAICS industries, thereby allowing the computation of industry-specific income measures and their frequency distributions from Census data.

A detailed discussion of the industry-specific data sources utilized are included in the respective sections describing the application of the model to the DS, candy manufacturing, cosmetics manufacturing, and RTE foods manufacturing industries.

[2] The DS establishment database has been compiled in 1999 and may not reflect the changes (i.e., mergers and acquisitions and entry and exit of firms from the industry) that occurred in the industry since then. Thus, the model will require updates as newer versions of the database become available.

1.3 Model Framework

The microeconomic basis for the model framework is that a profit-maximizing firm will shut down when short-run AVC exceed AR. Economic theory states that sunk costs (i.e., costs attributable to past capital purchases) are irrelevant to a firm's current decision making; only variable costs matter in the short run. This basic microeconomic principle can be observed in modern corporate finance where a firm is expected to close if its cash flow (i.e., net income plus depreciation) turns negative. Accounting cash flow, which is defined by operating costs and revenues, is analogous to comparing short-run variable costs and average revenues. By excluding depreciation (the accounting charge for the utilization of previously purchased capital equipment) from the cash flow calculation, cash flow essentially measures current operating revenues net of current operating costs.[3] Negative cash flow is equivalent to average variable costs exceeding average revenues where a firm is expected to close (Brealey and Myers, 1996 and Brigham and Gapenski, 1997).

The model assesses when and to what extent a facility is impacted by regulatory costs by measuring the facility's pre- and post-regulation cash flows. If cash flow becomes negative after regulatory costs are subtracted from pre-regulation cash flow, it can be reasonably inferred that the regulatory cost burden caused the facility closure. Impacts of the regulation then would include closure of a facility along with its lost output and employment. The model framework also evaluates impacts on small businesses by utilizing two alternative income measures, revenues and earnings before interest and taxes (EBIT). Although cash flow is the best predictor of facility survival, the additional income measures act as sensitivity analyses to check for consistency in model results.

[3] The cash flow calculation includes interest payments. Some may argue that interest payments also reflect costs associated with past capital purchases and therefore should be excluded from consideration in the shut down analysis. However, interest payments cannot be excluded from the analysis; if the facility cannot meet its interest payments, it will be in default on its loans and lending institutions will foreclose.

The model preparation covers four stages:

- *Stage 1* – Develop model facility income measures, including revenues, earnings before interest and taxes (EBIT), and cash flow, for establishments of different sizes;
- *Stage 2* – Estimate the frequency distribution of different income measures for the class of facilities represented by each model facility;
- *Stage 3* – Provide a framework of per-facility regulatory compliance costs for use as inputs in each model facility class by type of regulation; and
- *Stage 4* – Estimate the percentage of facilities with income less than estimated regulatory costs within each model facility class.

A detailed discussion of each of these stages is provided in the following sections.

1.3.1 Development of Model Facility Income Measures

In the first step, ERG developed a series of model facilities for the industry to be analyzed. The model facilities represent establishments of different employment sizes within the industry. The *1997 Economic Census: Manufacturing – Industry Series* data provide detailed revenue and cost information by employment class that ERG primarily used to build model facilities. ERG also utilized the *Annual Survey of Manufactures* (ASM), and Federal and state corporate tax rates, to estimate interest payments and relevant tax rates (see Section 2.1). For each model facility, the model computes revenues, earnings before interest and taxes (EBIT), and cash flow.

1.3.1.1 Revenues

The Census Bureau publishes the value of total shipments by employment size and the number of establishments in that class. The value of total shipments includes the value of primary and secondary shipments and the value of resale, contract, and other miscellaneous

receipts. Thus, the value of total shipments at the employment class level divided by the number of establishments within the class essentially equals total revenues per establishment, i.e.,

$$\text{Revenues} = \frac{\text{Value of Shipments}}{\text{Number of Establishments}} \quad (1\text{-}1)$$

for each employment class. Model facility revenues are the easiest and most accurate income measure to compute as the data are directly provided by the Census distributed to the employment class level. There is, however, no necessary casual link among regulatory costs, revenue impacts, and facility closure. Nonetheless, the model evaluates impacts on revenues (in addition to EBIT and cash flow) to check for consistency in model results.

1.3.1.2 Earnings Before Interest and Taxes (EBIT)

Using several assumptions, the model calculates EBIT as total revenues minus operating costs for each model facility. The Census provides most categories of operating costs that are included in the EBIT computation, including

- Value of shipments, payroll, and material costs directly distributed to the employment class level, and
- Benefits, depreciation, rent, and purchased services (listed below) at the NAICS industry level.

In addition to payroll and material costs, Census also provides capital expenditures and value added directly distributed at the employment class level.

To distribute industry level costs to the employment class level, ERG assumed that:

- Employment benefits are proportionate to payroll.
- Depreciation expense is proportionate to capital expenditures.
- Rent payments are proportionate to capital expenditures.

- Building repairs expenses are proportionate to capital expenditures.
- Equipment repairs expenses are proportionate to capital expenditures.
- Communications expenses are proportionate to value of shipments.
- Legal services expenses are proportionate to value of shipments.
- Accounting services expenses are proportionate to value of shipments.
- Data processing services expenses are proportionate to value of shipments.
- Advertising services expenses are proportionate to value added.
- Refuse removal expenses are proportionate to material costs.

In using capital expenditures to distribute depreciation, rent, and repair costs to the employment class level, ERG implicitly assumed that capital expenditures are proportionate to capital stocks. Presumably, expenditures on building repairs, for example, are a function of buildings owned; because that information is not available, however, the model uses an additional assumption that capital stocks by employment class are proportionate to capital expenditures by employment class.

The model calculates model facility EBIT as:

$$\text{EBIT} = \frac{(\text{Value of Shipments} - \text{Operating Costs})}{\text{Number of establishments}} \tag{1-2}$$

where

$$\text{Operating Costs} = \begin{pmatrix} \text{Payroll} + \text{Material Costs} + \text{Benefits} + \text{Depreciation} + \text{Rent} \\ + \text{Purchased Services} \end{pmatrix} \tag{1-3}$$

for each employment class. Because revenues, payroll, and cost of materials are the most significant components of EBIT, the error introduced by distributing industry level data among employment classes will be small.

1.3.1.3 Cash Flow

The model calculates cash flow for each model facility as EBIT plus depreciation, less tax and interest payments. Depreciation is estimated as a component of EBIT and added back into the cash flow calculation. To estimate taxes and interest payments, ERG utilized the ASM, the *1997 Economic Census*, and federal and state tax rates. Because an additional layer of assumptions, however reasonable, must be utilized to estimate cash flow, the uncertainty associated with the cash flow estimate is greater than that for EBIT.

The tax payment estimation assumes that establishment EBIT is equal to business entity EBIT, i.e., that the establishment represents the entire business. For the purposes of estimating facility tax payments, ERG multiplied the model facility's EBIT by the sum of relevant Federal corporate income tax rate and the average state corporate income tax rate and added it to the standard tax for the model facility's EBIT. Table 1-1 presents the applicable standard taxes and tax rates used in the computations (see Section 1.2.3).

The model estimates interest payments using a combination of ASM data on past investment by industry, Census data on relative investment in buildings and equipment, and assumptions about investment behavior. For each industry under consideration, ERG first scaled the ASM time series data on investment, which is based on Standard Industrial Classification (SIC) codes, to represent the applicable NAICS industries. ERG then used the average percentage of relevant industry investment in equipment and structures as presented in the Census data to divide the ASM investment time series into those two components.

To estimate interest payments from the time series of past investment in equipment and structures, the model uses assumptions about industry-borrowing behavior. More specifically, ERG assumed that:

- All investment in each year was funded through bank loans,
- The interest rate on those loans is equal to the nominal prime rate for that year plus 1 percent (since ASM investment time series data is in nominal terms, a nominal interest rate is appropriate), and
- The average loan period was ten years for equipment and 25 years for structures.

With these assumptions, ERG developed a time series estimate of loan payments made by the industry, and the portion of each year's loan payments accounted for by interest. Total interest payments in the baseline year equals the sum of this year's interest payments on the stream of past years' investment.[4] Interest payments were then attributed to each employment class based on the percentage of industry investment accounted for by that employment class in the Census data.

For each model facility, net income is calculated as:

$$\text{Net Income} = (\text{EBIT} - \text{Standard Tax}) \times (1 - \text{Tax Rate}) - \text{Interest Payments} \quad (1\text{-}4)$$

Next, cash flow is computed as

$$\text{Cash Flow} = \text{Net Income} + \text{Depreciation} \quad (1\text{-}5)$$

where depreciation was estimated for the calculation of model facility EBIT as described in Section 1.3.1.2.

The link between impacts measured by comparing cash flow with compliance costs is much stronger than the link between either EBIT or revenues and compliance costs: when post-

[4] For example, interest payments on equipment investment for the year 1997 would equal the sum of interest paid in year 25 of loans from 1973 plus the interest paid in year 24 of loans from 1974, and so on.

compliance cash flow is negative, the facility can be reasonably projected to close. Because the estimate of cash flow is dependent upon a series of assumptions, however, the uncertainty concerning the accuracy of the cash flow measure is much greater than that for revenues or EBIT. Thus, this analytic approach presents a tradeoff between the accuracy of the income measure and the certainty of the impacts based on that measure.

1.3.2 Distribution of Income Represented by Model Facilities

The model facilities reflect the average of a group of facilities, not a group of identical facilities. Income for a given group of facilities will lie in a distribution around the average. Ignoring this distribution of facility income will result in impact estimation errors. If the model facility is projected to remain open after incurring regulatory costs, then some facilities that it represents with smaller than average income may, in fact, close due to the regulation despite the model results. Conversely, if the model facility is projected to close as a result of regulatory costs, then some larger than average facilities that it represents may in reality remain open despite the regulatory costs. To address this, ERG estimated the distribution of income represented by model facilities. By modeling a facility income distribution with known mean and variance, the model can forecast how regulatory costs impact not just the model facility, but the facilities represented by it as well.

To estimate the distribution of income, ERG obtained special tabulations of the variances and covariances of relevant income components for each employment class (i.e., model facility) from the Census Bureau. Combining these data along with the starting assumption that these observations are normally distributed around their mean, ERG constructed cumulative probability distributions for the three income measures, revenues, EBIT, and cash flow. The following sections describe the cumulative probability distribution constructs for the individual income measures in further detail.

ERG also incorporated an alternative assumption on the frequency distribution of income to assess the sensitivity of model results to the assumption of normality. If, for instance, some

facilities within an employment class have atypically high incomes, then the income distribution for the class might be positively skewed rather than symmetric around a mean value. In such a case, using a normal symmetric distribution to approximate the skewed distribution would yield biased estimates. The Census Bureau further indicated that in general, the distribution of facilities in an employment size class tends to be positively skewed (Quash, 2001). Thus, for each of the industry models, ERG also generated an alternative set of income distributions based on the lognormal function for use in gauging the sensitivity of model results to the normality assumption.

1.3.2.1 Distribution of Revenues

To estimate the cumulative probability function of revenues, for each NAICS industry and model facility analyzed, ERG obtained the variance of the value of shipments, σ_R^2, around its mean, $\bar{x}_R$. Based on the distributional assumption employed, the model evaluates impacts as the number and percentage of facilities in an employment class for which compliance costs exceed revenues or a specified percentage of revenues.

