

RESPONDENT'S EXHIBIT 8



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: Electronic Document (e-Document) Management Policy Update

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TO: EFED Staff and Managers

This Environmental Fate and Effects Division (EFED) policy memorandum updates the requirements for formatting, naming, and storing final EFED documents, which are electronically stored on EFED's SAN drive¹ and Documentum². This policy supersedes previous versions, including the most recent version issued on March 20, 2015. The major updates to this policy include changes to CETIS file processing procedures, the archiving of final MS Word and Excel files in Documentum rather than on the H: drive, and changes in study classification terms.

This policy will continue to evolve as needed to capture and incorporate changes in the types of documents EFED produces; changing document management needs and requirements; and changes in our information technology and information management (IT/IM) environment. Contact a policy team member if you have questions about or need assistance with following this policy.

Policy Team Members

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¹ SAN drive address for EFED archive: <\\161.80.136.143\efedadminscans\Science Documents>

² Documentum address: <https://prismdocs.epa.gov/>

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A. Incoming Beans

All incoming Beans³ should be electronically delivered from the Risk Manager to the appropriate Environmental Risk Branch (ERB) via the RAPL and Branch Chief (BC). EFED RAPLs, BCs, and chemical assignments are identified on the intranet.⁴ The EFED Tracking Team does not receive Beans, but will forward emails with Beans to the appropriate RAPL if the Risk Manager sends them to the EFED Tracking Team and not to the RAPL or BC. This new procedure eliminates most of the EFED Tracking Team's involvement in processing incoming Beans.

B. Outgoing Work Products

Environmental Risk Branch (ERB) scientists or RAPLs are responsible, in accordance with this policy, for naming, assembling, and disseminating to the identified recipients and EFED Tracking Team the documents they author. Procedures for ERB scientists to follow can be found in **Sections C - G**. When final documents are disseminated, the responsibilities of the EFED Tracking Team and the ERB RAPL are as follows.

1. EFED Tracking Team's Procedures

The EFED Tracking Team will:

- Upload final files to the EFED archive on the SAN drive using the folder naming convention: PC Code (root directory) -> Action Code⁵ (subdirectory).
 - Signed .pdf documents are uploaded to the SAN drive EFED archive at: \\161.80.136.143\efedadminscans\Science Documents.
 - Response to Comment (RTC) memos are uploaded on the SAN drive to the "RTC" subdirectory if there's no associated action code. Otherwise, they are uploaded only to the subdirectory of the associated action code. For example, a "RTC" memo is filed in the "RTC" subdirectory, and a "PRA-RTC" memo is filed in the "PRA" subdirectory.
 - Risk assessments combined with drinking water exposure assessments or other documents are copied to the subdirectories for both Action Codes.
 - Documents with multiple PC codes are copied to the SAN archive directories for every cited PC code.

³ A Bean is a formal request for action from a risk manager that is tracked with a DP barcode.

⁴ EFED RAPLs and BCs are listed at: <http://intranet.epa.gov/pesticides/divisionswork/efed/index.htm>

⁵ An Action Code is a code used to classify EFED memoranda.

- Documents without a PC code (*e.g.*, DRT and NoPCcode documents) are uploaded to the root directory with the same name as the filename code used instead of a PC code (*i.e.*, “DRT” or “NoPCcode”).
- WinZip files are archived as submitted if supporting biological evaluation documents (under Action Code ESA) or upon request. Otherwise, the final files within a WinZip file are archived independently rather than within the WinZip file.
- Upload final files to Documentum, tagged with the metadata imbedded in the file name [PC code(s), DP Barcode(s), MRID(s), Guideline(s), Action Code(s), and date] along with the author name (“EFED”) and Documentum document type and sub-type.⁶
 - Final files include signed .pdf documents, final MS Word files, and any other related files (MS Excel, *etc.*).⁷
- Upload any CETIS database files (.mdb) to the CETIS master database.⁸ The study classification and DER primary reviewer’s name are recorded for each record.

a. DER Addenda

To complete DER addenda, the EFED Tracking Team will do the following:

1. Locate the original DER on the SAN drive and replace it with the addended DER (*i.e.*, once the new document is on the SAN drive, the old document will be deleted).
 - a. The EFED Tracking Team will check to make sure the original DER appended to the addendum within the new document matches the original DER to be deleted from the SAN drive.
2. Upload the addended DER to Documentum and remove the original DER if archived there.

b. Open Literature Review Summaries

The EFED Tracking Team will file Open Literature Review Summaries (OLRS) in the SAN drive and Documentum archives for final files. The EFED Tracking Team will also save a copy at:

⁶ Documentum “document type” and “document sub-type” fields are associated with file name action codes in the Action Code tables in **Section C**.

⁷ MS Word, MS Excel, and related files were previous archived on the H: drive at: \\W1818tdcec025\opp-opppshare\EFED_Chem_Files. As of this policy update, these files will be stored in Documentum when sent to the EFED Tracking Team. The H: drive archive of historical files will continue to be available until the files are migrated to Documentum.

⁸ CETIS .mdb files are not uploaded to the EFED archives on the SAN drive or in Documentum.

2. EFED RAPLs' Procedures

The EFED RAPLs will:

- Log out documents from OPPIN Data Entry by entering the classifications of all MRIDs associated with the Bean(s) and closing the Bean(s) associated with the listed DP Barcode(s).

C. File Naming Procedures

1. File Naming Convention for Memoranda

All EFED document file names begin with the lowest PC Code followed by the lowest DP barcode number associated with that action. DP barcode numbers are preceded by "DP" not by "D" alone.

The file naming convention below applies to ALL science documents, other than DERs and open literature review summaries.

