SUPPORTING STATEMENT
ENVIRONMENTAL PROTECTION AGENCY

National Oil and Hazardous Substances Pollution Contingency Plan, Revisions to Subpart J, Authorization of Use and Testing and Listing (40 CFR 300.900)

1. Identification of the Information Collection

1(a) Title and Number of the Information Collection

National Oil and Hazardous Substances Pollution Contingency Plan, Revisions to Subpart J, Authorization of Use and Testing and Listing (40 CFR 300.900). (EPA ICR #1664.14, OMB # 20560-0141).

1(b) Short Characterization/Abstract

This is a new Information Collection Request (ICR) to support activities required to comply with revisions to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), Subpart J (40 CFR 300.900, "Use of Dispersants and Other Chemicals").

The authority of the President to implement section 311(d)(2)(G) of the CWA is delegated to EPA in Executive Order 12777 (56 FR 54757, October 22, 1991). Subpart J of the NCP establishes the framework for the use of dispersants and any other chemical agents in response to oil discharges (40 CFR part 300 series 900). The Agency is further clarifying that the statutory schedule as required by CWA 311(d)(2)(G) includes the NCP Product Schedule, the Sorbent Product List, and authorization of use procedures which, when taken together, identify the waters and quantities in which such dispersants, other chemicals, or other spill mitigating devices and substances may be used safely.

The final action to which this information collection applies amends two distinct sets of requirements under Subpart J: (1) those related to chemical and biological agent testing and listing on the NCP Product Schedule, and (2) those related to authorization of use. This information collection specifically addresses information collected regarding listing on the NCP Product Schedule or the Sorbent Product List, including efficacy and toxicity testing protocols and listing, data and information requirements, processes for adding or removing a product to or from the NCP Product Schedule, and proprietary business information. The authorization of use requirements impose no information collection activities.

EPA considered relevant science related to efficacy and toxicity testing and has determined the science supports both establishing new protocols and updating existing testing protocols for listing on the NCP Product Schedule. These protocols, along with additional requirements for data and information, serve as the basis for a national level screening of chemical and biological agent products, and include procedures already familiar to commercial laboratories or which they can readily adopt. EPA is not aware of changes to the relevant science since the proposed rulemaking. Furthermore, the final action provides expanded opportunities for

decisionmakers to consider any advancements in science beyond efficacy and toxicity valuations as part of listing, planning and response activities.

The Agency anticipates the final amendments to Subpart J will provide more complete information about chemical and biological agent products to the public and to Federal, State and local agencies, and will help support planning and response entities when making decisions to authorize their use when responding to oil spills. The final rule will improve communication among the Agency, manufacturers and laboratories and will increase the efficiency in processing requests to list products on the NCP Product Schedule or Sorbent Product List.

EPA estimates that updated information for the existing 109 products will be submitted to EPA over a two-year transition period to comply with the revised regulations. Additionally, EPA estimates that 5 new products per year will be submitted to EPA for listing on the Schedule, along with 10 new products per year for the Sorbent Product List. These estimates are based on historical rates of product submission, as documented in the RIA accompanying the Agency's final rule. The average annual total public reporting burden over the three-year ICR period due to the final rule will be 517 to 1,195 hours. The average annual total cost (including labor and non-labor) to all manufacturers is estimated to be $1.04 to $1.09 million.

2. Need for and Use of the Collection

2(a) Need/Authority for the Collection

Under sections 311(d) and 311(j) of the Clean Water Act (CWA), as amended by section 4201 of the Oil Pollution Act of 1990 (OPA), Public Law 101–380, the President is directed to prepare and publish the NCP for removal of oil and hazardous substances. Specifically, section 311(d)(2)(G) directs the President to include a schedule identifying "(i) dispersants, other chemicals, and other spill mitigating devices and substances, if any, that may be used in carrying out the Plan, (ii) the waters in which such dispersants, other chemicals, and other spill mitigating devices and substances may be used, and (iii) the quantities of such dispersant, other chemicals, or other spill mitigating device or substance which can be used safely in such waters" as part of the NCP. The Agency has promulgated the NCP (see 40 CFR 300.1 *et seq*.), including the schedule of dispersants, other chemicals, and other oil spill mitigating devices and substances (see 40 CFR § 300.900 *et. seq*.) as required by section 311(d)(2)(G). The President is further authorized to revise or otherwise amend the NCP from time to time, as the President deems advisable. 33 U.S.C. 1321(d)(3). The authority of the President to implement section 311(d)(2)(G) of the CWA is delegated to EPA in Executive Order 12777 (56 FR 54757, October 22, 1991). Subpart J of the NCP establishes the framework for the use of dispersants and any other chemical agents in response to oil discharges (40 CFR part 300 series 900). The Agency is further clarifying that the statutory schedule as required by CWA section 311(d)(2)(G) includes the NCP Product Schedule, the Sorbent Product List, and the Subpart J authorization of use procedures that, when taken together, identify the waters and quantities in which such dispersants, other chemicals, or other spill mitigating devices and substances may be used safely.

2(b) Practical Utility/Users of the Data

EPA lists eligible oil spill mitigating agents on the Schedule if all the required data are submitted. The Product Schedule and Sorbent Product List are available for use by Federal On-Scene Coordinators (OSCs), Regional Response Teams (RRTs), and Area Committees (ACs) in determining the most appropriate products to use in various spill scenarios. Under 40 CFR 300.910(a), RRTs and Area Committees are required to address the desirability of using the products on the Product Schedule and Sorbent Product List in their Regional Contingency Plans (RCPs) and Area Contingency Plans (ACPs), respectively. The required information is needed from the respondent so that the OSCs, RRTs, and (ACs) can make informed decisions to safely employ chemical/biological countermeasures to control oil discharges. Correct product use is critical in emergency situations. Subpart J ensures that OSCs, RRTs, and ACs have the necessary data regarding the toxicity, effectiveness, and other characteristics of different products.

