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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DEC 2 0 2012

MEMORANDUM

SUBJECT: Environmental Chemistry Methods Guidance

FROM: Donald J. Brady, Ph.D., Director
Environmental Fate and Effects Division (7507P)
Office of Pesticide Programs

TO: Environmental Fate and Effects Division (7507P)
Office of Pesticide Programs

The purpose of this guidance, which is effective immediately, is to provide uniform procedures for processing environmental chemistry methods (ECM) in the Environmental Fate and Effects Division (EFED). This guidance supersedes the Standard Operating Procedure (SOP) for the Tracking, Reviewing, and Archiving of Environmental Chemistry Methods and the Standard Evaluation Procedure (SEP) for Reviewing Environmental Chemistry Methods, including its attachments, both dated December 1, 2010 and released to EFED on February 24, 2011. The ECM review template and review checklist that were attached to the ECM SEP are superseded by the ECM/ILV Report Review Guide provided separately.

This guidance was developed by the ECM Workgroup. For further information, please contact Greg Orrick or other workgroup members.

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A. Scope and Application

Validated analytical methods in environmental media (*i.e.*, environmental chemistry methods (ECM)) are useful for conducting and evaluating submitted environmental fate and toxicity field and monitoring studies and for addressing potential risks to the environment posed by the use and/or accidental release of pesticides. ECMs are routinely submitted to the Environmental Fate and Effects Division (EFED) of the Office of Pesticide Programs (OPP) in accordance with data reporting guidelines for environmental field studies. Most submitted ECMs apply to residues in soil or water, but ECMs are also submitted that apply to residues in other environmental compartments, such as sediment, air, plants, or other nontarget organisms.[1]

As part of their review process, EFED may ask the Environmental Chemistry Branch (ECB) of the Biological and Economic Analysis Division (BEAD) to examine the suitability of an ECM through a validation process. This validation process consists of a review of the ECM and the independent laboratory validation (ILV) documentation, and in some cases, may also involve a laboratory evaluation of the ECM when this appears necessary to BEAD ECB and EFED.

This guidance describes EFED procedures and criteria related to requesting, reviewing, archiving, posting, and updating ECM reports and associated ILV reports, as well as identifying which ECMs should be referred to BEAD ECB for validation. The procedures followed by BEAD ECB for ECM review, tracking, and laboratory evaluation are defined in separate BEAD ECB standard operating procedures (SOP) and standard evaluation procedures (SEP) (USEPA, 2005; 2003; and 2005a, respectively). The procedures in this guidance are intended to increase uniformity in processing and reviewing ECMs in EFED. However, professional judgment should be used to identify when there is a compelling reason to deviate from this guidance.

[1] Analytical methods for plants are also submitted to the Health Effects Division (HED), as they review analytical methods for target organisms, including plants and livestock. However, HED's procedures are not within the scope of this guidance.

B. Summary of Method

The purpose of this guidance is to standardize in EFED the following sequence of steps and criteria:

- Identify submitted and/or available ECM reports and ILV reports;
- Request ECMs to address data needs;
- Determine the acceptability of submitted ECM reports;
- Identify ECMs that should be reviewed or laboratory-validated by BEAD ECB;
- Coordinate with BEAD ECB for ECM review and validation, when necessary;
- Coordinate data requests with the Registration Division (RD) or Pesticide Re-evaluation Division (PRD) to address ECM-related deficiencies;
- Archive ECM reviews; and
- Provide ECMs for public posting.

In order to support registration actions and registration review, division scientists should ensure that relevant ECM reports and associated ILV reports regarding their assigned pesticides are submitted, reviewed, and found acceptable for the residues of concern, if defined. Acceptable ECMs for the residues of concern should have limits of quantitation (LOQ) that are adequate to address risk concerns. Chiral-specific ECMs should be available for isomers of concern except when the active ingredient is a racemic mixture and its isomers are similar in toxicity (Ulrich *et al.*, 2012).

