MEMORANDUM OF UNDERSTANDING

ON GOOD LABORATORY PRACTICE

between the

ISRAEL LABORATORY ACCREDITATION AUTHORITY

and the

ENVIRONMENTAL PROTECTION AGENCY

of the

UNITED STATES OF AMERICA

I. PURPOSE

This Memorandum of Understanding (the "Memorandum") reflects the intent of the Israel Laboratory Accreditation Authority (ISRAC) and of the Environmental Protection Agency (EPA) of the United States of America (the "Participants") to promote the quality and integrity of safety evaluation data that support, among other things, the approval of applications for research and/or marketing permits and licensing or registration or reregistration of pesticide products. The Participants share the view that health and environmental safety studies that are required to be submitted to a national authority should be conducted in accordance with the Principles of Good Laboratory Practice (GLP) that are internationally recognized, and that facilities conducting such tests should be monitored by effective national inspection programs. Accordingly, this Memorandum sets forth the Participants' intentions, under specified conditions, regarding:

(a) reciprocal recognition of each Participant's GLP program for pesticide products;
(b) acceptance of test data collected in Israel and the United States for review in making safety evaluations; and
(c) implementation of procedures for continuing cooperation between the Participants.

II. BACKGROUND

Safety evaluation data submitted for consideration to one national authority are frequently based on studies conducted by test facilities located in the other country. Therefore, the application of adequate GLP standards to studies conducted in Israel and the United States, supported by appropriate national GLP inspection programs, promotes the mutual acceptance of data generated in either country for review.

A. Good Laboratory Practices

The Participants have published comparable GLP standards or principles (the "**GLP standards**") relating to health and environmental safety studies which are in accordance with the Organization for Economic Cooperation and Development's "OECD Principles of Good Laboratory Practice", OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 1, ENV/MC/CHEM (98)17, adopted November 26th, 1997.

ISRAC (ISRAEL) GLP requirements for the testing of pesticide products and toxic substances are described in a quality manual according to the current ISRAEL Laboratory Accreditation Authority - GLP Manual (#1-200000).

EPA's GLP regulations for the testing of pesticide products are currently codified at Part 160 of Title 40 of the Code of Federal Regulations, and are entitled "Good Laboratory Practice Standards".

B. National Inspection Programs

National programs of inspection are required to verify the compliance of test facilities with the principles of GLP and must be consistent with the OECD Council Act set forth in C (89) 87(FINAL)/Revised in C(95)8 (FINAL), adopted on October 2, 1989 and revised on March 9, 1995, which addresses the operation of such programs.

In Israel, the Israel Laboratory Accreditation Authority (ISRAC) serves as a GLP Monitoring Authority (IL-GLP). ISRAC inspectors evaluate test facilities and audit data from pesticide studies conducted in Israel based on the OECD Principles of Good Laboratory Practice.

In the United States, EPA inspectors evaluate test facilities and audit data relating to pesticide studies based on EPA's GLP regulations relating to the pesticide program at 40 CFR Part 160.

The Participants intend that inspection procedures will be consistent between them. The Participants intend to assess compliance of a test facility with GLP standards by having trained inspectors conduct an inspection. The inspection programs would permit assessment of current facility operations as well as the audit of data from completed studies. Test facilities should generally be notified in advance of the inspection and audit. A report of the results of the inspection would be prepared to describe and address facility operations and conformity with GLP standards.

C. Compliance

Each Participant intends to establish satisfactory procedures to secure the compliance of test facilities with applicable GLP standards. The procedures might include, for example, notifying a facility of deficiencies observed, the issuance of corrective and warning notices, the refusal to include a facility in a national GLP compliance program, and the removal of a facility from such a program. These and other actions might lead regulatory authorities to reject specific studies, or, among other things, to cancel or refuse a pesticide product registration. In some cases, depending upon the gravity and extent of the violation, more severe penalties might be applied.

III. SUBSTANCE OF THE UNDERSTANDING

A. General Principles

The Participants share the view that:

1. adherence to adequate GLP standards is essential to the conduct of high-quality safety testing of pesticide products;
2. a national program of periodic inspections conducted by a trained inspectorate, is required to monitor adherence to GLP standards;

3. appropriate compliance procedures are necessary to assure adherence to GLP standards; and

4 studies conducted in accordance with the GLP standards promulgated by either Participant should be acceptable to the other Participant for review in the evaluation of the safety of pesticide products when the criteria specified in Article III.C. of this Memorandum have been fulfilled.

B. Inspections and Audits: Training and Evaluation

1. The Participants intend to carry out the following activities for promoting mutual understanding of their respective inspection programs and consistency of inspection practices;
   (a) The Participants share the view that training in inspection and audit techniques is essential and, as appropriate, each Participant plans to participate in the other's scheduled training activities.
   (b) The Participants plan to evaluate each other's GLP inspection and audit procedures by June 30, 2003.
   (c) The Participants intend to conduct joint inspections to be led by the Participant from the host country. Each Participant would bear its own costs.