3. Nonduplication, Consultations, And Other Collection Criteria

3(a) Nonduplication

Manufacturers do not report this information to any other Federal agency, and this is the only list of its kind at a national level, therefore, there is no duplication.

3(b) Public Notice Required Prior to ICR Submission to OMB

On January 22, 2015, EPA published a proposed rule in the Federal Register (80 FR 3380) to amend Subpart J of the NCP. The public comment period ended on April 22, 2015. The Agency received more than 80,000 total public comment submissions from industry, academia, state/local governments, environmental groups and individuals. A copy of the Proposed Subpart J rule and accompanying ICR can be found in the EPA docket: EPA-HQ-OPA-2006-0090.

The Agency did not receive any comments specifically on the proposed ICR. EPA will provide public notice by means of a Federal Register Notice of Final Rulemaking.

3(c) Consultations

In developing this ICR, EPA consulted with other Federal agencies; Federal OSCs, NCP Product Schedule experts, State agencies, international and domestic technical experts, and commercial laboratories. Specifically, many of the cost estimates used in the analysis are based on consultations with commercial laboratories that provided feedback on EPA's assumptions. The data provided by these consultations represent, in most cases, anecdotal information and may not capture the full range of costs faced by manufacturers and laboratories. In addition, labor hours and wage rates estimated for each information collection activity may vary across manufacturers. Nevertheless, they represent a reasonable average (Exhibit 1). For additional information on these estimates, see Section 5.3.2 in the RIA accompanying the Agency's final rule.

Exhibit 1. Final Rule Toxicity and Efficacy Test Unit Costs (2021$)

Product Submission Review Activity	Final Rule Cost per Test	Final Rule Cost Source	Baseline Cost per Test (see RIA Section 4.2.2.1)
Dispersant, Efficacy Testing	$5,749	Aqua Survey and Bio-Aquatic Testing	$4,687
Dispersant, Toxicity Testing	$12,247	Aqua Survey, Coastal Bioanalysts, and Pacific Eco-Risk	$4,166
Bioremediation Agents, Efficacy Testing	$23,953	Bio-Aquatic Testing	$18,748
Surface Washing Agents, Solidifiers, Herding Agency, and Bioremediation Agents; Toxicity Testing	$4,359	Coastal Bioanalysts, and Bio-Aquatic Testing	$4,166

3(d) Effects of Less Frequent Collection

Respondents must submit information when they apply to list a new product on the Product Schedule or Sorbent Product List when the composition, formulation, application, or contact information of a product currently listed is changed, or to update existing product testing data and information to come into compliance with the amended regulatory requirements. Because collection is not periodic, less frequent collection is not possible.

3(e) General Guidelines

The information collection activities discussed in this ICR comply with all regulatory guidelines under 5 CFR 1320.5(d)(2).

3(f) Confidentiality

At 40 CFR 300.920(c), respondents are allowed to assert that certain information in the technical product data submissions is confidential business information. EPA has revised the allowable confidential business information claims and reporting procedures, but will continue to handle such claims pursuant to the provisions in 40 CFR Part 2, Subpart B. Such information must be submitted separately from non-confidential information, clearly identified, and clearly marked "Proprietary Business Information." If the applicant fails to make such a claim at the time of submittal, EPA may make the information available to the public without further notice.

EPA has updated the terminology from "Confidential Business Information (CBI)" to "Proprietary Business Information (PBI)" in the title and throughout the provision under Subpart J in § 300.950. The final provisions reflect EPA policy to implement Executive Order 13556 (November 4, 2010) on the terminology used for certain types of information.

3(g) Sensitive Questions

The information collection activities discussed in this document do not involve any sensitive questions.

4. The Respondents and the Information Requested

4(a) Respondent NAICS Codes

Respondents include, include manufacturers of bioremediation agents, dispersants, surface-washing agents, solidifiers, herding agents, and sorbents used as countermeasures against oil spills, and government entities. The universe of domestic product submitters (i.e., product manufacturers) with products listed on the NCP Product Schedule provides the basis for identifying affected entities. EPA identified 89 affected domestic product manufacturers with products currently on the NCP Product Schedule and determined manufacturers' NAICS codes using Dun and Bradstreet (D&B) data, as described in the final rule RIA. The largest affected industry is chemical manufacturing (NAICS 325), with 22 manufacturers. The Agency was unable to obtain D&B data or otherwise confirm the NAICS code for 37 entities for reasons such as the entity not having a public website and/or or the Agency has not received a communication from that product manufacturer in several years. The unknown entities are likely to fall within the set of NAICS codes covered by the 52 known entities (Exhibit 2).

Exhibit 2. Number of Product Manufacturers, by NAICS Code

NAICS Code	NAICS Description	Number of Product Manufacturers
213	Support Activities for Mining	1
322	Paper Manufacturing	1
325	Chemical Manufacturing	22
326	Plastics and Rubber Products Manufacturing	1
423	Merchant Wholesalers, Durable Goods	2
424	Merchant Wholesalers, Nondurable Goods	6
454	Nonstore Retailers	1
493	Warehousing and Storage	1
541	Professional, Scientific, and Technical Services	9
561	Administrative and Support Services	3
562	Waste Management and Remediation Services	4
811	Repair and Maintenance	1
NA	Unknown	37
Total		**89**

4(b) Information Requested

(i) Data Items

Under the final rule, manufacturers who wish to list a product on the Schedule must report the following data items listed in Exhibit 3. Exhibit 4 presents the information required for products to be listed on the Sorbent Product List finalized in § 300.915(g). No specific recordkeeping activities are required.

