ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 110 and 300

[EPA–HQ–OPA–2006–0090; FRL–4526–01–OLEM]

RIN 2050–AE87

National Oil and Hazardous Substances Pollution Contingency Plan; Product Schedule Listing and Authorization of Use Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is amending the requirements in Subpart J of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) that govern the use of dispersants, other chemicals and other spill mitigating substances when responding to oil discharges into jurisdictional waters of the United States. This action addresses the efficacy and toxicity of dispersants and other chemical and biological agents, as well as public, state, local, and federal officials' concerns regarding their use. Specifically, the Agency is amending the Subpart J regulatory requirements for the NCP Product Schedule in two distinct ways. First, the Agency is adding new listing criteria, revising the efficacy and toxicity testing protocols, and clarifying the evaluation criteria for removing products from the NCP Product Schedule. Second, the Agency is amending requirements for the authorities, notifications, and data reporting when using chemical or biological agents in response to oil discharges to Clean Water Act (CWA) section 311 jurisdictional waters and adjoining shorelines. These requirements are anticipated to encourage the development of safer and more effective spill mitigating products and better target the use of these products to reduce the risks of oil discharges and response technologies to human health and the environment. Further, the amendments are intended to ensure that On-Scene Coordinators (OSCs), Regional Response Teams (RRTs), and Area Committees (ACs) have sufficient information to support agent authorization of use decisions.

DATES: This final rule is effective on December 11, 2023.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OPA–2006–0090. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general information, contact the Superfund, TRI, EPCRA, RMP, and Oil Information Center at 800–424–9346 or TDD at 800–553–7672 (hearing impaired). In the Washington, DC metropolitan area, contact the Superfund, TRI, EPCRA, RMP, and Oil Information Center at 703–412–9810 or TDD 703–412–3323. For more detailed information on this final rule contact Gregory Wilson at 202–564–7989 (*wilson.gregory@epa.gov*) or Vanessa Principe at 202–564–7913 (*principe.vanessa@epa.gov*). The contact address is U.S. Environmental Protection Agency, Office of Emergency Management, Regulations Implementation Division, 1200 Pennsylvania Avenue NW, Washington, DC 20460–0002, Mail Code 5104A, or visit the Office of Emergency Management website at *http://www.epa.gov/oem/.*

SUPPLEMENTARY INFORMATION: The contents of this preamble are:

I. General Information

In April 2010, the Deepwater Horizon underwater oil well blowout discharged significant quantities of oil into the Gulf of Mexico and raised questions about efficacy, toxicity, environmental tradeoffs, and the challenges of making dispersant use decisions in response operations for certain atypical dispersant use situations.

In this final action, EPA is establishing new agent testing, listing, and authorization of use requirements under Subpart J of the NCP to address these challenges. These revisions to Subpart J address the use of dispersants and other chemical and biological agents to respond to oil discharges into jurisdictional waters and their adjoining shorelines as provided under section 311(b)(3) of the CWA. Specifically, the Agency is adding, amending, or removing certain regulatory definitions and updating requirements associated with the authorization of agent use (including preauthorization plan development, approval, and review; prohibited agents; storage; agent use; recovery; and reporting of use); testing of products (including efficacy and toxicity testing protocols); and listing on the NCP Product Schedule (including data and information requirements and the use of toxicity data to determine listing eligibility; processes for listing and delisting, including transitioning products to the new NCP Product Schedule; and proprietary business information (PBI)). The revisions include improved laboratory protocols for dispersant and bioremediation efficacy and toxicity, and will increase the overall scientific soundness of the data collected. These amendments to Subpart J will help to ensure that only

products that perform effectively in laboratory testing will be listed on the NCP Product Schedule for use in mitigating the effects of oil discharges.

EPA estimates that, to comply with the revised requirements, industry may incur a total incremental cost of approximately $283,800 to $376,500 annually. Note that the range in annualized cost reflects differences due to using 3% and 7% discount rates as well as a range (low and high) for submitter's paperwork burden. This action does not impose significant impacts on a substantial number of small entities. The Regulatory Impact Analysis, which can be found in the docket, provides more detail on the cost methodology and benefits of this action.

II. Entities Potentially Affected by This Final Rule

Entities affected by the final rule 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 each manufacturer's NAICS code using Dun and Bradstreet (D&B) data.

NAICS code	Industrial category
213	Support Activities for Mining.
322	Paper Manufacturing.
325	Chemical Manufacturing.
326	Plastics and Rubber Products Manufacturing.
423	Merchant Wholesalers, Durable Goods.
424	Merchant Wholesalers, Nondurable Goods.
454	Nonstore Retailers.
493	Warehousing and Storage.
541	Professional, Scientific, and Technical Services.
561	Administrative and Support Services.
562	Waste Management and Remediation Services.
811	Repair and Maintenance.

The Agency's goal is to provide a guide for readers to consider regarding entities that potentially could be affected by this action. However, this action may affect other entities not listed in this table. If you have questions regarding the applicability of this action to a particular entity, consult the person(s) listed in the **FOR FURTHER INFORMATION CONTACT** section.

III. Statutory Authority and Delegation of Authority

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.

IV. Background

In the United States and around the world, chemical and biological agents are among the oil spill mitigation technologies available that responders may consider. Subpart J of the NCP sets forth the regulatory requirements for the use of chemical and biological agents, which includes separate provisions for product testing and listing, and for authorization of use procedures. These requirements provide the structure for the On-Scene Coordinator (OSC) to determine in each case the waters and quantities in which dispersants or other chemical agents may be safely used in such waters, if any. This determination is based on all relevant circumstances, testing and monitoring data and information, and is to be made in accordance with the authorization of use procedures, including the appropriate concurrences and consultations, found within the regulation. When taken together, the Subpart J regulatory requirements address the types of waters and the quantities of listed agents that may be authorized for use in response to oil discharges. EPA believes that the wide variability in waters, weather conditions, organisms living in the waters, and types of oil that might be discharged requires this approach.

The Deepwater Horizon underwater oil well blowout in 2010 raised questions about the challenges of making chemical agent use decisions in response operations, particularly for certain atypical dispersant use situations. To address these and other challenges, the Agency proposed to amend Subpart J of the NCP to revise the existing product listing criteria, testing protocols, and authorization of use procedures, as well as to establish new provisions for dispersant monitoring (80 FR 3383, January 22, 2015). In July 2021, EPA published a final rule addressing the environmental monitoring of dispersant use in response to major discharges and to certain dispersant use situations.

Specifically, the Agency established monitoring requirements for any subsurface use of dispersant in response to an oil discharge, surface use of dispersant in response to oil discharges of more than 100,000 U.S. gallons occurring within a 24-hour period, and surface use of dispersant for more than 96 hours after initial application in response to an oil discharge (86 FR 40234, July 27, 2021). This final action addresses the remaining Subpart J revisions proposed in 2015, including those associated with the product listing, testing protocols, and authorization of use procedures.

V. This Action

This final action amends two distinct sets of requirements under Subpart J: (1) Those related to chemical and biological agent testing and listing, and (2) those related to authorization of use. Specifically, in this action, the Agency adds, amends, or removes certain regulatory definitions associated with Subpart J, and updates requirements for the authorization of agent use (including preauthorization plan development, approval, and review; case by case authorization of prohibited agents; storage; agent use; recovery; and reporting of use); testing of products (including efficacy and toxicity testing protocols); and listing on the NCP Product Schedule (including data and information requirements, processes for adding or removing a product to or from the NCP Product Schedule, and proprietary business information.) The discussion below explains each of the amendments. It also summarizes and provides a response to highlighted public comments received on the 2015 proposal. See the *Response to Comment Document for Listing and Testing of Chemical and Biological Agents,* and for the *Response to Comment Document on the Authorization of Use of Chemical and Biological Agents* in the rulemaking docket for a complete summary and response to public comments. Sections of the NCP not identified to be revised in the proposed rule or addressed in this final rule are outside the scope of this final action.

Revisions to Subpart J were under consideration prior to the Deepwater Horizon oil spill. The subsequent Deepwater Horizon oil spill resulted in recommendations to update Subpart J from the National Commission on the *BP Deepwater Horizon Oil Spill and Offshore Drilling Report* [1] and the EPA Inspector General report titled *Revisions Needed to the National Contingency Plan Based on Deepwater Horizon Oil Spill* (Report #11–P–0534),[2] including that EPA review and update dispersant testing protocols for product listing. The Agency's final action addresses those recommendations.

This final action reflects relevant science and research that supports the specific provisions and their intent. The Agency considered the over 81,000 comments received that offered a wide range of perspectives and scientific information. Those comments remain relevant to the rulemaking, which will modernize and enhance the Subpart J regulatory provisions.

The Agency is updating the process for listing products on the NCP Product Schedule, including expanded testing and listing thresholds. In doing so, EPA identified the relevant science to establish a national screening process for products to be listed on the NCP Product Schedule. Specifically, in amending the NCP Product Schedule listing provisions, EPA considered relevant science related to efficacy and toxicity testing and has determined it supports both establishing new protocols and updating existing protocols under Subpart J for testing chemical and biological agent products for listing on the NCP Product Schedule. These product testing 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 that commercial laboratories are already familiar with or can readily adopt. EPA is not aware of changes to the relevant science since the proposed rulemaking and is proceeding with taking final action on the proposal. Furthermore, the final action builds upon the existing NCP framework, providing 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 is also updating the provisions for authorization of use by building upon the existing framework, providing further opportunities to consider advancements in science as part of the planning and authorization of use processes for chemical and biological agents. This performance-based approach provides flexibility in gathering, and allowing for the consideration of, scientific information relevant to a given site or geographic location. This allows for better targeting chemical and biological agent use during a response and is consistent with the broader NCP framework.

A. Discharge of Oil

The Agency is revising the text at 40 CFR 110.4 to harmonize it with the definitions for chemical and biological agents that are also being finalized for Subpart J. The revision replaces the terms ''dispersants and emulsifiers'' in § 110.4 with the broader term ''any chemical or biological agent, or any other substance.'' The revised definition in § 300.5 for chemical agents, as finalized in this action, includes elements, compounds, or mixtures designed to facilitate the removal of oil from a contaminated environment and mitigate any deleterious effects. The new definition for biological agents, also finalized in this action, includes microorganisms (typically bacteria, fungi, or algae) or biological catalysts, such as enzymes, able to enhance the biodegradation of a contaminated environment. By revising the provision at § 110.4, the Agency is clarifying that any chemical or biological agent or any other substance added to a discharge of oil with the intent to circumvent any provision of 40 CFR part 110 is prohibited. The final action replaces the specific qualifier ''as defined in § 300.5 of this title'' with the broader ''or any other substance'' to emphasize the intent of this provision is ultimately to prohibit circumventing part 110 requirements. The Agency has also amended the section title to ''Chemical or biological agents.''

Commenters on the 2015 proposal noted that the rule change would ensure no unintended or deliberate circumvention of § 110.4 through any inconsistencies with Subpart J definitions. EPA agrees and has finalized the rule as described above to refer to the terms ''chemical and biological agents'' as opposed to specifically ''emulsifiers'' and ''dispersants.'' In the finalized provision, EPA also made some editorial changes relative to the proposed text for increased clarity.

B. Subpart A—Introduction

1. Definitions

EPA is finalizing revisions to § 300.5 to amend the definitions for bioremediation agents, burning agents, chemical agents, dispersants, sinking agents, sorbents, and surface washing agents. Additionally, the Agency is finalizing new definitions for bioaccumulation, bioconcentration, biodegradation, biological agents, bioremediation, herding agents,

[1] See *https://www.govinfo.gov/content/pkg/GPO-OILCOMMISSION/pdf/GPO-OILCOMMISSION.pdf.*

[2] See *https://www.epa.gov/office-inspector-general/report-revisions-needed-national-contingency-plan-based-deepwater-horizon.*

products, and solidifiers. Finally, the Agency is removing the definitions for miscellaneous oil spill control agents (MOSCA) and surface collecting agents.

(a) Revised Definitions

Bioremediation agents—The Agency is revising the definition of bioremediation agents as proposed, to clarify the previous definition and add examples of bioremediation agents. Specifically, the final rule defines bioremediation agents as biological agents and/or nutrient additives deliberately introduced into a contaminated environment to increase the rate of biodegradation and mitigate any deleterious effects caused by the contaminant constituents. The definition identifies microorganisms and enzymes as bioremediation agents, as well as nutrient additives such as fertilizers containing bio-available forms of nitrogen, phosphorus, and potassium. This clarification will help manufacturers of products to identify the type of product, and hence, what testing requirements they will need to comply with to have a product listed on the NCP Product Schedule.

A commenter expressed concerns about grouping all bioremediation agents in the revised definition. The commenter stated that the definition for bioremediation agent should be broken down for the three types of bioremediation because there are significant differences in applicability and appropriateness for the application of each type. EPA disagrees that the definition of bioremediation agent must explicitly include a classification for different types of bioremediation. The definition for bioremediation agents in the final action includes microorganisms, enzymes, and nutrients, to capture their different mechanisms of action (*e.g.,* amending rate limiting nutrients vs. adding microbial cultures). The final revisions do not prevent EPA from grouping similar bioremediation agents together on the NCP Product Schedule, if appropriate.

A commenter suggested that the definition of bioremediation agents should include language prohibiting the use of biological agents that could result in non-indigenous species colonization. EPA is not prohibiting the use of non-indigenous species, because the addition of cultured microorganisms, which may include non-indigenous species, may enhance biodegradation of a contaminant in certain situations. EPA notes that decisions to use bioremediation agents are subject to § 300.910, *Authorization of Use,* and expects the OSC to utilize available resources to determine the most appropriate bioremediation agent, if any, for use in a response in light of incident and site-specific factors.

Burning agents—The Agency is revising the definition of burning agents as proposed, to identify as such those additives that improve the combustibility of the materials to which they are applied. This could be achieved through either physical or chemical means.

A commenter interpreted that the proposed definition combines burning agents (materials that actually change the combustibility of the material they are added to) and ignition agents (ignition devices or materials used to start combustion). The commenter recommended that the Agency adopt separate definitions for burning and ignition agents for clarity. Some commenters suggested that the Agency should either include ignition devices within the definition of ''burning agents'' or create a separate category for ignition devices. The Agency agrees with commenters that ignition devices are distinct from burning agents. The final provisions do not include ignition devices in the definition of burning agent. The Agency believes that the intent of ignition devices is to provide the initial energy to start a burn and typically do not enter the water column. While ignition devices provide the initial energy to start a burn, these devices are incidental to burning agents, which are intended to improve the combustibility of the oil. EPA is exercising its discretionary authority and not including ignition devices on the NCP Product Schedule given their intended use. Furthermore, EPA disagrees with a commenter's statement that burning agents are necessarily applied ''prior to ignition;'' EPA believes that burning agents could be added after ignition to improve combustibility. The definition of burning agents in the final action does not specifically state when during an in situ burning cycle a burning agent is to be applied. The Agency is finalizing the definition of burning agents from the proposed rule without any changes. EPA notes that burning agents remain subject to Subpart J authorization of use requirements, even though EPA is not requiring specific product information and data about burning agents to be submitted to EPA under § 300.955.

Chemical agents—The Agency is revising the definition of chemical agents to identify as such those elements, compounds, or mixtures that are designed to facilitate the removal of oil from a contaminated environment and to mitigate deleterious effects. The chemical agent category includes burning agents, dispersants, herding agents, solidifiers, surface washing agents, and those bioremediation agents that consist of nutrient additives. This revised definition reflects the Agency's distinction between chemical and biological agents, allowing product manufacturers to better target the testing requirements and OSCs to better inform their authorization in specific situations. The finalized language also removes from the definition certain agent categories that are being eliminated, prohibited, or amended, to conform to these changes.

Several commenters expressed concern with the Agency's proposed wording ''designed to facilitate the removal of oil from a contaminated environment.'' Commenters indicated that the definition of ''chemical agent'' does not make it clear that sinking agents, along with dispersants, do not remove or detoxify oil, but rather treat it. Commenters also stated that dispersants do not facilitate the removal of oil or mitigate deleterious effects. EPA notes that the NCP incorporates into § 300.5 the CWA section 311 statutory definition of ''remove.'' Under the NCP, ''remove'' or ''removal'' refers to containment and removal of oil or hazardous substances from the water and shorelines or the taking of such other actions as may be necessary to minimize or mitigate damage to the public health or welfare of the United States (including, but not limited to, fish, shellfish, wildlife, public and private property, and shorelines and beaches) or to the environment (40 CFR 300.5). Under the NCP, the term also includes monitoring of action to remove a discharge (40 CFR 300.5). Dispersants are substances that emulsify, disperse, or solubilize oil by promoting the formation of small droplets or particles of oil in the water column. The primary purpose of using dispersants is to facilitate dispersal of the oil into the water column, where the oil is then subject to several fate and transport processes (*e.g.,* dissolution). Thus, dispersant use may alter the behavior of oil to which it is applied and may result in an action that minimizes or mitigates damage, as described in the statutory definition of ''remove.'' In addition, depending on the oil composition, certain fractions of the dispersed oil may biodegrade over time. Dispersants are appropriately defined as chemical agents since they are designed to facilitate the removal of oil or mitigate oil's deleterious effects. Furthermore, EPA notes that the final provisions maintain the previous approach that

chemical agents ''. . . facilitate the mitigation of deleterious effects or the removal of the pollutant from the water.''

A commenter stated that the definition of chemical agents should clearly delineate between chemical agents that are intended to be removed from the environment and those that are not. EPA believes that the NCP, as revised under this amendment, sufficiently delineates between chemical agents that are intended to be recovered from the environment and those that are not. The NCP addresses recovery of agents from the environment in multiple chemical agent and substances definitions (*e.g.,* surface washing agents, sorbents) and under § 300.910(h) *Recovery of Agents from the Environment.*

Commenters recommended that sinking agents be removed from the proposed definition of chemical agents. A commenter suggested that including a definition for sinking agents in the context of other agents that may be put on the NCP Product Schedule contradicts the Agency's stated policy against the use of sinking agents to treat oil spills. EPA agrees that sinking agents do not remove oil from the environment and that sinking agents should not be included in the definition of chemical agents. The finalized definition of chemical agents has been modified relative to the proposed version to remove sinking agents.

Dispersants—The Agency is revising the definition of dispersants to identify as such those substances that emulsify, disperse, or solubilize oil by promoting the formation of small droplets or particles of oil in the water column. The Agency acknowledges that the primary purpose of dispersants is to facilitate oil transfer from one area to another (*e.g.,* oil transferred from the water surface into the water column) or to maintain entrainment within the water column (*e.g.,* oil maintained in the water column from a subsurface discharge). Dispersed oil is then subject to transport by water currents and other fate and transport processes (*e.g.,* dissolution, biodegradation), which involves many site- and incident-specific factors. Irrespective of dispersant use, oil droplets may interact with suspended particulate material in the water column. For example, oil naturally dispersed in the water column (*i.e.,* untreated dispersed oil) may also interact with suspended particulate material.

A commenter stated that the proposed definition should not identify what dispersants are ''typically'' composed of because formula components will vary by intended primary use setting. EPA agrees that the definition of dispersants should not identify the typical composition of dispersants (*e.g.,* solvents, surfactants), not necessarily because formula components will vary by intended primary use setting, but to avoid the potential misinterpretation that dispersants are necessarily comprised of these components. Thus, EPA is amending the definition of ''dispersant'' in this final rule by adding ''. . . substances that emulsify, disperse, or solubilize oil by promoting . . .'' and removing ''. . . typically mixtures comprised of solvents, surfactants, and additives that promote . . .'' The final provision maintains the general approach in the current definition to recognize that dispersants are substances ''. . . that emulsify, disperse, or solubilize oil . . .'' by promoting the formation of small droplets or particles of oil in the water column. Furthermore, based on other comments regarding oil-mineral aggregates on the proposed sorbent definition, EPA is amending the definition of dispersants to add ''. . . or particles . . .'' to indicate that certain particulate materials may also act as dispersants. EPA also removed the phrase ''. . . by reducing the oil-water interfacial tension'' in order not to identify any specific process and to recognize that other processes may also result in dispersion of oil.

Sinking agents—The Agency is revising the definition of sinking agents to identify them as those substances introduced into an oil discharge to submerge the oil to the bottom of a water body. The former definition was ambiguous in distinguishing chemical agents (*e.g.,* dispersants) that may submerge oil below the water surface from substances that would sink oil to the bottom of the water body. The revision clarifies the distinction between sinking agents and other agents, such as dispersants, that do not intend to sink oil to the bottom of a water body but may have the incidental effect of causing some of the discharged oil to settle to the bottom of a water body. The Agency believes it is critical to distinguish between sinking agents, which are intended to sink oil as the primary mechanism of response, and dispersants, which are primarily intended to promote the formation of small droplets or particles of oil in the water column. The Agency continues to prohibit the use of sinking agents in the remediation of oil discharges in water because of their potential for causing adverse effects on benthic organisms vital to the food chain of the aquatic environment.

Commenters expressed concerns with the way that the proposed definition distinguished between submersion and sinking. The commenters stated that both submersion and sinking could cause harm to benthic organisms and make oil more difficult to remove; several commenters suggested a broader definition of sinking agents to include any agent that causes oil to submerge below the water surface in a given waterbody, retains oil beneath the water surface, and/or increases aggregation of oil-sediment particles beneath the water surface, even if the treating agents also qualify for other categories (*e.g.,* dispersants, solidifiers, sorbents). The Agency disagrees with the recommendations to modify the sinking agent definition as this would conflate the definitions of dispersants and sinking agents and would effectively work to prohibit the use of dispersants. The final action balances the potential for deleterious effects from dispersant use against their potential for reducing or mitigating the environmental impacts of an oil spill, through the consideration of site-specific conditions and within the context of all response options. Adding language that characterizes sinking agents as facilitating the transfer of oil from the water surface into the water column or retention of oil below the water surface would cause confusion with the definition of dispersants.

A commenter provided specific recommended language to edit the definition of sinking agents, which included removing the proposed phrase ''. . . deliberately for the purpose of submerging . . .''. Additionally, another commenter suggested that the Agency's use of the term ''deliberately'' in the definition is unworkable because it fails to specify whose intent is relevant. EPA agrees that the term ''deliberately'' presents challenges to interpreting intent. Therefore, based on public comment, EPA is removing the term ''deliberately'' from the sinking agent definition in this final rule.

Sorbents—Under the revised definition of sorbents, EPA identifies sorbents as inert and insoluble substances that readily absorb and/or adsorb oil or hazardous substances and that are not combined with or act as a chemical agent, biological agent, or sinking agent. Sorbents may be used in their natural bulk form or as manufactured products in for example particulate form, sheets, rolls, pillows, or booms. Sorbents are generally collected and recovered from the environment. The definition also

includes a list of materials of which sorbents may consist. These revisions simplify the definition by removing the definitions of absorption and adsorption that were embedded in the former definition of sorbents; this is appropriate because absorption and adsorption are generally recognized scientific terms and sorbents are not distinguished or restricted under Subpart J based on whether they absorb or adsorb oil. The revised definition also adds the qualifier ''natural'' to organic substances, indicating that organic substances that have been treated with other substances do not necessarily fall under this category of agents and should not be considered a sorbent absent being listed on the Sorbent Product List as provided in this rule. It also expands on and simplifies the examples by removing the references to the type of birds that feathers could come from, by adding bagasse to the examples for natural organic substances, and by adding clay to the examples for inorganic/mineral compounds. While sorbents are not listed on the NCP Product Schedule, a list characterizing these materials is included in § 300.915(g) and EPA considers the Sorbent Product List in § 300.915(g) to be a part of the statutory schedule addressed in 33 U.S.C. 1321(d)(2)(G).

Commenters replied to the Agency's request for comments on the qualifier phrase, ''that are generally collected and recovered from the environment.'' Some commenters requested that EPA remove the term ''generally'' or remove the phrase that sorbents are ''generally collected and recovered from the environment.'' Other commenters requested that sorbents be used with the intent of collecting and removing them from the environment. A commenter requested that the Agency clearly require that all sorbent materials must be recovered from the environment, and that sorbent use is not authorized in the event that the sorbents cannot be removed from the environment. EPA disagrees with comments that the phrase ''generally collected and recovered from the environment'' should be removed from the definition. EPA believes that the phrase recognizes and captures the expectation that sorbents are not intended to be left in the environment. EPA recognizes that on very limited occasions an OSC may make the determination to not recover a sorbent after consideration of factors such as the safety of response personnel and potential for greater harm to the environment if the sorbent material is recovered rather than left in place. Therefore, EPA retained the sentence ''Sorbents are generally collected and recovered from the environment'' in the amended definition but did move it to later in the provision in order to improve editorial flow and clarity. The OSC retains discretion not to authorize or direct the use sorbents if the OSC believes that sorbent use is inappropriate in light of incident-specific determinations.

EPA received a range of comments regarding particulate materials (*e.g.,* clay) and the definitions of sorbent, sinking agents, and dispersants. EPA recognizes that some materials may behave differently in the environment based, in part, on the size or configuration of the substance. EPA disagrees with comments that clay necessarily behaves like a sinking agent in all cases. To address concerns regarding particulate materials, EPA is amending the definition of sorbents to recognize potentially differing behaviors and to distinguish between sorbents and sinking agents. The final revisions to the definition of sorbents includes that these substances are ''. . . not combined with or act as . . . sinking agents.'' EPA recognizes that substances such as clay may be used as a sorbent, but also agrees with commenters that they should not act as a sinking agent. EPA believes it is appropriate to continue to allow substances such as clay to be listed as sorbents and used as a sorbent during a response, provided that they are done so in manner that prevents them from acting as a sinking agent (*e.g.,* contained in a buoyant boom). The Agency expects that the Administrative Record for a response would provide the basis for continued sorbent use under OSC oversight or direction, and the Administrative Record should address any potential concerns with sorbents being used as a sinking agent. EPA also recognizes that particulate materials may be manufactured of such configuration (*e.g.,* micro- or nanosized) that they are, or are near, neutrally buoyant and remain in the water column over an extended time period. EPA recognizes comments that particulate materials may promote dispersion by forming oil-mineral aggregates (OMAs) and agrees with commenters that such substances should be addressed as dispersants rather than sorbents. Substances intended for use in a manner similar to a chemical or biological agent listed on the NCP Product Schedule (*e.g.,* dispersants) should be classified similarly and subject to the same authorization of use procedures. The final rule clarifies that dispersants are substances that emulsify, disperse, or solubilize oil by promoting the formation of small droplets or particles of oil in the water column. This revised definition clarifies that substances that emulsify, disperse, or solubilize oil include particulate materials because they promote the formation of particles of oil (*e.g.,* OMAs). Particulate materials that are used in a manner similar to chemical dispersants are appropriately categorized as dispersants on the NCP Product Schedule and are subject to the same dispersant authorization of use procedures under § 300.910.

Surface washing agents—The Agency is revising the term ''surface washing agent'' to ''surface washing agents'' and modifying the definition. EPA changed the term from singular to plural to be consistent with the other agent definitions. The revised definition identifies surface washing agents as those substances that separate oil from solid surfaces (*e.g.,* beaches, rocks, metals, or concrete) through a detergency mechanism. The revised definition specifies that detergency mechanism lifts and floats the oil. The final definition is modified slightly from the proposed phrasing to clarify that the product and oil are generally to be collected and recovered from the environment with minimal dissolution, dispersion, or transfer into the water column to be consistent with similar phrases included in the sorbents and solidifiers definitions. EPA recognizes that on occasion an OSC may make the determination to not recover a surface washing agent after consideration of factors such as the safety of response personnel and potential for greater harm to the environment if the surface washing agent material is recovered rather than left in place (see 40 CFR 300.910(h)).

A commenter suggested that surface washing agents used in fully self-contained structures (*e.g.,* tank farms, dry-dock vessels, sand-cleaning machines) or in a manner that prevents run-off to water (*e.g.,* cleaning/wiping of vessel hulls by hand) need not be listed on the NCP Product Schedule or require approvals from the OSC or RRT before use. A commenter suggested including the phrase ''that are not likely to cause additional harm, either alone or in combination with oil, to public health or welfare or to the environment'' in the definition. EPA is not revising the definition to include this phrase. EPA believes that the NCP must retain flexibility to allow for environmental tradeoffs that take into consideration incident-specific conditions when determining what actions should be taken to immediately and effectively address an oil discharge.

(b) New Definitions

The Agency is adding several new definitions for terms that are used in the amendments to Subpart J. These definitions include basic terminology and are consistent with how the terms are generally understood by the scientific community.

Bioaccumulation—The Agency is establishing the definition of bioaccumulation, as proposed, to mean the process of accumulation of chemicals in the tissue of organisms through any route, including respiration, ingestion, or direct contact with the ambient or contaminated medium. The Agency is finalizing the definition of bioaccumulation from the proposed rule without any changes.

A commenter expressed support for separate definitions of bioaccumulation and bioconcentration. The Agency appreciates and recognizes the commenter's perspective that bioaccumulation includes multiple routes of exposures to pollutants (*e.g.,* including dietary or food chain), whereas bioconcentration only includes water-borne routes of exposure (*e.g.,* absorption across the gills).

Bioconcentration—The Agency is establishing the definition of bioconcentration, as proposed, to mean the accumulation of chemicals in the tissues of organisms from water alone.

A commenter expressed support for separate definitions of bioaccumulation and bioconcentration, as described above. The Agency is finalizing the definition of bioconcentration from the proposed rule without any changes.

Biodegradation—The Agency is establishing the definition of biodegradation to mean the process by which microorganisms metabolically decompose contaminants into biomass and smaller molecular compounds such as carbon dioxide, water, and end products.

Commenters suggested expanding the definition of biodegradation to include the possibility of partial biodegradation, which can result in more toxic intermediate products. The commenters stated that partial biodegradation is likely to occur in the environment versus controlled laboratory conditions. EPA recognizes that partial biodegradation may occur in the environment. Therefore, the Agency amended the definition of biodegradation in the final rule to replace the phrase ''. . . simpler compounds . . .'' with ''. . . smaller molecular compounds . . .''. EPA also removed the term ''innocuous'' in the final action to recognize that not all end products may be innocuous.

Biological agents—The Agency is establishing the definition of biological agents to mean microorganisms (typically bacteria, fungi, or algae) or biological catalysts, such as enzymes, that can enhance the biodegradation of a contaminated environment. EPA has slightly amended the definition of biological agent in this rulemaking to replace the phrase ''. . . able to . . .'' with ''. . . that can . . .'' to better reflect the intent of the definition.

A commenter recommended that the definition of bioremediation agents include a ban on agents that may result in the colonization of non-indigenous species. While EPA understands that microorganisms capable of degrading oil are ubiquitous in nature, the Agency is maintaining its prior approach in this rulemaking to recognize the addition of microorganisms as a potential bioremediation process. In general, the addition of cultured microorganisms, which may include non-indigenous species, may enhance biodegradation of a contaminant.

Bioremediation—The Agency is establishing the definition of bioremediation to mean the process of enhancing the ability of microorganisms to convert contaminants into biomass and smaller molecular end products by the addition of materials into a contaminated environment to accelerate the natural biodegradation process.

Commenters suggested expanding the definition to include the possibility of partial bioremediation, which can result in more toxic intermediate products. The commenters stated that partial bioremediation is likely to occur in the environment versus controlled laboratory conditions. EPA recognizes that partial biodegradation may lead to the formation of intermediate products. The Agency is amending the definition of bioremediation in this final rule to replace the phrase ''. . . simpler compounds . . .'' with ''. . . smaller molecular compounds . . .''. EPA also removed the term ''innocuous'' to recognize that not all end products may be innocuous.

Herding agents—The Agency is establishing the definition of herding agents to mean substances that form a film on the water surface to control the spreading of the oil to allow for oil removal. The definition for surface collecting agent was removed and replaced with the definition for herding agent to better reflect the common terminology used in industry for these agents.

A commenter stated that the Agency should add language to the ''herding agents'' definition which includes that they are not likely to cause harm, either alone or in combination with oil, to public health or the environment and that they are intended to be collected and recovered from the environment. EPA disagrees with these suggested edits to the definition of herding agents. The NCP addresses discharges of oil to the environment and response authorities must retain flexibility to allow for environmental tradeoffs that consider incident-specific conditions when determining what actions should be taken to immediately and effectively address the discharge. EPA is amending the definition of herding agents in the final rule by replacing the proposed phrase ''. . . across the water surface.'' with the phrase ''. . . form a film on the water surface . . .'' and adding the phrase ''. . . allow for oil removal.'' to better reflect the mechanism of action of herding agents.

Products—The Agency is establishing the definition of products to mean chemical or biological agents or other substances manufactured using a unique composition or formulation.

A commenter suggested that the proposed definition of products is incomplete because it only includes agents that may be listed on the NCP Product Schedule. Other commenters suggested that the definition of products should include anything that may be used to mitigate oil spills (*e.g.,* burning agents, ignition devices, synthetic sorbents, organic or inorganic substances that may be used in bulk form, and substances that are manufactured using a unique composition or formulation). EPA's definition for products is intended to clarify the difference between a specific product and an agent type or category under the NCP Product Schedule and the Sorbent Product List. EPA agrees that the definition of a product should recognize sorbents by adding the term ''other substances.'' The finalized definition clarifies the distinction between an agent category (*e.g.,* surface washing agent) or substance (*e.g.,* sorbent) from a product for which a manufacturer submits an application to the Agency for listing on the NCP Product Schedule or the Sorbent Product List. The Agency is not revising the definition of ''product'' to specifically include burning agents since they are already included in the definition of chemical agents. Furthermore, the Agency disagrees to add ''other spill mitigating devices'' as it would not accurately reflect the applicability of the regulatory provisions for the purposes of the NCP Product Schedule or the Sorbent Product List in this final action.

Solidifiers—The Agency is establishing the definition of solidifiers to mean substances that through a chemical reaction cause oil to become a cohesive mass, preventing oil from dissolving or dispersing into the water column. Solidifiers are generally collected and recovered from the environment. Solidifiers was not previously a specific product category on the NCP Product Schedule. The final rule amends the definition to recognize that solidifiers are ''generally'' to be collected, to recognize that the OSC has flexibility to consider factors such as the safety of response personnel and harm to the environment in making recovery determinations (see 40 CFR 300.910(h)).

A commenter requested that the Agency add language to the definition to explain that solidifiers have no real advantage over sorbents or mechanical recovery and that they have limited practicality, may cross-link or react with other substances, and require immediate removal from the environment. The commenter mentioned that there has been very limited effectiveness testing or recent studies on solidifiers. The commenter requested that the definition of ''solidifiers'' include additional limitations to specify conditions under which solidifiers may be used such as proximity to shore and quantity of oil. The Agency acknowledges the commenter's concerns; however, the Agency disagrees with the suggested edits. The definition is intended to convey the mechanism of action and to distinguish solidifiers from other chemical or biological agents. Subpart J does not state or imply that chemical or biological agents are preferred over other response options such as mechanical recovery devices. EPA notes that mechanical recovery devices, including skimmers, are outside the scope of this action. EPA believes that the circumstances surrounding oil discharges and the factors influencing the choice of response methods are many. In addition, the final revisions under § 300.910(g) provide that RRTs may require supplementary toxicity and efficacy testing, or to obtain data or information to address site, area, or ecosystem-specific concerns relative to the use of any chemical or biological agent. The Agency believes that the specific conditions under which solidifiers may be used, such as proximity to shore and quantity of oil, are better addressed through the authorization of use process found at § 300.910 *Authorization of Use.*

(c) Removed Definitions

Miscellaneous Oil Spill Control Agent (MOSCA)—The Agency is removing the definition for miscellaneous oil spill control agent (MOSCA). The MOSCA category was used as a catchall for all types of products that did not meet other agent definitions; it is being replaced with a number of new and/or revised definitions for types of agents. As the Agency adds new, more stringent testing requirements for listing products on the NCP Product Schedule, there is a need for more specific category definitions to assist manufacturers in determining which of those testing requirements apply to their products. Commenters supported the removal of the definition for MOSCA. A commenter specifically expressed support for the removal of the MOSCA category provided that a subcategory is included in the ''sorbents'' definition to account for the uniqueness of certain products among the other sorbents.

The Agency agrees with comments supporting the removal of the MOSCA category and the final action removes the category and definition of MOSCAs from the NCP. The Agency has identified product categories to be listed on the NCP Product Schedule and revised it accordingly. The MOSCA category is no longer necessary or appropriate and is being removed from the NCP through this final action. EPA does not believe that removing the MOSCA definition results in listed products automatically being reassigned to fall under the definition of another chemical or biological agent, or substance. The final revisions provide for the process to transition listed products from the current NCP Product Schedule to the new NCP Product Schedule as described in § 300.955(f).

Surface collecting agents—The Agency is removing the definition for surface collecting agent and replacing it with a new herding agent definition to better reflect the common terminology used in industry for these agents.

EPA did not identify comments on the proposed amendment specific to removing the definition for surface collecting agents.

C. Subpart J—Use of Dispersants, and Other Chemical and Biological Agents

1. General

EPA is amending § 300.900 by revising the title and paragraphs (a) and (c), and by adding paragraph (d) to reserve for later use. The revisions clarify that Subpart J addresses not only chemical agents, but also those agents that now fall under the new biological agent category. The revisions reaffirm the notion that Subpart J is not only comprised of an NCP Product Schedule of chemical and biological agents, but also includes testing requirements and authorization of use procedures. Consistent with current Subpart J regulatory requirements, the Agency is reserving a section for ''Releases of Hazardous Substances'' to take place of the current placeholder in § 300.905, which is being removed.

Some commenters on the proposed rule expressed support for the update to § 300.900, which clarifies the Agency's duties under the CWA, but noted that the Agency should specify waters and quantities where products can be used safely, highlighting the importance of the word ''safely.'' The Agency recognizes support to clarify that Subpart J includes the identification of the waters and quantities in which chemical and biological agents may be safely used. In this final action, EPA is amending the last sentence of the proposed regulatory text under § 300.900 to include the term ''safely'' as provided in CWA section 311(d)(2)(G)(iii) based on the comment received.

In addition, the Agency is clarifying that the statutory schedule as required by CWA section 311(d)(2)(G) includes the NCP Product Schedule, the Sorbents Product List, and 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. EPA is amending the regulation text at § 300.900, and throughout Subpart J, to clarify that it is the ''NCP Product Schedule'' which EPA updates periodically, in order to avoid confusion with the statutory use of the term ''schedule'' referred to in CWA section 311(d)(2)(G).

Some commenters requested additional clarification related to Administrator authority and expressed uncertainty regarding federal authority. Specifically, these commenters indicated a need for additional clarity regarding the role of the Agency versus that of the U.S. Coast Guard or other public or private entities involved in spill response. While CWA section 311(c) provides statutory authority for certain removal actions and identifies the agencies that are to provide the federal OSC (which may include EPA or U.S. Coast Guard), it does not provide authority to revise the NCP and does not govern how the NCP regulates response actions. The authority to establish, revise, and maintain the NCP is addressed in CWA section 311(d), which has been delegated to the EPA Administrator in Executive Order 12777 (56 FR 54757, October 22, 1991). EPA will continue to exercise its authority

over the NCP, and CWA section 311(c) responses remain subject to NCP provisions as per Congressional direction at CWA section 311(c)(1), which provides that the President ''shall, *in accordance with the National Contingency Plan* and any appropriate Area Contingency Plan, ensure effective and immediate removal of a discharge . . . .'' (emphasis added).

2. Authorization for Agent Use

Section 300.910 sets forth the provisions for the authorization of use of products on the NCP Product Schedule in response to oil discharges. EPA is adding an introductory paragraph to § 300.910 that confirms, consistent with the intent of the NCP, that use of chemical or biological agents in response to oil discharges must be authorized by an OSC in accordance with Subpart J. In the final rule, EPA did not include the phrase ''. . . to waters of the U.S. or adjoining shorelines . . .'' under the opening clause to § 300.910 *Authorization for agent use* since the scope of Subpart J is already addressed under § 300.900. Unauthorized use can result in violations of sections 301 and 311 of the CWA. Section 301(a) makes unlawful ''the discharge of any pollutant by any person,'' except in compliance with certain provisions of the CWA. In addition, section 311(b) establishes penalties for persons who fail or refuse to comply with any regulation issued under section 311(j) of the CWA.

Commenters suggested that the Agency is already required by Congress to establish a list of products that may be used for response within navigable waters of the United States and EPA is therefore required to approve these products for use in response activities. EPA disagrees with the characterization that the Agency is required by Congress to establish a list of products such that those products are automatically authorized for use within the jurisdictional waters of the United States by their listing. The CWA provides the President with the authority to determine what products, if any, may be used in what waters, and in what quantities. The NCP Product Schedule addresses the chemical and biological agents that may be authorized for use upon consideration of both the appropriateness of their use in the impacted waters and the amount of product that may be used safely in response to the unique nature of each oil discharge. EPA does not believe a ''one size fits all'' approach to emergency response is appropriate or prudent. A ''one size fits all'' approach could lead to significant under- and over-use of products that could exacerbate oil discharges absent consideration of all the specific conditions of each individual discharge. The final action provides for flexibility to evaluate the specific nature of an oil discharge when considering the authorization of a chemical or biological agents.

(a) Use of Agents Identified on the NCP Product Schedule or Use of Burning Agents on Oil Discharges Addressed by a Preauthorization Plan

The Agency is revising § 300.910(a) to address the preauthorized use of chemical and biological agents identified on the NCP Product Schedule. The Agency reorganized paragraph (a) to provide greater clarity about RRT and Area Committee responsibilities. The revisions to § 300.910(a) clarify the process for preauthorization, the responsibilities of all involved parties, and the factors to consider during the preauthorization process, including the authorization for the use of agents by the OSC at the time of a discharge. The reorganized paragraph (a) also makes the regulatory text easier to read and follow. The Agency added procedure and review requirements at § 300.910(a)(3) intended to ensure preauthorization plans are maintained so they are up to date. The finalized provisions also address recommendations from the *National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling* report and EPA's Inspector General report titled *Revisions Needed to National Contingency Plan Based on Deepwater Horizon Oil Spill* (Report #11–P–0534). The final revisions do not change the NCP's fundamental policies regarding roles of Federal, state, and local representatives involved in planning for and responding to an oil discharge, but rather clarify the regulatory requirements and further explain the responsibilities for each party.

Some commenters expressed concerns that the proposed rule focused on preauthorization and suggested that the focus should instead be on consultation and concurrence. The Agency recognizes that the RRTs and/or Area Committees must consider whether preauthorization of chemical and biological agents is appropriate, while maintaining the existing concurrence and consultation roles on authorization of use. The revised preauthorization provisions provide greater clarity on the factors the RRT must address and those factors they should consider in developing a preauthorization plan. Department of the Interior (DOI) and Department of Commerce (DOC) natural resource trustees retain their concurrence role when approving preauthorization plans. DOI and DOC natural resource trustee concurrence is appropriate as preauthorization plans are developed during the contingency planning phase, when there is sufficient time to identify and resolve natural resource concerns.

A commenter advocated for clarification of ''mixed use'' products, indicating that some of the products on the NCP Product Schedule have multiple uses and that during preauthorization planning all potential uses of an agent or product should be factored into the planning decisions. EPA recognizes that a ''mixed use'' product that meets the definition of more than one chemical or biological agent category may raise authorization of use issues when (1) listed under more than one chemical or biological agent category or (2) listed under one chemical or biological agent category but still meets the definition of another product category because of an alternate mechanism of action. The listing of a product on the NCP Product Schedule should not cause confusion on how that product is authorized at the time of an incident. Noting these concerns, the final action allows for the evaluation of products on an individual basis and informs the decision on whether and under which category to list a product on the NCP Product Schedule.

Some commenters expressed concern or requested clarification on the roles and authorities of RRTs and Area Committees in preauthorization planning. Area Committees' roles and authorities under CWA section 311(j)(4) are outside the scope of this rulemaking. Nonetheless, CWA section 311(j)(4) provides the roles of the Area Committees in planning for the use of dispersants, including for Area Contingency Plans to list the equipment (including firefighting equipment), dispersants or other mitigating substances and devices, and personnel available to an owner or operator, Federal, State, and local agencies, and tribal governments, to ensure an effective and immediate removal of a discharge, and to ensure mitigation or prevention of a substantial threat of a discharge. EPA notes that not all spill mitigating equipment, substances or devices may be available or appropriate in certain planning areas. EPA believes that to create the best possible response system, it is important that the regional-level and area-level contingency planning efforts of the RRTs and Area Committees, respectively, are closely coordinated. RRTs and Area Committees

should work together to develop mutually acceptable preauthorization plans, as appropriate. The standing RRTs also have responsibilities for oil spill contingency planning on a regional basis and can facilitate consistency among Area Committees. In instances where the RRT and Area Committees exist as separate entities, several RRT representatives likely also serve on the Area Committees for that region, allowing for familiarity with the roles and responsibilities of each entity. In instances (*e.g.,* in the inland zone) where RRTs fulfill the role of the Area Committees, they are thus responsible for both regional and area-level contingency planning (see 57 FR 15197, April 24, 1992). EPA agrees that in the development of preauthorization plans, RRTs should either provide Area Committees with an opportunity to provide input or should consider relevant information in Area Contingency Plans (ACPs) (*e.g.,* Fish and Wildlife and Sensitive Environments Annex). The RRTs and Area Committees should identify all potentially affected biological resources and their habitats likely to be negatively impacted, and not only those that are expected to benefit.

Another commenter noted that not all regions have a use for preauthorization planning, suggesting that only regions with use for these plans should be required to develop planning materials. While RRTs and ACs must consider whether having a preauthorization plan is appropriate, the final action does not mandate preauthorization plans to be developed or preauthorization of any chemical or biological agents. EPA modified the proposed text to remove the phrase ''in a preauthorization plan'' to avoid a misinterpretation that § 300.910(a) requires that RRTs develop preauthorization plans. EPA also amended the final action under § 300.910(a) to further clarify the provision is to consider whether ''preauthorization of'' the use of chemical and biological agents is appropriate.

The final action provides that an OSC may authorize the use of agents listed on the NCP Product Schedule, or the use of burning agents, for the purpose for which they were specifically listed without obtaining the incident-specific concurrences and without the natural resource trustees consultations described in § 300.910(b). Some commenters supported approval of preauthorization plans by natural resource trustees. EPA amended the final provision to clarify that the OSC does not need to obtain the incident-specific natural resource trustees consultations described in paragraph (b) of this section when authorizing the use of certain agents under § 300.910(a) by adding the phrase ''. . . and without the natural resource trustees' consultations . . .'' described in paragraph (b) of this section. The final provisions provide for DOI and DOC natural resource trustees concurrence on preauthorization plans rather than consultations. EPA continues to believe that DOI and DOC natural resource trustee concurrence is more appropriate than consultation during the contingency planning phase, when there is sufficient time to identify and resolve natural resource concerns while considering whether preauthorization is appropriate. Consistent with previous preauthorization approval requirements, the final revisions provide for DOI and DOC natural resource trustee approval, approval with modification, or disapproval of preauthorization plans.

The final action provides that chemical or biological agents on the NCP Product Schedule may only be authorized for the purpose for which they were specifically listed. EPA amended the final provision to replace the phrase ''. . . intended purpose . . .'' with ''. . . for the purpose for which they were specifically listed . . .'' for greater clarity. This revision was made in response to a commenter's concern that chemical or biological agents may only be used for their intended use within a specific category (*e.g.,* an agent that is listed as a surface washing agent cannot be authorized for use as a dispersant).

In the finalized provision, EPA also made some editorial changes to the proposed text for increased clarity.

Preauthorization Plan Development. At § 300.910(a)(1), EPA is finalizing requirements for the preauthorization plan's site-specific factors. While the revisions simplify the language and clarify the requirements, the Agency kept in place the fundamental elements that were contained in the former § 300.910(a) text. The provision states that preauthorization plans must, at a minimum, specify limits for the quantities and duration of use, and use parameters for water depth, distance to shoreline, and proximity to populated areas for discharge situations identified in which agents may be used. The Agency believes that clearly stating the use parameters in a preauthorization plan will make it easier for planners to address concerns of preauthorizing agent use and in turn for responders to authorize their use. In meeting these provisions, the preauthorization plans should document how both regional and logistical factors were addressed when establishing use limits and parameters for chemical and biological agents. Regional factors include the likely sources and types of oil that might be discharged, various potential discharge scenarios, and the existence and location of environmentally sensitive resources or restricted areas that might be impacted by discharged oil. Logistical factors include inventory, storage locations and manufacturing capability of available agents, availability of equipment needed for agent use, availability of adequately trained operators, and the availability of appropriate means to monitor agent use in the environment.

Several commenters requested clarification on the need to specify limits to the quantities and duration of agent use and the proposed use parameters for water depth, distance from shoreline, and proximity to populated areas; commenters noted that it is not realistic to predict all scenarios. EPA recognizes that oil discharges may occur under various scenarios. EPA does not envision that preauthorization plans would address every scenario imaginable, but instead will only address those specific circumstances under which RRT member agencies with roles and responsibilities under the NCP agree that an OSC does not need to obtain specific concurrence and consultations under § 300.910(b) in effectuating a preauthorized action. For example, a potential oil discharge scenario may involve a response that occurs over several days. The use of a chemical or biological agent (*e.g.,* surface dispersant use) during the initial response phase may be preauthorized in a manner such that any use beyond that initial response phase would be subject to § 300.910(b) and in limited circumstances subject to § 300.910(b). While the preauthorization plan must specify limits for the quantities and the duration of use, and use parameters for water depth, distance to shoreline, and proximity to populated areas, RRTs may wish to include other criteria in defining the scope of the preauthorization plan. Based on public comments, EPA is amending the final provisions to reflect that the limits for the quantities and the duration of use, and use parameters for water depth, distance to shoreline, and proximity to populated areas are the minimum criteria that RRTs must specify by inserting the phrase ''at a minimum'' before the specific criteria in the regulatory text.

Commenters supported considering environmental tradeoffs in determining response options that provide the greatest environmental protection by

identifying the affected biological resources and their habitats likely to be negatively impacted, as well as those that are expected to benefit. For example, a commenter suggested that the Agency rely upon the Net Environmental Benefit Analysis (NEBA) framework as a foundation for preauthorization planning, as opposed to artificially setting limits on dispersant use. EPA's understanding is that ''NEBA'' is a term used by some stakeholders in the response community to engage with various interested parties to consider available response options, including mechanical recovery. EPA also acknowledges that different stakeholders have varying perspectives on what factors beyond environmental considerations (*e.g.,* economic, health, and safety) are included in a NEBA, or what response options may provide the ''greatest environmental protection.'' While there is no prohibition on the use of environmental tradeoff methodologies, the use of such methodologies must conform with all applicable statutory and regulatory authorities.