- PC Code_DP Barcode Number_Action Code_Appendix or Amendment (as applicable)_Date
- e.g., 268800_DP406660_PF_1-31-13.pdf

File Name Action Code	Description	Documentum Crosswalk – For Use by EFED Tracking Team
		<ul style="list-style-type: none"> • Document Type • Document Sub-type
CETIS	Full CETIS Report	n/a – not uploaded to Documentum
DCI	Data Call In Review Response	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Response to Registrant DCI Response
DER-Memo	DER Transmittal Memorandum	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Data Evaluation Records (DER) - Memo
DWA	Drinking Water Exposure Assessment	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Drinking Water Assessment
ESA	Endangered Species Act-related documents including Listed Species Assessments, Consultation Memos, Biological Evaluations	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Endangered Species Assessment
EUP	Experimental Use Permit - Ecological Risk Assessment	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Ecological Risk Assessment – EUP

File Name Action Code	Description	Documentum Crosswalk – For Use by EFED Tracking Team <ul style="list-style-type: none"> • Document Type • Document Sub-type
FRA	Final Ecological Risk Assessment for Registration Review	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Ecological Risk Assessment - FRA
Incident	Incident Review	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Incident Report
PF	Problem Formulation for Registration Review	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Reg Rev Problem Formulation / Scoping Document
PRA	Preliminary Ecological Risk Assessment for Registration Review	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Ecological Risk Assessment - PRA / DRA
ProtRev	Protocol Review	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Protocol Review
ROCKS	ROCKS Memorandum	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Residues of Concern Knowledge-based Subcommittee (ROCKS) Report
RRA	Reduced Risk Analysis	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Reduced Risk Analysis
RTC or <associated action code>-RTC	Response to Comments (The action code of the document commented on, if any, is given first, then “-RTC”, e.g., PF-RTC, or DER-RTC.)	<ul style="list-style-type: none"> • Assessment-Review-Report Document • <Document Sub-type of associated action code>, otherwise: Response to Comments
RTWVR	Response to Waiver Request	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Response to Waiver Request
S18	Section 18 - Ecological Risk Assessment	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Ecological Risk Assessment – S18
S24	Section 24 - Ecological Risk Assessment	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Ecological Risk Assessment – S24
S3NC	Section 3 New Chemical - Ecological Risk Assessment	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Ecological Risk Assessment – S3NC
S3NU	Section 3 New Use - Ecological Risk Assessment	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Ecological Risk Assessment – S3NU
SCR	45/90-Day Screen and New Chemical Screen Memos	<ul style="list-style-type: none"> • Assessment-Review-Report Document • 45/90-day new chemical / new use screen
Other	Category for Miscellaneous Documents	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Miscellaneous Document

For documents with multiple attachments, or several parts, all components should be included with the cover memo as a single .pdf. If multiple files are needed due to the size or type of the documents, add “attachment1ofX, attachment2ofX, etc.,” to the end of the file names described above. An exception is biological evaluation documents, which should be compressed into a single

.zip file named following this naming convention. The multiple biological evaluation documents within the .zip file are named following the naming convention used for posting these documents online.

For documents referencing multiple PC codes and/or DP Barcodes, the file name should list the lowest number PC code or DP barcode only and use (+) to denote that the document contains multiples. For the purposes of closing out Beans, the document will be opened to confirm the full list of DP barcodes that should be closed in OPPIN. When a document to be logged out is relevant to multiple PC codes, adding the (+) to the file name will ensure that the EFED Tracking Team knows to save the document under multiple PC codes in the archives.

- Example 1 – Multiple PC Codes: PCCode1+_DPCode_Action Code_Date
- *e.g.*, 288008+_DP419688_Other_12-15-14.pdf
- Example 2 – Multiple DP Barcodes: PCCode_DPCode1+_Action Code_Date
- *e.g.*, 119011_DP408799+_RTWVR_11-25-13.pdf
- Example 3 – Multiple PC and DP Codes: PCCode1+_DPCode1+_Action Code_Date
- *e.g.*, 079021+_DP402345+_PRA_3-12-15.pdf

For documents regarding Drift Reduction Technology (DRT) that are not specific to an active ingredient, use “DRT” rather than a PC code.

- *e.g.*, DRT_DP437570_DER-Memo_2-28-17.pdf

For documents that are not specific to an active ingredient and do not regard DRT, use “NoPCcode” rather than a PC code.

- *e.g.*, NoPCcode_DP437571_Other_3-1-17.pdf

For documents with multiple Action Codes, place all codes separated by a hyphen in the file name.

- *e.g.*, 122101_DP403896_S3NU-DWA_8-31-13.pdf

For documents with Confidential Business Information, place “_C” on the right end of the main document’s file name and “_CA” on the right end of the confidential attachment’s file name.

- *e.g.*, 268800_DP406660_PF_1-31-13_C.pdf
268800_DP406660_PF_1-31-13_CA.pdf

2. File Naming Convention for Data Evaluation Records

The file naming convention below applies to Data Evaluation Records (DER). MRIDs should not contain a hyphen.

- PC Code_MRID_Action Code_Guideline#_Addendum or Appendix (as applicable)_Date
- *e.g.*, 288009_48336015_DER-Fate_835.6200_1-23-13.pdf

File Name Action Code	Description	Documentum Crosswalk – For Use by EFED Tracking Team
DER-Fate	DER on Environmental Fate Data	<ul style="list-style-type: none"> • Document Type • Document Sub-type
DER-Eco	DER on Ecological Effects Data	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Data Evaluation Records (DER) - Fate
DER-Eco OLRS	Open Literature Review Summary	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Data Evaluation Records (DER) – Eco
DER-EDSP	DER on Endocrine Disruptor Data	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Open Literature Data Review
DER-EDSP	DER on Endocrine Disruptor Data	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Data Evaluation Records (DER) - EDSP
DER-DRT	DER on Drift Reduction Technology Data	<ul style="list-style-type: none"> • Assessment-Review-Report Document • Data Evaluation Records (DER) - DRT

For documents referencing multiple PC codes and/or MRIDs, the file name should list the lowest number PC code or MRID only and use (+) to denote that the document contains multiples.

