行政院及所屬各機關出國報告

（出國類別：出席國際會議）

出席『第卅五屆國際農藥殘留標準委員會』
(35th Session of Codex Committee on Pesticide Residues）
報告書

服務機關：行政院農委會農業藥物毒物試驗所
出國人職稱：研究員兼組長
姓　　名：翁愫慎
出國地點：荷蘭鹿特丹
出國期間：92年3月29日 至92年4月7日
報告日期：93年2月20日

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報告名稱:

出席『第卅五屆國際農藥殘留標準委員會』

主辦機關:

行政院農業委員會農業藥物毒物試驗所

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出國類別: 其他

出國地區: 荷蘭

出國期間: 民國 92 年 03 月 29 日 -民國 92 年 04 月 07 日

報告日期: 民國 93 年 02 月 20 日

分類號/目: F0／綜合（農業類） I5／化學與環境科學

關鍵詞: 國際農藥殘留標準委員會,食品安全,農藥殘留,最高殘留限量,農藥經取食之急性暴露量,農藥殘留分析方法,食品安全管理

內容摘要: 第卅五屆國際農藥殘留標準委員會(35th Session of Codex Committee on Pesticide Residues，簡稱CCPR)於2003年3月31日至4月5日在荷蘭鹿特丹（Rotterdam, The Netherlands）召開。CCPR為聯合國組織下食品安全主要委員會之一，由荷蘭衛生福利部主辦。每年定期集會，討論作物中農藥殘留標準等相關議題。本期計有聯合國Codex五十一 個會員國及十一個國際組織代表計178人參加。本人代表國際純化學及應用化學學會（IUPAC）出席。經費由本所公務預算支出。本會議計進行十八個議題，包括報告案及討論案。討論案內容主要為制定部分農藥在各類作物中之最高殘留限量。同時討論農藥經取食之急性暴露量容許標準及評估準則，農藥殘留分析方法相關準則，以國家MRLs作為Codex MRLs暫行標準之可行性，辛香料殘留標準研訂案，Codex殘留標準作物分類修正，加工及即食食品MRLs制訂準則等議題，結論提交聯合國食品安全委員會討論，作為世界農產品貿易及食品安全管理之依據。本人從事農藥殘留研究及安全評估等工作逾廿五年，目前負責國內農產品農藥殘留檢驗、國內及進口容許量標準研訂及農藥暴露量之安全評估等工作。農藥殘留一直為食品及農產品國際貿易上各國慣用之非關稅障礙，我國成為世界貿易組織之會員國後在農產品貿易諮商談判上該類資訊更為重要。政府應該充分了解聯合國食品標準委員會之組織及運作，尋求參與聯合國食品標準委員會議題討論之機會。重視國際農藥殘留標準委員會之重要性，參考Codex準則進行農藥殘留調查及整體性評估之運用，長期進行食品中農藥安全評估工作。檢討國內農藥管理制度，善用農藥管理研究專責機構之人力資源及研究成果。

摘要

第卅五屆國際農藥殘留標準委員會(35th Session of Codex Committee on Pesticide Residues，簡稱CCPR)於2003年3月31日至4月5日在荷蘭鹿特丹（Rotterdam, The Netherlands）召開。CCPR為聯合國組織下食品安全主要委員會之一，由荷蘭衛生福利部主辦。每年定期集會，討論作物中農藥殘留標準等相關議題。本期計有聯合國Codex五十一 個會員國及十一個國際組織代表計178人參加。本人代表國際純化學及應用化學學會（IUPAC）出席。經費由本所公務預算支出。

本會議計進行十八個議題，包括報告案及討論案。討論案內容主要為制定部分農藥在各類作物中之最高殘留限量。同時討論農藥經取食之急性暴露量容許標準及評估準則，農藥殘留分析方法相關準則，以國家MRLs作為Codex MRLs暫行標準之可行性，辛香料殘留標準研訂案，Codex殘留標準作物分類修正，加工及即食食品MRLs制訂準則等議題，結論提交聯合國食品安全委員會討論，作為世界農產品貿易及食品安全管理之依據。

