National Oil and Hazardous Substances Pollution Contingency Plan (NCP)

Amendments to Subpart J Product Schedule Listing and Authorization of Use

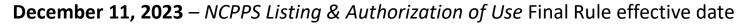
RRT 2 MEETING - NOVEMBER 9, 2023

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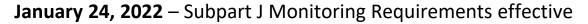


Timeline

December 12, 2025 – NCP Product Schedule Transition Period Ends



June 12, 2023 – NCP Product Schedule (NCPPS) Listing and Authorization of Use Requirements published in FR



December 2021 – GAO issues report on dispersants

August 2021 – Court-order to finalize by May 31, 2023

July 27, 2021 - Monitoring Requirements published in FR

February 2020 – EPA splits action into two rules



January 2020 – *Earth Island Institute, et al.* lawsuit

July 2019 - Congressional briefing on Subpart J

2017/2018 – USCG/NOAA/EPA support development of IMO subsea dispersant monitoring protocols

January 2015 – EPA proposed amendments to Subpart J

May 2013 – NRT guidance: *Environmental Monitoring for Atypical Dispersant Operations*

April 2010 – Deepwater Horizon Oil Spill

September 1994 – Last major revisions to Subpart J



Listing/Authorization of Use Final Rule

- Expanded data/testing requirements to encourage safer, more effective products.
- Better target product use to reduce risks of oil spills and response technologies to human health and the environment.
- Framework for authorizing agent use; does not mandate agent use nor removes agents from consideration.
 - Definitions (§ 300.5)
 - General Authorities (§ 300.900)
 - Listing on the NCP Product Schedule or Sorbent Product List (§ 300.915)
 - Appendix C
 - Proprietary Business Information (§ 300.950)
 - Addition of a Product (§ 300.955)
 - Mandatory Product Disclaimer (§ 300.965)
 - Removal of a Product (§ 300.970)
 - Authorization of Agent Use (§ 300.910)
 - Appendix E and 40 CFR Part 110.4



Definitions and General Authorities (§§ 300.5 & 300.900)



Definitions

Subpart J Definitions (§300.5)

- Amends definitions for Bioremediation agents, Burning agents,
 Chemical agents, Dispersants, Sinking agents, Sorbents, and
 Surface washing agents.
- New definitions for Bioaccumulation, Bioconcentration, Biodegradation, Biological agents, Bioremediation, Herding agents, Products, and Solidifiers.
- Removes definitions for Miscellaneous Oil Spill Control Agents (MOSCA) and Surface collecting agents.



General Authorities, (§ 300.900)

- Statutory Authority under CWA 311(d)(2)(G): Prepare a "schedule" identifying:
 - o dispersants, other chemicals, and other spill mitigating devices and substances, if any, that may be used in carrying out the NCP,
 - the waters in which they may be used, and
 - the quantities which can be used safely in such waters
- EO 12777 delegates statutory authority to EPA Administrator
- Implemented under NCP Subpart J (§ 300.900)
 - The schedule includes the NCP Product Schedule, the Sorbents Product List, and the authorization of use procedures
 - Taken together these identify waters and quantities in which chemical or biological agent products may be used safely

Listing Products on the NCP Product Schedule or Sorbent Product List

(§§ 300.915 – 300.970)



Listing Products on the NCP Product Schedule or Sorbent Product List (§§ 300.915 – 300.970)

- Revises general and technical information requirements.
- Amends and clarifies product categories
- Revises efficacy and toxicity testing protocols (Appendix C)
- Establishes efficacy and toxicity listing thresholds
- Specifies product listing to be for salt and/or freshwater environments (e.g., saltwater only for dispersants)
- Establishes a Sorbent Product List
- Revises allowable Proprietary Business Information claims
- Provides 2-year transition period for product resubmissions based on new testing/data requirements

General Product Information for NCP Product Schedule Listing and Sorbent Product List (§ 300.915(a))

Information required for all categories for which listing is requested includes:

- Name Brands
- Safety Data Sheets
- Storage and use conditions
- Shelf life
- Sample product labels
- Use Procedures
- Environmental persistence
- Physical and chemical properties
- All individual components

- Collection and recovery
- Pathogens and contaminants
- Laboratory accreditations
- Submission of all testing data and calculations
- Production capabilities
- Design for the Environment
- Any performance capabilities or environmental benefits data/certifications

Dispersant Testing and Listing Requirements - § 300.915(b)

Efficacy Testing & Listing Criteria

- Updated to baffled flask test method.
- New reference oil: Strategic Petroleum Reserve (SPR) Bryan Mound (BM).
- Listing Criteria: Effectiveness at the 95% lower confidence level (LCL₉₅) greater than or equal to: (i) 70% at 5 °C; and (ii) 75% at 25 °C.

