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AEIC /EPA DISCUSSION ON IMMUNOCHEMICAL METHODS

This letter is intended to summarize the discussions from the April 8, 1997 meeting between representatives of the Analytical Environmental Immunochemical Consortium (AEIC) and the Environmental Protection Agency (EPA). The focus of the meeting was to discuss a variety of topics related to validation and use of immunochemical methods incorporating a wide range of applications. Three primary topics were discussed: 1) Current EPA policies, 2) Guideline documents and 3) Training and Education needs. Each topic is summarized in detail below.

Meeting Participants:

Rick Lorranger - EPA/HED	Chuck Mihaliak - DowElanco
Randy Perfetti - EPA/HED	Chris Rankin - DuPont
Don Marlow - EPA/BEAD	Rosie Wong - Cyanamid Ag. Research
Elizabeth Loevey - EPA/EFED	Jim Brady - Novartis
Dick Griffith - EPA/OREB	Jan Sharp - Elf Atochem

1. CURRENT EPA POLICIES

Health Effects Division

Data Gathering Methods:
The preferred procedure for all immunochemcial methods used to support residue field trials is to generate data as outlined in the OPPTS 860.1340 guidelines. The only exception is that an Independent Laboratory Validation (ILV) is not required for data gathering methods. If an immunochemcial method has been validated according to the 860.1340 guidelines, then it is acceptable for use for data gathering during crop residue field trials. Additional information that should be provided but is not required by the guidelines include:

- Information on the specificity of the antibodies used in the method
- For method utilizing proprietary materials, information on the availability, supply (number of tests) and stability of the kits or reagents.
- Demonstration that results obtained with the immunochemical method are comparable to the enforcement method.

Tolerance Enforcement Methods

EPA is willing to review immunochemical methods an enforcement methods on a case-by-case basis. In addition to the requirements for data gathering methods, the immunochemical methods must be subjected to an ILV and may be evaluated by the EPA's Analytical Chemistry Laboratory. The method must include a confirmatory procedure. Sufficient data must be generated to demonstrate that comparable results can be obtains using the immunochemical and confirmatory (traditional) methods.

Environmental Fate and Effects Division

Immunochemical methods for analysis of soil and water samples should be validated according to the Federal Register Notice on Data reporting Guideline for Environmental Chemistry Methods (OPPTS 850.7100 Data Reporting for Environmental Chemistry Methods Guidelines - Public Draft). These guidelines require similar information as the OPPTS 860.1340 guidelines. One important exception is that an ILV is required for all soil and water methods.

When using immunochemical methods for data gathering or monitoring purposes, some degree of confirmation is expected. The level of confirmation is dependent on the nature of the study. All positives and a representative number of negatives should be confirmed during monitoring studies (i.e., where few if any positives are expected). During controlled trials (i.e., soil dissipation) some level of confirmation is also expected. The magnitude of the confirmation is currently being decided on a case - by - case basis.

Occupational and Residential Exposure Branch

Validation parameters for immunochemical methods for monitoring human exposure or foliar dislodgable residues are comparable to those described for the Environmental Fate and Effects Division.

2. GUIDELINE DOCUMENTS

AEIC agreed to assist EPA by developing a series of guideline and policy documents including:

1) A document to assist EPA reviewers with evaluation of information unique to methods utilizing immunochemical detection

2) A scheme to outline the routine use of immunochemical methods for food and non-food applications.

3) An AEIC informational document detailing the rationale for availability, stability, and supply of immunochemical reagents or kits incorporated into methods submitted to EPA.

3. TRAINING AND EDUCATION

General agreement was reached that there would be value in holding another training session similar to the AEIC Workshop presented two years ago. Of particular interest would be to have risk managers, new data reviewers, and individuals from BPPD and the labs attend the workshop. It was noted that hands-on demonstrations would be particularly valuable. AEIC members agreed to begin the planning process toward holding another workshop. EPA representatives supplied a list of office and branch contacts throughout OPP who would be helpful in organizing attendees for a workshop.

On behalf of the AEIC Regulatory Alliance Committee, I thank you for taking time to attend the this meeting to discuss with us the validation and use of immunochemcial methods to support registration of agricultural chemicals. If there are any inaccuracies or misinterpretations or a need to clarify any of the information in this letter, please contact me and I will issue a revised version.

Sincerely

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