本人從事農藥殘留研究及安全評估等工作逾廿五年，目前負責國內農產品農藥殘留檢驗、國內及進口容許量標準研訂及農藥暴露量之安全評估等工作。農藥殘留一直為食品及農產品國際貿易上各國慣用之非關稅障礙，我國成為世界貿易組織之會員國後在農產品貿易諮商談判上該類資訊更為重要。政府應該充分了解聯合國食品標準委員會之組織及運作，尋求參與聯合國食品標準委員會議題討論之機會。重視國際農藥殘留標準委員會之重要性，參考Codex準則進行農藥殘留調查及整體性評估之運用，長期進行食品中農藥安全評估工作。檢討國內農藥管理制度，善用農藥管理研究專責機構之人力資源及研究成果。

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目的

國際農藥殘留標準委員會(Codex Committee on Pesticide Residues，簡稱CCPR)為聯合國世界糧農組織及世界衛生組織食品安全標準委員會之一，任務為制定農藥對人體健康相關之標準，包括農藥每日可攝入量（ADI）、農藥急性毒參考值(Acute RfD)、農藥在各類作物中之最高殘留限量（MRLs）、外加最高殘留限量(EMRL's)及經取食安全評估值（Dietary Daily Intake Risk Assessment），主辦國為荷蘭。本會議每年四至五月於荷蘭召開，會期約一周，由聯合國世界糧農組織及世界衛生組織專家準備討論議題及會議資料提交會議討論，會議結論提送聯合國食品安全標準委員會(Codex Alimmentarius Commission(CAC))決議後作為世界性食品安全之準則，世界貿易組織（World Trade Organization ）有關食品安全方面皆以此為標準，因此深受各國重視。我國非聯合國會員國，參與非開放性國際組織相關會議之機會很少，此等聯合國組織下之會議更不可能參加，對我國參與國際活動及世界貿易組織談判上，因無法及時取得國際認同之資訊和同時反應國內的需求而增加其困難度。本人以國際純化學及應用化學學會（IUPAC）代表身分參加，除在會中說明IUPAC與本會議之關係及主要活動及研究報告外，同時收集會議資料，了解各項議題之討論程序及決定之準則，當有助於我國進出口食品及國內農產品中農藥殘留標準制訂之國際化，及在農產品及食品之國際貿易上能引用國際準則而替提高農產品之競爭力。本人每年與會均非常用心全程參與及撰寫詳盡之出國報告，希望所提之心得及建議事項能得到相關單位之重視，對提昇國內農藥殘留研究及管理能有所幫助。

過程

一、議程 Agenda

第卅五屆國際農藥殘留標準委員會（35th Session of CCPR）於2003年3月31日至4月5日在荷蘭鹿特丹召開。主要討論之十八項議題依序見表一。

表一、第卅五屆國際農藥殘留標準委員會討論議題

題號	主要議題	討論文獻
	開幕式Opening of the Session	
1	公告議題 Adoption of the agenda	CX/PR 03/1
2	推舉紀錄 Appointment of rapporteurs	
3	其它委員會轉請討論議題 Matters referred to the committee by the CAC or other Codex Committees	CX/PR 03/2
4	2001及2002年JMPR報告一般性建議 Report on general considerations by the 2000 and 2001 JMPR	2001 and 2002 JMPR Reports
5	農藥經取食之暴露量與殘留標準 Deitary Exposure in Relation to MRL setting：Discussion paper on the proposals for improvement methodology for point estimates	CX/PR 03/3
6	全球食品安全性取食評估報告GEMS/Food Porgress Report of Dietary Intake	CX/PR03/4
7	食品及動物飼料中農藥殘留標準 Proposed Draft MRLs in Foods and Feeds	CX/PR 03/5
8	危機分析在農藥殘留標準制定上之運用 Risk Analysis Policies Used in Establishing Codex MRLs for Pesticides	CX/PR 03/6
9	農藥殘留分析方法及取樣等相關準則 Matters Related to Methods of Analysis and Sampling： a.Single Laboratory validation of methods	CX/PR 03/7, 03/8, 03/9, 03/10, 03/11