For the base model, the revenues for a given employment size class are assumed to be normally distributed, i.e.,

(1-6) $$x_R \sim N\left(\bar{x}_R, \sigma_R^2\right)$$

For the lognormal assumption, where $x_R \sim Lognormal\left(\bar{x}_{\ln x_R}, \hat{\sigma}^2_{\ln x_R}\right)$, ERG transformed the mean and variance of revenues to obtain the relevant parameters for the lognormal distribution using the following formulas:

(1-7) $$\bar{x}_{\ln x_R} = \ln \bar{x}_R - \frac{1}{2}\sigma^2_{\ln x_R}$$

(1-8) $$\sigma^2_{\ln x_R} = \ln\left(1+\frac{\sigma^2_R}{\bar{x}^2_R}\right)$$

ERG applied the same transformation to the remaining income measures, EBIT and cash flow, to obtain the parameters for the lognormal distribution (see Sections 1.3.2.2 and 1.3.2.3).

1.3.2.2 Distribution of EBIT

Although the variance of revenues (value of shipments) is provided by the Census special tabulation, the variance of EBIT needs to be estimated. EBIT is a linear function of its revenue and cost components. Thus, the variance of EBIT can be estimated using the standard statistical relationship where the variance of a linear function, x, of n variables is itself a linear function of the variance and covariance of its constituents, such that

(1-9) if $$x = \sum_{i=1}^{n} x_i$$

then

(1-10) $$Var(x) = \sum_{i=1}^{n} Var(x_i) + 2\sum_i \sum_j Cov(x_i, x_j)$$

where the double sum is over all pairs (i, j) with $i < j$ (Mendenhall et al., 1990).

To estimate the distribution of EBIT for each model facility, ERG first obtained the variance, σ_i^2, and covariance, σ_{ij}, of the value of shipments (R), payroll (P), and material costs (M) for each employment class from the Census Bureau. Given that EBIT is

(1-11) $$\bar{x}_{EBIT} = \bar{x}_R - \bar{x}_P - \bar{x}_M$$

for each model facility class where $\bar{x}_i$ denotes the mean value of variable i, such that i = EBIT, R, P, and M, ERG computed the variance of EBIT, σ^2_{EBIT}, as

(1-12) $$\sigma^2_{EBIT} = \sigma^2_R + \sigma^2_P + \sigma^2_M - 2\sigma^2_{RM} - 2\sigma^2_{RP} + 2\sigma^2_{PM}$$

Although payroll and material cost do not comprise all operating expenses included in EBIT, they do comprise the vast majority of EBIT. Hence, excluding the variance for the remaining components should not cause a significant error in the variance estimate.

For the lognormal distributional assumption (i.e., $x_{EBIT} \sim Lognormal\left(\bar{x}_{\ln x_{EBIT}}, \sigma^2_{\ln x_{EBIT}}\right)$), ERG transformed the estimated mean and variance of EBIT using (1-7) and (1-8) above, such that

(1-13) $$\bar{x}_{\ln x_{EBIT}} = \ln \bar{x}_{EBIT} - \frac{1}{2}\sigma^2_{\ln x_{EBIT}}$$

(1-14) $$\sigma^2_{\ln x_{EBIT}} = \ln\left(1 + \frac{\sigma^2_{EBIT}}{\bar{x}^2_{EBIT}}\right)$$

1.3.2.3 Distribution of Cash Flow

The model estimates the variance of cash flow, σ^2_{CF}, for each model facility from its estimated variance for EBIT, σ^2_{EBIT}, which in turn is a linear function of the variance for net income (NI), σ^2_{NI}. If the mean of a distribution is multiplied by some scalar, a, then the variance

of that distribution increases by the square of a. That is, if the mean net income, $\bar{x}_{NI}$, for a model facility is some percentage of facility EBIT, such that

(1-15) $$\bar{x}_{NI} = a\bar{x}_{EBIT} \qquad \text{where } 0 < a < 1$$

then the variance of facility net income is equal to the square of that percentage multiplied by the variance of EBIT, i.e.,

(1-16) $$\sigma^2_{NI} = a^2\sigma^2_{EBIT}$$

Hence, in the model, ERG first used the ratio of facility net income to EBIT to determine the scalar, a, for estimating the variance of cash flow, σ^2_{NI}. Since cash flow is the sum of net income and depreciation (D) (see equation 1-5), the mean of cash flow is given by

(1-17) $$\bar{x}_{CF} = \bar{x}_{NI} + \bar{x}_D$$

Because the variance of depreciation is not available from the Census or any other published source and is not directly estimable, ERG assumed that it is negligible, i.e., $\sigma^2_D \approx 0$. This amounts to shifting the cumulative probability distribution of net income with mean $\bar{x}_{NI}$ and variance σ^2_{NI} along the x-axis. Thus, the variance for cash flow becomes

(1-18a) $$\sigma^2_{CF} = Var(x_{NI} + x_D) = Var(x_{NI}) + Var(x_D)$$

(1-18b) $$\sigma^2_{CF} = \sigma^2_{NI} + \sigma^2_D = a^2\sigma^2_{EBIT} + \sigma^2_D$$

Given that the variance of depreciations is assumed negligible, i.e., $\sigma^2_D \approx 0$, the variance of cash flow is equivalent to the variance of net income, i.e.,

(1-18c) $$\sigma_{CF}^2 = \sigma_{NI}^2 + \sigma_D^2 = a^2\sigma_{EBIT}^2$$

It should be noted that model results might be different if the above assumptions were changed regarding the scaling and shifting of distributions utilized in the computation of probabilities in the model. However, it is not possible to determine *a priori* the impacts of favoring one type of adjustment (scaling versus shifting a given distribution) over another without computing model impacts for the various alternatives.

For the lognormal distributional assumption (i.e., $x_{CF} \sim Lognormal\left(\bar{x}_{\ln x_{CF}}, \sigma_{\ln x_{CF}}^2\right)$), ERG transformed the estimated mean and variance of cash flow computed above using the following formulas:

(1-19) $$\bar{x}_{\ln x_{CF}} = \ln \bar{x}_{CF} - \frac{1}{2}\sigma_{\ln x_{CF}}^2$$

(1-20) $$\sigma_{\ln x_{CF}}^2 = \ln\left(1 + \frac{\sigma_{CF}^2}{\bar{x}_{CF}^2}\right)$$

1.3.2.4 Adjustments to Variance

ERG "smoothed" (reduction of statistical variance by adjusting observations) the variances of the income measures by applying the median coefficient of variation (i.e., standard deviation divided by mean) within a NAICS code to all employment classes in that code. This results in an identical probability that income is less than zero for all employment classes within a NAICS code. That probability, however, differs across NAICS codes. ERG judged that smoothing was appropriate because of (1) relatively small populations in some employment classes, and (2) relatively large differences in the coefficient of variation among employment classes within a NAICS code.

1.3.3 Regulatory Cost Inputs by Model Facility

The model incorporates a set of cost input options representing estimated unit costs of complying with the proposed regulatory options under consideration. In the model, the per-facility cost input options are independent of the regulation considered, hence allowing the user to evaluate practically any type of FDA regulation. FDA may want to use this model framework in a number of ways to estimate the potential impact of regulatory costs on small entities. The unit cost inputs to be used in the model may come from a wide variety of sources. For example, FDA may choose to:

- Use cost estimates developed under earlier regulatory guidelines (e.g., HACCP for fish and fishery products) for a scoping exercise examining a similar regulation in a different industry, or
- Examine preliminary estimates of regulatory costs under different types of regulatory scenarios within an industry.

To facilitate these different analyses with the model, ERG developed a cost input framework that requires the user to enter unit compliance costs for three facility employment size classes, including

- Facilities with less than 20 employees,
- Facilities with 20 to 499 employees, and
- Facilities with at least 500 employees.

Further, the unit compliance cost inputs distinguish among:

- One-time capital costs,
- One-time non-capital costs, and
- Annual, or recurring non-capital costs.

One time capital costs include equipment and other related purchases that will be depreciated over time. The setup of the cost input framework also requires the user to distinguish between the one-time and recurring components of non-capital regulatory costs. For example, both

paperwork costs and training costs typically have a one-time cost component, such as the startup costs of developing paperwork procedures and policies, or designing and implementing a training program. However, the cost of the frequency of training would be considered an annual, or recurring cost. Both of these cost types are also examples of non-capital costs because a firm usually cannot expense them over time. Equipment-related costs, such as operating or maintenance costs, are usually considered annual, or recurring, non-capital costs.

The three types of costs listed above will differ in magnitude across regulation types and business sizes. A HACCP regulation or ingredient ban, for example, may require the purchase of capital equipment. A labeling regulation, on the other hand, might result in a one-time non-capital expense of designing a new label and the annual, or recurring, cost of larger labels to meet a change in labeling requirements. Business size can influence costs as well. For example, larger establishments may need to purchase more expensive equipment or more labels per year to accommodate a larger scale of production.

Because regulatory costs may occur in different years or may be expensed in different years, the model annualizes costs. Annualization formulas, like mortgages, convert a capital cost into a stream of principal and interest payments necessary to pay for the item over its useful life. The model allows the user to specify the annualization time horizon and industry's cost of borrowing for one-time capital and non-capital costs separately, to capture the different impacts these costs have on facility cash flow. The annual, or recurring costs are added, as entered by the user, to the sum of the annualized one-time capital and non-capital costs.

1.3.4 Estimation of Small Business Impacts

In the final stage of computations, the model uses the model facility income measures and model facility compliance cost estimates to project the number of small business facilities expected to close due to regulatory action. The model also provides impacts short of facility closure, based on user-specified income thresholds. The following sections describe the model computations in further detail.

1.3.4.1 Accounting for Facilities Earning Negative Income

In the Census data, some facilities might have negative income. Mainly, the reasons for negative facility baseline income are attributable to the actual establishment financial data collected by the Census on which the estimated distribution is based:

- The parent company that owns the establishment does not assign costs and revenues that reflect the true financial health of the establishment. Two important examples are cost centers and captive sites, which exist primarily to serve other facilities under the same ownership[5]; or
- The facility is in financial trouble; that is, true costs exceed income.

To the extent that these establishments are contained in an employment class, the projection of negative baseline income is accurate. In either case, FDA would be unable to evaluate impacts to these establishments as a result of a rule under consideration. To accurately project impacts due to regulatory costs alone, these facilities need to be removed from the analysis. Thus, the model focuses on those facilities whose pre-regulation income (revenues, EBIT, or cash flow) is greater than zero, in the estimation of facility impacts.

In the model, baseline facility impacts are computed for all three income measures prior to the evaluation of incremental impacts. For quality assurance/quality control purposes, the baseline facility impacts, FC_i, predicted by each of the income measures (where $i = R$, $EBIT$, and CF) should be ranked, such that the following inequalities hold in all model computations:

$$FC_R < FC_{EBIT} \text{ and } FC_R < FC_{CF} \text{ and } FC_{EBIT} < or > FC_{CF} \quad (1\text{-}21)$$

[5] Captive sites may show revenues, but the revenues are set approximately equal to the costs of the operation. Cost centers have no revenues assigned to them.

1.3.4.2 Determination of Facility Closures

The mean and variance completely summarize the distribution of income for each model facility. To estimate facility closures, however, the model assesses impacts on facility cash flow. As previously discussed (see Section 1.3), cash flow is associated with a well-defined impact threshold: if post-regulation cash flow is positive (i.e., pre-regulation cash flow minus estimated regulatory costs), the facility is projected to remain open; if post-regulation cash flow is negative, the facility is assumed to close. Therefore, the threshold value for cash flow is equal to the estimated regulatory costs for each model facility. All facilities where regulatory costs exceed cash flow are projected to close due to the regulation considered.