- *e.g.*, PCCODE1+_MRID+_DER-Fate_Guideline#_Date
- *e.g.*, 090205+_40149519+_DER-Fate_835.4100_7-15-16.pdf

Guideline numbers for use in file naming are listed in **Appendix D**.

For documents with an accession number rather than an MRID, use “ACC” in front of the number.

- PCCODE_ACC<#>_DER-Fate_Guideline_Date
- *e.g.*, 090205_ACC45189_DER-Fate_835.6100_10-5-16.pdf

Use the guideline designator “NG” followed by a short description of the study for non-guideline studies. Chronic sediment studies currently use the guideline designator “NG-chronicsediment” rather than guidelines in preparation or guidelines from entities other than OCSPP.

- *e.g.*, 060109_46907718_DER-Eco_NG-Parasitic-Wasp_1-9-15.pdf
- *e.g.*, 084301_49551201_DER-Eco_NG-chronicsediment_9-14-16.pdf

For documents with Confidential Business Information, place “_C” on the right end of the main document’s file name and “_CA” on the right end of the confidential attachment’s file name.

- *e.g.*, 288009_48336015_DER-Fate_835.6200_1-23-13_C.pdf
288009_48336015_DER-Fate_835.6200_1-23-13_CA.pdf

a. File Naming Convention for Open Literature Review Summaries

This file naming convention supersedes that found in the EFED “Evaluation Guidelines for Ecological Toxicity Data in the Open Literature” (May 16, 2011) on pages 30 through 32.

Submit Open Literature Review Summaries (OLRS) of ECOTOX Articles or other peer-reviewed scientific literature to the EFED Tracking Team as text searchable .pdf files using the following file naming convention:

- PC Code_MRID (if applicable)_DER-Eco_ECOTOX #_OLRS_Guideline # (or non-guideline description)_Date
 - *e.g.*, 032201_49611201_DER-Eco_E014903_OLRS_850.1075_4-14-15.pdf

These reviews should be finalized with a transmittal memo like any other DER.

3. File Naming Convention for CETIS Files

a. CETIS Database Files

Use the following file naming convention for CETIS Sandbox records in .mdb format that need to be added to the master CETIS database:

- YYYY-MM-DD{date of the logout date} <PC Code> <Chemical name> CETIS (<last name> (<# of records exported>)
- *e.g.*, 2017-03-06 056065 Dilithium silicate CETIS (Smith) (6).mdb

b. CETIS Reports

It is recommended to name CETIS reports (Summary and Analytical reports in .pdf format) by PC Code, MRID, guideline number, CETIS, and a date⁹ (*e.g.*, 123456_12345678_850.1500_CETIS_3-5-17.pdf). However, this file by itself will no longer be submitted to the EFED Tracking Team as a separate logout attachment.

⁹ The date will distinguish it from the contractor’s report.

4. File Naming Convention for Miscellaneous Spreadsheets

Documents or spreadsheets with salient data and/or statistics (*e.g.*, notes to file) that are not captured in final archived files may be submitted to the EFED Tracking Team for archiving in the “Other” subdirectory. Or, if they are not records, they can be stored in ERB-specific working document folders¹⁰ by chemical name. However, residue of concern half-life calculations must be finalized via DER addenda or in an assessment. Use the following file naming convention for these files:

- PC Code_Other-<description>_Date
- *e.g.*, 206600_Other-Calculations_1-25-12.xlsx

D. Study Classifications

In DER cover pages or executive summaries and DER transmittal memoranda, EFED reviewers should use only the following three study classifications¹¹ for DERs prepared for studies that are sponsored and submitted by applicants and registrants:

EFED Study Classifications
Acceptable
Supplemental
Unacceptable

Unacceptable studies are not used in risk assessments. They have a major deficiency, for example being scientifically invalid or critically deviating from the study protocol, that precludes them from providing reliable information for an exposure or risk assessment. Supplemental studies are at least partially useful for risk assessments, either for exposure and risk estimation or for characterization. Acceptable studies are fully reliable for assessments.

This policy supersedes previous study classification policies. Therefore, previously used study classifications including “core” and “invalid” are now considered “acceptable” and “unacceptable”, respectively. Supplemental classifications are not qualified as “quantitative” or “qualitative”, except for studies from the open literature. This policy does not supersede the guidance memorandum “Evaluation Guidelines for Ecological Toxicity Data in the Open Literature” (dated May 16, 2011).

Studies that are not guideline-compliant may be classified as unacceptable under the most relevant guideline or classified as acceptable or supplemental if they provide useful information under a non-guideline protocol. Study classifications do not include the term “non-guideline”.

¹⁰ ERB-specific working document folders address: <\\W1818tdceec025\opp-efed-share\Branch and IO Info>

¹¹ OPPIN includes 21 study classification options, most of which EFED does not use.

Studies conducted on degradates of an active ingredient are classified as acceptable if they otherwise would be classified so.