Toxicity Testing & Listing Criteria

- Revised acute toxicity testing method (dispersant alone/dispersant + SPR-BM).
- New developmental & sub-chronic toxicity test method (dispersant alone).
- Listing Criteria (dispersant alone):
 - (i) median lethal concentration (LC_{50}) at the lower 95% confidence interval greater than 10 ppm;
 - (ii) 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.

Testing and Listing Requirements for Other NCP Product Schedule Categories

- Surface Washing Agents § 300.915(c)
- Bioremediation Agents § 300.915(d)
- Solidifiers § 300.915(e)
- Herding Agents § 300.915(f)

Sorbent Product List Requirements

Sorbents - § 300.915(g)

Appendix C to Part 300 – Product Testing Protocols and Summary Test Data

- New dispersant effectiveness (baffled flask) and toxicity tests
- Revised bioremediation agent effectiveness test
- Revised standard acute toxicity tests for bioremediation agents, surface washing agents, herding agents, and solidifiers



NCP Product Schedule and Technical Notebook

NCP Product Schedule

 Lists chemical and biological agent products that may be considered by a Federal On-Scene Coordinator (OSC) to authorize for use when responding to oil discharges in accordance with the NCP.

NCP Product Schedule Technical Notebook

 Presents manufacturer's summary information on the conditions under which each of the products is recommended to be used, including handling and worker precautions, storage information, recommended application procedures, physical properties, and toxicity, effectiveness, or other analyses.

https://www.epa.gov/emergency-response/national-contingency-plan-subpart-j



Submission of Proprietary Business Information (PBI) (§ 300.950)

- Updated "Confidential Business Information (CBI)" to "Proprietary Business Information (PBI)".
- Includes reporting procedures and PBI claims limitations.
 - Submitters may only assert PBI claims for concentration, maximum, minimum, and average weight percent, and units of each component in the product.
 - All other information submitted to EPA for listing on NCP Product Schedule or Sorbent Product List will be available for public disclosure upon submission, without further notice to the submitter.

Addition of a Product to the NCP Product Schedule or Sorbent Product List (§ 300.955)

- Updated submission requirements
 - Submitter certification of information accuracy
 - EPA may request clarification, additional information or testing
- Provided a 90-day EPA review timeframe
- Updated process to request review of an EPA decision to reject a listing
- Updated requirements to notify EPA of listed product changes
 - Administrative (e.g., contact information, product name)
 - Reformulation (components and/or concentrations)
 - Requires new complete submission under a new, distinct name
- Transitioning to new NCP Product Schedule
 - by December 12, 2025



Mandatory Product Disclaimer, § 300.965

- Mandatory disclaimer text is codified
- The listing of a product on the NCP Product Schedule <u>does not</u> constitute approval or recommendation of the product.
- Any label, advertisement, or technical literature for products listed on the NCP Product Schedule must:
 - display the disclaimer in its entirety,
 - be conspicuous, and
 - be fully reproduced on all product literatures, labels, and electronic media including website pages.



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

- Revises listing removal process, providing example causes:
 - Statements or information that are misleading, inaccurate, outdated,
 or incorrect regarding the composition or use of the product
 - Alterations to the components, concentrations, or use conditions of the product without proper notification to EPA per the procedures outlined in Subpart J
 - Failure to print the disclaimer provided in § 300.965 on all labels,
 advertisements, technical literature, or electronic media
- Revises the appeals process to be like process for listing determinations.
- Subpart J does not prohibit product submitter from removal of their product from listing

Authorization for Agent Use (§ 300.910)



Authorization for Agent Use Regulatory Elements

- Use of agents on the NCP Product Schedule, or use of burning agents, addressed by a preauthorization plan, § 300.910(a)
- Use of agents on the NCP Product Schedule, or use of burning agents, not addressed by a preauthorization plan, § 300.910(b)
- Reserved, § 300.910(c)
- Temporary exception, § 300.910(d)
- Prohibited agents or substances, § 300.910(e)
- Storage and use of agents listed on the NCP Product Schedule, § 300.910(f)
- Supplemental testing, monitoring, and information, § 300.910(g)
- Recovery of chemical agents and other substances from the environment,
 § 300.910(h)
- Reporting of agent use, § 300.910(i)

Preauthorization of agents on the NCP Product Schedule or burning agents, § 300.910(a)

- Revises and clarifies the preauthorization development and approval process, responsibilities of involved parties, and factors to consider.
- Includes review procedures for preauthorization plans.
- Does 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.
- Addresses 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).