Registrants are required to submit both ECM reports and associated ILV reports in order to support studies required in the Code of Federal Regulations (CFR) for a particular use pattern (40 CFR Part 158). These studies are categorized as follows:

- Field testing for nontarget organisms (§158.630; OCSPP guidelines 850.1950 and 850.2500);
- Tier III phytotoxicity, (§158.660; OCSPP guidelines 850.4300 and 850.4450);
- Field dissipation (§158.1300; OCSPP guidelines 835.6100, 835.6200, and 835.6300); and
- Ground water monitoring (§158.1300; OCSPP guideline 835.7100).

However, to address special concerns, registrants may be required to submit data beyond the data requirements published in the CFR [FIFRA §3(c)(2)]. These additional data may include ECM and ILV reports associated with studies that are not listed as data requirements in the CFR for a particular use pattern. ECMs and ILVs fall under OCSPP guideline 850.6100; however, this guideline is not currently cited in the CFR.

ECMs in soil and in water should be submitted as part of the registration package for all new chemicals with proposed outdoor uses and for new chemicals with no proposed outdoor uses if outdoor exposure is likely. This means that the registration package should include an ECM in water regardless of whether the proposed uses require an aquatic field dissipation study or a ground water monitoring study. Also, ECMs in soil, water, and other media should be requested as needed for chemicals in registration review to support submitted studies or probable monitoring efforts when submitted data are unavailable or inadequate.

It is noted that monitoring after an incident can be problematic because residues may dissipate to concentrations below the LOQ following an incident that is caused by concentrations above the LOQ. (LOQs should be below toxicological levels of concern that are based only on doses prior to dissipation.) Factors that may contribute to reduced analyzed concentrations include the rate of dissipation, including degradation, the speed of effects on organisms, the speed at which the incident is reported, and the speed of the response to the report, including the speed of analysis.

The procedures in this guidance are organized into three sections, as follows:

D.1. How to address ECMs in support of registration;
D.2. How to address ECMs in support of registration review; and
D.3. How to review ECMs, request BEAD ECB validation, and archive reviews.

C. Definitions

Terms and acronyms used in this guidance include:

a.i.—Active ingredient
BEAD—The Biological and Economic Analysis Division of the Office of Pesticide Programs
COR—Contracting Officer's Representative
CFR—Code of Federal Regulations
DCI—Data Call-In
DER—Data Evaluation Record
DP barcode—Data Package barcode; used to track work in the Office of Pesticide Programs.
ECB—Environmental Chemistry Branch, a branch within BEAD located at the Environmental Chemistry Laboratory in Bay St. Louis, Mississippi
ECM—Environmental chemistry method; analytical method for residues in an environmental medium
EFED—The Environmental Fate and Effects Division of the Office of Pesticide Programs
EISB—The Environmental Information and Support Branch, a branch within EFED
FIFRA—The Federal Insecticide, Fungicide, and Rodenticide Act (7 USC §136a)
HED— The Health Effects Division of the Office of Pesticide Programs
ILV—Independent laboratory validation
LOD—Limit of detection; the minimum concentration of a substance that can be distinguished from a method blank within a specific confidence bound using a particular analytical method.
LOQ—Limit of quantitation; the minimum concentration of a substance that can be distinguished from other concentrations within a specific confidence bound using a particular analytical method.
Matrix blank—*a.k.a.*, control matrix, sample blank; a sample containing the analyzed environmental medium that is analyzed to evaluate interference resulting from the sampled medium that is distinct from procedural noise.
Matrix spike—*a.k.a.*, fortified control sample; a sample containing the analyzed environmental medium that is spiked with the target analyte and analyzed in order to calibrate the analytical method.
Method blank—*a.k.a.*, reagent blank; a sample containing only the analytical method reagent(s) that is(are) analyzed to evaluate noise resulting from the analytical method procedure.

MDL—Method Detection Limit; the minimum concentration of a substance that can be identified, measured, and reported as greater than zero with 99% confidence as determined from replicate analyses of a sample using a particular analytical method. Sample types range from spiked method blanks to wastewater containing the substance.

MRID—Master Record Identification Number; assigned to all studies and reports submitted to the Office of Pesticide Programs.