Studies that do not include all sub-studies specified in the guideline cannot be classified as acceptable unless EPA required the limited number of sub-studies. For example, an original aerobic soil metabolism study with less than four soils may not be classified as acceptable, or an original terrestrial plant toxicity study with less than ten test species may not be classified as acceptable. However, if EPA requires follow-up studies, *e.g.*, an aerobic soil metabolism study with one soil or a terrestrial plant toxicity study with two test species, then the follow-up studies may be classified as acceptable if they otherwise would be classified so.

Study classification statements summarize any study deficiencies that affect the classification, and indicate if any endpoints should not be used in risk quotient (RQ) calculations and if any part of the study is not useful for risk assessment. For example, the classification statement for a terrestrial plant study classified as supplemental may indicate that there are acceptable data for four plant species, unacceptable data for the remaining six test species, and summarize the deficiencies behind the unacceptable data.

The DER transmittal memo indicates whether additional data are needed under a study's OCSPP guideline, regardless of the classifications of the available studies under the guideline. In some cases, more data may be needed under an OCSPP guideline for which an acceptable study is available, while more data may not be needed under an OCSPP guideline for which a supplemental study is available. For example, a Tier-1 or limit plant toxicity study may be classified as acceptable, but more data are needed under the OCSPP guideline because a significant effect was observed, triggering a Tier-2 study. Or for example, an aerobic aquatic metabolism study may be classified as supplemental because samples were not true replicates, but more data may not be needed under the OCSPP guideline.

E. Finalizing Documents

- Cover memoranda must reference the associated PC Code(s) and DP Barcode(s). Data Evaluation Record (DER) transmittal memoranda must also include ALL MRIDs reviewed, their OCSPP Guidelines, and their study classifications (the standard cover memorandum format is in **Appendix A**).
 - Transmittal memoranda for ecological toxicity study DERs indicate for each subject DER whether CETIS records (*i.e.*, test codes) should exist, do exist, and whether the contractor's CETIS records were altered or new records were created in the CETIS Sandbox.¹² See **Appendix A** for the recommended tabular format for flagging these issues.

¹² The CETIS database is envisioned to account for all effects studies, whether or not a statistical analysis was conducted. Identifying DERs without CETIS analyses flags studies that need to be accounted for in CETIS.

- Documents should not contain highly sensitive information, including Confidential Business Information (CBI), in most cases.
 - If Confidential Business Information (CBI) must be in a document, it should be placed in a confidential attachment that is clearly declared as CBI at the top of the cover page of the main document using the following statement “This document refers to Confidential Business Information (CBI) that is contained in a confidential attachment.” Where CBI is removed from the main document, its removal is noted with numbered statements, *e.g.*, “This section has been included as CROSS REFERENCE 5, page 3 of the Confidential Attachment.”
 - Highly sensitive information includes but is not limited to the identity of active ingredients not registered in the United States, personally identifiable information, and Confidential Business Information (CBI), which includes a) descriptions of manufacturing or quality control processes, b) details of analytical methods for inert ingredients, c) the identity or percentage of inert ingredients, and d) information about the production, distribution, sale, or inventories of a pesticide.
- Final documents must be in text searchable .pdf format and have a complete set of dated signatures (Acrobat signatures with the date field are required). Paper copies are no longer accepted (since 2013).

1. CETIS Files

The EFED reviewer is responsible for ensuring that DERs contain the correct CETIS output. The EFED Tracking Team will not verify this. Contact the CETIS administrator (currently Lisa Eisenhower) if you have questions about or need assistance with CETIS-related issues.

a. CETIS Database Files

- Export together into one .mdb file any modified CETIS Sandbox records (*i.e.*, test codes) that support the final DER and need to be added to the master database. Do not export any unchanged .mdb files that the master database already contains.

b. CETIS Reports

- The contractor submits a file called “<PC Code>_<MRID>_CETIS.pdf” with the draft DER if CETIS was used in the study review. This file should contain *all* CETIS Summary and Analytical reports for that study merged into a single document. All the Summary reports

should be placed above all the Analytical reports, including for studies with multiple Summary reports (*e.g.*, terrestrial plant studies).^{13,14}

- If the EFED reviewer made no CETIS modifications, then append this CETIS file to the back of the DER .pdf before the DER is signed.
- If the EFED reviewer modified a contractor's CETIS record or created a new analysis in the CETIS Sandbox, then create the final CETIS .pdf file by combining into a single document all the correct, final CETIS Summary and Analytical reports (*i.e.*, Hypothesis, Linear, Nonlinear, *etc.*).
 - The EFED reviewer can replace a subset of the contractor's CETIS reports for a subset of species without having to rerun reports for all species: Copy the contractor-created individual reports¹⁵ to the Desktop, replace the outdated reports with the updated reports, then recombine all final files into a single .pdf file using Adobe Acrobat.
 - Append to the back of the DER .pdf the pages of this combined report file before the DER is signed.

2. Logout Emails

- Submit final e-documents to the EFED Tracking Team via Agency email. Include as recipients of this email all other EFED authors of the documents, the authors' Branch Chief(s) and RAPL(s), and all named recipients in the "TO" block of the transmittal memo.
- Type in the email subject line "For logout:", the chemical name, and document type. If DERs are included, specify either "eco" or "fate". **Appendix B** provides an example logout email.

a. Attachments

- Attach the signed .pdf memos and all final DERs and/or supporting document .pdf files.
- Any Microsoft Office, CETIS, statistical, and other files related to the document being logged out should also be submitted to the EFED Tracking Team. These can be attached separately to the logout email or attached within the signed .pdf files.

¹³ Summary and Analytical reports were previously finalized separately from the DER, with the Summary reports also appended to the DER.

¹⁴ CETIS outputs are not combined with the Word version of a DER.