Exhibit 3. Data Items Required Under the Revised NCP Subpart J for the NCP Product Schedule

Response Form Items	Respondent Activity	Oil Spill Mitigating Agent				
		BA	D	SLD	HA	SWA
SDS form review and submission	Simple Information	X	X	X	X	X
Sample product label	Simple Information	X	X	X	X	X
Chemical and biological agent category	Short Answer	X	X	X	X	X
Product use	Narrative Answer	X	X	X	X	X
Information on persistence, bioconcentration, bioaccumulation, and biodegradability	Narrative Answer	X	X	X	X	X
Information on pathogens, contaminants, and certification that the product does not contain prohibited agents	Narrative Answer	X	X	X	X	X
Product volume capacity	Simple Information	X	X	X	X	X
Recognition under EPA's Design for the Environment (DfE) or Safer Choice programs, as applicable	Simple Information	X	X	X	X	X
International product testing, use data or certifications	Short Answer	X	X	X	X	X
Results of new and revised efficacy tests set forth in Appendix C of the NCP: dispersants, surface washing agents, bioremediation agents	Narrative Answer	X	X	NR	NR	X
Results of revised toxicity tests set forth in Appendix C of the NCP: dispersants, surface washing agents, bioremediation agents, solidifiers, herding agents	Narrative Answer	X	X	X	X	X
Key: BA = Bioremediation Agent, D = Dispersant, SLD = Solidifier, HA = Herding Agent Collecting Agent and SWA = Surface washing Agent, NR = Not Required.						

Exhibit 4. Data Items Required Under NCP Subpart J Final Rule for Sorbents under § 300.915(g)(2)

Response Form Items	Response Activity/Type
Name, physical address, email, and telephone number	Simple Information
Identity as the manufacturer of the product, vendor, importer, distributor of the product, and/or a designated agent acting on behalf of the manufacturer	Simple Information
Name, brand, or trademark, if any, under which the product is sold	Simple Information
Names, physical addresses, emails, and telephone numbers of the primary distributors, vendors, importers and/or designated agent acting on behalf of the manufacturer	Simple Information
Safety Data Sheet (SDS) for the product	Simple Information
Special handling information and worker precautions for storage and field application, including maximum and minimum storage temperatures	Short Answer
Shelf-life information	Simple Information

Response Form Items	Response Activity/Type
A sample product label for all name(s), brand(s), and/or trademark(s) under which the product is to be sold, including manufacture and expiration dates, and conditions for storage	Simple Information
List of product components	Narrative Answer
Information on microbiological cultures, enzyme additives, and nutrient additives	Short Answer
The concentrations or upper limits of any heavy metals, cyanide, and chlorinated hydrocarbons	Short Answer
Certification, including data, methodology, and supporting documentation, indicating that the product does not contain any of the prohibited agents or substances identified in § 300.910(e)	Narrative Answer

(ii) Respondent Activities

Except for effectiveness and toxicity testing, the data items discussed in section 4(b)(i) should be available already to respondents through customary business practices. Effectiveness and toxicity tests, where applicable, require respondents to send products to a laboratory for testing.

Processing, compiling, and reviewing the information required under Subpart J requires the following respondent activities:

- Inserting simple information
- Drafting short answers
- Drafting narrative answers and preparing backup documentation
- Secretarial/clerical and technical support; and
- Managerial review.

Under Subpart J, the respondent must also notify EPA when the composition, formulation, application, or contact information of a product currently listed on the Schedule changes. If the change is likely to alter the effectiveness or toxicity of the product, EPA may require retesting. If EPA decides that retesting is necessary, the respondent must have the product tested in a laboratory and send a summary of the results along with the qualifications of the laboratory staff to EPA.

5. Information Collected - Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

Under Subpart J, EPA will perform activities when a manufacturer applies to have a product listed on the Product Schedule. Once a manufacturer submits the technical product data required by Subpart J, EPA performs the following activities:

- Receive and process the application package for completeness and procedural accuracy.
- Conduct a technical evaluation of the data and information submitted, relevant information on potential impacts on human health and the environment, and the intended use of the product.
- Notify the respondent in writing of the decision of listing the product on the Schedule, or of a rejection decision and supporting rationale; and
- If approved, list the product on the Product Schedule, store the data, and supply the data upon request.

EPA reserves the right to determine whether the product will be listed, and under which product category. If a product is rejected for listing on the Product Schedule, the respondent may request that the EPA Administrator review the determination. The EPA Administrator may remove a product from the Schedule for reasons including, but not limited to: misleading, inaccurate, or incorrect statements within the product submission; alterations to the chemical components, concentrations, or use conditions of the product without proper notification to EPA; failure to print the required disclaimer on all labels, advertisements, or technical literature; new or previously unknown relevant information concerning the impacts or potential impacts of the product to human health or the environment. The Agency will notify the respondent in writing and they may appeal within 30 days.

5(b) Collection Methodology and Management

Respondents submit the required technical data and product information to EPA in hard copy. If the product is listed by EPA, the product information is entered electronically. This information is made available through the Agency's website and other electronic means to ensure that emergency planners and responders can obtain the information as efficiently as possible.

5(c) Small Entity Flexibility

EPA's RIA for the final rule estimates that up to 98 percent of manufacturers with listed products on the June 2021 Product Schedule are small businesses. Under Subpart J, small entities must follow the same collection procedures as other respondents. OSCs need the required information to choose products with which they can safely and effectively control oil discharges. The establishment of toxicity and effectiveness threshold requirements, and the requirements for technical data and use information for listing products on the Product Schedule are not anticipated to result in a significant adverse impact on a substantial number of small businesses.

5(d) Collection Schedule

EPA requires information to be collected whenever a manufacturer wants a product listed on the Product Schedule or Sorbent Product List; when a product already listed changes in composition, formulation, application; or, when other product information changes. The respondent must notify EPA in writing within 30 days of any changes to information submitted under Subpart J for a product on the Product Schedule.