Preauthorization of agents on the NCP Product Schedule or burning agents, § 300.910(a), cont.

- Area Committees and RRTs shall address whether preauthorization is appropriate.
 - No mandate to develop preauthorization plans
 - OSCs may still request case-by-case agent use authorization under § 300.910(b)
- Area Committees and RRTs to include applicable approved preauthorization plans in ACPs and RCPs.
- Approved preauthorization plans allow an OSC to consider and authorize the use of agents on the NCP Product Schedule, or the use of burning agents, for the purpose they were specifically listed without obtaining incident-specific concurrences/consultations required under § 300.910(b).



Preauthorization of agents on the NCP Product Schedule or burning agents, § 300.910(a), cont.

<u>Development - § 300.910(a)(1)</u>

- Developed by the Area Committees or the RRT in consultation with the Area Committee(s).
- 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.
 - RRTs may include additional criteria in defining the plan's scope.
- Should document how regional and logistical factors were addressed when establishing use limits and parameters.
 - Examples include likely sources/types of oil, environmentally sensitive resources, storage locations and manufacturing capability of available agents.

Preauthorization of agents on the NCP Product Schedule or burning agents, § 300.910(a), cont.

Approval - § 300.910(a)(2)

- Reviewed, and either approved, approved with modification, or disapproved by:
 - EPA representative to the RRT,
 - Department of Commerce and the Department of the Interior natural resource trustees, and
 - RRT representative from the state(s) with jurisdiction over waters and adjoining shorelines within the preauthorization plan area, as appropriate
- RRTs and ACs should expeditiously begin their reviews.
- Withdrawal of preauthorization plan approval
 - ACs and RRTs must address the withdrawal within 30 days; RRT must notify the National Response Team (NRT) of final status within 30 days of withdrawal.

Preauthorization of agents on the NCP Product Schedule or burning agents, § 300.910(a), cont.

Reviews - § 300.910(a)(3)

- RRT in consultation with the ACs must review, and revise as needed, approved preauthorization plans.
- Reviews must be conducted following a regular timeframe established by the RRT and documented in the plan, including at a minimum:
 - After major discharges or a Spill of National Significance (SONS) relevant to the plan area,
 - To address revisions of the NCP Product Schedule for agents that may be individually listed within a plan; and,
 - To reflect new threatened and/or endangered species applicable to the plan area.

Agent use not addressed by a preauthorization plan, § 300.910(b)

- Authorization of use determinations 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.
- Maintains same authorization structure: The OSC may authorize the use of chemical or biological agents identified on the NCP Product Schedule on an oil discharge provided they obtain:
 - Concurrence of the EPA representative to the RRT
 - Concurrence of the RRT representatives from jurisdictional states, as appropriate, and
 - Consultation with the DOC and DOI natural resource trustees.
- Authorization of products for the purpose they were specifically listed

Agent use not addressed by a preauthorization plan, § 300.910(b), cont.

For an authorization request to the RRT, the OSC:

- Must consider, at a minimum, 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.
- 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.
- Must document parameters for use.

Reserved, § 300.910(c) – formerly burning agents

- The final action reserves § 300.910(c) to maintain structural organization of the regulation that is familiar within the response community.
- Authorization of use of burning agents are now incorporated into the requirements under § 300.910(a) and § 300.910(b):
 - § 300.910(a) maintains preauthorization approach to address burning agents, and
 - § 300.910(b) incorporates burning agents in case-by-case authorization.



Temporary exception, § 300.910(d)

- Clarifies intent only applicable in unforeseen 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
 - When applicable, exception allows OSC to authorize the use of any chemical or biological agent, whether it is identified or not on the NCP Product Schedule, without obtaining required concurrences or consultations
- The OSC must document the circumstances and the reasons for use of the agent.

Temporary exception, § 300.910(d), cont.