A commenter disagreed with the use of the word ''likely'' in reference to the sources and types of oil that may be spilled and suggested keeping ''potential'' instead, as a more conservative term that is more appropriate for preauthorization planning. EPA believes the phrase ''likely sources and types of oil'' better focuses on the sources and types of oil specific to the preauthorization plan for which agents may be used. While RRTs and Area Committees should consider ''likely sources and types of oil'' in developing preauthorization plans, the Agency believes they should also have the flexibility to consider other potential sources and types of oil, as appropriate, and the final revisions do not preclude RRTs and Area Committees from considering them. In considering the use of the term ''potential'' as offered by the commenter, EPA decided to clarify the phrase ''various discharge scenarios'' as used in the proposed rule. EPA recognizes that when developing a preauthorization plan, Area Committees and RRTs should not misinterpret ''various discharge scenarios'' to only mean past incidences but should also consider potential discharges scenarios. While RRTs and Area Committees should consider past discharge scenarios, the Agency believes they should also have the flexibility to consider potential discharge scenarios. In this respect, EPA agrees with the commenter that the term ''potential'' is more appropriate and is amending the phrase in the regulatory text to include ''potential''. EPA believes the revised phrase ''various potential discharge scenarios'' more accurately reflects EPA's intent.

Some commenters expressed concern or requested clarification on the roles and authorities of RRTs and Area Committees in preauthorization planning. EPA agrees that in the development of preauthorization plans, RRTs should either provide Area Committees with an opportunity to provide input or should consider relevant information in ACPs (*e.g.,* Fish and Wildlife and Sensitive Environments Annex). The RRTs and Area Committees should identify all potentially affected biological resources and their habitats likely to be negatively impacted, and not only those that are expected to benefit. EPA amended the final provision to ensure that Area Committees are involved in preauthorization plan development. EPA notes that the broader area contingency planning provisions are established under § 300.210(c) and are outside the scope of this action.

Preauthorization Plan Approval. At § 300.910(a)(2), EPA is finalizing requirements related to the roles and responsibilities involved in reviewing and approving preauthorization plans, and procedures if preauthorization plan approval is withdrawn. The final action retains the concurrence requirement for preauthorization plans from the former version of the rule; given that preauthorization plans are developed during the contingency planning phase, DOC and DOI natural resource trustee concurrence is preferred over just consultation because it provides for sufficient time to identify and resolve natural resource concerns.

Commenters suggested that the preauthorization planning process be completed under mandatory timelines, including a suggestion that plans must be reviewed within a 90-day time frame, or that the Agency otherwise stipulate that the plan cannot be blocked from being used by an Area or Region. EPA does not believe that it is appropriate to establish specific deadlines for the review and approval of preauthorization plans because both the Area Committees and RRTs coordinate their approach to reviewing and revising existing preauthorization plans and determine what information they may need to amend their preauthorization plan, as appropriate. EPA believes RRTs and ACs should begin their reviews as expeditiously as possible where preauthorization plans exist, but they also must be afforded flexibility in implementing the final revisions to ensure preauthorization plans are up-to-date when implemented in the event of a discharge.

To be consistent with terminology for preauthorization plan approvals, EPA is revising the provision in the final action to substitute the phrase ''withdrawal of approval from a preauthorization plan . . .'' for ''withdrawal of concurrence . . .'' The amended rule offers specific procedures to follow should an authorizing agency decide to withdraw their approval from a preauthorization plan: the Area Committees and RRTs must address the withdrawal of approval from the preauthorization plan within 30 days of the withdrawal, allowing an opportunity to address the concerns. Additionally, the RRT must notify the National Response Team (NRT) of the final status of the preauthorization plan within 30 days from withdrawal. The absence of an approved preauthorization plan means authorizations for agent use are to be conducted in accordance with paragraph § 300.910(b) or in limited circumstances under § 300.910(d). Therefore, the Agency believes that the phrase ''the preauthorization plan becomes invalid and the authorization of use for chemical or biological agents must be performed according to paragraph (b)'' is unnecessary and redundant and is striking it from the final provision. The Agency continues to believe that preauthorization plans serve as a valuable advanced planning tool that supports decision making, and strongly encourages the resolution of any withdrawal of approval in a manner that addresses concerns raised.

Commenters expressed concerns over the potential impact of allowing for withdrawal of preauthorization plan approval. EPA disagrees that the ability to withdraw may incentivize the development of preauthorization plans with no intent of maintaining concurrence during a response. EPA also disagrees that the withdrawal of approval from a preauthorization plan subverts the OSC's authority to use dispersants and that this provision should be removed. RRT member agencies who have responsibilities in approving preauthorization plans have always had the discretion to withdraw their approval at any time. An OSC may still authorize the use of dispersants and other agents outside of an approved preauthorization plan in accordance with § 300.910(b) or in limited circumstances under § 300.910(d). Case-by-case authorization of use under § 300.910(b) is an appropriate and timely process to authorize the use of dispersants and other agents and should not delay response operations such as

the deployment of mechanical recovery. In contrast, restricting the flexibility to withdraw approval from a preauthorization plan could serve as a disincentive to approve a preauthorization plan or result in limiting the plan's scope and lead to more frequent requests for authorization by OSCs under § 300.910(b). EPA disagrees that the preauthorization plan should stay in effect for 30 days after withdrawal of approval while allowing RRTs and Area Committees to address the withdrawal. A withdrawal likely signals concerns amongst at least one of the approving bodies with actions or activities that had been preauthorized. The final provisions provide a 30-day timeframe for the RRT to notify the NRT of the status of the preauthorization plan after any such withdrawal. EPA believes that RRTs and Area Committees are likely to be aware of concerns prior to withdrawal of approval from a preauthorization plan, can work to resolve any perceived differences prior to any withdrawal, and are not prohibited from entering into new preauthorization plans addressing the same or similar areas in the future. For an active incident where chemical and biological agents have been authorized for use under a preauthorization plan, EPA encourages RRT member agencies with approval roles to work with the RRT to promptly resolve concerns and avoid potential withdrawal of plan approval during a response.

Several commenters suggested a need for public input and notification during the preauthorization plan approval process, including a requirement for public notification following the withdrawal of concurrence. Another commenter recommended a formal public review and comment period on each preauthorization decision, recommending that the RRTs and Area Committees should be required to provide a written peer-reviewed scientific and technical study to support any preauthorization plan, and provide a 60-day public review and comment period. EPA disagrees that the RRTs and Area Committees should be required to provide a written peer-reviewed scientific and technical study to support any preauthorization plan, or that they should provide a 60-day public review and comment period or formal public review and comment period on each preauthorization decision. The Agency believes that the RRTs and Area Committees should have the flexibility to tailor preauthorization plans to their regional needs. While EPA recognizes the benefits of public feedback on preauthorization plans including independent scientific input, the Agency does not believe it should be a mandatory requirement. Subjecting preauthorization plans to an external peer-review process may limit RRTs' and Area Committees' ability to utilize preauthorization plans. Nonetheless, public and private stakeholders may provide input, such as relevant scientific data and information, in area and regional contingency planning activities that are open to public participation, and RRTs and Area Committees retain flexibility to seek public comment or input on any preauthorization plan in accordance with applicable statutes and regulations if they believe such participation is warranted. EPA notes that the amendments to Subpart J include a public notification provision under § 300.910(i) *Reporting of Agent Use* to notify the public on chemical and biological agents used during a response and to provide certain required information.

In the finalized provision, EPA also made some editorial changes to the proposed text for increased clarity in addition to the specific changes described above.

Preauthorization Plan Reviews. At § 300.910(a)(3), EPA is finalizing new requirements related to the review and revision, if needed, of preauthorization plans. The review requirement is intended to ensure that preauthorization plans are actively maintained and updated to reflect revisions to the NCP Product Schedule. A periodic review, following a regular timeframe, is expected to ensure that the preauthorization plan is consistent with any revisions to the NCP Product Schedule, and also with revisions to ACPs, facility, and vessel response plans. The provision specifically requires reviews to be conducted at a minimum, after a major discharge (a ''major discharge'' means a discharge of more than 10,000 gallons of oil to the inland waters or more than 100,000 gallons of oil to the coastal waters) [3] or after a Spill of National Significance (SONS) relevant to the preauthorization plan area; to address revisions of the NCP Product Schedule impacting chemical or biological agents that may be individually listed within a preauthorization plan; and to reflect new listings of threatened and/or endangered species applicable to the preauthorization plan area. Review is to be done by the EPA RRT representative, the DOC and DOI natural resource trustees, and the RRT representative from the state(s) with jurisdiction over the waters of the area to which a preauthorization plan applies.

Several commenters recommended that additional entities should be able to participate in the review or comment process during the preauthorization plan review cycle (*e.g.,* local and tribal governments, the Occupational Safety and Health Administration (OSHA), Department of Health and Human Services (DHHS), and the public). EPA reiterates that all members of the ACs and RRTs will be afforded an opportunity to provide input during a review of a preauthorization plan. However, only the RRT representatives from EPA, the state(s) with jurisdiction over the waters of the area to which the plan applies, and the DOC and DOI natural resource trustees will have the authority to approve, disapprove, or approve with modification any revisions to an existing preauthorization plan. This approval process is consistent with the authorization procedures contained in the former § 300.910(a) and should minimize the time necessary for RRT approval of any amendments to an existing preauthorization plan. EPA amended the final provision by adding the phrase ''The RRT in consultation with the Area Committee(s) . . .'' to provide that review of preauthorization plans are coordinated with the applicable ACs so that ACs may amend relevant ACPs, as appropriate.

The proposal would have required plans to be reviewed at least every five years. Commenters provided a range of feedback on this proposed timeframe. EPA recognizes that some commenters supported a five-year review cycle, while others suggested shorter, longer, or no timeframes. As stated in the preamble to the proposed rule, a five-year review cycle is consistent with facility response planning requirements. EPA believes the five-year review process has worked well for facility response planning and believes preauthorization plans should be reviewed and revised in a similar fashion. While EPA still believes that a five-year review cycle is a reasonable time frame, the Agency also agrees with commenters that an alternative timeframe may be appropriate based on regional circumstances. Based on comments, EPA is amending the timeframe for preauthorization plan from five years to a regular timeframe established by the RRT and documented in the plan. Under the revised provision, the Area Committees and RRTs must still periodically review, and revise as needed, preauthorization plans. However, the Area Committees and RRTs are to establish the timeframe and document that timeframe in the

[3] See 40 CFR 300.5 ''Size classes''.

plan. The Area Committees and RRTs should also provide to the public the rationale for establishing said timeframe. EPA believes the revised provision is consistent with recommendations in the *National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling* report and EPA Inspector General report: *Revisions Needed to National Contingency Plan Based on Deepwater Horizon Oil Spill* (Report No. 11–P–0534) for periodic reviews of contingency plans. The Agency recognizes that development of preauthorization plans can be resource intensive; however, once developed, a periodic review, and revision as needed, should require much less effort. EPA disagrees that it is overly burdensome for RRTs to periodically review, especially with the revised provision to provide additional flexibility to the RRTs to establish and document their own review schedule.

EPA also made other changes to the proposed text based on comments received. Several commenters suggested additional triggering events for preauthorization plan review. The Agency agrees that changes other than the trigger events specifically listed in the revised rule may impact the conditions under which the use of chemical and biological agents is preauthorized. EPA amended the final provision to clarify that the triggering events are minimum criteria by including the phrase ''Reviews must also be conducted in any affected region, at a minimum . . .''. Some other commenters stated that reviews should be required only after major NCP Product Schedule listing changes to agents that may be used in the preauthorization plan area, as opposed to smaller less significant administrative changes in the NCP Product Schedule. The final provisions provide for preauthorization plans to be reviewed to address revisions to the NCP Product Schedule ''impacting chemical or biological agents that may be individually listed within a preauthorization plan.'' The revision is intended to avoid confusion with other, non-substantive changes to the NCP Product Schedule. EPA also amended the final provision to add the phrase ''. . . relevant to the preauthorization plan area; . . .'' to clarify the provision applies to the relevant RRT. The amendment also avoids misinterpretation that an RRT not impacted by a major discharge or by a Spill of National Significance (SONS) would be required to review their preauthorization plan as a result of events outside their region. Similarly, EPA amended the final provision by adding the phrase ''. . . applicable to the preauthorization plan area'' to clarify the applicability of the provision to the relevant RRT and to avoid confusion that new listings of threatened and/or endangered species in one or more regions requires all RRTs to review their preauthorization plans.

(b) Use of Agents Identified on the NCP Product Schedule or Use of Burning Agents on Oil Discharges Not Addressed by a Preauthorization Plan

The Agency is revising § 300.910(b) to address the use of chemical or biological agents identified on the NCP Product Schedule or the use of burning agents in spill situations that have not been addressed in preauthorization plans. The revisions clarify the authorities and responsibilities of relevant parties and the factors to consider when authorizing the use of agents in these situations. The revisions also clarify that the provision applies to burning agents as well as products that are listed on the NCP Product Schedule. The revisions to Subpart J do not change, from the former rule provisions, the Agency's fundamental policies regarding the roles of Federal, state, Tribal, and local representatives involved in an oil discharge response. The revisions maintain from the former rule the OSC's authority to authorize the use of chemical or biological agents on the oil discharge; the concurrence of the EPA representative to the RRT and, as appropriate, the concurrence of the RRT representatives from jurisdictional states; and the requirement for consultation with the DOC and DOI natural resource trustees.

As with paragraph (a), the final provisions under paragraph (b) specify the parameters that must be considered by the OSC for authorizing agent use on a case-by-case basis. Similar to preauthorization plans, the scope of the case-by-case authorization may include other criteria. EPA is amending the final provisions, relative to the proposal, to reflect that the parameters for the use of agents, including the quantities requested to be authorized, the duration of use, the depth of water, the distance to shoreline and proximity to populated areas, are the *minimum* criteria OSCs must specify by inserting the phrase ''for their authorization request to the RRT, at a minimum'' in the final regulatory text. The Agency is also replacing the phrase ''. . . to be used . . .'' with ''. . . requested to be authorized . . .'' to avoid confusion that the OSC must use the entirety of the requested quantities, rather than not exceeding the quantities authorized by the RRT. The Agency also specifies that OSCs should address factors such as environmentally sensitive resources or restricted areas that might be impacted, agent inventory and storage locations, agent manufacturing capability, availability of equipment needed for agent use, availability of adequately trained operators and appropriate means to monitor agent use in the environment.

Some commenters, for various reasons, opposed the use of any agents if the agents were not approved in a preauthorization process, even if they are listed on the NCP Product Schedule. EPA disagrees with commenters that agents should not be authorized for use if they are not covered under an approved preauthorization plan. EPA also disagrees that case-by-case authorization under § 300.910(b) provides a lesser standard for authorization. EPA notes the time critical nature of oil discharge responses and that the circumstances surrounding every potential discharge situation are not foreseeable or lend themselves to pre-planning. Not having a preauthorization plan approved by relevant RRT Agencies does not preclude the RRT or OSC from considering chemical or biological agent use for response during planning discussions. However, neither an approved preauthorization plan under § 300.910(a) nor case-by-case authorization under § 300.910(b) provide for a specific authorization outcome. Authorization of use determinations regarding chemical or biological agents are made for each individual discharge with consideration of the incident specific conditions and must be consistent with CWA section 311(d)(2)(G) and the Subpart J regulations. EPA believes there are multiple opportunities through regional and area contingency planning and from provisions included in the final action that RRTs may use to support case-by-case decision making. Contingency planning processes (*e.g.,* RCPs, ACPs, and vessel and facility response plans) may inform whether the use of chemical or biological agents is appropriate, including during case-by-case authorization under § 300.910(b). Separate from the regional and area contingency planning requirements described in the NCP, EPA acknowledges the benefits from advanced planning to support expedited decision making. The Agency recognizes that incident-specific authorization (*i.e.,* case-by-case authorization) for discharge situations

not covered by preauthorization plans may benefit from planning in advance to support expedited decision making. The final action supports contingency planning efforts by establishing provisions for RRTs to gather supplementary toxicity and efficacy testing, monitoring, or to obtain available data or information relative to the use of a chemical or biological agent (see § 300.910(g)). RRTs may need additional testing or information for situations that fall under § 300.910(b).

Some commenters advocated for EPA to require concurrence from natural resource trustees rather than consultation under § 300.910(b). Section 1011 of the Oil Pollution Act (OPA) states that ''*The President shall consult with the affected trustees designated under section 1006 on the appropriate removal action to be taken in connection with any discharge of oil.*'' Executive Order 12777 delegates this responsibility to the OSC. EPA believes the consultation requirement under § 300.910(b) is consistent with statutory requirements under OPA and maintains the approach of consultations with DOI and DOC natural resource trustees in the final provisions. It is important to note that consultation with the trustees does not mean that the OSC must obtain the concurrence of the trustees. EPA recognizes the decision to use a chemical or biological agent is highly dependent upon specific circumstances, locations, and conditions which must be assessed by the OSC and relevant RRT member agencies. The EPA and the state RRT representative(s), and DOC and DOI natural resource trustees, are in a unique position to understand local conditions and to collect and coordinate quickly the necessary local information.

Several commenters addressed the proposed removal of the term ''when practicable'' from the former rule text regarding consultation with the DOC and DOI. Some supported the removal of this language, stating that consultation and concurrence should always be pursued during case-by-case response decision making, since the situations may present unique challenges. Other commenters opposed the removal of the term ''when practicable'' and recommended leaving the language as is, asserting that it has worked well for years and that continued flexibility in the approval process is warranted. Commenters suggested that delays in discharge mitigation may occur when waiting for consultations, and that EPA should establish a consultation time limit. The Agency believes that the case-by-case decision making should include consultations with natural resource trustees since these discharge situations may present unique challenges when selecting a response option that involves chemical or biological agents. EPA also notes that OPA 1011 (33 U.S.C. 2711) provides for consultations with the affected trustees on the appropriate removal action to be taken in connection with an oil discharge. Furthermore, § 300.305(e) provides that the OSC shall consult with the affected trustees on the appropriate removal action to be taken. EPA disagrees with concerns that seeking natural resource trustee input could result in delays in the use of a chemical or biological agent. While EPA supports timely decision making, it does not interpret timely decision making to necessarily mean concurring with an OSC request to authorize the use of a chemical or biological agent; consultation can allow for a more immediate exchange of information and ideas when addressing a time-critical response. EPA disagrees with establishing a consultation timeframe (*e.g.,* 36 or 48 hours) for natural resource trustees and notes that it is contrary to the intent of seeking input on a removal action (*e.g.,* chemical agent use) prior to its use. While the Agency recognizes the time-critical nature of decision making during a response, advances in communication technology (*e.g.,* smart phones, email) provide OSCs with increased capabilities to communicate quickly. The Agency believes it is reasonable to expect an OSC to be able to notify and explain the circumstances requiring use of the certain agents to natural resource trustees in a timely manner. The final revisions to § 300.910(b) include removing the phrase ''when practicable'' with respect to consultation with the DOC and DOI natural resource trustees. EPA believes that the final revisions to Subpart J better align with the statutory and regulatory provisions.

A commenter supported the provision to authorize only products that are appropriate and used for their intended purpose under § 300.910(b). To provide additional editorial clarity, the revised provision replaces ''. . . chemical or biological agents identified on the Schedule for their intended purpose . . .'' with ''. . . for the specific purpose for which they were listed . . .''

A commenter expressed opposition to the requirement in § 300.910(b) to document the parameters for use of agents when there is not a preauthorization plan, emphasizing the need for quick decision making, noting that the information is already required elsewhere (33 CFR parts 154 and 155) or unnecessary at the time when action is required. Another commenter recommended revisions to the rule text which would increase the specificity of these parameters. While EPA supports timely decision making, EPA does not interpret timely decision making to be inhibited by documentation requirements that both inform RRT Agencies with roles and responsibilities under the NRT for chemical and biological agent use and support the OSC's decision making. Furthermore, EPA recognizes the request that § 300.910(b) increase the specificity of the parameters for the use of products. EPA agrees that site-specific factors are an important consideration when authorizing the use of a chemical or biological agent. For example, environmental characteristics such as local ocean water circulation patterns may affect oil transport and therefore influence whether dispersants are authorized for use, and if so, to what extent. Even within a chemical agent category (*e.g.,* dispersants), environmental conditions may vary locally, if not seasonally. EPA agrees that such information, if available, should be documented during case-by-case authorization of use. However, there may be several site-specific factors to consider where such information may be unavailable; the fact that information is unavailable, including assumptions used in lieu of unavailable information, should also be documented. EPA believes the relevant Agencies should be afforded flexibility in considering relevant factors when authorizing chemical and biological agents and to tailor the scope of the authorization with consideration of site-specific conditions. EPA does not believe that it is appropriate or feasible to include all potential site-specific information within the regulation. Rather, relevant site-specific factors to consider during case-by-case authorization are more appropriately addressed through development of guidance materials as appropriate, as well as through informed decision making.

A commenter requested that EPA provide notification within 24 hours of spills and product use to health care providers and the public, in the language(s) spoken in the impacted region. The final action includes new provision under § 300.910(i)(2) that requires the OSC to provide notification to the public in support of §§ 300.135(n) and 300.155(a) and (b). Under §§ 300.135(n) and 300.155(a) of the NCP, the OSC should ensure all appropriate public and private interests are kept informed and that their

concerns are considered throughout a response, to the extent practicable. However, EPA did not include a specific requirement to provide the notification in the language(s) spoken in the impacted region. The reporting provision does not preclude including public notification in different languages and EPA encourages consideration of impacted communities when communicating response actions, including developing materials in languages understood by local communities. However, it is impractical to require an OSC to provide notification in all language(s) spoken in the impacted region during an emergency response where chemical or biological agents may be authorized as the Agency cannot predict where and when an oil discharge occurs. The OSC retains discretion to provide public notification in additional languages if the OSC determines it to be appropriate.

A commenter stated that changing the language in this section, from ''navigable waters threatened'' to ''waters and adjoining shorelines threatened'' creates additional barriers to use dispersants and limits OSC actions. Another commenter stated that the proposed updates conflict with E.O. 12777 and the CWA because they do not distinguish between coastal and inland zones for planning and operational decision making reserved for the area where the OSC is directing the response. EPA believes that the amended provision provides consistency with the provisions in § 300.910(a); the Agency is not limiting the jurisdictional scope of the NCP as provided under section 311(b)(3) of the CWA.

In the final rule provision, EPA also made some editorial changes to the proposed text for increased clarity in addition to the changes described above.

(c) Burning Agents

EPA proposed to replace the current authorization of use for burning agents in § 300.910(c) to provide greater flexibility to OSCs for authorizing the use of burning agents. Specifically, the Agency proposed that OSCs may authorize the use of burning agents for authorized in-situ burns. EPA received comments that supported the proposed amendments, that requested clarification of the proposed changes, and that raised concerns regarding the consultation and concurrence role of the RRT. Based on public comments received, EPA is not revising § 300.910(c) as proposed, but is instead reserving § 300.910(c) and is amending the regulatory text in § 300.910(a) and (b) to specifically clarify that § 300.910(a) and (b) apply to the authorization of use of burning agents. For preauthorization requirements under the § 300.910(a), the final provisions maintain the previous approach to address burning agents. Under § 300.910(b), the final revisions incorporate burning agents in the case-by-case authorization, along with chemical and biological agents listed on the NCP Product Schedule. This approach eliminates the need to have a separate regulatory requirement for burning agents for case-by-case authorizations. To maintain consistency with the regulation's previous structural organization familiar within the response community, EPA is reserving § 300.910(c).

Several commenters expressed general concern about or opposition to the use of burning agents and the use of in-situ burning as a spill response method. Additionally, several commenters expressed concern regarding various environmental impacts, particularly the impacts to aquatic and benthic environments and to air quality, from the use of burning agents and in-situ burns. While burning agents are used in de minimis quantities relative to the discharged oil they would be applied to, and when considering the response as a whole, EPA recognizes that the use of burning agents and in-situ burning may have environmental impacts. However, Subpart J does not state or imply that chemical or biological agents are preferred over other response options. Neither the current nor final rule mandates the use of chemical or biological agents, nor removes them from consideration as a response option. Rather, the Subpart J regulations provide a framework for authorizing their use, as appropriate. EPA believes that the circumstances surrounding oil discharges may vary and therefore there are many factors influencing the choice of response methods. During a response, in-situ burning may be considered along with other response options. Burning agents may be used as part of the in-situ burning process. Depending on incident-specific conditions, timely deployment of several response options may occur while tradeoffs are evaluated to determine which response option (or combination thereof) addresses response objectives. In-situ burning may reduce the need for collection, storage, transport, and disposal of recovered material by converting a fraction of the oil to gaseous combustion products. However, the Agency also recognizes that combustion products may include smoke or soot in addition to carbon dioxide and water. Monitoring of in-situ burns through information collection can inform decision making during a response. EPA recognizes comments regarding air quality concerns, including generation of particulates and toxic gases (specifically VOCs and PAHs) and potential impacts on communities. Beyond Subpart J, the NCP includes provisions for OSCs to address health and safety concerns of workers under § 300.150. The NCP recognizes that the OSC may call upon DHHS to assist in determining public health threats throughout any response action (see § 300.135(h)). In addition, the OSC may monitor air quality to identify potential public health concerns from air residues from in-situ burning. EPA also recognizes that in-situ burning of crude petroleum oil may result in residues that are not only emitted to the air, but are also entrained in the water column. In-situ burning that is initiated using burning agents may lead to the possibility for organisms dwelling in the water column to come in physical contact with residues from the combusted oil. While the burning agent itself is expected to be consumed through combustion, the Agency believes that the harmful impact to an organism caused by physical contact (*e.g.,* ingestion by fish) with the residue from combusted oil from an in-situ burn initiated by a burning agent is just as concerning as the effects of any residual burning agent. Subpart J does not mandate the use of burning agents. Rather, it provides a framework to consider their authorization by RRTs and OSCs. EPA recognizes the commenters' concerns regarding potential environmental impacts from in-situ burning initiated by burning agents. The final provisions under § 300.910(a) and (b) maintain the current approach that keeps RRTs, including state(s) and natural resource trustees, actively involved in the authorization of burning agents for in-situ burns. EPA believes that the fact that an in-situ burn initiated by a burning agent may cause oil to enter the water column is sufficient reason for RRTs or OSCs to consider whether supplemental monitoring of in-situ burn residue is appropriate. In-situ burning operations are subject to OSC oversight, with OSC authorization required for burning agent use.

Some commenters supported not listing burning agents on the NCP Product Schedule, and several other commenters disagreed, stating that burning agents, like other spill response agents, should be listed on the schedule and be regulated with the same efficacy, toxicity, and public ingredient

disclosure standards as other listed agents. EPA recognizes comments supporting and opposing the listing of burning agent products on the NCP Product Schedule. EPA recognizes burning agents as a type of chemical agent that must be authorized for use in accordance with the provision under § 300.910. EPA disagrees with the comment that the increasing frequency of burning agent use contradicts the argument that the small quantities make listing considerations unnecessary. The Agency believes that burning agents are used in de minimis quantities relative to the discharged oil they would be applied to, and when considering the response as a whole, and are expected to rapidly burn off during use, which serves to remove them from the water. Burning agents are generally added to an oil slick to initiate an in-situ burn after which the oil slick itself is expected to maintain the burn. Although EPA is maintaining the current approach of not specifically listing burning agent products on the NCP Product Schedule, RRTs may still gather additional information on burning agents and monitor their use under § 300.910(g) *Supplemental Testing, Monitoring, and Information.* EPA agrees with comments that an in-situ burn may raise concerns regarding environmental impacts and believes that maintaining the current approach keeps RRTs appropriately and actively involved in the decision making to authorize the use of burning agents used in in-situ burning. Furthermore, provisions within the NCP but outside the scope of this rulemaking include requirements for OSCs to address health and safety concerns of workers and the public. For example, § 300.150 provides requirements to address worker health and safety.

(d) Temporary Exception

EPA is revising § 300.910(d) to clarify the intent of the existing exception to the preauthorization and case-by-case authorization of use regulations. The Agency is including the term ''temporary'' as a qualifier to the final provision's title, to reflect that there is a time limitation for operating under this provision during a response. The temporary exception provision provides that the OSC may authorize the use of any chemical or biological agent, whether it is identified or not on the NCP Product Schedule, without obtaining the concurrence of the EPA RRT representative and, as appropriate, the RRT representatives from the state(s) with jurisdiction over the waters and adjoining shorelines threatened by the release or discharge, and without consultation with the Department of Commerce and the Department of the Interior natural resource trustees. That is, it allows OSCs to authorize the use of any agent when it is determined that the use of the agent is necessary to prevent or substantially reduce an imminent threat to human life that cannot be immediately addressed by other procedures or provisions of the NCP. The Agency believes that the protection of human life is the primary consideration in responding to an oil discharge. Accordingly, the OSC must have the ability to use any agents that would effectively and expeditiously mitigate the threat to human life, particularly in situations where chemical agents on the NCP Product Schedule are not immediately available. The final provision includes the phrase ''and without consultation with the Department of Commerce and the Department of the Interior natural resource trustees'' to further clarify the OSC authority under this provision relative to concurrences and consultations otherwise required for the authorization of chemical and biological agent use under § 300.910(a) or (b). However, this exception cannot be used as a substitute for compliance with § 300.150, including the use of personal protective equipment, or when there is sufficient time to seek authorization in accordance with § 300.910(a) or (b). EPA notes that the temporary exception does not affect other authorities available to an OSC under the NCP, separate from Subpart J, to take actions to address a threat to human life, such as ordering evacuations or repositioning equipment and personnel.

The exception provides for authorization of agent use to occur, within a limited timeframe and for the specific purpose of preventing or substantially reducing an imminent threat to human life, if there is insufficient time to obtain the required concurrences for preauthorization or authorization of use for products on the NCP Product Schedule under paragraphs (a) and (b) respectively. To more clearly describe when the exception must not be used, EPA amended the final provision to add the phrase ''. . . or when there is sufficient time to seek authorization in accordance with paragraphs (a) or (b) of this section.'' The provision is not intended for the OSC to override an authorization decision of an RRT on chemical and biological agent use for the specific incident conditions. The revision in the final action is consistent with the intent of the provision as described in previous NCP final rulemakings (see 55 FR 8808, March 8, 1990).

The Agency recognizes oil discharges generally will not pose threats to human life of an immediacy or magnitude that would warrant invoking the temporary exception provision. However, EPA believes that there may be unforeseen circumstances where an oil discharge poses an immediate life-threatening situation, and for which an OSC must have the ability to use agents that could effectively and expeditiously mitigate the imminent threat to human life. The Agency interprets a situation that poses an imminent threat to human life to be one which could reasonably be expected to cause death or serious physical harm such that a part of the body would be severely damaged. Further, the Agency also interprets that this imminent threat to human life must be immediate for this exception provision to be applicable, meaning that it is expected that death or serious physical harm could occur immediately or before any other action can be otherwise implemented. The former language in § 300.910(d) used the terms ''hazard'' and ''threat'' interchangeably. The amended regulatory language replaces ''hazard'' with ''threat'' for consistency and to establish the intent and expectation of the use of the exception more clearly.

Several commenters recommended that the Agency remove the exception provision. These commenters claimed that it is unclear what circumstances would occur requiring the OSC to decide to apply dispersants to protect human health; the exceptions are not necessary; and that the rarity of use of this exemption is evidence that most oil discharges do not pose threats to human life of an immediacy and magnitude that warrant the exception provision. Some commenters suggested that without more direction, strict guidelines, or guidance from the Agency regarding when this provision could be invoked, the proposed rule allows for potential overreach in the use of the exception authority. The Agency recognizes the comments opposing the exception provision and the selection of spill response agents to focus on human health risks. Nonetheless, the Agency reiterates that protection of human life is the primary consideration in responding to an oil discharge. EPA notes that the other authorities available to an OSC under the NCP to take actions to address a threat to human life, such as ordering evacuations or repositioning equipment and personnel, are not affected by the revisions to the temporary exception provision in this final action. The Agency is maintaining

the exception provision and is finalizing the proposed amendments with modifications to further clarify the provision's intent and address the concerns regarding potential overreach. The finalized exception provision provides the OSC this authority only in circumstances to prevent or substantially reduce an unforeseeable threat to human life that cannot be immediately addressed by other procedures or provisions of the NCP. Additionally, the Agency added the term ''individual circumstances'' to provide the OSC flexibility to address one or more separate unforeseen threats to human life at any time during a response. The intent behind this temporary exception provision is to eliminate potential delays in responding to life-threatening situations. The modifications finalized in this action do not change previous policy but rather clarify the intent and scope of the exception. While the Agency expects this temporary exception to be rarely needed, it continues to believe it is appropriate that the NCP include a temporary exception provision to capture unforeseen and immediate life-threatening situations. However, it is important to note that, while all threats to human life are health and safety issues, not all health and safety issues in turn pose an immediate threat to human life. The Agency stresses the intent is for this temporary exception to be applicable only to those imminent life-threatening situations which cannot be addressed through the implementation of other procedures or provisions in the NCP and has amended the final provision accordingly. The final provision also clarifies that the exception must not be used as a substitute for compliance with § 300.150 of this part, including the use of personal protective equipment.

Some commenters suggested that the OSC should only be allowed to use products that are listed on the NCP Product Schedule under the exception; a commenter stated that use of products not on the NCP Product Schedule negates the purpose of contingency planning, and that the OSC should only be able to authorize the use of agents listed on the NCP Product Schedule when the agent is necessary to protect human life. Some commenters expressed concerns regarding use of agents without peer-reviewed scientific or technical evidence to show that the dispersant chemical is safe for humans, wildlife, or the ecosystem. A commenter noted that if the work required to add a product to the NCP Product Schedule was not complete prior to a spill then responders should not have the option of bypassing the process by using the exception clause. The Agency shares the concern for any use of chemical or biological agent products not listed on the NCP Product Schedule. The fact that the exception applies broadly to include chemical or biological agents not identified on the NCP Product Schedule necessitates the temporary nature of the exception. The Agency reiterates that the OSC authorities provided under this temporary exception are not intended to allow bypassing or circumventing the processes established under Subpart J. Specifically, the temporary exception is not intended to bypass those provisions for testing and listing chemical and biological agent products established under § 300.915. The provisions for testing and listing chemical and biological agent products on the NCP Product Schedule are intended to ensure that these products have met baseline efficacy and toxicity requirements, promoting the use of safer and more effective spill mitigating products. The limited timeframe addresses concerns regarding the extent of the temporary exception applicability, and promptly brings back into the decision making process the required environmental considerations that are built into the authorization of use provisions under § 300.910(a) and (b), including the use of chemical and biological agent products only when they are listed in the NCP Product Schedule.

Several commenters requested a 24-hour (or shorter) timeframe instead of 48 hours for OSC product use notification and concurrence. These commenters indicated that a 48-hour window for the OSC to operate without concurrence seemed excessive, and that members of the RRT and natural resource trustees should be engaged in this type of decision making as soon as is feasible, as well as OSHA and the DHHS for human health impacts. They noted that with advances in communication technology, a 24-hour timeframe for OSC notification should be attainable. The Agency acknowledges the support for specifying a timeframe for the temporary exception to best clarify the intent that this provision is to be a temporary and limited measure. Based upon comments, the Agency is finalizing the provision's language to modify the proposed 48-hour timeframe for which the temporary exception would be applicable. The Agency is finalizing a further limited timeframe of 24 hours, recognizing that those entities with concurrence and consultation roles under Subpart J, and who bring relevant environmental expertise to these types of decision making, should indeed be engaged as soon as possible. Additionally, this change acknowledges the advances in communications since the exception provision was last revisited under the NCP in 1994. Technologies are now available that allow the OSC to notify the EPA RRT representative, the state(s), and natural resource trustees of this decision within the 24-hour timeframe, if not sooner. This 24-hour timeframe further addresses concerns regarding the extent of the temporary exception's applicability, and promptly brings back into the decision making process the required environmental considerations that are built into the authorization of use provisions under § 300.910(a) and (b). The final amendments also include the phrase ''after initial application'' to further clarify when the 24-hour timeframe begins. The timeframe in the final rule balances the need to address an unforeseen imminent threat to human life during a response with the roles and responsibilities of EPA, the state(s), and DOI and DOC natural resource trustees regarding chemical or biological agent use under § 300.910(a) or (b). EPA notes that the temporary exception provision does not affect other authorities available to an OSC under the NCP, separate from Subpart J, to take actions to address a threat to human life, such as ordering evacuations or repositioning equipment and personnel.

Many commenters expressed support for the notification requirements in § 300.910(d). A commenter stated that the notifications should be made available to the public for awareness of the imminent threat to human life and the use of products to address the threat. Some other commenters cited concern regarding the notification requirement and recommended that there should not be any limits on the OSC's ability to make decisions protecting human life. A commenter asserted that the requirements are inappropriate, and that the Agency has not adequately justified the proposed notification requirements in terms of additional benefits compared with the existing requirements. The Agency recognizes the concerns regarding the notification requirements within the temporary exception. The final regulatory language includes the requirement for the OSC to notify as soon as possible, and to document the circumstances and the reasons for use of the agent, to the EPA RRT representative and, as appropriate, the RRT representatives from the affected state(s) and the DOC and DOI natural resource

trustees. While the Agency had proposed ''immediate'' notification, it believes that requiring notification ''as soon as possible'' is adequate in conjunction with a reduction in the timeframe for which this exception is applicable from 48 hours to 24 hours. The expectation is that this information will be provided to those federal and state entities with concurrence and consultation roles within a timeframe to consider further chemical or biological agent use. While the Agency recognizes the comment regarding limitations on the OSC's ability to protect human life, it does not believe that the notification requirement to the RRT members in any way hinders the OSC's ability to make decisions to protect human life. The Agency notes the notification provision does not apply to other authorities available to an OSC under the NCP, separate from Subpart J, to take actions to address a threat to human life. The Agency modified the regulatory language by changing the ''immediate'' reporting requirement terminology to ''as soon as possible,'' which still provides for the information to promptly be provided to those entities with concurrence and consultation roles. Additionally, the regulatory language was modified to add the phrase ''authorized pursuant to this paragraph'' to clarify the documentation requirement under the temporary exception.

Some commenters suggested that exceptions may not be protective of human health and safety, expressing concern with the replacement of the term ''worker safety'' with ''human life.'' These commenters indicated that the Agency should clarify the difference between threats to worker safety and protection of human life and indicate why the proposed change was needed. Other commenters requested that the Agency revise the section to clearly include worker safety, or to clarify that ''worker safety'' is considered the same as ''the protection of human life.'' The Agency disagrees that all worker safety considerations in a response would necessarily equate to threats to human life. EPA recognizes that all responses present multiple health and safety challenges. The Agency reiterates that, while all threats to human life are worker health and safety issues, not all worker health and safety issues pose an immediate threat to human life. The temporary exception provision is intended to capture unforeseen and immediate life-threatening situations. For those rare and unexpected situations which cannot be immediately addressed by any other means, this temporary exception provision allows the OSC to consider whether the use of an agent is appropriate. The exception provision being amended by this action did not previously include the term ''worker safety,'' but rather speaks to human life. Similarly, the Agency did not include the term ''worker safety'' in the proposed rule. The Agency is clarifying the term relative to the temporary exception to mean a ''threat'' to human life. While the provision before the amendment used the terms ''hazard'' and ''threat'' interchangeably, the final action replaces ''hazard'' with ''threat'' for consistency and to clearly establish the intent not to broadly cover ''worker safety.'' Section 300.150 of the NCP establishes worker health and safety provisions to ensure these concerns are addressed during all response actions. Specifically, the provisions provide for an occupational safety and health program, in compliance with applicable worker health and safety provisions of the Occupational Safety and Health Act of 1970 (OSH Act), to be available for the protection of workers at the response site. Among the OSH Act provisions are requirements for a site-specific health and safety plan that must include, at a minimum, employee training, personal protective equipment, medical surveillance, and air monitoring. In this amendment, the Agency is clarifying the regulatory text to specifically state that the exception is not to be used as a substitute for compliance with § 300.150 of this part, including the use of personal protective equipment; § 300.150 of this part is outside the scope of this action.

In the finalized provision, EPA also made some editorial changes to the proposed text for increased clarity.

(e) Prohibited Agents or Substances

Sinking Agents. The Agency is maintaining in § 300.910(e)(1) the current prohibition for the authorization of use of sinking agents and has clarified in the regulatory text that the prohibition applies to any chemical agent, biological agent, or any substance that is used to directly sink the oil to the bottom of a water body. EPA believes that the final revisions better reflect EPA's intent and avoid potential confusion with the use of other chemical and biological agents. The Agency believes the prohibition on sinking agents is appropriate in all cases and is consistent with the existing restriction in § 300.310(b) of NCP Subpart D. EPA notes that the final provision applies to sinking agents which are defined under § 300.5 as ''substances,'' and not included in the definitions of chemical or biological agents. The final action modifies the section title to include ''substances'' to provide greater clarity to the applicability of the section.

Commenters recommended that the proposed rule language be further amended to recognize the potential for some products to behave as sinking agents depending on environmental conditions; they suggested that the description of the prohibited agents should include those with the potential to cause oil to sink based on the receiving environment. Commenters also suggested that the Agency should define the difference between ''dispersing below the surface'' and ''sinking.'' The purpose of certain chemical agents (*e.g.,* dispersants) is to entrain oil into the water column; the definition of dispersants in the previous and final rules acknowledge dispersants entrain oil ''into the water column.'' EPA recognizes that, while these products are intended to transfer oil into the water column, they are distinct from sinking agents. To reflect commenter concerns, the Agency revised the proposed text, so that the finalized amendment prohibits ''sinking agents, or any other chemical agent, biological agent, or any substance that is used to directly sink the oil to the bottom of a water body.'' Refer to the section on definition of sinking agents in this preamble for further discussion.

Some commenters requested a requirement for a screening test or standard functional approach to determine if an agent is a sinking agent. A commenter noted that the prohibition of sinking agents is undermined if a product's propensity to act as a sinking agent is only discovered after the product has been used in a discharge event. The commenter further suggests that a test is needed to identify products that are otherwise categorized as dispersants or other agents, but which have the effect of submerging and sinking oil, because these products should also be recognized as sinking agents and be prohibited. EPA acknowledges the commenters' request for a screening test or standard functional approach to determine if an agent is a sinking agent. While the Agency is not including such a test or functional approach in this final action, the provisions finalized under § 300.915(a)(12) include that product manufacturers must provide physical and chemical properties such as specific gravity as part of the product submission package for listing on the NCP Product Schedule. In addition, the final rule at § 300.910(g) provides that the RRT may require available data or

information about agents be provided during planning or at the time of a response, allowing for modifications to the response as necessary. EPA believes responses to oil discharges are site-specific, and this approach provides flexibility to consider site-specific conditions.

Nonylphenol (NP) or nonylphenol ethoxylates (NPEs). The Agency had also proposed to add a prohibition from listing on the NCP Product Schedule and from authorizing use of any chemical or biological agents that contain nonylphenol (NP) or nonylphenol ethoxylates (NPEs) as components. However, the Agency has determined that chemical agents that have either NP and NPEs as components will not be prohibited from use under this final rule.

EPA proposed prohibiting NP and NPE to reflect the Agency's concerns for these substances as presented in EPA's Nonylphenol and Nonylphenol Ethoxylates Action Plan. The Agency proposed a Significant New Use Rule (SNUR) in September of 2014, which has not been finalized to date. The Agency is not finalizing the 2015 Subpart J proposed amendment on NP and NPE since final action has not been taken on the SNUR. EPA is reserving § 300.910(e)(2) in lieu of finalizing the proposed amendments. However, EPA notes that the final provisions of this rulemaking limit the scope of information that can be claimed as Proprietary Business Information (PBI) as part of a product submission. Information of product components will be available for RRTs and OSCs to consider as appropriate when reviewing authorization of use scenarios, including whether those products contain NP or NPE substances.

Other agents. Commenters on the proposed rule requested prohibitions on the use of chemical or biological agents that are formulated with any endocrine disrupting compounds (EDCs); that degrade in a manner such that its byproducts contain prohibited substances; that contain known or suspected human health hazards as listed on the material safety data sheet (MSDS) or safety data sheet (SDS); or that contain known or suspected carcinogens, hemolytic chemicals, mutagens, neurotoxins, teratogens, and that demonstrate human and aquatic toxicity. The Agency recognizes that there may be other substances that, given their use circumstances, may be of concern. The Agency has focused this final action on maintaining the existing prohibition of sinking agents. The Agency recognizes that there may be environmental and health concerns associated with any response. While the final action includes product information requirements focused on environmental impacts, the information may also be used by OSCs to address broader health and welfare concerns. For example, the final rule contains a provision to include the SDS for the product as part of the submission package (see § 300.915(a)(5)). The final rule also includes a requirement under § 300.915(a)(11) for the submitter to provide for environmental fate information on the persistence, bioconcentration factor, bioaccumulation factor, and biodegradability of the product and all of its components in the environment. Further, the final provisions at § 300.950 limit the information that can be claimed as Proprietary Business Information (PBI) as part of a product submission for listing on the NCP Product Schedule, so that product manufacturers will not be allowed to withhold information on product components. Thus, product component information will be available for RRTs and OSCs to consider as appropriate, for planning and authorization of use within the respective Area or Regional Contingency Plans. These considerations may include, for example, whether products contain substances of concern to human health or aquatic hazards. The final provision also includes updated ecotoxicity testing protocols and the listing thresholds for ecotoxicity.

A commenter expressed opposition to the proposal's opening language which they believed would allow the exception clause in § 300.910(d) to apply to § 300.910(e) and allow the OSC to use a prohibited product. The Agency disagrees with the commenter's interpretation of the proposed regulatory text in § 300.910(e). The temporary exception under § 300.910(d) applies to a ''chemical or biological agent.'' While subject to the provisions under Subpart J, the definitions of chemical or biological agents do not include sinking agents. Therefore, sinking agents are not included in the temporary exception under § 300.910(d). Nevertheless, in the final action, EPA is not including the proposed opening clause to the provision, ''Notwithstanding paragraph (d) of this section . . .'' because it is unnecessary and to avoid the misunderstanding described by the commenter.

(f) Storage and Use of Agents Listed on the NCP Product Schedule

The Agency is adding a new provision, § 300.910(f), to complement the existing information requirements for the person or entity submitting a product for listing (''submitter'') in § 300.915. The new requirements focus on the use of this information by the responder and the OSC. EPA has organized the final provisions into subsections (f)(1) and (f)(2) for greater clarity. Specifically, the provision at § 300.910(f)(1) requires the OSC to only authorize for use those products listed on the NCP Product Schedule that are documented and certified by the responsible party or its representative to have been stored under the conditions specified by the submitter of the product for listing, including the maximum, minimum and optimum temperatures, humidity and any other relevant conditions, and whose date of use does not exceed the expiration date listed on the container's label, unless otherwise specified for expired products as provided in § 300.910(f)(2), at the time of the incident. Under § 300.910(f)(2), the OSC may authorize for use products listed on the NCP Product Schedule that exceed their expiration date after the responsible party or its representative documents and certifies that the expired product has been stored under the conditions provided by the submitter under § 300.915(a)(6) and still meets the applicable efficacy and toxicity-listing provisions under § 300.915 based on testing of representative samples within the previous 12 months. The title of the provision has been changed from the proposed ''Storage and Use of Agents'' to ''Storage and Use of Agents Listed on the NCP Product Schedule'' to provide more clarity on its scope.

Some commenters recommended that the shelf life for biological agents and bioremediation agents be limited to one year since living products will degrade more quickly than chemical agents. The Agency notes that the product shelf life provision does not provide separate consideration for biological and bioremediation agents from chemical agents. However, the final rule amended the proposed five-year testing timeframe to recognize products may have shorter shelf lives as evidenced by some products currently on the NCP Product Schedule. The shelf life is provided by the product manufacturer based on the inherent properties of the product. The product manufacturer is required to submit documentation supporting the shelf life determination. Furthermore, the final provisions include a requirement for the responsible party or its representative to document and certify that an expired product still meets the applicable efficacy and toxicity provisions for listing under

§ 300.915 based on testing of representative samples within the previous 12 months for an OSC to consider authorizing products beyond their expiration dates.

Commenters suggested that other oil spill mitigating devices and substances should be included in this provision for consistency with other sections. The Agency disagrees the provisions under § 300.910(f) should include other oil spill mitigating devices and substances, other than the specific product categories of chemical and biological agents already identified for listing on the NCP Product Schedule. The final rule amends the section title and regulatory paragraph to clarify that the provision is applicable to agent products ''Listed on the NCP Product Schedule.''

Commenters also suggested that the rule require disposal of expired chemical agents. Some commenters suggested that the Agency should require the disposal of all products once the expiration date has passed, regardless of any testing. The Agency disagrees with the request to include provisions addressing the disposal of expired chemical agents in the final rule. Disposal of oil and contaminated materials recovered in cleanup operations is addressed in § 300.310 of the NCP. While the final provisions provide for the retesting of expired products, the disposal of products, including expired products, is outside the scope of this action.

Some commenters recommended that no additional requirements be put in place for product shelf life, other than what is recommended by the manufacturer. However, EPA is finalizing re-testing provisions to provide flexibility for chemical or biological agents to be considered for use past their designated shelf life provided they still meet efficacy and toxicity testing requirements. The provision under § 300.910(f)(2) is voluntary in that it does not require expired products to be retested but is an option for the responsible party if they want an OSC to be able to authorize their use.

Commenters suggested that there is no justification for mandating a shelf life that could limit the use of stockpiles that remain viable and effective. EPA did not mandate a specific shelf life for products listed on the NCP Product Schedule. However, EPA believes that users of products should follow the manufacturer's storage conditions and shelf life recommendations, as submitted according to § 300.915(a)(6) and (a)(7). Based on public comments, EPA made changes to the proposed re-testing provisions in the final amendments. The final provisions provide the OSC with the discretion to authorize products listed on the NCP Product Schedule that exceed their expiration date. However, this discretion is only available after the responsible party or its representative documents and certifies that the expired product still meets the applicable efficacy and toxicity provisions for listing under § 300.915, based on testing of representative samples within the previous 12 months.

Some commenters expressed support for retesting requirements but indicated that efficacy of the product is the only relevant endpoint for testing regardless of age. The commenters recommended that there is no scientific justification for toxicity re-testing, and that only effectiveness testing should be conducted rather than all of the tests described in Appendix C. A commenter stated that testing requirements should allow for acceptable levels of variability in efficacy results, recommending an allowable 10% variance in effectiveness test results. The Agency disagrees with the commenters' concerns that effectiveness testing is the only retesting that should be considered and that the efficacy testing requirements need to allow for acceptable levels of variability in efficacy results. The Agency recognizes that some products stored over time may not obtain the same efficacy or toxicity testing results for the product's original listing submission yet may still meet the applicable threshold(s) that were required to list the product on the NCP Product Schedule. However, EPA also recognizes that some products stored over time may not meet the applicable threshold requirements. EPA believes that products stored beyond the expiration date listed on the container's label and that, upon retesting, do not meet the applicable threshold(s) that were required to list the product on the NCP Product Schedule, no longer represent the product approved for listing on the NCP Product Schedule. A variance could allow expired products that do not meet the applicable threshold requirements for listing on the NCP Product Schedule to be available for authorization upon retesting, while other products with similar results would be denied listing on the NCP Product Schedule.

