

**Taipei Economic and Cultural Representative Office in the United States
(TECRO) - American Institute in Taiwan (AIT)**

Letter of Confirmation of Compatible Good Laboratory Practices Programs

Implementing Arrangement #8 (IA#8) to the Agreement between the Taipei Economic and Cultural Representative Office (TECRO) in the United States and the American Institute in Taiwan (AIT) for Technical Cooperation in the Field of Environmental Protection was signed by AIT and TECRO in December 2008.

Activity 13 of IA#8 is to “Establish a Good Laboratory Practices (GLP) program in Taiwan for industrial chemicals and pesticide products” that is compatible with the GLP program in the United States, to enable the exchange of research/study data between the AIT’s and TECRO’s designated representatives.

Implementation of Activity 13 involved collaboration between the designated representatives of AIT and TECRO, the US Environmental Protection Agency (US EPA) and the Environmental Protection Administration in Taipei (EPAT), respectively, to complete the following tasks:

- US EPA conducted Good Laboratory Practices training in Taiwan;
- Taiwan Good Laboratory Practices Monitoring Authority, as designated representative of EPAT, visited and evaluated US EPA’s GLP program; and
- US EPA visited and evaluated Taiwan’s GLP inspection program to determine compatibility with US EPA’s GLP inspection program.

US EPA and EPAT, through its designated representatives¹, the Ministry of Economic Affairs (MOEA), the Council of Agriculture (COA) and the Taiwan Accreditation Foundation (TAF), completed these tasks, and confirmed the compatibility of their respective GLP programs in June 2009. The designated representatives found and confirmed that:

- i) U.S. and Taiwan test facilities are required to adhere to respective Agency GLP requirements [Good Laboratory Practice Standards Regulations at 40 CFR part 160 for US EPA and Organization for Economic Cooperation and Development (OECD) Principles of GLP for EPAT];
- ii) US EPA and EPAT have established Compliance monitoring procedures which operate in accordance with OECD guidelines, “Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice” [OCDE/GD(95)66] and “Revised Guidance

¹ EPAT and the Council of Agriculture (COA) have delegated implementation of the Taiwan GLP Program to the Bureau of Standards, Metrology and Inspection (within the Ministry of Economic Affairs - MOEA), which has re-delegated it to TAF as the Good Laboratory Practices Monitoring Authority. Letters of delegation are attached to this letter.

for the Conduct of Laboratory Inspection and Study Audits” [OCDE/GD(95)67]. In addition, pre-inspection and inspection activities are conducted in a consistent manner by appropriately trained inspectors. Although the post-inspection activities of the designated representatives differ administratively, both include procedures for the review of inspection reports and correspondence compliance decisions as well as actions available to address test facility non-Compliance. Each program is thoroughly described in published documents, in accordance with OECD requirements, providing readily accessible information and guidance to both test facilities and inspectors;

- iii) Comparable electronic/hard copy records are maintained to track and obtain information related to GLP inspections, data audits and test facility status to satisfy the compatibility of record keeping of the designated representatives and for information sharing; and,
- iv) Each designated representative is able to respond, or ensure a response, to requests for test facility inspection/study audits and to requests to participate in such inspections/audits.

This document serves as acknowledgment by AIT and TECRO and their designated representatives that the necessary conditions have been met to confirm that EPA Taiwan and US EPA have compatible GLP programs.

IN WITNESS WHEREOF, the undersigned, being duly authorized, have signed this Letter of Confirmation.

DONE in duplicate in the English language.