Additionally, the model also estimates incremental impacts based on the two alternative income measures, revenues and EBIT, where facilities are impacted if post-regulation revenues and EBIT are negative. The two alternative computations are provided for comparison purposes only, and hence do not reflect actual facility closures.

1.3.4.3 Determination of Impacts Short of Closure

In evaluating small business impacts, it is also useful to routinely tabulate regulatory costs as a percent of the income measures. First, this tabulation for revenue, EBIT, and cash flow suggests the magnitude of impacts on facilities not projected to close. Second, by comparing projected impacts under the cash flow method with the number of facilities incurring regulatory costs as a percentage of revenues, EBIT or cash flow, it may be possible to determine a relationship between impacts on revenues, EBIT, and cash flow and projected closures. This information may be useful in the future for use in analyzing industries for which EBIT or cash flow cannot be reliably estimated. Thus, the model also estimates the number of facilities incurring regulatory costs exceeding a user-specified percentage of revenues, EBIT, and cash flow for each employment class in a given industry.

SECTION TWO

APPLICATION OF THE MODEL TO THE DIETARY SUPPLEMENTS (DS) INDUSTRY

The model framework described in Section One can be tailored to a wide variety of industries potentially affected by FDA regulations. In this section, ERG presents the model modified to address impacts on the dietary supplements (DS) industry.

The DS Small Business Impacts Model (DS-SBIM) is an Excel-based spreadsheet program that requires the user to input key model parameters and estimated unit (i.e., per-facility) regulatory costs. The model then calculates regulatory impacts according to the model framework described in Section One. Section 2.1 discusses the dietary supplement definition adopted for the small business impacts model. Section 2.2 presents the data sources that were used to tailor the model framework to the DS industry. Required data input for the model are discussed in Section 2.3. Finally, Section 2.4 describes the data link between the DS-SBIM and the Dietary Supplements Enhanced Establishment Database (DS-EED) and how to update the model as new plant-level data on the DS industry become available.

2.1 Definition

Congress defined the term dietary supplement in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product taken by mouth that contains a dietary ingredient intended to supplement the diet. The dietary ingredients in these products may include the following:

- Vitamins,
- Minerals,
- Herbs or other botanicals
- Amino acids, and
- Substances such as enzymes, organ tissues, glandulars, and metabolites.

Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of foods, not drugs, and requires that every supplement be labeled a dietary supplement (FDA, 2001c).

2.2 Data Sources

2.2.1 Census Data

As discussed in Section 1.2, the DS Small Business Impacts Model (DS-SBIM) derives the model facility income measures from the U.S. Census Bureau's *1997 Economic Census*. Based on the data provided in the Dietary Supplements Enhanced Establishment Database (DS-EED) (see Section 2.2.2 below), the DS industry is mainly comprised of firms in the following four NAICS codes:

- NAICS 311222, Soybean Processing,
- NAICS 311920, Coffee and Tea Manufacturing,
- NAICS 325411, Medicinal and Botanical Manufacturing, and
- NAICS 325412, Pharmaceutical Preparation Manufacturing.

2.2.2 Dietary Supplements Enhanced Establishment Database (DS-EED)

The Dietary Supplements Enhanced Establishment Database (DS-EED), compiled by Research Triangle Institute (RTI), provides data on 1,566 facilities in the DS industry. The facilities in the database are characterized by facility type, product type, NAICS code, and employment size class (as well as other criteria not relevant to the DS-SBIM). Given the

database's level of detail about facilities in the DS industry, ERG used the DS-EED database to complement the Census Data in calculating regulatory impacts.

First, ERG classified the facilities in the DS-EED database according to the following criteria:

- Product type, i.e., facilities producing only vitamins and minerals, facilities producing dietary supplements but not vitamins and minerals, and those producing both,
- Facility type, i.e., manufacturer, input supplier, repackager/relabeler/encapsulator, distributor, importer, or exporter,[8]
- Primary NAICS industry, i.e., NAICS 311222, NAICS 311920, NAICS 325199, and NAICS 325412, and
- Employment size class.

ERG found that some of the necessary data for these classifications were missing from the database. For those facilities missing product type or facility type data, ERG attempted to fill in the missing information from company Web sites. Such efforts, however, were unsuccessful and hence ERG eliminated those facilities from the analysis (see Table 2-1).

For those facilities missing NAICS data, ERG used the SIC code in the database and matched the SIC code to the NAICS code based on SIC to NAICS bridge tables and information provided in the DS-EED. In this way, ERG provided missing data for 47 facilities. The remaining facilities with missing NAICS codes were eliminated from the database.

For those facilities missing employment size class, ERG randomly applied the percentage distribution of facilities with employment size class data in the database. It should be noted that many facilities were missing multiple data items and hence classifying them according to employment size class did not necessarily mean that they were included in the final database used for the model.

[8] Some facilities operate as multiple facility types.

Table 2-1 summarizes the missing data before and after ERG supplemented the database. Ultimately, ERG used data on 1,248 facilities after completing as many observations as possible and then removing facilities with incomplete data (284 entries) and those not located in the U.S. (34 entries). Because the facilities data for the DS-SBIM need to be updated upon update of the DS-EED database, ERG linked the Excel-based spreadsheet program to the DS-EED revised by ERG as summarized above. The revised database will be referred to as the revised DS-EED from here on forward. The link enables the user to automatically incorporate any changes in the revised DS-EED into the model (see Section 2.4 for a detailed discussion of how to update the model as updates of the revised DS-EED become available).

Table 2-1

Data Deficiencies Encountered in the DS-EED

	Number of Facilities With Missing Data	
Missing Data Item	**Before ERG Modifications**	**After ERG Modifications**
Product type	137	137
Facility type	77	77
NAICS code	266	219
Employment size class	621	0
Total with missing data	774[a]	284[a]
Non-US facilities [b]	34	0

[a] Some facilities are missing multiple data items. Thus, the total observation with missing data is not the simple sum of the facilities with missing individual data items.
[b] All of these facilities had Canadian addresses.

2.3 User Input

The DS-SBIM requires the user to enter key model parameters and estimated unit regulatory costs. The data requirements for the spreadsheet model are outlined in Tables 2-2 and 2-3.

Table 2-2 requests input of key model parameters, including sector(s) affected, type of regulation to be analyzed, type of facilities affected, discount rates, annualization time horizons, and a price inflator. These parameters will determine how many establishments are affected by

the regulation and which unit regulatory costs need to be entered into the model. Table 2-3 requires the user to input estimates of unit regulatory costs for the model as predetermined (and highlighted in yellow) by the model parameters entered in the first page of data input.

After the data have been input, the model calculates baseline impacts, incremental impacts and threshold impacts short of closures. The model parameters and estimated unit regulatory cost inputs can be easily modified for the purpose of examining alternative scenarios.

2.3.1 Affected Sectors

In the model, the user must select the sector(s) that will be affected by the regulation. These must be mutually exclusive. Thus, the user needs to select only the vitamins and minerals sectors *or* all sectors except vitamins and minerals *or* all sectors in the industry by placing an "x" in the user input section. This parameter, along with facility type (see below), determines the number of affected establishments. If both the vitamins and minerals sector and all sectors, except vitamins and minerals are affected, facilities active in both sectors are counted only as one affected establishment. On the second page of data input, only the regulatory costs relevant to the affected sector(s) will be highlighted in yellow, based on this model parameter.

2.3.2 Type of Regulation to be Analyzed

The model requires the user to input the type of regulation to be analyzed, including HACCP, product labeling, product reformulation, use-by-dating, GMPs, sanitation, allergen testing, and holding costs. This data input does not enter the calculation of impacts, but requires the user to input costs on the second page of user input data for the type of regulation to be analyzed. If multiple regulations are under consideration for the industry, they need to be analyzed one at a time.

Table 2-2

User Input 1: Dietary Supplements (DS) Industry

1. Please indicate the sectors within the DS industry that will be impacted by the proposed regulations by placing an "x" in the appropriate box (please mark only one box):

Vitamins and Minerals	☐
All sectors, except vitamins and minerals	☐
All sectors	☐

2. Please indicate the type of proposed regulation for the DS industry by placing an "x" in the appropriate box. Please mark only one box. If multiple regulations are considered, they need to be analyzed one at a time

HACCP	☐
Product Labeling	☐
Product Reformulation	☐
Use-by-Dating	☐
GMPs	☐
Sanitation	☐
Allergen Testing	☐
Holding Costs	☐

3. Please indicate the types of facilities that will be impacted by the proposed regulation by placing an "x" in the appropriate box.

Manufacturer	☐
Input supplier	☐
Repackager, relabeler, or encapsulator	☐
Distributor	☐
Importer	☐
Exporter	☐

4. Please enter the values for the following items:

For capital expenditures:		
Discount rate	☐	Default value is 7%
Annualization time horizon (in years)	☐	Default value is 10 years
For non- capital expenditures:		
Discount rate	☐	Default value is 7%
Annualization time horizon (in years)	☐	Default value is 10 years

5. Regulatory impacts short of closure are defined as the number and percentage of establishments incurring compliance costs exceeding x% of revenues, here x is a threshold to be specified. Please enter the threshold:

Revenues	☐
EBIT	☐
Cash Flow	☐

5. The price inflator increases the model facility income measures by the percentage specified. Please specify a percentage or leave it blank to use the model facility income measures without price inflation.:

Price inflator	☐

Table 2-3

User Input 2: Dietary Supplements (DS) Industry

Industry Sector	Facility Type	Type of Cost ($)	Unit Costs by Model Class ($): Less Than 20 Employees	20 to 499 Employees	At Least 500 Employees
Vitamins and Minerals	Manufacturer	One-time capital			
		One-time non-capital			
		Recurring			
Vitamins and Minerals	Input Supplier	One-time capital			
		One-time non-capital			
		Recurring			
Vitamins and Minerals	Repackager	One-time capital			
		One-time non-capital			
		Recurring			
Vitamins and Minerals	Distributor	One-time capital			
		One-time non-capital			
		Recurring			
Vitamins and Minerals	Importer	One-time capital			
		One-time non-capital			
		Recurring			
Vitamins and Minerals	Exporter	One-time capital			
		One-time non-capital			
		Recurring			
All Other Sectors, Except Vitamins and Minerals	Manufacturer	One-time capital			
		One-time non-capital			
		Recurring			
All Other Sectors, Except Vitamins and Minerals	Input Supplier	One-time capital			
		One-time non-capital			
		Recurring			
All Other Sectors, Except Vitamins and Minerals	Repackager	One-time capital			
		One-time non-capital			
		Recurring			
All Other Sectors, Except Vitamins and Minerals	Distributor	One-time capital			
		One-time non-capital			
		Recurring			
All Other Sectors, Except Vitamins and Minerals	Importer	One-time capital			
		One-time non-capital			
		Recurring			
All Other Sectors, Except Vitamins and Minerals	Exporter	One-time capital			
		One-time non-capital			
		Recurring			

2.3.3 Types of Facilities Affected

Different types of facilities can be affected by the regulation and the model tracks costs associated with each facility type. The facility types accounted for include manufacturer, input supplier, repackager/relabeler/encapsulator, distributor, importer, and exporter. In the model, the user can select multiple facility types per regulatory option considered, as the model is capable of accounting for establishments that run multiple businesses (i.e., manufacturers that are also input suppliers). For multiple-business establishments, the model computes unit regulatory costs as the sum of unit costs by type of business.[9]

The selection of facility type, along with the selection of the sector(s) affected, determines the number of facilities affected. This also determines which unit regulatory costs will need to be input by the user on the second data input page.

