

MINUTES
from the
ANALYTICAL ENVIRONMENTAL IMMUNOCHEMISTRY CONSORTIUM
meeting
on
May 5 6, 1993
at

American Cyanamid
Princeton, NJ

I. INTRODUCTION

Rosie Wong, American Cyanamid, opened the meeting and introduced Alan Keraginan, Director of Human and Environmental Safety who welcomed the attendees to American Cyanamid. The attendees introduced themselves to the group (see appendix for list).

II. MEETING
OBJECTIVES

The meeting agenda was reviewed by Rosie Wong and a minor change in the sequence of the objectives was made to allow time for Don Marlow.

III. HISTORY OF THE AEIC
(Joe Dautlick and Sharon Berberich)

Formation. The formation of an organization to advocate the development and implementation of immunochemical methods for environmental analysis was initially proposed as a result of the Immunochemical Summit meeting held at US EPA/EMSL, Las Vegas by Dr. Jeanette M. van Emon on June 17, 1992.

Previous Meetings. The first meeting of the Immunochemical Discussion Group was held at Dow Chemical Company in Midland, MI on October 1-2, 1992 to define the objectives, organization definition, and form committees for guidelines, communication, and administration. The next meeting was held at CIBA-GEIGY in Greensboro, NC on January 28-29, 1993. During this

meeting, the Mission and Objectives were discussed and defined to include consensus, education, regulatory agencies, and performance based method acceptance. In addition, the organizational "character" was also discussed. The NCCLS (National Committee on Clinical Laboratory Standards) guidelines and clinical diagnostics criteria were recommended as starting points to define acceptance guidelines.

Mission Statement. The wording of the AEIC Mission Statement was presented and revised. The current statement is:

To establish immunochemical methods as recognized analytical tools, the Analytical Environmental Immunochemical Consortium (AEIC) will:

1. Provide a consensus voice for the environmental immunochemical industry,
2. Develop educational programs,
3. Furnish scientific expertise to regulatory agencies, and
4. Establish performance standards.

IV. PROPOSAL FOR BY-LAWS AND ADMINISTRATIVE PROCEDURE (Rick Birkmeyer, Pat Nugent, and Joe Dautlick)

AEIC Incorporation. It was proposed that the AEIC be incorporated as a nonprofit/non-stock corporation in Delaware. The Certificate of Incorporation was discussed and several attendees were uncertain of the need and their corporate support for an organization formed in this manner. After discussing these issues, it was generally agreed to accept the name, "Analytical Environmental Immunochemistry Consortium" and to table the incorporation of this organization until members could review this issue with their corporate legal counsel. Members were asked to submit comments regarding the need for, advantages and disadvantages to incorporation along with the advice from their corporate legal counsel.

By-Laws. This document was used to define the "character" of the organization to include membership, meetings, voting, selection of officers and directors, board meetings, committees, general provisions, liquidation, indemnification, and amendments to by-laws. These By-Laws will be sent to members for review with their corporate legal counsel.

Voting Process. All members attending meeting or in absentia due to schedule conflicts were considered to be voting members of the AEIC. Voting requires the presence of a majority of the AEIC membership and requires a quorum approval to pass the amendment.

V. MEMBERSHIP AND COMMUNICATION COMMITTEE
REPORTS
(Rosie Wong and Laure Kenyon)

Progress, Ideas for Future. During this session, the group discussed adding new members for the next meeting. It was of general consensus that the next meeting of the AEIC would not be announced to the public in order to limit new members. General membership would be announced after deciding the organizational structure and selecting the officers. AEIC participation increased to 33 attendees representing 22 organizations. Among them were agchem industries, government agencies, assay kit manufacturers, independent research organizations, and university researchers.

Possible Participation/Co-sponsoring of Symposia at Technical Meeting. It was proposed that the following annual meetings be targeted for presentations on AEIC and the use of immunochemical methods:

AOAC, 1994
ACS, 3/94
IUPAC, 1993
(Washington, D.C.)
ASTM (D22), 7/94

It was suggested that posters and educational videotapes be presented at these meetings.

VI. AFFILIATIONS
(Jim Brady and Rosie
Wong)

Jim Brady discussed the major points that resulted from the June, 1992 EPA/EMSL (Las Vegas) Immunochemistry Summit meeting hosted by Jeanette Van Emon. The group felt that it was important to draft a response letter before the next Las Vegas meeting (in September) describing the AEIC and our position on immunochemical methods. The communications committee agreed to send a letter and send copies to the members when it was submitted to Jeanette. The group nominated Chuck Mihaliak, and he accepted, to give a brief presentation about the AEIC at the next EPA-EMSL meeting.