¹⁵ Contractor-created individual CETIS reports are found here: [V:\Contractor Draft DERs\ECO Draft DERs\](#)

- For example, MS Excel files delivered by the contractor that summarize data should be sent to the EFED Tracking Team with the associated DER, either as email attachments or as attachments within the single DER .pdf file.
- Associated CETIS .pdf reports should no longer be submitted separately from the DER since they are appended to the DER file.
- When logging out more than three DERs, the email attachments should be compressed into a WinZip file (.zip) with a file name similar to that of the transmittal memo.
- The CETIS database (.mdb) file should be attached only if a new analysis was conducted or if the contractor's CETIS analysis was updated. EPA's current email system does not allow for the transfer of CETIS database files; therefore, any .mdb files should be compressed into a WinZip (.zip) file that is attached to the email.

b. E-mail body

- The logout email to the EFED Tracking Team should indicate any information for and action needed from the EFED Tracking Team. For example, when DER addenda are attached, provide the MRIDs, file names, and file paths of the superseded DERs and request their deletion. Also, CETIS flags may be further explained when warranted.

F. Addending DERs

DERs are modified with additional information, new calculations, and/or a study reclassification via an addendum.¹⁶ A DER is addended as follows:

1. Fill out a DER addendum template to describe the update (templates are in **Appendix C**).
2. Submit the addendum to a secondary reviewer.
3. Convert the final DER addendum document to .pdf.
4. Pull the old DER .pdf from the SAN drive archive, and merge it with the DER addendum, placing the addendum on top and preserving the original signatures.
5. Collect signatures from both the primary and secondary reviewer of the DER addendum.
6. Rename the updated DER file according to this policy.

¹⁶ A file correction that replaces a previously finalized DER with an error-corrected version is not a DER addendum.

7. Prepare a transmittal memo for the DER addendum/addenda similar to what is created for DERs.
8. Follow **Section E** of this policy to email the final memo and addendum/addenda to the risk manager and EFED Tracking Team.
 - a. In the logout email, reference the MRID, file name, and file path of the old DER .pdf that will be replaced and request its deletion.
 - b. Attach the updated DER .pdf file and MS Word version of the addendum to the email and send to the EFED Tracking Team, memo recipients, reviewers, and authors.

G. Archive Corrections

Corrections to the final file archives should be directed to the archive manager. Currently, Dewillsee Parsons manages the SAN drive and Documentum archives. Lisa Eisenhower manages the CETIS database archives. The EISB Branch Chief manages the EFED Tracking Team. Corrections may also be directed to a RAPL who will forward the request to the current contact.

APPENDIX A. Optional Recommended Memorandum Cover Page Format

When writing memoranda (ecological risk assessments, DWAs, DER transmittal memos, RTWRs, RTCs, *etc.*), the attached example cover page format should be used as a template. The example stops at the “TO” block for most documents and continues to Table 1 for DER transmittal memos. This format follows the recommendations in the EPA Correspondence Manual¹⁷ in order to increase consistency and professional appearance across EFED documents.

- Memo elements should be ordered SUBJECT > FROM > THRU > TO. “THRU” should not be replaced by “Approved by” or “Reviewed by”. All reviewers are required to sign the memo in the “THRU” element.
- The date (not in bold) should be centered two lines below the letterhead and two lines above the next element (which is the bolded PC code).
- The bolded, right-adjusted DP barcode(s) are on the “MEMORANDUM” line, directly below the bolded, right-adjusted PC code(s).
- The subject should begin with the active ingredient name(s) and colon in bold, then a non-bolded brief document title (*e.g.*, **Dilithium silicate**: Drinking Water Exposure Assessment for Proposed New Uses on Crop Group 19).
- “Office of Pesticide Programs” isn’t needed in the addresses (The AAship is already in the letterhead). For internal memoranda, the acronym of the branch and division may be used when necessary to save space.

Example memo cover page format:



056065_419211+_D
ER-Memo_1-5-17-exi

¹⁷ EPA Correspondence Manual address: <http://workplace.epa.gov/manual/memorandums.html>

The contents of the attached example memo cover page format appear as follows:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 5, 2017

PC Code: 056065

MEMORANDUM

DP Barcodes: 419211, 425786, 425787

SUBJECT: Dilithium Silicate: Transmittal of Data Evaluation Records (DER) for Ecological Effects Studies

FROM: Ace Reviewer, Biologist
Environmental Risk Branch 1
Environmental Fate and Effects Division (7507P)

THRU: Insightful Leader, Branch Chief
Helpful Teammate, Risk Assessment Process Leader
Environmental Risk Branch 1
Environmental Fate and Effects Division (7507P)

TO: Brilliant Colleague, Chemical Review Manager
Prescient Leader, Branch Chief
Risk Management and Implementation Branch 1
Pesticide Re-Evaluation Division (7508P)

This memorandum is to inform you that four DERs are finalized for ecological effects studies of dilithium silicate. Study MRIDs and classifications are listed in **Table 1** below.

Table 1. Ecological Effects Studies of Dilithium Silicate

MRID	OCSPP Guideline	Study Type	Study Classification	CETIS Flags ^A	Current Additional Data Need
49998221	850.2100	Avian acute oral	Unacceptable	NO (1 of 1)	Guideline-compliant study
49998222	850.4100	Seedling emergence	Supplemental	CO* (7 of 10), AT* (3 of 10)	Guideline-compliant study of two additional dicots
49998223	850.3020 & Non-guideline	Honeybee adult acute contact and oral	Acceptable	NO (1 of 3), AT (2 of 3)	None
49998224	Non-guideline / OECD 75	Semi-field testing for pollinators (tunnel study)	Supplemental	NA	None

^A CETIS flags include the following codes followed by the number of CETIS records (*i.e.*, test codes) for each flag and the total number of potential CETIS records for the study (*e.g.*, “AT (2 of 3)”):

“CO” – the contractor’s CETIS records were not altered.