	and analysis. b. Guidelines on Good Laboratory Practice in residue analysis. c. Estimation of uncertainty of measurements d. Multiple peaks for the estimation of uncertainty e. Revision of the list of methods of analysis for pesticide residues. f.New tropical fruits and vegetable commodities	
10	農藥評估優先順序 Establishment of Codex Priority Lists of Pesticides	CX/PR 03/12, 03/13
11	安全性高農藥引用各國MRLs為Codex MRLs暫行標準 Pilot project for the examination of national MRLs as interim Codex MRLs for safer replacement pesticides	CX/PR 03/14
12	辛香料殘留標準研訂案 Elaboration of MRLs for Spices	CX/PR 03/15
13	Codex殘留標準作物分類修正 The Revision of the Codex Classification of Foods and Animal Feeds	CX/PR 03/16
14	其它待辦事項 Other business and Future Work	
15	下次會議時間及地點 Date and Place of Next Session	
16	會議結論 Adoption of the Report	
17	加工或即食食品之MRLs MRLs for processed or ready to eat foods or feeds	CX/PR 03/17
18	排除JMPR額外之工作負擔 Removal of an extraneous burden from the workload of the JMPR	CX/PR/18

本會議除正式議程外，另有二個 Working group 在會期中安排時間召開，分別為3月29日討論農藥評估優先順序，4月1日討論農藥殘留分析採樣準則。

二、參加人員

本屆會議因受美伊戰爭影響，參加人數及單位均較以往減少，美國也未派員出席。計有來自聯合國五十一個Codex會員國及十一個國際組織代表共178人參加，參加國及國際組織代表人數見表二。本人則以國際純化學及應用化學學會（IUPAC）代表身分與會。

表二、參加卅五屆國際農藥殘留標準委員會國家及組織人員

國家	人數	國家	人數	國家	人數	國際組織	人數
Algeria	1	Germany	8	**Netherlands**	9	Uganda	1
Argentina	1	Greece	3	**New Zealand**	1	UK	3
Australia	7	Hungary	2	Nigeria	1	EC	3
Austria	1	Iceland	1	Norway	2	EU	1
Belgium	3	India	3	Peru	1	CLI	21
Brazil	5	Indonesia	4	Philippines	1	IBA	1
Bulgaria	1	Iran	2	Poland	3	ICA	1
Canada	2	Ireland	1	Romania	1	ISC	2
Chile	3	Israel	1	**South Africa**	1	IUPAC	2
China	5	Italy	1	Spain	4	IOSTA	4
Columbia	1	Jamaica	1	Sweden	3	FAO	2
Czech R.	1	Japan	4	Switzerlan d	3	FAO/IAEA	1
Denmark	1	Korea R.	8	Tanzania	1	WHO	3
Egypt	1	Latvia	2	Thailand	6	Secretariat	17
Finland	3	Malaysia	3	Tunisia	2		
France	3	Morocco	3	Turkey	1		

三、會議內容

本報告中所引用之專有名詞簡稱說明列於附件一。

開幕式(**Opening of the Session)**

開幕式由荷蘭健康福利部營養及保健處處長Dr. Dortland致開幕詞。他指出為提昇研討Codex MRLs之時效性，應以設法減輕JMPR之工作負擔，並考慮以國家標準作為Codex MRLs之暫行標準。也希望大會能注意非主要作物如辛香料及熱帶蔬果MRLs之研討。他也肯定本會議對農藥使用管理及食品安全所作之貢獻，並祝大會有豐碩的成果。

議題一、公告議題（**Adoption of the Agenda**）

說明本次會議之議題、特別議題會外討論時間及臨時議題，及大會秘書處服務項目。

議題二、推舉紀錄(**Appointment of Rapporteurs)**

大會主席推舉日本代表 Dr. Y. Yamada及紐西蘭代表Dr. David W.Lunn 為大會紀綠。

議題三、其它委員會轉請討論議題 (**Matters Referred to the Committee)**

本屆會議由其它食品安全委員會及CAC執行委員會反應至本委員會討論者不多且己含在其它討論議題內。另CAC會議決定考慮設置基金會以補助開發中國家出席Codex相關會議。