(g) Supplemental Testing, Monitoring, and Information

The Agency is finalizing at § 300.910(g) an amended provision that maintains the RRT's authority to require supplementary toxicity and efficacy testing, or to request available data or information that addresses site-, area-, or ecosystem-specific concerns relative to the use of product for both planning and authorization of use. The amendment adds flexibility to the former requirement by removing ''When developing preauthorization plans . . .'' and by including ''or submission of available data and information'' to recognize that existing data or information that addresses site-, area-, or ecosystem-specific concerns relative to the use of a product may be available. Additionally, in the final action, EPA modified the proposed language to specify that this supplemental testing, monitoring, and information may be required ''for both planning and response, including authorization of use'' to emphasize the broad potential use of this data. As proposed, the Agency is including the term ''ecosystem'' with area and site-specific concerns, as RRTs may want to gather additional information on the use of certain products when assessing the biological communities specific to their area. In the final amendment, EPA has modified the proposed regulatory text to streamline it to specify that ''The product manufacturer or responsible party shall provide, upon request of the RRT or OSC, additional monitoring or testing data and information to inform chemical or biological agent use decisions specific to a response.''

Some commenters expressed opposition to the RRT's authority to require supplemental testing, monitoring, and information, as provided in the proposed rule. Commenters provided several reasons for the opposition, including stating that the standard efficacy and toxicity tests already required are more than adequate, additional testing would cause a delay in the spill response; the current testing requirements in the rule and/or NCP are adequate and additional data is unlikely to provide valuable information for decision making; additional data may create confusion; additional data collection would increase costs for facilities; and unnecessary animal testing should be avoided. One commenter stated that no information is provided in the rule as to what circumstances might trigger an RRT's request for supplemental testing, monitoring, or information. The Agency disagrees with the commenters' opposition to recognizing that RRTs may require supplemental testing, monitoring, and information. In addition to planning, this provision aims to provide discharge-specific information that may assist in decision

making during a response. The Agency notes this is a discretionary provision for the RRT to require supplemental information, and that the RRT may coordinate with the OSC to address any concerns related to requiring additional information. Standard toxicity tests required in the final rule encompass only a few species and are not necessarily intended to be protective of site-, area- or ecosystem-specific concerns. Decades of research show that species can vary substantially in sensitivity, and that ecosystems contain a diversity of species of mostly unknown sensitivity. The Agency believes retaining the option for the RRT to require supplemental testing, monitoring, and information that addresses incident-specific concerns for planning and response relative to product use is reasonable and prudent. For example, the provision provides flexibility in gathering scientific information relevant to a given site or geographic location and allows for better targeting chemical and biological agent use during a response. The absence of the final provision for the RRTs to require supplemental testing, monitoring, and information may adversely impact the RRT's ability to provide informed concurrence and consultation determinations. EPA also notes that the provision under § 300.910(a) for preauthorizing an OSC to authorize the use of a chemical or biological agent does not preclude the RRT from requiring additional monitoring and information.

A commenter opposed this provision because they asserted that the required tests would not inform operational decision making during the response, but rather would develop data for the Natural Resource Damage Assessment (NRDA) process. EPA agrees with the comment that ''operational monitoring and NRDA are two different things''. This provision is separate from NRDA monitoring, testing, and data collection; NRDA monitoring, testing, and data collection is outside the scope of this provision. To clarify this point, EPA has modified the provision from the proposed language. The finalized, streamlined provision states that the RRT or OSC may request additional monitoring or testing data and information to ''inform chemical or biological agent use decisions specific to a response.'' EPA notes the purpose of the provision is to provide the OSC and RRT, if necessary, supplemental data, including monitoring data which may not be already derived from required monitoring plans included within ACPs.

Some commenters opposed the RRT authority to request additional monitoring associated with the use of a product during a discharge and expressed concern that this provision could be potentially used during a discharge situation to prevent or delay the use of chemical or biological agents for non-technical reasons and thus potentially reduce the effectiveness of the response. The Agency disagrees. This provision aims to provide incident-specific information that may assist in decision making during a response, not to hinder the overall response time. The Agency does not believe these requirements would delay or impede response actions such as the deployment of mechanical recovery or other response related equipment. EPA disagrees with the commenters' concern that giving the RRT authority to request additional monitoring associated with the use of a product during a discharge could specifically delay the use of a chemical or biological agent and reduce the effectiveness of a response. This provision is not intended to delay the use of an agent, but rather to inform and reduce the uncertainties associated with a chemical or biological agent during the response. The Agency notes this is a discretionary provision for the RRT to request supplemental information, and that the RRT may coordinate with the OSC to address any concerns related to the request.

A commenter suggested that the regulation should provide that Area Committees, in addition to RRTs, are authorized to request that the OSC require additional monitoring, and that the OSC may independently require this additional monitoring absent a particular request from the RRT or Area Committee. The Agency disagrees with the commenter's suggestion. The NCP establishes the roles and responsibilities for RRTs and Area Committees. The Area Committees are responsible for preparing ACPs for their designated areas as described in § 300.210(c). The RRT responsibilities under the NCP include the development and coordination of preparedness activities before a response action is taken, as well as coordination of assistance and advice to the OSC during response actions, as described in § 300.115. The Agency believes it is appropriate to focus this provision on the RRTs given their operational roles, including the role of certain RRT members in authorizing the use of chemical or biological agents. Thus, the final rule states the product manufacturer or responsible party shall provide, upon request of the RRT or OSC, additional monitoring or testing data and information to support chemical or biological agent use decisions specific to a response.

(h) Recovery of Chemical Agents and Other Substances From the Environment

The Agency is adding a new provision at § 300.910(h) to require the responsible party to recover solidifiers, sorbents, and surface washing agents from the environment following their use. The provision requires that the responsible party shall ensure that removal actions adequately contain, collect, store, and dispose of solidifiers, surface washing agents, and sorbents, unless otherwise directed by the OSC. EPA identifies each of these agents or other substances, in their respective finalized definitions in § 300.5, as needing to be recovered from the environment to minimize any potential adverse impact. The Agency recognizes there may be situations where the safety of response personnel is threatened, or where additional harm to the environment could occur during recovery operations, so the final provision provides that the OSC should, at a minimum, consider factors such as the safety of response personnel and harm to the environment in making recovery-related determinations. Furthermore, the Agency has modified the title of the section as ''Recovery of Chemical Agents and Other Substances from the Environment'' to recognize that sorbents are covered under § 300.910(h).

Commenters expressed support for the identification of the agent categories and substances intended to be removed from the environment following their use as described in the preamble to the proposed rule: solidifiers, sorbents, and surface washing agents. However, other commenters requested clarification in the regulatory text as to which substances or agents are covered, noting that it should apply to solidifiers, sorbents, and surface washing agents as well as other oil spill mitigating devices, oil-product combinations, and weathered oil. A commenter stated that the phrase ''agents that are intended to be recovered from the environment'' is ambiguous and suggested that EPA change the language to clarify that this provision applies to ''substances'' including sorbents, rather than solely agents. EPA recognizes the request to clarify in the regulatory text as to which substances or agents are covered. Based on comments, EPA amended the final provisions in § 300.910(h) relative to the proposal to address chemical agents and other substances to be recovered from the environment to specifically include solidifiers, surface washing agents, and sorbents.

Some commenters suggested additions to the proposed language to further specify requirements. EPA recognizes a commenter's request for additional language that would serve to quantify the term ''adequately,'' a commenter's suggestion that the language should be modified to clarify that recovery of substances should be completed ''to the extent possible,'' and the suggestion that removal action agents should always be recovered from the environment. Under § 300.120, the OSC directs response efforts and coordinates all other efforts at the scene of a discharge. EPA believes that it is the OSC who will make the determination of when the recovery of agents from the environment is adequate for the specific response. These activities are to be done in accordance with applicable federal, state, Tribal and local requirements. Thus, the Agency maintains in the final rule the requirements for the responsible party to ensure that removal actions adequately contain, collect, store, and dispose of chemical agents and other substances that are to be recovered from the environment, unless otherwise directed by the OSC. The Agency does not believe the final provision should be modified to include ''to the extent possible'' since it already provides for that expectation, subject to the direction of the OSC. The OSC should, at a minimum, consider factors such as the safety of response personnel and harm to the environment in making such determinations. EPA amended the final provision with the phrase ''at a minimum'' to recognize that factors other than the examples provided may be considered.

The Agency acknowledges a commenter's suggestion to make it explicitly clear in the regulatory text that the OSC has the authority to utilize the NEBA framework. The Agency is not taking action on this comment. The NCP continues not to require nor preclude the use of any specific environmental tradeoff methodology to identify protective strategies that may minimize the potential environmental impact of hazardous substance releases or oil discharges. In addition, the NCP continues not to define NEBA. While EPA recognizes the need to establish specific criteria and monitoring for removal actions overall, this section specifically focuses on actions when chemical or biological agents are used.

The Agency acknowledges the comment that the ability to use a given substance in a response should be dependent on the development of a removal/recovery plan, as well as the comment that removal action agents should not be considered for use if safety or environmental concerns regarding recovery of these agents exist prior to deployment. The Agency notes that there are certain chemical agents and other substances that are intended to be recovered from the environment; EPA amended the final provision to acknowledge that chemical agents and other substances to be recovered include solidifiers, surface washing agents, and sorbents, and revised the title accordingly. EPA believes RRTs and OSCs may consider these factors when determining under what conditions to authorize their use, as applicable. EPA also believes that the final provision provides stakeholders the opportunity to develop removal/recovery plans for these agents and substances. It is important to note that removal actions that consider the use of chemical or biological agents and other substances must do so in accordance with Subpart J.

Some commenters suggested that recovered materials should be treated as a hazardous waste so that they are not disposed of in public landfills, as a matter of public health. Under the NCP, oil and contaminated materials recovered in cleanup operations are to be disposed of in accordance with the Regional Contingency Plan (RCP), ACP, and any applicable laws, regulations, or requirements, as stated in § 300.310(c). The applicability of hazardous waste regulations is outside the scope of this final action.

(i) Reporting of Agent Use

The Agency is adding a new provision at § 300.910(i)(1), to require the OSC to provide to the RRT certain information for the use of a chemical or biological agent within 30 days of completion of agent use. The information required for any chemical or biological agent used in response to an oil discharge includes product name, product category, the quantity and concentration used, and the duration of use, the locations where the agent was used, any available data collected, and any available analyses of efficacy and environmental effects. This information may be submitted in accordance with the OSC reporting provisions under § 300.165 of this part, as applicable, subject to the 30-day timing requirement. While other existing notification requirements serve to activate an immediate response to an event, this requirement gathers information that will be useful in specifically evaluating the use of chemical or biological agents in the response, informing the review of preauthorization plans, and providing a basis for any necessary changes to improve environmental protection. Additionally, § 300.910(i)(2) requires that the authorizing OSC provide for notification to the public, to be updated during a response as appropriate, the following information on chemical and biological agents used in response to an oil discharge: product name, product category, quantity and concentrations used, duration of use, and location(s) of use.

Several commenters recommended that timely public notification of product use be required and that reports should be accessible to the public. A commenter recommended initial notification of product use within 24 hours and daily public notification thereafter, stating that accessibility is a matter of health and government accountability. This commenter also requested simultaneous notification of Tribal governments, Area Committees, and Citizens' Advisory Councils. A commenter recommended adding language requiring the responsible party to inform nearby landowners of dispersant use impacts that may affect natural or cultural resources. The Agency generally agrees with commenters' recommendations of providing timely public reporting of product use and is finalizing a new provision that will require the OSC to provide notification to the public. Under §§ 300.135(n) and 300.155(a), both of which are provisions outside the scope of this action, the NCP already provides that the OSC should ensure all appropriate public and private interests are kept informed and that their concerns are considered throughout a response, to the extent practicable. Based upon comments received requesting public notification of chemical and biological agent use, the Agency is including a new notification provision at § 300.910(i)(2) that requires the OSC to provide for public notification, updated during a response as appropriate, regarding information on chemical and biological agents used in response to an oil discharge to include the following: product name, quantity and concentrations used, duration of use, and location(s) of use. The new provision requires the OSC to provide notification to the public in support of §§ 300.135(n) and 300.155(a) and (b). While EPA agrees that the OSC should provide timely public notification, the Agency disagrees that the initial notification should be required to be within 24 hours of product use. EPA believes the OSC should have the flexibility to establish the initial timeframe to avoid potential delays in addressing roles and responsibilities under the NCP, such as obtaining the

necessary concurrences and consultations from certain RRT member agencies on chemical and biological agent use. EPA believes that the OSC, as the entity with overall responsibility to direct the response, is the appropriate party to provide the public notification. Public notification may occur, for example, through coordination with the RRT and posting on their website, as appropriate. EPA also believes that the public notification provision in the final rule also addresses commenter's request that reporting include notification of Tribal governments, Area Committees, Citizens' Advisory Councils, and landowners.

Some commenters suggested changes to the proposed reporting requirements. A commenter recommended that the regulatory text clarify that reporting is required in the case of sorbent use. Commenters suggested that reports should include an overview of the incident, description of how the agent applications were conducted, description of all monitoring conducted and the results, a description of any adverse environmental effects, water depth and proximity to shoreline, and the amount of product and oil-product recovered. This commenter suggested that the rule may need to include reference to consultations under section 7 of the Endangered Species Act (ESA), depending on the nature of environmental impacts from a given spill, and that the reporting requirements should be mandatory, not just if requested by the RRT or the natural resource trustee. EPA disagrees with expanding the scope of the Reporting of Agent Use provision to include other spill mitigating devices and substances including sorbents and other aspects of the removal operation. The purpose of the requirement is to gather information that will be useful in evaluating the use of chemical or biological agents in the response. Sorbents are not included in the definition of chemical or biological agents under Subpart J and are not subject to the authorization of use provisions under § 300.910(a) or (b); therefore, the Agency disagrees that reporting should be required in the case of sorbent use. The information reported through this reporting provision is also intended to inform the review of preauthorization plans and provide a basis for any necessary changes to improve environmental protection. The RRT has existing authority to require the OSC to submit a complete report under § 300.165 to obtain information that more broadly covers the removal operation and the actions taken, which may include the information suggested by the commenters (*e.g.,* overview of the incident). While the Agency recognizes that consultations under ESA section 7 may be warranted, it is important to clarify that a purpose of this reporting requirement is for the RRT and EPA to gather information specific to the use of a product in a response.

3. Data and Information Requirements for Listing on the NCP Product Schedule or Sorbent Product List

The Agency is revising the data and information requirements in § 300.915 of Subpart J for listing products on the NCP Product Schedule or Sorbent Product List, identifying the relevant science to establish a national screening process for products to be listed. The amendments revise the efficacy and toxicity testing protocols and listing criteria for all chemical and biological agents on the NCP Product Schedule, and requirements for listing on the Sorbent Product List. Additionally, the Agency is revising the requirements for general product information, Proprietary Business Information (PBI) claims, submission package contents, EPA review and listing procedures, requests for decision review, changes to products, transitioning products from the current NCP Product Schedule to the new NCP Product Schedule and for listing on the new Sorbent Product List, mandatory product disclaimer, and removal of products from the NCP Product Schedule or Sorbent Product List. The final action specifically includes references to the new Sorbent Product List as clarifying edits.

The Agency recognizes comments that asserted that burning agents should be added to the NCP Product Schedule and that the Agency should require toxicity testing of burning agents, of combustion products (*e.g.,* smoke plumes), and of the burn residue that results from application of burning agents to oil slicks. The Agency continues to believe that because of the nature of burning agents and the revisions to the authorization of use for burning agents in the final rule, it is not necessary to require product submissions for burning agents. See section V.C.2.c of this preamble for more information on burning agents.

(a) General Product Information

EPA is consolidating in paragraph (a) of § 300.915 the general submission requirements applicable to all types of agents that may be listed on the NCP Product Schedule or Sorbent Product List. The revisions group together and simplify the general submission requirements applicable to all product types. EPA believes that reorganizing the general requirements in a central location will clarify which requirements are applicable to all submissions, and which are specific to each product type by including them in separate sections. The general information requirements for products are as follows:

Submitter. Under § 300.915(a)(1), EPA is requiring the name, physical address, email, and telephone number of the submitter. Under § 300.915(a)(2), EPA is requiring the identity of the submitter (*i.e.,* manufacturer, vendor, importer, distributor, designated agent for the manufacturer), and documentation of such identity. This requirement is intended to clearly establish the point of contact responsible for the submission, and to avoid any conflicts or claims from unauthorized entities on products listed or submitted for consideration. No comments on these provisions were identified. EPA reorganized the provision under § 300.915(a)(2) to provide greater clarity by moving the documentation requirement forward and by making editorial changes.

General product information. Under § 300.915(a)(3), EPA is requiring the submitter to provide all name(s), brand(s), and/or trademark(s) under which the product is to be sold. No comments on § 300.915(a)(3) were identified.

Supplier. Under § 300.915(a)(4), EPA is requiring the names, physical addresses, emails, and telephone numbers of the primary distributors, vendors, importers, and/or designated agent acting on behalf of the manufacturer. No comments on § 300.915(a)(4) were identified. EPA made editorial changes from the proposed text to provide greater clarity.

Safety Data Sheet. The provision at § 300.915(a)(5) requires the submitter to provide a Safety Data Sheet (SDS). EPA recognizes that chemical and biological agents may contain substances that could potentially cause harm to oil spill responders who, if unaware of the product's composition, may not wear the proper personal protective equipment. SDSs describe the hazards that may be involved with the product and recommend safety measures that would minimize or avoid adverse consequences that may result from exposures. The Agency believes SDS information will be useful to both OSCs and responders when authorizing and using the product respectively. Several commenters suggested that the Agency should require that SDS information be submitted for each individual product component. Agency disagrees that that SDS information needs to be submitted for each individual product component.

EPA believes that the SDS for the product, rather than for each component, is more appropriate for responders to use during a response. EPA believes that requiring an SDS for each product component would add unnecessary burden to the submitter. The information that is required to be included in an SDS is the responsibility of the Occupational Safety and Health Administration (OSHA) and is outside the scope of this rulemaking. The Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)) requires that the chemical manufacturer, distributor, or importer provide Safety Data Sheets (SDSs) for each hazardous chemical to downstream users to communicate information on these hazards. The SDS includes information such as the properties of each chemical; the physical, health, and environmental health hazards; protective measures; and safety precautions for handling, storing, and transporting the chemical. In addition, OSHA requires that SDS preparers provide specific minimum information as detailed in Appendix D of 29 CFR 1910.1200. The Agency believes the SDS along with the NCP Subpart J Technical Notebook [4] provides useful information to OSCs, RRTs, and responders when authorizing and using the product respectively. EPA notes the final revisions to § 300.950, *Submission of Proprietary Business Information (PBI),* provide greater awareness of product components to OSCs, other stakeholders, and the public.

Product Storage and Shelf Life. Under § 300.915(a)(6), EPA is requiring the submitter to provide the maximum, minimum, and optimum temperature, humidity, and other relevant conditions for product storage and a brief description of the consequences to performance if the product is not stored within these limits. Under § 300.915(a)(7), EPA is requiring the anticipated shelf life of the product at the storage conditions noted in paragraph (a)(6) and documentation for this determination.

A commenter suggested requiring the submitter to identify the method of product storage (*e.g.,* 55-gallon drum, 200-gallon plastic tote, etc.) and provide information on the storage container materials. The Agency does not believe it necessary to amend the regulatory text for this purpose. EPA notes that § 300.915(a)(7) requires documentation to support a manufacturer's determination of the anticipated shelf life of the product at the storage conditions. EPA believes this provision satisfies the commenter's concern regarding information on the storage container materials and methods that are likely to affect the product shelf life.

Product Labels. The provision at § 300.915(a)(8) requires sample product labels for all name(s), brand(s), and/or trademark(s) under which the product is to be sold that includes manufacture and expiration dates, and conditions for storage, and notes that the submitter may use an existing label provided it already contains the required dates and storage information. This requirement is not intended in any way to supersede any other federal labeling requirement in place (*e.g.,* OSHA's HAZCOM). The requirement is intended to assist the OSC in ensuring that the product used to respond to an incident is still viable and effective, and the oil spill removal organizations or any other responder that is storing the product to ensure that their stockpile is viable and available to be authorized for use. No comments on § 300.915(a)(8) were identified.

Chemical or Biological Agent Category. The provision at § 300.915(a)(9) requires the chemical or biological agent category under which the product is to be considered for listing on the NCP Product Schedule, including detailed information on the specific process(es) through which the product affects the oil, and the specific environment(s) on which it is intended to be used (*e.g.,* waters and/or adjoining shorelines). If the product meets the definition of more than one chemical or biological agent category, submitters must identify all applicable categories and provide the test data to meet the listing criteria appropriate to each category. A commenter suggested revising § 300.915(a)(9) to allow the manufacturer to indicate the primary and other non-primary functions to help the response team determine whether a product is best suited for a given response situation. Another commenter suggested that bioremediation agent formulas should be restricted to only those components necessary for the proposed primary use of any listed product, noting, for example, that bioremediation agents formulated for land-based settings may not need components such as surfactants to be effective, whereas the product may not need other components such as sugars and nutrients to be effective for use in or near water. EPA does not believe such a revision is necessary in § 300.915(a)(9) because the final rule includes a requirement under § 300.915(a)(13) for the product submitter to provide information on the intended function of each component. The Agency believes these provisions will help OSCs determine whether a product is appropriate for any given response situation. EPA notes that some components other than those components necessary for the primary use may still serve to support the product's function. However, EPA also recognizes concerns that a product (*e.g.,* bioremediation agents) may contain components that may support an alternate mechanism of action (*e.g.,* surfactants) and could potentially meet the definition of another product category (*e.g.,* dispersants). Based on comments, EPA amended the final provision under § 300.915(a)(9) to remove the phrase ''. . . and you want it considered for listing on the NCP Product Schedule in more than one category . . .'' to ensure that product manufacturers identify all applicable chemical or biological agent categories. If a product meets the definition of more than one chemical or biological agent category, the product manufacturers must provide the test data appropriate to each category. The final provision ensures that the Agency will receive the information necessary to evaluate the product for listing on the NCP Product Schedule in all categories in which the product may be listed, regardless of whether the submitter requests it to be listed in a specific product category.

In these finalized provisions, EPA also made some editorial changes to the proposed text for increased clarity and consistency.

Recommended Product Use Procedures. Under § 300.915(a)(10), EPA is requiring the submission of recommended product use procedures, including product concentrations, use ratios, types of application equipment, conditions for use, any application restrictions; and, as applicable, for product and oil containment, collection, recovery, and disposal procedures. These procedures must address, as appropriate, variables such as weather, water salinity, water temperature, types and weathering states of oils or other pollutants. The procedures must include supporting documentation and current applicable standard methods used to determine them. EPA believes that providing detailed information on the recommended product use procedures is necessary to inform the OSC when authorizing these products. This supporting documentation and specific information on the methods and standards used to establish them will inform OSCs and other response personnel in selecting products that can be effectively used under the operating

[4] The NCP Subpart J Technical Notebook presents manufacturer's summary information on the conditions under which each of the products is recommended to be used.

conditions encountered for any given incident.

The Agency recognizes the commenter that recommended that EPA require turbidity measurement in § 300.915(a)(10); however, EPA did not make this change because the regulatory text in § 300.915(a)(10) for variables (*e.g.,* weather, water salinity, water temperature, types and weathering states of oils or other pollutants, and product and oil containment, collection) that the product use procedures must address is not an exhaustive set of variables. In addition, the provisions under § 300.915(a) apply to all product categories, unless otherwise specified, such as bioremediation agents that are typically used on shorelines. The provisions under § 300.915(a)(10) provide flexibility for product manufacturers to submit information relevant to their product and this final action does not preclude the submitter from measuring turbidity of its product or including turbidity measurements in its submission for listing on the NCP Product Schedule, where appropriate. Furthermore, the monitoring requirements for dispersant use in response to major oil discharges include a requirement at § 300.913 to measure ambient background, baseline, and dispersed oil plume water column samples for turbidity.

EPA also acknowledges the commenter who suggested that EPA require the following in a submission: training and personal protective equipment (PPE) needs of the workers applying the product, health monitoring for the workers, whether the product requires special waste disposal, and whether the product is safe to use in sensitive areas such as near communities or water supplies. EPA believes that various NCP provisions already address this request. This final action includes the requirement at § 300.915(a)(5) to provide a SDS for the product, which includes PPE information. Furthermore, EPA notes that the NCP addresses worker health and safety under § 300.150, including compliance with applicable OSHA regulations and addresses availability of adequately trained operators under § 300.910(a) and (b), respectively. Additionally, § 300.915(a)(10) requires recommended product use procedures, including product concentrations, use ratios, types of application equipment, conditions for use, and any application restrictions; and, as applicable, for product and oil containment, collection, recovery, and disposal procedures. The NCP addresses the disposal of oil and contaminated materials recovered in cleanup operations in accordance with the RCP, ACP, and any applicable laws, regulations, or requirements under § 300.310(c). Waste disposal is outside the scope of this final action.

In the final action, EPA reorganized the provision under § 300.915(a)(10) including moving forward the phrase regarding procedures for product and oil containment, collection, recovery, and disposal procedures to provide greater clarity and adding the term ''as applicable,'' to recognize that not all products may be collected and recovered. EPA also made other editorial changes for greater clarity.

Environmental Fate. Under § 300.915(a)(11), EPA is requiring environmental fate information, including any known measured data, methodologies, and supporting documentation, on the persistence, bioconcentration factor, bioaccumulation factor, and biodegradability of the product and all of its components in the environment. EPA believes environmental fate information is necessary to inform the OSCs when authorizing these products for use, given the potential for their extended use in significant quantities. However, given that these factors can be estimated, the final action is only requiring that available information or data be submitted on the product rather than specific product testing, as specific product testing for these factors can add significantly to the testing cost for each product.

Regarding the Agency's request for comment on whether testing for products' bioconcentration, bioaccumulation, and biodegradation should be required for listing purposes, some commenters stated that testing should be required, and one expressed concern that reliance on existing data, rather than specifying a core required data package, may result in variable and incomplete understanding of these key factors which in turn influence chemical fate and biological effects of the product. EPA notes that the final provision provides flexibility to submit the required information with supporting documentation and also does not preclude submitting results from product-specific testing of these parameters. The submitter may use estimation techniques/models, such as the EPA model EPI Suite™, to estimate environmental fate properties. Based on comments, EPA amended § 300.915(a)(11) for product submissions to include the test methodologies used to obtain the environmental fate information, providing additional context on the data. EPA notes that the Agency reserves the right to request clarification or additional information, as necessary (see § 300.955(c)(1)).

Regarding the Agency's request for comment on whether thresholds for bioconcentration factors and bioaccumulation factors should be established for listing a product on the NCP Product Schedule, some commenters recommended that EPA should set thresholds for a product's persistence, bioaccumulation, and biodegradability for listing a product on the NCP Product Schedule, and to assist the OSC in authorizing use and establishing safe application rates. Another commenter suggested having minimum ''pass or fail requirements'' with added optional information fields for NCP listing. EPA recognizes that environmental fate information informs OSCs when authorizing these products for use, given the potential for their extended use in significant quantities. The new provisions will assist EPA in evaluating a product's persistence, bioaccumulation, and biodegradability. However, for oil spill response products, the Agency does not have sufficient information to establish thresholds for all environmental conditions that may be potentially encountered. The Agency did not propose, nor did it identify any relevant information to establish, thresholds beyond those already included in the final action. While EPA is not establishing thresholds for environmental fate information of chemical and biological agents, the final provisions require the submission of available environmental fate information to the Agency for listing a product on the NCP Product Schedule. The Agency intends to make the submitted information available to the public and other interested stakeholders (*e.g.,* natural resource trustees).

The Agency amended the final provision to replace the phrase ''Environmental fate information . . .'' with ''Available information on environmental fate . . .'' to address the comment that environmental fate data should be reported only if it is already available and included the phrase ''current applicable'' to avoid the submission of data based on test methodologies that have been superseded by later updates. EPA also reorganized the paragraph to clarify the requirements.

Physical and Chemical Properties. Under § 300.915(a)(12), EPA is requiring that the submitter provide the physical and chemical properties of the product, as appropriate, and a citation for the current applicable standard methods used to determine them, including: (i) Physical state and appearance; (ii) vapor

pressure; (iii) flash point; (iv) pour point; (v) viscosity; (vi) specific gravity; (vii) particle size for solid components; and (viii) pH. Three of these elements are new physical or chemical property requirements under this final rule: physical state and appearance; vapor pressure; and particle size for solid components. The Agency believes these basic data requirements will provide added context when evaluating the products for listing determinations. These, in combination with the other general product information requirements, will assist the Agency in evaluating the expected product behavior, and the process through which it would affect the oil when used in the intended water and/or shoreline environment.

Additionally, the Agency has removed the incorporation by reference of specific standards to determine physical and chemical properties and replaced this with a requirement for a citation of the current applicable standard methodology used to determine these values. EPA believes that citing the current applicable standard methodology used to determine the required values is sufficient in lieu of specifying commonly recognized standard methodologies. Furthermore, EPA did not incorporate by reference specific test methodologies in the regulation to avoid the administrative burden of updating the NCP every time a test methodology is updated to a newer version. The Agency believes it is appropriate to make this change given the added requirement for accredited laboratories to conduct the testing (§ 300.915(a)(17)). EPA amended this provision relative to the proposed text to qualify ''standard methods'' by adding the term ''current applicable'' to address comments regarding additional specificity about the standard methods used to derive physical and chemical properties. EPA included the qualifier ''current applicable'' to provide for updates to test methodologies and avoid the submission of data based on test methodologies that have been superseded by later updates. EPA also made other editorial changes to the paragraph relative to the proposed text for greater clarity.

Under § 300.915(a)(13), EPA is requiring that the submitter provide the identity and concentration of all components in the product, including each specific component name; corresponding Chemical Abstract Service (CAS) Registry Number; the maximum, minimum, and average weight percent of each component in the product; and the intended function of each component (*e.g.,* solvent, surfactant).

A commenter suggested that product vendors should not be required to report the concentration of product components to the Agency, noting that this reporting requirement may threaten a proprietary advantage. EPA notes that the requirement to submit the identity and concentration of all components in the product is consistent with the previous rule. EPA believes that when chemical and biological agents are used on oil discharges, it is important for OSCs, RRTs, and the public to have information regarding the chemicals being added to the environment. EPA also believes that the concentration of the product components provides EPA with an understanding of how the product is intended to function that cannot be provided by the submission of the identity of the product components only. In addition, information on the concentration of product components assists EPA in evaluating on the listing of product on the NCP Product Schedule and under which category. The final rule specifies what information submitters are allowed to claim as PBI to balance public access to information with proprietary business needs. When a company submits a product for listing on the NCP Product Schedule, then it will be allowed to claim certain information identified in § 300.915(a)(13) or (14) as PBI.

Microorganisms, enzymes, and/or nutrients. For products that contain microorganisms, enzymes, and/or nutrients under § 300.915(a)(14), EPA is requiring that the submitter provide the following along with a citation or a description of the methodology used to determine: (i) The name of all microorganisms by current genus and species, including any reclassifications, and any physical, chemical, or biological manipulation of the genetic composition and the weight percent of each genus in the product; (ii) the name of all enzymes and their International Union of Biochemistry (I.U.B.) number(s); Enzyme Classification (EC) code numbers; the source of each enzyme; units; and specific oil-degrading activity; (iii) the name(s), maximum, minimum, and average weight percent of the nutrients contained in the product; and (iv) data, methodology, and supporting documentation for the levels of bacterial, fungal, or viral pathogens or opportunistic pathogens including, but not limited to: enteric bacteria such as *Salmonella,* fecal coliforms, *Shigella,* coagulase positive *Staphylococci,* and beta hemolytic *Streptococci* and enterococci. As noted above, the final rule specifies what information submitters are allowed to claim as PBI to balance public access to information with proprietary business needs. When a company submits a product for listing on the NCP Product Schedule, then it will be allowed to claim certain information identified in § 300.915(a)(13) or (14) as PBI.

To support product screening, this final rule includes a provision under § 300.915(a)(14)(iv) to address whether products that contain microorganisms, enzymes, and/or nutrients also contain bacterial, fungal, or viral pathogens or opportunistic pathogens to compare to existing applicable criteria. The Agency reconsidered, based on comments, whether it should establish listing thresholds for products based on National Ambient Water Quality Criteria, and whether the levels selected for certification are appropriate for this purpose. Comments received noted that states may develop standards that may be more stringent than national criteria. EPA recommends that states and authorized tribes consider the Agency's national recommended water quality criteria when developing their criteria. However, states and authorized tribes may adopt, where appropriate, other scientifically defensible criteria that differ from the EPA's recommendations. In addition, both national recommended water quality criteria and state water quality standards may be revised from time to time. The final provision under § 300.915(a)(14)(iv) requires that products submitters provide data, methodology, and supporting documentation for these pathogen levels to provide relevant information, but the provision does not require a certification that they do not exceed recommended National Ambient Water Quality Criteria, as applicable. The final provisions for listing products on the NCP Product Schedule or Sorbent Product List under § 300.955 allow the Agency to make listing determinations based on a technical evaluation of all data and information submitted in accordance with the requirements for each product category and the relevant information on impacts or potential impacts of the product. The Agency believes that this information is necessary to determine if a product is suitable for listing, particularly for bioremediation agents, which could potentially be used at recreational beaches. EPA amended the final provision to better reflect this approach. EPA may include information related to national recommended ambient water quality criteria, applicable state water quality standards, and other relevant

environmental screening information (*e.g.,* aquatic life benchmarks) in the NCP Product Schedule Technical Notebook for the RRTs, Area Committees, and OSCs to consider when planning for and responding to oil discharges.

A commenter suggested that § 300.915(a)(14)(iv) should only apply to bioremediation agents that fall into the microbiological cultures category, because categories of bioremediation agents that do not contain live cultures have completely different mechanisms of action. The Agency disagrees that the submission requirements in § 300.915(a)(14)(iv) should only apply to microbiological cultures. This provision applies to all bioremediation agents, which include microorganisms, enzymes, and nutrient additives, irrespective of a classification, to ensure all bioremediation agents (not just those that the product submitters characterize as microbiological cultures) are subject to the requirements under § 300.915(a)(14)(iv).

National Water Quality Standard Contaminants (NWQS). Under § 300.915(a)(15), EPA is requiring that the submitter provide data, methodology, and supporting documentation for the levels of the following: (i) Arsenic, cadmium, chromium, copper, lead, mercury, nickel, vanadium, zinc, and any other heavy metal reasonably expected to be in the product; (ii) cyanide; (iii) chlorinated hydrocarbons; (iv) pesticides; (v) polychlorinated biphenyls (PCBs); and (vi) polycyclic aromatic hydrocarbons (PAHs). The Agency may consider how these levels compare to recommended National Ambient Water Quality Standards, as applicable. Providing information (*i.e.,* upper limit/concentration, detailed analytical methods, and sample preparation) on most of these contaminants was previously required for all products, but with no established threshold levels for product listing. The Agency will continue to require information on the methodology and the data and supporting documentation used to determine the levels of these contaminants in a product. The Agency, however, is not specifying what analytical testing method the submitter should use to make these determinations, as it did for chlorinated hydrocarbons, allowing the submitter flexibility in testing their product. Additionally, the Agency is now requiring data on several additional contaminants: pesticides, PCBs, and PAHs. The Agency's concern with pesticides as contaminants is mostly due to their potential use on organic sorbents (*e.g.,* peat moss, corn cobs, and cellulose fibers). The concern for PCBs is for their toxicity and classification as persistent organic pollutants, having toxic effects such as endocrine disruption. PAHs are potent atmospheric pollutants, of concern because some compounds have been identified as carcinogenic, mutagenic, and teratogenic. The requirements for these contaminants are intended to provide information for listing decisions that ensure the use of any product considers established these recommended levels.

Some commenters suggested that the proposed requirement in § 300.915(a)(15) to certify that the product does not exceed NWQS standards is not appropriate for this use because NWQS are defined as concentrations in the water column, not in formulated products. Commenters argue that the requirement assumes exposure to full-strength product, but due to the dilution that occurs when a product is used in an oil spill situation, the requirements are unnecessary. Commenters also assert that the existing requirements to communicate hazardous impurities on product SDSs are sufficient. A commenter suggested that the Agency should establish a listing threshold for products based on the National Water Quality Criteria for both acute and chronic standards and should rank products based on their ability to not add additional contaminants to the water. A commenter also suggested that the Agency consider whether there are any state water quality standards that are more stringent than the national recommended water quality criteria. After considering comments, EPA amended the regulatory text in § 300.915(a)(15) to require the submitter to include data, methodology, and supporting documentation on the levels of substances identified in § 300.915(a)(15). The Agency recognizes that states may develop water quality standards that may be more or less stringent than national criteria and that those standards may vary from state to state. EPA recommends that states and authorized tribes consider the Agency's national recommended water quality criteria when developing their criteria. However, states and authorized tribes may adopt, where appropriate, other scientifically defensible criteria that differ from the EPA's recommendations. In addition, both national recommended water quality criteria and state water quality standards may be revised from time to time. While EPA is maintaining the requirements for product submitters to include data, methodology, and supporting documentation on the levels of substances identified in § 300.915(a)(15) in their product, the final provision does not require a certification related to National Recommended Water Quality Criteria or applicable State water quality standards. EPA may include information related to national recommended ambient water quality criteria, applicable state water quality standards, and other relevant environmental screening information (*e.g.,* aquatic life benchmarks) in the NCP Product Schedule Technical Notebook for the RRTs, Area Committees, and OSCs to consider when planning for and responding to oil discharges. To allow the submitter flexibility in testing their product, the Agency does not specify which analytical testing method the submitter should use to make these contaminant level determinations for purposes of product submission for listing on the NCP Product Schedule. The Agency notes that the previous rule does not specify thresholds for contaminants. Gathering data, methodology, and supporting documentation for substances identified in § 300.915(a)(15) provides a reasonable approach to inform RRTs, Area Committees, and OSCs on the potential addition of these substances into the environment and to address concerns on the potential detection of these substances during a response. EPA also notes that the final provisions include thresholds for listing on the NCP Product Schedule based on subchronic toxicity for dispersants. EPA included subchronic toxicity testing for dispersants because of EPA's experience with dispersant use, including the quantities and duration, and because dispersants are designed to transfer oil into the water column and are not intended to be recovered from the environment. The fact that dispersants cause oil to enter the water column is sufficient reason to test for the subchronic toxicological effects of dispersed oil. Based on past spill response activities, dispersants have the potential for use over extended durations and in larger quantities relative to other chemical and biological agents.

No prohibited agents or substances. Under § 300.915(a)(16), EPA is requiring that the submitter provide 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). No comments on this provision were identified. EPA is finalizing the provision with changes

to reflect the updated title to § 300.910(e) ''Prohibited Agents or Substances.''

Testing Laboratory Information and Data. Under § 300.915(a)(17), EPA is requiring that the submitter provide information about the laboratory that conducted the required tests, including: (i) Name of the laboratory, address, contact name, email, and phone number; and (ii) the national and/or international accreditations held by the laboratory. At § 300.915(a)(18), EPA provides the list of all test data and calculations that are required to be submitted, including: (i) Raw data and replicates, including positive controls; (ii) notes and observations collected during tests; (iii) calculated mean values and standard deviations; (iv) reports, including a summary of stock solution preparation; (v) source and preparation of test organisms; (vi) test conditions; and (vii) chain of custody forms.

In this final action, EPA is removing the previous requirement for laboratories performing the efficacy and toxicity testing to have prior experience specific to the required methodology. The Agency believes that it is more appropriate to require that laboratories be nationally or internationally accredited. Accredited laboratories are expected to be capable of following a prescribed testing protocol and good general practices, providing assurance that the test results will be reliable. National and international accreditation organizations include, for example, the International Organization for Standardization (ISO), and the Laboratory Accreditation Bureau (recognized in the U.S. through the National Cooperation for Laboratory Accreditation (NACLA) and the International Laboratory Accreditation Cooperation (ILAC)). Commenters expressed both support and opposition for this change. Various commenters noted that qualified laboratories should not be barred from conducting these analytical tests due to lack of prior experience with a specific methodology if it has been accredited by an appropriate authoritative body, and on the other hand that the removal of this requirement may lead to inaccurate results being submitted to the Agency because conducting these tests requires skilled and knowledgeable technical resources, and that by themselves, general accreditations do not guarantee a particular institution would have the resources and/or expertise to conduct the necessary efficacy and toxicity testing. The Agency believes that having no prior experience with a specific methodology should not disqualify a laboratory that has been accredited by an appropriate authoritative body. Therefore, the final provisions do not include a requirement to have prior experience specific to the required methodology. However, the Agency reserves the right to not accept data from a laboratory should EPA find cause to doubt the quality and integrity of the work. EPA also reserves the right to conduct its own testing of any product.

A commenter requested that the Agency be more specific regarding laboratory accreditation requirements. For example, a laboratory that is accredited to perform chemical analyses may not have a similar accreditation to conduct toxicity testing. The Agency understands that a laboratory may be accredited to perform some of the required testing but may not have accreditation to conduct all the required tests. A primary laboratory selected to conduct efficacy and/or toxicity testing may subcontract that test out to another laboratory with the required accreditation for testing if they do not have the requisite accreditation or capability. The final provisions require laboratories to have accreditation applicable to the test(s) they perform. EPA is finalizing these provisions with clarifying edits.

Production Capacity. Under § 300.915(a)(19), EPA is requiring that the submitter provide an estimate of the annual product production volume, the average and maximum amount that could be produced per day, and the time frame needed to reach that maximum production rate in days. In the final provision, EPA made editorial changes to provide greater clarity by specifying the time frame needed to reach maximum production rate ''in days'' in lieu of ''(days).'' There was previously no requirement for production capability information, and the Agency believes it is important for the OSCs and responders to have this information. The availability of a product may impact decisions of authorization of use, depending on inventory or production capabilities. This would prove to be of key importance, for example, in the event of a major environmental disaster (*e.g.,* a SONS event).

A commenter suggested that this requirement should be removed because production capacity is not fixed, but varies with available blending tankage, existing business demands, other product orders, and component supplies/shipping constraints, so the information provided at the time of the application would not be relevant to a future time when product manufacturing could be required during a response. The commenter suggested that the Agency alternatively modify the language to require product manufacturers to provide production capability within 24 hours of a request from an OSC. The Agency disagrees. It is important to have an estimate of product capacity in the event of a spill of any size to better understand product availability to inform OSCs and RRTs. EPA has no previous record of product capacity for the dispersants, or any other product, on the NCP Product Schedule. The EPA Inspector General Report entitled *Revisions Needed to National Contingency Plan Based on Deepwater Horizon Oil Spill* recommended the need to capture and maintain dispersant manufacturer production capacities.

Finally, EPA made editorial changes to this provision to provide greater clarity.

Recognition Received from EPA's Design for the Environment/Safer Choice Program. Under § 300.915(a)(20), EPA is requiring that the submitter provide recognition received from EPA's Design for the Environment (DfE) or Safer Choice programs, as applicable. In 2015, the Safer Choice label replaced the DfE product label. Therefore, in the finalized provision, EPA has added reference to the Safer Choice program. (The ''DfE'' certification is still used in some cases. Specifically, it is used on antimicrobial products (disinfectants and sanitizers) registered under FIFRA.) A manufacturer's participation in the Safer Choice program is voluntary. The Safer Choice label means that EPA scientists have evaluated all chemical ingredients, regardless of their percentage in the product. Every ingredient must meet strict safety criteria for both human health and the environment, including carcinogenicity, reproductive/developmental toxicity, toxicity to aquatic life, and persistence in the environment. For more information on the EPA's Safer Choice program, see: *https://www.epa.gov/saferchoice.*

A commenter suggested that submitting this information should not be required because the DfE certification is a voluntary program and therefore not required. EPA disagrees; the Agency provides the submitter with the opportunity to identify products that have met and are labeled DfE or Safer Choice certified as part of the general information submission, as applicable. This information may be included in the NCP Product Schedule Technical Notebook.

International product testing, data, or certifications. Under § 300.915(a)(21), EPA is requiring that the submitter provide international product testing or use data or certifications, if available,

informing the performance capabilities or environmental impacts of the product.

A commenter suggested that the Agency clarify the ability to use results from laboratories outside of the United States. The commenter also requested that the Agency clarify its statements regarding ''International Product Certifications, testing or use data informing the performance capabilities or environmental benefits of the product;'' the commenter stated that it is not clear whether the Agency would accept this information or whether it would be used to waive certain efficacy or toxicity requirements. Another commenter suggested that decision makers may benefit from knowing which products have been denied registrations in other countries, or been banned for use in other counties, including the reason(s) why the product was denied registration. The Agency believes that any additional data available from other countries may help identify the benefits or concerns for the listing and/or the authorization of use of a product. The Agency, however, is not associating any specific listing criterion or threshold with this broad information request, as some products may not have data available. The international product certifications data provision supplements but does not waive or replace toxicity and efficacy requirements in the listing requirements of the Subpart J final rule.

A commenter suggested that the Agency revise the use of the term ''environmental benefits'' in this section related to product information to a discussion of potential ''benefits and drawbacks.'' The commenter noted that their revised language would allow responders to make more informed decisions. The Agency agrees with the comment to revise the term ''environmental benefits.'' EPA amended the final provisions by replacing ''environmental benefits'' with ''environmental impacts'' to provide a neutral characterization. EPA believes the amended terminology avoids the potential misinterpretation associated with the term ''benefits.''

(b) Dispersant Testing and Listing Requirements

The Agency is revising the efficacy and toxicity testing protocols, as well as establishing new thresholds for listing dispersants on the NCP Product Schedule in § 300.915(b). As defined in § 300.5 of the final rule, dispersants are substances that emulsify, disperse, or solubilize oil by promoting the formation of small droplets or particles of oil in the water column. These droplets are typically driven into the water column by wave action. Emergency response personnel need to know whether a dispersant or any other type of chemical or biological agent on the NCP Product Schedule could have negative environmental impacts relative to the oil before decisions are made about its use in a particular oil discharge situation. Consequently, it is essential to consider comparative information about the efficacy and the toxicity of these products. The finalized revisions are in response to concerns not only for an increase in the frequency of planning for the use of these agents, but also for their potential use in large quantities, such as when responding to oil discharges from oil tanker accidents and offshore well blowouts, as evidenced during the Deepwater Horizon incident in 2010.

A commenter stated that there is no need for additional testing of chemical dispersants because it is well known that they contain toxic constituents. Another commenter asserted that the toxicity and effectiveness test requirements in the previous rule already allow for discrimination between good products and poorly performing dispersants, and it is not clear that the proposed revisions provide significant value with respect to protecting the environment in the event of an oil spill. EPA disagrees that there is no need for additional dispersant testing. Subpart J not only includes an NCP Product Schedule identifying chemical and biological agents, but also authorization of use procedures that, when taken together, identify the waters and quantities in which such chemical and biological agents may be used safely. The toxicity testing and listing threshold requirements for dispersant alone for listing on the NCP Product Schedule serve to screen dispersant products for hazard, while the authorization of use procedures provide for consideration of the conditions surrounding the specific oil discharge situation. In addition, the provisions under § 300.910(g) in this final action allow for new information, including specific to environmental toxicity, to be considered for planning and response activities. EPA believes that when chemical and biological agents are used on oil discharges, it is important for the OSCs and RRTs to have information regarding the chemicals being added to the environment, along with information about their toxicity. The NCP provides a framework for efficient, coordinated, and effective response to discharges of oil. This final action is consistent with that approach.

A commenter urged the Agency to consider regional differences in testing requirements for NCP Product Schedule listings. The commenter specified that some issues are better addressed at the regional level including dispersant effects in varying environmental contexts, such as colder versus warmer waters, changing water depths and distance, differing sensitive species and/or habitats and shoreline characteristics. The Agency recognizes regional differences in requirements and that some issues may be addressed at a regional level. EPA notes that the NCP Product Schedule is established on a national level, and that regional considerations are integrated into Subpart J through the authorization of use process during response activities, and also through the RRT's and Area Committee's regional and area planning activities. This final action provides for regional-level consideration opportunities under the authorization of use provisions codified at 40 CFR 300.910. For example, § 300.910(a)(1) provides for RRT and Area Committee consideration of the existence and location of environmentally sensitive resources during preauthorization planning development. Further, § 300.910(g), *Supplemental Testing, Monitoring, and Information,* provides for supplemental toxicity and efficacy testing and information to address site, area, and ecosystem-specific concerns. Finally, the NCP provides for national, regional and area contingency planning under § 300.210.

A commenter stated that it is unclear whether the thresholds for efficacy and toxicity will limit dispersant stockpiles to such a small level as to essentially eliminate their use and suggested that this potential issue be addressed in the analysis of the rule to provide supporting information for the Agency in making regulatory decisions for this rule. Another commenter also stated that the proposed revision of the rule under § 300.915(b)(1) *Dispersant Testing and Listing Requirements; Dispersant Efficacy Test and Listing Criteria* that increase the dispersant efficacy requirements for listing on the NCP Product Schedule will make it unlikely that any dispersants currently stockpiled in the United States would pass both the proposed efficacy and toxicity tests. Neither the previous nor final rule requires stakeholders to stockpile dispersants or other chemical or biological agents, nor removes them from consideration as a response option. The Agency notes that dispersants are not the only response option available during a response; there are other

response options (*e.g.,* mechanical recovery) available to consider that may lower overall environmental damage depending on the incident-specific nature of the response. Decisions on the authorization of use of dispersants and other agents during a response are to be made in accordance with the NCP and all applicable statutes and regulations. This final action includes provisions to transition products currently on the NCP Product Schedule through the revised listing process. This final action allows a grace period of 24 months for any product currently listed on the NCP Product Schedule to be authorized for use (see § 300.955(f) *Transitioning Listed Products to the New NCP Product Schedule or Sorbent Product List.*) Products on the NCP Product Schedule for which a new submission is not received or that do not meet the revised listing criteria will be removed from the NCP Product Schedule at the end of the 24-month transition period. This transition period provides time for retesting, production of additional products, and the continued ability of currently listed products to be offered and available in the event of a response.

(1) Dispersant Efficacy

The Agency is changing the testing protocol for measuring efficacy and revising the efficacy listing criteria for dispersants to be listed. Specifically, a dispersant must demonstrate that the Dispersant Effectiveness at the 95% lower confidence level (LCL_{95}) meets the new proposed efficacy listing criteria at two test temperatures. EPA is also replacing the reference oil with a new test oil: Strategic Petroleum Reserve (SPR) Bryan Mound.

Testing Protocol. Under § 300.915(b)(1), the Agency is adopting the Baffled Flask Test (BFT) method as the testing protocol for dispersant efficacy and providing this method in AppendixC to part 300. This testing protocol replaces the Swirling Flask Test (SFT) that was formerly listed in Appendix C to part 300 of the NCP. The BFT procedure incorporates a redesign of the testing flask by eliminating the side arm, incorporating baffles in the wall of the flask, and adding a stopcock at the bottom, which improves reproducibility in the hands of different operators. This protocol has undergone peer review [5] and has been tested in several laboratories, providing reproducible and repeatable results.