- Agent use under this exception shall be in accordance with § 300.910(a) or § 300.910(b) no later than 24 hours after initial application.
 - Not a substitute for compliance with § 300.150 worker health and safety provisions, including personal protective equipment use,
 - Not to be used when there is sufficient time to seek authorization in accordance with § 300.910(a) or § 300.910(b)
- OSC must notify as soon as possible the EPA RRT representative and as appropriate, the RRT representatives from the affected state(s) and the DOC and DOI natural resource trustees.
- Does not affect other authorities available to an OSC under the NCP, such as ordering evacuations or repositioning equipment and personnel.

Prohibited agents or substances, § 300.910(e)

Sinking Agents

- Maintains prohibition for use of sinking agents.
- Consistent with provision under § 300.310(b) of NCP (Subpart D).
- Clarifies sinking agent 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.
 - Avoids potential confusion with the use of other chemical and biological agents (e.g., dispersants).



Storage and Use of Agents Listed on the NCP Product Schedule, § 300.910(f)

- Requires storage in accordance with conditions specified for listing
 - maximum, minimum, and optimum temperature, humidity, and other relevant conditions for product storage
 - anticipated shelf life at recommended storage conditions
- Focuses on responder and OSC use of this information.
- Section 300.910(f)(1)
 - OSC may only authorize NCP Product Schedule listed products documented and certified by the RP or its representative to have been stored under the submitter specified conditions; and
 - Whose date of use does not exceed the expiration date on the container's label at the time of the incident, unless otherwise specified for expired products.

Storage and Use of Agents Listed on the NCP Product Schedule, § 300.910(f), cont.

Section 300.910(f)(2)

- Adds flexibility
- OSC may authorize for use products past their expiration date
 when the RP/representative documents and certifies:
 - Expired product has been stored under the conditions provided by the submitter for listing.
 - Expired product meets applicable efficacy and toxicity listing provisions based on testing representative samples within previous 12 months.
- Voluntary provision 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.

Supplemental testing, monitoring, and information, § 300.910(g)

- For both planning and response RRT may require 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.
- <u>For response</u> Product manufacturer or responsible party shall provide, upon RRT or OSC request, additional monitoring or testing data and information.
- Discretionary provision
 - Recognizes that existing data or information may be available
 - Aims to provide incident-specific information to inform a response (e.g., concurrence, consultation)

Recovery of chemical agents and other substances from the environment, § 300.910(h)

- RP to ensure removal actions adequately contain, collect, store, and dispose 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, sorbents, and surface washing agents.
- OSC should, at a minimum, consider factors such as the safety of response personnel and harm to the environment in making recovery-related determinations.
 - RRTs and OSCs may consider these factors when determining whether and under what conditions to authorize their use.

Reporting of agent use, § 300.910(i)

RRT Notification of Agent Use - § 300.910(i)(1)

- OSC to notify the RRT within 30 days of completion of agent use:
 - Product name, product category, the quantity and concentration used, the duration and locations of use, any available data collected, and any available analyses of efficacy and environmental effects.
- Information may be submitted as part of the OSC reports under § 300.165, as applicable, subject to the 30-day timing requirement.
 - Section 300.165 NCP provision for the OSC/RPM to submit to the NRT or RRT a complete report on the removal operation and the actions taken upon request.

Reporting of agent use, § 300.910(i), cont.

Public Notification of Agent Use - § 300.910(i)(2)

- OSC provides notification to the public and updated information during a response as appropriate:
 - Product name, product category, quantity and concentrations used, duration of use, and location(s) of use.
- OSC establishes the initial notification timeframe.
 - Public notification may occur, for example, through coordination with the RRT and posting on their website, as appropriate.



NCP - Appendix E & 40 CFR Part 110.4 (Appendix E & § 110.4)



Appendix E and 40 CFR Part 110.4

<u>Appendix E to Part 300 (Oil Spill Response) – Removed</u>

- Removed duplicative guidance on oil spill response.
 - Appendix E does not alter meaning or policy stated elsewhere in NCP.
 - As part of the CFR, it must be updated to reflect amendments to the NCP.

40 CFR 110.4

- Revised title and text under to be consistent with the Subpart J amendments.
 - The addition of <u>any chemical or biological agent</u>, or <u>any other</u> <u>substance</u>, to oil to be discharged that would circumvent the provisions of this part is prohibited.



Final Action Key Dates

- EPA Administrator Signature May 31, 2023
- Published in the Federal Register June 12, 2023 (88 FR 38280)
- Effective Date December 11, 2023
 - For existing plans, RRTs should establish and document the timeframe for plan review and any necessary updates by December 11, 2023.
- NCP Product Schedule Transition Period Ends December 12, 2025
 - Two years from the Effective Date