2.3.4 The Discount Rate and the Annualization Time Horizon

The model requires the user to input the discount rate and the annualization time horizon for both one-time capital and non-capital costs. These data are then used to annualize the unit regulatory costs that are input by the user on the second page of data input. The sum of the annualized one-time capital and non-capital costs and any recurring costs constitute the unit regulatory costs used in the model to determine facility closures as a result of a regulatory action under consideration.

The Office of Management and Budget (OMB) recommends using a real discount rate of 7 percent in constant-dollar cost-benefit analyses of proposed investments and regulations. This rate approximates the marginal pretax rate of return on an average investment in the private sector (OMB, 1992). Thus, in DS-SBIM, the default value for the discount rate is set at 7 percent for both one-time capital and non-capital costs. If warranted, industry-specific rates of return can be used to modify this rate via sensitivity analysis. Occasionally, industry-specific rates of return can be obtained from secondary data sources, such as Dun & Bradstreet.

[9] The model does not accommodate any scale economies multiple-business facilities may realize.

To estimate the present value of compliance costs, it is necessary to annualize capital and non-capital one-time costs over their respective lifetimes. The appropriate annualization time-horizons for one-time capital and non-capital expenditures typically depend on the nature of control responsibilities imposed by the regulation and other relevant industry characteristics (EPA, 1999). Therefore, the user needs to closely evaluate regulation and industry-specific factors in choosing the annualization time horizon and further experiment with alternative specifications. In DS-SBIM, the default value for the annualization time horizon is currently set at 10 years for both types of one-time costs.

2.3.5 Thresholds for Impacts Short of Closure

Users are also required to specify a threshold, as a percentage of income, for each of the facility income measures. The model uses this threshold to determine regulatory impacts short of closure. The model then computes the number and percentage of facilities that incur regulatory costs exceeding the threshold specified by the user.

The Environmental Protection Agency (EPA) uses the thresholds of 1 and 3 percent to determine impacts short of closure for their regulatory impact analyses. The basis of these estimates is that if compliance costs are less than one percent of revenues for the majority of establishments, then the requirements are generally considered affordable. If compliance costs are 3 percent of revenues for the majority of establishments, then EPA considers reducing costs with other regulatory alternatives (EPA, 2000). EPA primarily selected these thresholds to analyze the effect of compliance costs on governmental units, but also has applied them to analyze impacts on the private sector. To determine how many establishments might suffer significantly in terms of profit loss, the industry-specific profit margins can be used as the threshold values. A ratio of profit to sales, which is roughly analogous to a profit margin, can be calculated for SIC codes from *The Annual Statement Studies* published by RMA and mapped to NAICS codes. The user then may use the lowest and highest ratios for the NAICS codes as the lower and upper bound thresholds to examine impacts short of closure.

The threshold impacts computed are in addition to those of incremental impacts (i.e., facilities incurring compliance costs exceeding revenues, EBIT, or cash flow). Thus, all facilities incurring

incremental impacts in the model also incur (by definition) costs that exceed the user-specified percentage of the applicable income measure.

2.3.6 Price Inflator

As mentioned in Section 1.2.1, the model facility income measures are based on *1997 Economic Census* data. To account for possible price inflation since 1997, the model allows users to enter a price inflator. The price inflator increases each of the model facility income measures by the percentage specified. The Consumer Price and Producer Price Indices (PPI and CPI) published by the Bureau of Labor Statistics (BLS) are the most widely used measures of inflation and can be used to adjust model facility income measure to better reflect current market conditions.

2.3.7 Unit Regulatory Costs

Based on the data input provided for the sectors and types of facilities affected by the proposed regulation, the spreadsheet program highlights the relevant unit (i.e., per-facility) regulatory costs that need to be entered by the user on the second page of data input. As illustrated in Table 2-4, the user is required to enter one-time capital, one-time non-capital, and recurring costs (i.e., annual costs) for three employment size classes (less than 20 employees, 20 to 499 employees, and at least 500 employees). The one-time costs are then annualized and added to the recurring costs. The model uses these total annualized costs as the model-facility unit regulatory costs on which small business impacts are based.

2.4 The Data Link Between the DS-SBIM and the DS-EED

To enable the user to update model data as updates of the revised DS-EED become available, the Excel-based DS-SBIM is linked to the revised DS-EED. To update data, the user needs to click on the "Distribution of Income Calculations" button in the "Table of Contents" worksheet and then click the "Refresh Input Data" option in the top left-hand corner of the spreadsheet. The action enables the program to access the "Plant Data" table in the revised DS-EED and pull in the relevant fields, such as

product type, facility type, and plant employment class, into the program.[10] Prior to updating the revised DS-EED, however, the user needs to ensure that:

(1) The new version of the revised DS-EED is located in the default directory, C:\sba\.

(2) The "Plant Data" table in the new version of the revised DS-EED does not contain any entries with missing observations, such as a plant with missing product type, facility type, employment code or NAICS code information. If any observations are missing, a pop-up screen will show how many observations are missing after the model has finished refreshing the data. The entries with missing observations will be highlighted in red in the spreadsheet.

(3) The "Plant Data" table in the new version of the revised DS-EED does not contain any entries on non-U.S. facilities.

(4) The primary NAICS code of every facility in the "Plant Data" table of the DS-EED (i.e., "Plant NAICS" field in the table) is one of 311222, 311920, 325199, or 325412. If there are new plants added to the table with primary NAICS codes other than the ones aforementioned, Census and other relevant data as described in Section 1.2 need to be obtained on the additional NAICS codes and incorporated into the model prior to the data update.

(5) The ODBC Add-In is loaded as part of the Excel application. To check if it is loaded, click on "Tools" in the top tool bar, select "Add-Ins" and check off the ODBC Add-In option listed.

Note that violation of any of the above will either result in incorrect impact calculations or program malfunction.

[10] The total number of observations in the "Plant Data" table of the revised DS-EED is equal to 1,248. If the total number of observations exceeds 1,248 in a new version of the revised DS-EED, the model will automatically update through a feature in Excel that fills formulas in columns adjacent to the imported data. This feature can be found by clicking on "Data" in the top tool bar, selecting "Get External Data" and then clicking on "Data Range Properties". The feature listed at the bottom of the pop-up screen will be checked off.

SECTION THREE

APPLICATION OF THE MODEL TO THE CANDY MANUFACTURING INDUSTRY

In this section, ERG presents the small business impacts model modified to address impacts on the candy manufacturing industry.

The Candy Small Business Impacts Model (Candy-SBIM) is an Excel-based spreadsheet program that requires the user to input key model parameters and estimated unit (i.e., per-facility) regulatory costs. The model then calculates regulatory impacts according to the model framework described in Section One. Section 3.1 discusses the candy product definition adopted for the small business impacts model. Section 3.2 presents the data sources that were used to tailor the model framework to the candy manufacturing industry. Required data input for the model are discussed in Section 3.3.

3.1 Definition

No concise definition of candy is available in the literature, so the candy industry had to be defined by ERG in terms of the primary NAICS codes of which the industry is comprised. Thus, based on data provided in the Candy Buyers' Directory, Harris InfoSource, and Internet searches of company Web sites (see Section 3.1.2 below), the candy manufacturing industry is defined as consisting of the following NAICS industries:

- NAICS 311320, Chocolate and Confectionery Manufacturing from Cacao Beans,
- NAICS 311330, Confectionery Manufacturing from Purchased Chocolate, and
- NAICS 311340, Nonchocolate Confectionery Manufacturing.

3.2 Data Sources

3.2.1 Census Data

As discussed in Section 1.2, the Candy Small Business Impacts Model (Candy-SBIM) derives the model facility income measures from the U.S. Census Bureau's *1997 Economic Census* and other applicable secondary data sources for the three NAICS codes mentioned in Section 3.1. The first two industries (NAICS 311320 and 311330) comprise the chocolate candy manufacturing sector whereas the last industry (NAICS 311340) corresponds to the nonchocolate candy sector, such as chewing gum manufacturers. A related candy industry classification, NAICS 722213, Snack and Nonalcoholic Beverage Bars, is excluded from model scope because:

(1) It comprises of retail establishments that prepare and/or serve snacks, i.e. establishments that would be subject to the Food Code guidelines rather than product- and/or ingredient-specific CFSAN regulations, such as labeling, allergen testing, etc. (FDA, 2001b), and

(2) Census data necessary to derive the applicable income measures are unavailable for the NAICS industry.

Also, establishments that manufacture candy but are classified under a different primary NAICS code are not included in the model. First, Census does not provide any detailed product information on the secondary engagement of establishments in a given NAICS industry.[11] Furthermore, companies classified in a different primary NAICS are unlikely to be small businesses as their primary engagement is in another industry. Given the main concern of the user will be to do a small business analysis, this omission should not be significant. However, it also means that the user should have less confidence in the model results for large establishments.

3.2.2 2002 Candy Buyers' Directory

The 2002 Candy Buyers' Directory available from MC Publishing Company is a reference source of candy, chocolate, cough drop, chewing gum, cookie, snack, and other sweet goods industry in North America. The directory is published annually and lists manufacturers, sellers, and importers of these items including brand names and products. Also included in the directory is a listing of candy brokers and specialty brokers. The directory, however, does not provide any information

on the NAICS code and employment size of the companies listed. Although the directory is unlikely to be comprehensive, it constitutes the only source of company listings in the candy industry by type of product.

To render the Candy Buyers' Directory data usable for the purposes of the small business impacts model, ERG supplemented the information provided in the directory with company-specific information (i.e., NAICS codes) available from Harris InfoSource. Because not all companies listed in the directory were cross-listed in the Harris InfoSource, however, NAICS code data for companies are incomplete.

Based on CFSAN input as to the level of product detail desired, ERG then tallied the companies in the Candy Buyers' Directory by type. Table 3-1 presents the data gathered from the directory and Harris InfoSource on candy manufacturers by type of candy product.

Table 3-1

Number of Candy Manufacturing Companies by Product Type and NAICS Code

	Number/Percentage of Companies			
Product Type	**Total [a]**	**NAICS 311320**	**NAICS 311330**	**NAICS 311340**
Chocolate				
With nuts	137	55 (52%)	51 (48%)	NA
With liquor	28	3 (60%)	2 (40%)	NA
White chocolate	NA	NA	NA	NA
Chocolate-covered fruit [b]	71	30 (49%)	31 (51%)	NA
Diet	17	6 (43%)	8 (57%)	NA
Nonchocolate				
With nuts	54	NA	NA	15

Source: Candy Buyers' Directory, 2002 and Harris InfoSource, 2002.
NA = Not applicable.
[a] The total is not equal to the sum of the companies in each NAICS code provided since NAICS code information was not available for all companies identified.
[b] The figure only includes chocolate-covered cherries. Data on other type of chocolate-covered fruit were unavailable.

[11] ERG inquired about the availability of such data upon request (i.e., a custom tabulation) from the Census Bureau. As of the writing of this report, the Census Bureau has not responded to ERG's request.

ERG incorporated the above company counts into the model as a proxy for the total number of establishments manufacturing each type of candy product. Because employment size data were unavailable on a company basis for the industry, the number of establishments affected within a NAICS code is assumed to mirror the size distribution of establishments for that NAICS code as available from the *1997 Economic Census*.