The draft EPA Pesticide Registration Notice (fall 1992) regarding requirements for ECM Performance Data was referenced. Bill Stellar made the point that the comment and approval period (by NACA) for such a notice could take as long as 18 months. It would be important for our group to have some influence on the content of this notice before official announcement is published. Copies of the draft notice were distributed.

AOAC Research Institute. Aflatoxin, sulfamethazine, and tetracycline methods have been validated through the FDA Sanctioned Methods Program.

A. D. Little (Dan Enthel). This organization has been approved for use in third party validation.

NACA (Bill Steller). This organization is interested in new technology. There was a general consensus by the members that it was important to have NACA involved in AEIC.

EPA (Update on Communication). Rosie Wong invited Don Marlow from EPA Office of Pesticide Programs to attend the meeting and to present current information on the acceptance of immunochemical methods by this regulatory agency. Guidelines for immunoassay acceptance were developed in 1991 and were defined to provide comparable data to current methods. The next step for acceptance is to confirm all positives and a percentage (15-20%) of negatives with current method. It is important that all method requirements outlined in FIFRA subdivisions (i.e. O, N, E, K, U, M) are consulted and followed for immunochemical methods. He would prefer that the methods or "reagents. be commercially available. He supported the establishment of validation guidelines by groups like AEIC and referred to some FDA methods (multiresidue?) that have been approved by AOAC.

His lab is currently evaluating various available immunochemical kits or tests and is verifying chimis as well as procedure. He feels that his lab will need to conduct 4-5 studies to demonstrate the equivalency of immunochemical methods to current procedures. EFED is moving more readily in accepting immunochemical data since they are dealing with water samples while there is some resistance in the food area due to the complexity of the sample matrix. Items are important for acceptance include:

- a. quantitation as well as identification
- b. reference standards of key immunochemical reagents
- c. demonstrate equivalency with reference methods
- d. LOO should correspond to current methods
- e. should not detect common moeity
- f. product quality control

He sees the applications of immunochemical methods as stewardship or monitoring programs in which immunoassays are used to screen to eliminate negative samples and positive samples are confirmed by current method. Over time, immunoassay

will become primary or complementary method after adequate cross-validation has been conducted to demonstrate comparability to current methods.

He provided copies of a memo on "OPPTS' Response to EMSL-LV Immunochemistry Summit Meeting Document - March 18, 1993." QED for immunochemical methods will be available in August 1993. He also asked if there is another method better than linear regression for the analysis of correlation. There was general agreement by the attending members that linear regression had limitations and this item would be explored.

VII. GUIDELINES COMMITTEE REPORTS (Brian Skoczenski, Jim Rittenberg, and Brinton Miller)

Validation Parameters. A description of assay parameters that are critical to the validation of immunochemical methods were presented by Brian Skoczenski. Some attendees felt that the list of parameters needed some additions. Johanne Strahan volunteered to provide additional information from NCCLS publications. The guideline committee agreed to get more information and revise the "Validation Parameters Descriptions" prior to the next meeting. The group agreed that a suggested experimental design for evaluation and appropriate statistical analysis for each assay parameter would be useful.

Definitions. Jim Rittenberg presented a compilation of definitions related immunochemical methods. There were many comments and suggestions from the group. Jim will incorporate the changes and send out to the group for review before the next meeting.

Package Inserts. Brinton Miller presented the results of a survey that he had conducted on package inserts from 6 companies and 9 different kits. Headings for package inserts included Intended Use Including Analyte Description, Test Principle, Kit Contents, Kit Storage Conditions, Materials NOT Supplied, Sample Preparation or Other Information, Procedural Notes, Perform Test (Procedure), Interpretation of Results, Precautions/Limitations/Validation Information, QC or Performance Characteristics, Warranty, and Technical or Customer Service Information. He noted that there was considerable variation in the content and quality of information in these package inserts. A recommendation was made for subject headings in the package inserts to be limited to Intended Use, Test Principles, Test Kit Contents, Preparation for Using the Test, Test Procedures (or Protocols), Results, and Technical Service.