6. Estimating the Burden and Cost of the Collection

6(a) Estimating Respondent Burden

This section presents the respondent burden and cost for the three-year period of the ICR, including the transition period, to comply with the information collection activities under the Subpart J final rule. Respondents are manufacturers expected to submit products for listing on the Schedule.

Eighty-nine manufacturers and 109 products (25 bioremediation agents, 15 dispersants, 52 surface washing agents, 15 solidifiers, and 2 miscellaneous agents) are listed on the June 2021 Schedule.[1] Over the two-year transition period, EPA anticipates manufacturers will apply to re-list all 109 products currently on the Schedule. Additionally, EPA estimates that manufacturers will apply to list five new products on the Schedule each year, including one bioremediation agent, one dispersant, one solidifier, one herding agent, and one surface washing agent.

A respondent's burden for preparing a product for listing on the Schedule is the same regardless of whether EPA lists the product. Therefore, burden is determined for all manufacturers applying to list a product on the Schedule, rather than only for manufacturers whose products are ultimately listed by EPA

Exhibit 4 provides the respondent hour per-product. The Subpart J final rule will require all manufacturers to read and understand the rule. While manufacturers who are new to the Schedule may incur more burden than existing manufacturers to familiarize themselves with the revised NCP Subpart J as a whole, for this analysis, EPA assumes that on average manufacturers of existing and new products will spend 2.5 hours to read and understand the relevant sections of the final Subpart J requirements.

Manufacturers of products already on the Schedule will incur the burden of submitting data to EPA associated with the additional general and agent-specific revisions in the final rule.

Manufacturers who apply to list a new product on the Schedule will also incur the incremental burden of preparing and submitting the additional information requirements in the final rule (Exhibit 3). Exhibit 5 presents the labor hour estimates for the incremental burden resulting from the final rule. The burden estimates are presented by labor type (managerial, technical, clerical) for each product category. In addition, Exhibit 5 distinguishes between existing products already on the Schedule (with the option to submit a package to transition into the new Product Schedule based on the revised classification categories) and for new products applying for listing.

No technical data are required to be submitted for products to be listed on the Sorbent Product List finalized in § 300.915(g) if the sorbent product consists solely of a material or any combination of the materials found in the definition of sorbent (also listed in § 300.915(g)(1)(i)-(iii)). The estimated incremental unit burden for the Sorbent Product List is three hours (0.625

[1] U.S. Environmental Protection Agency (EPA). (2021). NCP Product Schedule. https://www.epa.gov/emergency-response/national-contingency-plan-subpart-j#schedule.

managerial, 2.375 technical). In addition, if the product consists of one or more natural organic substances, inorganic/mineral compounds, and/or synthetic compounds not specifically identified in paragraph (g)(1), but the submitter believes the product meets the definition of a sorbent, then the submitter must provide (i) the information required under § 300.915(a)(1) through (a)(8), and paragraph (a)(13) through (a)(15), as well as the certification required under § 300.915(a)(16). These information requirements are summarized in Exhibit 4. EPA assumes that 20 percent, or two of the ten sorbents submitted per year, will utilize the provisions under § 300.915(g)(2) for the Sorbent Product List. For these sorbents, EPA assumes an additional ten hours of burden per product, for a total of 13 hours each.

Exhibit 5. Unit Burden and Cost to Prepare and Submit Information to EPA Under the Final Rule – Product Manufacturers

Subpart J Rule Requirement	Unit Burden (hours)					
	Managerial		Technical		Total Burden Hours per Product	
	Low	High	Low	High	Low	High
Existing Products - Prepare and Submit Documentation to EPA						
Rule Familiarization	**0.5**	**0.5**	**2**	**2**	**2.5**	**2.5**
Bioremediation Agents	1.3	3.8	6.7	19.2	8	23
Dispersants	1.7	4.8	8.7	24.2	10.4	29
Solidifiers	1.1	3.4	5.7	17.2	6.8	20.6
Herding Agents	1.1	3.4	5.7	17.2	6.8	20.6
Surface Washing Agents	0.9	3	4.7	15.2	5.6	18.2
Average	**1.3**	**3.7**	**6.3**	**18.6**	**7.5**	**22.3**
New Products - Prepare and Submit Documentation to EPA						
Rule Familiarization	**0.5**	**0.5**	**2**	**2**	**2.5**	**2.5**
Bioremediation Agents	3.6	9.1	17.8	45.5	21.4	54.6
Dispersants	4	10.1	19.8	50.5	23.8	60.6
Solidifiers	3.4	8.7	16.8	43.5	20.2	52.2
Herding Agents	3.4	8.7	16.8	43.5	20.2	52.2
Surface Washing / Collecting Agents	3.1	8.1	15.3	40.5	18.4	48.6
Sorbents, under § 300.915(g)(1)	0.6	0.6	2.4	2.4	3.0	3.0
Sorbents, under § 300.915(g)(2)	2.6	2.6	10.4	10.4	13.0	13.0
Average	**2.9**	**6.8**	**14.2**	**33.8**	**17.1**	**40.6**

Infrequent Respondent Burden Items

In addition to the data requirements listed in Exhibit 1, certain infrequent respondent activities in the existing Subpart J rule will continue under the final rule, including review of Agency decisions and retesting for changes to listed products. The estimated burden hours for these activities are same under the final rule and the existing rule. Therefore, the final rule does not result in additional burden for those infrequent activities.

6(b) Estimating Respondent Costs

(i) Estimating Labor Costs

To estimate hourly labor costs for affected manufacturers, the Agency used December 2021 Employer Costs for Employee Compensation (ECEC) data reported by the Bureau of Labor Statistics (BLS) of the U.S. Department of Labor (BLS, 2021). ECEC measures the average cost per employee hour worked that a manufacturer pays for hourly wages and benefits, including paid leave, supplemental pay, insurance, retirement and savings, and legally required benefits. Two labor categories are included: technical and managerial, as summarized in Exhibit 6Error: Reference source not found. These labor rates are used to monetize manufacturers' labor burden associated with documentation preparation and submission of product information, for both existing and new products.