3.3 User Input

The Candy-SBIM requires the user to enter key model parameters and estimated unit (i.e., per-facility) regulatory costs. The data requirements for the spreadsheet model are outlined in Tables 3-2 and 3-3.

Table 3-2 requests input of key model parameters, including the product categories or subcategories affected and unit regulatory costs. If a given product category is not available in the list, the user is allowed to enter the number of establishments affected under the "other" classification.

By default, the model uses the *1997 Economic Census* establishment numbers for the number of affected establishments for each major category and the 2002 Candy Buyer's Directory number for the number of affected establishments for the subcategories (with the exception of chewing gum, bubble gum and chewing gum base). The user, however, is allowed to override the default by entering in a different establishment figure for the affected product type(s) if more recent data are available. Table 3-3 requests input of discount rates and annualization time horizons for one-time capital and non-capital expenditures, impact thresholds for each of the income measures, and a price inflator.

After the unit cost data and relevant model parameters have been input, the model calculates baseline regulatory impacts, incremental impacts, and threshold impacts short of closure. All model parameters and estimated unit regulatory cost inputs can be easily modified for the purpose of examining alternative scenarios.

Table 3-2

User Input 1: Candy Manufacturing Industry

	Number of Establishments From 1997 Census	Enter An "x" If Affected or the # of Estab. If Known	Type of Cost ($)	Unit Costs by Model Class ($) Less Than 20 Employees	20 to 499 Employees	At Least 500 Employees
CHOCOLATE						
Chocolate and chocolate-type confectionery products made from cacao beans [a]	164		One-time capital			
			One-time non-capital			
			Recurring			
With nuts [b]	71		One-time capital			
			One-time non-capital			
			Recurring			
With liquor [b]	17		One-time capital			
			One-time non-capital			
			Recurring			
White chocolate	n/a		One-time capital			
			One-time non-capital			
			Recurring			
Chocolate covered fruit [b] [c]	35		One-time capital			
			One-time non-capital			
			Recurring			
Diet [b]	7		One-time capital			
			One-time non-capital			
			Recurring			
Other	n/a		One-time capital			
			One-time non-capital			
			Recurring			
Chocolate and chocolate-type confectionery products made from purchased chocolate [a]	861		One-time capital			
			One-time non-capital			
			Recurring			
With nuts [b]	66		One-time capital			
			One-time non-capital			
			Recurring			

Table 3-2

User Input 1: Candy Manufacturing Industry

	Number of Establishments From 1997 Census	Enter An "x" If Affected or the # of Estab. If Known	Type of Cost ($)	Unit Costs by Model Class ($) Less Than 20 Employees	20 to 499 Employees	At Least 500 Employees
With liquor [b]	11		One-time capital			
			One-time non-Recurring			
White chocolate	n/a		One-time capital			
			One-time non-Recurring			
Chocolate covered fruit [b] [c]	36		One-time capital			
			One-time non-Recurring			
Diet [b]	10		One-time capital			
			One-time non-Recurring			
Other	n/a		One-time capital			
			One-time non-Recurring			
NONCHOCOLATE						
Nonchocolate confectionery [a]	625		One-time capital			
			One-time non-Recurring			
Chewing gum, bubble gum, and chewing gum base [d]	13		One-time capital			
			One-time non-Recurring			
With nuts [b]	54		One-time capital			
			One-time non-Recurring			
Diet	n/a		One-time capital			
			One-time non-Recurring			
Other	n/a		One-time capital			
			One-time non-Recurring			

n/a = Not available

[a] Estimated using the number of establishments in the NAICS code as a whole, might include companies that only manufacture products that are not regulated by CFSAN.

[b] The number is estimated based on information obtained from the Candy Buyers' Directory and Harris InfoSource..

[c] The figure only includes chocolate-covered cherries. Data on other type of chocolate-covered fruit were unavailable.

[d] Estimated using the sum of the number of companies in each relevant Census Product Code, multiplied by the total number of establishments to companies ratio for the NAICS code as a whole (unless otherwise noted). Estimate is an upper bound and if the upper bound exceeds the number of establishments in the NAICS code, the number of establishments is constrained to the total number of establishments for the NAICS code.

Table 3-3

User Input 2: Candy Manufacturing Industry

2. Please enter the values for the following items:

For capital expenditures:

Discount rate	☐	Default value is 7%
Annualization time horizon (in years)	☐	Default value is 10 years

For non- capital expenditures:

Discount rate	☐	Default value is 7%
Annualization time horizon (in years)	☐	Default value is 10 years

3. Regulatory impacts short of closure are defined as the number and percentage of establishments incurring compliance costs exceeding x% of revenues, here x is a threshold to be specified. Please enter the threshold:

Revenues	☐	Default values are 1 and 3 %
EBIT	☐	Default values are 1 and 3 %
Cash Flow	☐	Default values are 1 and 3 %

4. The price inflator increases the model facility income measures by the percentage specified. Please specify a

Price inflator	☐

3.3.1 Affected Product Categories

In the model, the user must select the product categories or subcategories that will be impacted by the regulation by placing an "x" or a number of establishments estimate in the field provided. If a given product category is not available in the list (see Table 3-2), the user is allowed to enter the number of establishments affected under the "other" classification.

The model allows the user to select only one subcategory per product category. For example, nonchocolate candy containing nuts and nonchocolate diet candy (both of which are subcategories under the nonchocolate confectionery category) should not be checked off simultaneously. Because some manufacturers of nonchocolate candy containing nuts may also manufacture diet candy, this will result in double counting of some establishments.[12] The model, however, allows the user to analyze, for example, a regulation impacting all candy products (chocolate and nonchocolate) containing nuts by checking off the "With Nuts" subcategory under each of the main categories.

Because employment size data were unavailable on a company basis for the industry, the number of establishments affected within a NAICS code is assumed to mirror the size distribution of establishments for that NAICS code as available from the *1997 Economic Census*.

3.3.2 Unit Regulatory Costs

As illustrated in Table 3-2, the user is required to enter one-time capital, one-time non-capital, and recurring costs (i.e., annual costs) for three employment size classes (less than 20 employees, 20 to 499 employees, and at least 500 employees) for each of the product categories and/or subcategories impacted by the regulation. The one-time costs are then annualized and added to the recurring costs. The model uses these total annualized costs as the model-facility unit regulatory costs on which small business impacts are based.

[12] There is no straightforward method of eliminating possible double counting of establishments without detailed plant-level data on candy manufacturers.

3.3.3 The Discount Rate and the Annualization Time Horizon

The model requires the user to input the discount rate and the annualization time horizon for both one-time capital and non-capital costs. These data are then used to annualize the unit regulatory costs that are input by the user on the first page of data input. The sum of the annualized one-time capital and non-capital costs and any recurring costs constitute the unit regulatory costs used in the model to determine facility closures as a result of a regulatory action under consideration.

The Office of Management and Budget (OMB) recommends using a real discount rate of 7 percent in constant-dollar cost-benefit analyses of proposed investments and regulations. This rate approximates the marginal pretax rate of return on an average investment in the private sector (OMB, 1992). Thus, in Candy-SBIM, the default value for the discount rate is set at 7 percent for both one-time capital and non-capital costs. If warranted, industry-specific rates of return can be used to modify this rate via sensitivity analysis. Occasionally, industry-specific rates of return can be obtained from secondary data sources, such as Dun & Bradstreet.

To estimate the present value of compliance costs, it is necessary to annualize capital and non-capital one-time costs over their respective lifetimes. The appropriate annualization time-horizons for one-time capital and non-capital expenditures typically depend on the nature of control responsibilities imposed by the regulation and other relevant industry characteristics (EPA, 1999). Therefore, the user needs to closely evaluate regulation and industry-specific factors in choosing the annualization time horizon and further experiment with alternative specifications. In Candy-SBIM, the default value for the annualization time horizon is currently set at 10 years for both types of one-time costs.

3.3.4 Thresholds for Impacts Short of Closure

Users are also required to specify a threshold, as a percentage of income, for each of the facility income measures. The model uses this threshold to determine regulatory impacts short of

closure. The model then computes the number and percentage of facilities that incur regulatory costs exceeding the threshold specified by the user.

The Environmental Protection Agency (EPA) uses the thresholds of 1 and 3 percent to determine impacts short of closure for their regulatory impact analyses. The basis of these estimates is that if compliance costs are less than one percent of revenues for the majority of establishments, then the requirements are generally considered affordable. If compliance costs are 3 percent of revenues for the majority of establishments, then EPA considers reducing costs with other regulatory alternatives (EPA, 2000). EPA primarily selected these thresholds to analyze the effect of compliance costs on governmental units, but also has applied them to analyze impacts on the private sector. To determine how many establishments might suffer significantly in terms of profit loss, the industry-specific profit margins can be used as the threshold values. A ratio of profit to sales, which is roughly analogous to a profit margin, can be calculated for SIC codes from *The Annual Statement Studies* published by RMA and mapped to NAICS codes. The user then may use the lowest and highest ratios for the NAICS codes as the lower and upper bound thresholds to examine impacts short of closure.

The threshold impacts computed are in addition to those of incremental impacts (i.e., facilities incurring compliance costs exceeding revenues, EBIT, or cash flow). Thus, all facilities incurring incremental impacts in the model also incur (by definition) costs that exceed the user-specified percentage of the applicable income measure.

3.3.5 Price Inflator

As mentioned in Section 1.2.1, the model facility income measures are based on *1997 Economic Census* data. To account for possible price inflation since 1997, the model allows users to enter a price inflator. The price inflator increases each of the model facility income measures by the percentage specified. The Consumer Price and Producer Price Indices (PPI and CPI) published by the Bureau of Labor Statistics (BLS) are the most widely used measures of

inflation and can be used to adjust model facility income measure to better reflect current market conditions.

SECTION FOUR

APPLICATION OF THE MODEL TO THE COSMETICS MANUFACTURING INDUSTRY

In this section, ERG presents the small business impacts model modified to address impacts on the cosmetics manufacturing industry.

The Cosmetics Small Business Impacts Model (Cosmetics-SBIM) is an Excel-based spreadsheet program that requires the user to input key model parameters and estimated unit (i.e., per-facility) regulatory costs. The model then calculates regulatory impacts according to the model framework described in Section One. Section 4.1 discusses the cosmetic product definition adopted for the small business impacts model. Section 4.2 presents the data sources that were used to tailor the model framework to the cosmetics manufacturing industry. Required data input for the model are presented in Section 4.3.

4.1 Definition of a Cosmetic Product

Chapter 2 Section 201 (321) (i) of the Federal Food Drug and Cosmetic (FD&C) Act as amended by the FDA Modernization Act of 1997 defines cosmetics as articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions (FDA, 1998a). Included in this definition are products such as skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, shampoos, permanent waves, hair colors, toothpastes, deodorants, and any material intended for use as a component of a cosmetic product. Soap products consisting primarily of an alkali salt of fatty acid and making no label claim other than cleansing of the human body are not considered cosmetics under the law (FDA, 1992).

Products that are cosmetics but are also intended to treat or prevent disease, or otherwise affect the structure or functions of the human body, are also considered drugs and must comply with both the drug and cosmetic provisions of the law. Such products include anticaries

toothpastes (e.g., "fluoride" toothpastes), hormone creams, suntanning preparations intended to protect against sunburn, antiperspirants that are also deodorants, and antidandruff shampoos. Most currently marketed cosmetics, which are also drugs, are over-the-counter (OTC) drugs (FDA, 1992). ERG excluded (to the extent possible) such OTC products from model scope as they are regulated by the Center for Drug Evaluation and Research (CDER) rather than CFSAN (Ritzert, 2002a).