MRM—Multi-residue method

New Chemical Screen—A screen of submitted studies prior to their review in order to identify potential data gaps in the submission package

OCSPP—The Office of Chemical Safety and Pollution Prevention

OPP—The Office of Pesticide Programs

OPPIN—Office of Pesticide Programs Information Network

OPPIN Query—A web-based query interface for OPPIN

PRD—The Pesticide Re-evaluation Division of the Office of Pesticide Programs

QA—Quality assurance

RAPL—Risk Assessment Process Leader

RD—The Registration Division of the Office of Pesticide Programs

RSD—Relative standard deviation

SD—Standard deviation

Section 3—Section 3 of FIFRA that regulates the registration of pesticides

SOP—Standard operating procedure

Toxicity endpoint—A measurable biological effect that will or will not occur for a stated proportion of a species-specific population (*e.g.*, a mallard LD_{50})

Toxicity value—A chemical concentration associated with a toxicity endpoint

Toxicological level of concern—A toxicity value multiplied by a corresponding risk level of concern (*e.g.*, an aquatic life benchmark)

D. Procedures

D.1. How to Address ECMs in Support of Registration

1. Follow this part of the procedure for Section 3 New Chemical actions with proposed outdoor uses and with no proposed outdoor uses if outdoor exposure is likely. Also follow this part of the procedure for Section 3 New Use actions when the proposed use involves the first outdoor use of the active ingredient, and for Section 3 New Use actions when the proposed use is indoors, the use is expected to result in introductions into the outdoor environment, and the chemical is not currently registered for outdoor uses. ECMs may be addressed during registration review in the case of Section 3 New Use actions that follow earlier actions that involved outdoor uses or expected introductions into the outdoor environment.

Locating Submitted ECM Documentation

2. Review the active ingredient's MRID bibliography in OPPIN Query[2] for submitted ECM reports and ILV reports. They may be found under a variety of guideline numbers.

3. Make sure that reports for at least one ECM for soil and at least one ECM for water have been submitted for the active ingredient along with their corresponding ILV reports. ECM reports are separate from their associated ILV reports, *i.e.*, the ILV report does not contain the ECM report.

    a. In cases in which the initial validation was performed by a governmental agency, a reference to the agency's documentation of the ECM will serve as the ECM report. More specifically, if the applicant submits an ILV report and documentation of the agency's ECM, the initial validation report for the ECM does not need to be submitted.

    b. In cases in which the initial validation was performed by a private entity, the current applicant needs to submit two reports of performance data, as usual, one for the initial or other internal validation and one for the ILV.

4. Use **Section D.3** of this guidance to review paired ECM and ILV reports and move on to **Step 5**.

Determining Data Gaps

5. Use this step when the risk assessments are nearing finalization in order to determine whether submitted ECMs are adequate to address risk concerns.

    a. If there is a risk concern for an assessed taxon, ECMs should be available for the environmental media in which organisms of the taxon reside. These ECMs should have limits of quantitation for the residues of concern that are lower than the relevant toxicological levels of concern.

        i. Ask the biologist working on the chemical for its lowest toxicological levels of concern for aquatic organisms (*i.e.*, aquatic life benchmarks) and, if established, for terrestrial organisms (in terms of soil concentrations). Toxicological levels of concern are produced by multiplying the lowest toxicity values for organisms by the relevant risk levels of concern (LOC), which are 0.5 for acute risk to animals and 1.0 for chronic risk to animals and for risk to plants.

        ii. If the lowest toxicological level of concern in water is below the LOQ(s) of the available ECM(s) in water, the ECM(s) is/are not adequate to address the risk concern.

[2] https://w2032pcctr562.aa.ad.epa.gov:8080/pls/prism10p_open/opp_open.open_page

iii. If the lowest toxicological level of concern in soil, if any, is below the LOQ(s) of the available ECM(s) in soil, the ECM(s) is/are not adequate to address the risk concern.