FOR THE TAIPEI ECONOMIC AND
CULTURAL REPRESENTATIVE OFFICE
IN THE UNITED STATES

Jo Jung Chang
Name

Deputy Representative
Title

February 3, 2010
Date

Washington, D.C.
Place

FOR THE AMERICAN INSTITUTE IN
TAIWAN

Baron J. Schry
Name

Managing Director
Title

1/19/2010
Date

Washington, D.C.
Place

ATTACHMENT: Letters of delegation

INDUSTRIAL DEVELOPMENT BUREAU
MINISTRY OF ECONOMIC AFFAIRS

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Da-An District, Taipei City
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To : Bureau of Standards, Metrology and Inspection,
Ministry of Economic Affairs

Date Issued : August 4, 2009

Ref. No. : Kung-hua-tzu-ti-09800649320

Type : Express

Confidentiality classification and declassification conditions: general

Attachments : (Blank)

Re: The minutes of the deliberation meeting, held on July 15, 2009 at 09:00 a.m. with participation by the Council of Agriculture (COA), the Executive Yuan, Environmental Protection Administration (EPA), the Executive Yuan and the Industrial Development Bureau (IDB), the Ministry of Economic Affairs (MOEA) by your invitation, on the "Letter of Confirmation of Compatible Good Laboratory Practices (GLP) Programs" under the Implementing Arrangement #8 (IA#8) to the "Agreement between the American Institute in Taiwan (AIT) and the Taipei Economic and Cultural Representative Office (TECRO) in the United States for Technical Cooperation in the Field of Environmental Protection". Please see our reply below.

Details:

1. This letter is in reply to your letter of July 20, 2009 with Ref. No. Ching-piao-szu-tzu-ti-09840003480.
2. Regarding the resolution of agenda 3 recorded in the minutes of the deliberation meeting, conducted on July 15, 2009, on the "Letter of Confirmation of Compatible Good Laboratory Practices (GLP) Programs" under the Implementing Arrangement #8 (IA#8) to the "Agreement between the American Institute in Taiwan (AIT) and the Taipei Economic and Cultural Representative Office (TECRO) in the United States for Technical Cooperation in the Field of

Environmental Protection", the Bureau herein agrees to include the scope of industrial chemicals into the contents of the confirmation letter, and to delegate you, the Bureau of Standards, Metrology and Inspection (BSMI), the Ministry of Economic Affairs (MOEA), to re-delegate the Taiwan Accreditation Foundation (TAF) as the Good Laboratory Practice (GLP) Compliance Monitoring Authority.

COUNCIL OF AGRICULTURE
THE EXECUTIVE YUAN

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To : Ministry of Economic Affairs

Date Issued : November 16, 2009

Ref. No. : Nung-fang-tzu-ti-0980170796

Type : Express

Confidentiality classification and declassification conditions: general

Attachments : (Blank)

Re: The "Letter of Confirmation of Compatible Good Laboratory Practice (GLP) Programs" which is to be signed by the American Institute in Taiwan (AIT) and the Taipei Economic and Cultural Representative Office (TECRO). Please see our reply below.

Details:

1. This is to reply to your letter of November 9, 2009 with Ref. No. Ching-shou-piao-tzu-ti-09820050550.
2. For the matters provided in the Subject, the Council of Agriculture (COA), the Executive Yuan hereby agrees on the contents of the "Letter of Confirmation of Compatible Good Laboratory Practices (GLP) Programs", and authorizes the Bureau of Standards, Metrology and Inspection (BSMI), the Ministry of Economic Affairs (MOEA) to delegate the Taiwan Accreditation Foundation (TAF) as the Good Laboratory Practice (GLP) Compliance Monitoring Authority.

ENVIRONMENTAL PROTECTION ADMINISTRATION
THE EXECUTIVE YUAN

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To : Ministry of Economic Affairs

Date Issued : November 11, 2009

Ref. No. : Huan-shu-ke-tzu-ti-0980102084

Type : (Blank)

Confidentiality classification and declassification conditions: (Blank)

Attachments : (Blank)

Re: The Environmental Protection Administration (EPA), the Executive Yuan agrees that the Taiwan Good Laboratory Practices (GLP) Program to be implemented by the Bureau of Standards, Metrology and Inspection (BSMI), the Ministry of Economic Affairs (MOEA) and that the organization delegated by the BSMI should take on the role of the Good Laboratory Practice (GLP) Compliance Monitoring Authority. Please check accordingly.

Details: This is to reply to your letter of November 9, 2009 with Ref. No. Ching-shou-piao-tzu-ti-09820050550.