Some commenters opposed switching from the SFT to the BFT. A commenter stated that the Agency should not replace the accepted standard Swirling Flask Test, developed by the EPA Canada, and that the BFT is a non-standard test designed by industry. Another commenter expressed concerns with EPA proposing a non-standard method in lieu of one well accepted and used around the world (ASTM F2059–06; 2012). The Agency's decision to adopt the test in the final rule is based on the BFT method's attributes; the Agency could not identify other potentially applicable standards that would incorporate the considerations of the BFT. The BFT is designed to be more representative of the moderately turbulent sea conditions where dispersants are more likely to be successful when used. The new BFT procedure incorporates a redesign of the testing flask by eliminating the side arm, incorporating baffles in the wall of the flask, and adding a stopcock at the bottom, which improves reproducibility in the hands of different operators. Specifically, the new baffled trypsinizing flask design, fitted with a glass stopcock positioned at the bottom side, promotes less manipulation that could result in erroneous re-suspension of non-dispersed oil. Additionally, the BFT provides higher, consistent turbulent mixing energy within the flask, resulting in the possibility of better dispersion and more repeatable and reproducible dispersant effectiveness testing results. The BFT was tested extensively in an iterative inter-laboratory calibration test using commercially available dispersant products.

Reference oils. The provision at § 300.915(b)(1) specifies the type of oil that the efficacy testing must use, SPR Bryan Mound. The use of reference oils was proposed, in part, to ensure that testing of the effectiveness of a dispersant product is done in a uniform manner, across manufacturers, and is performed in a way to ensure that EPA can be confident in the results of that testing before a dispersant product is listed on the NCP Product Schedule for subsequent consideration for use in a response under the NCP. The Agency proposed requiring product manufacturers to test their dispersant products against two new reference oils, ANS and IFO–120, or similar oils, to provide representative information on the potential efficacy of products when used on different types of oils. These two oils were proposed to replace the previously required reference oils. In the proposal, EPA considered testing requirements for dispersant products against two reference oils; however, the final action provides for dispersant efficacy and toxicity testing to be performed using one reference oil: SPR Bryan Mound. The Agency and the Strategic Petroleum Reserve (SPR) successfully identified multiple potential oil blends stored at the SPR. After multiple rounds of testing, EPA has selected one oil, the Bryan Mound oil blend, from the SPR, to serve as the selected reference oil for the final action.

While the proposal considered testing requirements for dispersant products against two reference oils, this final action provides for dispersant efficacy and toxicity testing to be performed using one reference oil: SPR Bryan Mound. After confirmatory testing, 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. This final rule establishing a sole screening reference oil is consistent with the purpose of product testing for NCP Product Schedule listing. The NCP Product Schedule was created to allow for consideration of comparative information about the efficacy and the toxicity of products by establishing a national level screening baseline of products that can be considered for use. The reference oil used in Appendix C is not intended to be representative of every type of oil or condition that may be encountered during a response where a product may be considered for authorization of use. The reference oil is used to establish a nationally consistent testing regime for product listing on the NCP Product Schedule, which informs authorization of use and planning decisions when applied to regional planning and site-specific responses.

Commenters had concerns and suggestions about the proposed reference oils. A commenter noted that if only two types of oils are tested (as under the proposal), it is unclear how results will be extrapolated to other untested oils, particularly for those oil types which exceed the tested range, *e.g.,* those oils that are heavier than IFO–120 or lighter than ANS crude oil. A commenter suggested testing dispersants' efficacy on blended alcohol-hydrocarbon fuel, given that alcohol-based biofuel spills are an emerging research priority. Some commenters expressed concern about the lack of reference oils for Unconventional Oil and Gas (UOG) and

[5] Venosa, Albert D., National Risk Management Research Laboratory, US EPA; Sorial, George A., Department of Civil & Environmental Engineering, University of Cincinnati; King, Dennis W., Statking Consulting; *Round-Robin Testing of a New EPA Dispersant Effectiveness Protocol,* International Oil Spill Conference, 2001.

that the use of conventional reference oils for products intended for use on UOG will lead to erroneous and misleading information about product toxicity and efficacy. The Agency's intent with proposing the use of ANS and IFO–120, or similar oils that represent a wider range of oil gravities, was that it would provide information on the efficacy of the products that could represent their use on different types of oils. The final action updates the reference oil used for dispersant efficacy and toxicity testing to SPR Bryan Mound in lieu of ANS and IFO–120. The Agency believes SPR Bryan Mound meets the needs as a screening reference oil for a baseline comparison of products to establish the NCP Product Schedule listing. The required reference oil is not intended to be representative of every type of oil or condition that may be encountered during a response where a product may be considered for authorization. Rather, the final rule recognizes different types of oil under the authorization of use provisions. For example, § 300.910(a)(1) provides that preauthorization plans should address likely sources and types of oil that might be discharged when developing a preauthorization plan. The provision under § 300.910(a)(1) provide RRTs with the flexibility to tailor the scope of the preauthorization plan to account for different types of oil, including unconventional oils. In addition, § 300.910(g) provides for, among other provisions, the supplementary efficacy testing to provide greater flexibility to tailor testing conditions to address area- and site-specific concerns relative to the use of a product for planning and authorization of use. This provision provides RRTs with the flexibility to gather additional information for different types of oil, including unconventional oils.

Temperature. The provision at § 300.915(b)(1) requires that efficacy testing be conducted at two different temperatures, 5 and 25 degrees Celsius (°C), rather than at an ambient temperature range of 20 to 23 °C as previously required. The Agency recognizes the current and future interest in arctic and deep water drilling, and the continued oil production in the southern areas of the country. Given the potential range of locations where dispersants may be used, the Agency believes it is appropriate to have products tested at temperatures that would reflect that range. These temperatures are intended to capture dispersant use scenarios in a wide range of geographic locations and under different temperatures that may occur in the same geographical location (such as, for example, the deep sea and surface water in the Gulf of Mexico, where the temperatures are typically between 5 °C and 25 °C, respectively).

Some commenters suggested that testing at different temperatures will not add value for relative comparison between dispersants. A commenter mentioned that dispersants can be effective at a range of ambient temperatures and the requirement to perform multiple tests on two oils at two temperatures does not provide significantly more information than would otherwise be obtained by testing oils at a single temperature. The commenter stated that the use of a single temperature should be adequate for determining relative ranking of different dispersants. A commenter recommended that a dispersant's efficacy should only need to be tested within the temperature range of 20 +/− 3 °C and this range would account for the variances in testing that will occur when the BFT is conducted by different laboratories and different technicians. A commenter suggested that requiring an effectiveness test at 5 °C is unnecessary, mentioning that it is of greater importance to determine that the dispersant itself maintains desirable rheology at cold temperatures and that it is able to be used with the existing spray systems. Another commenter recommended testing be conducted at 1 °C instead of 5 °C for the lower test range because the Arctic waters typically range between 0 °C and 4 °C. Another commenter suggested that for dispersants proposed for use in the Arctic, the Agency should consider requiring efficacy testing under even colder water conditions, as marine waters do not typically freeze until they reach approximately −1.8 °C (roughly 29 degrees Fahrenheit).

The Agency acknowledges comments opposing testing at different temperatures. The Agency recognizes the current and future interest in crude petroleum oil exploration and production throughout the United States. The Agency believes it is appropriate to have dispersant products tested on a national level at temperatures that would reflect a range of water temperatures in which dispersants might be used. The efficacy testing criteria for temperature are intended to capture dispersant use scenarios in a wide range of geographic locations and under different temperatures that may occur in the same geographical location. Water temperature may vary seasonally or with water depth even within the same geographical location. For example, the temperatures specified in the dispersant efficacy testing protocol span the range of temperatures of the deep sea and surface water in the Gulf of Mexico. Even within a geographical region, there may be seasonal variations in temperature that could affect the dispersant use considerations. This final rule screens dispersant products for efficacy at two different temperatures to ensure the dispersant products meet the efficacy thresholds provided for in the final action and avoid uncertainty associated with listing a dispersant product tested at only one temperature. Even if oil remains dispersible at lower temperatures, the efficacy testing at a lower temperature screens dispersants that may become ineffective due to changes in their temperature-dependent physical or chemical properties (*e.g.,* increased viscosity). Efficacy testing at two different temperatures also avoids potential confusion of listing dispersant products for use at specific temperatures.

The Agency also recognizes comments to extend the temperature testing range below 5 °C. This final rule provides for consideration of geographically specific temperatures within the general listing requirements under § 300.915(a) and authorization of use procedures under § 300.910. For example, the final provisions require product submissions (*e.g.,* dispersant submission) to provide the recommended product use procedures under § 300.915(a)(10). These procedures must address, as appropriate, variables such as water temperature, and must include supporting documentation. The information required to be submitted to support the listing, including testing results from multiple temperatures, provides the OSC and RRT with relevant information that may be used to inform authorization of use determinations. The final rule also allows for supplemental efficacy testing under § 300.910(g), *Supplemental Testing, Monitoring, and Information.* The OSCs and RRTs may require these tests to be conducted, due to site- or area-specific concerns, using parameters other than those specified in Appendix C, including dispersant efficacy test at different temperatures than that specified in Appendix C. In conjunction with the required product listing information, these supplemental testing provisions also provide OSCs and RRTs with flexibility to gather more detailed information as needed for authorization of use determinations.

Confidence Level (LCL_{95}). The provision at § 300.915(b)(1) requires dispersant effectiveness testing results

to be reported in terms of 95% lower confidence level (LCL_{95}). This accounts for between- and within laboratory error variability and the inherent error of the method.

A commenter expressed support for this requirement because the LCL_{95} is a lower threshold value than the average dispersant effectiveness criteria that was previously used. Another commenter suggested that reporting only the LCL_{95} reduces the amount of information available on a product and recommended that the test average and standard deviation also be provided for additional information on the precision of the testing. The Agency disagrees with the comment suggesting reporting the LCL_{95} reduces the information available. As described in the **Federal Register** notice for the proposed rule, only one number is reported compared to reporting a mean and standard deviation, as the variation has already been subtracted in the reported number (80 FR 3403–3404, January 22, 2015). Furthermore, the final provisions require under § 300.915(a)(18) that product submission for listing on the NCP Product Schedule provide all test data and calculations, including raw data and replicates (including positive controls), notes and observations collected during tests, calculated mean values and standard deviations, reports, including a summary of stock solution preparation, source and preparation of test organisms, test conditions, and chain of custody forms.

Dispersant Efficacy Thresholds. The Agency is revising the efficacy criteria for dispersants to be listed on the NCP Product Schedule. Specifically, the dispersant must demonstrate a Dispersant Effectiveness (DE) at the 95% lower confidence level (LCL_{95}) greater than or equal to: (i) 70% for SPR Bryan Mound at 5 °C; and (ii) 75% for SPR Bryan Mound at 25 °C.

Commenters suggested that the efficacy thresholds as proposed in § 300.915(b)(1) were high, even for highly effective dispersants; a commenter cited a BFT study suggesting that a certain dispersant product may not be listed based on its percent effectiveness results of 69% and 61% on different oils. Other commenters suggested that the proposed thresholds are too restrictive and do not sufficiently take into account the variability of the BFT. A commenter stated that it would be better to set a minimum threshold for efficacy tests of 65% at any temperature as a minimum requirement for listing. Another commenter recommended that the requirements for percent effectiveness at various temperatures and oils should be changed to a single value of 45% effectiveness. The Agency recognizes that the final provisions update the SFT efficacy testing protocols to the new BFT efficacy testing protocol, which is designed to be more representative of moderately turbulent sea conditions where dispersants are more likely to be successful when used. The revised testing protocol improves test repeatability and reproducibility within and between laboratories, as well as greatly reduces both the inherent error of the method and the human error associated with the SFT protocol. In addition, reporting the test results in terms of the product's LCL_{95} accounts for between- and within laboratory error variability and the inherent error of the method. The BFT provides higher, consistent turbulent mixing and better enables more reproducible and repeatable dispersant. The BFT provides such mixing and better enables more repeatable and reproducible dispersant effectiveness than the SFT. The mixing energy within the baffled flask is higher than the mixing energy within the swirling flask, and, as a result of this increased mixing energy, better dispersion is possible. The efficacy thresholds in the final provisions are higher than the previous efficacy threshold and reflect improvements from the BFT protocols. These higher thresholds also reflect the Agency's intent to strengthen the requirements for listing dispersant products on the NCP Product Schedule that are more efficacious. The Agency believes the final action provides reasonable thresholds for the purposes of listing a dispersant on the NCP Product Schedule without being overly restrictive.

(2) Dispersant Toxicity

The Agency is revising the toxicity testing requirements for dispersants, including the testing protocols and the use of the test results. The provision at § 300.915(b)(2) requires acute toxicity testing for the dispersant alone, and the dispersant mixed with SPR Bryan Mound. It also requires developmental toxicity and subchronic testing on the dispersant alone. These tests must be performed using the methods specified in Appendix C. While the toxicity testing results were previously used by the OSC to assist in authorization of use determinations, the Agency will now use the testing results for the dispersant tested alone to determine eligibility for listing on the NCP Product Schedule.

Commenters asserted that the Agency needs to clearly distinguish between the requirements of the toxicity testing required to assess which dispersants should be listed on the NCP Product Schedule, and toxicological studies with appropriate oils, test organisms, and exposure conditions that will inform discussions about how the listed dispersants might cause impacts in U.S. waters under the specific circumstances of an oil spill or release. Specifically, a commenter suggested that the Agency clarify the objective and rationale of the proposed acute exposure toxicity testing of dispersant-oil mixtures and explain how this relates to the listing of a product on the NCP Product Schedule. The Agency seeks to clarify that the toxicity testing and listing threshold requirements for the dispersant alone, serve to screen dispersant products for hazard. EPA is unaware of any single toxicity testing protocol that represents every potential exposure situation that may be encountered during an oil spill. There are numerous factors that come into play and affect an organism's exposure under the wide range of field conditions, which are not necessarily represented by the commenters suggestion to use short-term exposure durations under spiked exposure concentrations. In addition, even short-term exposure to dispersed oil can have harmful effects to certain species and life stages. The exposure to individual organisms during an incident depends on many factors including, but not limited to, the type of oil discharge (*e.g.,* continuous discharge), proximity of the organisms to the oil discharge, and organism mobility. The Agency believes the protocols provide for a conservative decision approach and establish an adequate safety margin without being overly restrictive. The Agency also believes that testing the oil alone, as well as the oil and dispersant mixture, will provide useful data on the relative toxicity of the oil and the potential hazards associated with dispersant use (*i.e.,* data derived from the oil and dispersant mixture test) relative to the hazards associated with non-treatment of the oil (*i.e.,* data derived from the oil only test). EPA believes that the comparative nature of the data will benefit the OSCs, RRTs, and Area Committees in their decision making and planning activities.

Dispersant Tested Alone and/or Mixed with Reference Oil. The provision at § 300.915(b)(2) requires acute toxicity testing for the dispersant alone, and the dispersant mixed with SPR Bryan Mound. It also requires developmental toxicity and subchronic testing on the dispersant alone.

Commenters had varied opinions about whether a dispersant should be tested alone or mixed with the reference oil. Some commenters recommended

that toxicity testing should focus only on the dispersant alone, and that the Agency should eliminate testing requirements for dispersant mixed with reference oil. Another commenter stated that toxicity testing of dispersant plus oil is more relevant than testing with the dispersant alone because the dispersant would not be used if no spilled oil was present and because the potential for toxic effects when dispersants are used on spilled oil at sea is caused by the dispersed oil, not by the dispersant. A commenter noted that screening tests conducted in the absence of reference oils give no indication of whether product-oil combinations are more toxic than the dispersant alone, and a commenter stated that it is important to know whether chemically dispersing the oil would increase or decrease toxicity of the oil itself. Commenters noted that the relative toxicity of any dispersant and oil mix will largely be a function of how much oil is dispersed into the water sample being analyzed, with the greater the quantity of oil dispersed, the more toxic the resultant oil and dispersant mix will be. A commenter specifically opposed the proposed dispersant-oil acute toxicity testing requirement because any concerns about the potential for toxic effects on marine organisms resulting from the use of modern dispersants should consider the potential effects of dispersed oil, not the dispersant itself.

In response to these comments, the Agency is not eliminating toxicity testing for dispersed oil from the rule. To clarify the intent of such testing, the Agency described the rationale for the dispersed oil toxicity test in previous preambles published in the **Federal Register**. For example, EPA notes that the current regulation includes acute toxicity testing of dispersant-oil mixtures and provided a rationale in the 1994 NCP final rule (59 FR 47411–47412, September 15, 1994). Dispersants are intended to increase the rate at which an oil slick is dispersed into the water column. This dispersed oil is, by definition, a mixture of the dispersant and the spilled oil. As a result of this dispersion of oil, the possibility exists for organisms dwelling in the water column to come in physical contact with the dispersed oil. The Agency believes that it should not make any difference whether the mortality of an organism was caused by the effects of a dispersant in the water or due to physical contact with the dispersed oil (*e.g.,* dispersed oil covering the gills of a fish, thereby inhibiting respiration). EPA believes that the fact that dispersants cause oil to enter the water column is sufficient reason to test for the toxicological effects of dispersed oil. The Agency also believes that testing the oil alone, as well as the oil and dispersant mixture, will provide useful data on the relative toxicity of the oil and the potential hazards associated with dispersant use (*i.e.,* data derived from the oil and dispersant mixture test) relative to the hazards associated with non-treatment of the oil (*i.e.,* data derived from the oil only test). EPA believes that the comparative nature of the data will benefit the OSCs, RRTs, and Area Committees in their decision making and planning activities. The final action maintains the approach used in the previous rule for acute toxicity testing on dispersant mixed with oil.

Oil-only acute toxicity testing. In the **Federal Register** notice for the proposed rule, the Agency requested comment on whether the submitter should be required to conduct the oil-only acute toxicity testing for the test oil (80 FR 3405, January 22, 2015). In response to the Agency's request for comment, commenters stated that there should be a requirement to conduct oil-only acute toxicity testing (in addition to the dispersant alone and the dispersant-oil combination) to give the Agency the opportunity to detect anomalies in the submitted data and to provide a comparison to assist in evaluating whether a net environmental benefit is achieved with the proposed dispersant. A commenter also stated that the Agency should calculate toxicity thresholds with oil alone, oil-dispersant mixed together, and dispersant alone to assist in comparing the relative toxicity. The Agency considered requiring submitters to conduct the oil acute toxicity testing as it would provide an opportunity to detect anomalies in the submitted data. However, EPA decided to conduct the oil-only acute toxicity tests itself for the reference oil with both *Americamysis bahia* (*A. bahia*) and *Menidia. beryllina* (*M. beryllina*) and provide this data for comparisons to dispersant and dispersant-oil mixture acute toxicity tests. EPA intends to make the reference oil toxicity test results available to the public on its website, including calculated median LC_{50} values. By providing this information, the Agency is reducing the number of required toxicity tests that the submitter would need to conduct in relation to the previous requirement. To address concerns about detecting anomalies in the submitted data, EPA notes that the final provisions under § 300.915(a)(17) and § 300.915(a)(18) require the product submission for listing on the NCP Product Schedule to provide information about the laboratory that conducted the required tests and to provide all test data and calculations.

Test species. The finalized provision at § 300.915(b)(2) requires acute toxicity testing and testing for subchronic effects using the crustacean species *A. bahia* and the fish species *M. beryllina,* as well as developmental toxicity testing using a sea urchin species, either *Strongylocentrotus purpuratus* (*S. purpuratus*) or *Arbacia punctulata* (*A. punctulata*) to facilitate further flexibility to laboratories conducting the developmental assay based on test guidance and organism availability. Protocols are detailed in Appendix C to part 300. The finalized provision specifies the sea urchin species to be used for developmental toxicity, to be consistent with specifying species in the acute and subchronic toxicity tests (*A. bahia* and *M. beryllina*) and to provide greater clarity by replacing the proposal's more general reference to the ''a sea urchin assay.''

Commenters requested that the Agency consider including more geographically or ecologically representative species in the testing protocol. Commenters specifically suggested that the Agency select test species that would be representative of those found in California and Arctic/Alaskan waters. A commenter noted that anadromous or marine fish would be ecologically relevant to arctic waters since dispersants are only effective (and used) in marine waters. The commenter recommended the use of Pacific herring (*Ciupea pallasiz*) as a model species, since they are known to be quite sensitive to chemical disturbance and are an ecologically and economically important species to Alaska. Another commenter recommended testing on Arctic species, specifically in vitro cell line studies to assess acute and chronic effects on important Arctic species including ice seals, walrus, beluga whales, bowhead whales, phytoplankton and zoo plankton, benthic invertebrates, and Arctic fish species. Another commenter recommended that the Agency require product testing on Arctic species such as Arctic copepods and algae. The Agency notes that the required toxicity testing protocols in Appendix C use standard test species to screen dispersant products for hazard for listing on the NCP Product Schedule at a national level. While the toxicity testing requirements use test species commonly used in EPA toxicity testing methods, EPA recognizes that other species may be more sensitive to

dispersed oil under the same test conditions. This final action provides for consideration of regional conditions under the authorization of use provisions under § 300.910. For example, § 300.910(a)(1) provides for consideration of the existence and location of environmentally sensitive resources when developing a preauthorization plan. In addition, § 300.910(g) provides for supplemental testing and information to address site, area, and ecosystem-specific concerns.

A few commenters expressed concerns about the proposed updates to § 300.915(b)(2) regarding developmental toxicity testing, stating that the use of the purple urchin assay is arbitrary and capricious given that this species' habitat is the shallow nearshore, tidal environment, which is unlikely to be exposed to dispersants during a response effort. Commenters also expressed concerns related to the lack of experience in conducting this type of assay and the potential difficulty in interpreting results between multiple laboratories. EPA disagrees that the use of the purple urchin assay is arbitrary and capricious. EPA notes that, along with the other toxicity test, the sea urchin developmental assay and listing threshold requirements screen dispersant products for hazard. The sea urchin developmental assay established as part of the final rule serve as a sensitive surrogate test for echinoderm early life stages. This test organism is intended to expand the taxonomic diversity of species used in product hazard assessment and is not intended to represent any particular species or habitat in affected environments. EPA adapted an existing toxicity testing approach to allow inclusion of this species in product hazard assessment. To facilitate further flexibility to laboratories conducting the developmental assay, the Agency amended the final provisions to include the option to use the purple sea urchin *A. punctulata* in lieu of *S. purpuratus* for the developmental assay. In addition, EPA amended the final provision under § 300.915(b)(2) to replace the phrase ''. . . using a sea urchin assay . . .'' with the phrase ''. . . using *Strongylocentrotus purpuratus* or *Arbacia punctulata* . . .'' to recognize the additional species flexibility for laboratories conducting the developmental assay based on guidance and organism availability, and to be consistent with regulatory text for the other toxicity tests where the organisms are identified.

Toxicity Thresholds. In the finalized provisions at § 300.915(b)(2)(i)–(iii), EPA is providing thresholds to determine eligibility for listing on the NCP Product Schedule. Specifically, to be listed on the NCP Product Schedule, the dispersant tested alone must demonstrate: (i) A median lethal concentration (LC_{50}) at the lower 95% confidence interval greater than 10 ppm; (ii) an inhibition concentration for 50% of the test species (IC_{50}) at the lower 95% confidence interval greater than 1 ppm; and (iii) a subchronic No Observed Effect Concentration (NOEC) greater than 1 ppm. The finalized regulatory text has been modified from that proposed to list these requirements in subsections (i) through (iii), to provide greater clarity.

Commenters expressed concern that the proposed dispersed oil toxicity test and its threshold could result in the elimination of many dispersants (and potential future dispersants) from the NCP Product Schedule. A commenter stated that it might be difficult for any effective dispersant, mixed with crude oil, to meet the Agency's 10 ppm LC_{50} concentration requirement. The commenter noted that a significant fraction of the toxicity reported from these tests can be attributed to the crude oil alone, masking the dispersant toxicity. Another commenter explained that, based on a toxicity study, a specific product would not pass the proposed toxicity limit, and that given the reported LC_{50} of ANS oil alone, it is unlikely that any of the current dispersants on the NCP Product Schedule would meet the proposed toxicity limit. The commenter notes that this is consistent with the results of a study using Louisiana sweet crude oil in which all of the nine investigated dispersants currently included on the NCP Product Schedule failed a toxicity threshold requirement of 10 ppm. Furthermore, commenters suggested it is not clear whether any dispersant will be approved for the NCP Product Schedule when both toxicity and effectiveness tests are required, and that the standard static acute toxicity testing of dispersant-oil mixtures do not represent real world exposures. The Agency recognizes comments regarding establishing a listing threshold for the dispersant-oil mixture toxicity test for the purposes of being listed on the NCP Product Schedule. The final provisions establish that the listing threshold for acute toxicity testing applies to the results from the dispersant-only toxicity test and not the results from the dispersant-oil mixture toxicity test. Nonetheless, the results from toxicity testing for dispersant alone and dispersant-oil mixture as required under § 300.915 are to be made available in the NCP Product Schedule Technical Notebook for OSCs, ACs, and RRTs to consider in planning for and responding to an oil discharge.

(3) Limitations

In the finalized provision at § 300.915(b)(3), EPA specifies that a dispersant may only be listed on the NCP Product Schedule for use in saltwater environments for which it meets the efficacy and toxicity listing criteria. Dispersants are typically designed and traditionally used for responding to oil discharges in saltwater in the United States. In general, the effectiveness of dispersants decreases as the salinity of the water decreases. In waters with no salinity, many dispersants have shown a very low effectiveness or are sometimes completely ineffective.[6] The Agency is also concerned with using dispersants in freshwater environments because of the limited dilution typically available as compared with the open sea and because of the existence of water intakes in rivers, streams, and lakes for use in drinking water supplies. Using dispersants in freshwater has the potential for compounding the impacts caused by already discharged petroleum products, particularly near potable and non-potable subsurface water intakes.

Several commenters suggested explicit temperature and salinity limits for dispersant use. A commenter noted that it is not clear whether dispersants could be used in estuaries, or other saltwater/freshwater mixing zones, and therefore a salinity threshold is needed. Commenters suggested that dispersant use should be restricted to saltwater with a salinity of greater than 20 ppt and temperatures greater than 10 °C or 50 °F. The Agency is not amending the rule to require specific salinity or temperature limits for dispersant use. The Agency believes it is more appropriate to address water salinities regionally rather than in a definition applicable at a national level and is not including a definition of ''saltwater'' in the final rule. Dispersants are typically designed and traditionally used for responding to oil discharges in saltwater in the United States. In general, the effectiveness of dispersants used in marine waters decreases as the salinity of the water decreases. EPA agrees that dispersants may be effective in brackish waters that have salinities lower than typical ocean water (*e.g.,* 35 ppt). EPA also believes that dispersants may be effective in water with salinities greater

[6] Fingas, M., (Ed.), 2011, *Oil Spill Science and Technology,* Gulf Professional Publishing, pp. 513–518.

than typical ocean water. However, dispersant effectiveness may vary depending upon factors such as product formulation and mixing energy. Water temperature is also an important variable that may influence the effectiveness of dispersant applications. For example, cold temperatures may, among other environmental factors, impact the effectiveness of dispersants as it affects certain oil properties (*e.g.,* viscosity). Colder temperatures also may affect the degree of oil weathering (*e.g.,* evaporation), and the amount of dispersant-oil mixing energy (wave action) needed to effectively disperse oil relative to warmer temperatures. The final provisions require product submissions (*e.g.,* dispersant submission) to provide the recommended product use procedures under § 300.915(a)(10). These procedures must address, as appropriate, variables such as water salinity, water temperature, types and weathering states of oils or other pollutants, and must include supporting documentation. EPA believes that the information on salinity and water temperature from the product submission provides flexibility to OSCs, RRTs, and other interested parties when considering dispersant products for use on an oil discharge.

In the finalized provisions, EPA made some editorial changes to the proposed text for increased clarity. EPA also added the phrase ''for which it meets the efficacy and toxicity listing criteria'' to be consistent with the requirements in § 300.915(b)(1) and (2).

(c) Surface Washing Agent Testing and Listing Requirements

In § 300.915(c), the Agency is revising the toxicity testing protocols for surface washing agents (SWAs), establishing efficacy testing protocols, and establishing both toxicity and efficacy listing thresholds. As defined in § 300.5 in the final action, surface washing agents are substances that separate oil from solid surfaces, such as beaches, rocks, metals, or concrete, through a detergency mechanism that lifts and floats oil. Product and oil are generally to be collected and recovered from the environment with minimal dissolution, dispersion, or transfer into the water column. The finalized revisions in § 300.915(c) respond to concerns regarding surface washing agents' frequent use and the potential for residual impacts after their use.

(1) Surface Washing Agent Efficacy

Under § 300.915(c)(1), the Agency is establishing a surface washing agent efficacy testing requirement. Specifically, EPA is requiring that to be listed on the NCP Product Schedule, the surface washing agent must meet an efficacy of greater than or equal to 30% in either freshwater or saltwater, or both, depending on the intended product use. The Agency is allowing the use of standard recognized efficacy testing methodologies for surface washing agents. An example of such a standard recognized methodology is the American Society for Testing and Materials (ASTM) Standard Test Method for Evaluating the Effectiveness of Cleaning Agents.[7] Another methodology is Environment Canada's Test Method.[8] The capability of a particular surface washing agent depends upon the application procedures and the characteristics of the surface being cleaned, such as size, shape, and material. The ASTM test method in particular covers a procedure for evaluating the capability of the agents, providing a relatively rough surface to which the oil can adhere. The Environment Canada method uses a stainless-steel 'trough' which is placed at a specified angle. The target oil is placed on an area on the trough. The treating agent is then applied in droplets to the surface of the oil and after 10 minutes at 5-minute intervals, rinses of water are applied to the trough. After drying, the trough is weighed, and the removal calculated from the weight loss. Repeatability is within 5 percent.

Commenters expressed support for the use of the Environment Canada efficacy protocol, which EPA provided as an example of a standard recognized efficacy testing methodology in the preamble to the proposed rule. Commenters recommending the use of the Environment Canada efficacy protocol cited the availability of a large database of testing results from this protocol and indications that test results are thoroughly reviewed and thought to be highly reliable. EPA acknowledges the commenters' support for the proposed requirements at § 300.915(c) and the use of the Environment Canada efficacy protocol. There are no requirements for the submitter to use a specific efficacy testing methodology in the NCP Subpart J for surface washing agents to determine listing eligibility on the NCP Product Schedule. The final rule requires that the submitter use an applicable standard methodology to meet the surface washing agent efficacy testing and listing requirements. The Agency continues to develop a laboratory testing protocol to evaluate the efficacy of surface washing agents.

A commenter suggested that the Agency should not require efficacy testing until a standard protocol is developed. The commenter expressed concern that the results from the ASTM and Environment Canada tests may not be comparable and suggested that within-test variability is already large. The commenter also noted that in the published data, Environment Canada tests were performed only on a Canadian oil using only one test. While the Agency's goal is to develop a standard bench-scale testing protocol for surface washing agent product evaluation, the Agency believes that using existing applicable protocols provides useful information that would otherwise be unavailable to screen products. The Agency continues to develop a laboratory testing protocol to evaluate the efficacy of surface washing agents and would propose this protocol in the **Federal Register** through notice and comment before adopting it as part of the Subpart J requirements. The EPA surface washing agent protocol is outside the scope of this rulemaking. Nonetheless, the final rule provides for the use of standard efficacy testing methodologies for surface washing agents. To clarify the provision, EPA amended the final provision to replace the term ''. . . recognized standard methodology . . .'' with ''. . . applicable standard methodology . . .'' to better reflect the applicability of the methodology to surface washing agents. While EPA recognizes the potential for test variability, the Agency agrees that there may be other potential benefits to these methodologies. The Agency believes that general surface washing agent efficacy tests that are currently available will develop efficacy results that can be measured against the efficacy threshold of 30% in either freshwater or saltwater or both, depending on the intended product use.

EPA also made some editorial changes to the proposed text for increased clarity.

(2) Surface Washing Agent Toxicity

Under § 300.915(c)(2), the Agency is revising the toxicity testing requirements for surface washing agents, including the testing protocol. While the toxicity testing results were previously used by the OSC to assist in authorization of use determinations, the Agency will now use these toxicity

[7] ASTM Standard Test Method for Evaluating the Effectiveness of Cleaning Agents. Designation: G122—96 (Reapproved 2008). ASTM International, 100 Barr Harbour Dr., P.O. Box C–700 West Conshohocken, Pennsylvania 19428–2959, United States.

[8] Fingas, Merv and Fieldhouse, Ben; ''Surface Washing Agents or Beach Cleaners'' (2010). Chapter 21 Surface-Washing Agents or Beach Cleaners. In Oil Spill Science and Technology (p716). London: Gulf Professional Publishing.

testing results to determine listing eligibility on the NCP Product Schedule. The Agency requires the use of the toxicity test methodology in Appendix C to part 300 to test the surface washing agent for acute toxicity against freshwater species *Ceriodaphnia dubia* and *Pimephales promelas,* or saltwater species *Americamysis bahia* and *Menidia beryllina,* or both, depending on the intended product use. The revisions to the testing protocols for surface washing agents are detailed in Appendix C to part 300. The protocol is based on EPA's *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters for Freshwater and Marine Organisms.*[9] To be listed on the NCP Product Schedule, the surface washing agent must demonstrate an LC_{50} at the lower 95% confidence interval of greater than 10 ppm in either freshwater or saltwater for all tested species. EPA believes that with this threshold level, the Agency is establishing an adequate safety margin without being overly restrictive.

In addition to testing the surface washing agent alone, some commenters suggested that the Agency require toxicity testing with surface washing agent-oil mixtures, to determine whether the addition of the surface washing agent may enhance or alter toxicity of the oil. Commenters asserted that this would better approximate conditions that organisms may encounter in the natural environment. EPA believes the final rule provisions for acute toxicity testing for surface washing agents is adequate given these products are not likely to be used in the same quantities or durations as dispersants. EPA notes surface washing agents are intended to be recovered from the environment, unlike dispersants. In addition, while the Agency requested comment on a protocol for preparation of product/oil mixtures for toxicity testing, the Agency did not identify comments or sufficient information to tailor the exposure solutions for oil-SWA mixtures. Nonetheless, EPA believes the final provisions will help the Agency gather additional technical information specific to the product category. In addition, EPA may request clarification or additional information as necessary under § 300.955(c)(1) to inform the Agency's evaluation of a product.

In the finalized provisions, EPA made only editorial changes to the proposed text for increased clarity.

[9] *http://water.epa.gov/scitech/methods/cwa/wet/upload/2007_07_10_methods_wet_disk2_atx1-6.pdf.*

(3) Limitations

At § 300.915(c)(3), the Agency specifies that surface washing agents may only be used in those water environments (freshwater and/or saltwater) for which the product was tested and for which it met the efficacy and toxicity listing threshold criteria. The Agency recognizes that products may yield effective results in certain environments and not in others. Products that may be effective in freshwater environments may not necessarily be so in saltwater environments, and vice versa. Product manufacturers maintain flexibility to select which environment the product is to be tested and authorized for use within these limitations.

No comments on this provision were identified. EPA made editorial changes to the final provisions to provide greater clarity.

(d) Bioremediation Agent Testing and Listing Requirements

The Agency is establishing toxicity testing protocols, revising the efficacy testing protocols, and establishing both efficacy and toxicity listing thresholds for bioremediation agents in § 300.915(d). As now defined in § 300.5, bioremediation agents are biological agents and/or nutrient additives deliberately introduced into a contaminated environment to increase the rate of biodegradation and mitigate any deleterious effects caused by the contaminant constituents. Bioremediation agents include microorganisms, enzymes, and nutrient additives such as fertilizers containing bioavailable forms of nitrogen, phosphorus, and potassium.

A commenter suggested that bioremediation agent formulas should be restricted to only those components necessary for the proposed primary use of any listed product, noting, for example, that bioremediation agents formulated for land-based settings may not need components such as surfactants to be effective, whereas the product may not need other components such as sugars and nutrients to be effective for use in or near water. This final rule requires product listing submissions to provide information on the intended function of each component (*e.g.,* solvent, surfactant) under § 300.915(a)(13). EPA notes that some components other than those components necessary for the primary use may still serve to support the product's function. However, EPA also recognizes concerns that a product (*e.g.,* bioremediation agents) may contain components that may support an alternate mechanism of action (*e.g.,* surfactants) and could potentially meet the definition of another product category (*e.g.,* dispersants). EPA amended the final provision under § 300.915(a)(9) to remove the phrase ''. . . and you want it considered for listing on the NCP Product Schedule in more than one category . . .'' to ensure that product manufacturers identify all applicable chemical or biological agent categories. If a product meets the definition of more than one chemical or biological agent category, the product manufacturer must provide the test data appropriate to each category. The final provision ensures that the Agency has the information necessary to evaluate the product for listing on the NCP Product Schedule regardless of whether the submitter requests it to be listed in a specific product category.

A commenter expressed concern related to the use of nonindigenous or genetically modified bioremediation agents, stating that they may colonize areas where they are being applied. The commenter suggested that the Agency should not allow use of genetically modified agents in response activities. The Agency disagrees that the NCP should completely prohibit the use of nonindigenous or genetically modified agents in response activities. The final action establishes requirements for submitters to disclose bioremediation agent product information under § 300.915(a)(13) and (14), including components and any physical, chemical, or biological manipulation of the genetic composition. In addition, § 300.950, *Submission of Proprietary Business Information (PBI),* specifies that only certain information as identified in § 300.915(a)(13) and (14) may be claimed as PBI. All other information submitted to EPA for listing on the NCP Product Schedule as required under § 300.915 and § 300.955 cannot be claimed as PBI and will be available for public disclosure upon submission without further notice to the submitter. The Agency believes that the final provisions afford OSCs, Area Committees, and RRTs with the flexibility to establish the appropriate agent to use during response and response planning activities.

(1) Bioremediation Agent Efficacy

The final provisions reflect a series of changes from the previous requirements for the efficacy testing protocol for bioremediation agents. The new protocol includes freshwater testing in addition to the updated saltwater-based test and uses artificial water for both freshwater and saltwater testing, replacing the natural seawater

previously used. The protocol also eliminates several gravimetric and microbiological analyses and testing endpoints not used in the proposed listing determinations. Additionally, the protocol limits the levels at which external nutrients may be added, which allows the addition for product formulations without nutrients, or for product formulations that have nutrient concentrations at insufficient levels for the experimental setup. Finally, the methodology streamlines the statistical analysis. The revisions address concerns with the existing methodology (as discussed in detail in the **Federal Register** notice for the proposed rule, 80 FR 3408, January 22, 2015), expanding its application to include freshwater environments, improving the consistency and comparability of the test results, and generally streamlining the protocol.

Bioremediation Efficacy Threshold. Under § 300.915(d)(1), to be listed on the NCP Product Schedule, a bioremediation agent must successfully degrade both alkanes and aromatics as determined by gas chromatography/mass spectrometry (GC/MS) in freshwater or saltwater, or both, depending on the intended product use, following the test method specified in Appendix C to part 300. The percentage reduction of total alkanes (aliphatic fraction) from the GC/MS analysis must be greater than or equal to 85% at day 28, based on the ninety-fifth (95th) percentile Upper Confidence Limit (UCL_{95}) for both freshwater and saltwater. The percentage reduction of total aromatics (aromatic fraction) must be greater than or equal to 35% at day 28 for both saltwater and freshwater based on the UCL_{95}.

Some commenters suggested that the proposed efficacy threshold requirements are unattainably high (originally proposed as a 95% reduction of aliphatic and 70% reduction in aromatics for saltwater) and are significantly higher than the efficacy standards for dispersants. The commenters were concerned that these thresholds would essentially exclude bioremediation products. Commenters suggested amending the efficacy standard to 50% reduction in 28 days of both aliphatics and aromatics in both freshwater and saltwater. The Agency disagrees with these comments. EPA did not receive information to conclude that the revised thresholds would exclude a large portion of bioremediation products currently available. While the Agency disagrees with these comments, it recognizes that a reduction in percent thresholds would appropriately address the inherent variability of microbial consortium to degrade oil, also accounting for the different types of bioremediation agents.

After review of the proposed bioremediation agent thresholds and protocol, the Agency is amending the efficacy thresholds at 28 days to be greater than or equal to 85% for total alkanes and 35% for total aromatics in both saltwater and freshwater. While maintaining the efficacy protocol's approach as proposed, the Agency believes the final action provides reasonable thresholds for the purposes of listing a bioremediation agents on the NCP Product Schedule without being overly restrictive. The efficacy criteria finalized in this action demonstrate that the product can cause a substantial degradation of the alkane and aromatic fractions of weathered crude oil compared to a control, as determined by GC/MS analysis. The Agency disagrees that an equally high efficacy threshold is needed for dispersants. The efficacy thresholds for bioremediation agents are unrelated to and established separately from dispersants. EPA based the efficacy thresholds on individual assessments of the bioremediation agents and dispersant product categories, including consideration of their modes of action. Furthermore, efficacy for dispersant and bioremediation agents are evaluated using different analytical techniques. For example, the bioremediation agent efficacy test protocol described efficacy in terms of reduction in total alkanes and total aromatics of a weathered crude oil, ANS 521, using high-resolution gas chromatograph/mass spectrometer (GC/MS) over a 28-day period. Of note, the total alkanes and total aromatics described in the bioremediation agent efficacy testing protocol do not represent all of the components in crude petroleum oil. Dispersant efficacy is evaluated using a different test oil, non-weathered SPR Bryan Mound, using a UV-visible spectrophotometer. In the finalized provisions, EPA made only editorial changes to the proposed text for increased clarity.

Protocol Specific to Products Containing Enzymes Only. Regarding EPA's request for comment on whether an additional protocol specific to products containing enzymes only would be appropriate, commenters suggested that a testing protocol specific to products containing enzymes would be useful, because effectiveness data would help determine whether the technology would be beneficial during a response. Commenters recommended that testing of these products should consist of water exposure, weathered oil, and enzymatic product in the concentrations specified by the manufacturer. The intent of the protocol including specified concentrations is to provide a consistent, standardized approach that will allow the Agency to screen products for listing on the NCP Product Schedule; having each manufacturer specifying their own test parameters is contrary to this. EPA notes the final action does not restrict products with enzymes to testing under only one bioremediation agent procedure. The final rule includes a specific procedure within the bioremediation efficacy protocol in Appendix C that captures bioremediation agent products containing enzymes. Table 15 in Appendix C describes the summary of experimental setup for the bioremediation efficacy test and includes the treatment for products (such as an enzyme) containing no live microorganisms and no nutrients. (See: Test Type 3 in Table 15 in Appendix C). In addition, section 5.4.9 of Appendix C provides the entry for the experimental setup and procedure for non-living products (*e.g.,* enzymes) other than nutrients.

(2) Bioremediation Agent Toxicity

Prior to this amendment, there were no bioremediation agent toxicity testing requirements for purposes of listing these agents on the NCP Product Schedule. The Agency is finalizing an acute toxicity testing protocol for bioremediation agents to include both freshwater and saltwater. The Agency will use these testing results to determine listing eligibility on the NCP Product Schedule. The required testing protocols for bioremediation agents, detailed in Appendix C, are based on EPA's protocol, *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters for Freshwater and Marine Organisms.*

Toxicity Threshold. Under § 300.915(d)(2), the bioremediation agent must be tested for acute toxicity in freshwater or saltwater, or both, depending on the intended product use, following the method specified in Appendix C to part 300. To be listed on the NCP Product Schedule, the bioremediation agent must demonstrate an LC_{50} at the lower 95% confidence interval of greater than 10 ppm in either freshwater or saltwater for all tested species.

A commenter suggested that it is unclear why the proposed toxicity testing appears to be more stringent for bioremediation products than for chemical dispersants. The commenter asserted that all agents, no matter their type, should be required to meet toxicity standards before being listed on the NCP

Schedule and suggested a threshold of 100 ppm, rather than the Agency's proposed threshold of 10 ppm. The Agency notes that all chemical and biological agent categories have acute toxicity testing and associated threshold criteria to be considered for listing on the NCP Product Schedule. The Agency disagrees that the listing threshold for acute toxicity tests should be set to 100 ppm. The final provisions establish a listing threshold for 10 ppm for acute toxicity testing under § 300.915(d) for bioremediation agents, which is the same threshold as for other product categories. EPA's toxicity classification scheme classifies LC_{50} values ranging from 10 ppm to 100 ppm as slightly toxic and values above 100 ppm substances are considered practically nontoxic to aquatic organisms. This threshold level establishes an adequate safety margin without being overly restrictive.

A commenter stated that the Agency should establish thresholds where agents that contain known pathogens, bacteria, or fungi, that are harmful to humans or the environment, should be ineligible for listing. To support product screening, this final rule includes a provision under § 300.915(a)(14)(iv) to address whether products that contain microorganisms, enzymes, and/or nutrients also contain bacterial, fungal, or viral pathogens or opportunistic pathogens to compare to existing applicable criteria. The Agency reconsidered, based on comments, whether it should establish listing thresholds for products based on National Ambient Water Quality Criteria, and whether the levels selected for certification are appropriate for this purpose. The final provision under § 300.915(a)(14)(iv) requires that product submitters provide data, methodology, and supporting documentation for the levels of these pathogens, to provide relevant information. The Agency may consider how these levels compare against recommended National Ambient Water Quality Criteria, as applicable. The final provisions for listing products on the NCP Product Schedule under § 300.955 allow the Agency to make listing determinations based on a technical evaluation of all data and information submitted in accordance with the requirements for each product category and the relevant information on impacts or potential impacts of the product. Thus, the Agency can determine not to list the product on the NCP Product Schedule based on information received on contaminants that may raise concerns.

Bioremediation agent-oil mixtures. Regarding EPA's request for comment on the need for acute toxicity tests conducted with bioremediation agents-reference oil mixtures, commenters stated that toxicity testing should be conducted with mixtures of oil and products. Commenters expressed concern about the potential for toxicity from the partial degradation products of bioremediation and the potential for toxicity from agent-oil combinations that may not be captured if products are tested alone. The final action balances gathering the information necessary to support responses and response planning against the burden to conduct additional tests to list a product on the NCP Product Schedule, with the understanding that additional information may be incorporated at the regional level. Unlike dispersants that emulsify, disperse, or solubilize oil by promoting the formation of small droplets or particles of oil in the water column, bioremediation agents are introduced into a contaminated environment to increase the rate of biodegradation and mitigate any deleterious effects caused by the contaminant constituents. EPA believes the final rule provisions for acute toxicity testing for bioremediation agents are adequate, given these products are not likely to have the potential to be used in the same quantities or durations as dispersants based on past experience with spill response activities.

Subchronic toxicity testing. A commenter suggested that EPA require subchronic toxicity testing in addition to the proposed acute testing, because bioremediation products are expected to remain in the environment for at least 28 days. EPA did not take this suggestion. EPA believes the final rule balances the information necessary against the burden to conduct additional tests to list a product on the NCP Product Schedule at a national level, with the understanding that additional information may be incorporated at the regional level. According to the finalized provisions of § 300.910(g), RRTs may require supplementary toxicity and efficacy testing to address site, area, or ecosystem-specific concerns relative to the use of a product for planning and authorization of use.

In the finalized provisions, EPA made only editorial changes to the proposed text for increased clarity.

(3) Limitations

At § 300.915(c)(3), the Agency specifies that bioremediation agent listing would be for use only in the freshwater and/or saltwater environments for which the product was tested and for which it met the efficacy and toxicity listing criteria.

No comments on the provision were identified. EPA made only editorial changes to the final provision for greater clarity. EPA removed the phrase ''Based on testing . . .'' because it was unnecessary. EPA also replaced the term ''product'' with ''Bioremediation agents'' and the term ''fresh'' with ''freshwater'' for clarity.

(4) Generic Listing

The Agency recognizes that there may be oil discharge situations where it is determined that the addition of nutrients in the form of salts of nitrogen, phosphorus and potassium (*i.e.,* fertilizers) to stimulate or enhance bioremediation may be an effective and environmentally favorable mitigation method. However, nonproprietary commercially available formulations of nutrients are not specifically listed on the NCP Product Schedule, even though as nutrient additives they are subject to Subpart J requirements. Therefore, the Agency is finalizing at § 300.915(d)(4) a provision providing that if the product consists solely of: ammonium nitrate, ammonium phosphate, ammonium sulfate, calcium ammonium nitrate, sodium nitrate, potassium nitrate, synthetically-derived urea, sodium triphosphate (or tripolyphosphate), sodium phosphate, potassium phosphate (mono- or dibasic), triple super phosphate, potassium sulphate, or any combination thereof, then no technical product data are required. The product will be generically listed as non-proprietary nutrients on the NCP Product Schedule, and no further action is necessary under § 300.955. For these nonproprietary commercial nutrients, the Agency believes there is no need for submission of readily available information. In the proposal, this provision was titled ''Exceptions.'' EPA changed the name in the final amendment to ''Generic Listing'' to better describe the purpose of the provision and to avoid confusion with the provision under § 300.910(d).

Commenters recommended that products that require nutrient additions and additional proprietary components should have to follow toxicity and efficacy testing protocols. A commenter suggested that few if any of the listed fertilizers would pass the 10 ppm acute toxicity threshold that is proposed for other bioremediation agents, and that the requirement should be that the commercial formulations be no more toxic than their inorganic components. For these non-proprietary commercial nutrients, the Agency believes there is

no need for submission of readily available information. The Agency notes that the generic listing applies to substances comprised solely of those specifically identified in § 300.915(d)(4). The generic listing applies only to products commonly formulated entirely of those mineral nutrients and synthetically derived urea listed. The final action requires no technical product data submission or further action on the part of a manufacturer prior for the purposes of listing products commonly formulated of said materials on the NCP Product Schedule. However, the Agency notes that the use of such substances remain subject to the authorization of use provisions under § 300.910. For products that may contain components not specifically identified in § 300.915(d)(4), the requirements under § 300.955 *Addition of a Product to the NCP Product Schedule or Sorbent Product List* apply, including the bioremediation agents testing and listing provisions under § 300.915(d).

In the finalized provisions, EPA made only editorial changes to the proposed text for increased clarity.

(e) Solidifier Testing and Listing Requirements

The Agency is revising the toxicity testing protocol and establishing a toxicity listing threshold for solidifiers in § 300.915(e). As now defined in § 300.5, solidifiers are substances that through a chemical reaction cause oil to become a cohesive mass, preventing oil from dissolving or dispersing into the water column, and which are collected and recovered from the environment. Although solidifiers are intended to be recovered from the environment, the revisions and new toxicity listing threshold respond to concerns regarding the general increase in the use of chemical and biological agents as tools available for oil discharge responses.

Commenters recommended removing solidifiers from the NCP Product Schedule because they preclude the use of other mechanical countermeasures, noting that once a solidifier is applied to the slick, it becomes too heavy and viscous for mechanical recovery. A commenter asserted that solidifiers offer no measurable advantage over sorbents or mechanical recovery, have limited practicality, may cross-link or react with other substances, and require immediate removal from the environment. The commenter stated that there has been relatively few studies and tests on the effectiveness of solidifiers and referenced several reports supporting their position. The Agency disagrees that solidifiers should be removed from the NCP Product Schedule. The final action under § 300.915(a)(10) requires that information be provided on solidifier use procedures, including application equipment, conditions for use, any application restrictions, and as applicable, procedures for product and oil containment, collection, recovery, and disposal. This information will be available to the OSC and the RRT when making agent authorization of use determinations; agent authorization of use determinations are subject to OSC direction under the NCP. Further, the final action provides requirements under § 300.910(h) for the recovery of chemical agents and other substances from the environment. The final action provisions establish that the responsible party shall ensure that removal actions adequately contain, collect, store, and dispose of chemical agents and of other substances that are to be recovered from the environment, unless otherwise directed by the OSC. The requirements in § 300.910(h) apply to solidifiers. Finally, these requirements are reinforced by the definition provided for under § 300.5 for solidifiers, which specifies these agents are generally collected and recovered from the environment. The Agency believes these provisions sufficiently address solidifier recovery from the environment.