Exhibit 6. Hourly Labor Cost ($2021)

Occupational Category	Hourly Wages	Hourly Total Benefits[1]	Hourly Labor Rate
Managerial	$53.49	$24.16	$77.65
Technical	$44.99	$22.84	$67.83

[1]Benefits include paid leave, supplemental pay, insurance, retirement and savings, and legally required benefits. Source: United States Department of Labor, Bureau of Labor Statistics (BLS 2021). Employer Costs for Employee Compensation, Employment Cost Trends, Table 4 -- Employer Costs for Employee Compensation for private industry workers by occupational and industry groups, December 2021, accessed at https://www.bls.gov/news.release/pdf/ecec.pdf.

Applying the labor costs to the above respondent unit burdens, Exhibit 7 presents respondent labor costs per product for submission.

Exhibit 7. Respondent Labor Cost per Product ($2021)

Subpart J Rule Requirement	Cost per Product	
	Low	High
Existing Products - Prepare and Submit Documentation to EPA		
Rule Familiarization	**$174**	**$174**
Bioremediation Agents	$556	$1,598
Dispersants	$722	$2,015
Solidifiers	$472	$1,431
Herding Agents	$472	$1,431
Surface Washing Agents	$389	$1,264
Average	**$522**	**$1,548**
New Products - Prepare and Submit Documentation to EPA		
Rule Familiarization	**$174**	**$174**
Bioremediation Agents	$1,487	$3,793
Dispersants	$1,653	$4,210
Solidifiers	$1,403	$3,626
Herding Agents	$1,403	$3,626

Exhibit 7. Respondent Labor Cost per Product ($2021)

Subpart J Rule Requirement	Cost per Product	
	Low	High
Surface Washing / Collecting Agents	$1,278	$3,376
Sorbents, under § 300.915(g)(1)	$210	$210
Sorbents, under § 300.915(g)(2)	$908	$908
Average	**$1,192**	**$2,821**

(ii) Operating and Maintenance (O&M) Costs for Product Manufacturers

Respondents are not expected to incur capital/start-up costs for this ICR.

The final rule revisions to Subpart J involve changes to the effectiveness and toxicity tests currently required in part 300.915 and Appendix C to part 300 of the NCP. Because manufacturers are purchasing services (laboratory testing), the laboratory-testing costs are characterized as operating and maintenance (O&M) costs.

To estimate final rule testing unit costs, EPA contacted eight commercial laboratories from the Agency's list of laboratories qualified to perform Subpart J testing,[6] as well as one laboratory not currently on the Agency's list.[7] EPA received test quotes from four of the laboratories contacted.[8] Each laboratory provided estimates for some, but not all, of the tests. For tests with more than one laboratory estimate, EPA calculated the average cost, and all quoted costs are adjusted from 2022-Q1 dollars to 2021 dollars.[9]

Exhibit 8 presents the unit costs for efficacy and toxicity testing under the final rule. The Exhibit also shows current, or baseline, testing costs, which are documented in EPA's current ICR implementing the NCP Subpart J program[10] and the final rule RIA.

Exhibit 8. Final Rule Toxicity and Efficacy Test Unit Costs ($2021)

Product Test	Final Rule Cost per Test	Baseline Cost per Test	Incremental Cost per Test	
			Existing Products	New Products
Dispersant, Efficacy Testing[1]	$5,749	$4,687	$8,144	$3,457
Dispersant, Toxicity Testing[2]	$12,247	$4,166	$17,691	$13,525

[6] EPA's list of qualified laboratories is not to be construed as an endorsement or recommendation, but rather is provided as a courtesy based on laboratories included in applications submitted for product listing. Any qualified laboratory, as defined in § 300.915(a)(17), may perform Subpart J tests.

[7] Laboratories contacted by EPA included: Aqua Survey, Bio-Aquatic Testing, Inc., Bonner Analytical Testing Company, Coastal Bioanalysts, Inc., Environmental Enterprises USA, Inc., New England Bioassay, Pacific Eco-Risk, Southwest Research Institute, and McCampbell Analytical.

[8] EPA obtained test quotes from Aqua Survey, Bio-Aquatic Testing, Inc., Coastal Bioanalysts, Inc, and Pacific Eco-Risk.

[9] U.S. Bureau of Economic Analysis (BEA). (2022). Table 1.1.9. *Implicit Price Deflators for Gross Domestic Product*. February 2022. https://www.bea.gov/data/prices-inflation/gdp-price-deflator

[10] U.S. Environmental Protection Agency (EPA). (2020). The National Oil and Hazardous Substances Pollution Contingency Plan Regulation, Subpart J (40 CFR 300.900) (ICR Renewal). EPA ICR # 1664.12, OMB # 2050-0141

Product Test	Final Rule Cost per Test	Baseline Cost per Test	Incremental Cost per Test	
			Existing Products	New Products
Bioremediation Agents, Efficacy Testing[3]	$23,953	$18,748	$23,953	$5,205
Surface Washing Agents, Solidifiers, Herding Agency, and Bioremediation Agents; Toxicity Testing[4]	$4,359	$4,166	$4,359	$193

Sources:
[1] Aqua Survey and Bio-Aquatic Testing
[2] Aqua Survey, Coastal Bioanalysts, and Pacific Eco-Risk
[3] Bio-Aquatic Testing
[4] Coastal Bioanalysts, and Bio-Aquatic Testing