2. The provisions of Article III.D of this Memorandum are intended to be operative upon an exchange of letters between the Participants confirming that they have compatible GLP programs, as determined by the criteria specified in Article III.C. This exchange of letters is expected to occur prior to December 31, 2003.

3. Until provisions of Article III.D are operative, it is expected that a Participant will inform the other Participant of its intent to inspect test facilities or audit studies in the other Participant's country before conducting any such inspections or audits.

C. Criteria for Determining Compatibility of GLP Programs

The criteria for determining compatibility of GLP programs are as follows:

1. In conducting safety testing of pesticide products, Israel and US facilities are to follow principles of Good Laboratory Practice equivalent to either the OECD Principles or the GLP regulations of the Environmental Protection Agency, respectively.

2. Procedures are developed and implemented for monitoring compliance, by trained personnel, with GLP standards in accordance with the OECD "Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice", OECD/GD (95)66, dated March 9, 1995 and the OECD "Revised Guidance for the Conduct of Laboratory Inspections and Study Audits", OECD/GD (95)67, Dated March 9, 1995, or subsequent revisions.

3. National authorities have the capability to: ensure effective implementation of GLP standards and compliance monitoring , as detailed above; provide timely information about inspections and audits performed; and respond, or ensure a response, to requests for facility inspection/study audits as provided for in Article III.D and to requests to participate in such test facility inspection/study audits.

D. Mutual Recognition of GLP Programs

1. As a routine matter, each Participant carries out inspections of health and environmental test facilities and audit studies in its respective country. In those exceptional situations where one Participant has special concerns and explains the bases for those concerns to the other Participant, the Participant with the concerns may designate one or more of its scientists to participate in a facility inspection or the audit of a study conducted by the other party.

2. Each Participant intends to inform the other Participant of changes in its GLP program.

3. At regular intervals, the Participants intend to provide each other with the names and addresses of health and environmental test facilities operating within their respective countries, the dates on which the facilities were inspected, and their compliance status.

4. Each Participant intends to provide, upon request by the other Participant, further information regarding whether or not a test facility or study has been demonstrated to be in compliance with applicable GLP standards.

5. Each Participant intends to honor a request by the other Participant to conduct a GLP inspection or data audit on behalf of the other Participant at a specified test facility whenever:

   (a) there is serious concern about the quality or integrity of the data submitted to a Participant;
   (b) an inspection has not been performed within the last two years; or
   (c) an approval of an application for a research and/or marketing permit is pending based upon tests performed by a specified facility whose results are relevant to granting the approval.

6. The Participants intend that, on occasion, representatives of each Participant will participate as invited observers in an inspection of a test facility conducted by the other Participant to maintain a continuing understanding of their respective inspection procedures. These inspections are expected to alternate between Israel - ISRAC and the United States - EPA.

7. Information is to be exchanged only where such exchange is authorized by the domestic laws of the Participants. Data that are designated as confidential by the Participant providing such data to the receiving Party is to be protected by the receiving Participant under this Memorandum to the same extent as the domestic data of the receiving Participant.

IV. PARTICIPANTS

A. United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
USA

B. Israel Laboratory Accreditation Authority
2 Habonim St.
Beit Habonim
Ramat Gan 52522
ISRAEL

V. LIAISON OFFICERS

The Participants respectively appoint the following officials to serve as liaison officers for all communications regarding matters relative to this Memorandum. The Participants may designate successor liaison officers as necessary.

1. For the Environmental Protection Agency:
Rick Colbert, Director
Agriculture Division
Office of Compliance (2225A)
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
USA

2. For the Israel Laboratory Accreditation Authority:
Orna Dreazen, General Director
Israel Laboratory Accreditation Authority
2 Habonim St.
Beit Habonim
Ramat Gan 52522
ISRAEL

VI. MODIFICATION

This Memorandum may be modified at any time by written consent of both Participants.

VII. DURATION

This Memorandum is effective on signature by both Participants and remains in effect unless one or both Participants gives notice of its intention to cease cooperation under this Memorandum.

VIII. NATURE OF THE MEMORANDUM

This Memorandum sets forth the intent of the Parties to cooperate and does not create binding rights and obligations under international law.

FOR THE ENVIRONMENTAL PROTECTION AGENCY

By: _____ DEC 19 2002

Christine Todd Whitman
Administrator
Environmental Protection Agency

Date

FOR THE ISRAEL LABORATORY ACCREDITATION AUTHORITY

BY: _____ Jan 26 2003

Orna Dregzen
General Director
Israel Laboratory Accreditation Authority

Date