Statistics Needed for Reporting Assay Validation Data. Brian Skoczenski reviewed information from published papers and kit data on validation parameters. These items included intra-assay precision, inter-assay precision, inter-laboratory precision, sensitivity,

cross-reactivity, correlation to standard method, dilution/linearity, spike and recovery, stability, sample stability, and environmental constraints. Recommendations for validation parameters were presented and generally agreed as being acceptable.

VIII. PROPOSAL "GUIDELINES FOR EPA ACCEPTABLE DATA FROM IMMUNOCHEMICAL ANALYTICAL METHODS..." (Sharon Berberich and Chuck Mihaliak)

Draft Document Outline. The draft outline of the proposed "AEIC Industry Standard" for acceptance of data generated by immunochemical methods was presented. Several comments were made by the group but the content of the draft was generally accepted. Additional comments should be sent to Sharon Berberich.

In addition to the outline, a draft of the minimum data set for validation of an immunochemical method was briefly presented. This minimum data set would most likely be an appendix to the guideline document and was of great interest to the group. The minimum data set requirements will be discussed at the next meeting.

IX. ESTABLISH GOALS/MILESTONES/TIMELINES FOR FUTURE (Chuck Mihaliak)

Goals for Consortium

- finalize mission statement
- decide on organizational structure
- create guidelines document
- sponsor a symposium and/or participate in symposia on immunochemical methods at an appropriate meeting in the future
- set up a "technical library" and system to share information
- provide educational demonstrations of immunoassays

Committee Activities

Guidelines Committee (Sharon Berberich)

- have a revised outline for "Data Acceptance". guidelines prepared before next meeting
- finalize definitions
- work on refining "Assay Parameters". descriptions
- work on recommendations for minimum information needed in kit "product inserts" to ensure consistency across products

Communication (Rosie Wong and Laure Kenyon).

- prepare letter providing feedback on June, 1992 EPA-EMSL Immunochemistry Summit meeting and send to Jeanette Van Emon and all AEIC members
- send out revised mission statement for vote
- prepare and distribute minutes from May 5-6, 1993 meeting
- feedback on incorporation issue to Laure Kenyon by July 1, 1993.
- Joseph Dautlick, Allen Iske, and Larry Miller were added to this committee.

Administration (Pat Nugent).

- revise by-laws document based on comments from AEIC members

X. PLANNING
(Joe Dautlick and Sharon Berberich)

Minutes. Minutes from the previous meeting were distributed and reviewed. No significant corrections were noted.

Next Meeting. Brian Skcozenski offered to host the next meeting in Portland, ME on September 23 and 24, 1993. The co-chairpersons will be Sharon Berberich and James Rittenburg.

Communication to Public/Agencies.

Voting. If a ballot of issues are to be voted on, a majority of responses will carry the vote and only one vote per company.

Next EPA-EMSL Las Vegas Meeting. Information on this meeting will be disseminated to the group after meeting notice has been received.

AEIC Attendees
 May 5-6, 1993 Meeting
 American Cyanamid, NJ

Name	Organization
Goro Asato	American Cyanamid Co.
Doris Ash	Tennessee Valley Authority
Sharon Berberich	Monsanto Agricultural Co.
Richard Birkmeyer	Stategic Diagnostics Inc.
James Brady	CIBA-GEIGY Corporation
Audrey Chen	FMC Corporation
Joseph Dautlick	Ohmicron, Inc.
James Devine	American Cyanamid Co.
Chris Hall	Univeristy of Guelph
William Horton	American Cyanamid Co.
Penny Hunst	Novo Nordisk
Allen Iske	Miles, Inc.
Tak Iwata	Zeneca
Laure Kenyon	DuPont Agricultural Products
Alan Kingman	American Cyanamid Co.
An-horng Lee	American Cyanamid Co.
Don Marlow	EPA-OPP
Charles Mihaliak	DowElanco
Brinton Miller	Neogen
Larry Miller	Battelle
Thomas Murphy	American Cyanamid Co.
Pat Nugent	The Dow Chemical Co.
James Rittenburg	Quantix Systems
Richard Rocco	IDETEK
David Salladay	Tennessee Valley Authority
Craig Schweitzer	BioNebraska
Brian Skoczenski	Millipore/ImmunoSystems
Alan Smith	FMC Corporation
Larry H. Stanker	USDA ARS Food Animal Protection Lab
Alan Staple	Ensys
William Steller	American Cyanamid Co.
Johanne Strahan	DuPont Agricultural Products
Catherine Tsalta	American Cyanamid Co.
Rosie Wong	American Cyanamid Co.