1. A 6-inch soil depth and the density of the soil in the ecotoxicity study are used to convert units of mass/area to mass/mass, *e.g.*, lbs a.i./acre to mg a.i./kg soil.[3] The 6-inch soil depth is a default to use unless there is a reason to use an alternative depth.

iv. If the chemical is expected to predominantly partition to sediment and the lowest toxicological level of concern in aquatic sediment is below the LOQ(s) of the available ECM(s) in sediment, the ECM(s) is/are not adequate to address the risk concern.

b. If the Health Effects Division (HED) has identified a dietary risk concern driven by drinking water, an ECM in water should be available with a limit of quantitation for the residues of concern that is lower than any drinking water level of concern (whether deterministic or estimated via back-calculation).

c. If all residues of toxicological concern are not included as analytes in the available ECMs, ECMs should be requested for the residues of toxicological concern that are not analytes.

Following Up on Data Gaps

6. If an ECM report(s) for water or soil (or, in some cases, sediment) and/or an associated ILV report is/are missing and/or a submitted ECM(s) is/are inadequate to address risk concerns, identify the data gap(s) in the risk assessment memoranda and contact the risk manager to request submission of the needed report(s).

    a. When waiting for a requested ECM and/or ILV report, follow up with the risk manager, periodically if necessary, to confirm whether the registrant has been asked for the data and to confirm the expected submission date.

D.2. How to Address ECMs in Support of Registration Review

Determining a Need for ECMs

1. Use this step to determine which ECMs should be requested for the registration review of the pesticide.

[3] *E.g.*, [1 lb a.i./acre] × [1/6 inches] × [1/1.5 kg/L] × [4.54 (10^5) mg/lb] × [3.94 inches/dm] × [2.47 (10^{-6}) acres/dm^2] = [0.5 mg a.i./kg soil]. *I.e.*, assuming a 6-inch soil depth and a 1.5 kg/L soil density, [X lbs a.i./acre] = [0.5X mg a.i./kg soil].

a. If there is risk concern for an assessed taxon, ECMs should be available for the environmental media in which organisms of the taxon reside. These ECMs should have limits of quantitation for the residues of concern that are lower than the relevant toxicological levels of concern.

   i. Ask the biologist working on the chemical for its most recent lowest toxicological levels of concern for aquatic organisms (*i.e.*, aquatic life benchmarks) and, if established, for terrestrial organisms (in terms of soil concentrations). Toxicological levels of concern are produced by multiplying the lowest toxicity values for organisms by the relevant risk levels of concern (LOC), which are 0.5 for acute risk to animals and 1.0 for chronic risk to animals and for risk to plants.

      1. Toxicological levels of concern for aquatic organisms may be listed on OPP's aquatic life benchmark website.[4]

      2. If not, they may be obtained from the lowest toxicity values for aquatic organisms in the most recent assessment for the chemical.

   ii. If the lowest toxicological level of concern in water is below the LOQ(s) of the available ECM(s) in water, the ECM(s) is/are not adequate to address the risk concern.

   iii. If the lowest toxicological level of concern in soil, if any, is below the LOQ(s) of the available ECM(s) in soil, the ECM(s) is/are not adequate to address the risk concern.

      1. A 6-inch soil depth and the density of the soil in the ecotoxicity study are used to convert units of mass/area to mass/mass, *e.g.*, lbs a.i./acre to mg a.i./kg soil.[5] The 6-inch soil depth is a default to use unless there is a reason to use an alternative depth.

   iv. If the chemical is expected to predominantly partition to sediment and the lowest toxicological level of concern in aquatic sediment is below the LOQ(s) of the available ECM(s) in sediment, the ECM(s) is/are not adequate to address the risk concern.

b. If the Health Effects Division (HED) has identified a dietary risk concern driven by drinking water, an ECM in water should be available with a limit of quantitation for the residues of concern that is lower than any drinking water level of concern (whether deterministic or estimated via back-calculation).

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[4] http://www.epa.gov/oppefed1/ecorisk_ders/aquatic_life_benchmark.htm

[5] *E.g.*, [1 lb a.i./acre] × [1/6 inches] × [1/1.5 kg/L] × [4.54 (10^5) mg/lb] × [3.94 inches/dm] × [2.47 (10^{-6}) acres/dm^2] = [0.5 mg a.i./kg soil]. *I.e.*, assuming a 6-inch soil depth and a 1.5 g/mL soil density, [X lbs a.i./acre] = [0.5X mg a.i./kg soil].

c. If all residues of toxicological concern are not included as analytes in the available ECMs, ECMs should be requested for the residues of toxicological concern that are not analytes.

d. If incident data or other compelling information indicate a need for an ECM, an ECM may be requested for the relevant environmental medium.

e. Use of the above criteria to identify a need under registration review for any ECM is independent of the determination of whether ECM documentation is needed to support submitted field studies.

    i. If an acceptable ECM report has not been submitted to support a field study that was conducted as of April 19, 1996 or later, the field study should be classified supplemental or unacceptable until acceptable ECM and ILV documentation is submitted.

