## APPENDIX D: INDUSTRY COST CALCULATIONS AND OPTIONS/SENSITIVITY ANALYSES

This appendix provides an explanation of the assumptions and estimates used to develop industry costs associated with microbial product submissions that would be required under the rule. In addition, it provides information on the options and sensitivity analyses used to generate costs associated with appropriate cases. The appendix is organized as follows:

- Section A provides a breakdown of the costs of the various types of submissions (e.g. TERA, MCAN) and recordkeeping requirements;

- Section B provides estimates of total industry costs resulting from various regulatory alternatives; and

- Section C provides the sensitivity analyses.

### A. Submission Reporting Costs

The steps and assumptions used to generate per-submission costs for TERAs, MCANs, and Tier I and Tier II exemptions are presented here. Costs were derived from data presented by Stanford Research Incorporated, International (SRI) on the amount of time and level of expertise needed to develop and submit information anticipated to be required for biotechnology Premanufacture Notices. The SRI data were originally presented with a probability rating (presented on a quartile basis) indicating the likelihood of the submitter having the information in-house as part of on-going or basic research for product development or that the data are otherwise available to the submitter. The probability for any particular data element is presented as a range (e.g., 51-75 percent).

For this Regulatory Impact Analysis, the SRI data have been adapted to estimate the cost of developing and submitting certain information required in the rule. This section describes the cost areas identified from the rule and the method for deriving that information from the SRI data, as well as any assumptions that were necessary to quantify other parameters or to supply alternate estimates for each cost element. Tables D-1 and D-2 relate the SRI

Table D-1. TERA Cost Elements for Components of the Final Rule[a]

| CFR from Rule | Information Required | SRI Data Elements | Comments |
|---|---|---|---|
| §725.255c | | | |
| 1 | Name, address and telephone number of TERA submitter | | Negligible administrative cost |
| 2 | Name, address, and telephone number of technical contact | | Negligible administrative cost |
| §725.255d | | | |
| 1i | Data substantiating the taxonomy of the recipient microorganism and the TERA microorganism to the level of strain | A1a-1/i, a-1/ii, e[b] | |
| 1ii | Information on the morphological and physiological features of the TERA microorganism | B5a, d[b] | |
| 1iii | Other data by which the TERA microorganism may be uniquely identified | A3g[b] | |
| 2i | Taxonomy of donor organism | | Labor requirements included under 1i |
| 2ii | Description of the traits for which the TERA microorganism(s) has been selected or developed and other traits known to have been added or modified. | A1c | |
| 2iii | Methods used to alter the microorganism including function of added genetic material | B1a, b, c<br>B2a, b, c | |
| 3i | Habitat and geographic distribution of precursor microorganisms | A3b-1, b-2 | |
| 3ii | Survival and dissemination under relevant environmental conditions including a description of methods for detecting the microorganism in the environment and the minimum limit of detection | | Labor requirements included under 1i |
| 3iii | Biological interactions, pathogenicity, capacity for genetic transfer | | Negligible cost attributable to providing a summary or available data |
| 3iv | Involvement in biogeochemical or biological cycling processes | | Labor requirements included under 3iii |

Table D-1. TERA Cost Elements for Components of the Final Rule (Continued)[a]

| CFR from Rule | Information Required | SRI Data Elements | Comments |
|---|---|---|---|
| §725.255e | | | |
| 1i | Detailed description of the planned activity, including the objectives and significance of the activity, and a rationale for testing the microorganisms in the environment. | A1g | |
| 1ii | Number of microorganism's and method of application | D2b[b] | |
| 1iii | Characteristics of release site including those affecting dispersal. | [c] | |
| 1iv | Activity on target organism | B4f[b] | May not be applicable in all cases, only for cases in which the microorganism, is designed to have specific activity on some other organism. |
| 1v | Planned start date and duration of the activity | | Negligible administrative costs |
| 1vi | Evidence of State notification | | Negligible administrative costs |
| 2i | Confinement procedures | | Labor requirements included under 2v |
| 2ii | Mitigation and emergency procedures | | Labor requirements included under 2v |
| 2iii | Measures to detect and control potential adverse effects | | Labor requirements included under 2v |
| 2iv | Name of principal investigator and chief of site personnel responsible for emergency procedures | | Labor requirements included under c(1),(2) |
| 2v | Personal protective equipment, engineering controls, and procedures to be followed to minimize dispersion of the microorganism by people, or equipment | C3c-1, c-2, d, c<br>D2c,f[b] | |
| 2vi | Procedures for disposal of any articles, waste, clothing, or other equipment involved in the activity, including methods for inactivation of the microorganism, containment, disinfection, and disposal of contaminated items. | D2f[b] | Labor requirements included under 2v |

Table D-1 TERA Cost Elements for Components of the Final Rule (Continued)[a]

| CFR from Rule | Information Required | SRI Data Elements | Comments |
|---|---|---|---|
| §725.260 a,b | Summary of the unpublished health and envionmental effects data on the TERA microorganism and on the nonmodified donor and recipient organisms, and a list of published health and environmental effects data on the TERA microorganism and on the nonmodified parent organisms | 40 hours of JP<br>8 hours of SP | This estimate provided by ETD |
| | Managerial Review | 8 to 20 hours of RM | This estimate provided by ETD. |
| | Clerical preparation | 8 to 20 hours | This estimate provided by ETD (20 to 100 pages at 24 minutes per page) |
| | Submission Writeup | 40 to 200 hours of JP | This estimate provided by ETD (20 to 100 pages at 2 hours per page). |

[a] Based on SRI data elements, and ETD estimates.

[b] The costs for these data elements were estimated by the Agency for the low cost case (OPTS 1992).

[c] The cost for this data element was estimated by the Agency for both the low and high cost cases (OPTS 1992).

Sources: SRI 1987, OPTS 1992, ETD estimates.

Table D-2. MCAN Cost Elements for Components of the Final Rule[a]

| CFR from Rule | Information Required | SRI Data Elements | Comments |
|---|---|---|---|
| §725.155c | | | |
| 1 | Name and headquarters address of notice submitter | | Negligible administrative cost |
| 2 | Name, address and office telephone number of principal technical contact representing submitter | | Negligible administrative cost |
| §725.155d | | | |
| 1i | Data substantiating the taxonomy of the recipient microorganisms and the MCAN microorganisms to the level of strain. | A1a-1/i, a-1/ii, A1e[b] | Required for TERA, no additional cost of providing this data element for a MCAN |
| 1ii | Information on the morphological and physiological features of the MCAN microorganisms. | B5a,d[b] | Required for TERA, no additional cost of providing this data element for a MCAN |
| 1iii | Other data by which the MCAN microorganisms may be uniquely identified. | A3g[b] | Required for TERA, no additional cost of providing this data element for a MCAN |
| 2i | Taxonomy of donor organism | | Labor requirements included under 1i |
| 2ii | Identification of the traits for which the microorganism has been developed[c] | A1c | Required for TERA, no additional cost of providing this data element for a MCAN |
| 2iii | Detailed description of the methods used to genetically engineer the microorganism[c] | B1a, b, c<br>B2a, b, c | Required for TERA, no additional cost of providing this data element for a MCAN |
| §725.155d | | | |
| 3i | Habitat and geographic distribution of non-modified parent organism[c] | A3b-1, b-2 | Required for TERA, no additional cost of providing this data element for a MCAN |
| 3ii | Survival and dissemination under relevant environmental conditions including a description of methods for detecting the microorganisms in the environment and the minimum limit of detection. | | Required for TERA, no additional cost of providing this data element for a MCAN<br>Labor requirements included under 1i |
| 3iii | Biological interactions, pathogenicity, capacity for genetic transfer | | Required for TERA, no additional cost of providing this data element for a MCAN |
| 3iv | Involvement in biogeochemical or biological cycling processes | | Labor requirements included under 3iii |

Table D-2. MCAN Cost Elements for Components of the Final Rule (Continued)[a]

| CFR from Rule | Information Required | SRI Data Elements | Comments |
|---|---|---|---|
| §725.155 | | | |
| e | Byproducts | | Labor requirements included under h(1ii) |
| f | Use volume (intended) | C1c | |
| g | Intended categories of use by function and application | | Labor requirements included under 'f' |
| §725.155h | | | |
| 1i | Name and address of each site where the microorganism is intended to be manufactured, imported, or processed for environmental release | C1a-1 | |
| 1ii | Process description of each manufacture, processing, and use operation | C1b | |
| 1iii | Worker exposure information | C2a, b-1, c, F1a, F2a, b[b] | C2a included under 6vi |
| 1iv | Intended uses and releases and methodology of release[c] | B4f, E1a, C3C-2, C3d, D1b-1, D2b, D2c, D2f | Required for TERA |
| 1v | Transport of microorganism | C1a-1, C3e | C1a-1 included under 'h(1i)' |
| 1vi | Procedures for disposal of any articles, waste, clothing, or other equipment involved in the activity, including methods for inactivation of the microorganism, containment, disinfection, and disposal of contaminated items. | C3c-1, c-2, d, e, D2c, f | Required for TERA, no additional cost of providing this data element for a MCAN<br>D2c,f included under h(iv) |
| 2 | For sites not controlled by the submitter, description of processing, use, exposure[b] | C2a, C3c-1, D1a | C3c-1, D1a are necessary for TERA |

Table D-2. MCAN Cost Elements for Components of the Final Rule (Continued)[a]

| CFR from Rule | Information Required | SRI Data Elements | Comments |
|---|---|---|---|
| §725.160 a,b | A summary of the unpublished health and environmental effects data on the MCAN microorganisms and on the nonmodified donor and recipient organisms, and a list of published health and environmental effects data on the MCAN microorganism and on the nonmodified parent organisms[c] | 40 hours of JP[d]<br>8 hours of SP | Required for TERA, no additional cost of providing this data element for a MCAN |
| | User fee [See §700.45(b)] | $2500 | |
| | Managerial Review of MCAN Submission | 8 to 20 hours of RM | This estimate provided by ETD. Based on review requirements for this type of submission. |
| | Clerical preparation | 8 to 20 hours | This estimate provided by ETD (20 to 100 pages at 24 minutes per page). |
| | Submission writeup | 40 to 200 hours of JP | This estimate provided by ETD (20 to 100 pages at 2 hours per page). |

[a] Based on SRI data elements except as noted.

[b] The costs of these data elements were estimated by the Agency for the low cost case (OPTS 1992).

[c] The costs associated with this element will be incurred for a MCAN if no previous TERA has been submitted.

[d] The cost of providing a summary of unpublished health and environmental effects data was estimated by ETD.

Sources: SRI 1987, ETD estimates.

data elements to the rule categories of information for TERAs and MCANs respectively.

