Appendix E

Nonrecurring Cost Estimates

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Appendix E contains the methodology and costs staff used to assign nonrecurring costs for each category. Nonrecurring costs are those associated with research and development to reformulate complying products and are independent of, and in addition to, the costs of ingredients to produce a product. For each category proposed for regulation, staff estimated a low cost and a high cost.

For both low and high cost scenarios, the initial statement of product development goals, to final delivery of the new product to the marketplace was divided into eight phases. The phases are: product development, including reformulation and development of a new delivery system if necessary; stability testing; efficacy testing; safety testing; labeling modification; registration with regulatory agencies, if necessary; manufacturing change; and marketing.

1. Nonrecurring Costs Considered

A brief description of the nonrecurring cost factors considered is provided below.

Product Development

Given a set of new product requirements, in the product development phase a laboratory prototype for product evaluation and testing is produced. This includes formulating the contents and specifying the packaging and raw materials. New packaging and chemical formula components might need to be sourced.

Stability Testing

Stability testing ensures that the newly formulated chemical composition and/or packaging are compatible with each other and with product function for a reasonable period of time. Food and Drug Administration (FDA) and U.S. EPA regulated products require extra steps to ensure the stability of active ingredients and kill claims of products such as disinfectants and pesticides.

Efficacy Testing

Efficacy testing is the process to ensure that the product maintains the ability to perform label claims and to meet customer expectations. For U.S. EPA Federal Insecticide, Fungicide, and Rodenticide (FIFRA) registered products this would require extensive testing by a specialized laboratory to validate anti-microbial efficacy claims. The testing must be documented with and meet the approval of U.S. EPA.

Safety Test

Safety testing costs include testing of the new product to ensure safety to manufacturing personnel during fabrication, logistics personnel during transit, and to consumers during use and storage.

Labeling Modifications

Costs assigned for labeling modifications are those required when product qualities or use instructions change.

Registration Fees

Registration expenses are generally incurred for products requiring U.S. EPA registration or FDA regulation whenever changes are made to the label or formula.

Marketing

The costs for marketing consider: focus group testing, conducting surveys, advertising, and design and publication of print and Internet materials.

Manufacturing

The costs for manufacturing consider the technology and infrastructure required to mass-produce a product. A new VOC limit which must be met by changes to the production requirements would incur a manufacturing cost proportional to the magnitude of the change. Manufacturing costs to comply with proposed standards can include 'pilot plant' testing and/or retooling of production lines or construction of completely new facilities.

A pilot plant test is a small scale version of full scale production which is large enough to approximate the physical characteristics and challenges which will be encountered in the full-scale version. A pilot test run consumes considerably less resources and raw materials than a full scale run to produce a batch of product which will not necessarily be ready or suitable for a commercial market.

Literature

Literature costs are those incurred when new sales and marketing and/or technical literature need to be developed and distributed in order to inform customers of the attributes of a new product.

2. Assigning Costs

A set of per product reformulation costs in 1991 dollars has been established for each phase of bringing a reformulated product into the market. The costs are adjusted to

2010 dollars using a well-established method of rationing chemical engineering plant cost indices as follows (Peters and Timmerhaus, 1980):

$$\text{Non-Recurring Costs (in 2010 dollars)} = \text{Non-Recurring Costs (in 1991 dollars)} \times \frac{\text{C.E. 2010 Index}}{\text{C.E. 1991 Index}}$$

where,

C.E. 2010 index = 2010 Chemical Engineering Plant Cost Index = 539.1 (Chemical Engineering, 2010).

C.E. 1991 index = 1991 Chemical Engineering Plant Cost Index = 361.3 (Chemical Engineering, 1991).

Tables E-1 and E-2 show the costs assigned to each phase for the low and high cost scenarios for "household product" and "Pesticide and Disinfectant" product categories.

To develop the costs shown in Tables E-1 and E-2, personnel costs are assigned. Beyond personnel costs, additional cost elements were considered at each phase and added as appropriate. These cost elements are facility; equipment; tool; jig; fixture and miscellaneous materials handling equipment; purchased material; packaging; distribution; warehousing; technical data; research studies and tests; promotional literature; residual inventory and disposal; consumer tests; general and administrative expense; patent; registration fees; and computer support. The result of these considerations is a per-product nonrecurring cost for developing a reformulated product and bringing it to market.

The length of time in each phase was estimated based on an industry analysis of 80 new product innovations. Most of the phases occur in sequence; however, there is some time overlap in each phase.

Next, estimated personnel resources were allocated to each phase considering the most probable types of skills needed including general engineering; technician; drafting; packaging engineering; specification engineering; model making; chemical engineering; technical publication; production support; quality assurance; marketing; warehousing; word processing; and clerical. For high cost elements, additional personnel were allocated to each phase.

Staff used different assumptions for the low and high cost analyses, and considered the specific likelihood that each of the cost elements would occur for each product category individually.