4.2 Data Sources

4.2.1 Census Data – 6-Digit NAICS Basis

The Cosmetics Small Business Impacts Model (Cosmetics-SBIM) derives the model facility income measures from the U.S. Census Bureau's *1997 Economic Census* and other applicable secondary data sources. CFR 21 Section 720.4 (c) outlines the different types of cosmetic products by their intended use on which FDA collects ingredient information through its Voluntary Cosmetics Registration Program (VCRP) (FDA, 2000). Based on an analysis of the cosmetics products in the aforementioned CFR section and those manufactured by establishments classified in various manufacturing NAICS industries (also see Section 4.2.2 below), ERG mapped the cosmetics manufacturing industry onto the following two NAICS codes:

- NAICS 325611, Soap and Other Detergent Manufacturing, and
- NAICS 325620, Toilet Preparation Manufacturing.

Additionally, some cosmetics manufacturers (approximately 13 percent of companies with listings in the Cosmetics Browser) are classified in NAICS 325412, Pharmaceutical Manufacturing (World Market Watch, Inc., 2002). ERG, however, tentatively excluded this NAICS code from model scope as (1) companies classified in NAICS 325412 are unlikely to be small businesses (as their primary engagement is pharmaceutical preparation manufacturing

rather than toilet preparations), and (2) Census does not provide any detailed product information on the secondary engagement of establishments classified in a given NAICS industry.[13]

As noted in the model spreadsheet, some of the establishments classified in NAICS 325611 and 325620 may manufacture non-cosmetic products. Because there is no plant-level data (i.e., type of product manufactured) available on cosmetics manufacturers, however, these establishments cannot effectively be eliminated from the analysis.

4.2.2 Census Data – 10-Digit NAICS Basis

The U.S. Census Bureau publishes a Product Summary report that includes data from the Current Industrial Reports (CIR) and a special table with data on products that are primary to more than one industry, which are not in the industry reports. The report includes data on the number of companies, value of product shipments, quantity of production, and quantity of product shipments. The data in the report are presented at the 6-, 7-, 8-, and 10-digit NAICS code levels. The summary report, however, does not provide data by employment size at the 10-digit NAICS code level.

In Cosmetics-SBIM, the 10-digit Census data are used to generate number of establishments estimates for the subcategories under each main cosmetics category. Because the reporting basis is different for the product statistics data (company versus establishment), ERG estimated the number of establishments for each subcategory using the sum of the number of companies in each relevant 10-digit NAICS code multiplied by the total number of establishments to companies ratio for the 6-digit NAICS code, except where noted in the spreadsheet. For those cases where the computed estimate exceeded the number of establishments in the 6-digit NAICS code, ERG constrained the estimate to the total number of establishments for the 6-digit NAICS code.

[13] ERG inquired about the availability of such data upon request (i.e., a custom tabulation) from the Census Bureau. As of the writing of this report, the Census Bureau has not responded to ERG's request.

4.3 User Input

Similar to the previous models, the Cosmetics-SBIM requires the user to enter key model parameters and estimated unit (i.e., per-facility) regulatory costs. The data requirements for the spreadsheet model are outlined in Tables 4-1 and 4-2.

Table 4-1 requests input of key model parameters, including the product categories or subcategories affected and unit regulatory costs. If a given product category is not available in the list, the user is allowed to enter the number of establishments affected under the "other" classification. The Cosmetics-SBIM maps data entered for the "other" category onto the Census data for NAICS 325620. Also, it should be noted almost all categories are mapped onto NAICS 325620 and that the toothpaste and fragrant and moisturizing soap categories are the only categories mapped onto NAICS 325611. By default, the model uses the *1997 Economic Census* establishment numbers for the number of affected establishments for each category. The user, however, is allowed to override the default by entering in a different establishment figure for the affected product type(s) if more recent data are available. Table 4-2 requests input of discount rates and annualization time horizons for one-time capital and non-capital expenditures, impact thresholds for each of the income measures, and a price inflator.

After the unit cost data and relevant model parameters have been input, the model calculates baseline impacts, incremental impacts, and threshold impacts short of closures. All model parameters and estimated unit regulatory cost inputs can be easily modified for the purpose of examining alternative scenarios.

4.3.1 Affected Product Categories

In the model, the user must select the product categories or subcategories that will be impacted by the regulation by placing an "x" or a number of establishments estimate in the field

Table 4-1

User Input 1: Cosmetics Manufacturing Industry

	Number of Establishments From 1997 Census	Enter An "x" If Affected or the # of Estab. If Known	Type of Cost ($)	Unit Costs by Model Class ($)		
				Less Than 20 Employees	20 to 499 Employees	At Least 500 Employees
1 Cosmetics, excluding soap and toothpaste [a]	729		One-time capital			
			One-time non-capital			
			Recurring			
Shaving preparations [b]	42		One-time capital			
			One-time non-capital			
			Recurring			
Perfumes, toilet waters, and colognes [b]	75		One-time capital			
			One-time non-capital			
			Recurring			
Shampoos and conditioners [b]	140		One-time capital			
			One-time non-capital			
			Recurring			
Hair permanents [b]	22		One-time capital			
			One-time non-capital			
			Recurring			
Hair dyes [b]	30		One-time capital			
			One-time non-capital			
			Recurring			
Hair sprays, rinses, dressings, and mousse [b]	176		One-time capital			
			One-time non-capital			
			Recurring			
Other hair preparations (including heat-wave setting solutions) [b]	14		One-time capital			
			One-time non-capital			
			Recurring			
Denture cleaners and other oral hygiene products [b]	41		One-time capital			
			One-time non-capital			
			Recurring			

Table 4-1

User Input 1: Cosmetics Manufacturing Industry

	Number of Establishments From 1997 Census	Enter An "x" If Affected or the # of Estab. If Known	Type of Cost ($)	Unit Costs by Model Class ($)		
				Less Than 20 Employees	20 to 499 Employees	At Least 500 Employees
Suntan lotion/oils [b]	20		One-time capital			
			One-time non-capital			
			Recurring			
Other creams, lotions, and oils, excluding shaving, hair, deodorant, eye, manicuring, and bath [b]	329		One-time capital			
			One-time non-capital			
			Recurring			
Lipsticks [b]	45		One-time capital			
			One-time non-capital			
			Recurring			
Blushers [b]	20		One-time capital			
			One-time non-capital			
			Recurring			
Eye cosmetics [b]	30		One-time capital			
			One-time non-capital			
			Recurring			
Feminine hygiene douches and deodorants [b]	3		One-time capital			
			One-time non-capital			
			Recurring			
Nail enamel and polish [b]	26		One-time capital			
			One-time non-capital			
			Recurring			
Nail enamel and polish remover [b]	7		One-time capital			
			One-time non-capital			
			Recurring			
Other manicuring preparations [b]	15		One-time capital			
			One-time non-capital			
			Recurring			

Table 4-1

User Input 1: Cosmetics Manufacturing Industry

	Number of Establishments From 1997 Census	Enter An "x" If Affected or the # of Estab. If Known	Type of Cost ($)	Unit Costs by Model Class ($) Less Than 20 Employees	20 to 499 Employees	At Least 500 Employees
Other	n/a		One-time capital			
			One-time non-capital			
			Recurring			

n/a = Not available

[a] Estimated using the number of establishments in the NAICS code as a whole, might include companies that only manufacture products that are not regulated by CFSAN.

[b] Estimated using the sum of the number of companies in each relevant Census Product Code, multiplied by the total number of establishments to companies ratio for the NAICS code as a whole (unless otherwise noted). Estimate is an upper bound and if the upper bound exceeds the number of establishments in the NAICS code, the number of establishments is constrained to the total number of establishments for the NAICS code.

Table 4-2

User Input 2: Cosmetics Manufacturing Industry

2. Please enter the values for the following items:

For capital expenditures:		
Discount rate		Default value is 7%
Annualization time horizon (in years)		Default value is 10 years
For non- capital expenditures:		
Discount rate		Default value is 7%
Annualization time horizon (in years)		Default value is 10 years

3. Regulatory impacts short of closure are defined as the number and percentage of establishments incurring compliance costs exceeding x% of revenues, here x is a threshold to be specified. Please enter the threshold:

Revenues		Default values are 1 and 3 %
EBIT		Default values are 1 and 3 %
Cash Flow		Default values are 1 and 3 %

4. The price inflator increases the model facility income measures by the percentage specified. Please specify a percentage or leave it blank to use the model facility income measures without price inflation.:

Price inflator	

provided. If a given product category is not available in the list (see Table 4-1), the user is allowed to enter the number of establishments affected under the "other" classification.

The model allows the user to select only one subcategory per product category. For example, shaving preparations and shampoos and conditioners (both of which are subcategories under the general cosmetics, excluding soap and toothpaste category) should not be checked off simultaneously. Because some manufacturers of shaving preparations may also manufacture shampoos and/or conditioners, this will result in double counting of some establishments.[14]

Because employment size data were unavailable on a company basis for the industry, the number of establishments affected within a NAICS code is assumed to mirror the size distribution of establishments for that NAICS code as available from the *1997 Economic Census.*

4.3.2 Unit Regulatory Costs

As illustrated in Table 4-1, the user is required to enter one-time capital, one-time non-capital, and recurring costs (i.e., annual costs) for three employment size classes (less than 20 employees, 20 to 499 employees, and at least 500 employees) for each of the product categories and/or subcategories impacted by the regulation. The one-time costs are then annualized and added to the recurring costs. The model uses these total annualized costs as the model-facility unit regulatory costs on which small business impacts are based.

4.3.3 The Discount Rate and the Annualization Time Horizon

The model requires the user to input the discount rate and the annualization time horizon for both one-time capital and non-capital costs. These data are then used to annualize the unit regulatory costs that are input by the user on the first page of data input. The sum of the annualized one-time capital and non-capital costs and any recurring costs constitute the unit

[14] There is no straightforward method of eliminating possible double counting of establishments without detailed plant-level data on cosmetics manufacturers.

regulatory costs used in the model to determine facility closures as a result of a regulatory action under consideration.

The Office of Management and Budget (OMB) recommends using a real discount rate of 7 percent in constant-dollar cost-benefit analyses of proposed investments and regulations. This rate approximates the marginal pretax rate of return on an average investment in the private sector (OMB, 1992). Thus, in Cosmetics-SBIM, the default value for the discount rate is set at 7 percent for both one-time capital and non-capital costs. If warranted, industry-specific rates of return can be used to modify this rate via sensitivity analysis. Occasionally, industry-specific rates of return can be obtained from secondary data sources, such as Dun & Bradstreet.

To estimate the present value of compliance costs, it is necessary to annualize capital and non-capital one-time costs over their respective lifetimes. The appropriate annualization time-horizons for one-time capital and non-capital expenditures typically depend on the nature of control responsibilities imposed by the regulation and other relevant industry characteristics (EPA, 1999). Therefore, the user needs to closely evaluate regulation and industry-specific factors in choosing the annualization time horizon and further experiment with alternative specifications. In Cosmetics-SBIM, the default value for the annualization time horizon is currently set at 10 years for both types of one-time costs.

4.3.4 Thresholds for Impacts Short of Closure

Users are also required to specify a threshold, as a percentage of income, for each of the facility income measures. The model uses this threshold to determine regulatory impacts short of closure. The model then computes the number and percentage of facilities that incur regulatory costs exceeding the threshold specified by the user.