There are several assumptions that lay the groundwork for this analysis. They can be summarized as follows:

- It was assumed that for any particular data element identified from the SRI data, most companies submitting notification data would be likely to have at least some of the data of interest and would fall at the upper end of the assigned probability range (ETD Assumption). Probabilities are, therefore, applied to cost elements as the difference between unity and the upper bound of the probability range (e.g., if there is a 51-75 percent probability of having certain data, the cost of acquiring the data element is calculated as 25 percent of the associated unit cost).

- The costs for any data element anticipated as a requirement both for the TERA and MCAN submissions were counted only once. It was assumed that information or data developed in support of a TERA submission would need to be included in a subsequent MCAN package, but that there would be a negligible additional cost of including this information once a submission reaches the MCAN stage.

- Agency estimates of labor requirements and the percentage of cases to which these requirements were applied were used instead of the SRI data for some of the data elements required by the rule (OPTS 1992).

- The submissions will require managerial review of all information to be provided to EPA in order to verify for completeness and appropriateness of the data. (ETD Assumption).

This section discusses these cost components and provides the basis for determining the submission costs for each type of notification. The costs are presented according to the information requirements set forth in the rule for TSCA biotechnology submissions. After submission costs are derived, the number of submissions expected and the incremental costs associated with each submission are used to generate the total industry costs associated with all aspects of the rule including other non-submission factors, such as rule familiarization. These costs are presented in Section B of this analysis.

1. Calculating Average Expected Costs

The labor rates used to predict costs based on time requirements provided by SRI have been developed by Kearney-Centaur and are as follows (Kearney-Centaur 1988):

- $25.00 per hour for clerical employee;
- $42.78 per hour for research technician;
- $54.14 per hour for junior professional;
- $71.35 per hour for senior professional; and
- $103.99 per hour for research manager.

These hourly wage rates are used throughout the analysis of the costs to industry associated with the rule.

For industry costs, the labor time associated with any given cost element of the regulation is presented under the appropriate labor category. In most cases, this time is presented in total weeks.* In order to calculate labor costs, the number of hours was multiplied by the fully loaded hourly rate.** In the case of weeks, the number of weeks was multiplied by the fully loaded hourly rate and that product was multiplied by 40.

Once labor costs were calculated, the percent of cases was applied to labor costs in order to determine the average expected costs for each element of the TERA and MCAN. The "percent of cases" entry in the detailed cost tables is an estimate of the likelihood that a firm would not have the information readily available and is based on the SRI data. If a firm was likely to have the necessary information, it was assumed that the cost of providing this information for any of the reporting documents was negligible.

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For costs associated with MCANs and TERAs, time estimates are based on the SRI International estimates. See SRI International, "Availability and Cost of Information in the Points to Consider in the Preparation of TSCA Premanufacture Notices for Genetically Engineered Microorganisms," prepared for Office of Toxic Substances, U.S. Environmental Protection Agency, February 12, 1987. These estimates were adjusted in some case based on Agency experience (OPTS 1992).

Fully loaded rates include the base salary plus fringe benefits and overhead costs.

The average expected cost for each element results from multiplying the expected labor costs by the corresponding percent of cases. The average expected costs for each data element were totalled to yield the average expected cost for each type of submission.

In the cost component tables below, some cost elements have been divided down into subcategories in order to identify more clearly all cost components. In such cases, a subtotal of all cost factors: time, labor costs, percent of cases, and average expected costs is provided. For total time and average expected costs, the relevant items were summed. The subtotal for percent of cases was derived by dividing the subtotal of average expected costs by the unadjusted subtotal of labor costs. Totals were derived in the same manner.

2. Industry Cost Components for TERA Submissions

Many of the costs associated with TERA submissions will be incurred over several years as submitters develop and provide material to EPA. It is assumed for this analysis, however, that all costs associated with developing and preparing the TERA information are incurred in the year in which the TERA is submitted.

In addition, although it is likely that a submitter will have much of the information required for a TERA in-house, it is possible that some of the components of the rule will require the submitter to produce data that are not generated from basic research. The probability that the company does not have certain information is the basis for generating the average expected cost of preparing the TERA. The TERA cost components and the estimated costs for reporting are presented in Tables D-3 and D-4.

3. Industry Cost Components for MCAN Submissions

This section presents the components of the rule as they pertain to industry costs for MCAN submissions. It was assumed that each component of the per-submission costs would be incurred by each submitter and that the

Table D-3. Components of the Cost of Preparing a TERA

Low Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Costs | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.255 | | | | | | | |
| c. Company contacts | | | | | | | |
| 1. Name, Address - Submitter | | | | | | | negligible (a) |
| 2. Name, Address, Telephone - Technical Contact | | | | | | | negligible (a) |
| d. Identity of microorganism | | | | | | | |
| 1. Description of recipient microorganism and new microorganism | | | | | | | |
| i. Taxonomy to level of strain | | 1.00 | | | $2,166 | 0% | negligible (a) |
| ii. Morphology, physiology | | | | | | | labor requirements covered under '1i' |
| iii. Other data by which to ID microorganism | | | | | | | labor requirements covered under '1i' |
| Subtotal for description | | 1.00 | | | $2,166 | 0% | negligible (a) |
| 2. Genetic characteristics | | | | | | | |
| i. Taxonomy of donor | | | | | | | labor requirements covered under '1i' above |
| ii. Traits for which microorganism has been developed | 2.00 | 2.00 | 1.00 | | $10,608 | 0% | negligible (a) |
| iii. Methods of developing microorganism | 41.00 | 32.00 | 6.50 | 0.75 | $161,129 | 0% | negligible (a) |
| Subtotal for genetic characteristics | 43.00 | 34.00 | 7.50 | 0.75 | 171,737 | 0% | negligible (a) |
| 3. Microorganism (or parental strains) Information | | | | | | | |
| i. Habitat, geographical distribution | | 2.00 | | | $4,331 | 0% | negligible (a) |
| ii. Survival, dissemination, detection methods | | | | | | | labor requirements covered under '1i' above |
| iii. Biological interactions, genetic transfer | | | | | | | negligible (a) |
| iv. Biogeochemical/biological cycling | | | | | | | labor requirements covered under '3iii' above |
| Subtotal for Microorganism Information | | 2.00 | | | $4,331 | 0% | neglibible (a) |
| e. Information on R&D Activity | | | | | | | |
| 1. Description of Planned Activity | | | | | | | negligible (a) |
| i. Objectives and significance | | | | | | | neglibible (a) |
| ii. Numbers of microorganism and method of application | | | 1.00 | | $2,854 | 0% | negligible (a) |
| iii. Characteristics of release site | 1.00 | | 1.00 | | $4,565 | 0% | neglibible (a) |
| iv. Activity on target organisms | | | | 0.75 | $3,120 | 0% | negligible (a) |
| v. Planned start date and duration of activity | | | | | | | negligible (a) |
| vi. Evidence of state notification | | | | | | | negligible (a) |
| Subtotal for Description of Activity | 1.00 | | 2.00 | 0.75 | $10,539 | 0% | negligible (a) |

Table D-3. Components of the Cost of Preparing a TERA (Continued)
Low Cost Case

| Rule Reference Elements | Total Weeks | | | | Labor Costs | Percent of Costs | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| CFR | RT | JP | SP | RM | | | |
| §725.255 | | | | | | | |
| e. Information on R&D Activity (continued) | | | | | | | |
| 2. Control equipment and procedures | | | | | | | |
| i. Confinement procedures for activity | 1.00 | | 1.00 | | $4,565 | 25% | $1,141 |
| ii. Mitigation and emergency procedures | | 0.50 | | | $1,083 | 15% | $162 |
| iii. Measures to detect & control potential adverse effects | | 1.00 | | | $2,166 | 25% | $541 |
| iv. Name of Principal Investigator and Chief of Site | | | | | | | negligible (a) |
| v. Measures to minimize disperstion of microorganisms | | | | | | labor requirements covered under '2i' above | |
| vi. Procedures for waste decontamination and disposal | | | | | | labor requirements covered under '2v' above | |
| Subtotal for Information on Procedures | 1.00 | 1.50 | 1.00 | | $7,844 | 24% | $1,844 |
| §725.260 Effects of microorganism on health or environment | $288 | 0.20 | 0.05 | | $576 | 50% | |
| User fee | | | | | | | $0 |
| Clerical preparation (8 hours) | | | | | $200 | 100% | $200 |
| Managerial review of TERA | | | | 0.20 | $832 | 100% | $832 |
| Submission writeup | | 1.00 | | | $2,166 | 100% | $2,166 |
| TOTAL | 45.00 | 39.70 | 10.55 | 1.70 | $200,391 | 2.6% | $5,330 |

(a) Nonscientific costs of collecting and providing data are included under "submission writeup."

Source: SRI 1987, OPTS 1992, and ETD estimates.

Table D-4. Components of the Cost of Preparing a TERA
High Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Costs | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.255 | | | | | | | |
| c. Company contacts | | | | | | | |
| 1. Name, Address - Submitter | | | | | | | negligible (a) |
| 2. Name, Address, Telephone - Technical Contact | | | | | | | negligible (a) |
| d. Identity of micoroorganism | | | | | | | |
| 1. Description of recipient microorganism and new microorganism | | | | | | | |
| i. Taxonomy to level of strain | 2.50 | 2.50 | 5.00 | | $23,961 | 0% | negligible |
| ii. Morphology, physiology | 8.00 | 4.00 | 2.00 | 1.00 | $32,220 | 16% | $5,261 |
| iii. Other data by which to ID microorganism | 4.00 | 4.00 | 2.00 | | $21,215 | 25% | $5,304 |
| Subtotal for Identity of microorganism | 14.50 | 10.50 | 9.00 | 1.00 | $77,396 | 14% | $10,565 |
| 2. Genetic characteristics of microorganism | | | | | | | |
| i. Taxonomy of donor | | | | | | labor requirements covered under '1i' above | |
| ii. Traits for which microorganism has been developed | 8.00 | 4.00 | 1.00 | | $25,206 | 0% | negligible (a) |
| iii. Methods of developing microorganism | 95.00 | 80.00 | 15.00 | 2.50 | $389,006 | 0% | negligible (a) |
| Subtotal for Genetic Development | 103.00 | 84.00 | 16.00 | 2.50 | $414,212 | 0% | negligible (a) |
| 3. microorganism (or parental strains) Information | | | | | | | |
| i. Habitat, geographical distribution | 8.00 | 16.00 | 12.00 | | $82,585 | 12% | $10,039 |
| ii. Survival, dissemination, detection methods | | | | | | labor requirements covered under '1i' above | |
| iii. Biological interactions, genetic transfer | | | | | | | negligible (a) |
| iv. Biogeochemical/biological cycling | | | | | | labor requirements covered under '3iii' above | |
| Subtotal for microorganism Information | 8.00 | 16.00 | 12.00 | | $82,585 | 12% | $10,039 |
| e. Information on R&D Activity | | | | | | | |
| 1. Descripiton of Planned Activity | | | | | | | |
| i. Objectives and significance | | | 0.50 | | $1,427 | 0% | negligible (a) |
| ii. Numbers of microorganism and method of application | | | 4.00 | | $11,416 | 0% | neglibible (a) |
| iii. Characteristics of release site | 4.00 | | 4.00 | | $18,261 | 6% | $1,096 |
| iv. Activity on target organisms | | | | 1.25 | $5,199 | 0% | negligible (a) |
| v. Planned start date and duration of activity | | | | | | | negligible (a) |
| vi. Evidence of state notification | | | | | | | negligible (a) |
| Subtotal for Conditions of Activity | 4.00 | | 8.50 | 1.25 | $363,303 | 3% | $1,096 |