“AT” – a CETIS database file is attached to the logout email because the contractor’s CETIS records were updated or new CETIS records were created.

“NO” – CETIS records do not exist for at least one statistical analysis in this study for which a CETIS data template is available.

“NA” – A CETIS data template is not available for this study type.

“*” – Indicates for “CO” and “AT” flags that at least one regulatory endpoint in the DER differs from that concluded in the CETIS statistical output.

<This example memorandum cover page format should be used as a template for all EFED memoranda. The example stops at the “TO” block for most documents. This format follows the recommendations in the EPA Correspondence Manual in order to increase consistency and professional appearance across EFED documents. The example continues to **Table 1** for DER transmittal memos. However, **Table 1** is not a prescriptive format. Alternate formats for **Table 1** may be used if they include the fields shown at a minimum. The “CETIS Flags” table column and footnote are used only for effects studies.>

<DER transmittal memos should indicate whether additional data are needed following the review of the studies listed in **Table 1**. This should be done in the “Current Additional Data Need” column of **Table 1**, or by appending updated data gap tables. A brief statement above the table may be added, as needed, to further explain the data need. These memos may also indicate whether the new DERs impact past assessments, as needed.>

APPENDIX B. Example Format for Logout Emails

An example logout email follows:

To: OPP EFED Tracking Team OPP_EFED_Tracking_Team@epa.gov; RD Risk Manager; RD TL; RD BC

Cc: EFED coauthors; EFED reviewers; EFED RAPL; EFED BC

Subject: For logout: dilithium silicate eco DERs

Attached: 056065_123456+_DER-Memo_6-7-17.pdf; 056065_123456+_DER-Memo_6-7-17.docx; 056065_4000001_DER-Eco_850.1075_6-7-17.pdf; 056065_4000001_DER-Eco_850.1075_6-7-17.docx; 056065_4000011_DER-Eco_850.1010_6-7-17.pdf; 056065_4000011_DER-Eco_850.1010_6-7-17.docx; 056065_4000012_DER-Eco_850.1035_6-7-17.pdf; 056065_4000012_DER-Eco_850.1035_6-7-17.docx; 2017-03-06 056065 Dilithium silicate CETIS (Smith) (1).zip

Hello,

Attached for archiving are 2 eco DERs, 1 eco DER addendum, and a transmittal memo for dilithium silicate (PC 056065, DP 123456+).

The DER addendum supersedes the DER for MRID 4000001 in Documentum <provide file name of superseded DER> and on the SAN drive at <provide filepath of superseded DER>. Please delete the superseded versions of the DER.

Best regards,
EFED Reviewer

APPENDIX C. DER Addenda Templates

Example DER Addenda templates are attached.



DER-Eco_Addendum_Generic.docx



DER-Fate_Addendum_Generic.docx

APPENDIX D. OCSP Guideline Numbers

835 – Fate, Transport, and Transformation Guidelines

Group A – Laboratory Transport Test Guidelines

835.0001 - Principles and Strategies Related to Biodegradation Testing of Organic Chemicals under the Toxic Substances Control Act (TSCA) (November 2008)

835.1110 - Activated Sludge Sorption Isotherm (January 1998)

835.1210 - Soil Thin Layer Chromatography (January 1998)

835.1220 - Sediment and Soil Adsorption/Desorption Isotherm (January 1998)

835.1230 - Adsorption/Desorption (Batch Equilibrium) (November 2008)

835.1240 - Leaching Studies (November 2008)

835.1410 - Laboratory Volatility (November 2008)

Group B – Laboratory Abiotic Transformation Test Guidelines

835.2120 - Hydrolysis (November 2008)

835.2130 - Hydrolysis as a Function of pH and Temperature (January 1998)

835.2210 - Direct Photolysis Rate in Water by Sunlight (January 1998)

835.2240 - Photodegradation in Water (November 2008)

835.2310 - Maximum Direct Photolysis Rate in Air from UV/Visible Spectroscopy (January 1998)

835.2370 - Photodegradation in Air (November 2008)

835.2410 - Photodegradation in Soil (November 2008)

Group C – Laboratory Biological Transformation Test Guidelines

835.3100 - Aerobic Aquatic Biodegradation (January 1998)

835.3110 - Ready Biodegradability (January 1998)

835.3140 - Ready Biodegradability – CO₂ in Sealed Vessels (Headspace Test) (November 2008)
[SUPERSEDES 3120]

835.3160 - Biodegradability in Sea Water (January 1998)

835.3170 - Shake Flask Die-Away Test (January 1998)

835.3180 - Sediment/Water Microcosm Biodegradation Test (January 1998)

835.3190 - Aerobic Mineralization in Surface Water – Simulation Biodegradation Test (October 2008)

835.3200 - Zahn-Wellens/EMPA Test (January 1998)

835.3210 - Modified SCAS Test (January 1998)

835.3215 - Inherent Biodegradability – Concawe Test (October 2008)

835.3220 - Porous Pot Test (January 1998)

835.3240 - Simulation Test – Aerobic Sewage Treatment: A. Activated Sludge Units (October 2008)

835.3260 - Simulation Test – Aerobic Sewage Treatment: B. Biofilms (October 2008)

835.3280 – Simulation Tests to Assess the Primary and Ultimate Biodegradability of Chemicals Discharged to Wastewater (October 2008)

835.3300 - Soil Biodegradation (January 1998)