- **Dispersants: *Efficacy and Toxicity Testing*.** The new, Baffle Flask Test (BFT) requires additional equipment (e.g., flasks, stopcocks for the first such test) and new laboratory procedures, compared to the baseline SFT. The cost for the dispersant efficacy testing under the final rule is estimated to be $5,749 per product. For toxicity testing, submitters are required to use the methods specified in Appendix C to part 300 to perform the standard acute toxicity test, as well as the new developmental, and sub-chronic toxicity testing required for dispersants under the final rule. Based on laboratory quotes, EPA estimates that dispersant toxicity testing is $12,247 per product. The requirements in the final action provide for dispersant efficacy and toxicity testing to be performed using one reference oil: SPR Bryan Mound. As detailed in Section V.C.3.(b).1 of the final rule preamble, the Agency has determined that the use of SPR Bryan Mound as the sole screening reference oil is sufficient and appropriate for use in establishing a baseline comparison of products considered for listing on the NCP Product Schedule. The efficacy and toxicity cost estimates above are based on laboratory estimates for one reference oil.[11]

- **Bioremediation Agents: *Efficacy Testing*.** Bioremediation agents must be tested for efficacy using the method specified in Appendix C to part 300. EPA estimates that the bioremediation saltwater efficacy test for both saltwater and freshwater for new bioremediation agents will each cost $23,953 per test.

  EPA will require the revised saltwater efficacy test for bioremediation products currently on the Schedule. EPA assumes that half of the manufacturers with bioremediation agents currently on the Schedule will test their product with the freshwater efficacy test for use in freshwater. Because manufacturers applying to list new products on the Schedule will be required to test their product for efficacy in the type of waters that the product will be used, EPA assumes that half of these manufacturers will test their product with the revised saltwater efficacy test for use in saltwater, while the other half will test their product using the freshwater efficacy test for use in freshwater.

[11] Aqua Survey, BioAquatic Testing, and Coastal Bioanalysts provided per sample estimates; however, Pacific Eco-Risk provided estimates based on the proposed Appendix C requirements, using two reference oils, without further specification. EPA reduced its toxicity test estimate by half to reflect the use of one reference oil in the final action, versus two reference oils in the proposed rule.

- **Surface Washing Agents, Solidifiers, Herding Agency, and Bioremediation Agents:** ***Toxicity Testing***. Bioremediation agents must be tested for acute toxicity in saltwater, freshwater or both, depending on the intended product use, following the method specified in Appendix C to part 300. EPA estimates that the freshwater and saltwater toxicity tests required for solidifiers, herding agents, surface-washing agents, and certain bioremediation agents will cost $4,439 each per test. EPA assumes half of the manufacturers with bioremediation agents listed on the Schedule will conduct both saltwater and freshwater toxicity testing, and the other half will conduct only one. EPA uses this same assumption for manufacturers applying to have new bioremediation agents listed on the Schedule.

  Surface washing agents, solidifiers, and herding agents also must be tested for acute toxicity in saltwater, freshwater or both, depending on the intended product use, following the method specified in Appendix C to part 300. Based on testing, product listing will be for use only in fresh water and/or saltwater environments for which it was tested and for which it met the toxicity listing criteria. The cost per test is $4,439. EPA assumes that manufacturers of SWAs, solidifiers, and herding agents currently on the Schedule will all conduct freshwater toxicity testing in addition to the existing saltwater toxicity test requirement. The Agency also assumes future applications for new products in these categories will include both saltwater and freshwater testing.

6(c) Estimating Agency Burden and Costs

This section presents the estimated unit burden and unit cost to EPA for maintaining the Product Schedule and Sorbent Product List. Burden estimates are based on EPA's experience with listing products on the Product Schedule under Subpart J. Exhibit 9 shows the labor burdens to EPA for each activity under the revised NCP Subpart J. The burden to EPA under the final rule includes burden to review and process product submissions and to make the listing decision. The labor burden to the Agency under the existing regulations – 20 hours per product – is reported in the OMB-approved ICR for Subpart J (OMB Control No. 2050-0141), and in the final rule RIA. The labor burden to the Agency under the final rule includes the additional burden above and beyond the baseline burden.

The Agency's burden to implement a product listing on the Subpart J list is, on average, 7 hours to process submitted data, 6 hours to review data to make a listing determination, 4 hours to notify a respondent of the decision, and 3 hours to store data, yielding an average total of 20 hours in the baseline. The latter two activities should not be affected by the new requirements. However, EPA assumes that the new rule requirements will increase the burden of the first two activities by 50 percent, increasing the total Agency burden to 26.5 hours per product submission.

EPA labor costs are based on the 2021 General Schedule (GS) pay schedule. EPA assumed that a staff person at the GS-13 Step 1 level will be required to maintain the Schedule. Based on the GSA pay schedule, the hourly rate is $49.68 (OPM, 2021). EPA then applied the standard government overhead factor of 1.6 to estimate a fully loaded hourly labor rate of $79.49. The EPA labor rate is used to monetize the labor burden associated with processing and

reviewing product submissions. For sorbents, the incremental Agency burden is $238 (3 hours) per product.

Exhibit 9 presents the Agency labor burden and cost per product submission. For existing products, the burden is the 26.5 hours. For new products, the incremental effect of the final rule is 6.5 hours ($517), after removing the 20 hours of baseline burden that would occur absent the rule for the products.

Exhibit 9. Unit Burden and Cost to EPA per Product Schedule Submission ($2021)

Product Submission Review Activity	Burden Hours	Cost Per Product
Unit Burden and Cost per Product for NCP Product Schedule	**26.5**	**$2,106**
Process submitted data	10.5	$835
Review data for approval	9	$715
Notify respondent of decision	4	$318
Store data	3	$238
Unit Burden and Cost per Product for Sorbent Product List	**3.0**	**$238**

[1] EPA assumes burden hours for each information collection activity will be the same for each oil spill mitigation agent type.

6(d) Estimating the Respondent Universe and Total Burden and Costs

Estimated Total Annual Burden and Costs for All Respondents

The total annual burden is arrived at by multiplying the average unit burden by the estimated frequency of responses per year for each oil spill mitigating agent type. The average annual respondent burden under the final NCP Subpart J will be 517 to 1,195 hours and $1.04 to $1.09 million.