Table D-4. Components of the Cost of Preparing a TERA (continued)
High Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Costs | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.255 | | | | | | | |
| e. Information on R&D Activity (continued) | | | | | | | |
| 2. Control equipment and procedures | | | | | | | |
| i. Confinement procedures for activity | | | 2.00 | | $5,708 | 25% | $1,427 |
| ii. Mitigation and emergency procedures | | 2.00 | 4.00 | 1.00 | $19,907 | 12% | $2,467 |
| iii. Measures to detect & control potential adverse effects | 8.00 | 8.00 | 4.00 | 2.00 | $50,750 | 25% | $12,687 |
| iv. Name of Principal Investigator and Chief of Site | | | | | | | negligible (a) |
| v. Measures to minimize dispersion of microorganisms | | | 10.00 | 0.50 | $30,619 | 0% | negligible (a) |
| vi. Procedures for waste decontamination and disposal | | | | | | labor requirements covered under '2v' above | |
| Subtotal for Information on Procedures | 8.00 | 10.00 | 20.00 | 3.50 | $106,984 | 15% | |
| | $16,581 | | | | | | |
| §725.260 Effects of microorganism on health or environment | | 1.00 | 0.20 | | $2,736 | 100% | $2,736 |
| User fee | | | | | | | $0 |
| Clerical preparation (20 hours) | | | | | $500 | 100% | $500 |
| Managerial review of TERA | | | | 0.50 | $2,080 | 100% | $2,080 |
| Submission writeup | | 5.00 | | | $10,828 | 100% | $10,828 |
| TOTAL | 137.50 | 126.50 | 65.70 | 8.75 | $1,060,624 | 5% | $54,425 |

(a) Nonscientific costs of collecting and providing data are included under "submission writeup."

Source: SRI 1987, OPTS 1992, and ETD estimates.

total costs per submission would include the costs of submitting the information to EPA and the costs of developing the information when necessary. The cost analysis for MCAN per submission costs is provided in Tables D-5 and D-6.

4. Industry Cost Components for Biotechnology PMNs

In order to estimate the baseline cost of reporting under thecurrent regulatory environment, it is also necessary to estimate the cost of submissions in the form of PMNs. Tables D-7 through D-10 present the estimated costs for these submissions. It is assumed that the same information would need to be included in these submissions as in a MCAN, but the costs per submission are different than for MCANs, because PMNs for environmental applications would not be preceded by previous submissions.

For biotechnology PMNs for environmental applications, the Agency would expect to review all of the information from previous field tests that would have been reported in TERAs under the rule. Each submission is assumed to have been preceded by three field tests for which the cost of collecting information is assumed to be one third the cost of the scientific information collection costs for the PMN.

5. Industry Costs for Recordkeeping

A detailed description of the costs associated with recordkeeping for the rule was presented in Chapter IV. The industry recordkeeping costs for the rule and the other regulatory options are presented again in this section. Tables D-11 and D-12 show estimates for recordkeeping costs for Year 1 and Year 5 for each option.

B. Total Industry Costs

Submission reporting costs and ICF Survey (ICF 1988) results were used to estimate the costs to industry associated with the rule. The baseline

Table D-5. Components of the Cost of Preparing an MCAN

Low Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| c. Company contacts | | | | | | | |
| 1. Name, Address - Submitter | | | | | | | negligible (a) |
| 2. Name, Address, Telephone - Technical Contact | | | | | | | negligible (a) |
| d. Identity of microorganism | | | | | | | |
| 1. Description of recipient microorganism and new microorganism | | | | | | | |
| i. Taxonomy to level of strain | | 1.00 | | | $2,166 | 0% (c) | negligible |
| ii. Morphology, physiology | | | | | | labor requirements covered under '1i' | |
| iii. Other data by which to ID microorganism | | | | | | labor requirements covered under '1i' | |
| Subtotal for description | | 1.00 | | | $2,166 | 0% (c) | negligible |
| 2. Genetic Characteristics of microorganism | | | | | | | |
| i. Taxonomy of donor | | | | | | labor requirements covered under '1i' above | |
| ii. Traits for which microorganism has been developed | 2.00 | 2.00 | 1.00 | | $10,608 | 0% (c) | negligible |
| iii. Methods of developing microorganism | 41.00 | 32.00 | 6.50 | 0.75 | $161,129 | 0% (c) | negligible |
| Subtotal for Genetic Characteristics of microorganism | 43.00 | 34.00 | 7.50 | 0.75 | $171,737 | 0% | negligible |
| 3. Microorganism (or parental strains) information | | | | | | | |
| i. Habitat, geographic distribution of parent microorganism | | 2.00 | | | $4,331 | 0% (c) | negligible |
| ii. Survival and dissemination | | | | | | labor requirements covered under 'h(1iv)' | |
| iii. Biological interactions | | | | | | | negligible (b) |
| iv. Biogeochemical/biological cycling | | | | | | labor requirements covered under '3iii' above | |
| Subtotal for microorganism information | | 2.00 | | | $4,331 | 0% | negligible |
| e. Byproducts | | | | | | labor requirements covered under 'h(1vi)' | |
| f. Estimate total quantity of microorganism to be manufactured | | | 1.00 | 0.50 | $4,934 | 0% (c) | negligible |
| g. Description of intended categories of use | | | | | | labor requirements covered under 'h(1iv)' | |

Table D-5. Components of the Cost of Preparing an MCAN (continued)
Low Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| h. Worker exposure and environmental release | | | | | | | |
| 1. Sites controlled by submitter | | | | | | | |
| i. Name, Address - Each site where microorganism is to be manufactured, imported, processed, or disposed of | | | 2.00 | 0.50 | $7,787 | 0% (c) | negligible |
| ii. Description of manufacturing/processing and disposal methodology for microorganism | 8.00 | 8.00 | 4.00 | 1.00 | $46,588 | 0% (c) | negligible |
| iii. Worker, human and environmental exposure information | 4.00 | 6.00 | 4.00 | 1.00 | $35,414 | 0% (c) | negligible |
| iv. Intended Uses of microorganism and estimated total quantity of microorganism to be released to environment | 11.00 | 10.00 | 16.00 | 5.25 | $107,981 | 0% (b) | negligible |
| v. Description of procedure for transport of microorganism | | | 1.00 | 0.50 | $4,934 | 25% | $1,233 |
| 2. For sites not controlled by submitter - A description of each type processing use operation involving microorganism | 2.00 | 2.00 | 3.00 | 1.00 | $20,475 | 0% (c) | negligible |
| Subtotal for Site Information | 25.00 | 26.00 | 31.00 | 9.75 | $228,113 | 1% | $1,233 |
| §725.160 | | | | | | | |
| a,b. Summary of unpublished health and environmental effects data on microorganism, list of published data on the same. | | 0.20 | 0.05 | | $576 | 0% (b) | negligible |
| User fee | | | | | | 100% | $2,500 (d) |
| Clerical preparation (8 hours) | | | | | $200 | 100% | $200 |
| Managerial review of MCAN submission | | | | 0.20 | $832 | 100% | $832 |
| Submission writeup | | 1.00 | | | $2,166 | 100% | $2,166 |
| TOTAL | 68.00 | 64.20 | 39.55 | 11.20 | $415,055 | 2% | $6,931 |

(a) Nonscientific costs of collecting and providing data are included under "submission writeup."
(b) The percent of cases incurring costs for these items is assumed to be zero, assuming that the items were completed previously for the submission of a TERA.
(c) The percent of cases incurring costs for these items is assumed to be zero, assuming that the sites will already have this information
(d) Fee would be $100 for a small business.

Source: SRI 1987, OPTS 1992, and ETD estimates.

Table D-6. Components of the Cost of Preparing an MCAN
High Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| c. Company contacts | | | | | | | |
| 1. Name, Address - Submitter | | | | | | | negligible (a) |
| 2. Name, Address, Telephone - Technical Contact | | | | | | | negligible (a) |
| d. Identity of microorganism | | | | | | | |
| 1. Description of recipient microorganism and new microorganism | | | | | | | |
| i. Taxonomy to level of strain | 2.50 | 2.50 | 5.00 | | $23,962 | 0% (b) | negligible |
| ii. Morphology, physiology | 8.00 | 4.00 | 2.00 | 1.00 | $32,220 | 16% | $5,261 |
| iii. Other data to identify microorganism | 4.00 | 4.00 | 2.00 | | $21,215 | 25% | $5,304 |
| Subtotal for Identity of microorganism | 14.50 | 10.50 | 9.00 | 1.00 | $77,397 | 14% | $10,565 |
| 2. Genetic Characteristics of microorganism | | | | | | | |
| i. Taxonomy of donor | | | | | | labor requirements covered under '1i' above | |
| ii. Traits for which microorganism has been developed | 8.00 | 4.00 | 1.00 | | $25,206 | 0% (b) | negligible |
| iii. Methods of developing microorganism | 95.00 | 80.00 | 15.00 | 2.50 | $389,006 | 0% (b) | negligible |
| Subtotal for Genetic Characteristics of microorganism | 103.00 | 84.00 | 16.00 | 2.50 | $414,212 | 0% | negligible |
| 3. Microorganism (or parental strains) information | | | | | | | |
| i. Habitat, geographic distribution of parent microorganim | 8.00 | 16.00 | 12.00 | | $82,585 | 0% (b) | negligible |
| ii. Survival and dissemination | | | | | | labor requirements covered under 'h(1iv)' | |
| iii. Biological interactions | | | | | | | negligible (b) |
| iv. Biogeochemical/biological cycling | | | | | | labor requirements covered under '3iii' above | |
| Subtotal for microorganism information | 8.00 | 16.00 | 12.20 | | $82,585 | 0% | negligible |
| e. Byproducts | | | | | | labor requirements included under 'h(1iv)' | |
| f. Estimate total quantity of microorganism to be manufactured | | | 2.00 | 1.00 | $9,867 | 0% (b) | negligible |
| g. Description of intended categories of use | | | | | | labor requirements included under 'h(1iv)' | |

