

IR-4 Project Policy

Policy Title: Sharing Data Volumes (Reports) and Raw Data Developed by IR-4 with Third Parties

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Purpose: IR-4 is granted financial resources from the US government to develop data to support the registration of pest management products on specialty crops and minor uses. Because the data development costs are funded through predominantly public funds, there should be a process to make these data reports to interested parties who request such data. The purpose of this policy is to provide clear direction and process when data developed by the IR-4 Project can be released to a third party that requested the data.

Scope: This policy applies to data developed by the IR-4 Project using federal funds. It applies only to non-confidential data that are required to be submitted to EPA or other federal/state regulatory authority to support a registration of a pest management product. Product performance data is not included under this policy unless this data must be submitted to EPA (i.e. Public Health Uses) or other federal/state regulatory authority.

A “Third Party” is defined any party not directly involved and/or not participating in the data development and subsequent regulatory approval. Typical parties participating in data development (and not subject to this policy) include IR-4 personnel, contributing scientists/technicians working for USDA-ARS, the state agriculture experiment stations and contract research organizations, foreign government personnel participating in a joint project and appropriate representatives of the company that participated in the data development by providing the characterized test and/or reference substances.

Process: Non-confidential data volumes and/or raw data will only be released after US EPA approves the requested action and at least one product registration containing the use in question is available for sale in the appropriate geographic area. No data volumes/raw data will be released prior to product registration. Any release of data volume and/or raw data that would be in conflict with any state or federal laws will not be released.

Submit all requests for data volumes/raw data to IR-4 Executive Director, via electronic mail (jjbaron@ncsu.edu) or US Mail (***Jerry Baron, Executive Director, IR-4 Project, 1730 Varsity Drive, Raleigh, NC 27606***). The requester must identify the specific data volumes and/or raw data being requested by including the Project Clearance Request Number (PCR) the chemical and the crop identifier, where to send the requested data report and the intended use of the data volume and/or raw data. The requestor is also required to identify if an electronic copy of the data volume is acceptable.

IR-4 Executive Director will inform the study participants when it received a request for data volume and/or raw data. Written objections to the release of data volumes and/or raw data must be submitted within five working days of notification. If there are objections to releasing the raw data, the IR-4 Executive Director will facilitate dialogue between the parties to develop consensus. If the consensus direction is not possible, the final decision of the release of data will be made by the IR-4 Project Management Committee.

Fees:

- There is no charge to provide an electronic copy of a data volume
- Paper copies of data volumes will be provided at a cost of \$0.50 per page.
- Electronic copies of the raw data pages will be provided at a rate of \$0.25/page.
- Paper copies of raw data pages cost \$0.50 cents/page.