835.3400 - Anaerobic Biodegradability of Organic Chemicals (January 1998)

835.3420 - Anaerobic Biodegradability of Organic Compounds in Digested Sludge: By Measurement of Gas Production (October 2008)

Group D – Transformation in Water and Soil Test Guidelines

- 835.4100 - Aerobic Soil Metabolism (October 2008)
- 835.4200 – Anaerobic Soil Metabolism (October 2008)
- 835.4300 - Aerobic Aquatic Metabolism (October 2008)
- 835.4400 – Anaerobic Aquatic Metabolism (October 2008)

Group E – Transformation Chemical-Specific Test Guidelines

- 835.5045 - Modified SCAS Test for Insoluble and Volatile Chemicals (January 1998)
- 835.5154 - Anaerobic Biodegradation in the Subsurface (January 1998)
- 835.5270 - Indirect Photolysis Screening Test: Sunlight Photolysis in Waters Containing Dissolved Humic Substances (January 1998)

Group F – Field Dissipation Test Guidelines

- 835.6100 - Terrestrial Field Dissipation (October 2008)
- 835.6200 - Aquatic (Sediment) Field Dissipation (October 2008)
- 835.6300 - Forestry Dissipation (October 2008)
- 835.6400 - Combination and Tank Mixes Field Dissipation (October 2008)

Group G – Ground Water Monitoring Test Guidelines

- 835.7100 - Guidance for Prospective Ground-Water Monitoring Studies

Group H – Volatility from Soil Test Guidelines

- 835.8100 - Field Volatility (November 2008)

840 – Spray Drift Test Guidelines

- 840.1000 - Background for Pesticide Aerial Drift Evaluation (March 1998)
- 840.1100 - Spray Droplet Size Spectrum (March 1998)
- 840.1200 - Spray Drift Field Deposition (March 1998)

850 – Ecological Effects Test Guidelines

Group A – Aquatic Fauna

- 850.1010 – Aquatic Invertebrate Acute Toxicity, Test, Freshwater Daphnids
- 850.1020 – Gammarid Acute Toxicity Test
- 850.1025 – Oyster Acute Toxicity Test (Shell Deposition)
- 850.1035 – Mysid Acute Toxicity Test
- 850.1045 – Penaeid Acute Toxicity Test
- 850.1055 – Bivalve Acute Toxicity Test (Embryo Larval)
- 850.1075 – Fish Acute Toxicity Test, Freshwater and Marine
- 850.1085 – Fish Acute Toxicity Mitigated by Humic Acid
- 850.1300 – Daphnid Chronic Toxicity Test
- 850.1350 – Mysid Chronic Toxicity Test
- 850.1400 – Fish Early-Life Stage Toxicity Test
- 850.1500 – Fish Life Cycle Toxicity

850.1710 – Oyster BCF
850.1730 – Fish BCF
850.1735 – Whole Sediment Acute Toxicity Invertebrates, Freshwater
850.1740 – Whole Sediment Acute Toxicity Invertebrates, Marine
850.1790 – Chironomid Sediment Toxicity Test
850.1800 – Tadpole/Sediment Subchronic Toxicity Test
850.1850 – Aquatic Food Chain Transfer
850.1900 – Generic Freshwater Microcosm Test, Laboratory
850.1925 – Site-Specific Aquatic Microcosm Test, Laboratory
850.1950 – Field Test for Aquatic Organisms

Group B – Terrestrial Wildlife

850.2000 - Background and Special Considerations- Tests with Terrestrial Wildlife (June 2012)
850.2100 - Avian Acute Oral Toxicity Test (June 2012)
850.2200 - Avian Dietary Toxicity Test (June 2012)
850.2300 - Avian Reproduction Test (June 2012)
850.2400 - Wild Mammal Toxicity Testing (June 2012)
850.2500 - Field Testing for Terrestrial Wildlife (June 2012)

Group C – Terrestrial Beneficial Insects, Invertebrates, and Soil and Wastewater Microorganisms

850.3000 - Background and Special Considerations- Tests with Terrestrial Beneficial Insects, Invertebrates and Microorganisms (June 2012)
850.3020 - Honey Bee Acute Contact Toxicity Test (June 2012)
850.3030 - Honey Bee Toxicity of Residues on Foliage (June 2012)
850.3040 - Field Testing for Pollinators (June 2012)
850.3100 - Earthworm Subchronic Toxicity Test (June 2012)
850.3200 - Soil Microbial Community Toxicity Test (June 2012)
850.3300 - Modified Activated Sludge, Respiration Inhibition Test (June 2012)

Group D – Terrestrial and Aquatic Plants, Cyanobacteria, and Terrestrial Soil Core Microcosm

850.4000 - Background and Special Considerations-Tests with Terrestrial and Aquatic Plants, Cyanobacteria, and Terrestrial Soil-Core Microcosms (June 2012)
850.4100 - Seedling Emergence and Seedling Growth (June 2012)
850.4150 - Vegetative Vigor (June 2012)
850.4230 - Early Seedling Growth Toxicity Test (June 2012)
850.4300 - Terrestrial Plants Field Study (June 2012)
850.4400 - Aquatic Plant Toxicity Test Using Lemna spp. (June 2012)
850.4450 - Aquatic Plants Field Study (June 2012)
850.4500 - Algal Toxicity (June 2012)
850.4550 - Cyanobacteria (Anabaena flos-aquae) Toxicity (June 2012)
850.4600 - Rhizobium-Legume Toxicity (June 2012)
850.4800 - Plant Uptake and Translocation Test (June 2012)
850.4900 - Terrestrial Soil-Core Microcosm Test (June 2012)