The average number of responses for the Product Schedule expected annually over the ICR period is estimated to be 41, and the average number of responses per year for the Sorbent Product List is 10, as shown in Exhibit 10. EPA estimates that all manufacturers of existing products will submit applications to re-list their products during the initial two-year transition period, manufacturers will apply to list an average of 5 new products per year, and manufacturers will submit 10 new sorbent products per year.

Exhibit 10. Estimated Number of Responses per Year

Compliance Period	Number of Responses for NCP Product Schedule			Estimated Number of Responses for the Sorbent Product List
	Existing Products (Re-submission)	New Products	Total Number of Responses for Product Schedule	
Year 1	55	5	60	10
Year 2	54	5	59	10

Year 3	0	5	5	10
Average	**36**	**5**	**41**	**10**

The total annual burden and cost for all respondents are presented in Exhibit 11 and 12. Exhibit 11 presents the total burden and cost for the preparation and submission of product documentation for existing and new products. The total burden and cost for new products will recur annually during each of the three years of the ICR. The burden and cost for existing products will be split equally between year one and year two of the ICR, reflecting the final rule's transition period and EPA's assumption that half of the existing products will resubmit in each year of that period. The labor burden and associated labor cost is expressed as a range, per Exhibit 5.

Exhibit 11. Total Respondent Product Documentation Labor Burden and Cost, Detail

Product Documentation Activity	Number of Products	Total Labor Hours	Total Labor Cost
Rule Familiarization			
Manufacturers of Existing Products	89	223	$15,529
Manufacturers of New Products	5	12.5	$872
Manufacturer Product Documentation			
Prepare and submit documentation - Existing Products - Low			
Prepare & submit documentation - Bioremediation	25	200	$13,893
Prepare & submit documentation - Dispersants	15	156	$10,837
Prepare & submit documentation - SWA	52	291	$20,229
Prepare & submit documentation - Solidifiers	15	102	$7,086
Prepare & submit documentation - Herding Agents	2	14	$945
Total Existing Products - Low	***109***	***763***	***$52,989***
Prepare and submit documentation - Existing Products - High			
Prepare & submit documentation - Bioremediation	25	575	$39,943
Prepare & submit documentation - Dispersants	15	435	$30,218
Prepare & submit documentation - SWA	52	946	$65,743
Prepare & submit documentation - Solidifiers	15	309	$21,465
Prepare & submit documentation - Herding Agents	2	41	$2,862
Total Existing Products - High	***109***	***2307***	***$160,232***
Prepare and submit documentation - New Products - Low			
Prepare & submit documentation - Bioremediation	1	21	$1,487
Prepare & submit documentation - Dispersants	1	24	$1,653
Prepare & submit documentation - SWA	1	18	$1,278
Prepare & submit documentation - Solidifiers	1	20	$1,403
Prepare & submit documentation - Herding Agents	1	20	$1,403
Prepare & submit documentation - Sorbents	10	80	$5,590
Total New Products - Low	***15***	***184***	***$12,815***
Prepare and submit documentation - New Products - High			
Prepare & submit documentation - Bioremediation	1	55	$3,793
Prepare & submit documentation - Dispersants	1	61	$4,210
Prepare & submit documentation - SWA	1	49	$3,376

Exhibit 11. Total Respondent Product Documentation Labor Burden and Cost, Detail

Product Documentation Activity	Number of Products	Total Labor Hours	Total Labor Cost
Prepare & submit documentation - Solidifiers	1	52	$3,626
Prepare & submit documentation - Herding Agents	1	52	$3,626
Prepare & submit documentation - Sorbents	10	80	$5,590
Total New Products - High	***15***	***348***	***$24,221***
Total Product Documentation Burden & Cost - High		***2,655***	***$184,453***
Total Product Documentation Burden & Cost - Low		***947***	***$65,804***

Exhibit 12 presents the total annual O&M cost for product testing by year, for existing and new products to be listed on the Product Schedule.

Exhibit 12. Total Respondent Product Testing O&M Cost, Detail

Product Testing Activity	Year 1		Year 2		Year 3		Total, Years 1 - 3	
	# Products Testing	Testing Cost	# Products Testing	Testing Cost	# Products Testing	Testing Cost	# Products Testing	Testing Cost
Dispersant Efficacy								
Existing	7.5	$43,115	7.5	$43,115	0	$0	15	$86,231
New	1	$1,062	1	$1,062	1	$1,062	3	$3,185
Dispersant Toxicity								
Existing	7.5	$91,853	7.5	$91,853	0	$0	15	$183,705
New	1	$8,081	1	$8,081	1	$8,081	3	$24,242
Bioremediation Efficacy								
Existing	12.5	$449,119	12.5	$449,119	0	$0	25	$898,238
New	1	$17,181	1	$17,181	1	$17,181	3	$51,544
Bioremediation Toxicity								
Existing	12.5	$81,740	12.5	$81,740	0	$0	25	$163,479
New	1	$6,539	1	$6,539	1	$6,539	3	$19,618
SWA Efficacy								
Existing	26	$448,400	26	$448,400	0	$0	52	$896,801
New	1	$17,246	1	$17,246	1	$17,246	3	$51,739
SWA Toxicity								
Existing	26	$226,691	26	$226,691	0	$0	52	$453,383
New	1	$4,553	1	$4,553	1	$4,553	3	$13,658
Solidifiers Toxicity								
Existing	7.5	$65,392	7.5	$65,392	0	$0	15	$130,783
New	1	$4,553	1	$4,553	1	$4,553	3	$13,658
Herding Agents Toxicity								

Exhibit 12. Total Respondent Product Testing O&M Cost, Detail

Product Testing Activity	Year 1		Year 2		Year 3		Total, Years 1 - 3	
	# Products Testing	Testing Cost	# Products Testing	Testing Cost	# Products Testing	Testing Cost	# Products Testing	Testing Cost
Existing	1	$8,719	1	$8,719	0	$0	2	$17,438
New	1	$4,553	1	$4,553	1	$4,553	3	$13,658
Total Efficacy and Toxicity Test Costs		**$1,478,796**		**$1,478,796**		**$63,767**		**$3,021,360**

Estimated Total Annual Burden and Cost to EPA

The annual costs to EPA under the NCP Subpart J final rule are presented in Exhibit 13 for each year of the ICR period. The annual agency burden is calculated by multiplying the unit agency burden by the expected frequency of applications. The average annual burden to EPA under the final NCP Subpart J will be approximately 1,025 hours per year. The average annual cost to EPA under the final NCP Subpart J will be $81,502.