        1. Submission of acceptable ECM and ILV documentation may not be needed if other submitted field and ECM data are acceptable and fulfill the data needs under their guideline.

        2. If the same ECM is used to analyze multiple types of an environmental medium such as soil or water, then the method validations should be conducted using the most difficult analytical sample condition for the medium (*e.g.*, a soil of high organic content versus soils of low organic content). If these validations are done, additional performance data are not needed for use of the ECM in less difficult analytical sample conditions (*e.g.*, additional soils of low organic content), including those of separate field studies.

    ii. Field studies conducted as of April 18, 1996 or earlier do not require supporting ECM reports or ILV reports in order to be acceptable. However, if there is evidence that the ECM used in a study was not adequate, this deficiency should still be noted and could cause the study to be classified as unacceptable or supplemental.

Locating Submitted ECM Documentation

2. Review the active ingredient's MRID bibliography in OPPIN Query for submitted ECM reports and ILV reports. They may be found under a variety of guideline numbers.

3. Look for reviews of ECM reports in soil, in sediment, and in water for the active ingredient in the EFED file room folders and in the on-line ECM Index.[6]

[6] http://www.epa.gov/pesticides/methods/ecmindex.htm

Meeting the Need

4. Determine whether the submitted ECM documentation (found in **Step 2**) is acceptable for the active ingredient's residues of concern (based on the reviews found in **Step 3**) or is expected to be acceptable if it is not reviewed. In addition, determine whether the ECMs meet the requirements for registration review (identified in **Step 1**).

    a. When identifying data needs, consider the method performance needed to address any risk concerns.

        i. In a case where an ECM report is needed to support a field study and it does not meet a risk-concern-based data need, it may not be necessary to request this ECM report (which should contain the same method used in the field study). A report for an ECM that employs the newest and best available technology to address a risk concern should be requested.

    b. If an ECM report and a corresponding ILV report are found that have not been reviewed, use **Section D.3** of this guidance to review them and move on to **Step 5**.

Writing the Problem Formulation

5. Identify the submitted ECM and ILV reports for the active ingredient in the problem formulation and indicate whether they are acceptable, supplemental, upgradeable, unacceptable, or in review.

    a. If submitted ECM documentation is not expected to meet the data needs for registration review, identify needed ECM and ILV reports for soil, water, and/or sediment in the problem formulation.

    b. When identifying needed ECM reports, encourage the registrant to submit state-of-the-art ECMs. When requesting a method to meet a risk-concern-based data need rather than to support a field study, also encourage the registrant to attempt to base the method on an existing multi-residue method (MRM). For example, state: "Submission of an ECM based on an existing multi-residue method is encouraged. Also, state-of-the-art ECMs that can be performed with the least amount of cost and effort are preferred." MRMs are in a variety of locations on-line. One source for MRMs is the National Environmental Methods Index.[7]

[7] https://www.nemi.gov/

D.3. How to Review ECM Documentation, Request BEAD ECB Validation, and Archive Reviews

Reviewing ECM Documentation

1. If an ECM report and its associated ILV report that are in review are not linked by their MRIDs to a DP barcode, ask your RAPL to link them either to an existing bean for review of environmental fate studies, if available, or to a new bean requested from the appropriate risk manager.