Group F – Field Test Data Reporting Guidelines

850.6100 - Environmental Chemistry Methods and Associated Independent Laboratory Validation (June 2012)

890 – Endocrine Disruptor Screening Program Test Guidelines

890.1100 – Amphibian Metamorphosis (Frog)

890.1150 – Androgen Receptor Binding (Rat Prostate)

890.1200 – Aromatase (Human Recombinant)

890.1250 – Estrogen Receptor Binding

890.1300 – Estrogen Receptor Transcriptional Activation (Human Cell Line HeLa-9903)

890.1350 – Fish Short-Term Reproduction

890.1400 – Hershberger (Rat)

890.1450 – Female Pubertal (Rat)

890.1500 – Male Pubertal (Rat)

890.1550 – Steroidogenesis (Human Cell Line – H295R)

890.1600 – Uterotrophic (Rat)

OECD Test Guidelines

Test No. 209 – Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation) – 23 Jul 2010

Test No. 213 – Honeybees, Acute Oral Toxicity Test – 21 Sept 1998

Test No. 223 – Avian Acute Oral Toxicity Test – 23 July 2010

Test No. 229 – Fish Short Term Reproduction Assay – 02 Oct 2012

Test No. 231 – Amphibian Metamorphosis Assay – 08 Sept 2009

Test No. 237 – Honeybee (*Apis mellifera*) Larval Toxicity Test, Single Exposure – 26 July 2013

Test No. 305 – Bioaccumulation in Fish: Aqueous and Dietary Exposure – 02 Oct 2012

Test no. 315 – Bioaccumulation in Sediment-dwelling Benthic Oligochaetes – 16 Oct 2008

For non-guideline studies that do not fall under any of the categories above, use the guideline designator “NG” followed by a short description of the study. Chronic sediment studies use the guideline designator “NG-chronicsediment” rather than guidelines in preparation or guidelines from entities other than OCSPP.

- *e.g.*, 060109_46907718_DER-Eco_NG-Parasitic-Wasp_1-9-15.pdf
- *e.g.*, 084301_49551201_DER-ECO_NG-chronicsediment_09-14-16.pdf

Appendix E. Acronyms and Definitions

Acronyms¹⁸

BC – Branch Chief

CETIS – Comprehensive Ecological Toxicity Information System - the statistical analysis program and database currently used for ecological toxicity study DERs

CBI – Confidential Business Information

DER – Data Evaluation Record

DP Barcode – Data Package Barcode – code specific to a Bean

DRT – Drift Reduction Technology

EFED – Environmental Fate and Effects Division

EISB – EFED Information and Support Branch

ERB – Environmental Risk Branch

IT/IM – Information technology and information management

MRID – Master Record Identifier – 8-digit code used for studies and reports submitted to OPP

NG – Non-guideline

OPP – Office of Pesticide Programs

OPPIN – Office of Pesticide Programs Information Network – an OPP database in which Beans are tracked

OCSPP – Office of Chemical Safety and Pollution Prevention

PC Code – Product Chemistry Code (formerly Shaughnessy Code) – OPP 6-digit code specific to an active ingredient

RAPL – Risk Assessment Process Leader

RQ – Risk Quotient

SAN – Shared Area Network

¹⁸ Action Codes are tabulated on page 5.

Definitions

Action Code – a code used to classify EFED memoranda

Bean – a formal request for action from a risk manager that is tracked with a DP barcode

CETIS Sandbox – EFED’s CETIS front-end for creating new or updating existing CETIS records. CETIS records that are created in the Sandbox are not included in the CETIS master database, unless the CETIS database file is submitted to the EFED Tracking Team with a finalized DER.

Documentum – OPP’s central storage database



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 26, 2017

EFED Management Concurrence Form

Policy or Guidance: Electronic Document (e-Document) Management Policy Update

By signing below, the EFED management team acknowledges that we are aware of the content and implications of the associated guidance or policy, we, or our designated expert, have participated in discussions surrounding this policy or guidance; and we are responsible for ensuring that the guidance is followed from the date of this signature and thereafter.

<i>Sankula, Sujatha</i>	Digitally signed by Sankula, Sujatha Date: 2017.09.27 07:17:05 -04'00'	09/27/2017
ERB1. Sujatha Sankula		Date
<i>Philip Villanueva</i>	PHILIP VILLANUEVA 2017.09.27 08:19:43 -04'00'	09/27/2017
ERB2. Phil Villanueva (Acting)		Date
<i>Dana Spatz</i>	2017.09.27 08:31:18 -04'00'	09/27/2017
ERB3. Dana Spatz		Date
<i>Holmes, Jean</i>	Holmes, Jean 2017.10.05 10:44:49 -04'00'	10/05/2017
ERB4. Jean Holmes		Date
<i>Elyssa Arnold</i>	2017.10.09 11:34:27 -04'00'	10/09/2017
ERB5. Elyssa Arnold (Acting)		Date
<i>Mark Corbin</i>	Digitally signed by MARK CORBIN Date: 2017.10.10 10:43:30 -04'00'	10/10/2017
ERB6. Mark Corbin		Date
<i>Nelson Thurman</i>	Digitally signed by NELSON THURMAN Date: 2017.10.10 11:09:05 -04'00'	10/10/2017
EISB. Nelson Thurman (Acting)		Date
<i>Kimberly Nesci</i>	Digitally signed by KIMBERLY NESCI Date: 2017.10.11 19:38:00 -04'00'	10/11/2017
Deputy Director. Kimberly Nesci		Date
<i>Brian Anderson</i>	2017.10.16 10:44:53 -04'00'	10/16/2017
Associate Director. Brian Anderson (Acting)		Date