Table D-6. Components of the Cost of Preparing an MCAN (continued)
High Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| h. Worker exposure and environmental release | | | | | | | |
| 1. Sites controlled by submitter | | | | | | | |
| i. Name, Address - Each site where microorganism is to be manufactured, imported, processed, or disposed of. | | | 4.00 | 1.00 | $15,575 | 0% (b) | negligible |
| ii. Description of manufacturing/processing and disposal methodology for microorganism | 24.00 | 24.00 | 12.00 | 2.00 | $135,606 | 0% (b) | negligible |
| iii. Worker, human and environmental exposure information | 8.00 | 16.00 | 22.00 | 2.00 | $119,446 | 1% | |
| $1,096 | | | | | | | |
| iv. Intended uses and estimated total quantity of microorganism to be released to environment | 56.00 | 42.00 | 42.00 | 7.25 | $336,807 | 0% (c) | negligible |
| v. Description of procedure for transport of microorganism | | | 2.00 | 1.00 | $9,868 | 25% | $2,467 |
| 2. For sites not controlled by submitter - A description of each type processing use operation involving microorganism | 4.00 | 4.00 | 8.00 | 2.00 | $46,657 | 0% (b) | negligible |
| Subtotal for Site Information | 92.00 | 86.00 | 92.00 | 16.25 | $673,826 | 1% | $3,563 |
| §725.160 | | | | | | | |
| a,b. Summary of unpublished health and environmental effects data on microorganism, list of published data on the same. | | 1.00 | 0.20 | | $2,736 | 100% | $2,736 |
| User fee | | | | | | 100% | $2,500 (d) |
| Clerical preparation (20 hours) | | | | | $500 | 100% | $500 |
| Managerial review of MCAN submission | | | | 0.50 | $2,080 | 100% | $2,080 |
| Submission writeup | | 5.00 | | | $10,828 | 100% | $10,828 |
| TOTAL | 217.50 | 202.50 | 129.2 | 20.25 | $1,264,164 | 2.5% | $32,772 |

(a) Nonscientific costs of collecting and providing data are included under "submission writeup."
(b) The percent of cases incurring costs for these items is assumed to be zero, assuming that the sites will already have this information.
(c) The percent of cases incurring costs for this item is assumed to be zero because this analysis assumes the high cost MCAN would be for a fermentation application.
(d) The fee would be $100 for a small business.

Source: SRI 1987, OPTS 1992, and ETD estimates.

Table D-7. Components of the Cost of Preparing a Biotechnology PMN[a] for a Fermentation Application
Low Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| c. Company contacts | | | | | | | |
| 1. Name, Address - Submitter | | | | | | | negligible (b) |
| 2. Name, Address, Telephone - Technical Contact | | | | | | | negligible (b) |
| d. Identity of microorganism | | | | | | | |
| 1. Description of recipient microorganism and new microorganism | | | | | | | |
| i. Taxonomy to level of strain | | 1.00 | | | $2,166 | 0% (c) | negligible |
| ii. Morphology, physiology | | | | | | labor requirements covered under '1i' | |
| iii. Other data by which to ID microorganism | | | | | | labor requirements covered under '1i' | |
| Subtotal for description | | 1.00 | | | $2,166 | 0% (c) | negligible |
| 2. Genetic Characteristics of microorganism | | | | | | | |
| i. Taxonomy of donor | | | | | | labor requirements covered under '1i' above | |
| ii. Traits for which microorganism has been developed | 2.00 | 2.00 | 1.00 | | $10,608 | 0% (c) | negligible |
| iii. Methods of developing microorganism | 41.00 | 32.00 | 6.50 | 0.75 | $161,129 | 0% (c) | negligible |
| Subtotal for Genetic Characteristics of microorganism | 43.00 | 34.00 | 7.50 | 0.75 | $171,737 | 0% | negligible |
| 3. Microorganism (or parental strains) information | | | | | | | |
| i. Habitat, geographic distribution of parent microorganism | | 2.00 | | | $4,331 | 0% (c) | negligible |
| ii. Survival and dissemination | | | | | | labor requirements covered under 'h(1iv)' | |
| iii. Biological interactions | | | | | | | negligible (c) |
| iv. Biogeochemical/biological cycling | | | | | | labor requirements covered under '3iii' above | |
| Subtotal for microorganism information | | 2.00 | | | $4,331 | 0% | negligible |
| e. Byproducts | | | | | | labor requirements covered under 'h(1vi)' | |
| f. Estimate total quantity of microorganism to be manufactured | | | 1.00 | 0.50 | $4,934 | 0% (c) | negligible |
| g. Description of intended categories of use | | | | | | labor requirements covered under 'h(1iv)' | |

Table D-7. Components of the Cost of Preparing a Biotechnology PMN[a] for a Fermentation Application (continued)
Low Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| h. Worker exposure and environmental release | | | | | | | |
| 1. Sites controlled by submitter | | | | | | | |
| i. Name, Address - Each site where microorganism is to be manufactured, imported, processed, or disposed of | | | 2.00 | 0.50 | $7,787 | 0% (c) | negligible |
| ii. Description of manufacturing/processing and disposal methodology for microorganism | 8.00 | 8.00 | 4.00 | 1.00 | $46,588 | 0% (c) | negligible |
| iii. Worker, human and environmental exposure information | 4.00 | 6.00 | 4.00 | 1.00 | $35,414 | 0% (c) | neglibible |
| iv. Intended Uses of microorganism and estimated total quantity of microorganism to be released to environment | 11.00 | 10.00 | 16.00 | 5.25 | $107,981 | 0% (d) | negligible |
| v. Description of procedure for transport of microorganism | | | 1.00 | 0.50 | $4,934 | 25% | $1,233 |
| 2. For sites not controlled by submitter - A description of each type processing use operation involving microorganism | 2.00 | 2.00 | 3.00 | 1.00 | $20,475 | 0% (c) | negligible |
| Subtotal for Site Information | 25.00 | 26.00 | 31.00 | 9.75 | $228,113 | 2% | $1,233 |
| §725.160 | | | | | | | |
| a,b. Summary of unpublished health and environmental effects data on microorganism, list of published data on the same. | | 0.20 | 0.05 | | $576 | 50% | $288 |
| User fee | | | | | | 100% | $2,500 (e) |
| Clerical preparation (8 hours) | | | | | $200 | 100% | $200 |
| Managerial review of MCAN submission | | | | 0.20 | $832 | 100% | $832 |
| Submission writeup | | 1.00 | | | $2,166 | 100% | $2,166 |
| TOTAL | 73.00 | 69.20 | 42.55 | 11.20 | $428,147 | 1.7% | $7,219 |

(a) Data Elements for a biotechnology PMN are assumed to be the same as the requirements for an MCAN.
(b) Nonscientific costs of collecting and providing data are included under "submission writeup."
(c) The percent of cases incurring costs for these items is assumed to be zero, assuming that the sites will already have this information.
(d) The percent of cases incurring costs for this item is assumed to be zero because the submission is for a fermentation application.
(e) Fee would be $100 for a small business.

Source: SRI 1987, OPTS 1992, and ETD estimates.

Table D-8. Components of the Cost of Preparing an Biotechnology PMN[a] for a Fermentation Application
High Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| c. Company contacts | | | | | | | |
| 1. Name, Address - Submitter | | | | | | | negligible (b) |
| 2. Name, Address, Telephone - Technical Contact | | | | | | | negligible (b) |
| d. Identity of microorganism | | | | | | | |
| 1. Description of recipient microorganism and new microorganism | | | | | | | |
| i. Taxonomy to level of strain | 2.50 | 2.50 | 5.00 | | $23,962 | 0% (c) | negligible |
| ii. Morphology, physiology | 8.00 | 4.00 | 2.00 | 1.00 | $32,220 | 16% | $5,261 |
| iii. Other data to identify microorganism | 4.00 | 4.00 | 2.00 | | $21,215 | 25% | $5,304 |
| Subtotal for Identity of microorganism | 14.50 | 10.50 | 9.00 | 1.00 | $77,397 | 14% | $10,565 |
| 2. Genetic Characteristics of microorganism | | | | | | | |
| i. Taxonomy of donor | | | | | | labor requirements covered under '1i' above | |
| ii. Traits for which microorganism has been developed | 8.00 | 4.00 | 1.00 | | $25,206 | 0% (c) | negligible |
| iii. Methods of developing microorganism | 95.00 | 80.00 | 15.00 | 2.50 | $389,006 | 0% (c) | negligible |
| Subtotal for Genetic Characteristics of microorganism | 103.00 | 84.00 | 16.00 | 2.50 | $414,212 | 0% | negligible |
| 3. Microorganism (or parental strains) information | | | | | | | |
| i. Habitat, geographic distribution of parent microorganism | 8.00 | 16.00 | 12.00 | | $82,585 | 0% (b) | negligible |
| ii. Survival and dissemination | | | | | | labor requirements covered under 'h(1iv)' | |
| iii. Biological interactions | | | | | | | negligible (b) |
| iv. Biogeochemical/biological cycling | | | | | | labor requirements covered under '3iii' above | |
| Subtotal for microorganism information | 8.00 | 16.00 | 12.20 | | $82,585 | 0% (b) | negligible |
| e. Byproducts | | | | | | labor requirements included under 'h(1iv)' | |
| f. Estimate total quantity of microorganism to be manufactured | | | 2.00 | 1.00 | $9,867 | 0% (c) | negligible |
| g. Description of intended categories of use | | | | | | labor requirements included under 'h(1iv)' | |

Table D-8. Components of the Cost of Preparing a Biotechnology PMN[a] for a Fermentation Application (continued)
High Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| h. Worker exposure and environmental release | | | | | | | |
| 1. Sites controlled by submitter | | | | | | | |
| i. Name, Address - Each site where microorganism is to be manufactured, imported, processed, or disposed of. | | | 4.00 | 1.00 | $15,575 | 0% (c) | negligible |
| ii. Description of manufacturing/processing and disposal methodology for microorganism | 24.00 | 24.00 | 12.00 | 2.00 | $135,606 | 0% (c) | negligible |
| iii. Worker, human and environmental exposure information | 8.00 | 16.00 | 22.00 | 2.00 | $119,446 | 1% | |
| | $1,096 | | | | | | |
| iv. Intended uses and estimated total quantity of microorganism to be released to environment | 56.00 | 42.00 | 42.00 | 7.25 | $336,807 | 0% (b) | negligible |
| v. Description of procedure for transport of microorganism | | | 2.00 | 1.00 | $9,868 | 25% | $2,467 |
| 2. For sites not controlled by submitter - A description of each type processing use operation involving microorganism | 4.00 | 4.00 | 8.00 | 2.00 | $46,657 | 0% (c) | negligible |
| Subtotal for Site Information | 92.00 | 86.00 | 92.00 | 16.25 | $673,826 | 1% | $3,563 |
| §725.160 | | | | | | | |
| a,b. Summary of unpublished health and environmental effects data on microorganism, list of published data on the same. | | 1.00 | 0.20 | | $2,736 | 100% (b) | $2,736 |
| User fee | | | | | | 100% | $2,500 (e) |
| Clerical preparation (20 hours) | | | | | $500 | 100% | $500 |
| Managerial review of MCAN submission | | | | 0.50 | $2,080 | 100% | $2,080 |
| Submission writeup | | 5.00 | | | $10,828 | 100% | $10,828 |
| TOTAL | 217.50 | 202.50 | 129.2 | 20.25 | $1,274,031 | 2.6% | $32,722 |

(a) Data elements for a biotechnology PMN are assumed to be the same as the requirements for an MCAN.
(b) Nonscientific costs of collecting and providing data are included under "submission writeup."
(c) The percent of cases incurring costs for these items is assumed to be zero, assuming that the sites will already have this information.
(d) The percent of cases incurring costs for this item is assumed to be zero because the PMN is submitted for a fermentation application.
(e) The fee would be $100 for a small business.