2. Prior to conducting a full review, use the following screening questions (2a-f) to determine the ECM and ILV reports' reviewability. If the answer to any of the questions below is "No," the ECM is not reviewable. Document for the risk manager the deficiencies identified in this initial screen and request an acceptable submission. If the answer to all of the questions below is "Yes," then continue to **Step 3**.

    a. Is an ILV report for the ECM available?
    b. Does the ILV validate the ECM without major modifications?
    c. Is there a detailed stepwise description of all ECM procedures?
    d. Were two complete sets of performance data provided, one from the initial validation and one from the independent laboratory validation? Or, in cases in which the initial validation was performed by a governmental agency, was at least a reference to the agency's documentation of the ECM (if not the full method report including performance data) and one complete set of performance data from the registrant's ILV provided?
    e. For the ILV, were at least five spiked samples analyzed at the LOQ and at 10 x LOQ?
    f. For the ECM validation, was the number of spiked samples analyzed at each level at least as many as were analyzed for the ILV?

3. Use the following screening questions (3a-e) to determine whether to conduct the review in EFED. Review of relevant articles in the open literature, such as Stockl *et al.*, 2009 and Stashenko and Martinez, 2004, is recommended in order to gain knowledge of issues and concepts associated with analytical methods and their validations. If the answer to any of the questions below is "Yes," then request review of the method by BEAD ECB (go to **Step 4** of the guidance). If the answer to all of the questions below is "No," then the ECM may be reviewed by EFED, which may include use of a contractor. Use the ECM/ILV Review Guide to conduct the review and skip to **Step 6** of this guidance to finalize the review.

    a. Were difficulties experienced in the ILV?
    b. Does the ECM use new or novel technology?
    c. Are the ILV mean recoveries outside of the acceptable range of 70-120%?
    d. Are the ILV relative standard deviations (RSD) of the replicates greater than 20% at or above the LOQ at each spiking level?
    e. Are there other reasons to question the acceptability of the ECM or to request review by the BEAD ECB?

4. If **Step 3** indicates that review should be conducted by the BEAD ECB or there is another reason to seek BEAD ECB review, submit to the EFED ECB-contact the ECM report, ILV report, and the DP barcode to which they are linked. Request review of the method by the BEAD ECB as well as confirmation of a proposed deadline.

    a. BEAD ECB, in consultation with you, may choose to evaluate the ECM in the laboratory.

    b. If you wish to initiate a request for a laboratory evaluation, you must do so in consultation with your branch chief, the EFED ECB-contact, and BEAD ECB.

5. When the review (or evaluation) is completed by BEAD ECB, a signed electronic copy of a review report will be returned to you by the EFED ECB-contact.

Finalizing ECM Reviews

6. When ready to finalize the DP barcode to which the ECM and ILV reports are linked, submit electronic copies and hard copies of the signed review(s) (*i.e.*, signed by you or by BEAD ECB staff) to the EFED Tracking Team using the procedures for finalizing environmental fate DERs (USEPA, 2002; 2006). (The EFED Tracking Team archives all ECM Reviews regardless of their classification or whether they were conducted within BEAD or EFED.)

Following Up on Reviews

7. If a needed ECM, its documentation, or both are not acceptable, request revised ECM and ILV reports through the appropriate RD or PRD risk manager.

    a. The risk manager should bean the revised ECM report and its associated ILV report to you when they are submitted. Before this occurs, follow up with the risk manager, periodically if necessary, to confirm whether the registrant has been asked to upgrade the ECM documentation and to confirm the expected submission date of the revised reports.

    b. Update the ECM review to reflect the requested revised ECM documentation upon its receipt. If BEAD conducted the initial review, forward the revised reports to the BEAD reviewer(s) and ask for a revised review.

        i. If the revised ECM documentation remains not acceptable, determine whether further revision is necessary to address risk concerns. If BEAD reviewed the method, communicate with the reviewer(s) whether another revision will be pursued.

            1. If further ECM documentation revision is unnecessary to address risk concerns, finalize the ECM review using **Step 6** of this guidance and address the deficiency in the review for any submitted study in which this method was used.

2. If additional revision of the ECM documentation is necessary to address risk concerns, repeat **Step 7** of this guidance.

c. If the risk manager does not request revised ECM documentation or the registrant does not provide the requested revised ECM documentation within a reasonable timeframe, finalize the ECM review using **Step 6** of this guidance and identify any data gaps in the assessment memoranda.

i. If BEAD reviewed the method, notify the reviewer(s) not to expect a revision.

E. References

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