The Environmental Protection Agency (EPA) uses the thresholds of 1 and 3 percent to determine impacts short of closure for their regulatory impact analyses. The basis of these estimates is that if compliance costs are less than one percent of revenues for the majority of

establishments, then the requirements are generally considered affordable. If compliance costs are 3 percent of revenues for the majority of establishments, then EPA considers reducing costs with other regulatory alternatives (EPA, 2000). EPA primarily selected these thresholds to analyze the effect of compliance costs on governmental units, but also has applied them to analyze impacts on the private sector. To determine how many establishments might suffer significantly in terms of profit loss, the industry-specific profit margins can be used as the threshold values. A ratio of profit to sales, which is roughly analogous to a profit margin, can be calculated for SIC codes from *The Annual Statement Studies* published by RMA and mapped to NAICS codes. The user then may use the lowest and highest ratios for the NAICS codes as the lower and upper bound thresholds to examine impacts short of closure.

The threshold impacts computed are in addition to those of incremental impacts (i.e., facilities incurring compliance costs exceeding revenues, EBIT, or cash flow). Thus, all facilities incurring incremental impacts in the model also incur (by definition) costs that exceed the user-specified percentage of the applicable income measure.

4.3.5 Price Inflator

As mentioned in Section 1.2.1, the model facility income measures are based on *1997 Economic Census* data. To account for possible price inflation since 1997, the model allows users to enter a price inflator. The price inflator increases each of the model facility income measures by the percentage specified. The Consumer Price and Producer Price Indices (PPI and CPI) published by the Bureau of Labor Statistics (BLS) are the most widely used measures of inflation and can be used to adjust model facility income measure to better reflect current market conditions.

SECTION FIVE

APPLICATION OF THE MODEL TO THE READY-TO-EAT (RTE) FOOD MANUFACTURING INDUSTRY

In this section, ERG presents the small business impacts model modified to address impacts on the ready-to-eat (RTE) food manufacturing industry.

The RTE Small Business Impacts Model (RTE-SBIM) is an Excel-based spreadsheet program that requires the user to input key model parameters and estimated unit (i.e., per-facility) regulatory costs. The model then calculates regulatory impacts according to the model framework described in Section One. Section 5.1 discusses the RTE definition adopted for the small business impacts model. Section 5.2 presents the data sources that were used to tailor the model framework to the RTE manufacturing industry. Required data input for the model are presented in Section 5.3.

5.1 Definition of Ready-to-eat (RTE) Foods

According to Section 1-201.10 (B) (70) of the 2001 Food Code, a "ready-to-eat" food refers to food that:

> "(i) Is in a form that is edible without additional preparation to achieve *food* safety, as specified under § 3-401.11(A) – (C) or § 3-401.12 or 3-402.11; or
>
> (ii) Is a raw or partially cooked animal *food* and the consumer is advised as specified under Subparagraphs 3-401.11(D)(1) and (2); or
>
> (iii) Is prepared in accordance with a variance that is granted as specified under Subparagraphs 3-401.11(D)(1) and (3); and
>
> (iv) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes."

Further, according to the same source, ready-to-eat foods include: properly frozen or cooked animal food, washed raw fruits and vegetables, fruits and vegetables cooked for hot holding,

cooked and cooled potentially hazardous food; plant food for which further washing, cooking, or other processing is not required for food safety, including the removal of rinds, seeds, husks, or shells; spices, seasonings, and sugar; bakery items, such as bread, cakes, pies, fillings, or icing; products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens, such as dry, fermented sausages, salt-cured meat and poultry products, and dried *meat* and *poultry* products; thermally processed low-acid foods packaged in hermetically sealed containers (Section 1-201.10 [B] [70] [b]).

Alternatively, a ready-to-eat food has also been defined as a food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or consumer and that is reasonably expected to be consumed in that form (FDA, 1998).

Based on input from FDA, ERG adopted the second definition of RTE for the small business impacts model (Ritzert, 2002). A product containing at least 2 percent poultry or 3 percent meat is a poultry or meat product whose manufacture is monitored by the U.S. Department of Agriculture (USDA) rather than the FDA (Boyle, 1995). Thus, ERG excluded these RTE meat and poultry products from model scope.

5.2 Data Sources

5.2.1 Census Data – 6-Digit NAICS Basis

Similar to the previous models, the RTE Small Business Impacts Model (RTE-SBIM) derives the model facility income measures from the U.S. Census Bureau's *1997 Economic Census* and other applicable secondary data sources. Based on an analysis of products manufactured by establishments classified in the various food manufacturing/processing NAICS industries (also see Section 5.2.2 below), the RTE food manufacturing industry mainly consists of 30 NAICS codes.

Table 5-1 presents the RTE food manufacturing NAICS codes selected by FDA and ERG in joint discussion for use in the small business impacts model to characterize the industry. As

noted in the model spreadsheet, some of the NAICS industries included may contain some establishments that manufacture non-RTE food products. Because there is no plant-level data (i.e., type of product manufactured) available on RTE food manufacturers, however, these establishments cannot effectively be eliminated from the analysis.

Table 5-1

List of NAICS Industries Comprising the RTE Food Manufacturing Industry

NAICS Code	Title
311111	Dog and Cat Food Manufacturing
311119	Other Animal Food Manufacturing
311225	Fats and Oils Refining and Blending
311230	Breakfast Cereal Manufacturing
311312	Cane Sugar Refining
311313	Beet Sugar Manufacturing
311411	Frozen Fruit, Juice, and Vegetable Processing
311421	Fruit and Vegetable Canning
311422	Specialty Canning
311423	Dried and Dehydrated Food Manufacturing
311511	Fluid Milk Manufacturing
311512	Creamery Butter Manufacturing
311513	Cheese Manufacturing
311514	Dry, Condensed, and Evaporated Dairy Product Manufacturing
311520	Ice Cream and Frozen Dessert Manufacturing
311711	Seafood Canning
311811	Retail Bakeries
311812	Commercial Bakeries
311821	Cookie and Cracker Manufacturing
311830	Tortilla Manufacturing
311911	Roasted Nuts and Peanut Butter Manufacturing
311919	Other Snack Food Manufacturing
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing
311942	Spice and Extract Manufacturing
311991	Perishable Prepared Food Manufacturing
311999	Other Miscellaneous Food Manufacturing
312111	Soft Drink Manufacturing
312112	Bottled Water Manufacturing
312113	Ice Manufacturing
312120	Breweries

Source: OMB, 1998

5.2.2 Census Data – 10-Digit NAICS Basis

The U.S. Census Bureau publishes a Product Summary report that includes data from the Current Industrial Reports (CIR) and a special table with data on products that are primary to

more than one industry, which are not in the industry reports. The report includes data on the number of companies, value of product shipments, quantity of production, and quantity of product shipments. The data in the report are presented at the 6-, 7-, 8-, and 10-digit NAICS code levels. The summary report, however, does not provide data at the 10-digit NAICS code level by employment size.

In RTE-SBIM, the 10-digit Census data are used to generate number of establishments estimates for the subcategories under each main RTE category. Because the reporting basis is different for the product statistics data (company versus establishment), ERG estimated the number of establishments for each subcategory using the sum of the number of companies in each relevant 10-digit NAICS code multiplied by the total number of establishments to companies ratio for the 6-digit NAICS code, except where noted in the spreadsheet. For those cases where the computed estimate exceeded the number of establishments in the 6-digit NAICS code, ERG constrained the estimate to the total number of establishments for the 6-digit NAICS code.

5.3 User Input

Similar to the previous models, the RTE-SBIM requires the user to enter key model parameters and estimated unit (i.e., per-facility) regulatory costs. The data requirements for the spreadsheet model are outlined in Tables 5-2 and 5-3.

Table 5-2 requests input of key model parameters, including the product categories or subcategories affected and unit regulatory costs. If a given product category is not available in the list, the user is allowed to enter the number of establishments affected under the "other" classification. By default, the model uses the *1997 Economic Census* establishment numbers for the number of affected establishments for each category. The user, however, is allowed to override the default by entering in a different establishment figure for the affected product type(s) if more recent data are available. Table 5-3 requests input of discount rates and

Table 5-2

User Input 1: RTE Food Manufacturing Industry

	Number of Establishments From 1997 Census	Enter An "x" If Affected or the # of Estab. If Known	Type of Cost ($)	Unit Costs by Model Class ($) Less Than 20 Employees	20 to 499 Employees	At Least 500 Employees
ANIMAL FOOD						
Dog and Cat Food	164		One-time capital			
			One-time non-capital			
			Recurring			
Dog Food [b]	71		One-time capital			
			One-time non-capital			
			Recurring			
Cat Food [b]	17		One-time capital			
			One-time non-capital			
			Recurring			
Other	n/a		One-time capital			
			One-time non-capital			
			Recurring			
Other Animal Food	35		One-time capital			
			One-time non-capital			
			Recurring			
Chicken and Turkey Feed, Supplements Concentrates and Premixes [b]	7		One-time capital			
			One-time non-capital			
			Recurring			
Dairy Cattle Feed, Complete [b]	n/a		One-time capital			
			One-time non-capital			
			Recurring			
Dairy Cattle Feed, Supplements Concentrates and Premixes [b]	861		One-time capital			
			One-time non-capital			
			Recurring			
Swine Feed, Complete [b]	66		One-time capital			
			One-time non-capital			
			Recurring			

n/a = Not available
[a] Estimated using the number of establishments in the NAICS code as a whole, might include companies that only manufacture products that are not regulated by CFSAN.
[b] Estimated using the sum of the number of companies in each relevant Census Product Code, multiplied by the total number of establishments to companies ratio for the NAICS code as a whole (unless otherwise noted). Estimate is an upper bound and if the upper bound exceeds the number of establishments in the NAICS code, the number of establishments is constrained to the total number of establishments for the NAICS code.

Table 5-2

User Input 2: RTE Food Manufacturing Industry

2. Please enter the values for the following items:

For capital expenditures:

Discount rate	☐	Default value is 7%
Annualization time horizon (in years)	☐	Default value is 10 years

For non- capital expenditures:

Discount rate	☐	Default value is 7%
Annualization time horizon (in years)	☐	Default value is 10 years

3. Regulatory impacts short of closure are defined as the number and percentage of establishments incurring compliance costs exceeding x% of revenues, here x is a threshold to be specified. Please enter the threshold:

Revenues	☐	Default values are 1 and 3 %
EBIT	☐	Default values are 1 and 3 %
Cash Flow	☐	Default values are 1 and 3 %

4. The price inflator increases the model facility income measures by the percentage specified. Please specify a percentage or leave it blank to use the model facility income measures without price inflation.:

Price inflator	☐

annualization time horizons for one-time capital and non-capital expenditures, impact thresholds for each of the income measures, and a price inflator.

After the unit cost data and relevant model parameters have been input, the model calculates regulatory impacts, facility closures and impacts short of closures. All model parameters and estimated unit regulatory cost inputs can be easily modified for the purpose of examining alternative scenarios.

5.3.1 Affected Product Categories

In the model, the user must select the product categories or subcategories that will be impacted by the regulation by placing an "x" or a number of establishments estimate in the field provided. If a given product category is not available in the list (see Table 5-2), the user is allowed to enter the number of establishments affected under the "other" classification.