Minister: Stephen Shu-Hung Shen (going abroad)

Deputy Minister: Wen-Yan Chiau (acting for the Minister)

Matter is assigned to the authorized department head(s) for processing pursuant to the authority delegation system.

駐美國臺北經濟文化代表處與美國在臺協會 優良實驗室操作計畫相容確認書

駐美國臺北經濟文化代表處(TECRO)與美國在臺協會(AIT)，於 2008 年 12 月簽署駐美國臺北經濟文化代表處與美國在臺協會間環保技術合作協定第 8 號執行辦法(IA#8)。

IA#8 第 13 項活動，乃是「在臺建立工業化學與農藥製品優良實驗室操作(GLP)計畫」，並與美國優良實驗室操作計畫相容，以利美國在臺協會與駐美國臺北經濟文化代表處之指定代表，得以彼此交流研發/研究數據。

為求落實第 13 項活動，需由美國在臺協會與駐美國臺北經濟文化代表處各別指定代表—即美國環境保護署(US EPA)與中華民國行政院環境保護署(EPAT)—相互合作以完成下列任務：

- 美國環境保護署在臺灣辦理優良實驗室操作訓練。
- 臺灣之優良實驗室操作監控機構，作為行政院環境保護署之指定代表，將造訪並評估美國環境保護署之優良實驗室操作計畫。以及
- 美國環境保護署造訪並評估臺灣優良實驗室操作查核計畫，以決定與美國環境保護署優良實驗室操作查核計畫之相容性。

美國環境保護署與行政院環境保護署，透過所指派之代表¹-經濟部(MOEA)、行政院農業委員會(COA)及財團法人全國認證基金會，著手完成上述任務，並於 2009 年 6 月確認彼此之優良實驗室操作計畫之相容性。指定代表茲發現且證實如下：

- i) 臺美兩地之試驗單位，須切實遵守各自權責機關之優良實驗室操作規定 [美國環境保護署為優良實驗室操作標準法規，彙整於美國聯邦法規第 40 章第 160 部分；行政院環境保護署為經濟合作暨發展組織(OECD)優良實驗室操作規範]。
- ii) 美國環境保護署與行政院環境保護署已建立符合性監控程序，該程序之運作符合 OECD 操作規範「優良實驗室操作符合性監控程序修訂版指引」[OCDE/GD(95)66]與「實驗室查核與研究稽核實施規範修訂版」[OCDE/GD(95)67]。此外，查核前(pre-inspection)活動與查核活動，

¹ 行政院環境保護署與行政院農業委員會，已委由標準檢驗局(經濟部所屬單位)執行臺灣的優良實驗室操作計畫，該局又委託財團法人全國認證基金會，擔任優良實驗室操作監控機構。委託函隨附於本確認書。

均由受過妥善訓練之查核員，按照一致之查核程序進行。儘管指派代表之查核後活動在行政管理方面有所差異，但均包括審查查核報告與符合性決定之程序，及處理試驗單位不符合事項之有效措施。每項計畫皆於出版文件中詳述，切實遵守 OECD 之規定，便於試驗單位與查核員即時取得所需資訊及指引。

- (iii) 妥善保管類似電子/書面紀錄，藉此追蹤及取得優良實驗室操作查核相關資訊、數據稽核與試驗單位狀態，以利指定代表達成保管紀錄之相容性與資訊分享。以及
- (iv) 每名指定代表均能回應/確保回應試驗單位查核/研究稽核方面之要求，及參與此類查核/稽核之要求。

美國在臺協會、駐美國臺北經濟文化代表處及其指定代表，透過本文件承認完成必要條件，並確認行政院環境保護署與美國環境保護署具備彼此相容的優良實驗室操作計畫。

爰此，雙方代表各經合法授權，爰於本確認書簽字，以昭信守。

本英文版確認書共一式兩份。

駐美國臺北經濟文化辦事處：

美國在臺協會：

姓名

姓名

職稱

職稱

日期

日期

地點

地點

附件：授權書