Table E-1
Assigned Nonrecurring Costs for Product Development:
Generic per Product Reformulation Costs (Low Cost Approach)

	Household	Pesticide & Disinfectant
Product Development Material	$149	$149
Computer Support	$149	$149
Personnel/Formulation	$5,521	$5,521
Personnel/Delivery System	$0	$0
Prototype Equipment	$0	$0
Testing Material	$448	$448
Computer Support	$0	$0
Personnel/Stability Test	$1,194	$1,194
Personnel/Efficacy Test	$1,194	$1,194
Personnel/Safety Test	$2,984	$2,984
Labeling Modifications Material	$149	$149
Technical Data	$298	$298
Personnel	$895	$895
Registration/Fees	$298	$298
Personnel	$597	$1,641
Manufacturing Equipment	$0	$0
Technical Data	$149	$149
Computer Support	$0	$0
Other	$0	$0
Personnel	$1,343	$1,343
Marketing Studies	$298	$298
Literature	$149	$149
Inventory	$0	$0
Computer Support	$0	$0
Personnel	$298	$298
TOTAL	**$16,113**	**$17,157**

2010 C.E. Plant Cost Index =539.1 (final February 2010)
1991 C.E. Plant Cost Index = 361.3

Table E-2
Assigned Nonrecurring Costs for Product Development:
Generic per Product Reformulation Costs (High Cost Approach)

	Household	Pesticide & Disinfectant
Product Development Material	$746	$895
Computer Support	$895	$746
Personnel/Formulation	$18,950	$18,950
Personnel/Delivery System	$24,172	$22,382
Prototype Equipment	$1,492	$1,492
Testing Material	$448	$448
Computer Support	$448	$448
Personnel/Stability Test	$6,715	$6,715
Personnel/Efficacy Test	$5,521	$5,521
Personnel/Safety Test	$9,997	$9,997
Labeling Modifications Material	$298	$298
Technical Data	$895	$895
Personnel	$5,372	$5,372
Registration/Fees	$448	$746
Personnel	$4,476	$4,924
Manufacturing Equipment	$37,303	$37,303
Technical Data	$746	$746
Computer Support	$149	$149
Other	$1,044	$1,044
Personnel	$30,738	$30,738
Marketing Studies	$1,492	$1,492
Literature	$746	$597
Inventory	$2,984	$2,984
Computer Support	$149	$149
Personnel	$12,235	$9,699
TOTAL	**$168,459**	**$164,730**

2010 C.E. Plant Cost Index = 539.1 (final February 2010)
1991 C.E. Plant Cost Index = 361.3

Low Cost Scenario

In the low cost scenario it is assumed that only minor modification to the current formulation is necessary to come into compliance. Therefore, for the low cost analysis no major costs were added for changing delivery systems or other product attributes.

In addition, it is common that large companies having significant market share and broad product lines offer both complying products and noncomplying products. In some cases, relatively low costs would be incurred where these companies could increase sales and distribution of complying products and discontinue sales of noncomplying products.

If products do not change significantly, it is assumed that major retooling of manufacturing equipment would not be required, technical data changes would be minor, and the change in marketing costs would be small. It was also assumed that these reformulated products would be marketed nationally.

High Cost Scenario

Each category was analyzed individually to determine which of the elements, discussed above, and shown in Table E-2, manufacturers would likely incur in their reformulation efforts. High costs for specific steps of the reformulation process were only included in the cost analysis where staff believed they were likely to occur. If staff believed a markedly different product would be needed to comply with the proposed limit, such as a new delivery system, then high personnel and capital resources, especially in product development and manufacturing changes, were assumed. In addition, a new delivery system would require investment for prototypes, new filling machines training, and technical data, so these high costs were also included in these scenarios. Additional costs were also added for packaging, distribution and warehousing. In areas where it was expected that little or no reformulation would occur, or that the cost of reformulation would be minimal, the value for low cost was used.

For especially challenging limits, it was assumed for the high cost approach that, because of a markedly different product, there would also be additional marketing costs, including research studies and tests, promotional literature, and consumer tests. These costs vary by the type of product, however the household products being proposed for further regulation typically having a larger expense in this area. The cost analysis did not include the costs for an extensive advertising campaign. New products are regularly brought onto the market, and the advertising for a new product, whether reformulated or not, would replace the advertising for the existing product, and would be a normal cost. It was assumed that the new product would be marketed nationally.

The staff also recognized that development of a new product does not occur in isolation. Few companies have only one product line; for those that have more than one product line, the product lines can be very similar. Development and production tasks, from the initial concept through marketing, would be proceeding simultaneously on more than

one product line, with a transfer of information and work-sharing between the products. For these companies, this "technology transfer" would substantially reduce the cost of developing and marketing a new product on a per product basis. For categories where the majority of products were held by a few companies it was assumed that this "technology transfer" would occur, and high costs adjusted accordingly.

Other Assumptions

Staff considered only nonrecurring costs that are likely to occur on a per category basis. If it was determined that for a majority of products in the category, the most likely scenario was that only minor changes to the product's reformulation were necessary to comply with the new proposed limit then only the lower end of the nonrecurring cost was included. For some categories, it was appropriate, based on the variety of products and reformulation approaches needed to meet the proposed limit, that certain high cost factors be included in the analysis, but not others, on a case-by-case basis. We believe that this approach gives a more realistic estimate of the costs of a given limit.

REFERENCES

1. Chemical Engineering magazine. Chemical Engineering Plant Cost Index. February, 2010. (Chemical Engineering, 2010)

2. Chemical Engineering magazine. Chemical Engineering Plant Cost Index. April, 1997. (Chemical Engineering, 1997)

3. Peters, M. S. and Timmerhaus, K. D. Plant Design and Economics for Chemical Engineers. 3rd Edition, McGraw-Hill Book Company, 1980, pp. 159-162. (Peters and Timmerhaus, 1980)