Source: SRI 1987, OPTS 1992, and ETD estimates.

Table D-9. Components of the Cost of Preparing a Biotechnology PMN[a] for an Environmental Application
Low Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| c. Company contacts | | | | | | | |
| 1. Name, Address - Submitter | | | | | | | negligible (b) |
| 2. Name, Address, Telephone - Technical Contact | | | | | | | negligible (b) |
| d. Identity of microorganism | | | | | | | |
| 1. Description of recipient microorganism and new microorganism | | | | | | | |
| i. Taxonomy to level of strain | | 1.00 | | | $2,166 | 0% (c) | negligible |
| ii. Morphology, physiology | | | | | | labor requirements covered under '1i' | |
| iii. Other data by which to ID microorganism | | | | | | labor requirements covered under '1i' | |
| Subtotal for description | | 1.00 | | | $2,166 | 0% (c) | negligible |
| 2. Genetic Characteristics of microorganism | | | | | | | |
| i. Taxonomy of donor | | | | | | labor requirements covered under '1i' above | |
| ii. Traits for which microorganism has been developed | 2.00 | 2.00 | 1.00 | | $10,608 | 0% (c) | negligible |
| iii. Methods of developing microorganism | 41.00 | 32.00 | 6.50 | 0.75 | $161,129 | 0% (c) | negligible |
| Subtotal for Genetic Characteristics of microorganism | 43.00 | 34.00 | 7.50 | 0.75 | $171,737 | 0% | negligible |
| 3. Microorganism (or parental strains) information | | | | | | | |
| i. Habitat, geographic distribution of parent microorganism | | 2.00 | | | $4,331 | 0% (c) | negligible |
| ii. Survival and dissemination | | | | | | labor requirements covered under 'h(1iv)' | |
| iii. Biological interactions | | | | | | | negligible (c) |
| iv. Biogeochemical/biological cycling | | | | | | labor requirements covered under '3iii' above | |
| Subtotal for microorganism information | | 2.00 | | | $4,331 | 0% | negligible |
| e. Byproducts | | | | | | labor requirements covered under 'h(1vi)' | |
| f. Estimate total quantity of microorganism to be manufactured | | | 1.00 | 0.50 | $4,934 | 0% (c) | negligible |
| g. Description of intended categories of use | | | | | | labor requirements covered under 'h(1iv)' | |

Table D-9. Components of the Cost of Preparing a Biotechnology PMN[a] for an Environmental Application (continued)
Low Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| h. Worker exposure and environmental release | | | | | | | |
| 1. Sites controlled by submitter | | | | | | | |
| i. Name, Address - Each site where microorganism is to be manufactured, imported, processed, or disposed of | | | 2.00 | 0.50 | $7,787 | 0% (c) | negligible |
| ii. Description of manufacturing/processing and disposal methodology for microorganism | 8.00 | 8.00 | 4.00 | 1.00 | $46,588 | 0% (c) | negligible |
| iii. Worker, human and environmental exposure information | 4.00 | 6.00 | 4.00 | 1.00 | $35,414 | 0% (c) | negligible |
| iv. Intended Uses of microorganism and estimated total quantity of microorganism to be released to environment | 11.00 | 10.00 | 16.00 | 5.25 | $107,981 | 0% (c) | negligible |
| v. Description of procedure for transport of microorganism | | | 1.00 | 0.50 | $4,934 | 25% | $1,233 |
| 2. For sites not controlled by submitter - A description of each type processing use operation involving microorganism | 2.00 | 2.00 | 3.00 | 1.00 | $20,475 | 0% (c) | negligible |
| Subtotal for Site Information | 25.00 | 26.00 | 31.00 | 9.75 | $228,113 | 1% | $1,233 |
| §725.160 | | | | | | | |
| a,b. Summary of unpublished health and environmental effects data on microorganism, list of published data on the same. | | 0.20 | 0.05 | | $576 | 50% | $288 |
| Scientific information costs from field tests (d) | | | | | $1,521 | 100% | $1,521 |
| User fee | | | | | | 100% | $2,500 (e) |
| Clerical preparation (8 hours) | | | | | $200 | 100% | $200 |
| Managerial review of MCAN submission | | | | 0.20 | $832 | 100% | $832 |
| Submission writeup | | 1.00 | | | $2,166 | 100% | $2,166 |
| TOTAL | | | | | $411,642 | 2% | $8,740 |

(a) Data elements for a biotechnology PMN are assumed to be the same as the requirements for an MCAN.
(b) Nonscientific costs of collecting and providing data are included under "submission writeup."
(c) The percent of cases incurring costs for these items is assumed to be zero, assuming that the sites will already have this information
(d) This cost to a company is for the information they collect during field tests that precede the submission. Each PMN for an environmental application is assumed to be preceded by three prior field tests each of which has a cost of one-third of the PMN's direct scientific information costs. For an MCAN these costs are accounted for in the cost of preceding TERAs.
(e) Fee would be $100 for a small business.

Source: SRI 1987, OPTS 1992, and ETD estimates.

Table D-10. Components of the Cost of Preparing a Biotechnology PMN[a] for an Environmental Application
High Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| c. Company contacts | | | | | | | |
| 1. Name, Address - Submitter | | | | | | | negligible (b) |
| 2. Name, Address, Telephone - Technical Contact | | | | | | | negligible (b) |
| d. Identity of microorganism | | | | | | | |
| 1. Description of recipient microorganism and new microorganism | | | | | | | |
| i. Taxonomy to level of strain | 2.50 | 2.50 | 5.00 | | $23,962 | 0% (c) | negligible |
| ii. Morphology, physiology | 8.00 | 4.00 | 2.00 | 1.00 | $32,220 | 16% | $5,261 |
| iii. Other data to identify microorganism | 4.00 | 4.00 | 2.00 | | $21,215 | 25% | $5,304 |
| Subtotal for Identity of microorganism | 14.50 | 10.50 | 9.00 | 1.00 | $77,397 | 14% | $10,565 |
| 2. Genetic Characteristics of microorganism | | | | | | | |
| i. Taxonomy of donor | | | | | | labor requirements covered under '1i' above | |
| ii. Traits for which microorganism has been developed | 8.00 | 4.00 | 1.00 | | $25,206 | 0% (c) | negligible |
| iii. Methods of developing microorganism | 95.00 | 80.00 | 15.00 | 2.50 | $389,006 | 0% (c) | negligible |
| Subtotal for Genetic Characteristics of microorganism | 103.00 | 84.00 | 16.00 | 2.50 | $414,212 | 0% | negligible |
| 3. Microorganism (or parental strains) information | | | | | | | |
| i. Habitat, geographic distribution of parent microorganism | 8.00 | 16.00 | 12.00 | | $82,585 | 12% | $10,039 |
| ii. Survival and dissemination | | | | | | labor requirements covered under '1i'above | |
| iii. Biological interactions | | | | | | | negligible (b) |
| iv. Biogeochemical/biological cycling | | | | | | labor requirements covered under '3iii' above | |
| Subtotal for microorganism information | 8.00 | 16.00 | 12.20 | | $82,585 | 12% | $10,039 |
| e. Byproducts | | | | | | labor requirements included under 'h(1iv)' | |
| f. Estimate total quantity of microorganism to be manufactured | | | 2.00 | 1.00 | $9,867 | 0% (c) | negligible |
| g. Description of intended categories of use | | | | | | labor requirements included under 'h(1iv)' | |

Table D-10. Components of the Cost of Preparing a Biotechnology PMN[a] for an Environmental Application (continued)
High Cost Case

| Rule Reference Elements CFR | Total Weeks RT | JP | SP | RM | Labor Costs | Percent of Cases | Average Expected Costs |
|---|---|---|---|---|---|---|---|
| §725.155 | | | | | | | |
| h. Worker exposure and environmental release | | | | | | | |
| 1. Sites controlled by submitter | | | | | | | |
| i. Name, Address - Each site where microorganism is to be manufactured, imported, processed, or disposed of. | | | 4.00 | 1.00 | $15,575 | 0% (c) | negligible |
| ii. Description of manufacturing/processing and disposal methodology for microorganism | 24.00 | 24.00 | 12.00 | 2.00 | $135,606 | 0% (c) | negligible |
| iii. Worker, human and environmental exposure information | 8.00 | 16.00 | 22.00 | 2.00 | $119,446 | 1% | |
| $1,096 | | | | | | | |
| iv. Intended uses and estimated total quantity of microorganism to be released to environment | 56.00 | 42.00 | 42.00 | 7.25 | $336,807 | 4% | $14,114 |
| v. Description of procedure for transport of microorganism | | | 2.00 | 1.00 | $9,868 | 25% | $2,467 |
| 2. For sites not controlled by submitter - A description of each type processing use operation involving microorganism | 4.00 | 4.00 | 8.00 | 2.00 | $46,657 | 0% (c) | negligible |
| Subtotal for Site Information | 92.00 | 86.00 | 92.00 | 16.25 | $673,826 | 2% | $17,677 |
| §725.160 | | | | | | | |
| a,b. Summary of unpublished health and environmental effects data on microorganism, list of published data on the same. | | 1.00 | 0.20 | | $2,736 | 100% (b) | $2,736 |
| Scientific information costs from field tests. (d) | | | | | $41,017 | 100% | $41,017 |
| User fee | | | | | | 100% | $2,500 (e) |
| Clerical preparation (20 hours) | | | | | $500 | 100% | $500 |
| Managerial review of MCAN submission | | | | 0.50 | $2,080 | 100% | $2,080 |
| Submission writeup | | 5.00 | | | $10,828 | 100% | $10,828 |
| TOTAL | | | | | $1,315,048 | 7% | $97,942 |

(a) Data Elements for a biotechnology PMN are assumed to be the same as the requirements for an MCAN.
(b) Nonscientific costs of collecting and providing data are included under "submission writeup."
(c) The percent of cases incurring costs for these items is assumed to be zero, assuming that the sites will already have this information.
(d) This cost to a company is for the information they collect during field tests that precede the submission. Each PMN for an environmental application is assumed to be preceded by three prior field tests each of which has a cost of one-third of the PMN's direct scientific information costs. For an MCAN these costs are accounted for in the cost of preceding TERAs.
(e) The fee would be $100 for a small business.