(1) Solidifier Efficacy

The Agency did not propose nor is it finalizing an efficacy testing requirement for solidifiers. EPA's focus has been on reviewing the protocols for dispersants and bioremediation agents, given that their specific process for affecting the oil allows them to be left in the environment, whereas solidifiers are intended for removal from the environment.

A commenter expressed support for the adoption of efficacy testing requirements, suggesting that the Agency should rely on recommendations from the experts. Another commenter suggested that while they did not have a specific methodology to propose, the Agency should consider performance criteria when adopting an efficacy standard including buoyancy of the product (to ensure that the oil-solidifier mixture does not sink) and ease of collection and removal from the environment. The Agency acknowledges the comments supporting efficacy testing requirements for solidifiers, and it notes that no specific methodology was suggested. EPA does not have sufficient information to establish an efficacy protocol for solidifiers at this time. While the final action does not establish efficacy testing requirements for solidifiers for the purposes of listing products on the NCP Product Schedule, these agents are subject to the data and information provisions under § 300.915(a), which specifically includes specific gravity as one of the data points for physical and chemical properties of the product, and the toxicity testing provisions under § 300.915(e). The new data and information provisions, including the new classification of solidifiers as chemical agents, will assist EPA in evaluating solidifier agent products and gather additional technical information specific to the product category. Additionally, EPA may request clarification or additional information as necessary under § 300.955(c)(1) to inform the Agency's evaluation.

(2) Solidifier Toxicity

EPA is revising the acute toxicity testing requirements for solidifiers, including the testing protocol. While the Agency previously provided the acute toxicity testing results to the OSC to assist in authorization of use determinations, it will now use these results to determine listing eligibility on the NCP Product Schedule. The revisions to the testing protocols for solidifiers are detailed in Appendix C to part 300. The acute toxicity test protocol for solidifiers is based on EPA's protocol, *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters for Freshwater and Marine Organisms.* According to § 300.915(e)(1), solidifiers must now be tested for acute toxicity in freshwater or saltwater, or both, depending on the intended product use, following the method specified in Appendix C to part 300. To be listed on the NCP Product Schedule, the solidifier must demonstrate an LC_{50} at the lower 95% confidence interval of greater than 10 ppm in either freshwater or saltwater for all tested species.

Similar to surface washing agents, the Agency is not requiring submitters to conduct acute toxicity tests with solidifier-oil mixtures. Regarding the Agency's request for comment on the need for acute toxicity tests conducted with solidifier-oil mixtures, a commenter noted that toxicity tests with oil may help to evaluate the efficiency of solidifiers in retaining water soluble hydrocarbons and preventing them from leaching into water, whereas simple efficiency tests may not provide such data. However, the Agency is unaware of information to tailor the acute toxicity protocol for the exposure solution for oil-product mixtures for solidifiers for the purpose of listing a product on the NCP Product Schedule.

EPA has experience with preparing oil-product combination for certain product categories and the final rule incorporates these updates where applicable. For solidifier products, the Agency does not have sufficient information to tailor the acute toxicity protocol for oil-solidifier mixtures, and the final action requires toxicity testing of solidifier products in conjunction with new toxicity thresholds for listing on the NCP Product Schedule. The final action also provides for the Agency to request clarification or additional information as necessary under § 300.955(c)(1) to inform the product submission evaluation.

In the finalized provision at § 300.915(e)(1), EPA made only editorial changes to the proposed text for increased clarity.

(3) Limitations

The Agency recognizes that products may yield effective results in certain environments and not in others. Products that may be effective in freshwater may not necessarily be so in saltwater, and vice versa. The Agency is specifying at § 300.915(e)(2) that the listing of solidifiers is limited to use only in those water environments (freshwater and/or saltwater) for which the product was tested and for which it met the listing threshold criteria. Product manufacturers maintain the flexibility to select which environment the product is to be tested and could be authorized for use, either saltwater, freshwater, or both within these limitations.

EPA made editorial changes to this provision to provide greater clarity.

(f) Herding Agent Testing and Listing Requirements

The Agency is revising the toxicity testing protocol and establishing a listing threshold for toxicity for herding agents in § 300.915(f). As defined in § 300.5 in the final rule, herding agents are substances that are used to control the spreading of oil across the water surface. The revisions and new toxicity listing threshold respond to concerns regarding the general increase in the use of chemical and biological agents as tools available for responses to oil discharges.

Because the final action eliminates surface collecting agents as a category and redefines herding agents to better reflect their specific process for affecting the oil, and because the agents will need to be identified in order for the required testing to be submitted, the Agency has eliminated the test requirement for distinguishing surface collecting agents from other chemical agents.

(1) Herding Agent Efficacy

There were previously no efficacy testing requirements for herding agents to determine listing eligibility on the NCP Product Schedule. These agents would have been included in the former surface collecting agent category, which had no efficacy testing requirements, and which the rule amendment eliminates. The Agency did not propose, nor is it finalizing, an efficacy testing methodology for herding agents.

Commenters expressed general support to establish a herding agent efficacy threshold. One commenter suggested that EPA rely on expert guidance and recommendations related to the adoption of efficacy protocols. Another commenter suggested considering performance criteria, including buoyancy of the product (to ensure oil-herder agent mixtures do not sink) and some measure of the ease of collection and removal from the environment. The commenter also indicated concern related to how OSCs will evaluate the utility of the agents without the use of efficacy testing. The Agency does not have sufficient information to establish an efficacy protocol for herding agents at this time. While the final action does not establish efficacy testing requirements for herding agents for listing on the NCP Product Schedule, herding agents are subject to the data and information provisions under § 300.915(a) and the toxicity testing provisions under § 300.915(f). The revised classification will assist EPA in evaluating herding agent products and gather additional technical information specific to the product category.

(2) Herding Agent Toxicity

EPA is revising the acute toxicity testing requirements for herding agents, including the testing protocol. While the Agency previously provided the acute toxicity testing results to the OSC to assist in authorization of use determinations, these results will now be used to determine listing eligibility on the NCP Product Schedule. According to § 300.915(f)(1), herding agents must now be tested for acute toxicity in freshwater or saltwater, or both, depending on the intended product use, following the method specified in Appendix C to part 300. Furthermore, to be listed on the NCP Product Schedule, the herding agent must demonstrate an LC_{50} at the lower 95% confidence interval greater than 10 ppm in either freshwater or saltwater for all tested species.

A commenter expressed opposition to toxicity testing as an NCP Product Schedule listing criteria for herding agents, stating that since herding agents are used in very limited quantities, they should not be held to the same toxicity standards as dispersants. The commenter stated that during actual response activities, dilution and mixing in the natural environment would decrease concentrations of herding agents immediately following application to levels below 0.15 ppm, which is below the toxic threshold. The Agency disagrees with this comment. Toxicity testing results assist in determining listing eligibility on the NCP Product Schedule. Toxicity testing results may also be used by RRTs and OSCs for comparative purposes between products when authorizing their use.

In the finalized provisions, EPA made editorial changes to the proposed text for increased clarity. EPA added the qualifier ''To be listed on the NCP Product Schedule'' for clarity and consistency with other provisions.

(3) Limitations

The Agency recognizes that herding agent products may yield effective results in certain environments and not in others. Products that may be effective in freshwater may not necessarily be so in saltwater, and vice versa. The Agency is specifying at § 300.915(f)(2) that the listing of herding agents is limited to use only in those water environments (freshwater and/or saltwater) for which the product was tested and for which it met the listing threshold criteria. Product manufacturers maintain the flexibility to select which environment the product is to be tested and could be authorized for use, either saltwater, freshwater, or both within these limitations.

In the finalized provisions, EPA made only editorial changes to the proposed text for increased clarity.

(g) Sorbent Requirements

The statutory schedule as required by CWA section 311(d)(2)(G) includes the NCP Product Schedule, the Sorbent Product List, and 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. Sorbents are not listed on the NCP Product Schedule. Rather, the Agency proposed to establish a separate Sorbent Product List from the NCP Product Schedule and to include sorbent materials and products on Sorbent Product List that meets the definition of a sorbent. Previously, a list that characterized sorbent materials was included in § 300.915(g). Under the

finalized revisions to § 300.915(g), EPA is establishing a publicly available Sorbent Product List identifying known sorbent materials and products for emergency responders to use when responding to an oil discharge. The Sorbent Product List is separate from the NCP Product Schedule. Sorbents, as now defined in § 300.5, are inert and insoluble substances that readily absorb and/or adsorb oil or hazardous substances, and that are not combined with or act as a chemical agent, biological agent, or sinking agent. Sorbents may be used in their natural bulk form or as manufactured products in particulate form, sheets, rolls, pillows, or booms. Sorbents are generally collected and recovered from the environment. The list of sorbent materials provided in the definition includes natural organic substances (*e.g.,* feathers, cork, peat moss, and cellulose fibers such as bagasse, corncobs, and straw); inorganic/mineral compounds (*e.g.,* volcanic ash, perlite, vermiculite, zeolite, clay); and synthetic compounds (*e.g.,* polypropylene, polyethylene, polyurethane, polyester).

According to § 300.915(g)(1), if a sorbent product that 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)), then no technical data are required to be submitted for listing on the Sorbent Products List, and no further action is necessary for use as a sorbent. EPA added the phrase ''to be submitted on the Sorbent Products List'' in the final action, for clarity.

The Agency recognizes that a sorbent material may consist of one or more substances not specifically identified in the non-proprietary list in § 300.915(g)(1)(i)–(iii). The final action includes a process for submitters to request to include other products as sorbents if they can certify they meet the inert, insoluble criteria. For sorbent products consisting of one or more substances not specifically identified in § 300.915(g)(1)(i)–(iii), a manufacturer may submit information for consideration for listing it as a sorbent on the Sorbent Product List. The required information includes: the information required under § 300.915 (a)(1) through (8), and (a)(13) through (a)(15); the certification required under § 300.915(a)(16); and information, including data, to support the claim that the product meets the sorbent definition under § 300.5.

A commenter opposed the establishment of a separate list for sorbents and indicated that these products should be added to the NCP Product Schedule with all of the other potential agents used in spill responses activities. Along similar lines, another commenter suggested that NCP Product Schedule listing should be required for all synthetically manufactured sorbent products. EPA disagrees that sorbents should be added to the NCP Product Schedule. For the purposes of Subpart J, EPA's 1994 final rule noted that the use of sorbents, by themselves, will not create deleterious effects on the environment because sorbent materials are essentially inert and insoluble in water and because the basic components of sorbents are non-toxic. (59 FR 47407; September 15, 1994). The rule previously provided that, prior to deciding on the use of a particular sorbent material, an OSC could request a written certification from the manufacturers that their sorbent product is comprised solely of those sorbent materials identified in the rule. Furthermore, for sorbents that consist of materials that are not specifically listed in the rule, the Agency issued written notification of its decision to add the product to the NCP Product Schedule under the miscellaneous oil spill control agent category if it met the definition of a sorbent. In this final rule, the Agency is maintaining the same overarching approach but offering an alternative administrative structure by establishing a publicly available Sorbent Product List in lieu of providing written certifications to sorbent manufacturers. EPA notes that the sorbent definition under § 300.5 specifically includes synthetic compounds (*e.g.,* polypropylene, polyethylene, polyurethane, polyester).

A commenter stated that EPA should require certain General Information listing requirements for sorbents, including the requirements in § 300.915(a)(1)–(8), (10), (11), (12)(i), (iv), and (vii), (19), and (20). The final action requires under § 300.915(g)(2) sorbent product submissions to include information required under § 300.915(a)(1) through (8), and (a)(13) through (a)(15), the certification required under § 300.915(a)(16), and information, including data, to support the claim the product meets the definition of sorbent under § 300.5. EPA does not believe that the information under § 300.915(a)(10) *Recommended product use procedures,* (11) *Environmental fate information,* (12) *The physical and chemical properties,* (19) *Annual product production volume,* and (20) *Design for the Environment* is necessary to determine whether the product meets the definitions of a sorbent to be placed on the Sorbent Product List. The Agency believes the Sorbent Product List will be helpful during preparedness planning and response to assist stakeholders, OSCs, and other responders in understanding what sorbents have been reviewed by EPA and are available for oil spills. EPA notes that the Sorbent Product List is separate from the NCP Product Schedule and is not subject to the preauthorization process under § 300.910(a). However, response actions, including the use of sorbents, are subject to OSC oversight under the NCP.

A commenter suggested that the Agency develop efficacy tests for sorbents based on expert recommendations that include parameters such as absorption amounts and rates. Another commenter expressed concerns related to the use of synthetic sorbent products and suggested that additional discussion of known toxicity of these compounds should be added to determine whether or not additional toxicity testing is warranted. The final provisions do not include sorbent efficacy or toxicity testing requirements. Under § 300.5, sorbents are defined as inert and insoluble substances that readily absorb and/or adsorb oil or hazardous substances, and that are not combined with or act as a chemical agent, biological agent, or sinking agent. Therefore, the Agency believes that sorbents are inert and insoluble substances that are removed from the environment, so the submission requirements for inclusion on the Sorbent Product List is a reasonable approach. Nonetheless, EPA notes that their use is subject to OSC oversight under the NCP. The definition also states that sorbents are generally collected and recovered from the environment. As noted above, for the purposes of Subpart J, EPA's 1994 final rule noted that the use of sorbents, by themselves, will not create deleterious effects on the environment because sorbent materials are essentially inert and insoluble in water and because the basic components of sorbents are non-toxic (59 FR 47407; September 15, 1994).

4. Submission of Proprietary Business Information (PBI)

EPA notes that the Agency has updated the terminology from ''Confidential Business Information (CBI)'' to ''Proprietary Business Information (PBI)'' in the title and throughout the provision. The final provisions reflect EPA policy to implement Executive Order 13556 (November 4, 2010) on the terminology used for certain types of information. The final action addresses the PBI

provisions for product submission under Subpart J in § 300.950.

Previously, manufacturers were able to assert a claim of confidential business information (CBI) for any information in their product package submissions to EPA. Typically, manufacturers claimed as CBI the chemical identity (*e.g.,* chemical name and chemical abstracts number [CASRN]), the chemical components, and the concentration (weight percent) of each chemical component in the product. However, EPA believes that when chemical and biological agents are used on oil discharges, it is critically important for the public and all other stakeholders to have information regarding the components, including the chemicals, being added to the environment, along with information about their toxicity and fate. This is particularly true for major discharge events where larger quantities of chemical or biological agents may be authorized for use. Prompt and accurate information will allow the public to evaluate and understand the potential human and environmental effects of these chemical agents. The Agency is establishing limitations to what submitters are allowed to claim as PBI in an effort to balance public access to information with proprietary business needs. The final action provides that product manufacturers submitting a product for listing on the NCP Product Schedule or the Sorbent Product List may only assert, and the Agency will only consider, PBI claims covering the following information contained in product submissions: concentration, maximum, minimum, and average weight percent, and units of each component in the product as identified in § 300.915(a)(13) and (14). All other information submitted to EPA for listing a product on the NCP Product Schedule or the Sorbent Product List as required under § 300.915 and § 300.955 will not be considered PBI and will be available for public disclosure upon submission without further notice to the submitter. The final rule provides public access to the identity of components and relevant health and environmental effects information submitted by the product manufacturer while providing confidential treatment for the concentrations of product components.

In the final action, EPA modified the proposed language in § 300.950(a) to replace the term ''disclosed to the public'' with ''available for public disclosure upon submission without further notice to the submitter'' to maintain the focus of information in the NCP Product Schedule Technical Notebook by providing OSCs and RRTs the most relevant information to consider for planning and response. EPA also amended the final provision by replacing the phrase ''You may only claim the concentration and the maximum, minimum, and average weight percent of each chemical component or microorganism in your product, as identified in § 300.915(a)(13) or (14), to be CBI'' with ''You may only claim as PBI the concentration; the maximum, minimum, and average weight percent; and the units of each component as identified in § 300.915(a)(13) and (14) and as applicable.'' EPA included the phrase ''. . . as applicable'' to recognize that product reporting requirements may vary depending on the type of component (*e.g.,* chemical, microorganism). EPA modified the regulatory text in § 300.950(b)(1) to include the term ''or Sorbent Product List'' to clarify this requirement also applies to submissions for listing sorbent products. Finally, EPA modified the language in § 300.950(b)(2) from that proposed, to more clearly explain the process for submitting PBI; the information does not need to be redacted but included in a separate marked inner envelope in the submission package.

Some commenters expressed concerns related to the public disclosure of proprietary information. A commenter suggested that while EPA may require disclosures of product formulas, this information does not need to be made public. The commenter noted that this disclosure could put the manufacturer at a competitive disadvantage. The commenter also suggested that this rule may have the unintended consequence of discouraging companies from listing products which in turn could decrease the number of products available for response activities in the United States. Another commenter suggested that the disclosure requirement would allow competitors to develop ''copycats'' of existing products with the release of proprietary trade secrets. Other commenters expressed concerns related to the potential impacts of the proposed rule on innovation for manufacturers, with some emphasizing impacts to small businesses. The Agency acknowledges the opposition to the final rule amendments relating to those elements identified in § 300.915(a)(13) and (14) in the product to be claimed as PBI. While providing submitters the ability to claim the concentrations, weight percentages, and units of all chemical components, microbiological cultures, enzymes, or nutrients as identified in § 300.915(a)(13) and (14) as PBI, the final rule allows greater public access to other information (that is, all the information required under § 300.915 and § 300.955 except for specific data as per § 300.950) submitted by the product manufacturer to EPA for listing on the NCP Product Schedule, including the identity of chemical components and relevant health and environmental effects information. EPA recognizes the need to balance a product manufacturer's interest in keeping as much information about a product confidential as possible with the general public's interest to be informed about products that may be used during a response under CWA section 311 authorities. As such, EPA believes the approach in the final action provides the appropriate balance between the public interest in knowing the constituents of products being used during a response and a product manufacturer's interest in protecting the product's formulation. The Agency also recognizes the concern with disclosure of product formulas, which some commenters argue would allow the development of ''copycats'' of existing products, thereby impacting manufacturers and small businesses, their incentive to develop products, and the ability of small, disadvantaged businesses to compete and innovate. The final action balances public access to information with proprietary business needs. The final rule allows product manufacturers to assert a claim of PBI for the concentrations, weight percentages, and units of all chemical components, microbiological cultures, enzymes, or nutrients as identified in § 300.915(a)(13) when submitting a product for listing on the NCP Products Schedule. The remainder of the information submitted as required under § 300.915 and § 300.955 will be available for public disclosure upon submission without further notice to the submitter.

Another commenter suggested that the EPA's duty under the Clean Water Act mandates that all ingredients for products listed on the NCP Product Schedule be disclosed, including precise formulations, in order to assess potential exposure and toxicity. Some commenters suggested that applications for agents that have claimed specific ingredients as CBI should not be listed on the NCP Product Schedule, and thus precluded from use. The Agency does not agree that mandatory disclosure of ingredients is required by the Clean Water Act and has chosen a balanced approach to ensure that relevant information is available to the public while maintaining important

confidentiality protections for product manufacturers. This final action allows only for the concentrations, weight percentages, and units of all chemical components, microbiological cultures, enzymes, or nutrients as identified in § 300.915(a)(13) and (14) to be claimed as PBI. All other information submitted to EPA for listing on the NCP Product Schedule as required under §§ 300.915 and 300.955 cannot be claimed PBI and will be available for public disclosure upon submission without further notice to the submitter.

A commenter requested clarification on what and how product components or confidential business information would be disclosed publicly. PBI claims associated with a product for listing on the NCP Product Schedule are limited to the concentrations, weight percentages, and units of all chemical components, microbiological cultures, enzymes, or nutrients as identified in § 300.915(a)(13) and (14); all other information submitted to EPA for listing a product on the NCP Product Schedule as required under § 300.915 and § 300.955 will not be considered PBI and will be available for public disclosure upon submission without further notice to the submitter. EPA does not disclose PBI to the public; EPA safeguards this information under the requirements in 40 CFR part 2, subpart B. EPA intends to publish non-PBI product component information in the NCP Product Schedule Technical Notebook, which is publicly available on EPA's NCP Product Schedule web page.

5. Addition of a Product to the NCP Product Schedule or Sorbent Product List

The final action at § 300.955 establishes the requirements for submitters to request a product to be listed on the NCP Product Schedule or the Sorbent Product List. These provisions provide administrative information, such as the address where to submit the package, as well as details of the requirements for a complete submission package. Additionally, they address how a submitter may request a listing determination review and the requirements when there are changes in a listed product. Finally, these provisions address the process the Agency will follow to review all new submissions, requests for review of decisions and product changes, as well as how it will transition from the current NCP Product Schedule to a new one that reflects the new and amended testing and data requirement.

EPA revised the title for § 300.955 relative to the proposal from ''Addition of a Product to the Schedule'' to ''Addition of a Product to the NCP Product Schedule or Sorbent Product List'' to clarify the applicability under § 300.955(a) and (b) of requirements as described in § 300.915(g), *Sorbent Requirements,* for adding sorbents to the Sorbent Product List.

(a) Submission

At § 300.955(a), the Agency has updated the address where the package is to be submitted. No comments on the proposed changes at § 300.955(a) were identified. EPA is finalizing this provision as proposed.

(b) Package Contents

The provision at § 300.955(b) specifies what a complete package must include. Because of their intended function in responding to oil discharges, products listed on the NCP Product Schedule will certainly impact the environment. It is important that the information provided by the submitter is true and accurate, as it serves as the basis for evaluating those potential environmental impacts. The Agency believes that it is appropriate for the submitter to be held accountable for the technical data and information provided to make these listing determinations. The final action requires the submitter to certify the accuracy of the information submitted, and EPA will reject any submission that is determined to be incomplete or noncompliant, misleading, or inaccurate.

No comments on the proposal at § 300.955(b) were identified. EPA amended the proposed phrase ''Your package shall include in this order:'' to include the term ''as applicable'' to recognize that those provisions under § 300.955 apply to sorbents submission as described in § 300.915(g), *Sorbent Requirements.* The term ''as applicable'' was also added to § 300.955(b)(2) for the same reason. Finally, EPA also made other editorial changes to provide greater clarity.

(c) EPA Review

The final action maintains most of the previous Agency process for reviewing product submissions. The final action increases the number of days allowed for the Agency to complete its product review from 60 days to 90 days from the date of receipt. This change, as described in the proposal, considers the additional amount of technical data and information required under the revised rule, as well as the Agency's past experience with submission packages.

As described in § 300.955(c), EPA will first review the package for completeness and compliance with all data and information requirements. EPA will contact the submitter to verify information, or to request clarification or additional information, including a product sample, as necessary. The Agency will make product listing determinations based on a technical evaluation of all data and information submitted in accordance with the requirements for each product category, any relevant information on impacts or potential impacts of the product or any of its components on human health or the environment, and on the intended use of the product. Within the 90-day timeframe, the Agency will notify the submitter, in writing, of its decision to either list the product on the NCP Product Schedule, or of its decision and supporting rationale to reject the submission. Submitters may revise submission packages to address test results, data, or information deficiencies and resubmit them. Because the Agency will need a complete set of data and technical information to make a listing determination, the 90-day review time period will start anew once a complete package is resubmitted.

A commenter stated that the listing process should be as transparent as possible, and that the Agency does not explain the standard that a dispersant must meet to be listed. The commenter suggested that the Agency clearly explain how it will evaluate studies that show sub-lethal impacts to humans and wildlife—particularly, information other than toxicity and efficacy tests. EPA reiterates that for a dispersant to be listed on the NCP Product Schedule, it must meet the specific dispersant testing and listing requirements in § 300.915(b), in addition to the general information requirements under § 300.915(a). The Agency will evaluate a submission package in accordance with the provisions under § 300.955(c) of this final rule. The Agency's product listing determination will be based on a technical evaluation of all data and information submitted, in accordance with the requirements for each product category, relevant information on impacts or potential impacts of the product or any of its components on human health or the environment, and the intended use of the product. EPA amended the provision to include the phrase ''. . . in accordance with the requirements for each product category . . .'' to clarify the applicability for each product category.

In the final action, EPA removed the proposed sentence ''EPA reserves the right to make a determination on whether the product will be listed, and under which category'' because it is unnecessary. Likewise, the final action

under § 300.955(c)(3) does not include the phrase ''. . . and in which category or categories. . .'' because it too is unnecessary. The provision under § 300.955(c)(3) already states that EPA will provide notification of the Agency's decision to list (or not) a product on the NCP Product Schedule, which will include how the product is listed, as applicable. EPA reorganized the sentence under § 300.955(c)(3)(i) for greater clarity to read ''You may revise and resubmit a complete package to . . .''. Finally, EPA also made other editorial changes to provide greater clarity.

(d) Request for Review of Decision

The final action does not substantively change the process for a submitter to request that the Agency review its determination on a product. If the Agency rejects a product for listing on the NCP Product Schedule, the rule at § 300.955(d) continues to allow for a submitter to appeal to the EPA Administrator to review its determination to reject the product listing. Such a request must be made in writing, within 30 days of receipt of the written notification of EPA's decision. The request to review the Agency's determination must include a clear and concise statement with supporting facts and technical analysis that demonstrates why the submitter believes the product meets the listing requirements. The Administrator or designee may request additional information or a meeting opportunity. Within 60 days of receipt of any such request, or within 60 days of receipt of any requested additional information, the Administrator or designee must notify the submitter in writing of the review decision.

No comments on the proposed provision at § 300.955(d) were identified. In the final provision, EPA replaces the phrase ''. . . why you believe EPA's decision was incorrect.'' with ''. . . why the product meets the listing requirements.'' to better reflect the intent of the provision. EPA also made other editorial changes to provide greater clarity and consistency.

(e) Changes to a Product Listing

The Agency is revising the provisions for notification of changes to a product listing. Under the final action at § 300.955(e), submitters must notify EPA in writing within 30 days of any changes to the general product information submitted for listing on the NCP Product Schedule so the OSCs have timely updated information. Changes applicable to this provision are any changes to information submitted under § 300.915(a)(1) through (8), and (a)(19) through (21), for a product on the NCP Product Schedule. Submitters must provide the reasons for such changes and the supporting data and information. EPA maintains the ability to request additional information and clarification regarding these changes. For any changes to the components and/or their concentrations, the final action requires retesting of the reformulated product according to the requirements for the product category, and the resubmission of a new complete package in accordance with § 300.955(b) for review and consideration for a listing determination by the Agency. In the final action, EPA split the proposed paragraph into two subparagraphs, that is § 300.955(e)(1) and (2), to distinguish requirements for administrative changes from those for when a listed product is reformulated.

Some commenters expressed support of the 30-day written notification requirement for changes to listed product information. The commenters suggested expanding the requirement to provide a mechanism for the RRT to request retesting where field performance falls short of expectations. EPA acknowledges that there may be instances when a product performs differently in the field than when it was tested. The final rule contains provisions at § 300.910(g) that allow the RRT or OSC, during a discharge response, to require a responsible party to conduct additional monitoring associated with the use of a product. For any changes to the components and/or their concentrations, the final rule requires retesting of the product according to the requirements for the product category, and the resubmission of a new, complete package for review and consideration for a listing determination of the reformulated product by the Agency. The Agency believes that when the components or concentrations of a product change, an automatic retesting requirement is merited.

EPA modified the final provision by deleting the proposed term ''chemical'' to clarify that the provision applies to changes to non-chemical components in biological agents, such as microorganisms and enzymes. EPA also added the qualifier ''in accordance with § 300.955(b)'' to clarify the procedure for submission of a new package for review and consideration for reformulated products. Finally, EPA amended the final provision by adding the phrase ''. . . a new complete package under a new, distinct name . . .'' to clarify the submission requirements for reformulated products. Providing a new, distinct name for the reformulated product avoids potential confusion with existing products listed on the NCP Product Schedule and helps to distinguish products with the previous formulation that may be stockpiled. EPA also made additional editorial changes to this provision from the proposed text to provide greater clarity.

(f) Transitioning Listed Products to the New NCP Product Schedule or Sorbent Product List

The Agency believes it important that products on the current NCP Product Schedule continue to be available during the transition period to a new NCP Product Schedule that reflects the amended requirements. Therefore, according to § 300.955(f), during this transition period, all products on the current NCP Product Schedule as of December 11, 2023 will remain conditionally listed and available for planning and response activities. Because of the finalized revisions to test protocols and listing criteria, and because of the additional test requirements, all products currently on the NCP Product Schedule must be retested, and the new data and information be submitted to the Agency for reevaluation of the current listings by December 12, 2025. The Agency believes that this 24-month transition period starting on the effective date of the final action provides adequate time for submitters to prepare and submit new packages to EPA and for the Agency to review and make decisions on these products. For a product to be transitioned to the new NCP Product Schedule, manufacturers would be required to submit a new, complete package according to the amended test and listing criteria, and EPA would need to make a favorable finding to list the product on the new NCP Product Schedule, either as currently listed or with modifications. Products on the current NCP Product Schedule for which a new submission is not received, or that upon review of their submissions do not meet the revised listing criteria, will be removed from the NCP Product Schedule at the end of the 24-month transition period. Likewise, it is important that all products that have previously received EPA letters identifying them as sorbents remain available for use until December 12, 2025. Similar to the 24-month transition period allowed for products listed on the NCP Product Schedule, the Agency believes this provides an adequate timeframe for sorbent product manufacturers, as appropriate, to prepare and submit new packages to EPA and for the Agency to review and

make decisions on listing these products on the Sorbent Product List. Under the new § 300.955(f) provisions, all sorbent products must have submitted information as applicable under § 300.955(a) and (b) and be listed in the new Sorbent Product List at the end of the 24-month transition period to be considered for use. Known sorbent materials identified under § 300.915(g)(1), or any combination thereof, for which no technical data are required to be submitted for listing on the Sorbent Product List, are not subject to relisting review.

Some commenters suggested that the transition period should be shortened from two years to one, due to an increased risk of harm from products listed on the old Schedule. A commenter noted that a one-year timeframe would be adequate for manufacturers to perform all required product retesting and recertification. Some commenters expressed concern that the proposed transition timeframe is too short. A few commenters stated that the 24-month transition period is inadequate to allow for the depth of technical work required for the recertification and relisting of products on the new NCP Product Schedule. Another commenter suggested extending the transition period to the lesser of five years, the product expiration date, or until a suitable replacement is available and listed on the Schedule. Another commenter suggested that the proposed transition timeframe is unreasonable because the Agency is overestimating the number of laboratories capable of performing the required testing (specifically, bioremediation testing). The Agency believes that the 24-month transition period provides adequate time for submitters to prepare and submit new, complete packages to EPA and for the Agency to review and make decisions on these products. EPA updates the NCP Product Schedule when new products are listed. EPA has identified laboratories with sufficient capability to conduct testing for bioremediation agents to meet the expected demand under the revised rule.

Several commenters provided suggestions related to keeping products that are currently on the NCP Product Schedule, without requiring further retesting or recertification. Several commenters expressed concern that the updates to the rule would invalidate the significant amount of time and effort previously spent to obtain Schedule listing and suggested that products on the existing Schedule should be grandfathered into the new listing. Some commenters expressed concern related to potential impacts on small businesses, including advocating for additional transition time for small businesses to complete testing and for short-term extensions for small businesses with products that have been recently added to the Schedule. On the other hand, a commenter expressed concern that grandfathering products on the current NCP Product Schedule would undermine efforts to ensure all listed products meet the most up-to-date toxicity and efficacy standards. EPA acknowledges the comments requesting both shorter and longer timeframes for the transition period. EPA believes the 24-month transition period provides adequate time for retesting, production of additional products, and the continued ability of currently listed products to be offered and available in the event of a response. Furthermore, the Agency believes that the 24-month transition period provides adequate time for submitters to prepare and submit new, complete packages to EPA and for the Agency to review and make decisions on these products regardless of entity size. Finally, EPA agrees with commenters that opposed grandfathering of existing products on the Product Schedule. The final provisions ensure that all products transitioned to the new NCP Product Schedule meet the updated efficacy and toxicity listing criteria, follow the amended testing protocols, and have submitted updated data and information to the Agency.

In the final provision, EPA replaced ''. . . according to the amended test and listing criteria . . .'' with ''in accordance with § 300.955(b)'' to avoid confusion by clarifying the procedure for submission of a new, complete package for review and consideration. EPA also added specific regulatory language clarifying the transition period is applicable to listing products on the Sorbent Product List. Finally, EPA made additional editorial changes to the provisions in § 300.955(f) relative to the proposed text to provide greater clarity, and to specifically address the transition period for sorbent products.

6. Mandatory Product Disclaimer

It remains the Agency's position that listing a product on the NCP Product Schedule does not constitute approval or endorsement of that product, nor a recommendation of its use. The Agency continues to believe that it is important to avoid any possible misinterpretation or misrepresentation of this policy. Thus, the requirement for a disclaimer to be included on any label, advertisement, or technical literature for the product is maintained at § 300.965. As proposed, the final action removes the alternative to reproduce in its entirety EPA's written notification that it will add the product to the NCP Product Schedule. The Agency believes it will be able to update the NCP Product Schedule list within a reasonable timeframe given the advances in information technology, and thus the option of producing the EPA letter of notification for a product listing should no longer be necessary. The Agency is modifying the previously required disclaimer language to include the sentence ''Only a Federal On-Scene Coordinator (OSC) may authorize use of this product in accordance with Subpart J of the NCP in response to an oil discharge.'' This revision is intended to clarify that the use of these products is conditional to OSC authorization following the requirements set forth under the NCP regulations. The disclaimer language must continue to be conspicuously displayed in its entirety, and must be fully reproduced on all product literatures, labels, and electronic media, including website pages.

A commenter suggested a change to the last sentence in the disclaimer language related to decision authority as follows, ''Only a Federal On-Scene Coordinator, using pre-authorizations or incident-specific approvals issued by the Regional Response Team (RRT), may authorize . . .'' Another commenter suggested further clarification to the disclaimer language to indicate that NCP Product Schedule listing is only approval to be on the NCP Product Schedule, not approval for use or application during a response. EPA did not adopt the commenter's recommended disclaimer language because authorization of use is already addressed under Subpart J. However, the Agency did modify the last sentence of the proposed regulatory text in § 300.965 to clarify an OSC's authority to authorize a product for use in accordance with Subpart J of the NCP. The amended disclaimer language clarifies that only a Federal On-Scene Coordinator (OSC) may authorize use of this product by replacing the phrase ''according to the NCP'' with ''in accordance with Subpart J of the NCP in response to an oil discharge.'' The Agency acknowledges the commenter's suggestion to add further clarification to indicate that the NCP Product Schedule listing is only approval to be on the NCP Product Schedule but disagrees that this clarification is necessary. The Agency believes the mandatory product disclaimer language in this final action already clearly indicates that a product's

listing on the NCP Product Schedule does not constitute approval or recommendation of the product. However, the final provision under § 300.965 includes the phrase ''. . . listed on the NCP Product Schedule . . .'' to read ''To avoid possible misinterpretation or misrepresentation, any label, advertisement, or technical literature for products listed on the NCP Product Schedule must display in its entirety the disclaimer shown below.'' for greater clarity.

EPA also made additional editorial changes to the provisions in § 300.965 relative to the proposed text to provide greater clarity.

7. Removal of a Product From the NCP Product Schedule or the Sorbent Product List

Products that are not properly used in the field may cause harm to human health and the environment, and may constitute violations of the CWA, and other federal, state, Tribal, or local laws. Misleading, inaccurate, or incorrect statements within a product submittal package or within language that refers to the listing of a product on the NCP Product Schedule or the Sorbent Product List may result in their improper or incorrect use. Falsification of federal documents, unsupported toxicity or efficacy claims, submission of incorrect product composition or use information, or withholding technical product data are some examples of these acts. For these reasons, EPA is providing explicit criteria and process for the removal of a product from the NCP Product Schedule or the Sorbent Product List at § 300.970. In the final action, EPA is modifying the title from that which was proposed, to include ''or the Sorbent Product List'' to clarify that sorbents placed on the Sorbents Product List may also be removed. EPA made similar modifications throughout the paragraph of § 300.970.

(a) Removal Reasons

To minimize potential misuse of listed products, the Agency believes it is appropriate to clarify the criteria for the removal of a product from the NCP Product Schedule or Sorbent Product List. In § 300.970(a), EPA specifically includes, but does not limit, as causes for removal from the NCP Product Schedule or Sorbent Product List: statements or information that are misleading, inaccurate, outdated, or incorrect regarding the composition or use of the product to remove or control oil discharges made to any person, or private or public entity, including on labels, advertisements, technical literature, or electronic media, or within the product submission to EPA; any alterations to the components, concentrations, or use conditions of the product without proper notification to EPA as required by § 300.955(e); failure to print the disclaimer provided in § 300.965 on all labels, advertisements, technical literature, or electronic media; or any new or relevant information not previously considered concerning the impacts or potential impacts of the product to human health or the environment.

Commenters suggested the need for public input in the removal process, *e.g.,* for the public to request product removal from the NCP Product Schedule, such as following a decrease in rating of Tribe or community acceptance criteria for product use. The final provisions provide that misleading, inaccurate, or incorrect information provided to any private or public entity is a reason for removal from the NCP Product Schedule. However, the Agency disagrees that the listing of products on the NCP Product Schedule on a national level should include criteria developed by outside entities. Section 311(d)(2)(G) of the CWA solely delegates authority to EPA to prepare a schedule identifying dispersants, other chemicals, other spill mitigating devices and substances if any, that may be used in carrying out the NCP; and the waters and quantities in which they may be used safely. Thus, the final action does not allow for entities other than EPA to remove a product from the NCP Product Schedule, nor is the removal of a product based on ratings from a non-EPA entity. The final rule does not preclude any person or private or public entity to bring to EPA's attention information, including relevant scientific data, that they believe may warrant consideration for EPA to remove a product from the NCP Product Schedule.

Other commenters requested explicit clarification that changes to product chemical components or reformulation would result in removal from the NCP Product Schedule and would require product retesting and recertification, since changes to the composition can change impacts on human health or the environment. As provided in § 300.970 of the final rule, the EPA Administrator or designee may remove a listed product from the NCP Product Schedule for alterations to the components, concentrations, or use conditions of the product without proper notification to EPA as required by § 300.955(e). If the manufacturer changes the components and/or concentrations, then the manufacturer must retest the reformulated product according to the requirements for the product category and submit a new, complete package for a review and EPA's consideration for listing on the NCP Product Schedule.

A commenter suggested that the Agency should set a threshold for product impact levels that would necessitate list removal. The final action includes thresholds in the testing and listing protocols for each product category in § 300.915, as applicable, to screen products at a national level. However, EPA believes potential impacts from chemical and biological agent use is situational and more appropriately considered when authorizing their use and overseen by the OSC. The final action includes authorization of use provisions that provide for consideration of potential impacts. Further, the final action also includes provisions for RRTs to consider supplemental testing, monitoring and information under § 300.910(g) to address site, area, and/or ecosystem-specific concerns relative to the potential impact from the use of a chemical or biological agent.

In the final action, EPA has included ''information'' and added ''outdated'' to the list of types of statements and information that could be reasons for removal from the NCP Product Schedule. EPA has also updated the proposed text by including ''electronic media'' to the methods by which statements or information and disclaimers may be disseminated. The final action removes the qualifier ''chemical'' before the term ''component'' to clarify that the provision applies to ''non-chemical'' components (*e.g.,* microorganisms) and to be consistent with similar changes under § 300.955(e). The final action also replaces the term ''previously unknown'' with ''not previously considered'' to clarify what information the Agency may consider when removing a product from the NCP Product Schedule. EPA also made additional editorial changes to the provisions in § 300.970(a) relative to the proposed text to provide greater clarity.

(b) Notification and Appeals

The final action also establishes a process for removal if the Agency obtains evidence of cause for removal. As per § 300.970(b), EPA will notify the submitter in writing, at the address of record, of its reasons for removal of the product from the NCP Product Schedule. The provision at § 300.970(c) allows for an appeals process similar to the one set forth for listing determinations. Appeals must be received within 30 days of receipt of

EPA's removal notification and must contain a clear and concise statement with supporting facts and technical analysis demonstrating why the product should not be removed. Written notification from the Administrator or designee will be sent to the submitter within 60 days of any appeal, or within 60 days of receipt of any requested additional information. If no appeal is received within the 30 days of receipt of EPA's removal notification, the product will be delisted without further notice.

EPA did not identify any comments specifically related to the provisions at § 300.970(b) and (c). In the final action, EPA revised § 300.970(c) to replace the phrase ''. . . demonstrating why you believe EPA's decision was incorrect.'' This phrase is replaced with ''. . . demonstrating why the product should not be removed'' to better describe the appeal process. EPA also made other editorial changes to these provisions from the proposed text to provide greater clarity.

8. Appendix C to Part 300

The Agency is revising Appendix C to change its title to Appendix C—*Requirements for Product Testing Protocols and Summary Test Data: Dispersant Baffled Flask Efficacy and Toxicity Tests; Standard Acute Toxicity Test for Bioremediation Agents, Surface Washing Agents, Herding Agents, and Solidifiers; and Bioremediation Agent Efficacy Test.* Revisions to this appendix reflect the new and revised testing protocols for listing agents on the NCP Product Schedule as finalized in this action. A description of the technical changes and rationale are discussed for each agent in section V.C.3 of this preamble—Data and Information Requirements for NCP Product Schedule Listing. The appendix reflects the technical considerations and listing requirements.

Commenters expressed general concern regarding the potential limitations of screening tests relative to field performance, and specifically to product performance in marine environments. EPA reiterates that the product efficacy and toxicity testing protocols provide essential information for listing chemical and biological agent products on the NCP Product Schedule. These laboratory testing protocols provide testing procedures for evaluating product efficacy for dispersant and bioremediation agents and product toxicity for all chemical and biological agent product categories, allowing for a comparative screening of products to be listed. The Agency acknowledges that tests like the BFT, under the parameters set in the protocol, cannot simulate the range of parameters and processes that may potentially influence dispersant effectiveness under actual spill discharge conditions. The Agency reiterates that the testing protocols are to provide data and information in support of screening for product listing at the national level. Nonetheless, the final action still adopts the BFT for screening products for the NCP Product Schedule because the BFT screening process not only improves test repeatability and reproducibility within and between laboratories, but also reduces both inherent and human error associated with the SFT. The Agency recognizes field performance may not be directly reflected for each product and spill situation by the testing results based on the protocols used for listing products on the NCP Product Schedule. Nonetheless, the testing protocols finalized in this action account for relevant oil spill parameters, including salinity, mixing energy, and temperature. These protocols provide a measure of efficacy for products that serves to establish a comparative screening baseline for a national level listing on the NCP Product Schedule. For example, the revised BFT testing protocol for dispersant effectiveness is designed to be more representative of moderately turbulent sea conditions where dispersants are more likely to be successfully used. Additionally, the final action provides for testing products at temperatures reflective of the potential range of locations where dispersants may be used. The final action also provides for product listing on the NCP Product Schedule to reflect testing for the specific salinity environments where the product could be considered for use.

Commenters requested that the Agency audit or independently vet all tests with third-party scientists or peer review to ensure fairness and transparency, as well as recommended using independent science as opposed to government or industry, to review all studies conducted by the spiller, product vendor, or manufacturer. Commenters recommended that toxicity tests and efficacy tests be required to be conducted with certified chemists and scientists working in certified laboratories using certified procedures and best available technology. The Agency acknowledges the comments regarding laboratory certification. The final rule specifies in Appendix C the procedures for efficacy and toxicity tests that all laboratories must follow for each product category to maintain consistency and provide comparative information and data. The Appendix C procedures include a quality assurance (QA) provision. For example, the dispersant toxicity test under section 3 of Appendix C includes verification of laboratory accreditation, including subcontractor facilities (see Appendix C section 3.8.8) and analytical method summary including Limit of Detection (LOD)/Limit of Quantitation (LOQ) and QA summary (including calibration curves, method blank and surrogate recovery, analytical results summary) (see Appendix C section 3.8.10). Furthermore, the final provisions under § 300.915(a)(17) require the product submission for listing on the NCP Product Schedule to provide information about the laboratory that conducted the required tests, including the name of the laboratory, address, contact name, email, and phone number and the national and/or international accreditations held by the laboratory. The final provisions under § 300.915(a)(18) require the submission to provide all test data and calculations including raw data and replicates (including positive controls), notes and observations collected during tests, calculated mean values and standard deviations, reports, (including a summary of stock solution preparation), source and preparation of test organisms, test conditions, and chain of custody forms. The final provisions under § 300.915(a)(21) provide for the submission of international product testing or use data or certifications, if available, informing the performance capabilities or environmental impacts of the product. EPA believes these requirements sufficiently address informational needs concerning laboratory certification and independent science.

Dispersant Baffled Flask Efficacy Tests. A commenter questioned how realistic the turbulent mixing associated with *the Baffled Flask Test* would be, relative to the range of ambient conditions and sea-states that might be expected during operational use of dispersants. The commenter recommended that the Agency explore other methods that would replicate mixing of oil and dispersants under moderate to low-energy sea conditions. The commenter stated that dispersion is much less effective in nonbreaking wave conditions relative to breaking wave conditions, citing a study. While the BFT is designed to be more representative of moderately turbulent sea conditions where dispersants are more likely to be successful when used, the Agency reiterates that laboratory efficacy and toxicity testing protocols provide relatively rapid and simple

testing procedures for evaluating product efficacy and toxicity, allowing for a comparative screening of products at a national level to be listed on the NCP Product Schedule. The final BFT methodology is modified to remove the step to test a dispersant as a positive control as the final action includes sufficient quality assurance and quality control procedures specific to the updated dispersant efficacy protocol, as well as the submittal of raw data and information for product testing, that make this requirement unnecessary.

Dispersant Toxicity Tests. A commenter recommended that wherever practicable, dispersant toxicity test species should either be indigenous to the spill area or have been shown to be appropriate surrogates for species from the area. EPA selected the final rule test species because of their general acceptability in applicable toxicity testing methods. To facilitate further flexibility to laboratories conducting the developmental assay, the Agency amended the final provisions to include the option to use the purple sea urchin *Arbacia punctulata* (*A. punctulata*) in lieu of *Strongylocentrotus purpuratus* (*S. purpuratus*) for the developmental assay. Separately, the final rule allows for species- or region-specific toxicity testing to be required by the RRT and/or OSC under § 300.910(g). EPA considers the toxicity tests being finalized in this rule to be the most practical for judging product hazard. Additional comments on specific protocol considerations were summarized and answered in the Response to Comments document. EPA also updated the reference oil used for the acute toxicity testing of the dispersant product-oil mixture. Finally, the final action does not include phrase ''. . . (iii) egg production must occur in 50% of female *Americamysis bahia* in the replicate control treatments.'' under section 3.7.5. EPA determined that excluding the fecundity endpoint was unlikely to influence the sensitivity of the test, while having the practical advantage of simplifying the test method.

Standard Acute Toxicity Test for Bioremediation Agents, Surface Washing Agents, Herding Agents, and Solidifiers. Prior to this amendment, the rule did not include any requirements for toxicity testing for bioremediation agents. The final provisions establish acute toxicity testing requirements for all product categories, including bioremediation agents. The acute toxicity testing protocols for all product categories use the same test species for saltwater environments. Likewise, the acute toxicity testing protocols for all product categories, except for dispersants, use the same test species for freshwater environments; a dispersant may only be listed on the NCP Product Schedule for use in saltwater environments and therefore do not have acute toxicity testing requirements for freshwater. Finally, dispersant toxicity testing requirements include a developmental toxicity test and a subchronic toxicity test that are not required for bioremediation agents.

No substantive changes were made to the proposed text to this section of the Appendix. A commenter recommended including toxicity testing for species that are representative of in-shore and/or nearshore environments as well as longer term monitoring that reflects toxicity during continuous/long term application. A commenter noted that toxicity testing involving intertidal and estuarine species would be particularly appropriate for surface washing agents. A commenter asked for clarification regarding why the Agency test species required for bioremediation agents have changed from previous requirements and are different than those required for dispersant tests. The Agency recognizes the comments regarding the specific test species the Agency specifies for use in the protocols included in the final action. The laboratory efficacy and toxicity testing protocols in the final action provide relatively rapid and simple testing procedures for evaluating product efficacy and toxicity, allowing for a comparative screening of products at a national level; this applies to the selection of test species. Test species are generally chosen because they are easily cultured in the laboratory and tend to be sensitive to a wide variety of pollutants, serving as good indicators of chemical hazards. These species are also small enough to be easily tested in groups in relatively small containers under laboratory conditions. The species included in the protocols have been identified to be aquatic species commonly used in laboratory tests, and consistent with EPA standard methods. While the data and information from laboratory testing results in the final action may broadly inform potential field performance or impacts, they are intended for the Agency's screening of agent products for listing on the NCP Product Schedule.

Bioremediation Agent Efficacy Test. No substantive changes were made to the proposed text to this section of the Appendix. A commenter stated that all testing should be conducted with the original medium (*i.e.,* seawater and/or freshwater), and that all bioremediation types should be tested in aqueous solutions closest to the original environment in which these products were intended for use. They recommended that test procedures involving bioremediation agents should allow for microbes or nutrients, which are naturally occurring in nature, to be added at the manufacturer's discretion. The protocol required by the final action uses a standardized artificial saltwater formula called GP2, whose components and concentrations are generally recognized, and which is easily made. Requiring standardized artificial saltwater avoids the potential for variable results due to the compositional variability of natural seawater both chemically and microbiologically, resulting in better test reproducibility. Additionally, the protocol also provides for efficacy testing in freshwater, which allows for a better screening of the use of these agents in this environment.

9. Appendix E to Part 300

The 1994 revisions to the NCP established Appendix E, *Oil Spill Response,* which separates the oil spill response requirements of the NCP from the hazardous substance release requirements (59 FR 47414). The purpose of creating this appendix was to compile general oil discharge response requirements into one document to aid responsible parties and responders with their duties under the national response system. The Agency's intent was to provide guidance, and not to alter in any way the meaning or policy stated in other sections or subparts of the NCP. However, some minor variations between the Appendix E provisions and the analogous provisions of the NCP rule language were necessary to ensure that the appendix addressed only oil discharges; hazardous substance releases continue to be addressed in the NCP rule but were not addressed in Appendix E. The Agency is removing Appendix E in this final action. While having all of the information pertaining to oil discharges compiled in one location may offer useful guidance, it is not necessary that this guidance be codified as a regulatory appendix to the NCP. Because all requirements in Appendix E are part of the NCP, any revisions to the NCP necessitate revisions to this appendix. This adds burden not only for the Agency in revising and ensuring consistency, but also for the regulated community in reviewing redundant and duplicative requirements.