議題四、**2001及2002年JMPR報告一般性建議(Report on general considerations by the 2001 and 2002 JMPR)**

世界糧農組織及衛生組織農藥殘留專家聯合會議(JMPR)每年九月集會一次，每次會期約一個月，評估農藥毒理及殘留問題，制訂農藥每日可攝入量（ADI）、農藥急性毒參考值(Acute RfD)、農藥在各類作物中之最高殘留限量（MRLs）、外加最高殘留限量(EMRL's)及經取食安全評估值（Dietary Daily Intake

Risk Assessment）。平均每年評估廿五種農藥。會議中亦討論一般性議題，結論提翌年CCPR會議報告及討論。

本會議討論JMPR之報告內容摘要如下：

1. 農藥急性毒參考值(Acute RfD)之研訂準則及評估方式為2002年JMPR之重要工作項目。JMPR作成以下結論:
（1） acute RfD以mg/bw.kg為單位，以24小時內會對人體健康造成威脅者為訂定依據。
（2） ADI值必須大於或等於Acute RfD值。
（3） 若劑量大於500mg/kg bw不會有影響或大於1000mg/kg bw不會死亡之藥劑不需訂Acuate RfD值。
（4） acute RfD值研訂以case-by case，無訂定Acute RfD值者需說明理由。
（5） 2002年研訂結果DDT, 2-Phenylphenol, propargite不需研訂；bentazone, dimethipin, imazalil資料不足；dodine acute RfD 0.2 mg/kg bw, permethrin acute RfD 1.5 mg/kg bw.
2. JMPR持續進行最低毒理需求及區域性整合之研訂，以減少資料的需求量並加速Codex MRLs之研訂。
3. JMPR結論以cattle代表其它哺乳動物（mammalian），以20% fat + 80% muscle為meat用於取食評估用；chicken代表其它家禽（poultry），以10% fat + 90% muscle為meat。
4. JMPR結論不可能有殘留之MRLs應以最低偵測界限（LOQ, Limit of quantification）為 MRLs，但需加註解。

<u>議題五</u>、農藥經取食之暴露量與殘留標準（**Deitary Exposure in Relation to MRL setting：Discussion paper on the proposals for improvement methodology for point estimates**）

本議題乃2003年CCPR決議辦理事項。2002年南非提供國內安全評估結果部分主食之攝食風險高於安全值25倍。2001年JMPR計算經口攝食慢毒性暴露量評估初步結果加保利carbaryl、合氯氟 haloxyfop 及撲克拉 prochloraz 高於ADI值。 經口攝食急毒性暴露量評估初步結果得滅克 Aldicarb在香蕉及馬鈴薯、chlorpropham 在馬鈴薯、納乃得 methomyl及得芬諾 tebufenozide 在部分作物中高於 Acute RfD值。大會決議由IUPAC、荷蘭、美國及澳洲合組工作小組規畫以 probabilistic 統計分析程式之評估方法作為對高於Acute RfD值之農藥作風險管理之依據。荷蘭代表報告推崇IUPAC委員會所完成之「Pesticide Residues in Food-Acute Dietary Exposure」已對此有詳細之分析，可供Codex及各國評估時之參考。本篇文章本人亦為作者之一，該文即將發表於Pest Management Science。

<u>議題六</u>、全球食品安全性取食評估報告（**GEMS/Food Porgress Report of Dietary Intake**）

GEMS /food Porgress (Global Environment Monitoring System)確定以十三個區域為全球取食評估之base。該計畫已完成各區域之取食量資料，目前加強收集開發中國家及加工食品之相關資料。各類食品之typical unit weight and edible portion database也由英國修訂完成。