Source: SRI 1987, OPTS 1992, and ETD estimates.

Table D-11. Year 1 Costs of Recordkeeping Associated with Contained Experiments under TSCA

| Alternative[a] | Number of Institutions Subject to Regulatory Option | Percent of Experiments Working with New Microorganisms | Number of Facilities Subject to Verification[b] | | Number of Records Generated[c] | | Unit Cost of Containment Verification | | Unit Cost of Recordkeeping | | Total Cost of Recordkeeping Requirements | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Low | High | Low | High | Low | High | Low | High | Low | High |
| Final Rule | 72 | 26 | 4 | 11 | 94 | 187 | $22 | $44 | $44 | $88 | $4,224 | $16,940 |
| Alternative 1 | 72 | 26 | 4 | 11 | 94 | 187 | $22 | $44 | $44 | $88 | $4,224 | $16,940 |
| Alternative 2 | 72 | 100 | 4 | 11 | 360 | 720 | $22 | $44 | $44 | $88 | $15,928 | $63,844 |
| Alternative 3 | 72 | 100 | 4 | 11 | 360 | 720 | $22 | $44 | $44 | $88 | $15,928 | $63,844 |

[a] Alternatives are outlined in Table D-18.

[b] The number of facilities subject to verification is equal to: 72 companies * 0.05 at BL2 or higher = 3.6 companies. 3.6 companies * 1 to 3 verifications per company = 4 to 11 verifications for the industry for each option.

[c] The number of records generated is equal to: 72 companies * 5 to 10 records per company = 360 to 720 records. Multiplying this figure by the percent of experiments subject to oversight generates the number of records for each option.

Sources: ICF 1987, NIH 1989, OTS 1991.

Table D-12. Year 5 Costs of Recordkeeping Associated with Contained Experiments under TSCA

| Alternative[a] | Number of Institutions Subject to Regulatory Option | Percent of Experiments Working with New Microorganisms | Number of Facilities Subject to Verification[b] | | Number of Records Generated[c] | | Unit Cost of Containment Verification | | Unit Cost of Recordkeeping | | Total Cost of Recordkeeping Requirements | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Low | High | Low | High | Low | High | Low | High | Low | High |
| Final Rule | 84 | 26 | 4 | 13 | 109 | 218 | $22 | $44 | $44 | $88 | $4,884 | $19,756 |
| Alternative 1 | 84 | 26 | 4 | 13 | 109 | 218 | $22 | $44 | $44 | $88 | $4,884 | $19,756 |
| Alternative 2 | 84 | 100 | 4 | 13 | 420 | 840 | $22 | $44 | $44 | $88 | $18,568 | $74,492 |
| Alternative 3 | 84 | 100 | 4 | 13 | 420 | 840 | $22 | $44 | $44 | $88 | $18,568 | $74,492 |

[a] Alternatives are outlined in Table D-18.

**b** The number of facilities subject to verification is equal to: 84 companies * 0.05 at BL2 or higher = 4.2 companies. 4.2 companies * 1 to 3 verifications per company = 4 to 13 verifications for the industry for each option.

[c] The number of records generated is equal to: 84 companies * 5 to 10 records per company = 420 to 840 records. figure by the percent of experiments subject to oversight generates the number of records for each option.

Sources: ICF 1987, NIH 1989, OTS 1991.

costs to industry under the current regulatory framework are subtracted to generate the total industry cost attributable to the rule. These costs are presented in Table D-13. Tables D-14 through D-17 present the total industry costs of implementing the 1986 Policy Statement (i.e., the current regulatory framework) through a rulemaking and three other alternative options.

1. Total Industry Costs for the Final Rule

There are five categories of costs that contribute to the total industry costs of the rule: rule familiarization; reporting costs; CBI substantiation costs, recordkeeping costs, and post-review monitoring costs. Reporting costs were estimated using the numbers of industry microbial submissions estimated in Appendix C.

2. Regulatory Options

Tables D-14 through D-17 present the cost analysis for various regulatory options (including the costs of subjecting all microorganisms to the requirements of the rule). Table D-18 presents the important elements of each of these options.

C. Sensitivity Analysis

In this section, a description of the variables examined and a discussion of the basis for alternative assumptions used in the sensitivity analysis are provided. The cases considered in the analysis, including cases in which several assumptions are altered at once, are then provided. Finally, the results of the analysis are presented and discussed.

1. Variables Considered

The sensitivity analysis examines the effects of changing assumptions in four areas: the rates of growth in the number of products in research and in the markets subject to TSCA; the numbers of TERA submissions per released marketed product; the numbers of Significant New Use MCANs per released marketed product; and the rates of compulsory monitoring of released

Table D-13. Industry Costs Associated with the Final Rule: Intergeneric Only

| Cost Category | Year 1 Units | Year 1 Cost per Case | Year 1 Cost Low | Year 1 Cost High | Year 5 Units | Year 5 Cost per Case | Year 5 Cost Low | Year 5 Cost High |
|---|---|---|---|---|---|---|---|---|
| Rule Familiarization | 378 | $2,080 - $4,160 | $786,240 | $1,572,480 | 3 | $2,080 - $4,160 | $6,240 | $12,480 |
| Change from baseline | | | $786,240 | $1,572,480 | | | $0 | $0 |
| Reporting Costs | | | | | | | | |
| R&D | | | | | | | | |
| First-time TERA | 6 | $5,330 - $54,425 | $31,980 | $326,550 | 6 | $5,330 - $54,425 | $31,980 | $326,550 |
| Follow-on TERA | 18 | $1,777 - $18,142 | $31,986 | $326,556 | 18 | $1,777 - $18,142 | $31,986 | $326,556 |
| Commercial | | | | | | | | |
| MCAN | 4 | $6,931 - $32,772 | $27,724 | $131,088 | 6 | $6,931 - $32,772 | $41,586 | $196,632 |
| Tier 1 Exemption | 9 | $727 - $1,872 | $6,543 | $16,848 | 12 | $727 - $1,872 | $8,724 | $22,464 |
| Tier 2 Exemption | 9 | $3,198 - $13,408 | $28,782 | $120,672 | 12 | $3,198 - $13,408 | $38,376 | $160,896 |
| Sub-total | | | $127,015 | $921,714 | | | $152,652 | $1,033,098 |
| Change from baseline | | | ($34,845) | $70,390 | | | ($66,960) | ($80,402) |
| CBI Substantiation Costs | | | | | | | | |
| First-time TERA | 6 | $1,015 - $1,509 | $6,090 | $9,054 | 6 | $1,015 - $1,509 | $6,090 | $9,054 |
| Follow-on TERA | 18 | $560 - $641 | $10,080 | $11,538 | 18 | $560 - $641 | $10,080 | $11,538 |
| MCAN, Tier 2 | 13 | $1,104 - $2,852 | $14,352 | $37,076 | 18 | $1,104 - $2,852 | $19,872 | $51,336 |
| Sub-total | | | $30,522 | $57,668 | | | $36,042 | $71,928 |
| Change from baseline | | | ($3,776) | ($5,076) | | | ($10,728) | ($13,632) |
| Recordkeeping Costs (a) | 72 | | $4,224 | $16,940 | 84 | | $4,884 | $19,756 |
| Monitoring | | | | | | | | |
| R&D | | | | | | | | |
| First-time TERA | 6 | $12,500 - $75,000 | $75,000 | $450,000 | 6 | $12,500 - $75,000 | $75,000 | $450,000 |
| Follow-on TERA | 18 | $3,750 - $7,500 | $67,500 | $135,000 | 18 | $3,750 - $7,500 | $67,500 | $135,000 |
| Commercial | 0 | | | | 0 | | | |
| Sub-total | | | $142,500 | $585,000 | | | $142,500 | $585,000 |
| Incremental Costs Resulting from Final Rule | | | $894,343 | $2,239,734 | | | $69,696 | $510,722 |

(a) Costs for recordkeeping and monitoring are incremental costs compared to the current regulatory framework.

Table D-14. Industry Costs Associated with Implementing Current Policy with Rulemaking

| Cost Category | Year 1 Units | Year 1 Cost per Case | Year 1 Cost Low | Year 1 Cost High | Year 5 Units | Year 5 Cost per Case | Year 5 Cost Low | Year 5 Cost High |
|---|---|---|---|---|---|---|---|---|
| Rule Familiarization | 378 | $2,080 - $4,160 | $786,240 | $1,572,480 | 3 | $2,080 - $4,160 | $6,240 | $12,480 |
| Change from baseline | | | $786,240 | $1,572,480 | | | $0 | $0 |
| Reporting Costs | | | | | | | | |
| R&D | 0 | | $0 | $0 | 0 | | $0 | $0 |
| Closed System Application PMN | 20 | $7,219 - $32,772 | $144,380 | $655,440 | 28 | $7,219 - $32,772 | $202,132 | $917,616 |
| Environmental Application PMN | 2 | $8,740 - $97,942 | $17,480 | $195,884 | 2 | $8,740 - $97,942 | $17,480 | $195,884 |
| Sub-total | | | $161,860 | $851,324 | | | $219,612 | $1,113,500 |
| Change from baseline | | | $0 | $0 | | | $0 | $0 |
| CBI Substantiation Costs | | | | | | | | |
| R&D | 0 | | $0 | $0 | 0 | | $0 | $0 |
| Biotechnology PMN | 22 | $1,559 - $2,852 | $34,298 | $62,744 | 30 | $1,559 - $2,852 | $46,770 | $85,560 |
| Sub-total | | | $34,298 | $62,744 | | | $46,770 | $85,560 |
| Change from baseline | | | $0 | $0 | | | $0 | $0 |
| Recordkeeping costs (a) | | | | | | | | |
| Incremental Costs Resulting from Final Rule | | | $786,240 | $1,572,480 | | | $0 | $0 |

(a) Recordkeeping costs for this case are zero because these costs are defined incrementally compared to the baseline.