A commenter suggested that the Agency continue to provide guidance on response activities through other formats. EPA agrees that it is more appropriate to provide guidance on

response activities through other formats. In this action, EPA is finalizing revisions to remove Appendix E. EPA will consider what additional guidance, if any, may be appropriate.

VI. Summary of Final Rule Provisions

This section summarizes the final changes to 40 CFR parts 110 and 300. Subpart J has been renumbered to include new, consolidated, and revised sections. Some of the rule sections have been retained, removed, or moved in their entirety. The Table below provides an overview of the formerly existing rule and final rule citations for a quick reference of the final changes.

Section 110.4 was revised to reflect the new and amended regulatory definitions for Subpart J product categories.

Section 300.5, Definitions, was revised to include new, amended, and deleted definitions.

Subpart J—heading was revised as Use of Dispersants, and Other Chemical and Biological Agents, to reflect new and amended regulatory definitions for product categories.

Section 300.900, General, paragraphs (a) and (c) were revised to reflect new and amended regulatory definitions for product categories. Paragraph (d) has been added to reserve for later use.

Section 300.905, NCP Product Schedule, was removed.

Section 300.910 was renamed Authorization for Agent Use, was revised, and new paragraphs were added to clarify the provisions for the authorization of use of products on the NCP Product Schedule.

- Paragraph (a) was revised to clarify the process for preauthorization, the responsibilities of all involved parties, and the factors to consider during the preauthorization process. Subparagraphs (1) through (3) were added to clarify the development, approval, and review of a preauthorization plan.
- Paragraph (b) was revised to clarify the requirements for using a listed product or a burning agent on an oil discharge not addressed by a preauthorization plan and add new parameters for use considerations.
- Paragraph (c) was deleted and reserved for later use.
- Paragraph (d) was revised to clarify the exception requirements, emphasize its temporary nature, and add specific time frames for notification of continued agent use.
- Paragraph (e) was revised to maintain the prohibition on the authorization of use of sinking agents and reorganized to clarify and specifically include substances.
- Paragraph (f) was revised to add new regulatory requirements for agent storage and use. Former paragraph (f) requirements were moved to new paragraph (g), Supplemental Testing, Monitoring, and Information.
- New paragraph (g) Supplemental Testing, Monitoring, and Information, was added to clarify the requirements for supplemental testing, monitoring and information and their applicability.
- New paragraph (h), Recovery of Chemical Agents and other Substances from the Environment, adds regulatory requirements for recovery of agents and other substances during removal actions.
- New Paragraph (i), Reporting of Agent Use, adds regulatory requirements for notification of agent use on an oil discharge to both the RRT and to the public.

Section 300.915 was renamed Data and information requirements for listing on the NCP Product Schedule or Sorbent Product List. This section was revised to consolidate general submission requirements applicable to all product categories and was restructured to include new testing and listing requirements for specific product categories.

- Paragraph (a) was revised to consolidate general information requirements from former paragraphs (a), (b), (d), and (f). The paragraph includes revisions and new requirements for the identification of and testing for all product categories designated for listing. Former paragraph (a) requirements specific to dispersants were moved to new section 300.915(b), Dispersant Testing and Listing Requirements. The paragraph was also revised to add new toxicity and efficacy testing requirements, limitations for use, and new criteria for listing a dispersant on the NCP Product Schedule.
- Former paragraph (b) was moved to new paragraph (c), Surface Washing Agent Testing and Listing Requirements. The paragraph was revised to add new toxicity and efficacy testing requirements, limitations for use, and new criteria for listing a surface washing agent on the NCP Product Schedule.
- Former paragraph (c), Surface Collecting Agents, was deleted.
- Paragraph (d) was renamed Bioremediation Agent Testing and Listing Requirements. The paragraph was revised to add new toxicity and efficacy testing requirements, limitations for use, and new criteria for listing a bioremediation agent to the NCP Product Schedule. Former paragraphs (d)(9) and (10) were moved to new paragraph (a), General Product Information.
- Former paragraph (e), Burning Agents, was deleted.
- New paragraph (e), Solidifier Testing and Listing Requirements, was added to provide new regulatory requirements for submission and listing of a solidifier.
- Former paragraph (f), Miscellaneous Oil Spill Control Agents, was deleted.
- New paragraph (f), Herding Agent Testing and Listing Requirements, adds new toxicity testing requirements, limitations of use, and criteria for listing a herding agent on the NCP Product Schedule.
- Paragraph (g) was renamed Sorbent Requirements and revised to add new provisions for listing a sorbent to the Sorbent Product List.

Section 300.920, Addition of Products to Schedule, was moved to new § 300.955, Addition of a Product to the NCP Product Schedule or Sorbent Product List.

- Paragraph (a) was revised to include submission instructions for all product categories. Former paragraphs (a)(1) through (3), regulatory text specific to dispersant applications, was moved to new §§ 300.915(b) and 300.955(c) and (d).
- Paragraph (b) was revised to add new regulatory text for preparation of complete submission packages. Former paragraph (b) regulatory text was moved to new § 300.955(c) and (d).
- Paragraph (c) was revised to add regulatory text for EPA's review of submission packages and decision criteria for listing. Former paragraph (c) was moved to new § 300.950, Submission of Proprietary Business Information (PBI). The term Confidential was changed to Proprietary to reflect updated nomenclature.
- Paragraph (d) was revised to add regulatory text for requesting a listing decision review. Former paragraph (d) was moved to new § 300.955(e), Changes to a Listed Product.
- Paragraph (e) was revised to add new regulatory text for notification of changes to a listed product. Former paragraph (e) was moved to new § 300.965, Mandatory Product Disclaimer.
- New paragraph (f) adds new regulatory requirements for transitioning products to the new NCP Product Schedule or Sorbent Product List.

New § 300.950, Proprietary Business Information (PBI), revises and clarifies the allowable PBI claims in a submission package.

New § 300.965, Mandatory Product Disclaimer, clarifies the regulatory text

for including a disclaimer statement on all product labels and literature for products listed on the NCP Product Schedule.

New § 300.970, Removal of a Product from the NCP Product Schedule or Sorbent Product List, adds basis for removal of products from the NCP Product Schedule or Sorbent Product List, EPA notification of decision, and appeals process.

Appendix C to Part 300—Requirements for Product Testing Protocols and Summary Test Data: Dispersant Baffled Flask Efficacy and Toxicity Tests; Standard Acute Toxicity Test for Bioremediation Agents, Surface Washing Agents, Herding Agents, and Solidifiers; and Bioremediation Agent Efficacy Test was revised to update and add test methodology.

Appendix E to Part 300—Oil Spill Response was removed.

40 CFR Part 100 Discharge of Oil—Distribution Table

Current citation	Final rule citation
110.4 Dispersants ...	110.4 Chemical or biological agents.

40 CFR Part 300—National Oil and Hazardous Substances Pollution Contingency Plan—Distribution Table

Current citations	Final rule citations
300.5 Definitions	300.5 Definitions.
Subpart J—Use of Dispersants and Other Chemicals	Subpart J—Use of Dispersants, and Other Chemical and Biological Agents.
300.900 General	300.900 General.
300.900(a)	300.900(a).
300.900(c)	300.900(c).
[new]	300.900(d) Reserved.
300.905 NCP Product Schedule	Deleted.
300.910 Authorization of use	300.910 Authorization for agent use.
300.910(a)	300.910(a) Use of Agents Identified on the NCP Product Schedule or Use of Burning Agents on Oil Discharges Addressed by a Preauthorization Plan.
300.910(b)	300.910(b) Use of Agents Identified on the NCP Product Schedule or Use of Burning Agents on Oil Discharges Not Addressed by a Preauthorization Plan.
300.910(c)	300.910(c) Reserved.
300.910(d)	300.910(d) Temporary Exception.
300.910(e)	300.910(e) Prohibited Agents or Substances.
300.910(f)	300.910(g) Supplemental Testing, Monitoring, and Information.
[new]	300.910(f) Storage and Use of Agents Listed on the NCP Product Schedule.
[new]	300.910(h) Recovery of Chemical Agents and Other Substances from the Environment.
[new]	300.910(i) Reporting of Agent Use.
300.915 Data requirements	300.915 Data and information requirements for listing on the NCP Product Schedule or Sorbent Product List.
300.915(a) Dispersants	300.915(a)(1) through (21) General Information for any Product Category; and 300.915(b) Dispersant Testing and Listing Requirements.
300.915(b) Surface washing agents	300.915(a)(1) through (21) General Information for any Product Category; and 300.915(c) Surface Washing Agent Testing and Listing Requirements.
300.915(c) Surface collecting agents	Deleted.
300.915(d) Bioremediation Agents	300.915(a)(1) through (21) General Information for any Product Category; and 300.915(d) Bioremediation Agent Testing and Listing Requirements.
300.915(e) Burning Agents	Deleted.
300.915(f) Miscellaneous Oil Spill Control Agents	Deleted.
300.915(g) Sorbents	300.915(g) Sorbent Requirements.
300.915(h) Mixed products	Deleted.
[new]	300.915(e) Solidifier Testing and Listing Requirements; 300.915(a)(1) through (21) General Information for any Product Category.
[new]	300.915(f) Herding Agent Testing and Listing Requirements; 300.915(a)(1) through (21) General Information for any Product Category.
300.920 Addition of products to Schedule	300.955 Addition of a Product to the NCP Product Schedule or Sorbent Product List.
300.920(a)(1) Dispersants	300.955(a) Submission.
300.920(a)(2)	300.955(c) EPA Review.
300.920(a)(3)	300.955(d) Request for review of decision.
300.920(b)(1) Surface washing agents, surface collecting Agents, bioremediation agents, and miscellaneous oil spill control agents.	300.955(a) Submission.
300.920(b)(2)	300.955(c) EPA Review.
[new]	300.955(b) Package contents.
300.920(c)	300.950 Submission of Proprietary Business Information (PBI).
300.920(d)	300.955(e) Changes to a product listing.
[new]	300.955(f) Transitioning Listed Products to the New NCP Product Schedule or Sorbent Product List.
300.920(e)	300.965 Mandatory Product Disclaimer.

40 CFR PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN—DISTRIBUTION TABLE—Continued

Current citations	Final rule citations
[new]	300.970 Removal of a Product from the NCP Product Schedule or Sorbent Product List.

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review; Executive Order 13563: Improving Regulation and Regulatory Review; and Executive Order 14094: Modernizing Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket for this action. In addition, EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, *Regulatory Impact Analysis, Final Revisions to the National Oil and Hazardous Substances Pollution Contingency Plan Regulations (40 CFR part 300 Subpart J),* is available in the docket for this action.

B. Paperwork Reduction Act

The information collection activities in this final action will be submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR No. 1664.14. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The NCP Product Schedule listing and authorization of use provisions of the final rule include requirements for submission of general product information and documentation of information related to product testing. For this ICR, EPA has estimated an average annual total burden for respondents of 487 to 1,165 hours per year in the first three years, and average annual labor and O&M costs of $1,040,969 to $1,088,123. EPA has carefully considered the burden imposed upon the regulated community by the regulations. EPA believes that the activities required are necessary and, to the extent possible, has attempted to minimize the burden imposed. The minimum requirements specified in the final rule are intended to encourage the development of safer and more effective spill mitigating products, and to better target the use of these products to reduce the risks to human health and the environment.

Respondents/affected entities: Manufacturers of dispersants, other chemical and biological agents, other spill mitigating devices and substances.

Respondent's obligation to respond: Mandatory if manufacturer wishes to have a product listed on the NCP Product Schedule (40 CFR part 300, subpart J).

Estimated number of respondents: 109 responses by 89 existing product respondents during year one and two of the ICR period; in addition, 5 new product responses per year, and 10 sorbent submissions per year. The overall average number of responses during the ICR period is 51.

Frequency of response: Occasional.

Total estimated burden: 487 to 1,165 hours per year. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,040,969 to $1,088,123 per year.

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 the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are 88 potentially small businesses in the following industries: Support Activities for Mining; Specialty Trade Contractors; Paper Manufacturing; Petroleum and Coal Products Manufacturing; Chemical Manufacturing; Plastics and Rubber Products Manufacturing; Durable Goods Merchant Wholesalers; Nondurable Goods Merchant Wholesalers; Non-store Retailers; Warehousing and Storage; Professional, Scientific, and Technical Services; Administrative and Support Services; Waste Management and Remediation Services; Repair and Maintenance; and Religious, Grantmaking, Civic, Professional, and Similar Organizations. The Agency has determined that up to five of the affected small entities may experience an impact of 1% to 3% of revenues and up to five of the affected small entities may experience an impact of greater than 3% of revenues. Details of this analysis are presented in EPA's *Regulatory Impact Analysis, Final Revisions to the National Oil and Hazardous Substances Pollution Contingency Plan Regulations (40 CFR part 300 Subpart J),* which is available in the docket for this action.

D. Unfunded Mandates Reform Act

This action does not contain any unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This final rule imposes no new enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has Tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized Tribal governments, nor preempt Tribal law. EPA has concluded that this action may have Tribal implications because all Tribes can be affected by oil spills and the subsequent use of oil spill mitigating agents, such as dispersants and bioremediation agents. Furthermore, CWA section 311(j)(4)(A)(ii) provides for qualified members of federally

recognized Indian Tribes, where applicable, to be members of Area Committees. Additionally, E.O. 12777 provides that RRTs may include representatives from Tribal governments.

EPA consulted with Tribal officials under EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to enable them to have meaningful and timely input into its development. A summary of that consultation is provided in *Regulatory Impact Analysis, Final Revisions to the National Oil and Hazardous Substances Pollution Contingency Plan Regulations (40 CFR part 300 Subpart J),* which is available in the docket for this action.

As required by section 7(a), EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The Agency has concluded that the effect of the requirements codified in this final rule will mitigate the adverse effects of environmental and socio-economic damage that could otherwise result from major oil spills. This final action will therefore not have a disproportionate adverse effect on children.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The requirements specified in the final rule are intended to encourage the development of safer and more effective spill mitigating products, and to better target the use of these products to reduce the risks to human health and the environment; thus, the rule will result in greater overall environmental protection. The final rule will not cause reductions in the supply or production of oil, fuel, coal, or electricity; nor will it result in increased energy prices, increased cost of energy distribution, or an increased dependence on foreign supplies of energy.

I. National Technology Transfer and Advancement Act

This rulemaking involves technical standards. Therefore, the Agency conducted a search to identify potentially applicable voluntary consensus standards. However, EPA identified no such standards for efficacy and toxicity testing, and none were brought to the Agency's attention in comments. Therefore, EPA developed the Baffled Flask Efficacy Test; the Dispersant Toxicity Test; the Standard Acute Toxicity Testing for Surface Washing Agents, Bioremediation Agents, Herding Agents, and Solidifiers; and the Bioremediation Efficacy Test provided in Appendix C of this final rule.

Additionally, EPA has decided to use voluntary consensus standards for several product property data points, such as pH, flash point, and pour point. The product toxicity testing relies on existing protocols that are universally accepted. The Agency has removed the incorporation by reference of specific standards to determine physical and chemical properties and replaced this with a requirement for a citation of the current applicable standard methodology used to determine these values. EPA believes that citing the current applicable standard methodology used to determine the required values is sufficient in lieu of specifying commonly recognized standard methodologies. Furthermore, EPA did not incorporate by reference specific test methodologies in the regulation to avoid the administrative burden of updating the NCP every time a test methodology is updated to a newer version.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

The EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on people of color, low-income populations and/or indigenous peoples. Discharges of oil from facilities regulated by this action likely pose disproportionate risks to historically marginalized communities.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples. EPA has concluded that the regulatory requirements will advance fair treatment of those populations by reducing the disproportionate damages that oil discharges might otherwise inflict on those populations. EPA has concluded that the requirements codified in this final rule will mitigate the adverse effects of environmental and socio-economic damage that could otherwise result from major oil spills and are likely to reduce existing disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples. EPA has concluded that the regulatory requirements will advance fair treatment of those populations by reducing the disproportionate damages that major oil spills might otherwise inflict on those historically marginalized populations.

The focus of this action is to modernize and update Subpart J of the NCP. Nonetheless, the EPA identified environmental justice concerns associated with the final rule and qualitatively assessed whether the requirements codified in this final rule will mitigate the adverse effects of environmental and socioeconomic damage that could otherwise result from oil spills. EPA has concluded that, while the changes in this rule were independent of environmental justice considerations, the regulatory requirements will advance fair treatment of those populations by reducing the disproportionate damages that discharges might otherwise inflict on those historically marginalized populations. Specifically, EPA has concluded that:

- The amended requirements to add new listing criteria and revise efficacy and toxicity testing protocols emphasize development and listing of ''greener'' oil spill mitigating products and will increases public transparency on chemical and biological agent composition.
- The amended requirements for authorization of use, notifications, and data reporting better target agent use to reduce risks to human health and the environment. The amended requirements will increase both public awareness on chemical and biological

agent preparedness planning and response activities, including potential engagement opportunities, and access to information on the components for any chemical and biological agent listed on the NCP Product Schedule. EPA expects the final rule requirements will also enhance EPA's ability to address area- and regional-specific concerns and provide greater public awareness of chemical and biological agent use during a response through public notification.

• EPA expects that the final action's emphasis on developing safer and more effective spill mitigating products, and on better targeting their use, will reduce the risks to human health and the environment when chemical and biological agents are used during oil spill responses in these newly developed areas.

The information supporting Executive Order 12898 review is contained in the *Regulatory Impact Analysis, Final Revisions to the National Oil and Hazardous Substances Pollution Contingency Plan Regulations (40 CFR part 300 Subpart J),* which includes an environmental justice analysis and is available in the docket for this action.

K. Congressional Review Act

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 110

Environmental protection, Oil pollution, and Reporting and recordkeeping requirements.

40 CFR Part 300

Air pollution control, Area contingency planning, Bioremediation, Chemicals, Dispersants, Environmental protection, Hazardous materials, Hazardous substances, Intergovernmental relations, Natural resources, Oil spills, Oil spill mitigating devices, Regional response teams, Sorbents, and Surface washing agents.

Michael S. Regan,

Administrator.

For the reasons set out in the preamble, the Environmental Protection Agency amends 40 CFR parts 110 and 300 as follows:

PART 110—DISCHARGE OF OIL

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.,* 33 U.S.C. 1321(b)(3) and (b)(4) and 1361(a); E.O. 11735, 38 FR 21243, 3 CFR parts 1971–1975 Comp., p. 793.

■ 2. Revise § 110.4 to read as follows:

§ 110.4 Chemical or biological agents.

The addition of any chemical or biological agent, or any other substance, to oil to be discharged that would circumvent the provisions of this part is prohibited.

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 3. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.;* 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Subpart A—Introduction

■ 4. Amend § 300.5 by:
■ a. Adding in alphabetical order definitions of ''Bioaccumulation'', ''Bioconcentration'', ''Biodegradation'', ''Biological agents'', and ''Bioremediation'';
■ b. Revising the definitions of ''Bioremediation agents'', ''Burning agents'', ''Chemical agents'', ''Dispersants'';
■ c. Adding in alphabetical order the definition of ''Herding agents'';
■ d. Removing the definition of ''Miscellaneous Oil Spill Control Agents (MOSCA)'';
■ e. Adding in alphabetical order the definition of ''Products'';
■ f. Revising the definition of ''Sinking agents'';
■ g. Adding in alphabetical order the definition of ''Solidifiers'';
■ h. Revising the definition of ''Sorbents'';
■ i. Removing the definitions for ''Surface collecting agents'' and ''Surface washing agent''; and
■ j. Adding in alphabetical order the definition of ''Surface washing agents''.

§ 300.5 Definitions.

* * * * *

Bioaccumulation is the process of accumulation of chemicals in the tissue of organisms through any route, including respiration, ingestion, or direct contact with the ambient or contaminated medium.

Bioconcentration is the accumulation of chemicals in the tissues of organisms from water alone.

Biodegradation is a process by which microorganisms metabolically decompose contaminants into biomass and smaller molecular compounds such as carbon dioxide, water, and end products.

Biological agents are microorganisms (typically bacteria, fungi, or algae) or biological catalysts, such as enzymes, that can enhance the biodegradation of a contaminated environment.

Bioremediation is the process of enhancing the ability of microorganisms to convert contaminants into biomass and smaller molecular end products by the addition of materials into a contaminated environment to accelerate the natural biodegradation process.

Bioremediation agents are biological agents and/or nutrient additives deliberately introduced into a contaminated environment to increase the rate of biodegradation and mitigate any deleterious effects caused by the contaminant constituents. Bioremediation agents include microorganisms, enzymes, and nutrient additives such as fertilizers containing bioavailable forms of nitrogen, phosphorus, and potassium.

Burning agents are additives that, through physical or chemical means, improve the combustibility of the materials to which they are applied.

* * * * *

Chemical agents are elements, compounds, or mixtures designed to facilitate the removal of oil from a contaminated environment and to mitigate any deleterious effects. Chemical agent categories include burning agents, dispersants, herding agents, solidifiers, surface washing agents, and bioremediation agents that consist of nutrient additives.

* * * * *

Dispersants are substances that emulsify, disperse, or solubilize oil by promoting the formation of small droplets or particles of oil in the water column.

* * * * *

Herding agents are substances that form a film on the water surface to control the spreading of the oil to allow for oil removal.

* * * * *

Products are chemical or biological agents or other substances manufactured using a unique composition or formulation.

* * * * *

Sinking agents are substances introduced into an oil discharge for the purpose of submerging the oil to the bottom of a water body.

* * * * *

Solidifiers are substances that through a chemical reaction cause oil to become

a cohesive mass, preventing oil from dissolving or dispersing into the water column. Solidifiers are generally collected and recovered from the environment.

Sorbents are inert and insoluble substances that readily absorb and/or adsorb oil or hazardous substances, and that are not combined with or act as a chemical agent, biological agent, or sinking agent. Sorbents may be used in their natural bulk form or as manufactured products in particulate form, sheets, rolls, pillows, or booms. Sorbents are generally collected and recovered from the environment. Sorbents consist of:

(1) Natural organic substances (*e.g.,* feathers, cork, peat moss, and cellulose fibers such as bagasse, corncobs, and straw);

(2) Inorganic/mineral compounds (*e.g.,* volcanic ash, perlite, vermiculite, zeolite, clay); and

(3) Synthetic compounds (*e.g.,* polypropylene, polyethylene, polyurethane, polyester).

* * * * *

Surface washing agents are substances that separate oil from solid surfaces, such as beaches, rocks, metals, or concrete, through a detergency mechanism that lifts and floats oil. Product and oil are generally to be collected and recovered from the environment with minimal dissolution, dispersion, or transfer into the water column.

* * * * *

Subpart J—Use of Dispersants, and Other Chemical and Biological Agents

■ 5. Revise the heading of Subpart J as set out above.

■ 6. Amend § 300.900 by revising paragraphs (a) and (c), and by adding paragraph (d) to read as follows:

§ 300.900 General.

(a) Section 311(d)(2)(G) of the Clean Water Act (CWA) requires EPA to prepare a schedule identifying dispersants, other chemicals, other spill mitigating devices and substances, if any, that may be used in carrying out the NCP; and the waters and quantities in which they may be used safely. This subpart establishes a schedule that includes the NCP Product Schedule identifying chemical and biological agents, the Sorbents Product List, and the 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.

* * * * *

(c) This subpart applies to the use of chemical and biological agents as defined in Subpart A of this part, or other substances that may be used to remove, control, or otherwise mitigate oil discharges.

(d) [Reserved]

§ 300.905 [Removed]

■ 7. Remove § 300.905.

■ 8. Revise § 300.910 to read as follows:

§ 300.910 Authorization for agent use.

Use of chemical or biological agents in response to oil discharges must be authorized by the OSC in accordance with the provisions of this section.

(a) *Use of agents identified on the NCP Product Schedule or use of burning agents on oil discharges addressed by a preauthorization plan.* Area Committees and RRTs shall address, as part of their planning activities, whether preauthorization of the use of chemical and biological agents listed on the NCP Product Schedule or the use of burning agents on certain oil discharges is appropriate. Area Committees and RRTs shall, as appropriate, include applicable approved preauthorization plans in ACPs and RCPs. When a preauthorization plan is approved in advance for the use of certain agents under specified discharge situations, then the OSC may authorize the use of agents listed on the NCP Product Schedule, or the use of burning agents, for the purpose for which they were specifically listed without obtaining the incident-specific concurrences and without the natural resource trustees consultations described in paragraph (b) of this section.

(1) *Preauthorization plan development.* For discharge situations identified where such agents may be used, the preauthorization plan must, at a minimum, specify limits for the quantities and the duration of use, and use parameters for water depth, distance to shoreline, and proximity to populated areas. In meeting the provisions of this paragraph, preauthorization plans should document how regional factors are addressed including likely sources and types of oil that might be discharged, various potential discharge scenarios, the existence and location of environmentally sensitive resources or restricted areas that might be impacted by discharged oil, and logistical factors including inventory, storage locations and manufacturing capability of available agents, availability of equipment needed for agent use, availability of adequately trained operators, and means to monitor agent use in the environment. Preauthorization plans are to be developed by the Area Committees or the RRT in consultation with the Area Committee(s).

(2) *Preauthorization plan approval.* The EPA representative to the RRT, the Department of Commerce and the Department of the Interior natural resource trustees and, as appropriate the RRT representative from the state(s) with jurisdiction over waters and adjoining shorelines within the preauthorization plan area shall review and either approve, approve with modification, or disapprove the preauthorization plans. The Area Committees and RRTs shall address the withdrawal of approval from a preauthorization plan, and the RRT shall notify the NRT of the status of the preauthorization plan within 30 days from any such withdrawal.

(3) *Preauthorization plan reviews.* The RRT in consultation with the Area Committee(s) must review, and revise, as needed, approved preauthorization plans. These reviews must be conducted following a regular timeframe, established by the RRT and documented in the plan, to address changes that may impact the conditions under which the use of chemical and biological agents have been preauthorized. Reviews must also be conducted in any affected region, at a minimum, after a major discharge or after a Spill of National Significance (SONS) relevant to the preauthorization plan area; to address revisions of the NCP Product Schedule impacting chemical or biological agents that may be individually listed within a preauthorization plan; and to reflect new listings of threatened and/or endangered species applicable to the preauthorization plan area. The EPA RRT representative, the Department of Commerce and Department of the Interior natural resource trustees, and the RRT representative from the state(s) with jurisdiction over the waters of the area to which a preauthorization plan applies shall review and either approve, approve with modification, or disapprove any revisions to the preauthorization plans.

(b) *Use of agents identified on the NCP Product Schedule or use of burning agents on oil discharges not addressed by a preauthorization plan.* For discharge situations that are not addressed by a preauthorization plan developed pursuant to paragraph (a) of this section, the OSC may authorize the use of chemical or biological agents identified on the NCP Product Schedule on an oil discharge, or the use of burning agents, for the specific purpose for which they were listed with the concurrence of the EPA RRT representative and, as appropriate, the

concurrence of the RRT representatives from the state(s) with jurisdiction over the waters and adjoining shorelines threatened by the release or discharge, and in consultation with the Department of Commerce and Department of the Interior natural resource trustees. In meeting the provisions of this paragraph, the OSC must consider and document for their authorization request to the RRT, at a minimum, the parameters for the use of agents including the quantities requested to be authorized, the duration of use, the depth of water, the distance to shoreline and proximity to populated areas, and should consider and document factors such as environmentally sensitive resources or restricted areas that might be impacted, agent inventory and storage locations, agent manufacturing capability, availability of equipment needed for agent use, availability of adequately trained operators and appropriate means to monitor agent use in the environment.

(c) [Reserved]

(d) *Temporary exception.* In circumstances to prevent or substantially reduce an imminent threat to human life that cannot be immediately addressed by other procedures or provisions of the NCP, the OSC may authorize the provisional use of any chemical or biological agent, whether it is identified or not on the NCP Product Schedule, without obtaining the concurrence of the EPA RRT representative and, as appropriate, the RRT representatives from the state(s) with jurisdiction over the waters and adjoining shorelines threatened by the release or discharge, and without consultation with the Department of Commerce and the Department of the Interior natural resource trustees. This exception shall not be used as a substitute for compliance with § 300.150 of this part, including the use of personal protective equipment, or when there is sufficient time to seek authorization in accordance with paragraphs (a) or (b) of this section. If an agent is authorized for use pursuant to this paragraph, the OSC shall notify as soon as possible the EPA RRT representative and as appropriate, the RRT representatives from the affected state(s) and the Department of Commerce and Department of the Interior natural resource trustees. The OSC shall document the circumstances and the reasons for use of the agent authorized pursuant to this paragraph. Agent use for individual circumstances under this exception shall be in accordance with paragraphs (a) or (b) of this section no later than 24 hours after initial application.

(e) *Prohibited agents or substances.* The OSC may not authorize the use of the following:

(1) Sinking agents, or any other chemical agent, biological agent, or any substance that is used to directly sink the oil to the bottom of a water body.

(2) [Reserved]

(f) *Storage and use of agents listed on the NCP Product Schedule.* (1) The OSC may authorize for use only products listed on the NCP Product Schedule that are documented and certified by the responsible party or its representative to have been stored under the conditions provided by the submitter under § 300.915(a)(6), and whose date of use does not exceed the expiration date listed on the container's label unless otherwise specified for expired products as provided in § 300.910(f)(2), at the time of the incident.

(2) The OSC may authorize for use products listed on the NCP Product Schedule that exceed their expiration date after the responsible party or its representative documents and certifies that the expired product has been stored under the conditions provided by the submitter under § 300.915(a)(6) and still meets the applicable efficacy and toxicity listing provisions under § 300.915, based on testing of representative samples within the previous 12 months.

(g) *Supplemental testing, monitoring, and information.* The RRT may require, for both planning and response, including authorization of use, supplemental toxicity and efficacy testing, or submission of available data and information that addresses site, area, and ecosystem-specific concerns relative to the use of any chemical or biological agent. The product manufacturer or responsible party shall provide, upon request of the RRT or OSC, additional monitoring or testing data and information to inform chemical or biological agent use decisions specific to a response.

(h) *Recovery of chemical agents and other substances from the environment.* The responsible party shall ensure that removal actions adequately contain, collect, store, and dispose of chemical agents and other substances that are to be recovered from the environment, unless otherwise directed by the OSC. Chemical agents and other substances to be recovered include solidifiers, surface washing agents, and sorbents. The OSC should, at a minimum, consider factors such as the safety of response personnel and harm to the environment in making determinations pursuant to this paragraph.

(i) *Reporting of agent use.* (1) The authorizing OSC shall provide the RRT the following information on chemical and biological agents used in response to an oil discharge: product name, product category, quantity and concentrations used, duration of use, location(s) of use, any available data collected, and any available analyses of efficacy and environmental effects. This information must be provided within 30 days of completion of agent use. This information may be submitted in accordance with the OSC reporting provisions under § 300.165 of this part, as applicable, subject to the 30-day timing requirement.

(2) In support of sections 300.135(n) and 300.155(a) and (b) of this part, the authorizing OSC shall provide for notification to the public, updated during a response as appropriate, the following information on chemical and biological agents used in response to an oil discharge: product name, product category, quantity and concentrations used, duration of use, and location(s) of use.

■ 9. Revise § 300.915 to read as follows:

§ 300.915 Data and information requirements for listing on the NCP Product Schedule or Sorbent Product List.

If you are submitting an application for listing a product to the NCP Product Schedule or Sorbent Product List, you must provide EPA the information required under § 300.955. Technical product data submissions are not required for burning agents. Your submission for each product must contain:

(a) *General information for any product category.* (1) Your name, physical address, email, and telephone number;

(2) Your identity and documentation of that identity, as the manufacturer of the product, vendor, importer, distributor of the product, and/or a designated agent acting on behalf of the manufacturer.

(3) All name(s), brand(s), and/or trademark(s) under which the product is to be sold;

(4) Names, physical addresses, emails, and telephone numbers of the primary distributors, vendors, importers and/or designated agent acting on behalf of the manufacturer;

(5) The Safety Data Sheet (SDS) for the product;

(6) The maximum, minimum, and optimum temperature, humidity, and other relevant conditions for product storage and a brief description of the consequences to performance if the product is not stored within these limits;

(7) The anticipated shelf life of the product at the storage conditions noted in paragraph (a)(6) of this section and documentation for this determination;

(8) A sample product label for all name(s), brand(s), and/or trademark(s) under which the product is to be sold that includes manufacture and expiration dates, and conditions for storage. You may use an existing label provided it already contains the required dates and storage information;

(9) The chemical or biological agent category under which you want the product to be considered for listing on the NCP Product Schedule, including detailed information on the specific process(es) through which the product affects the oil, and the specific environment(s) on which it is intended to be used (*e.g.,* waters and/or adjoining shorelines). If your product meets the definition of more than one chemical or biological agent category, you must identify all applicable categories and provide the test data to meet the listing criteria appropriate to each;

(10) Recommended product use procedures, including product concentrations, use ratios, types of application equipment, conditions for use, any application restrictions; and, as applicable, procedures for product and oil containment, collection, recovery, and disposal. These procedures must address, as appropriate, variables such as weather, water salinity, water temperature, types and weathering states of oils or other pollutants. The procedures must include supporting documentation and current applicable standard methods used to determine them;

(11) Available information on environmental fate, including any known measured data, methodologies, and supporting documentation, on the persistence, bioconcentration factor, bioaccumulation factor, and biodegradability of the product and all of its components in the environment;

(12) The physical and chemical properties of the product, as appropriate, and a citation for the current applicable standard methods used to determine them, including:

(i) Physical state and appearance;

(ii) Vapor pressure;

(iii) Flash point;

(iv) Pour point;

(v) Viscosity;

(vi) Specific gravity;

(vii) Particle size for solid components; and

(viii) pH;

(13) The identity and concentration of all components in the product, including each specific component name; corresponding Chemical Abstract Service (CAS) Registry Number; the maximum, minimum, and average weight percent of each component in the product; and the intended function of each component (*e.g.,* solvent, surfactant);

(14) For products that also contain microorganisms, enzymes, and/or nutrients, provide the following along with a citation or a description of the methodology used to determine:

(i) The name of all microorganisms by current genus and species, including any reclassifications, and any physical, chemical, or biological manipulation of the genetic composition and the weight percent of each genus in the product;

(ii) The name of all enzymes and their International Union of Biochemistry (I.U.B.) number(s); Enzyme Classification (EC) code numbers; the source of each enzyme; units; and specific oil-degrading activity;

(iii) The name(s), maximum, minimum, and average weight percent of the nutrients contained in the product; and

(iv) Data, methodology, and supporting documentation, for the levels of bacterial, fungal, or viral pathogens or opportunistic pathogens including, but not limited to: enteric bacteria such as *Salmonella,* fecal coliforms, *Shigella,* coagulase positive *Staphylococci,* and beta hemolytic *Streptococci* and enterococci;

(15) Data, methodology, and supporting documentation for the levels of the following:

(i) Arsenic, cadmium, chromium, copper, lead, mercury, nickel, vanadium, zinc, and any other heavy metal reasonably expected to be in the product;

(ii) Cyanide;

(iii) Chlorinated hydrocarbons;

(iv) Pesticides;

(v) Polychlorinated Biphenyls (PCBs); and

(vi) Polycyclic aromatic hydrocarbons (PAHs).

(16) 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);

(17) Information about the accredited laboratory that conducted the required tests, including:

(i) Name of the laboratory, address, contact name, email, and phone number; and

(ii) The national and/or international accreditations held by the laboratory that are applicable to the test(s) performed;

(18) All test data and calculations, including:

(i) Raw data and replicates, including positive controls;

(ii) Notes and observations collected during tests;

(iii) Calculated mean values and standard deviations;

(iv) Reports, including a summary of stock solution preparation;

(v) Source and preparation of test organisms;

(vi) Test conditions; and

(vii) Chain of custody forms;

(19) An estimate of the annual product production volume, the average and maximum amount that could be produced per day, and the time frame needed to reach that maximum production rate in days;

(20) Recognition received from EPA's Design for the Environment (DfE) or Safer Choice programs, as applicable; and

(21) International product testing or use data or certifications, if available, informing the performance capabilities or environmental impacts of the product.

(b) *Dispersant testing and listing requirements*—(1) *Dispersant efficacy test and listing criteria.* Test the dispersant product for efficacy using the Baffled Flask Test (BFT) method in Appendix C to part 300. To be listed on the NCP Product Schedule, the dispersant must demonstrate for each temperature a Dispersant Effectiveness (DE) at the 95% lower confidence level (LCL_{95}) greater than or equal to:

(i) ≥70% for Strategic Petroleum Reserve Bryan Mound at 5 °C;

(ii) ≥75% for Strategic Petroleum Reserve Bryan Mound at 25 °C;

(2) *Dispersant toxicity tests and listing criteria.* Use the methods specified in Appendix C to part 300 to test the dispersant alone, and the dispersant mixed with Strategic Petroleum Reserve Bryan Mound for acute toxicity, using *Americamysis bahia* and *Menidia beryllina.* Use the methods specified in Appendix C to part 300 to test the dispersant alone for developmental toxicity using *Strongylocentrotus purpuratus* or *Arbacia punctulata* and for subchronic effects using *Americamysis bahia* and *Menidia beryllina.* To be listed on the NCP Product Schedule, the dispersant alone must demonstrate:

(i) A median lethal concentration (LC_{50}) at the lower 95% confidence interval greater than 10 ppm;

(ii) An inhibition concentration for 50% of the test species (IC_{50}) at the lower 95% confidence interval greater than 1 ppm; and

(iii) A subchronic No Observed Effect Concentration (NOEC) greater than 1 ppm.

(3) *Limitations.* A dispersant may only be listed on the NCP Product Schedule for use in saltwater environments for which it meets the efficacy and toxicity listing criteria.

(c) *Surface washing agent testing and listing requirements*—(1) *Surface washing agent efficacy test and listing criteria.* To be listed on the NCP Product Schedule, using an applicable standard methodology, the surface washing agent must meet an efficacy of greater than or equal to 30% in either freshwater or saltwater, or both, depending on the intended product use.

(2) *Surface washing agent toxicity test and listing criteria.* Using the toxicity test methodology in Appendix C to part 300, test the surface washing agent for acute toxicity against freshwater species *Ceriodaphnia dubia* and *Pimephales promelas,* or saltwater species *Americamysis bahia* and *Menidia beryllina,* or both, depending on the intended product use. To be listed on the NCP Product Schedule, the surface washing agent must demonstrate an LC_{50} at the lower 95% confidence interval greater than 10 ppm in either freshwater or saltwater for all tested species.

(3) *Limitations.* Surface washing agent listing would be for use only in freshwater and/or saltwater environments for which it was tested and for which it met the efficacy and toxicity listing criteria.

(d) *Bioremediation agent testing and listing requirements*—(1) *Bioremediation agent efficacy test and listing criteria.* To be listed on the NCP Product Schedule, a bioremediation agent must successfully degrade both alkanes and aromatics as determined by gas chromatography/mass spectrometry (GC/MS) in freshwater or saltwater, or both, depending on the intended product use, following the test method specified in Appendix C to part 300. The percentage reduction of total alkanes (aliphatic fraction) from the GC/MS analysis must be greater than or equal to 85% at day 28, based on the ninety-fifth (95th) percentile Upper Confidence Limit (UCL_{95}) for both freshwater and saltwater. The percentage reduction of total aromatics (aromatic fraction) must be greater than or equal to 35% at day 28 for both saltwater and freshwater based on the UCL95.

(2) *Bioremediation agent toxicity test and listing criteria.* The bioremediation agent must be tested for acute toxicity in freshwater or saltwater, or both, depending on the intended product use, following the method specified in Appendix C to part 300. To be listed on the NCP Product Schedule, the bioremediation agent must demonstrate an LC_{50} at the lower 95% confidence interval greater than 10 ppm in either freshwater or saltwater for all tested species.

(3) *Limitations.* Bioremediation agent listing would be for use only in the freshwater and/or saltwater environments for which it was tested and for which it met the efficacy and toxicity listing criteria.

(4) *Generic listing.* If the product consists solely of: ammonium nitrate, ammonium phosphate, ammonium sulfate, calcium ammonium nitrate, sodium nitrate, potassium nitrate, synthetically-derived urea, sodium triphosphate (or tripolyphosphate), sodium phosphate, potassium phosphate (mono- or dibasic), triple super phosphate, potassium sulphate, or any combination thereof, no technical product data are required. The product will be generically listed as non-proprietary nutrients on the NCP Product Schedule, and no further action is necessary.

(e) *Solidifier testing and listing requirements.* (1) Solidifiers must be tested for acute toxicity in freshwater or saltwater, or both, depending on the intended product use, following the method specified in Appendix C to part 300. To be listed on the NCP Product Schedule, the solidifier must demonstrate an LC_{50} at the lower 95% confidence interval greater than 10 ppm in either freshwater or saltwater for all tested species.

(2) *Limitations.* Solidifier listing would be for use only in the freshwater and/or saltwater environments for which it was tested and for which it met the toxicity listing criteria.

(f) *Herding agent testing and listing requirements.* (1) Herding agents must be tested for acute toxicity in freshwater or saltwater, or both, depending on the intended product use, following the method specified in Appendix C to part 300. To be listed on the NCP Product Schedule, the herding agent must demonstrate an LC_{50} at the lower 95% confidence interval greater than 10 ppm in either freshwater or saltwater for all tested species.

(2) *Limitations.* Herding agent listing would be for use only in freshwater and/or saltwater environments for which it was tested and for which it met the toxicity listing criteria.

(g) *Sorbent requirements.* Known sorbent materials and products will be identified on a publicly available Sorbent Product List for the use of such products when responding to an oil discharge as follows:

(1) For sorbent products that consist solely of the following materials, or any combination thereof, no technical data are required to be submitted for listing on the Sorbent Product List, and no further action is necessary for use as a sorbent:

(i) Feathers, cork, peat moss, and cellulose fibers such as bagasse, corncobs, and straw;

(ii) Volcanic ash, perlite, vermiculite, zeolite, and clay; and

(iii) Polypropylene, polyethylene, polyurethane, and polyester.

(2) 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) of this section but you believe the product meets the definition of a sorbent then, as applicable under § 300.955(a) and (b), you must submit the following information for consideration for listing it as a sorbent on the Sorbent Product List:

(i) The information required under paragraphs (a)(1) through (a)(8), and paragraph (a)(13) through (a)(15) of this section;

(ii) The certification required under paragraph (a)(16) of this section; and

(iii) Information, including data, to support the claim your product meets the sorbent definition under § 300.5.

§ 300.920 [Removed]

■ 10. Remove § 300.920.

■ 11. Add § 300.950 to read as follows:

§ 300.950 Submission of Proprietary Business Information (PBI).

(a) Except as provided in paragraph (b) of this section, all product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter.

(b) You may only claim as PBI the concentration; the maximum, minimum, and average weight percent; and the units of each component as identified in § 300.915(a)(13) and (14) and as applicable. EPA will handle such claims in accordance with 40 CFR part 2, subpart B Confidentiality of Business Information.

(1) You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule or Sorbent Product List.

(2) You must separate the PBI from all other submitted information. Include all PBI separately with your submission package, marking it as ''Proprietary Business Information'' and placing it in a separate inner envelope labeled with ''PROPRIETARY BUSINESS INFORMATION—TO BE OPENED BY

THE PRODUCT SCHEDULE MANAGER ONLY.''

■ 12. Add § 300.955 to read as follows:

§ 300.955 Addition of a product to the NCP Product Schedule or Sorbent ProductLlist.

(a) *Submission.* Submit your complete package to: U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Mail Code: 5104A, Room 1448, William J. Clinton North, Washington, DC 20460, Attention: Product Schedule Manager.

(b) *Package contents.* Your package shall include, as applicable, in this order:

(1) A cover letter on company letterhead signed and dated by you certifying that:

(i) All testing was conducted on representative product samples;

(ii) Testing was conducted at a nationally or internationally accredited laboratory in accordance with the methods specified in Appendix C to part 300, and other applicable methods as appropriate; and

(iii) All test results and product technical data and information are true and accurate.

(2) A page numbered Table of Contents showing the information and data submitted under § 300.915(a) through (g), as applicable;

(3) All required data and information arranged in the same order as specified in § 300.915(a) through (g); and

(4) A separate envelope containing and labeled Proprietary Business Information as specified in § 300.950(b), if applicable.

(c) *EPA Review.* EPA shall, within 90 days of receiving a submission package:

(1) Review the package for completeness and compliance with all data and information requirements in §§ 300.915, 300.950, and this section; verify information; and request clarification or additional information, including testing as necessary;

(2) Make a product listing determination based on a technical evaluation of all data and information submitted in accordance with the requirements for each product category, relevant information on impacts or potential impacts of the product or any of its components on human health or the environment, and the intended use of the product; and

(3) Notify you in writing of its decision to list the product on the NCP Product Schedule or the Sorbent Product List, or of its decision and supporting rationale to reject the submission. If your submission is rejected:

(i) You may revise and resubmit a complete package to address test results, data, or information deficiencies.

(ii) EPA's 90-day review will not start until a complete package is resubmitted.

(d) *Request for review of decision.* If your product is rejected for listing on the NCP Product Schedule or the Sorbent Product List, you may request that the EPA Administrator or designee review the determination. Your request must be in writing within 30 days of receipt of notification of EPA's decision not to list the product on the NCP Product Schedule or the Sorbent Product List. Your request must contain a clear and concise statement with supporting facts and technical analysis demonstrating why the product meets the listing requirements.

(1) The EPA Administrator or designee may request additional information from you and may offer an opportunity for you to meet with EPA.

(2) The EPA Administrator or designee will notify you in writing of the decision within 60 days of receipt of your request, or within 60 days of receipt of requested additional information.

(e) *Changes to a product listing*—(1) *Administrative change.* You must notify EPA in writing within 30 days of any changes to information submitted under § 300.915(a)(1) through (8) and § 300.915(a)(19) through (21) for a product on the NCP Product Schedule. In the notification, you must detail the specific changes, the reasons for such changes and supporting data and information. EPA may request additional information and clarification regarding these changes.

(2) *Reformulation.* If you change the components and/or concentrations, you must retest the reformulated product according to the requirements for the product category and submit a new complete package under a new, distinct name in accordance with § 300.955(b) for review and consideration for listing on the NCP Product Schedule or Sorbent Product List by EPA.

(f) *Transitioning Listed Products to the New NCP Product Schedule or Sorbent Product List.* All products on the current NCP Product Schedule as of December 11, 2023 will remain conditionally listed until December 12, 2025 at which time all products that have not been submitted and listed in the new NCP Product Schedule based on the amended test and listing criteria will be removed. Your product will be transitioned from the current NCP Product Schedule to the new NCP Product Schedule prior to December 12, 2025 after you submit a new complete package in accordance with § 300.955(b), and EPA makes a determination to list the product on the new NCP Product Schedule. All products previously identified as sorbents by EPA will remain available for use until December 12, 2025, at which time all sorbent products must have submitted information as applicable under § 300.955(a) and (b) and be listed in the new Sorbent Product List.

■ 13. Add § 300.965 to read as follows:

§ 300.965 Mandatory Product Disclaimer.

The listing of a product on the NCP Product Schedule does not constitute approval or recommendation of the product. To avoid possible misinterpretation or misrepresentation, any label, advertisement, or technical literature for products listed on the NCP Product Schedule must display in its entirety the disclaimer shown below. The disclaimer must be conspicuous and must be fully reproduced on all product literatures, labels, and electronic media including website pages.

Disclaimer

[PRODUCT NAME] is listed on the National Contingency Plan (NCP) Product Schedule. This listing does NOT mean that EPA approves, recommends, licenses, or certifies the use of [PRODUCT NAME] on an oil discharge. This listing means only that data have been submitted to EPA as required by Subpart J of the NCP. Only a Federal On-Scene Coordinator (OSC) may authorize use of this product in accordance with Subpart J of the NCP in response to an oil discharge.

■ 14. Add § 300.970 to read as follows:

§ 300.970 Removal of a product from the NCP Product Schedule or Sorbent Product List.

(a) The EPA Administrator or designee may remove your product from the NCP Product Schedule or the Sorbent Product List for reasons including, but not limited to:

(1) Statements or information that are misleading, inaccurate, outdated, or incorrect regarding the composition or use of the product to remove or control oil discharges made to any person, or private or public entity, including on labels, advertisements, technical literature, electronic media, or within the product submission to EPA; or

(2) Alterations to the components, concentrations, or use conditions of the product without proper notification to EPA as required by § 300.955(e); or

(3) Failure to print the disclaimer provided in § 300.965 on all labels, advertisements, technical literature, or electronic media for products listed on the NCP Product Schedule; or

(4) New or relevant information not previously considered concerning the impacts or potential impacts of the product to human health or the environment.

(b) EPA will notify you in writing, at your address of record, of its reasons for deciding to remove the product from the NCP Product Schedule. If EPA receives no appeal from you in 30 days, the product will be removed from the NCP Product Schedule without further notice to you.

(c) You may appeal the decision to remove your product from the NCP Product Schedule within 30 days of receipt of EPA's notification. Your appeal must contain a clear and concise statement with supporting facts and technical analysis demonstrating why the product should not be removed. The EPA Administrator or designee will notify you in writing of the decision within 60 days of your appeal, or within 60 days of receipt of any requested additional information.

■ 15. Revise Appendix C to Part 300 to read as follows:

Appendix C to Part 300—Requirements for Product Testing Protocols and Summary Test Data: Dispersant Baffled Flask Efficacy and Toxicity Tests; Standard Acute Toxicity Test for Bioremediation Agents, Surface Washing Agents, Herding Agents, and Solidifiers; and Bioremediation Agent Efficacy Test

Table of Contents

1.0 *Applicability and Scope.* This Appendix establishes laboratory protocols required under Subpart J (Use of Dispersants and Other Chemical and Biological Agents) of 40 CFR part 300 (National Oil and Hazardous Substances Pollution Contingency Plan) to make listing determinations for the Product Schedule. The protocols apply, based on product type, to dispersants, bioremediation agents, surface washing agents, herding agents, and solidifiers as defined in Subpart A (Introduction) of 40 CFR part 300.

2.0 *Baffled Flask Dispersant Efficacy Test (BFT)*

2.1 *Summary.* This laboratory protocol establishes procedures to evaluate the degree to which a product effectively disperses oil spilled on the surface of seawater, using a modified 150-mL screw-cap trypsinizing flask (an Erlenmeyer flask with baffles) with a glass and Teflon® stopcock near the bottom to allow removal of subsurface water samples without disturbing the surface oil layer. The efficacy of a dispersant is measured using one reference oil, Strategic Petroleum Oil Reserve Bryan Mound at two temperatures (5 °C and 25 °C). Six replicates and one method blank are required at each temperature. A layer of oil is placed on the surface of artificial seawater, and the dispersant is added to the slick at a dispersant:oil ratio (DOR) of 1:25 (4%) by volume. A standard orbital shaker table provides turbulent mixing at a speed of 250 revolutions per minute (rpm) for 10 minutes, immediately after which it is maintained stationary for 10 minutes to allow non-dispersed oil to rise to the water's surface. An undisturbed water sample is removed from the bottom of the flask through the stopcock, extracted with dichloromethane (DCM), and analyzed for oil content by UV-visible absorption spectrophotometry at wavelengths ranging between 340 and 400 nm.