The model allows the user to select only one subcategory per product category. For example, natural cheese, except cottage cheese and processed cheese and related products (both of which are subcategories under the cheese category) should not be checked off simultaneously. Because some manufacturers of natural cheese products may also manufacture processed cheese, this will result in double counting of some establishments.[15]

Because employment size data were unavailable on a company basis for the industry, the number of establishments affected within a NAICS code is assumed to mirror the size distribution of establishments for that NAICS code as available from the *1997 Economic Census*.

5.3.2 Unit Regulatory Costs

As illustrated in Table 5-2, the user is required to enter one-time capital, one-time non-capital, and recurring costs (i.e., annual costs) for three employment size classes (less than 20 employees, 20 to 499 employees, and at least 500 employees) for each of the product categories and/or subcategories impacted by the regulation. The one-time costs are then annualized and added to the recurring costs. The model uses these total annualized costs as the model-facility unit regulatory costs on which small business impacts are based.

5.3.3 The Discount Rate and the Annualization Time Horizon

The model requires the user to input the discount rate and the annualization time horizon for both one-time capital and non-capital costs. These data are then used to annualize the unit regulatory costs that are input by the user on the first page of data input. The sum of the annualized one-time capital and non-capital costs and any recurring costs constitute the unit regulatory costs used in the model to determine facility closures as a result of a regulatory action under consideration.

The Office of Management and Budget (OMB) recommends using a real discount rate of 7 percent in constant-dollar cost-benefit analyses of proposed investments and regulations. This rate approximates the marginal pretax rate of return on an average investment in the private sector (OMB, 1992). Thus, in RTE-SBIM, the default value for the discount rate is set at 7 percent for both one-time capital and non-capital costs. If warranted, industry-specific rates of return can be used to modify this rate via sensitivity analysis. Occasionally, industry-specific rates of return can be obtained from secondary data sources, such as Dun & Bradstreet.

To estimate the present value of compliance costs, it is necessary to annualize capital and non-capital one-time costs over their respective lifetimes. The appropriate annualization time-horizons for one-time capital and non-capital expenditures typically depend on the nature of

[15] There is no straightforward method of eliminating possible double counting of establishments without detailed plant-level data on RTE food manufacturers.

control responsibilities imposed by the regulation and other relevant industry characteristics (EPA, 1999). Therefore, the user needs to closely evaluate regulation and industry-specific factors in choosing the annualization time horizon and further experiment with alternative specifications. In RTE-SBIM, the default value for the annualization time horizon is currently set at 10 years for both types of one-time costs.

5.3.4 Thresholds for Impacts Short of Closure

Users are also required to specify a threshold, as a percentage of income, for each of the facility income measures. The model uses this threshold to determine regulatory impacts short of closure. The model then computes the number and percentage of facilities that incur regulatory costs exceeding the threshold specified by the user.

The Environmental Protection Agency (EPA) uses the thresholds of 1 and 3 percent to determine impacts short of closure for their regulatory impact analyses. The basis of these estimates is that if compliance costs are less than one percent of revenues for the majority of establishments, then the requirements are generally considered affordable. If compliance costs are 3 percent of revenues for the majority of establishments, then EPA considers reducing costs with other regulatory alternatives (EPA, 2000). EPA primarily selected these thresholds to analyze the effect of compliance costs on governmental units, but also has applied them to analyze impacts on the private sector. To determine how many establishments might suffer significantly in terms of profit loss, the industry-specific profit margins can be used as the threshold values. A ratio of profit to sales, which is roughly analogous to a profit margin, can be calculated for SIC codes from *The Annual Statement Studies* published by RMA and mapped to NAICS codes. The user then may use the lowest and highest ratios for the NAICS codes as the lower and upper bound thresholds to examine impacts short of closure.

The threshold impacts computed are in addition to those of incremental impacts (i.e., facilities incurring compliance costs exceeding revenues, EBIT, or cash flow). Thus, all facilities

incurring incremental impacts in the model also incur (by definition) costs that exceed the user-specified percentage of the applicable income measure.

5.3.5 Price Inflator

As mentioned in Section 1.2.1, the model facility income measures are based on *1997 Economic Census* data. To account for possible price inflation since 1997, the model allows users to enter a price inflator. The price inflator increases each of the model facility income measures by the percentage specified. The Consumer Price and Producer Price Indices (PPI and CPI) published by the Bureau of Labor Statistics (BLS) are the most widely used measures of inflation and can be used to adjust model facility income measure to better reflect current market conditions.

APPENDIX

FREQUENTLY ASKED QUESTIONS

Below is a list of frequently asked questions to aid in using the four SBIM models. The questions are relevant to all four models and where there are exceptions, these have been noted in the question or in the answer to the question.

QUESTION 1. What happens to the input when the user is navigating among worksheets in the models, using the "Back", "Back to TOC", and "Continue" buttons?

The input is always retained when navigating between worksheets. If the user is only making a slight modification to input previously entered, this modification can be made to the data already entered. If new categories are being considered or entirely new data is being entered, the user input should be cleared using the "Clear User Input" button on the user input worksheet before proceeding further. The model will always remind the user to do so when navigating to a page that may contain previously entered input. The "Clear User Input" button clears all input.

In the RTE model, the user is returned to the list of RTE categories after clearing the input so that the user can easily return to the category of interest. In the other models, the user is returned to the top of the user input page that was cleared.

QUESTION 2. What do the red flags mean on the user input worksheet and summary of impacts worksheet?

On the user input worksheet, the red flags give the user information on the NAICS code to which the category has been mapped. If that category is checked, the model will use Census data from that NAICS code to calculate impacts. Similarly, if any of the subcategories under that

NAICS code are checked (including the "Other" subcategory), the model will use Census data from that NAICS code to calculate impacts. In the RTE model, the categories also have a heading that references all the NAICS codes that fall under that heading.

On the summary of impacts worksheet, the red flags provide an explanation of the impact measure.

QUESTION 3. In Section 1.3.4.1, the following ranking is discussed in terms of baseline facility closures for the three income measures:

$FC_R < FC_{EBIT}$ and $FC_R < FC_{CF}$ and $FC_{EBIT} < or > FC_{CF}$

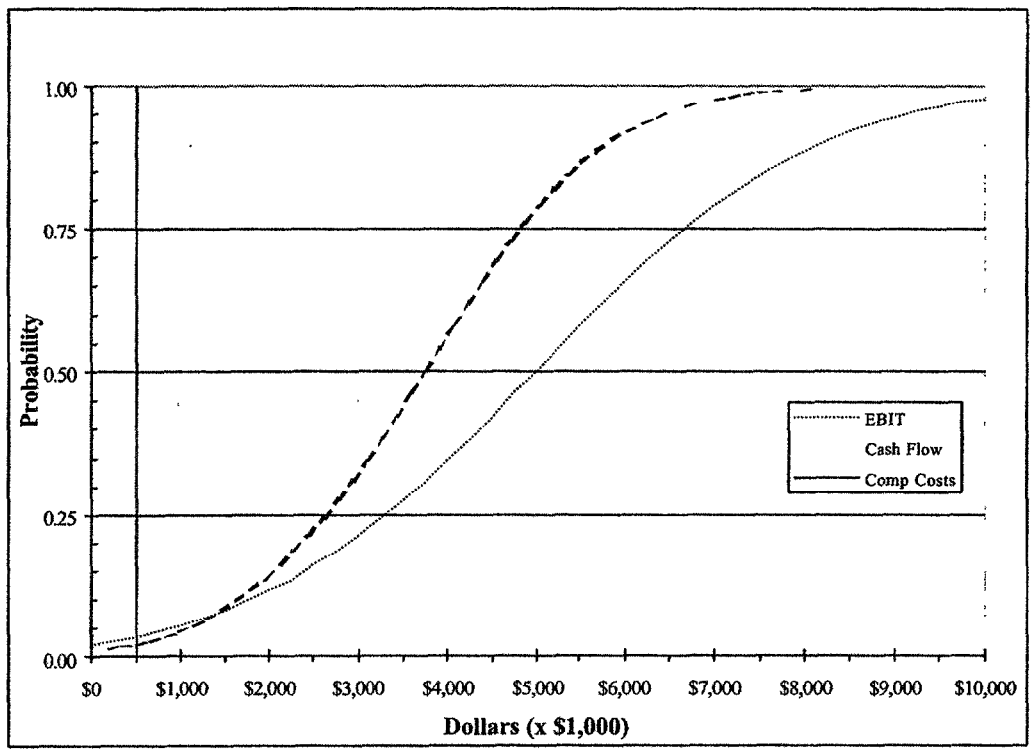
Is there a similar ranking that applies to impacts other than baseline facility closures and if not, why not?

No, a similar ranking does not apply to any of the other impacts. Furthermore, this ranking only applies to the normal, not the lognormal, distribution because baseline facility closures for the lognormal are based on the Census death rate of firms for the NAICS code (see Section 1.2.5), which is constant for all three income measures. The ranking exists for the normal distribution because the probability of cash flow and EBIT baseline closures is always greater than that of revenues, as the revenue measure is always greater than cash flow and EBIT by definition (see Figure A-1). No such relationship exists between EBIT and cash flow, however.

A similar ranking does not apply to any of the other impact measures because the ranking is dependent on where the regulatory costs are on the curve (see figure A-1). Given that the estimated curves for each of the income measures can cross at any point along the curves, the ranking changes depending on the size of the regulatory cost.

Figure A-1

Impact Comparison



QUESTION 4. In the "Summary of Impacts" worksheet, why does the model report zero for the number of affected establishments and employees even though I entered a positive number in the user input for affected establishments?

In the case of a small number of estimated affected establishments, the model may distribute the affected establishment across size categories in such a way that rounding in the "Summary of Impacts" worksheet results in a zero entry for affected establishments and employees. The decimal figure can be recovered by increasing the number of decimal spaces shown in the worksheet.

QUESTION 5. How does the number of affected establishments entered in the user input worksheets get distributed among employee size classes in the models?

In the DS-SBIM model, this question is irrelevant since the number of affected establishments is determined automatically by the selection of facility type and sector affected. In the other three models, the distribution of the number of affected establishments among employee size classes is assumed to mirror the Census data size distribution of that NAICS code. This can be changed in the "Model Facility Income Calculations by NAICS" worksheet by overriding the formulas in the "Affected Establishments" column and entering in the desired distribution of establishments across size classes. Should this be chosen, the user needs to ensure that all size classes have either a zero or a positive number entered for the affected NAICS code. If not done as indicated, some of the formulas that distribute the total number of establishments will continue to work, resulting in incorrect computations.

QUESTION 6. Why are the facility and employment impacts so much larger under the assumption of the lognormal distribution versus the normal distribution?

Impacts will consistently be greater under the lognormal distribution due to the skewedness of this distribution. This is true with the exception of baseline impacts, which might

be smaller or larger than those under the normal distribution. Baseline impacts for the lognormal are dependent on the U.S. Census death rate for firms in the affected NAICS code and thus are independent of the distribution itself.

QUESTION 7. Why does the "Continue" button in the user input sheets not work when clicked on?

Please ensure that you have pressed the Enter key on the keyboard after entering your input.

QUESTION 8. Why are some of the numbers highlighted in red in the "Model Facility Income Calculation by NAICS" worksheet of the DS-SBIM?

The numbers highlighted in red are updated figures received as part of the 1997 Economic Census customized tabulation. The *1997 Economic Census* data undergo frequent revisions and ERG decided to incorporate these revisions to reflect the most recent data available. Please note that this was not done for the Candy-SBIM, Cosmetics-SBIM, or RTE-SBIM because the Census Bureau did not provide the updated data as part of the customized tabulations for these industries.

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