Table D-15. Industry Costs Associated with Regulatory Alternative 1: Intergeneric Only, No Exemptions

| Cost Category | Year 1 Units | Year 1 Cost per Case | Year 1 Cost Low | Year 1 Cost High | Year 5 Units | Year 5 Cost per Case | Year 5 Cost Low | Year 5 Cost High |
|---|---|---|---|---|---|---|---|---|
| Rule Familiarization | 378 | $2,080 - $4,160 | $786,240 | $1,572,480 | 3 | $2,080 - $4,160 | $6,240 | $12,480 |
| Change from baseline | | | $786,240 | $1,572,480 | | | $0 | $0 |
| Reporting Costs | | | | | | | | |
| R&D | | | | | | | | |
| First-time TERA | 6 | $5,330 - $54,425 | $31,980 | $326,550 | 6 | $5,330 - $54,425 | $31,980 | $326,550 |
| Follow-on TERA | 18 | $1,777 - $18,142 | $31,986 | $326,556 | 18 | $1,777 - $18,142 | $31,986 | $326,556 |
| Commercial | | | | | | | | |
| MCAN | 22 | $6,931 - $32,772 | $152,482 | $720,984 | 30 | $6,931 - $32,772 | $207,930 | $983,160 |
| Tier 1 Exemption | 0 | $727 - $1,872 | $0 | $0 | 0 | $727 - $1,872 | $0 | $0 |
| Tier 2 Exemption | 0 | $3,198 - $13,408 | $0 | $0 | 0 | $3,198 - $13,408 | $0 | $0 |
| Sub-total | | | $216,448 | $1,374,090 | | | $271,896 | $1,636,266 |
| Change from baseline | | | $54,588 | $522,766 | | | $52,284 | $522,766 |
| CBI Substantiation Costs | | | | | | | | |
| First-time TERA | 6 | $1,015 - $1,509 | $6,090 | $9,054 | 6 | $1,015 - $1,509 | $6,090 | $9,054 |
| Follow-on TERA | 18 | $560 - $641 | $10,080 | $11,538 | 18 | $560 - $641 | $10,080 | $11,538 |
| MCAN, Tier 2 | 22 | $1,104 - $2,852 | $24,288 | $62,744 | 30 | $1,104 - $2,852 | $33,120 | $85,560 |
| Sub-total | | | $40,458 | $83,336 | | | $49,290 | $106,152 |
| Change from baseline | | | $6,160 | $20,592 | | | $2,520 | $20,592 |
| Recordkeeping (a) | 72 | | $4,224 | $16,940 | 84 | | $4,884 | $19,756 |
| Monitoring | | | | | | | | |
| R&D | | | | | | | | |
| First-time TERA | 6 | $12,500 - $75,000 | $75,000 | $450,000 | 6 | $12,500 - $75,000 | $75,000 | $450,000 |
| Follow-on TERA | 18 | $3,750 - $7,500 | $67,500 | $135,000 | 18 | $3,750 - $7,500 | $67,500 | $135,000 |
| Commercial | 0 | | | | 0 | | | |
| Sub-total | | | $142,500 | $585,000 | | | $142,500 | $585,000 |
| Incremental Costs Resulting from Option | | | $993,712 | $2,717,778 | | | $202,188 | $1,148,114 |

(a) Costs for recordkeeping and monitoring are incremental costs compared to the current regulatory framework.

Table D-16. Industry Costs Associated with Regulatory Alternative 2: Include Naturally Occurring

| Cost Category | Year 1 Units | Year 1 Cost per Case | Year 1 Cost Low | Year 1 Cost High | Year 5 Units | Year 5 Cost per Case | Year 5 Cost Low | Year 5 Cost High |
|---|---|---|---|---|---|---|---|---|
| Rule Familiarization | 378 | $2,080 - $4,160 | $786,240 | $1,572,480 | 3 | $2,080 - $4,160 | $6,240 | $12,480 |
| Change from baseline | | | $786,240 | $1,572,480 | | | $0 | $0 |
| Reporting Costs | | | | | | | | |
| First-time TERA | 74 | $5,330 - $54,425 | $394,420 | $4,027,450 | 72 | $5,330 - $54,425 | $383,760 | $3,918,600 |
| Follow-on TERA | 74 | $1,777 - $18,142 | $131,498 | $1,342,508 | 72 | $1,777 - $18,142 | $127,944 | $1,306,224 |
| Commercial | | | | | | | | |
| MCAN | 37 | $6,931 - $32,772 | $256,447 | $1,212,564 | 42 | $6,931 - $32,772 | $291,102 | $1,376,424 |
| Tier 1 Exemption | 74 | $727 - $1,872 | $53,798 | $138,528 | 85 | $727 - $1,872 | $61,795 | $159,120 |
| Tier 2 Exemption | 74 | $3,198 - $13,408 | $236,652 | $992,192 | 85 | $3,198 - $13,408 | $271,830 | $1,139,680 |
| Sub-total | | | $1,072,815 | $7,713,242 | | | $1,136,431 | $7,900,048 |
| Change from baseline | | | $910,955 | $7,551,382 | | | $974,571 | $7,738,188 |
| CBI Substantiation Costs | | | | | | | | |
| First-time TERA | 74 | $1,015 - $1,509 | $75,110 | $111,666 | 72 | $1,015 - $1,509 | $73,080 | $108,648 |
| Follow-on TERA | 74 | $560 - $641 | $41,440 | $47,434 | 72 | $560 - $641 | $40,320 | $46,152 |
| MCAN, Tier 2 | 111 | $1,104 - $2,852 | $122,544 | $316,572 | 127 | $1,104 - $2,852 | $140,208 | $362,204 |
| Sub-total | | | $239,094 | $475,672 | | | $253,608 | $517,004 |
| Change from baseline | | | $204,796 | $412,928 | | | $206,838 | $431,444 |
| Recordkeeping Costs (a) | 72 | | $15,928 | $63,844 | 84 | | $18,568 | $74,492 |
| Monitoring | | | | | | | | |
| R&D | | | | | | | | |
| First-time TERA | 74 | $12,500 - $75,000 | $925,000 | $5,550,000 | 72 | $12,500 - $75,000 | $900,000 | $5,400,000 |
| Follow-on TERAs | 74 | $3,750 - $7,500 | $277,500 | $555,000 | 72 | $3,750 - $7,500 | $270,000 | $540,000 |
| Sub-total | | | $1,202,500 | $6,105,000 | | | $1,170,000 | $5,940,000 |
| Incremental Costs Resulting from Option | | | $3,120,419 | $15,705,634 | | | $2,369,977 | $14,184,124 |

(a) Costs for recordkeeping and monitoring are incremental costs compared to the current regulatory framework.

Table D-17. Industry Costs Associated with Regulatory Alternative 3: Include Naturally Occurring, No exemptions

| Cost Category | Year 1 Units | Year 1 Cost per Case | Year 1 Cost Low | Year 1 Cost High | Year 5 Units | Year 5 Cost per Case | Year 5 Cost Low | Year 5 Cost High |
|---|---|---|---|---|---|---|---|---|
| Rule Familiarization | 378 | $2,080 - $4,160 | $786,240 | $1,572,480 | 3 | $2,080 - $4,160 | $6,240 | $12,480 |
| Change from baseline | | | $786,240 | $1,572,480 | | | $0 | $0 |
| Reporting Costs | | | | | | | | |
| R&D | | | | | | | | |
| First-time TERA | 74 | $5,330 - $54,425 | $394,420 | $4,027,450 | 72 | $16,174 - $69,076 | $1,164,528 | $4,973,472 |
| Follow-on TERA | 74 | $1,777 - $18,142 | $131,498 | $1,342,508 | 72 | $5,391 - $23,025 | $388,152 | $1,657,800 |
| MCAN | 185 | $6,931 - $32,772 | $1,282,235 | $6,062,820 | 212 | $6,931 - $32,772 | $1,469,372 | $6,947,664 |
| Sub-total | | | $1,808,153 | $11,432,778 | | | $3,022,052 | $13,578,936 |
| Change from baseline | | | $1,646,293 | $11,270,918 | | | $2,860,192 | $13,417,076 |
| CBI Substantiation Costs | | | | | | | | |
| First-time TERA | 74 | $1,015 - $1,509 | $75,110 | $111,666 | 72 | $1,015 - $1,509 | $73,080 | $108,648 |
| Follow-on TERA | 74 | $560 - $641 | $41,440 | $47,434 | 72 | $560 - $641 | $40,320 | $46,152 |
| MCAN | 185 | $1,104 - $2,852 | $204,240 | $527,620 | 212 | $1,104 - $2,852 | $234,048 | $604,624 |
| Sub-total | | | $320,790 | $686,720 | | | $347,448 | $759,424 |
| Change from baseline | | | $286,492 | $652,422 | | | $313,150 | $725,126 |
| Recordkeeping Costs (a) | 72 | | $15,928 | $63,844 | 84 | | $18,568 | $74,492 |
| Monitoring | | | | | | | | |
| R&D | | | | | | | | |
| First-time TERA | 74 | $12,500 - $75,000 | $925,000 | $5,550,000 | 72 | $12,500 - $75,000 | $900,000 | $5,400,000 |
| Follow-on TERA | 74 | $3,750 - $7,500 | $277,500 | $555,000 | 72 | $3,750 - $7,500 | $270,000 | $540,000 |
| Sub-total | | | $1,202,500 | $6,105,000 | | | $1,170,000 | $5,940,000 |
| Incremental Costs Resulting from Option | | | $3,937,453 | $19,664,664 | | | $4,361,910 | $20,156,694 |

(a) Costs for recordkeeping and monitoring are incremental costs compared to the current regulatory framework.