2.2 *Apparatus.* All equipment must be maintained and calibrated per standard laboratory procedures.

2.2.1 *Modified Trypsinizing Flask.* A modified 150 mL glass screw-capped Erlenmeyer flasks with baffles (*e.g.,* Wheaton No. 355394 or equivalent) fitted with a 2 mm bore Teflon® stopcock and glass tubing, the center of which is no more than 1.3 cm from the bottom, as shown in Figure 1.

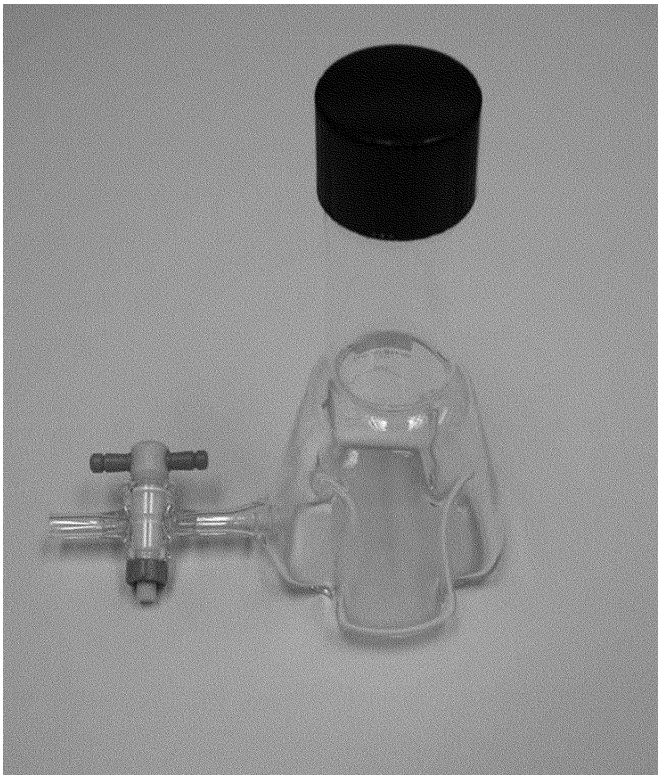

Figure 1. A Baffled Trypsinizing Flask

2.2.2 *Orbital Shaker Table.* An orbital shaker table with a variable speed control unit capable of maintaining 250 rpm. The orbital diameter must be approximately 1.0 inch (2.5 cm) +/−0.1 inch (0.25 cm).

2.2.3 *Spectrophotometer.* A UV-visible spectrophotometer capable of measuring absorbance between 340 and 400 nm (*e.g.,* Shimadzu UV–1800, Agilent 8453, or equivalent). Use standard transmission-matched quartz 10-mm path length rectangular cells with PTFE cover for absorbance measurements.

2.2.4 *Glassware.* Including: 25-ml graduated mixing cylinders (a graduated cylinder with a ground glass stopper); 50- and 100-ml graduated cylinders; 125-mL separatory funnels with Teflon stopcocks; 10-ml volumetric flasks; 30-ml crimp style glass serum bottles; 1-, 2-, 5-mL pipettes; other miscellaneous laboratory items.

2.2.5 *Micropipettor.* Use a micropipettor capable of dispensing 4 µL of dispersant and 100 µL of oil (*e.g.,* Brinkmann Eppendorf repeater pipettor with 100 µL and 5 mL syringe tip attachments or equivalent).

2.2.6 *Syringes.* 25-, 100-, 250-, 1,000-, 2,500-, 5,000-µl gas-tight syringes.

2.2.7 *Constant temperature rooms or incubators to hold the shaker at* 5 °C and 25 °C.

2.2.8 *Analytical Balance.*

2.2.9 *Chemical fume hood.*

2.3 *Reagents.*

2.3.1 *Artificial seawater.* Use the artificial seawater GP2 formulation shown in Table 1 of this Appendix.

2.3.2 *Test oil.* Use the EPA standard reference oil Strategic Petroleum Reserve Bryan Mound. To obtain this oil at no charge (except for a minimal shipping fee), see the instructions at *http://www.epa.gov/emergencies/content/ncp/index.htm.* Selected properties are summarized in Table 2 of this Appendix.

2.3.3 *Dichloromethane (DCM) (also known as methylene chloride), pesticide quality.*

2.4 *Container Handling and Storage.*

2.4.1 *Glassware.* If the glassware has been used with oil before, rinse with DCM to remove as much of the oil adhering to the sides of the flask as possible; waste DCM may be used. Soak in warm water with detergent and individually wash with bristled brushes. First rinse with tap water, then follow with two de-ionized water rinses. Dry either on a rack or in a 110 °C drying oven. After drying, rinse with fresh DCM (use sparingly).

2.4.2 *Serum bottles and other non-volumetric glassware.* Bake for at least 4 hours in a muffle furnace at 450 °C.

2.5 *Calibration Curve for the UV-visible spectrophotometer.*

2.5.1 *Stock Standard Solution Preparation.* Stock standard solution concentrations are based on the mass measurements after each addition and density determinations of the oil/dispersant/DCM solution using a density bottle or a 1-mL gas tight syringe. An example calculation is given in Table 3 of this Appendix according to the following equation:

$$\text{theoreticalconcentration},\frac{\text{mg}}{\text{mL}}=\frac{\text{massofoil,g*1000mg/g}}{\text{totalmass,g}/\rho_{\text{solution,g/mL}}}\ theoretical\ concentration,\frac{mg}{mL}=$$

$$\frac{mass\ of\ oil,\ \ g*1000\,mg/g}{total\ mass,\ \ g/\rho_{solution,\,g/mL}} \qquad \text{(Equation 1)}$$

Use the reference oil and the specific dispersant being tested for a particular set of experimental test runs. Prepare the stock standard solution of dispersant-oil mixture in DCM, starting with 2 ml of the oil, then adding 80 µl of the dispersant followed by 18 ml of DCM.

2.5.2 Six-*point Calibration Curve.* For the reference oil, add specific volumes of its stock standard solution (given in Table 4 of this Appendix) to 30 ml of artificial seawater in a 125 ml separatory funnel. Extract the oil/dispersant water mixture with triplicate 5 ml volumes of DCM. Follow each DCM addition by 15 seconds of vigorous shaking, carefully releasing the initial pressure inside the separatory funnel by partially removing the

glass stopper inside a fume hood after the first few shakes. Then, allow a 2-minute stationary period for phase separation for each extraction. Drain the extracts into a 25-mL graduated mixing cylinder. Release any entrained bubbles of DCM from the water layer by sideways shaking of the funnel. Use precaution not to drain water into the DCM extract as it can affect the absorbance readings. Adjust the final volume of the collected extracts to 25 mL in the mixing cylinder using DCM. Determine specific masses for oil concentrations in the standards as volumes of oil/dispersant solution multiplied by the concentration of the stock solution. An example calculation is given in Table 4 of this Appendix. One calibration curve is needed for the reference oil and dispersant combination.

2.6 *Sample Preparation and Testing.* See section 2.7 of this Appendix for a detailed description of the spectrophotometer's linear calibration procedure.

2.6.1 Six replicates of the oil and test dispersant are required at each temperature plus two additional tests of method blanks (artificial seawater without oil and dispersant), one at each temperature. A completed test consists of 14 baffled flask tests (a total of six replicates for the reference oil/test dispersant combination at two temperatures (5 °C and 25 °C), plus two method blanks).

2.6.2 Attach a 3-inch length of Teflon tubing to the stopcock of each of the 150-mL baffled flasks. Add 120 mL of artificial seawater to each flask. Put screw cap on flasks and place them at the appropriate temperature (either 5 °C or 25 °C) for equilibration.

2.6.3 Calibrate and adjust the shaker table to 250 ± 10 rpm.

2.6.4 Prepare and time separately each baffled flask. Sequentially add 100 µL of oil and 4 µL of dispersant to the flask layering them onto the center of the seawater to give a dispersant-to-oil ratio (DOR) of 1:25. Avoid any oil or dispersant splashing on the flask walls, as it may reduce efficacy or cause errors in the calculated results. Discard the sample and repeat the setup if: (1) any oil or dispersant splashing occurs during the additions, or (2) the dispersant contacts the water first rather than the oil. This is especially important for 5 °C work because of increased oil viscosity.

2.6.5 For the oil, fill the tip of the pipettor, using a wipe to remove any oil from the sides of the tip. Holding the pipettor vertically, dispense several times back into the reservoir to ensure that the oil flows smoothly. Insert the syringe tip vertically into the baffled flask and let the bottom of the pipettor rest on the neck of the flask. Slowly and carefully dispense the oil one time onto the center of the water's surface. The remainder of the oil can either be returned to the oil bottle or set aside for use in the next test flask.

Note to 2.6.5: If a Brinkmann Eppendorf repeater pipettor is used for dispensing the oil, attach a 5-mL syringe tip, and set the dial to 1.

2.6.6 For the dispersant, use the same procedure as for the oil to dispense onto the center of the oil slick surface. As the dispersant first contacts the oil, it will usually push the oil to the sides of the flask. Replace the screw cap onto the flask.

Note to 2.6.6: If a Brinkmann Eppendorf repeater pipettor is used for dispensing the dispersant, attach a 100-µL syringe tip, and set the dial to 2.

2.6.7 Carefully place flask securely onto the shaker and agitate for 10 ± 0.25 minutes at 250 ± 10 rpm.

2.6.8 Remove the flask from the shaker table and allow a stationary, quiescent period of 10 ± 0.25 minutes to allow undispersed and/or recoalesced oil droplets to refloat to the surface.

2.6.9 Carefully open the screw cap, then the stopcock at the bottom, and discard the first several mL of seawater into a waste beaker to remove non-mixed water-oil initially trapped in the stopcock tubing. Collect a volume slightly greater than 30-mL into a 50-mL graduated cylinder. Adjust the collected volume to the 30-mL mark by removing excess with a disposable glass Pasteur pipette. A web-like emulsion may form at the solvent/water interface during the water sample extraction. Avoid pulling any emulsion phase into the DCM extract as it may cloud the DCM-extract, leading to error.

2.6.10 Transfer the water-oil sample from the graduated cylinder into a 125-mL glass separatory funnel fitted with a Teflon stopcock.

2.6.11 Add 5 mL DCM to the separatory funnel. Start shaking, releasing pressure into the fume hood by loosening the glass stopper. Shake vigorously at least 20 times for 15 seconds.

2.6.12 Allow the funnel to remain in a stationary position for 2 minutes to allow phase separation of the water and DCM.

2.6.13 Drain the DCM layer from the separatory funnel into a 25 mL mixing cylinder. Avoid pulling any emulsion phase into the DCM extract as it may cloud the DCM extract.

2.6.14 Repeat the DCM-extraction process two or three additional times until the DCM is clear. Collect each extract in the graduated cylinder. After the final extraction, lightly shake the separatory funnel sideways once or twice to dislodge entrained bubbles of DCM and drain.

2.6.15 Adjust the final volume to a known quantity, 25 mL, in the mixing cylinder. Using a syringe, dispense 2.5 mL or 5.0 mL of a reference oil sample into a 10-mL volumetric flask, and fill with DCM to make either a 1:4 or 1:2 dilution, respectively.

2.6.16 If analysis cannot be conducted immediately, store the extracted DCM samples at 4 ± 2 °C until time of analysis. Glass-stoppered mixing cylinders may be used for short-term storage or prior to bringing the extracts up to volume. After bringing to volume, transfer the DCM extracts to 25–30 ml crimp-style serum vials with aluminum/Teflon seals.

2.6.17 Complete all analysis within 10 consecutive days from when the sample was collected.

2.7 *UV-Visible Spectrophotometer Linear Stability Calibration*

2.7.1 A six-point calibration of the UV-visible spectrophotometer is required at least once per day for each oil. The stability calibration criterion is determined with the six oil standards identified in Table 4 of this Appendix.

2.7.2 Turn on spectrophotometer and allow it to warm up for at least 30 minutes before beginning analysis. Blank the instrument for the wavelengths between 340 and 400 nm with DCM.

2.7.3 If refrigerated, allow all extracts, standards, and samples to warm to room temperature.

2.7.4 Determine the absorbance of the six standards between the wavelengths of 340 and 400 nm. This can be done by either one of the following methods:

2.7.4.1 *Trapezoidal Rule.* Program the spectrophotometer to take readings every 5λ or 10λ and calculate the area under the curve using the Trapezoidal rule:

$$\acute{R}\int_{340\lambda}^{400\lambda} f(x)dx \approx \frac{H}{2}\sum_{k=1}^{N}\left(f(x_{k+1})+f(x_k)\right) \qquad \text{(Equation 2)}$$

where N + 1 = number of absorbance measurements to delineate N equally spaced sections of the curve, and H = the distance (λ) between each reading. For H = 5, N + 1 = 13 measurements, for H = 10, N + 1 = 7.

The following formula illustrates readings taken every 10λ.

$$\text{Area} = \frac{(\text{Abs}_{340}+\text{Abs}_{350})*10}{2} + \frac{(\text{Abs}_{350}+\text{Abs}_{360})*10}{2} + \cdots \frac{(\text{Abs}_{390}+\text{Abs}_{400})*10}{2} Area =$$

$$\frac{(Abs_{340}+Abs_{350})*10}{2} + \frac{(Abs_{350}+Abs_{360})*10}{2} + \cdots \frac{(Abs_{390}+Abs_{400})*10}{2} \qquad \text{(Equation 3)}$$

When using readings taken every 5λ, each absorbance sum is multiplied by 5.

2.7.4.2 Automatic *Integration*. Program the spectrophotometer to automatically integrate the area under the curve between 340 nm and 400 nm.

2.7.4.3 If the wavelengths must be manually set on the spectrophotometer, the older method of only measuring at 340λ, 370λ, and 400λ may be used. Then calculate using the trapezoidal rule for N + 1 = 3, H = 30. While the resulting area count with the older method is less accurate, the final results are similar since the inaccuracy is systematic.

2.7.5 After determining the area count for each standard, determine the response factor (RF) for the oil at each concentration using the following equation:

$$\mathrm{RF} = \frac{\mathrm{TheoreticalConcentration}, \frac{\mathrm{g}}{\mathrm{mL}}(\mathrm{Eq.1})}{\mathrm{area(Eq.3)}} \quad RF = \frac{Theoretical\ Concentration, \frac{g}{mL}(Eq.1)}{area\ (Eq.3)}$$

(Equation 4)

2.7.6 Spectrophotometer stability for the initial calibration is acceptable when the RFs of the six standard extracts are less than 10% different from the overall mean value for the six standards, as calculated in Equation 5 of this Appendix and depicted in the example in Table 4 of this Appendix.

$$\%\mathrm{difference} = \frac{|\mathrm{RF}\text{-}\overline{\mathrm{RF}}|}{\overline{\mathrm{RF}}} * 100\% \quad difference = \frac{|RF - \overline{RF}|}{\overline{RF}} * 100$$

(Equation 5)

2.7.7 If this criterion is satisfied, begin analysis of sample extracts. Absorbances greater than or equal to 3.5 are not included because absorbance saturation occurs at and above this value. If any of the standard oil extracts fails to satisfy the initial-stability criterion, the source of the problem (*e.g.,* preparation protocol for the oil standards, spectrophotometer stability, etc.) must be corrected before analysis of the sample extracts begins.

2.7.8 Determine the slope of the calibration points by using linear regression forced zero intercept:

$$\mathrm{Y(areaunderabsorbancecurve)} = \mathrm{m(slope)}*\mathrm{x(concentrationofoil)} \quad Y(area\ under\ absorbance\ curve) = m(slope) * x(concentration\ of\ oil)$$

(Equation 6)

2.8 Spectrophotometric *Analysis and Calculations*

2.8.1 Once a successful calibration curve for the reference oil has been created and verified, measure experimental replicates for the reference oil at each temperature followed by a standard check sample.

2.8.2 Determine the area for the absorbance values obtained for the experimental samples by using Equation 2 of this Appendix and illustrated by Equation 3 of this Appendix.

2.8.3 Calculate the Total Oil dispersed and the percentage of oil dispersed (%OD) based on the ratio of oil dispersed in the test system to the total oil added to the system, as follows:

$$\mathrm{TotalOilDispersed, mg} = \frac{\mathrm{Area(Eq.2)}}{\mathrm{CalibrationCurveSlope}} * \mathrm{V_{DCM}} * \frac{\mathrm{V_{tw}}}{\mathrm{V_{ew}}} \quad Total\ Oil\ Dispersed, mg = \frac{Area\ (Eq.2)}{Calibration\ Curve\ Slope} * V_{DCM} * \frac{V_{tw}}{V_{ew}}$$

(Equation 7)

where:

V_{DCM} = final volume of the DCM extract (mL)

V_{tw} = total seawater in Baffled Flask (120 mL)

V_{ew} = volume seawater extracted (30 mL)

$$\%\mathrm{OD} = \frac{\mathrm{TotalOilDispersed}}{\rho_{\mathrm{Oil}} * \mathrm{V_{Oil}}} * 100\% \quad OD = \frac{Total\ Oil\ Dispersed}{\rho_{Oil} * V_{Oil}} * 100$$

(Equation 8)

where:

r_{Oil} = density of the specific test oil, mg/mL and

V_{Oil} = Volume (mL of oil added to test flask (100 µL = 0.1 mL))

2.8.4 The %ODs for the six replicates within a particular treatment are then subjected to an outlier test, the Grubb's Test

or Maximum Normal Residual test (6). A convenient internet-based calculator of a Grubbs outlier may be found at: *http://www.graphpad.com/quickcalcs/Grubbs1.cfm.* If an outlier is detected ($p < 0.05$), analyze an additional replicate to obtain the required six replicates.

2.8.5 Report the Dispersion Efficacy value for each oil and each temperature, which is the lower 95% confidence level of the 6 independent replicates (DE_{LCL95}) for each oil/temperature combination. Error bars are not needed as reporting the lower confidence level computationally takes the variability of the replicates into account as shown in Equation 9 of this Appendix.

$$DE_{LCL95} = \overline{\%OD} - \left(\frac{t_{(n-1,1-\alpha)} * s}{\sqrt{n}}\right) DE_{LCL95} = \overline{\%OD} - \left(\frac{t_{(n-1,1-\alpha)} * s}{\sqrt{n}}\right)$$

(Equation 9)

where $\overline{\%OD}\overline{\%OD}$ = mean percentage oil dispersed for the n = 6 replicates, S = standard deviation, and $t_{(n-1,1-\alpha)}$ = 100 * (1-α)th percentile from the t-distribution with n-1 degrees of freedom. For 6 replicates, $t_{n-1,1-\alpha}$ = 2.015, where α = 0.05. An example of the calculations is given in Table 5 of this Appendix.

2.9 *Performance Criterion*

The dispersant product tested will remain in consideration for listing on the NCP Product Schedule if the dispersant efficacy (DE_{LCL95}), as calculated in section 2.8.6 of this Appendix, is:

Oil	Temp (°C)	DE_{LCL95} (%)
Bryan Mound	5	≥70
Bryan Mound	25	≥75

2.10 *Quality Control (QC) Procedures for Oil Concentration Measurements*

2.10.1 *Absorbance readings.* Perform at least 5% of all UV-visible spectrophotometric measurements in duplicate as a QC check on the analytical measurement method. The absorbance values for the duplicates must agree within ±5% of their mean value.

2.10.2 *Method blanks.* Analytical method blanks involve an analysis of artificial seawater blanks (artificial seawater without oil or dispersant in a baffled flask) through testing and analytical procedures. Analyze method blanks with a frequency of at least two per completed test. Oil concentrations in method blanks must be less than detectable limits.

2.10.3 *Accuracy.* Determine accuracy by using a mid-point standard calibration check after each set of replicate samples analyzed. The acceptance criterion is based on a percent recovery of 90–110% using the following equation:

$$\%recovery = 100 * \frac{measuredconcentrationofcheckstandard}{theoreticalconcentrationofcheckstandard} \%recovery = 100 *$$

$$\frac{measured\ concentration\ of\ check\ standard}{theoretical\ concentration\ of\ check\ standard}$$

(Equation 10)

2.10.4 Calibration *QC checks.* Before analyzing samples, the spectrophotometer must meet an instrument stability calibration criterion using the oil standards. The instrument stability for initial calibration is acceptable when the RFs (Equation 5 of this Appendix) for each of the six standard concentration levels are less than 10% different from the overall mean value.

TABLE 1—CONSTITUENT CONCENTRATIONS FOR GP2 ARTIFICIAL SEAWATER

[Based on Spotte et al., 1984]

Constituent	Concentration (g/L)
NaCl	21.03
Na_2SO_4	3.52
KCl	0.61
KBr*	0.088
$Na_2B_4O_7 \times 10H_2O$*	0.034
$MgCl_2 \times 6H_2O$	9.50
$CaCl_2 \times 2H_2O$	1.32
$SrCl_2 \times 6H_2O$*	0.02
$NaHCO_2$*	0.17

* Use Stock Solution, 1 mL/L GP2 for 100X stock solution for Bromide, Borate, and Strontium. 10 mL/L GP2 for bicarbonate—10X stock solution as it is not soluble in a 100X solution. Adjust to pH 8.0 prior to autoclaving.

TABLE 2—TEST OIL CHARACTERISTICS

[April 2023 oil assay]

Oil	Density, mg/mL @15 °C	API gravity @15 °C	Viscosity @25 °C, (cSt)	Category by API gravity
SPR Bryan Mound	0.8320	38.6	4.721	Light Oil.

TABLE 3—SAMPLE CALCULATION FOR PREPARATION OF OIL + DISPERSANT STOCK STANDARD SOLUTION

Item	Identifier	Amount
Mass of Bottle, g	A	29.498
Mass of Bottle + oil, g	B	31.225
Mass of bottle + disp + oil + DCM, g	C	54.380
Mass of oil, g (*derived*)	F = B − A	1.727
Mass of disp + oil + DCM, g (*derived*)	G = C − A	24.882
Mass of 1 mL syringe, g	D	14.556
Mass of 1 mL syringe + solution, g	E	15.820
Density of solution, g/mL (*derived*)	H = E − D	1.264
Volume of solution, mL (*derived*)	I = G/H	19.687
Conc. of stock solution, mg/mL (*derived*)	J = F*1000/I	87.704

TABLE 4—SAMPLE CALCULATIONS FOR OIL + DISPERSANT SIX POINT CALIBRATION

Oil + Dispersant Stock Standard Solution Concentration = 87.7 mg/mL (*Table 3*)

Standard—stock vol. (uL)	Theoretical conc., mg/mL	Area *(340–400 nm)*	RF	Avg. RF	Dev. from avg. RF	Slope
25	0.088	4.126	0.021	0.021	2.931	48.759
50	0.175	8.757	0.020	.....	3.017	.....
100	0.351	16.559	0.021	.....	2.577	.....
150	0.526	25.666	0.021	.....	0.731	.....
200	0.702	34.142	0.021	.....	0.500	.....
250	0.877	43.006	0.020	.....	1.260	.....

TABLE 5—LCL95 SAMPLE CALCULATION WITH TEST OIL AND EXAMPLE DISPERSANT 'A'

Rep	Area (340–400 nm)	Dilution factor	Extract volume (ml) *	Conc, mg/mL.	Mass in 30 mL, mg	Total oil dispersed, mg	Efficiency, %	Average	Std. dev.	Variance	Coef. of variation	LCL95
1	32.197	1	25	0.66	16.51	66.03	79.76	81.30	4.46	19.85	5.48	81.30
2	35.470	1	25	0.73	18.19	72.75	87.87	.....	.....	.....	.....	.....
3	30.260	1	25	0.62	15.52	62.06	74.96	.....	.....	.....	.....	.....
4	31.831	1	25	0.65	16.32	65.28	78.85	.....	.....	.....	.....	.....
5	33.355	1	25	0.68	17.10	68.41	82.63	.....	.....	.....	.....	.....
6	33.791	1	25	0.69	17.33	69.30	83.71	.....	.....	.....	.....	.....

*= 25 ml of DCM extract captured oil from 30 ml of aqueous DE test.

2.11 References for Section 2.0

(1) U.S. Environmental Protection Agency (1994), ''Swirling Flask Dispersant Effectiveness Test,'' *Title 40 Code of Federal Regulations,* Pt. 300, Appendix C, pp 47458–47461.

(2) Sorial, G.A., A.D. Venosa, K.M, Koran, E. Holder, and D.W. King. 2004. ''Oil spill dispersant effectiveness protocol: I. Impact of operational variables.'' ASCE J. Env. Eng. 130(10):1073–1084.

(3) Sorial, G.A., A.D. Venosa, K.M, Koran, E. Holder, and D.W. King. 2004. ''Oil spill dispersant effectiveness protocol: II. Performance of revised protocol.'' ASCE J. Env. Eng. 130(10):1085–1093.

(4) Venosa, A.D., D.W. King, and G.A. Sorial. 2002. ''The baffled flask test for dispersant effectiveness: a round robin evaluation of reproducibility and repeatability.'' Spill Sci. & Technol. Bulletin 7(5–6):299–308.

(5) Spotte, S., G. Adams, and P.M. Bubucis. 1984. ''GP2 medium is an synthetic seawater for culture or maintenance of marine organisms,'' Zoo Biol, 3:229–240.

(6) Grubbs, F. 1969. ''Sample Criteria for Testing Outlying Observations,'' Annals of Mathematical Statistics, pp. 27–58.

3.0 Dispersant Toxicity Testing

3.1 *Summary.* This laboratory protocol includes testing for: (1) dispersant standard static acute toxicity tests for the mysid shrimp, *Americamysis bahia* (48-hr duration) and the inland silverside, *Menidia beryllina* (96-hr duration); (2) dispersant-oil mixture static acute toxicity tests for *Americamysis bahia* and *Menidia beryllina* (48-hr and 96-hr duration, respectively); (3) dispersant developmental assay for *Strongylocentrotus purpuratus* or *Arbacia punctulata,* (72-hr duration); and (4) dispersant 7-day static subchronic tests with *Americamysis bahia* and *Menidia beryllina* (Table 6 of this Appendix).

TABLE 6—TOXICITY TESTING REQUIREMENTS FOR DISPERSANTS

Test substance	Test procedure			
	96-Hr static acute: *Menidia beryllina*	48-Hr static acute: *Americamysis Bahia*	72-Hr sea urchin *developmental assay*	7-Day subchronic: *M. beryllina & A. bahia*
Dispersant only	*yes*	*yes*	*yes*	*yes.*
Dispersant—Reference Oil Mixture	*yes*	*yes*	*no*	*no.*

3.2 *Preparation of Stock Solutions*

3.2.1 *Dispersant.* Prepare a 1000 µL/L primary stock solution prior to test initiation by adding 1.1 mL of dispersant to 1100 mL of dilution water consisting of salinity

adjusted uncontaminated natural or artificial seawater, in a glass vessel. Using a laboratory top stirrer equipped with a stainless-steel blade, center the stirrer blade in the mixing vessel one inch off the bottom. Initially mix the resulting stock solution for approximately five seconds at speeds of <10,000 rpm to avoid foaming. Thereafter, set the speed to provide a 70% vortex. Using a glass pipette, remove appropriate aliquots of stock solution from between the mixing vessel wall and edge of the vortex and place directly into the dilution water within an exposure vessel. Suspend mixing of the stock solution after the removal of each aliquot. Base the preparation of exposure solutions on the nominal concentration of the stock solution and follow procedures outlined in sections 3.5 and 3.6 of this Appendix.

3.2.2 *Dispersant-Reference Oil(s) Mixtures.* Use Strategic Petroleum Reserve Bryan Mound reference oil. To obtain this oil at no charge (except for a minimal shipping fee) see *https://www.epa.gov/emergency-response/national-contingency-plan-subpart-j#howto.* Assessment of dispersant-reference oil mixture (DOM) toxicity is determined for each reference oil using the aqueous phase of a chemically enhanced-water accommodated fraction (CE–WAF). Fit a glass aspirator bottle (approximately 23 L) equipped with a hose bib at the base with a length of silicon tubing containing a hose clamp. Fill the bottle with 19L of seawater leaving a 20% headspace above the liquid, place on a magnetic stir plate then add and center a stir bar. Add the reference oil at 25 g/L using a silicon tube attached to a glass funnel that reaches just below the water surface. Using this method reduces the production of air bubbles on the oil surface slick. Adjust the stir plate to obtain an oil vortex of 25% of the total volume of the seawater, then add the dispersant to be tested at a ratio of 1:10 dispersant:oil (2.5 g/L). Securely seal the bottle to reduce the loss of volatiles using a silicon stopper and wraps of Parafilm and stir for 18 hours, then allow the solution to settle for 6 hours. Maintain the temperature at 25 °C during stirring and settling. Purge the hose at the base of the bottle of any material followed by removal of the CE–WAF (aqueous phase) into a clean glass container without disturbing the surface oil slick. The CE–WAF should be remixed and 1 to 2 L removed for chemical analysis of total petroleum hydrocarbons (TPH) following the procedures outlined in section 3.4 of this Appendix. The remaining volume will be used for the preparation of exposure solutions following procedures outlined in section 3.3 of this Appendix. To reduce time and cost, mix sufficient amounts of dispersant product-reference oil mixture CE–WAF to allow preparation of exposure solutions for conducting simultaneous acute tests with both *Americamysis bahia* and *Menidia beryllina.*

3.3 *Preparation of Exposure Concentrations.*

3.3.1 *Concentration Selection.* Preliminary rangefinder tests may be necessary using a series of logarithmic concentrations (*e.g.* 0.1, 1, 10, 100 µl dispersant product/L or mg TPH/L) to determine the appropriate exposure concentration range necessary to determine LC_{50} values and 95% confidence intervals. For definitive tests, conduct a minimum of five test concentrations using a geometric ratio between 1.5 and 2.0 (*e.g.* 2, 4, 8, 16, and 32). Note that when testing only the dispersant product, the highest test concentration must not exceed the dispersant's self-dispersibility limit.

3.3.2 *Exposure Concentrations.* Exposure solutions are prepared by adding the appropriate amount of stock solution directly to dilution water in each test chamber. Mix each exposure solution using five rotations in one direction followed by five rotations in the opposite direction using a solid glass stir rod.

3.3.3 *Reference Toxicants.* Separate toxicity tests must be performed with a reference toxicant for each species tested. Conduct additional reference toxicity tests any time a change in the population or source of a test species occurs. Use sodium dodecyl sulfate (SDS), also known as dodecyl sodium sulfate (DSS), and sodium lauryl sulfate (SLS) as the reference toxicant for exposures conducted with *Menidia beryllina* and *Americamysis bahia.* Use copper chloride as the reference toxicant for exposures conducted with the sea urchin developmental test. Use reagent grade quality SDS and copper chloride for tests. Information on procedures for conducting reference toxicant tests with these species can be found in the specific EPA methods documents cited in sections 3.5.1, 3.6.1, and 3.7.1 of this Appendix.

3.4 *Chemical Analysis of Stock Solutions.* Add the 1 L sample of CE–WAF (Section 3.2.2 of this Appendix) solutions directly to amber glass bottles with Teflon®-lined cap. Collect a replicate sample in the event of accidental loss or if reanalysis of the stock solution becomes necessary. Adjust sample to a pH=2 using 50% hydrochloric acid, immediately refrigerate and analyze within 48 hours of collection. Analyze samples for C9–C32 TPH by gas chromatography-flame ionization detection (GC–FID) following EPA SW–846, Method 8015B–DRO (4). Report TPH concentration of stock solutions as milligrams TPH/L and use in the calculation of exposure concentrations for all toxicity tests conducted with CE–WAF.

3.5 *Static Acute Tests with M. beryllina and A. bahia*

3.5.1 *General.* Use EPA's *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms* (EPA–821–R–02–012) (1) for testing each species separately with dispersant product or a mixture of dispersant product and reference oil (DOM).

3.5.2 *Test Solutions.* Modify procedures in EPA–821–R–02–012 specifically dealing with the handling and toxicity testing of effluents or receiving water samples as follows: Prepare stock solutions following section 3.2 of this Appendix and exposure concentrations following section 3.3 of this Appendix.

3.5.3 *Number of Treatments, Replicates and Organisms.* Conduct a minimum of three replicates of at least five exposure treatments plus a minimum of three replicate dilution water controls. Expose ten organisms per replicate treatment.

3.5.4 *Exposure Period.* Test duration is 48-hr for *Americamysis bahia* and 96-hr for *Menidia beryllina.* Mortality must be recorded at each 24-hour period of each test.

3.5.5 *Test Acceptability.* For each test performed, survival of control animals must be >90% and test results must allow determination of statistically valid LC_{50} and 95% confidence interval values except in cases where the LC_{50} is >1000 µl/L or is determined to be greater than the limits of water solubility of dispersibility.

3.5.6 *Static Acute Test Summary.* A summary of required test conditions is provided in Table 7 of this Appendix.

3.6 *Sea Urchin Developmental Test with Dispersant Product*

3.6.1 *General.* Use Section 15, ''Purple Urchin, *Strongylocentrotus purpuratus* and Sand Dollar, *Dendraster excentricus* Larval Development Test Method'' of EPA's *Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to West Coast Marine and Estuarine Organisms* (EPA/600/R–95–136) (2). Alternatively, the development of the urchin *Arbacia punctulata* may be tested (see Table 7).

3.6.2 *Test Organism.* Tests of dispersant products are to follow methods for the purple urchin only. Tests with the sand dollar are not required.

3.6.3 *Test Solutions.* Modify procedures in EPA/600/R–95–136, Section 15 specifically dealing with the handling and toxicity testing of effluents or receiving water samples as follows: Prepare stock solutions following section 3.2.1 of this Appendix and exposure concentrations following section 3.3 of this Appendix.

3.6.4 *Number of Treatments and Replicates.* Conduct a minimum of four replicates of five exposure treatments plus a minimum of four replicate dilution water controls.

3.6.5 *Exposure Duration and Test Endpoint.* Examine the effects of the dispersant product on normal development of sea urchin embryos over a period of 72 hours. An IC_{50} (the exposure concentration at which normal development is inhibited in 50% of the embryos) with 95% confidence intervals are to be determined in place of an $IC_{25.}$ The concentration of dispersant causing inhibition of development in 50% of exposed embryos (IC_{50}) with the lower and upper 95% confidence intervals (LCI_{95} and $ULCI_{95}$) must be calculated at the end of the exposure period. Mortality determinations are not required.

3.6.6 *Test Acceptability.* Requirements of the assay are: (i) ≥80% normal larval development in the control treatment, (ii) the minimum significant difference (MSD) that can be statically detected relative to the control is ≤25%, iii) test results which support the determination of a statistically valid IC_{50} and 95% confidence interval unless the LC_{50} is >1000 µl/L or is greater than the limits of water solubility of dispersibility.

3.6.7 *Urchin Developmental Test Summary.* A summary of required test conditions is provided in Table 7 of this Appendix.

3.7 *Seven-day Subchronic Tests with M. beryllina and A. bahia*

3.7.1 *General.* Use Section 13, Method 1006.0, ''Inland Silverside (*Menidia beryllina*) Larval Survival and Growth Method,'' and Section 14, Method 1007.0, ''Mysid (*Mysidopsis* [renamed *Americamysis*] *bahia*) Survival, Growth, and Fecundity Method'' of EPA's *Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms* (EPA–821–R–02–014) (3) for testing of dispersant product.

3.7.2 *Test Solutions.* Modify procedures in EPA–821–R–02–014, sections 13 and 14 specifically dealing with the handling and toxicity testing of effluents or receiving water samples as follows: Prepare stock solutions following section 3.2.1 of this Appendix and exposure concentrations following section 3.3 of this Appendix. Exposure solutions should be renewed every 24 hours for the duration of the test.

3.7.3 *Number of Treatments, Replicates and Organisms.* (i) *Menidia beryllina:* Conduct a minimum of four replicates of at least five exposure treatments plus a minimum of four replicate dilution water controls. Expose ten *M. beryllina* per replicate treatment. (ii) *Americamysis bahia:* Conduct a minimum of eight replicates of at least five exposure treatments plus a minimum of eight replicate dilution water controls. Expose five *A. bahia* per replicate treatment.

3.7.4 *Exposure Duration and Test Endpoint.* The test duration is seven days for both species. Test endpoints for *Menidia beryllina* are survival and growth (dry weight) and for *Americamysis bahia* is survival, growth (dry weight) and fecundity. Calculate an LC_{50} and 95% confidence interval for survival and IC_{25} and IC_{50} with 95% confidence intervals for growth (and fecundity for *A. bahia* only). Report the lowest observed effect concentration (LOEC) and no observed effect concentration (NOEC) for each endpoint.

3.7.5 *Test Acceptability.* Requirements of the assay are: (i) ≥80% survival in the control treatment for each species, (ii) dry weights must meet the specific requirements as stipulated in Method 1006.0 for *Menidia beryllina* and Method 1007.0 for *Americamysis bahia.*

3.7.6 *Subchronic Test Summary.* A summary of required test conditions for each species is provided in Table 7 of this Appendix.

3.8 *Laboratory Report.* The laboratory must include, for each toxicity test report, all applicable information, data and analyses as follows:

3.8.1 *Test Objective:* protocol title and source, endpoint(s);

3.8.2 *Product Information:* product name, manufacturer contact information, lot number, production date, date received/chain of custody;

3.8.3 *Contract Facility:* contact information;

3.8.4 *Dilution Water:* source, pretreatment, physical and chemical characteristics (pH, salinity);

3.8.5 *Test Conditions:* date and time of test (start and end), test chambers type and volume, volume of solution per chamber, number of organisms per chamber, number of replicate chambers per treatment, feeding frequency, amount and type of food, test concentrations, test temperature (mean and range), test salinity (mean and range);

3.8.6 *Test Organisms:* common and scientific name, source contact information, age and date purchased, acclimation conditions (*e.g.,* temperature, salinity, both mean and range), age at test start;

3.8.7 *Reference toxicant:* date received, lot number, date of most recent test, results and current Cumulative Sum Chart, dilution water used, physical and chemical methods used;

3.8.8 *Quality Assurance:* verification of laboratory accreditation, including subcontractor facilities;

3.8.9 *Test Results:* raw data in tabular and graphical form, daily records of affected organisms in each concentration replicate and controls, table of required endpoints (*i.e.,* LC_{50} with 95% confidence interval (CI), IC_{25} and IC_{50} with 95% CI, LOEC and NOEC), statistical methods used to calculate endpoints, summary tables of test conditions and QA data;

3.8.10 *Analytical Results:* method summary including Limit of Detection (LOD)/Limit of Quantitation (LOQ), deviations and reasons if any, sample summary, results including chromatograms and data qualifiers, QA summary including calibration curves, method blank and surrogate recovery, analytical results summary; and

3.8.11 *Conclusions:* Relationship between test endpoints and threshold limit.

TABLE 7—SUMMARY OF TEST CONDITIONS—DISPERSANT TOXICITY

	Acute *M. beryllina*	Acute *A. bahia*	Subchronic *M. beryllina*	Subchronic *A. bahia*	Development *S. purpuratus/A. punctulata*
Test type	Static non-renewal.	Static non-renewal.	Static renewal (daily)	Static renewal (daily)	Static non-renewal.
Test duration	96 hours	48 hours	7 days	7 days	72 ± 2 hours.
Salinity	20 ± 2‰	20 ± 2‰	20 ± 2‰	20 ± 2‰	34 ± 2‰.
Temperature	25 ± 1 °C. Test temperatures must not deviate (maximum minus minimum temperature) by for than 3 °C during the test.				15 ± 1 °C.
Light quality	Ambient laboratory illumination.				
Light intensity	10–20 µE/m²/s.				
Photoperiod	16 h light, 8 h darkness, with phase in/out period recommended.				
Test chamber size [1]	250 mL	250 mL	600 mL–1 L	400 mL	30 mL.
Test solution volume [1]	200 mL	200 mL	500–750 mL	150 mL	10 mL.
Age of test organism [2]	9–14 days	1–5 days	7–11 days	7 days	1 hr old fertilized eggs.
No. organisms per test chamber	10	10	10	5	25 embryos per mL.
No. of replicate chambers per concentration	3	3	4	8	4.
Feeding regime	Refer to specific feeding procedures provided in each test method.				None.
Aeration	None, unless DO falls below 4.0 mg/L, then aerate all chambers. Rate: <100 bubbles/minute.				
Test concentrations	5 exposure concentrations and a control (minimum required).				
Test acceptability (required)	≥90% survival in controls.	≥90% survival in controls.	For controls: ≥80% survival; average dry weight ≥0.5mg where test starts with 7 day old larvae, or ≥0.43 mg for larvae preserved for ≤7days.	For controls: ≥80% survival; average dry weight ≥0.20 mg.	≥80% normal shell development in controls.

[1] Recommended minimum value.
[2] Less than or equal to 24-hr range in age.

3.9 *References for Section 3.0*

(1) U.S. EPA. 2002. *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms.* Fifth Edition. U.S.

Environmental Protection Agency, Washington, DC (EPA–821–R–02–012).
(2) U.S. EPA. 1995. *Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to West Coast Marine and Estuarine Organisms.* First Edition. U.S. Environmental Protection Agency, Washington, DC (EPA/600/R–95–136)
(3) U.S. EPA. 2002. *Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms.* Third Edition. U.S. Environmental Protection Agency, Washington, DC (EPA–821–R–02–014).
(4) U.S. EPA. 2008. *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods* U.S. Environmental Protection Agency, Washington, DC (SW–846) *http://www.epa.gov/osw/hazard/testmethods/sw846/online/index.htm.*

4.0 *Standard Acute Toxicity Testing of Surface Washing Agents, Bioremediation Agents, Herding Agents, and Solidifiers.*

4.1 *Summary.* This laboratory protocol includes testing for: (1) saltwater standard static acute toxicity tests for test products with the mysid shrimp, *Americamysis bahia* (48-hr duration) and the inland silverside, *Menidia beryllina* (96-hr duration); and (2) freshwater standard static acute toxicity tests for test products with the daphnid, *Ceriodaphnia dubia* (48-hr duration) and the fathead minnow, *Pimephales promelas* (96-hr duration) (see Table 8 of this Appendix).

TABLE 8—TOXICITY TESTING REQUIREMENTS FOR SURFACE WASHING AGENTS, HERDING AGENTS, BIOREMEDIATION AGENTS AND SOLIDIFIERS

Application environment	Test procedure			
	96-hr Static acute: *Menidia beryllina*	48-hr Static acute: *Americamysis bahia*	96-hr Static acute: *Pimephales promelas*	48-hr Static acute: *Ceriodaphnia dubia*
Saltwater only	yes	yes	no	no.
Freshwater only	no	no	yes	yes.
Freshwater and saltwater use.	yes	yes	yes	yes.

4.2 *Dilution Water.* Use Section 7 of EPA's *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms* (EPA–821–R–02–012) [1] for preparation of the appropriate dilution water for each species tested. Use of clean natural or synthetic seawater for tests conducted with saltwater species is acceptable.

4.3 *Preparation of Stock Solutions.*

4.3.1 Liquid *Surface Washing Agents and/or Herding Agents.* Prepare a 1000 µL/L stock solution prior to test initiation by adding 1.1 mL of test product to 1100 mL of dilution water in a glass vessel. Place on a magnetic stir plate then add and center a stir bar and adjust the stir plate to obtain a vortex of 25% of the total volume of the liquid. Mix the resulting stock solution for approximately five minutes at room temperature. Using a glass pipette, remove appropriate aliquots of stock solution from between the mixing vessel wall and edge of the vortex and place directly into the dilution water within an exposure vessel. Base the preparation of exposure solutions on the nominal concentration of the stock solution and follow procedures outlined in sections 4.6 and/or 4.7 of this Appendix, as appropriate.

4.3.2 *Bioremediation Agents.* For products consisting of two or more liquid and/or solid components, prepare the product following the manufacturers recommended procedure and ensure the test product mixture is completely blended. Prepare a 1000 µL/L stock solution prior to test initiation by adding 1.1 mL of the test product mixture to 1100 mL of dilution water in a glass vessel. Place on a magnetic stir plate then add and center a stir bar and adjust the stir plate to obtain a vortex of 25% of the total volume of the liquid. Mix the resulting stock solution for approximately five minutes at room temperature. Using a glass pipette, remove appropriate aliquots of stock solution from between the mixing vessel wall and edge of the vortex and place directly into the dilution water within an exposure vessel. Base the preparation of exposure solutions on the nominal concentration of the stock solution and follow procedures outlined in sections 4.5 and/or 4.6 of this Appendix, as appropriate.

4.3.3 *Solid Phase Products.* Assessment of the toxicity of solidifiers and other solid phase products are determined using the aqueous phase of water-accommodated fractions (WAFs) of the test product. Fit a glass aspirator bottle (approximately 23L) equipped with a hose bib at the base with a length of silicon tubing containing a hose clamp. Fill the bottle with 19L of dilution water leaving a 20% headspace above the liquid, place on a magnetic stir plate then add and center a stir bar. Add the test product at 25 g/L and securely seal the bottle using a silicon stopper and wraps of parafilm. Adjust the stir plate to obtain a vortex of 25% of the total fluid volume, stir for 18 hours then settle for 6 hours. Maintain the temperature at 25 °C during stirring and settling. Purge the hose at the base of the bottle of any material followed by removal of the WAF (aqueous phase) into a clean glass container without disturbing the product on the surface. The WAF should be remixed and used for the preparation of exposure solutions following procedures outlined in section 4.4 of this Appendix.

4.4 *Preparation of Exposure Concentrations.*

4.4.1 *Concentration Selection.* Preliminary rangefinder tests may be necessary using a series of logarithmic concentrations (*e.g.* 0.1, 1, 10, 100 µl test product/L) to determine the appropriate exposure concentration range necessary to determine LC_{50} values and 95% confidence intervals. For definitive tests, conduct a minimum of five test concentrations using a geometric ratio between 1.5 and 2.0 (*e.g.* 2, 4, 8, 16, and 32). Note that when testing the product, the highest test concentration should not exceed the test product's self-dispersibility limit.

4.4.2 *Exposure Concentrations.* Exposure solutions are prepared by adding the appropriate amount of stock solution directly to dilution water in each test chamber. Mix each exposure solution using five rotations in one direction followed by five rotations in the opposite direction using a solid glass stir rod.

4.4.3 *Reference Toxicants.* Separate toxicity tests must be performed with a reference toxicant for each species tested. Conduct additional reference toxicity tests any time a change in the culture population or source of a test species occurs. Use reagent grade quality sodium dodecyl sulfate (SDS), also known as dodecyl sodium sulfate (DSS), and sodium lauryl sulfate (SLS) as the reference toxicant. Information on procedures for conducting reference toxicant tests with these species can be found in section 4 of EPA's *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms* (EPA–821–R–02–012) (3).

4.5 *Saltwater Static Acute Tests with Menidia beryllina and Americamysis bahia*

4.5.1 *General.* Use EPA's *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms* (EPA–821–R–02–012) (1) for testing each species separately with the test product.

4.5.2 *Test Solutions.* Modify procedures in EPA–821–R–02–012 specifically dealing with the handling and toxicity testing of effluents or receiving water samples as follows: Prepare stock solutions following the appropriate sections (4.3.1, 4.3.2, or 4.3.3) of this Appendix and exposure concentrations following section 4.4 of this Appendix.

4.5.3 *Number of Treatments, Replicates and Organisms.* Conduct a minimum of three replicates of at least five exposure treatments plus a minimum of three replicate dilution water controls. Expose ten organisms per replicate treatment.

4.5.4 *Exposure Period.* Test duration is 48-hr for *A. bahia* and 96-hr for *M. beryllina.*

Mortality must be recorded at each 24 hour period of each test.

4.5.5 *Test Acceptability.* For each test performed, survival of control animals must be >90% and test results must allow determination of statistically valid LC_{50} and 95% confidence interval values except in cases where the LC_{50} is >1000 µl/L or is determined to be greater than the limits of water solubility or dispersibility.

4.5.6 *Static Acute Test Summary.* A summary of required test conditions is provided in Table 9 of this Appendix.

4.6 *Freshwater Static Acute Tests with Pimephales promelas and Ceriodaphnia dubia*

4.6.1 *General.* Use EPA's *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms* (EPA–821–R–02–012) (1) for testing each species separately with the test product.

4.6.2 *Test Solutions.* Modify procedures in EPA–821–R–02–012 specifically dealing with the handling and toxicity testing of effluents or receiving water samples as follows: Prepare stock solutions following the appropriate sections (4.3.1, 4.3.2, or 4.3.3) of this Appendix and exposure concentrations following section 4.4 of this Appendix.

4.6.3 *Number of Treatments, Replicates and Organisms. P. promelas:* Conduct a minimum of three replicates of at least five exposure treatments plus a minimum of three replicate dilution water controls. Expose ten organisms per replicate treatment. *C. dubia:* Conduct a minimum of four replicates of at least five exposure treatments plus a minimum of four replicate dilution water controls. Expose five organisms per replicate treatment.

4.6.4 *Exposure Period.* Test duration is 48-hr for *C. dubia* and 96-hr for *P. promelas.* Mortality must be recorded at each 24 hour period of each test.

4.6.5 *Test Acceptability.* For each test performed, survival of control animals must be >90% and test results must allow determination of statistically valid LC_{50} and 95% confidence interval values except in cases where the LC_{50} is >1000 µl/L or is determined to be greater than the limits of water solubility of dispersibility.

4.6.6 *Static Acute Test Summary.* A summary of required test conditions is provided in Table 9 of this Appendix.

4.7 *Laboratory Report.* The laboratory must include, for each toxicity test report, all applicable information, data and analyses as follows:

4.7.1 *Test Objective:* protocol title and source, endpoint(s);

4.7.2 *Product Information:* product name, manufacturer contact information, lot number, production date, date received/ chain of custody;

4.7.3 *Contract Facility:* contact information;

4.7.4 *Dilution Water:* source, pretreatment, physical and chemical characteristics (pH, salinity);

4.7.5 *Test Conditions:* date and time of test (start and end), test chambers type and volume, volume of solution per chamber, number of organisms per chamber, number of replicate chambers per treatment, feeding frequency, amount and type of food, test concentrations, test temperature (mean and range), test salinity (mean and range);

4.7.6 *Test Organisms:* common and scientific name, source contact information, age and date purchased, acclimation conditions (*e.g.,* temperature, salinity, both mean and range), age at test start;

4.7.7 *Reference toxicant:* date received, lot number, date of most recent test, results and current Cumulative Sum Chart, dilution water used, physical and chemical methods used;

4.7.8 *Quality Assurance:* verification of laboratory accreditation, including subcontractor facilities;

4.7.9 *Test Results:* raw data in tabular and graphical form, daily records of affected organisms in each concentration replicate and controls, table of required endpoints (*i.e.,* LC_{50}, 95% CI, inhibited concentration for 50% of the species (IC_{50}), lower observed effect concentration (LOEC) and no observed effect concentration (NOEC)), statistical methods used to calculate endpoints, summary tables of test conditions and QA data; and

4.7.10 *Conclusions:* Relationship between test endpoints and threshold limit.

