Guidance on Data Compensation

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Guidance on Data Compensation Considerations in Connection with Decisions to Waive Typical Data Requirements

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This guidance is a companion to the "Data Requirements: Guiding Principles" document[1], issued in May, 2013. It is intended to help risk managers in meeting EPA's obligations to ensure applicants and registrants comply with FIFRA's requirements regarding data compensation and exclusive use. This document provides guidance for determining whether data or information might be compensable when used by the Agency in lieu of otherwise required data. Although the focus of this guidance is on circumstances when the Agency makes the determination that a typically required type of study is not required for a specific pesticide, much of this guidance is applicable to registrant-initiated waiver requests.

This guidance provides a brief overview of the "Data Requirements: Guiding Principles" document, an overview of data compensation and exclusive use, examples of circumstances when data or information are and are not compensable, and contacts to help risk managers determine whether data compensation or exclusive use protections are required. This guidance does not address implementation issues such as which Agency action (e.g., issuance of a data call-in (DCI) or final decision) triggers protections of data submitter's interests, nor the mechanism for enforcing protections (e.g., issuing data compensation DCIs or lists of data used). This guidance does not alter any existing policy.

A primary purpose of the "Data Requirements: Guiding Principles" document is to encourage teams to consider all available information and data when performing risk assessments in support of registration and registration review determinations. Pursuant to the guidance, teams should consider, as scientifically appropriate, data submitted by any registrant, including data generated to support different chemicals from the one being reviewed. The potential eligibility of the data for exclusive use or data compensation, by itself, does not preclude EPA from using the best data available when conducting a scientific assessment in support of a regulatory determination under FIFRA.

[1] www.epa.gov/pesticide-registration/guiding-principles-data-requirements.

When making a determination that a guideline or other typically required type of study is not necessary, the evaluation that forms the basis for the decision must be clear (i.e., the data and information relied upon to make the determination and the basis for the conclusion that a particular type of study is not necessary to adequately assess risk). For chemicals undergoing registration review, the rationale should be described in work plans and supporting documentation, risk assessments and/or in the EPA reviews of requests to waive studies required by Part 158 or through a DCI. For registration decisions, the rationale should be described in the supporting risk assessments and/or in the EPA review of waiver requests. The determination may be based on studies submitted by other registrants in support of registrations for other active ingredients. In cases where existing data were relied upon to make the determination that a study is not required, each study deemed necessary to support that determination must be clearly indentified. The ownership of a study rarely affects whether EPA may rely on the data in scientific assessments. However, the Agency's reliance on data previously submitted by another registrant to satisfy EPA registration, reregistration or registration review data requirements for another applicant or registrant may give rise to data compensation and exclusive use requirements.

Registrants may be entitled to both "data compensation" and "exclusive use" protections for data submitted in support of their registration. "Data compensation" refers to a registrant financially compensating the data submitter for the right to rely on the data to support their own registration. "Exclusive use" is a higher form a protection that gives the data submitter the right to refuse permission for the Agency to rely on its data in support of another entity's registration(s). Because exclusive use treatment only applies to data submitted to support the first registration for an active ingredient, it is unlikely to apply during reevaluations of chemicals. Generally, studies submitted to support or maintain a FIFRA registration are compensable for a period of 15 years from the date of submission to EPA. The period for exclusive use treatment commences with EPA's registration of the initial product containing a previously unregistered active ingredient and runs for a period of 10 years (with a potential for extensions of up to 3 years with the addition of minor uses). In the rare event that EPA relies on a study entitled to exclusive use treatment in support of another registration, the data submitter must provide written permission prior to its use for

decision making. However, the risk management divisions need to be aware that the Agency might have used a study that is entitled to exclusive use treatment to support a decision not to require other data. Since most situations that chemical teams encounter will involve data compensation rather than exclusive use protection, the rest of this document usually refers only to compensability.