Table D-18. Options Matrix for Biotechnology Rulemaking

| | Current Regulatory Environment[a] | Final Rule | Alternative 1 | Alternative 2 | Alternative 3 |
|---|---|---|---|---|---|
| Type of microorganism subject | Intergeneric microorganisms | Intergeneric microorganisms | Intergeneric microorganisms | All microorganisms (naturally occurring included) | All microorganisms (naturally occurring included) |
| Deferral to Other Agencies | No formal procedure | Formal Deferral | Formal Deferral | Formal Deferral | Formal Deferral |
| Microorganisms in Commercial R&D | | | | | |
| - Lab Scale | Small Quantities Exemption Provision | Contained Structure Exemption Provision | Contained Structure Exemption Provision | Contained Structure Exemption Provision | Contained Structure Exemption Provision |
| - Environmental Testing | Voluntary Reporting (PMN) | Reporting required (TERA); TERA Exemption Provision | Reporting required (TERA) | Reporting required (TERA); TERA Exemption Provision | Reporting required (TERA) |
| Microorganisms in General Commercial Use | | | | | |
| - Pilot Scale | TME Provision | TME Provision | TME Provision | TME Provision | TME Provision |
| - Commercial Distribution & Use | Reporting required (PMN) | Reporting required (MCAN) | Reporting required (MCAN) | Reporting required (MCAN) | Reporting required (MCAN) |
| | No exemption provision | Tier I Exemption Provision; Tier II Exemption Provision | No exemption provision | Tier I Exemption Provision; Tier II Exemption Provision | No exemption provision |

[a] This RIA uses the current regulatory environment as the baseline for the total cost estimates of the other regulatory alternatives. This case is intended to reflect the cost of implementing the current policy with a rulemaking. The only incremental cost in this case is for rule familiarization.

microorganisms at the research and general commercial use stage resulting from EPA action. In addition, because all cost estimates are performed using ranges of unit costs for submissions, the sensitivity of the results to changes in unit cost assumptions are clear.

a. Growth Rates in Numbers of Products

The number of submissions in later years will depend largely on the growth rate of products in R&D and entering the market. This report uses annual growth rate estimates based on survey responses to questions about current and anticipated numbers of products in R&D.

The overall growth rate is in line with the average rate of growth in biotechnology products subject to TSCA anticipated for the next several years according to an industry trade association (IBA 1991). On the other hand, a study conducted by Ernst & Young (Burrill 1989) showed that growth rates can vary significantly across sectors of the biotechnology industry. Growth rates projected in the Ernst & Young study ranged from 8 percent (for medical diagnostic products) to 28 percent per year (for agricultural biotechnology products). To capture this range of uncertainty, this sensitivity analysis examined near-term growth rates of one half and two times the rates predicted by the survey. These changes in growth rate affect the expected baseline costs as well as the costs under the rule.

b. TERA Follow-ons

This report assumes that each "new" product intended for environmental use will be associated with four TERAs before commercialization -- an initial TERA and three follow-on TERAs. The actual average number of TERAs per released new product is unknown, but prior submissions and conversations with researchers in industry and the scientific community suggest that between two and ten additional TERAs (some covering multiple strains) are likely to follow each initial TERA submission before a product is

ready for the market. The sensitivity analysis incorporates a range of assumptions about numbers and costs of follow-on TERAs based on characterizations of the industry R&D process (see Appendices A, B, and G).

d. Monitoring

This report assumes that monitoring will be required by EPA for research and development environmental applications of reportable microorganisms, but that no monitoring will be required for environmental applications at the general commercial use level. It may be, however, that EPA will not require monitoring for field tests of some microorganisms. Conversely, there may be some microorganisms for which monitoring is required even after commercialization. Consequently, the sensitivity analysis considers cases both with higher and lower rates of mandatory monitoring, resulting in higher and lower unit cost estimates, respectively.

2. Sensitivity Cases Considered

In all, eight sensitivity cases are compared to the base case in this analysis. Some of the sensitivity cases differ from the base case in only one area. For others, two or more factors have been varied. This section describes the salient features of each case, and then presents the results of the analysis. The assumptions in each case are presented in Table D-19 and the cost results are presented in Table D-20.

a. Case 1: Final Rule

This is the case described in the main text of this chapter and is presented here for purposes of comparison.

b. Case 2: Slow Growth in Submissions

Case 2 differs from the "Final Rule" (case 1) only in that it assumes the number of products in research and ready for commercialization grow at only one half the rate assumed in the rule. The results also show how

**Table D-19. Summary of Sensitivity Case Characteristics**

| Case Number | Title | Submission Growth Rate | Follow-on TERAs Per Initial TERA | SNUNs Per Released Commercial Product | Monitoring Rate for Released Commercial Product | Monitoring Rate for TERAs |
|---|---|---|---|---|---|---|
| 1 | Base Case | Varies by Sector | 3 | 0 | 0% | 100% |
| 2 | Low Growth Rate | One half expected | 3 | 0 | 0% | 100% |
| 3 | High Growth Rate | Twice expected | 3 | 0 | 0% | 100% |
| 4 | Low TERA Follow-Ons | Varies by Sector | 1 | 0 | 0% | 100% |
| 5 | High TERA Follow-Ons | Varies by Sector | 10 | 0 | 0% | 100% |
| 6 | SNUNs for Commercial Releases | Varies by Sector | 3 | 10 | 0% | 100% |
| 7 | Lower TERA Monitoring | Varies by Sector | 3 | 0 | 0% | 66% |
| 8 | Monitoring for Commercial Environmental Applications | Varies by Sector | 3 | 0 | 20% | 100% |
| 9 | "Worst Likely" | Twice expected for Environmental Applications | 10 | 10 | 20% | 100% |

**Note: SNUN = MCANs used for Significant New Use Notices**

Table D-20. Year 5 Industry Costs for Sensitivity Cases

| Case | Number of Submissions | Total Cost (thousands of $) |
|---|---|---|
| 1. Final Rule | | |
| Low | 54 | 69.7 |
| High | 54 | 510.7 |
| 2. Slow Growth in Submissions (half expected rate) | | |
| Low | 44 | 31.1 |
| High | 44 | 361.4 |
| 3. Rapid Growth in Submissions (twice expected rate) | | |
| Low | 101 | 289.8 |
| High | 101 | 1,489.8 |
| 4. Low Rate of Follow-on TERAs (1 per initial TERA) | | |
| Low | 42 | -3.3 |
| High | 42 | 195.3 |
| 5. High Rate of Follow-on TERAs (10 per initial TERA) | | |
| Low | 96 | 325.3 |
| High | 96 | 1,614.6 |
| 6. Ten Significant New Use MCANs per General Commercial Use Environmental Application | | |
| Low | 64 | 100.5 |
| High | 64 | 713.6 |
| 7. Low Rate of Monitoring (66% of R&D environmental application submissions) | | |
| Low | 42 | 21.2 |
| High | 42 | 311.8 |
| 8. Some General Commercial Use Monitoring Required (20% of environmental applications) | | |
| Low | 42 | 70.1 |
| High | 42 | 511.6 |
| 9. Worst Case (high growth in environmental applications; high monitoring; high follow-ons) | | |
| Low | 128 | 529.2 |
| High | 128 | 2,634.0 |

the results would change if numbers of submissions were lower for reasons other than slow growth.

c. Case 3: Rapid Growth in Submissions

Case 3 differs from the "Final Rule" only in that it assumes growth rates of twice those assumed in the base case. The results also show how the results would change if numbers of submissions were higher for reasons other than high growth, such as the addition of university reporting.

d. Case 4: Low Numbers of Follow-on TERAs

Case 4 differs from the "Final Rule" in that it assumes there will be one follow-on TERA for each initial TERA.

e. Case 5: High Numbers of Follow-on TERAs

Case 5 differs from the "Final Rule" in that it assumes there will be ten follow-on TERAs for each initial TERA.

f. Case 6: Significant New Use MCANs Assumed for Released Commercial Products

Case 6 differs from the "Final Rule" only in that it assumes there will be 10 Significant New Use MCANs for each environmental application MCAN, while the "Final Rule" assumes there will be no Significant New Use MCANs.

g. Case 7: Low Monitoring Rates

Case 7 differs from the "Final Rule" only in that it assumes that monitoring will be required for only 66 percent of TERAs and MCANs, rather than the 100 percent assumed in the rule.

h. Case 8: Some General Commercial Use Monitoring Required

Case 8 differs from the "Final Rule" only in that it assumes that monitoring will be require for 20 percent of environmental applications at the general commercial use level, whereas the base case assumes no general commercial use monitoring.

i. Case 9: "Worst Case"

Case 9 recognizes that the real world could differ from the "Final Rule" in several ways, and that changes in several factors can compound one another. Case 9 combines several different assumptions to show how high the costs of the rule could be under an unfavorable constellation of circumstances. It differs from the "Final Rule" in that it assumes:

- growth at twice the expected rate for environmental applications,;
- ten follow-on TERAs per initial TERA, as in Case 5; and
- some general commercial use monitoring required as in case 8.

3. Results

Table D-20 presents the results of the sensitivity analysis. For the Base Case and each of the 8 sensitivity cases, the table shows the number of submissions and the total cost to industry (in millions of dollars) projected for Year 5. Costs are shown both for the low and high unit cost assumptions. Sensitivity results are shown only for Year 5, as the sensitivity of the results is greater (particularly for changes in the growth rate) in the out-years.

Changes in the growth rate would have pronounced effects on industry costs through their effects on the number of submissions. However it is important to note that the baseline costs would change with higher and lower growth rates and this mitigates the effect of the changes. Incremental costs under both the higher and lower growth rates assumed in Cases 2 and 3, therefore, are reduced. At generally lower growth rates, costs are reduced compared to the baseline because there are fewer additional environmental applications that have higher per product costs than under the baseline. At generally higher growth rates, costs are reduced because there are increased savings from closed system applications for which the rule has lower per product costs than for the baseline. Given that this industry is quite new

and that its near-term prospects are uncertain, its true growth rate could easily turn out to be close to either end of the range considered.

Uncertainty about costs stemming from uncertainty about the growth rate may not be a serious problem for policy makers, however. Changes in the growth rate change the total number of products subject to the rule, but will in themselves affect neither regulatory costs per product nor the incentives for developing products. Thus, uncertainty over how large the industry will be in the future does not increase the uncertainty about the relative burden the regulations will place on it. In addition, while the total costs rise with the size of the industry, the total benefits of the regulations can be expected to increase with the size of the industry.

In contrast, uncertainty about the number of submissions that will be necessary for each product may have a greater effect. Higher numbers of submissions per final product raise costs per product, thereby increasing the relative burden imposed on the industry without necessarily increasing the benefits. The sensitivity analysis shows that increases in the number of submissions as a result of follow-on TERAs could have significant impacts on costs. A smaller number of TERA follow-ons (Case 4) would mean a drop in costs. If each initial TERA were associated with ten follow-on TERAs (Case 5), costs would also be higher by greater than 60 percent. Note that an increase in submissions for Significant New Use MCANs (Case 6) would not result in a change in incremental industry costs because these submissions would also occur under the baseline.

Case 9, intended to show how much greater costs could be if several cost-increasing factors were combined, indicates that industry costs could be several times higher than estimated in the "Final Rule." Note that in order to provide the highest costs, only the growth rate for environmental applications (and not closed system applications) was increased for this case.