TABLE 9—SUMMARY OF TEST CONDITIONS—SURFACE WASHING AGENTS, HERDING AGENTS, BIOREMEDIATION AGENTS AND SOLIDIFIERS TOXICITY

	Saltwater acute *M. beryllina*	Saltwater acute *A. bahia*	Freshwater acute *P. promelas*	Freshwater acute *C. dubia*
Test type	Static non-renewal	Static non-renewal	Static non-renewal	Static non-renewal.
Test duration	96 hours	48 hours	96 hours	48 hours.
Salinity	20 ± 2‰	20 ± 2‰	NA	NA.
Temperature	25 ± 1 °C. Test temperatures must not deviate (maximum minus minimum temperature) by more than 3 °C during the test.			
Light quality	Ambient laboratory illumination.			
Light intensity	10–20 µE/m²/s.			
Photoperiod	16 h light, 8 h darkness, with phase in/out period recommended.			
Test chamber size [1]	250 mL	250 mL	250 mL	30 mL.
Test solution volume [1]	200 mL	200 mL	200 mL	15 mL.
Age of test organism [2]	9–14 days	1–5 days	1–14 days	<24 hours.
No. organisms per test chamber.	10	10	10	5.
No. of replicate chambers per concentration (minimum).	3	3	3	4.
Feeding regime	Refer to specific feeding procedures provided in each test method.			
Aeration	None, unless DO falls below 4.0 mg/L, then aerate all chambers. Rate: <100 bubbles/minute.			
Test concentrations	5 exposure concentrations and a control (minimum required).			
Test acceptability (required).	≥90% survival in controls.			

[1] Recommended minimum value.
[2] Less than or equal to 24-hr range in age.

4.8 *References for Section 4*

(1) U.S. EPA. 2002. *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms.* Fifth Edition. U.S. Environmental Protection Agency, Washington, DC (EPA–821–R–02–012).

5.0 *Bioremediation Agent Efficacy Test Protocol*

5.1 *Summary.* This protocol quantifies changes in weathered Alaska North Slope (ANS) crude oil composition of alkanes and

aromatics resulting from the use of a bioremediation agent in either artificial seawater or freshwater. The manufacturer may test either one or both freshwater or saltwater, depending on the product's intended use. Biodegradation of the alkanes and aromatics is monitored for 28 days at 20–23 °C. Product flasks at Day 28 are compared to Day 0 flasks to determine reductions in alkanes and aromatics. A positive control of a known oil-degrading bacterial consortium supplied by EPA is tested. A negative, sterile control is also set up containing exposure water, weathered crude oil, product, and a sterilant, sodium azide. The purpose of the negative, killed control is to make sure the disappearance of the oil constituents at day 28 is due to biodegradation and not some physical loss such as volatilization. The day 28 GC/MS results from the killed control must not be less than 90% of the day 0 results. The sample preparation procedure extracts the oil phase into the solvent dichloromethane (DCM) (also known as methylene chloride) with a subsequent solvent exchange into hexane. The hexane extracts are analyzed by a high-resolution gas chromatograph/mass spectrometer (GC/MS) operated in the selected ion monitoring mode (SIM) at a scan rate of >5 scans per second.

Note to 5.1: Alaska North Slope (ANS) crude oil is artificially weathered by distillation at 521 °F (272 °C) to remove the low molecular weight hydrocarbons to approximate natural weathering processes that occur after a spill.

5.2 *Apparatus.* All equipment must be maintained and calibrated per standard laboratory procedures.

5.2.1 Assorted flasks and other glassware;

5.2.2 Graduated cylinders (100 mL);

5.2.3 Deionized water;

5.2.4 250 mL borosilicate glass Erlenmeyer flasks;

5.2.5 250 mL separatory funnels with stopcocks

5.2.6 Pasteur pipettes;

5.2.7 Multichannel pipettor (5–50 mL and 50–200 mL);

5.2.8 Autoclave; environmental room or incubator;

5.2.9 Balance accurate to 0.1 mg;

5.2.10 Orbital shaker table with clamps sized to hold flasks securely;

5.2.11 GC/MS instrument equipped with a DB–5 capillary column (30 m, 0.25 mm ID, and 0.25 mm film thickness) or equivalent, and a split/splitless injection port operating in the splitless mode, such as an Agilent 6890 GC/5973 MS (or equivalent) equipped with an auto-sampler for testing multiple samples; and

5.2.12 Fixed Rotor Centrifuge.

5.3 *Reagents and consortium medium.*

5.3.1 *Stock Seawater Preparation.* Prepare the artificial seawater GP2 (modified from Spotte *et al.,* 1984) following the procedures in section 2.3 of this Appendix, to obtain the final concentration of the salts listed in Table 1 of this Appendix, except for the sodium bicarbonate ($NaHCO_3$) which is prepared separately. Autoclave the artificial seawater. Filter sterilize the concentrated solution of sodium bicarbonate through a 0.45 µm membrane filter and add to the autoclaved and cooled artificial seawater GP2 to obtain the final concentration listed in Table 1 of this Appendix.

5.3.2 *Seawater for the positive control flasks.* Prepare sodium triphosphate (a.k.a., sodium tripolyphosphate) ($Na_5P_3O_{10}$), potassium nitrate (KNO_3), and ferric chloride hexahydrate ($FeCl_3 \cdot 6H_2O$) as a concentrated solution. Filter sterilize through a 0.45 µm membrane filter and add to autoclaved artificial seawater to obtain the final nutrient concentrations listed in Table 10 of this Appendix. Calibrate the pH meter at room temperature (approximately 20–23 °C) using commercial buffers of pH 4.0, 7.0, and 10.0, as appropriate, prior to use. Adjust the pH of the artificial seawater with concentrated hydrochloric acid (HCl) or 10 normality sodium hydroxide (10 N NaOH), as appropriate.

TABLE 10—ARTIFICIAL SEAWATER NUTRIENT CONCENTRATIONS

Constituent	Final concentration, g/L
* $FeCl_3 \cdot 6H_2O$	0.050
KNO_3	2.890
* $Na_5P_3O_{10}$	0.297

* Added aseptically after the GP2 has been autoclaved to limit phosphorus and iron precipitation.

5.3.3 Seawater for bioremediation agents that do not include nutrients. If a bioremediation agent contains living microorganisms but not nutrients (or limiting concentrations of nutrients), then nutrients may be added by the manufacturer. However, the total concentration of the nutrients added to the bioremediation agent must not exceed the final concentrations listed in Table 11 of this Appendix.

TABLE 11—ARTIFICIAL SEAWATER NUTRIENT CONCENTRATIONS FOR BIOREMEDIATION AGENTS HAVING NO NUTRIENTS INCLUDED

Constituent	Final concentration, g/L
as Iron (Fe)	0.010
as Nitrogen (N)	0.400
as Phosphorus (P)	0.075

If nutrients are supplied by the product manufacturer, the specific composition and concentration used in the efficacy testing must be submitted.

5.3.4 *Freshwater Preparation.* The artificial freshwater, which is a modification of Bushnell-Haas medium (Haines *et al.,* 2005), is prepared following the concentrations listed in Table 12 of this Appendix and then autoclaved. The pH is adjusted to 7.4 before autoclaving. Constituents removed from the original formulation are KNO_3, K_2HPO4 and KH_2PO_4.

TABLE 12—CONSTITUENT CONCENTRATIONS FOR ARTIFICIAL FRESHWATER

[Bushnell-Haas]

Constituent	Final concentration (mg/L)
$MgSO_4 \cdot 7H_2O$	200
$CaCl_2 \cdot 2H_2O$	20
$FeCl_3 \cdot 6H_2O$	50
$MnSO_4 \times H_2O$	0.0302
H_3BO_3	0.0572
$ZnSO_4 \times 7H_2O$	0.0428
$(NH_4)_6Mo_7O_2$	0.0347

5.3.5 *Freshwater for the positive control.* To prepare the freshwater for the positive controls, prepare the nutrients potassium phosphate monobasic (KH2PO4), potassium phosphate dibasic (K2HPO4) and potassium nitrate (KNO3) as a concentrated solution. Filter sterilize and add to autoclaved artificial freshwater to obtain the final concentrations given in Table 13 of this Appendix. Calibrate the pH meter at room temperature (approximately 20–23 °C) using commercial buffers of pH 4.0, 7.0, and 10.0, as appropriate, prior to use. Adjust the pH of the artificial freshwater to 7.4 with 1 N HCl or 1 N NaOH, as appropriate.

TABLE 13—FRESHWATER NUTRIENT CONCENTRATIONS

Constituent	Final concentration (g/L) [1]
KNO_3	2.89
KH_2PO_4	1.00
K_2HPO_4	1.00

[1] Adjust pH to 7.4 prior to autoclaving.

5.3.6 *Freshwater for bioremediation agents that contain living microorganisms but not nutrients or limiting concentrations of nutrients.* If a bioremediation agent does not include nutrients, then nutrients may be added. However, the total concentration of the nutrients added to the bioremediation agent must not exceed the final concentrations provided in Table 14 of this Appendix.

TABLE 14—ARTIFICIAL FRESHWATER NUTRIENT CONCENTRATIONS FOR BIOREMEDIATION AGENTS HAVING NO NUTRIENTS INCLUDED

Constituent	Final concentration, g/L [1]
as Iron (Fe)	not added since iron is already in the freshwater solution.
as Nitrogen (N)	0.400.
as Phosphorus (P).	0.400.

[1] Adjust to pH 7.4 prior to autoclaving.

If nutrients are supplied by the product vendor, the specific composition and concentration used in the efficacy testing must be submitted.

5.3.7 *Oil Preparation.* The test oil, weathered ANS521 crude oil, can be obtained from EPA at no charge (except for a minimal shipping fee). See *https://www.epa.gov/emergency-response/national-contingency-plan-subpart-j#howto* for more information.

5.3.8 *Sodium azide sterilant.* Prepare a stock solution of NaN_3 for addition to the negative killed control. The final concentration in the killed controls will be 0.5 g/L.

5.4 *Experimental Setup and Procedure*

5.4.1 Autoclave clean borosilicate glass Erlenmeyer flasks (250 mL) for 20 minutes at 121 °C at 15 psig.

5.4.2 Label flasks with the appropriate code (negative control, positive control, or product; day to be sampled (0 or 28); letter indicating replicate number) to reflect the following treatment design in Table 15 of this Appendix:

TABLE 15—BIOREMEDIATION EFFICACY TEST—SUMMARY OF EXPERIMENTAL SETUP

Treatment	Number of replicates at sampling times		Analysis
	Day 0	Day 28	
Negative (killed) Control (oil + exposure water + product + EPA consortium + NaN_3 sterilant)	0	3	GC/MS
*Positive control (oil + exposure water + nutrients + EPA consortium)	6	6	GC/MS
Test Type 1: Product containing living microorganisms (oil + exposure water + living product + supplemented nutrients (if necessary))	6	6	GC/MS
Test Type 2: Product containing proprietary nutrients but no live microorganisms (oil + exposure water + product + EPA consortium)	6	6	GC/MS
Test Type 3: Product (such as an enzyme) containing no live microorganisms and no nutrients (oil + exposure water + product)	6	6	GC/MS

*The laboratory must report positive control test results conducted within the year of any test results for bioremediation products, for one or both types of water as applicable.

5.4.3 Aseptically dispense 100 mL of pre-sterilized artificial exposure water (seawater or freshwater) into each sterile flask. For the positive control flasks, use exposure water containing nutrients.

5.4.4 Tare the labeled flasks containing exposure water and other additions, as necessary, on the balance with a minimum accuracy of 0.01 g. Add drop-wise 0.50 g oil (this results in a final oil concentration of 5 g/L) using a sterile Pasteur pipette to the center of the flask taking care to avoid splashing the oil onto the sides of the flasks. Record the precise weight. ANS521 may be previously warmed in a hot water bath at 60 °C for 40–60 minutes to facilitate its flow. Take precautions when handling and charging the flasks to minimize the likelihood of contamination by exogenous microbes, including using a new sterile pipette for each series of flasks.

5.4.5 Preparation of the EPA consortium for both the positive control flasks and the flasks containing non-living bio-stimulation products. Use the supplied vials containing approximately 5 mL of the known EPA consortium frozen in glycerol. Thaw the supplied vials at room temperature (*do not allow cultures preserved in glycerol to sit at room temperature past thawing*), transfer the contents of the thawed vials to a single sterile centrifuge tube, rinse tubes with two volumes each of sterile exposure water, centrifuge at between 6,000- and 7,000-times gravity (6,000–7,000 × *g*) for 15 minutes using a fixed rotor to fully pellet the cells. Carefully resuspend the cell pellet in sterile exposure water using the appropriate volume to achieve the desired seeding density, which will be provided by EPA upon shipment of the consortium.

5.4.6 Positive control flasks contain exposure water, oil, nutrients, and the EPA consortium.

5.4.7 Negative killed control flasks for all products shall contain exposure water, oil, product, the EPA consortium for products not containing a living culture, and the sodium azide sterilant at a final concentration of 0.5 g/L. Add the sodium azide sterilant prior to adding any product or EPA consortium. For the negative killed control flasks and product flasks, prepare and add the product to the flasks in a concentration specified by the manufacturer or vendor.

5.4.8 For non-living products that contain nutrient only, use the EPA consortium as the inoculum.

5.4.9 For other non-living products (*e.g.,* enzymes), do not add nutrients or the EPA consortium as the inoculum as they are not needed.

5.4.10 For products containing living microorganisms, prepare 6 flasks the same way as in Steps a–d, but without the EPA consortium. A product that contains its own nutrients must not be amended with nutrients, unless the product contains insufficient nutrients. Since this is a closed flask test, nutrients could be limiting if they are at the same concentration as used in the field. This could cause the product to fail the test. Thus, the manufacturer has the option to supplement its product with a higher concentration of nutrients than that contained in the product. Any nutrient supplements to a product must be reported and must not exceed the concentration limits in Table 10 (for seawater) and 13 (for freshwater) of this Appendix, as applicable.

5.4.11 Cap all flasks either with sterile cotton stoppers or loosely applied aluminum foil to allow gas exchange with the atmosphere. Set aside the T = 0 flasks for immediate extraction and analysis. Place the rest of the flasks onto the orbital shaker table. Do not tip the flasks excessively to avoid stranding oil above the mixing area of the flask. Set the orbital shaker to 200 rpm and shake the flasks for 28 days at 20–23 °C in the dark.

5.4.12 Submit all information on added microorganisms and nutrients for testing in the data report.

5.5 *Sampling and Chemical Analysis.*

5.5.1 *Summary.* At each sampling event (Days 0 and 28), product and control flasks are sacrificed for analysis of residual oil concentrations (SOP 4 of this Appendix). Record all physical observations for each flask (such as degree of emulsification, whether the oil has congealed into tar balls, wall growth, color, etc.) at each sampling. The analytical procedure is summarized in Table 16 of this Appendix. Dichloromethane (DCM) is the solvent used for the initial extraction. Solvent-exchange the extract into hexane prior to injection into the gas chromatograph. The solvent exchange is done to prevent asphaltenes from contaminating the column.

TABLE 16—BIOREMEDIATION EFFICACY—SUMMARY OF ANALYTICAL PROCEDURES

Matrix	Measurement	Sampling/ measurement method	Analysis method	Sample container/quantity of sample	Preservation/ storage (°C)	Holding times (months)
DCM	N/A	Solvent Exchange to Hexane	N/A	Capped Vial with Teflon septa, 30 mL.	4	6

TABLE 16—BIOREMEDIATION EFFICACY—SUMMARY OF ANALYTICAL PROCEDURES—Continued

Matrix	Measurement	Sampling/ measurement method	Analysis method	Sample container/quantity of sample	Preservation/ storage (°C)	Holding times (months)
Hexane	Hydrocarbon Concentration	SOP 4	GC/MS	Capped Vial with Teflon septa, 10 mL.	4	6

5.5.2 *Hydrocarbon Extraction.* To measure extraction efficiency, 200 µL of the 400 mg/L surrogate recovery standard (compounds and concentrations described in SOP 1 in this Appendix) is added to each flask. Add 50 mL DCM to each flask. Transfer the contents to a 250 mL separatory funnel and shake for 2 minutes; allow the phases to separate for 2 minutes. If an emulsion remains after 2 minutes, centrifuge the emulsion in Teflon® centrifuge tubes for at least ten minutes in a low-speed centrifuge at 3,000 times gravity (3,000 × *g*) to break the emulsion and recover the DCM phase. Pass the DCM extract through a funnel plugged with glass wool and containing approximately 20 g anhydrous, granular sodium sulfate (Na_2SO_4) to remove water. Repeat the steps above two more times with 25 mL DCM each (100 mL DCM used in total). Add 10 mL DCM on to the sodium sulfate after the third extraction to rinse off any oil residue. Collect the extract in 125 mL serum vials, capped with Teflon lined septa and aluminum crimp seals, and store at 4 °C for up to 6 months.

5.5.3 *Solvent Exchange.* Perform a solvent exchange (DCM to hexane) prior to GC/MS analysis to prevent injection of asphaltenes into the GC/MS column. Transfer the DCM extract to concentration tubes. Place the tubes in a 29 °C water bath under a stream of dry nitrogen gas. Reduce the sample to 1 mL and transfer the extract to a 10 mL volumetric flask. Rinse the concentration tube with hexane and add it to the volumetric flask 2 times. Adjust the final volume with hexane to 10 mL.

5.5.4 *Hydrocarbon Analysis.* Quantify the concentrations of 25 alkanes, 32 aromatics and hopane (SOP 4, Table SOP 4.4 of this Appendix) using an Agilent 6890 GC/5973 MS or equivalent equipped with a 30-m × 0.25-mm ID × 0.25-µm film thickness DB–5 or equivalent fused silica column. To prepare the samples, transfer 1.0 mL of the hexane extract into a 2 mL autosampler vial with Teflon lined cap. Add 20 µL of internal standard solution to each vial with a syringe or positive displacement pipettor. SOP 2 of this Appendix outlines the procedure for preparing the internal standard solution. Load vials onto the autosampler tray and analyze in selected ion monitoring mode (SIM). Sum the individual alkane concentrations for the total alkane concentration and the individual aromatic concentrations for total aromatic concentrations in each flask.

5.6 *Quality Assurance/Quality Control (QA/QC).*

5.6.1 *Objectives.* The critical variables to be analyzed for each set of experimental conditions are the individual petroleum hydrocarbons, *i.e.,* the alkanes ranging in carbon number from nC–14 to nC–35, plus pristane and phytane, and the 2- to 4-ring polycyclic aromatic hydrocarbons (PAHs) and their alkylated homologs as listed in SOP 4 of this Appendix. The quality assurance objectives for precision, accuracy, and detection limits are ±20%, 75–125% recovery, and 22.5 µg/L on average for the 58 compounds, respectively. For more details, refer to the SOPs of this Appendix.

5.6.2 *Precision Objectives.* Precision is presented as relative percent difference (RPD) for duplicate measurements and as relative standard deviation (RSD, or coefficient of variance) for triplicate measurements, applicable to replication of treatments as separate samples.

5.6.3 *Accuracy Objectives.* These are based on the check standards and standard oil samples run concurrently with the sample analyses for GC/MS analysis of critical compounds. Critical compounds in the check standards and in the oil standards must fall within 75–125% of expected values for the analysis to be valid. Six surrogate compounds (SOP 1 of this Appendix) added to each sample before extraction can also serve as a surrogate for determining accuracy. The measured surrogate concentrations must fall within 75–125% of expected values.

5.6.4 *Calibration Range.* Conduct all measurements within the linear calibration range of the instrument. The calibrated concentration range for GC/MS analysis is 0.1 mg/L to 30 mg/L. If the measured concentration of any critical compound is above the calibration range, dilute the sample and re-analyze to quantify that particular compound within the linear calibration range.

5.6.5 *Quality Control.* Table 17 of this Appendix summarizes the QC checks for each measurement. See the corresponding SOP in this Appendix for detailed descriptions of QC checks, frequency, acceptance criteria, and corrective actions.

TABLE 17—QA/QC CHECKS

Sample matrix	Measurement	QA/QC check	Frequency	Acceptance criteria	Corrective action
DCM	GC/MS hydrocarbon analysis.	Blanks	Once per calibrated run.	Peak area of interfering peaks <10% of lowest standard peak area.	Flush with solvent, clean injection port, and/or bake column.
DCM	GC/MS hydrocarbon analysis.	DFTPP Check Standard.	Once per calibrated run.	Must pass all DFTPP criteria	If any criteria fail, retune and rerun DFTPP check standard.
DCM	GC/MS hydrocarbon analysis.	Initial Calibration Samples.	Once per calibrated run.	Response Factor RSD ≤25% or R2 >0.99.	If RSD for any one compound >25%, recalibrate.
DCM	GC/MS hydrocarbon analysis.	Calibration Check Standards.	Every 10–15 samples	±25% of expected values	If >5 compounds are out of range, recalibrate and rerun samples.
Hexane	GC/MS hydrocarbon analysis.	Surrogates	Every Sample	±30% of expected values	Re-inject.
Hexane	GC/MS hydrocarbon analysis.	Biomarker Concentration.	Every Sample	±25% of average values	Re-inject.

5.7 *Pass/Fail Criteria.*

5.7.1 Calculate the mean and standard deviation of the hopane-normalized total aromatics (sum of all resolved aromatics) and hopane-normalized total alkane concentrations (sum of all resolved alkanes) from the 6 independent replicates at days 0 and 28. To normalize, divide the sum of the alkane analytes and the sum of the aromatic analytes in each replicate by the hopane concentration in the corresponding replicate.

5.7.2 From those data, calculate the 95% Upper Confidence Level (UCL95) at days 0 and 28 using the following formula (Equation 11 of this Appendix):

$$UCL_{95} = \bar{x}_{t(0 and 28)} + \left(\frac{t_{95,5df} \times \sigma}{\sqrt{n}} \right) \quad \text{(Equation 11)}$$

where:

$\bar{x}_{t(0and28)}$ = total hopane-normalized alkane or total hopane-normalized aromatic mean of 6 replicates at days 0 and 28,

$t_{95,\ 5\ df}$ = the 95% one-tailed t-value with 5 degrees of freedom (2.015),

s = the standard deviation of the 6 replicates at day 0 and 28, and

n = no. of replicates = 6.

$$\%\ reduction = 100 \times \left[1 - \left(\frac{t_{28(UCL95)}}{t_{0(UCL95)}} \right) \right] \quad \text{(Equation 12)}$$

where:

$t_{28(UCL95)}$ = UCL_{95} of the hopane-normalized total alkane or total aromatic mean of 6 replicates on day 28, and

$t_{0(UCL95)}$ = UCL_{95} of the hopane-normalized total alkane or total aromatic mean of 6 replicates on day 0.

5.7.4 A product is successful in saltwater or freshwater if the % reduction of total alkanes (aliphatic fraction) from the GC/MS analysis is greater than or equal to 85% and the % reduction of total aromatics (aromatic fraction) is greater than or equal to 35% at day 28 based on the UCL_{95} (Equation 12 of this Appendix). The benchmark reduction ranges in aliphatic and aromatic fractions for the positive control are the same as for the products specified above. The average concentration of the biomarker hopane at day 28 must not differ from the average concentration at day 0 by more than 12% in the positive control. If the conditions for the positive control are not met, the entire procedure must be repeated.

5.8 *Data Verification and Reporting.* GC/MS data files are generated by MS ChemStation software (the Agilent standard software for GC/MS) or equivalent for each injection. Data files contain summed ion chromatograms and selected ion chromatograms. Calibration curves are generated within MS ChemStation software, and all data files are calculated against the calibration curve by MS ChemStation. Data verification would be done by crosschecking between analysts for 10% of the raw data and its reduction process.

5.9 *Laboratory Report.* The summary of findings from a product test must include the data listings for each analyte that was analyzed (*i.e.,* all individual alkanes and aromatics in the list of required analytes), along with QA/QC checks (see Table 17) and instrument detection/reporting limits for each analyte. Express all concentrations as mg analyte/L exposure water.

5.10 *Standard Operating Procedures (SOPs) 1–4*

5.10.1 *SOP 1. Preparation of Surrogate Recovery Standards*

5.10.1.1 *Preparation:*

5.10.1.1.1 *Solvents:* Dichloromethane (DCM), Optima grade or equivalent.

5.10.1.1.2 *Reagents:*

D36-Heptadecane (C17)
D50-Tetracosane (C24)
D66-Dotriacontane (C32)
D10-1-Methylnaphthalene
D10-Phenanthrene
D10-Pyrene
5-beta-cholestane (coprostane)

Note: Deuterated reagents are available from Cambridge Isotope Laboratories, Andover, MA.

5.10.1.1.3 *Equipment:*

Micro-spatula
Small beakers
Glass funnel
Analytical balance (0.0001g)
Vials with Teflon-lined caps
Teflon wash bottle with Optima grade DCM
Volumetric flask (250 mL), class A
Pasteur pipettes

5.10.1.2 *Procedure:*

5.10.1.2.1 Using a calibrated analytical balance, weigh 100 mg (0.100 g) of each reagent into separate 10–25 mL beakers.

5.10.1.2.2 Dissolve the reagents in their beakers by adding 10 mL DCM. Use a Pasteur pipette to transfer the solutions to a single 250 mL volumetric flask.

5.10.1.2.3 Wash the beakers 3 or 4 times with DCM. Use a Pasteur pipette to transfer each of the washings to the 250 mL volumetric flask.

5.10.1.2.4 Dilute the solution to the 250 mL volume mark on the volumetric flask with DCM.

5.10.1.2.5 Use a glass stopper to seal the flask and homogenize the solution by inverting the flask 5 or more times. The final concentration of this solution is 400 mg/L for each of the reagents.

5.10.1.2.6 Transfer the solution into 40 mL storage vials and cap with Teflon-lined caps and label each with the date of preparation, operator, sample names, and concentrations.

5.10.1.2.7 Weigh each vial and record its weight on the label. This weight is used to monitor possible evaporation during storage.

5.10.1.2.8 Store these vials at 0 °C or lower.

5.10.1.2.9 Before using, allow the solution to come to room temperature, and then shake it well.

5.10.1.2.10 Weigh the vial before using it and compare the weight with the last weight recorded on the vial.

5.10.1.2.11 If the weights are consistent, the integrity of the solution can be assumed. If not, investigate and resolve the cause.

5.7.3 Using Equation 12 of this Appendix, calculate the % reduction of each oil fraction from day 0 to day 28, using the day 0 and 28 UCL_{95} hopane-normalized values for each fraction:

Prepare a new solution if the integrity has been compromised.

5.10.1.3 *Quality Control:* Inject 20 µL of the surrogate stock solution into 1 mL DCM. Add 20 µL of the internal standard solution (SOP 2 of this Appendix). Analyze this solution by GC/MS using a calibrated method (SOPs 3 and 4 of this Appendix). The expected concentration of each of the corresponding surrogate compounds is 8 ± 2 mg/L. If the measured value does not fall within this range, prepare and measure another independent surrogate solution. If the measured concentration of the second surrogate solution is within the allowable tolerance range, the calibration and instrument conditions are acceptable; properly discard the first surrogate solution. If the concentration of the second surrogate solution is also out of range, then clean and recalibrate the instrument until the problem is resolved.

5.10.2 *SOP 2. Preparation of Internal Standard Solution*

5.10.2.1 *Preparation:*

5.10.2.1.1 *Solvents:* Dichloromethane (DCM), Optima grade or equivalent

5.10.2.1.2 *Reagents:*

D34 n-Hexadecane (C16)
D42 n-Eicosane (C20)
D62 n-Triacontane (C30)
D8-Naphthalene
D10-Anthracene
D12-Chrysene
5-alpha-Androstane

Note: Deuterated reagents are available from Cambridge Isotope Laboratories, Andover, MA.

5.10.2.1.3 *Equipment:*

Micro-spatula
Small beakers
Glass funnel
Analytical balance (0.0001g), calibrated and checked for accuracy
Amber vials with Teflon-lined caps, labeled
Teflon wash bottle with DCM
Volumetric flask (200 mL), class A
Pasteur pipettes

5.10.2.2 *Procedure:*

5.10.2.2.1 Using a calibrated analytical balance, weigh 100 mg (0.100 g) of each of the reagents into separate small beakers.

5.10.2.2.2 Dissolve the reagents in their beakers by adding 10 mL DCM; using a Pasteur pipette, transfer the solutions to a single 200 mL volumetric flask.

5.10.2.2.3 Wash the beakers 3 or 4 times with DCM; use a Pasteur pipette to transfer each of the washings to the 200 mL volume mark on the volumetric flask.

5.10.2.2.4 Dilute the solution with DCM to the 200 mL volume.

5.10.2.2.5 Seal the flask with a glass stopper and homogenize the solution by inverting the flask a minimum of 5 times. The final concentration of this solution is 500 mg/L of each reagent.

5.10.2.2.6 Transfer the solution into 40 mL storage vials and cap with Teflon-lined caps. Label each vial with the date of preparation, operator, sample names, and concentrations.

5.10.2.2.7 Weigh each vial, and record its weight on the label. This weight is used to monitor possible evaporation during storage.

5.10.2.2.8 Store this solution at 0 °C or lower.

5.10.2.2.9 Before using, allow the solution to come to room temperature, and then shake it well.

5.10.2.2.10 Weigh the vial before using it, and compare the weight with the last weight recorded on the vial.

5.10.2.2.11 If the weights are consistent, the integrity of the solution can be assumed. If not, investigate and resolve the cause. Prepare a new solution if the integrity has been compromised.

5.10.2.3 *Quality Control:* Inject 20 µL of the internal standard solution into 1 mL DCM. Analyze this solution by GC/MS. The only peaks corresponding to the internal standards must appear. If other peaks appear, particularly close to the internal standard peaks, discard the internal standard solution and prepare a new solution.

5.10.3 *SOP 3. Preparation of Working Standards, Check Standards, and Oil Standards for GC/MS Consistency.*

5.10.3.1 *Preparation:*

5.10.3.1.1 *Solvent:* Dichloromethane (DCM), Optima grade or equivalent

5.10.3.1.2 *Stock solutions:*

5.10.3.1.2.1 *Oil analysis standard:* 44 compounds, 100 mg/L in hexane/DCM (9:1), four, 1-mL vials required. Available from Absolute Standards, Inc., Hamden, CT, Part #90311.

5.10.3.1.2.2 *Nine compound PAH standard:* 1,000 mg/L in DCM, one vial. Available from Absolute Standards, Inc., Hamden, CT, Part #90822.

5.10.3.1.2.3 1,2-Benzodiphenylene sulfide, (synonym for naphthobenzothiophene). Prepare a 2 mg/mL stock solution. Available from Sigma-Aldrich Co., Part # 255122, purity 99%.

5.10.3.1.2.4 Hopane solution (17 α (H), 21β (H), 0.1 mg/mL in isooctane. Available from Sigma-Aldrich Co. Part #90656.

5.10.3.1.2.5 *Surrogate solution:* 400 mg/L of each reagent in DCM (see SOP 1 of this Appendix).

5.10.3.1.2.6 Internal standard solution, 500 mg/L in DCM (see SOP 2 of this Appendix).

5.10.3.1.3 Alaska North Slope Crude Oil 521 (ANS521).

5.10.3.1.4 *Equipment:*

5.10.3.1.4.1 Glass storage vials with Teflon-lined caps (2 mL and 40 mL capacity);

5.10.3.1.4.2 Volumetric flasks, Class A, 5 mL, 10 mL, and 100 mL

5.10.3.1.4.3 Glass syringes capable of dispensing 25–500 µL with an accuracy and precision of ± 1%, or equivalent

5.10.3.1.4.4 Wheaton repetitive dispenser, Model 411 STEP–PETTE or equivalent

5.10.3.1.4.5 Teflon wash bottle filled with Optima grade DCM or equivalent grade DCM

5.10.3.1.4.6 Pasteur pipettes

The volumes of stock solutions required to make the working standards are listed in Table SOP 3.1 of this Appendix.

TABLE SOP 3.1—AMOUNT OF STOCK SOLUTIONS REQUIRED TO MAKE THE WORKING STANDARDS

Stock standards	A	B	C	D	E		F
Working standards concentration, mg/L	Oil analysis mix (44 compounds, 100 mg/L) µL	Aromatics mix (9 compounds, 1,000 mg/L) µL	1,2-Benzo-diphenylene sulfide (NBT) (2 mg/mL) µL	Surrogate solution (100 mg/L) µL	Hopane solution (100 mg/L) µL	Volumetric flask volume mL	ISTD (500 mg/L) µL
STD 30 (no hopane)	1,500	150	75	375	0	5	100
STD 20 (5 mg/L hopane)	1,000	100	50	250	250	5	100
STD 10 (2.5 mg/L hopane)	500	50	25	125	125	5	100
STD 5* (1 mg/L hopane)	500	50	25	125	100	10	200
STD 5-Utility (1 mg/L hopane)	500	50	25	125	100	10 (used for preparation of STD 2.5 & STD 1).	0
STD 2.5 (0.5 mg/L hopane)	Use 5 mL of STD 5-Utility and dilute to 10 mL.						200
STD 1 (0.2 mg/L hopane)	Use 2 mL of STD 5-Utility and dilute to 10 mL.						200
STD 0.1 (0.2 mg/L hopane)	Use 0.2 mL of STD 5-Utility and dilute to 10 mL.						200

*Make extra STD 5 for use as check standard.

5.10.3.2 *Procedure for Working Standards and Check Standards:*

5.10.3.2.1 Label three 5 mL volumetric flasks as STD30, STD20, STD10, and two 10 mL volumetric flasks as STD5, and STD5-utility.

5.10.3.2.2 Add 1–2 mL of DCM to each volumetric flask.

5.10.3.2.3 Using glass syringes, add the appropriate volume of stock solution A (as listed in Table SOP 3.1 of this Appendix) to the flasks labeled STD30, STD20, STD10, STD5, and STD5-utility.

5.10.3.2.4 Wash the walls of the inner neck of the flasks with several drops of DCM to rinse off the residue of the stock solution into the flasks.

5.10.3.2.5 Repeat Step 3 and Step 4 to dispense stock solutions B–E (do not add stock solution F, internal standard solution, at this step).

5.10.3.2.6 Dilute to volume with DCM for all the above flasks, seal with glass stoppers, and invert several times to homogenize the solutions.

5.10.3.2.7 Label three additional 10 mL volumetric flasks as STD2.5, STD1, and STD0.1. Wet with 1–2 mL DCM.

5.10.3.2.8 Dispense 5 mL of STD5-utility solution into flask STD2.5, 2 mL of STD5-utility solution into flask STD1, and 0.2 mL of STD5-utility solution into flask STD0.1.

5.10.3.2.9 Dilute to volume with DCM, seal with glass stoppers, and invert several times to homogenize the solutions.

5.10.3.2.10 Using a 100 µL glass syringe, dispense 100 µL of internal standard solution into flasks STD30, STD20, and STD10. Dispense 200 µL into flasks STD5, STD2.5, STD1, and STD0.1 to give a final concentration of 10 mg/L internal standard.

5.10.3.2.11 Seal with glass stoppers, and invert the flasks several times to homogenize the solutions.

5.10.3.2.12 Transfer the solutions into 2 mL storage vials, and cap with Teflon-lined caps.

5.10.3.1.13 Label each vial with date of preparation, analyst, sample names, and concentrations.

5.10.3.2.14 Weigh each storage vial and record its weight on the label. This weight is used to monitor possible evaporation during storage.

5.10.3.2.15 Store this solution at 0 °C or below.

5.10.3.2.16 Before using, allow the solution to come to room temperature, and shake it well.

5.10.3.2.17 Weigh the vial before opening, and compare the weight with the last weight recorded on the vial. If the weights are consistent, the integrity of the solution can be assumed. If not, investigate and resolve the cause. Do not use the solution if the integrity has been compromised.

5.10.3.3 *Procedure for Oil Standard.* In a 100 mL volumetric flask, weigh 0.500 g of the standard ANS521 crude oil, add 2 mL of surrogate solution (see SOP 1 of this

Appendix), and bring to volume with DCM. Add 2 mL of internal standard solution (see SOP 2 of this Appendix). Follow steps 5.10.3.2.11 through 5.10.3.2.17 of this SOP, substituting 40 mL storage vials for the 2 mL vials.

5.10.3.4 *Quality Control/Quality Assurance:*

5.10.3.4.1 Run the seven standard solutions using the GC/MS method (SOP 4) on a tuned GC/MS. Use the EnviroQuant software or equivalent to calculate the average Relative Response Factor (RRF) and the relative standard deviation (RSD) of the RRFs for each analyte over the six concentrations. The RRF is defined as:

$$RRF = \frac{\text{area analyte}}{\text{area internal standard}} \times \frac{\text{concentration of internal standard}}{\text{concentration of analyte}} \quad \text{(Equation 13)}$$

5.10.3.4.2 The RSD of the RRFs for all analytes must be 25% or less. Alternatively, the coefficients of determination (R2) for the calibration curve for each target compounds and surrogate should be over 0.99.

5.10.4 *SOP 4. GC/MS Method for the Analysis of Crude Oil Samples.*

5.10.4.1 *Instrument Specifications:*

5.10.4.1.1 Use an Agilent 6890 GC coupled with an Agilent 5973 mass selective detector (MSD) and an Agilent 6890 series auto sampler or equivalent, equipped with a DB–5 capillary column (30 m, 0.25 mm I.D., and 0.25 μm film thickness) or equivalent, and a split/splitless injection port operating in the splitless mode. Data acquisition occurs in the SIM (selected ion monitoring) mode for quantitative analysis. In SIM mode, the dwell time of each ion is set to be 10 milliseconds and the ions are split up into groups by retention time. One way to divide the ions is by retention time grouping as shown in Table SOP 4.1 of this Appendix. The number of ions in each ion group must be constant, yielding the same scan rate for each group.

TABLE SOP 4.1—IONS ASSOCIATED WITH RETENTION TIME GROUPS

Group	Ions
1	57, 66, 128, 136, 142, 152, 156, 166, 170, 184.
2	57, 66, 166, 170, 178, 180, 184, 188, 192, 194, 198, 208.
3	57, 66, 178, 184, 188, 192, 194, 198, 202, 206, 208, 212, 220, 226.
4	57, 66, 192, 198, 202, 206, 208, 212, 216, 220, 226, 230, 234, 245.
5	57, 66, 191, 217, 228, 240, 242, 248, 256, 262, 264, 270, 276, 284.

5.10.4.1.2 Table SOP 4.2 of this Appendix summarizes the instrumental conditions for crude oil analysis. Use only ultra-high purity helium (99.999% pure) as the carrier gas. In series, connect a moisture trap, an oxygen trap, and an organic trap to the carrier gas line before it enters the column.

TABLE SOP 4.2—INSTRUMENTAL CONDITIONS FOR CRUDE OIL ANALYSIS

Instrument	Agilent 6890 Series II Gas Chromatograph (GC) with an Agilent 5973MSD and an Agilent 6890 auto sampler, or equivalent.
Column	DB–5 capillary column (30 m, 0.25 mm I.D., and 0.25-mm film thickness) or equivalent.
Carrier Gas	Helium, ultra-high purity grade (99.999%).
Inlet Temperature	300 °C.
Transfer Line (detector) Temperature	310 °C.
Oven Temperature Program	50 °C for 4 minutes, then 7 °C/min to 310 °C, hold for 18 minutes.
Flow Rate	Constant flow at 1mL/min. Linear velocity: 36.2 cm/sec.
Injection Volume	1 μL.
Split/Splitless Mode	Splitless.
Total Run Time	59.18 minutes.

5.10.4.2 *Procedure for preparing the instrument:*

5.10.4.2.1 Lower the injection port temperature and the oven temperature to 50 °C or less to avoid oxidation of the column.

5.10.4.2.2 Replace the liner with a clean, silanized liner. Do not touch the liner with bare fingers. A small piece of muffled glass wool may be inserted to protect the column.

5.10.4.2.3 Return the injection port and oven to the appropriate temperatures.

5.10.4.2.4 Wait five minutes after the temperature equilibrates before using the instrument.

5.10.4.3 *Procedure for tuning the MSD:*

5.10.4.3.1 Perform an air/water check. The value reported for the relative abundance of water (m/z 18), nitrogen (m/z 28), oxygen (m/z 32), or carbon dioxide (m/z 44) shall be less than 5% of the base peak for the system to be considered leak free and are expected to be closed to 1% for a stable system.

5.10.4.3.2 Tune the MSD using the Standard Autotune program and the decafluorotriphenylphosphine (DFTPP) Tune program to reduce instrument variability. The Autotune report file is referenced by the instrument when performing an air/water check and thus must be run at least once per month. Run standards and samples using DFTPP Tune parameters, and retune the instrument using DFTPP Tune at least once per week. The tune programs use three fragment ions of perfluorotributylamine (PFTBA) as a standard for tuning: m/z 69, 219, and 502. Tune reports must meet the following criteria:

5.10.4.3.2.1 Symmetrical peaks;

5.10.4.3.2.2 Mass assignments within ±0.2 amu's from 69, 219, and 502;

5.10.4.3.2.3 Peak widths within 0.5 ± 0.1 amu's;

5.10.4.3.2.4 Relative abundance is 100% for ion 69, at least 35% for ion 219, and at least 1% for ion 502;

5.10.4.3.2.5 Relative abundances for isotope masses 70, 220, and 503 ± 0.2 amu's are 0.5–1.5%, 2–8%, and 5–15%, respectively; and

5.10.4.3.2.6 Air and water peaks at m/z = 18, 28, 32, and 44 amu's must be very small and consistent with historical values.

5.10.4.4 *Maintaining a log book.* Maintain an instrument log book, and make entries for each use. Include the following information in the logbook: operator name, helium cylinder tank pressure and outlet pressure, vacuum gauge reading, any maintenance performed on the instrument (such as changing the injection port liner, gold seal, guard column, source cleaning), sequence

name, data path, samples in order of injection, method information, GC column number, and the Standard Auto Tune report and DFTPP Tune report.

5.10.4.5 *Running a Solvent Blank:* Following a liner change or at the start of a new run, run an injection of a pure solvent to confirm that the system is free of excessive or interfering contamination. Analyze the solvent in SCAN mode using the same temperature program used for sample analysis. If contamination is present, analyze additional samples of fresh solvent until the interfering contamination is removed.

5.10.4.6 *Checking the DFTPP Tune:* Prior to running the first calibration standard, verify the instrument tune conditions by running a 10 ng/µL DFTPP check standard to check the mass measuring accuracy of the MS, the resolution sensitivity, the baseline threshold, and the ion abundance ranges. Run the standard using the DFTPP method provided with the instrument. Each of the criteria identified in Table SOP 4.2 of this Appendix must be met before using the instrument for analysis:

TABLE SOP 4.3—ION ABUNDANCE CRITERIA FOR DFTPP

Mass, M/z	Relative to mass	Relative abundance criteria	Purpose of checkpoint
51	442	10–80% of the base peak	Low mass sensitivity.
68	69	<2% of mass 69	Low mass resolution.
70	69	<2% of mass 69	Low mass resolution.
127	442	10–80% of the base peak	Low-mid mass sensitivity.
197	198	<2% of mass 198	Mid mass resolution.
198	442	Base peak or >50% of 442	Mid mass resolution and sensitivity.
199	198	5–9% of mass 198	Mid mass resolution and isotope ratio.
275	442	10–60% of the base peak	Mid-high mass sensitivity.
365	442	>1% of the base peak	Baseline threshold.
441	443	Present and < mass 443	High mass resolution.
442	442	Base peak or >50% of 198	High mass resolution and sensitivity.
443	442	15–24% of mass 442	High mass resolution and isotopic ratio.

5.10.4.7 Calibrating *with a Multiple-Point Calibration Curve.* A 5- or 6-point calibration curve is obtained by running 5 or 6 working standards (see SOP 3) on the tuned GC/MS instrument. Calculate the relative response factor (RRF) for each compound relative to its corresponding deuterated internal standard as indicated in Table SOP 4.3 of this Appendix. The relative standard deviation (RSD) of the RRFs for each compound must be less than 25%. Run an independently prepared check standard immediately after the calibration standards to validate the accuracy of the calibration curve.

5.10.4.8 *Running Samples.* Once the calibration curve has been validated, samples can be analyzed. Dispense 1,000 µL of sample extract into labeled auto-sampler vials. Add 20 µL of the internal standard solution (see SOP 2 of this Appendix) to the extract using a syringe or a positive displacement pipettor. Run a check standard every 10 samples to ensure the consistency of the instrument. The RRF for each compound in the check standard must be within 25% of the average RRF obtained in the initial calibration.

5.10.4.9 *Quantification:* Once a calibration table has been generated, quantify each data file using the ''Calculate and Generate'' function in the MS ChemStation software, or equivalent software. Review individual peak integration manually to ensure proper baseline integration. The quantification of a compound is based on the peak area of the primary ion (Q Ion) indicated in Table SOP 4.4 of this Appendix.

TABLE SOP 4.4—TARGET COMPOUND LIST

Compound name	Quantitation ion	Reference compound for response factor	Internal standard for quantitation
N D34 C16	66	N D34 C16	D34 n C16 Q Ion 66.
n-C14	57	n C14.	
n-C15	57	n C15.	
n-C16	57	n C16.	
N D34 C17	66	N D34 C17.	
n-C17	57	n C17.	
Pristane	57	Pristane.	
n-C18	57	n C18.	
Phytane	57	Phytane.	
n C19	57	n C19.	
N D42 C20	66	N D42 C20	D42 n C20 Q Ion 66.
n C20	57	n C20.	
n C21	57	n C21.	
n C22	57	n C22.	
n C23	57	n C23.	
N D50 C 24	66	N D50 C 24.	
n C24	57	n C24.	
n C25	57	n C25.	
n C26	57	n C26.	
n C27	57	n C27.	
n C28	57	n C28.	
n C29	57	n C29.	
N D62 C30	66	N D62 C30	D62 n C30Q Ion 66.
n C30	57	n C30.	
n C31	57	n C31.	
N D66 C32	57	N D66 C32.	
n C32	57	n C32.	
n C33	57	n C33.	
n C34	57	n C34.	

TABLE SOP 4.4—TARGET COMPOUND LIST—Continued

Compound name	Quantitation ion	Reference compound for response factor	Internal standard for quantitation
n C35	57	n C35.	
D8 Naphthalene	136	D8 Naphthalene	D8 Naphthalene Q Ion 136.
Naphthalene	128	Naphthalene.	
D10 1-Methylnaphthalene	152	D10 1-Methylnaphthalene.	
C1 Naphthalene*	142	C1 Naphthalene.	
C2 Naphthalene*	156	C2 Naphthalene.	
C3 Naphthalene*	170	C3 Naphthalene.	
C4 Naphthalene*	184	C3 Naphthalene.	
D10 Anthracene	188	D10 Anthracene	D10 Anthracene Q Ion 188.
D10 Phenanthrene	188	D10 Phenanthrene.	
Phenanthrene	178	Phenanthrene.	
C1 Phenanthrene*	192	C1 Phenanthrene.	
C2 Phenanthrene*	206	C2 Phenanthrene.	
C3 Phenanthrene*	220	C2 Phenanthrene.	
C4 Phenanthrene*	234	C2 Phenanthrene.	
Fluorene	166	Fluorene.	
C1 Fluorene*	180	Fluorene.	
C2 Fluorene*	194	Fluorene.	
C3 Fluorene*	208	Fluorene.	
Dibenzothiophene	184	Dibenzothiophene.	
C1 Dibenzothiophene*	198	Dibenzothiophene.	
C2 Dibenzothiophene*	212	Dibenzothiophene.	
C3 Dibenzothiophene*	226	Dibenzothiophene.	
Naphthobenzothiophene (NBT)	234	Naphthobenzothiophene.	
C1 NBT*	248	Naphthobenzothiophene.	
C2 NBT*	262	Naphthobenzothiophene.	
C3 NBT*	276	Naphthobenzothiophene.	
Fluoranthene	202	Fluoranthene.	
D10 Pyrene	212	D10 Pyrene.	
Pyrene	202	Pyrene.	
C1 Pyrene*	216	Pyrene.	
C2 Pyrene*	230	Pyrene.	
D12 Chrysene	240	D12 Chrysene	D12 Chrysene Q Ion 240.
Benzo(a)anthracene/Chrysene*	228	Chrysene.	
C1 Chrysene*	242	Chrysene.	
C2 Chrysene*	256	Chrysene.	
C3 Chrysene*	270	Chrysene.	
C4 Chrysene*	284	Chrysene.	
5α-androstane	245	5α-androstane	5α-androstane Q Ion 245.
Coprostane	219	Coprostane.	
Hopane	191	Hopane.	

*Summed compounds; draw an integration line underneath all peaks with selected ion.

5.10.4.10 Equation 14 of this Appendix is used to calculate the concentration of analytes in units of µg/g oil added:

$$Concentration\ of\ analyte\ (\mu g / g\ oil) = \frac{100 \times A_{analyte} \times C_{istd}}{A_{istd} \times RRF} \qquad \text{(Equation 14)}$$

where:

$A_{analyte}$ = the peak area of the analyte,
C_{istd} = the concentration of the internal standard,
A_{istd} = the area of the internal standard,
RRF = the relative response factor, and
100 is the conversion factor to convert mg/L DCM to µg/g oil added.

5.10.4.11 If some analytes are not commercially available, the RRFs of other compounds (usually the parent compound) are used to quantify those analytes. For example, the RRF of C3-naphthalene may be used to calculate the concentrations of C3- and C4-naphthalenes. See Table SOP 4.4 of this Appendix for details. The quantification of these alkylated PAHs is relative because it is assumed that the molecular ions of the alkylated PAHs have the same RRFs as the parent compound ions. Nevertheless, these relative concentrations are useful for monitoring the fate of these compounds during the course of any analysis, as long as their concentrations are measured in a consistent way throughout the analysis.

5.10.4.12 Concentration calculations for all target compounds are performed using EnviroQuant software or equivalent. Data for each sample can be printed directly using a customized report template. Data can also be automatically entered into a spreadsheet within the EnviroQuant software.

5.10.5 *Quality Assurance/Quality Control.* The following criteria must be met before any samples are analyzed:

5.10.5.1 Air/water check to verify the system is leak free.

5.10.5.2 AutoTune and DFTPP Tune pass all criteria.

5.10.5.3 DFTPP check standard passes all criteria.

5.10.5.4 Solvent blank scan indicates the GC/MS system is free of interfering contamination.

5.10.5.5 Prepare and monitor a control chart of a standard oil analysis.

Concentrations of the analytes in the control chart must be no more than 25% different from their historical averages.

5.10.5.6 Relative response factors for analytes in the check standards inserted between every 10 samples must be no more than 25 percent different from the average RRF of those same analytes in the calibration curve. Peak shapes must be symmetrical.

5.11 *References for Section 5*

(1) Haines, J.R., E.J. Kleiner, K.A. McClellan, K.M. Koran, E.L. Holder, D.W. King, and A.D. Venosa. 2005. ''Laboratory evaluation of oil spill bioremediation products in salt and freshwater systems.'' J. Ind. Microbiol. Biotech 32: 171–185.

Appendix E to Part 300 [Removed]

■ 16. Remove Appendix E to Part 300.

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