EPA staff making the determination that a particular type of study is not needed must identify all of the information used, and explain how it was used, to make the determination. The risk management divisions, working in consultation with the Office of General Counsel (OGC) as needed, will be responsible for documenting what information and data support a registration and what compensation or permission is required. It is imperative that risk management divisions are consistent in how they implement these requirements for registrations actions and re-evaluation. Below are examples of situations that risk management divisions may encounter. This is not intended to be an exhaustive list, but it should cover the majority of situations that risk management divisions may encounter. The final determinations of whether studies are compensable often will require close coordination among scientists, risk managers, and OGC.

Compensable studies & data

The following are examples of compensable studies/data that might be used to make the determination that an otherwise-required study is not needed:

- Task Force data, such as those from the Agricultural Reentry Task Force (ARTF), the Antimicrobial Exposure Assessment Task Force (AEATF), and the Agricultural Handler Exposure Task Force (AHETF).
- Data submitted in support of a registration that are used by EPA to conclude that a study is not required for the same or another active ingredient. There are three recent examples that are illustrative.
    - OPP has learned from a reproductive vigor study for a sulfonylurea (SU) herbicide that we do not need this type of study for other SUs. Other SU registrants will either need to offer compensation for the existing reproductive vigor study or elect to conduct a new reproductive vigor study in support of their registrations.
    - OPP's review of the first six developmental neurotoxicity studies (DNTs) submitted in support of certain pyrethroid registrations

provided sufficient information about developmental neurotoxic effects for all of the pyrethroids; therefore, other registrants can satisfy the DNT requirement by citing the six existing DNTs in lieu of conducting a DNT with their active ingredients.

- OPP's review of a large number of immunotoxicity studies, submitted to support the registrations for specific chemicals, allowed OPP to determine that immunotoxicity studies for chemicals in the same class as those tested were unnecessary. When the results of a specific sub-set of these studies, e.g, studies for a specific class of chemicals, form the primary basis to determine that an immunotoxicity study is not needed, registrants can satisfy the immunotoxicity requirement by citing the existing immunotoxicity studies in lieu of conducting an immunotoxicity study with their active ingredients.

- Data submitted by a registrant that leads the Agency to the conclusion that a specific assessment is not needed, but changes the regulatory outcome; i.e., leads to a label change.
  - For example, a registrant submitted data that led to a label change reducing restrictions designed to protect ground water when the pesticide was used in areas with karst geology. Submission or citation of these data (together with any required offer to pay) would be necessary for other registrants of products containing the same active ingredient wishing to similarly reduce the use limitations on product labeling.
- Models built primarily using guideline studies submitted in support of registrations.
  - For example, the spray drift model parameters were based on guideline studies that the Agency called in. Given the spray drift data are over 15 years old, however, the studies used for this particular model are no longer compensable.
- Studies EPA cites as the bases for default values, assumptions, or refinements to defaults that EPA uses in lieu of requiring a study.
- Data used on an active ingredient which may be present as a result of the application of another active ingredient.
  - For example, active ingredient A is a degradate of active ingredient B, which is under review. If EPA uses data on active ingredient A to conclude that a specific assessment and additional data are not necessary to complete the review of active ingredient B, the registrants of active ingredient B would

be required to address this data requirement by either submitting data from a comparable study or citing registrant A's data (and offering to pay compensation), even if the regulatory outcome does not change.

Non-compensable studies & data

Generally, studies that were submitted over 15 years ago or that were not submitted to support or maintain a registration are not compensable. The following are examples of studies and data which, when used to reach a conclusion that otherwise-required data are not needed, are not compensable:

- Studies/data from the open literature.
- Proprietary data purchased by the Agency, such as usage data.
- Data generated solely by the government or using government funds and models based on such data.
    - For example, ORD generated data at its lab in Duluth that EPA used to develop a model, the Endocrine Receptor Binding Expert System. If EPA determines, based on these data or modeling results, that an otherwise-required study is not needed, this is not compensable. That is, the registrant does not need to offer compensation for the use of those studies to meet its data requirements.
- Generally, studies conducted and submitted by USDA's IR-4 program. In rare circumstances, a study conducted by IR-4 is funded by a registrant, which may make the study compensable provided the registrant submits the study. Note, the Agency does not apply exclusive use protection to any study involving the use of government resources.
- Studies generated solely to support advancing the science, a new approach or methodology that are not submitted to support specific registration actions.
    - One example is data used to develop computational toxicology approaches. However, as mentioned above, data that are critical to establishing parameters for an alternative approach to support registrations, such as the spray drift model, are compensable.

    - Another example is the core science work to validate an alternative to a traditional dermal toxicity study. However, studies using the new methodology that are submitted in support of a registration are compensable.
- A circumstance involving EPA review of a large body of data where EPA's determination of future data needs is based primarily on EPA's own assessment rather than on a particular guideline study or on a single or particular group of registrant studies.
    - Example 1: In establishing crop groupings, OPP uses knowledge of the commodity, existing field trial studies for members of the crop group, data from USDA's Pesticide Data Program, and any other available data to determine which crops belong in a crop group. This combined information forms a Weight of Evidence (WoE). Although existing field trial data are used to set a tolerances for specific crops within the crop group, because they are part of a weight of evidence (i.e., the studies do not eliminate the need for data independent of other information), those studies are not compensable.
    - Example 2: OPP recently analyzed over a hundred immunotoxicity studies submitted to support registrations of specific chemicals and concluded that for many other chemicals, the study may not be needed. When this conclusion is based on Weight of Evidence (i.e., a combination of data and other information) rather than on specific studies for chemicals within the same class, compensation is not required. However, as noted above, if a specific sub-set of studies conducted on similar chemicals forms the basis for the determination, those studies would be compensable.
- In situations where two registrants of the same or similar active ingredient elect to submit separate studies to fulfill the same guideline, neither registrant has to compensate the other even if the results from only one study are used for assessment purposes, provided that the Agency found both studies to be acceptable. A third registrant entering the market could cite either study or submit another study accepted by EPA.
- Data submitted by a registrant that leads the Agency to change the conclusions of a risk assessment without resulting in labeling changes or other changes to the FIFRA registration.

    - For example, during reregistration, a chemical was classified as a carcinogen and data requirements were satisfied for the guideline battery of cancer studies. After the RED, one registrant submitted new data for the sole purpose of changing the chemical's cancer classification. These data led OPP to change the cancer classification and no labeling changes or other changes to the FIFRA registration were needed.
- The analysis or arguments submitted to support a waiver request. However, the individual studies cited in the analysis may be compensable.
- The analysis submitted to support an alternative means of satisfying a data requirement. Note that "waiver requests" are sometimes in fact a proposed alternative means. Again, individual studies cited in the analysis may be compensable.
- A data management tool (e.g., a calculator), provided the particular submitted tool is not critical to EPA's ability to evaluate and use the data. For example, the Agricultural Reentry Task Force submitted the Agricultural Handler Exposure Database (AHED) which is a tool for extracting dermal and inhalation exposure estimates for different pesticide formulations and different application scenarios. OPP does conduct handler exposure assessments without this tool. However, the specific underlying studies extracted from the database are compensable when they are used in an assessment.
- A study generated for a cancellation or suspension hearing provided it can be established the hearing is its sole purpose. However, the study may become compensable if it is also submitted to support a registration.

In summary, OPP staff is encouraged to consider all data and information in making any determination that a particular type of data should not be required for a specific chemical. When such data were submitted by another registrant, risk management divisions need to determine compensability and document whether such data are entitled to exclusive use treatment before approving a registration for another registrant. These determinations are sometimes difficult. In such circumstances, there are people in OPP and OGC who can help guide you in the process. Within OPP, contact Richard Dumas (703-308-8015) or John Leahy (703-305-6703) or Mark Dyner in OGC (202-564-1754).