Exhibit 13. Total Agency Burden and Cost

EPA Submission Review Activity	Number of Products	Total Burden	Total Cost
Year 1			
Existing Product Schedule Products	54.5	1,444	$114,801
New Product Schedule Products	5.0	33	$2,583
New Sorbent Product List Products	10.0	30	$2,385
Total	**69.5**	**1,507**	**$119,769**
Year 2			
Existing Product Schedule Products	54.5	1,444	$114,800
New Product Schedule Products	5.0	33	$2,583
New Sorbent Product List Products	10.0	30	$2,385
Total	**69.5**	**1,507**	**$119,768**
Year 3			
Existing Product Schedule Products	0	0	$0
New Product Schedule Products	5.0	33	$2,583
New Sorbent Product List Products	10.0	30	$2,385
Total	**15.0**	**63**	**$4,968**
Total, Years 1 – 3			
Existing Product Schedule Products	109.0	2,889	$229,601
New Product Schedule Products	15.0	98	$7,750
New Sorbent Product List Products	30.0	90	$7,154
Total	**124**	**2,986**	**$237,351**
Average per Year	**51**	**1,025**	**$81,502**

6(e) Bottom Line Burden Hours and Costs

(i) Respondent Tally

The total respondent burden and costs for each of the three years of the ICR period are summarized in Exhibit 14. These include both labor and O&M costs, which vary depending on product type and the test(s) required. Exhibit 14 combines Exhibit 11 and 12 to summarize the overall total burden and cost for all respondents by ICR year.

Exhibit 15 presents the bottom-line burden and cost estimates. Over the three-year ICR period, the average annual respondent burdens are 517 to 1,195 hours and $1.04 to $1.09 million.

Exhibit 14. Total Respondent Burden and Cost by ICR Year

	Year 1		Year 2		Year 3		Total, Years 1 - 3	
	Total Burden	**Total Cost**	**Total Burden**	**Total Cost**	**Total Burden**	**Total Cost**	**Total Burden**	**Total Cost**
Existing Products								
Familiarization	111	$7,765	111	$7,765	0	$0	**223**	**$15,529**
Product documentation, Low	381	$26,495	381	$26,495	0	$0	**763**	**$52,989**
Product documentation, High	1,153	$80,116	1153	$80,116	0	$0	**2,307**	**$160,232**
Product Testing	0	$1,415,029	0	$1,415,029	0	$0	**0**	**$2,830,058**
New Products								
Familiarization	12.5	$872	0.0	$0	0	$0	**12.5**	**$872**
Product documentation, Low	184	$12,815	184	$12,815	184	$12,815	**552**	**$38,444**
Product documentation, High	348	$24,221	348	$24,221	348	$24,221	**1,045**	**$72,663**
Product Testing	0	$63,767	0	$63,767	0	$63,767	**0**	**$191,302**
Total for All Products Submitted								
Familiarization	124	$8,637	111	$7,765	0	$0	**235**	**$16,402**
Product documentation, Low	565	$39,309	565	$39,309	184	$12,815	**1,315**	**$91,433**
Product documentation, High	1,502	$104,337	1502	$104,337	348	$24,221	**3,351**	**$232,895**
Product Testing	0	$1,478,796	0	$1,478,796	0	$63,767	**0**	**$3,021,360**

Exhibit 15. Bottom-Line Respondent Burden and Cost

ICR Cost Estimate	Total (3 years)		Average Annual	
	Hours	**Cost**	**Hours**	**Cost**
Low	1,550	$3,129,195	517	$1,043,065
High	3,586	$3,270,656	1,195	$1,090,219

(ii) The Agency Tally

As shown in Exhibit 16, the final Subpart J average annual burden for EPA is 1,025 hours, and the average annual labor costs for EPA are $81,502.

Exhibit 16. Bottom-Line Agency Burden and Cost

Compliance Period	EPA Hours	EPA Cost
Year 1	1,507	$119,769
Year 2	1,507	$119,768
Year 3	63	$4,968
Total	3,076	$244,505
Average	**1,025**	**$81,502**

(iii) Variations in the Annual Bottom-Line

The annual burden and cost vary by year over the course of the ICR period because existing products are assumed to all re-submit their product during the first two years.

6(f) Reasons for the Change in Burden

The burden estimates included in this ICR represent the incremental burden resulting from the Subpart J revisions for the revised product and testing requirements in the May 2023 final rule.

6(g) Burden Statement

The collection of information required to prepare and submit material for listing a product under the final NCP Subpart J is estimated to have an average public reporting burden of 11 to 24 hours per response over the three-year ICR period. The estimate varies depending on the type of product to be listed. Further, there is no required recordkeeping burden associated with listing a product on the NCP Product Schedule.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the

use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OPA-2006-0090, which is available for online viewing at www.regulations.gov, or in person viewing at the Superfund Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW, Washington, D.C. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Superfund Docket is (202) 566-0276. An electronic version of the public docket is available at www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select "search," then key in the Docket ID Number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, D.C. 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-OPA-2006-0090 and OMB Control Number 2050-0141 in any correspondence.