<u>議題七</u>、食品及動物飼料中農藥殘留標準 **(Proposed Draft MRL in Foods and Feeds)**

1. Codex MRL's

此為本會最主要之議題，共進行二個會議日。即討論由JMPR 製備完成毒理及殘留量評估之藥劑，制訂其在不同作物中之最高殘留限量(Codex MRL's)，或依毒理評估結果或作物中殘留量評估結果取消其MRL’s或ADI值。

Codex食品安全標準之研提須經過八個作業及審核程序：

Step1,step2,step3: 由委員會提議議題經決議為「Criteria for the Establishment of Work Priorities」，及交付相關委員會成立工作小組，草擬「proposed draft standard」。

Step 4: 由委員會秘書將proposed draft standard工正式送交各相關委員會討論及提供建議。

Step 5: 草案提送Excusive Committee 討論通過後定義為「draft standard」。意見送回草擬委員會討論修正。

Step 6: 委員會秘書將draft standard送交所有會員國及相關國際組織徵詢意見。

Step 7: 委員會秘書彙整意見送回研擬之委員會作最後之修正。

Step 8: CAC通過後公告為 Codex Standard.

食品標準定案後由委員會秘書處予以公告。該等標準法案在網站上均可查詢下載（http//fao.codex.alimentarius）。委員會之使用語言為英文、法文、西班牙文、阿拉伯文及中文（世界衛生組織增加俄文）。

因此CCPR研議農藥在作物中之Codex MRLs之程序為:

Step 1: 由CCPR建議農藥審議名單

Step 2: 由JMPR進行毒理資料審查，制訂ADI值。由殘留量值分析研議結果建議最高殘留限量值。

Step3: 建議值第一次提交各國政府提供意見。

Step4: CCPR進行第一次審查。

Step5:由CCPR轉交食品安全委員會(CAC)認定。

Step6: 建議值第二次提交各國政府提供意見。

Step7: CCPR進行最後審查。

Step7a: 建議值等待JMPR提供定案之ADI值。

Step7b: 建議值退回JMPR再評估。

Step7c: 建議值等待新資料補充。

Step8: 建議值定案為Codex MRL (CXL)。

Step5/8: 建議值無須經step 6, 7,直接定案。

本議題討論之藥劑MRL's為進入step4及step7之藥劑。美國書面提議暫緩有機磷劑之討論因其尚未完成加成毒性評估。本次會議共討論六十二個藥劑之ADI或acute RfD或MRL值，摘要如表三。另DDT之EMRL值也列入討論。

表三、食品及動物飼料中農藥殘留最高限量本會討論摘要

Code No	農藥名稱	決議事項
007	Captan 蓋普丹	1.可能應研訂acute RfD 2.待2004毒理評估後再修訂MRL's
008	Carbaryl 加保利	1.acute RfD 0.2 mg/kg bw 2.取消rice維持polished rice之 MRLs 3.residue經取食評估超過ADI，考慮取消部分作物之MRLs
015	Chlormequat 克美素	1. acute RfD 0.05 mg/kg bw 2.增修訂多項grains MRL's
017	Chlorpyrifos 陶斯松	1.屬有機磷暫停增訂MRL's 2. acute RfD 0.1 mg/kg bw 3.以pome fruits, poultry meat MRLs取代單一作物MRLs
020	2,4-D 二四地	1.不需訂定acute RfD 2. 以citrus fruits MRLs取代單一作物MRLs
022	Diazinon 大利松	1.屬有機磷暫停增訂MRL's 2. acute RfD 0.03 mg/kg bw
026	Dicofol 大克蟎	1.大部分MRL's為最低檢出界限(LOD) 2.日本建議降低tea MRLs
027	Dimethoate 大滅松	1. 屬有機磷暫停增訂MRL's 2.2003JMPR研訂acute RfD

Code No	農藥名稱	決議事項
030	Dipheylamine	1. 不需訂定acute RfD 2.meat MRLs修正為fat-soluble
032	Endosulfan 安殺番	1. acute RfD 0.02 mg/kg bw 2.列入2005JMPR評估藥劑
034	Ethion 愛殺松	No longer support to use，下次取消 cirus MRLs
037	Fenitrothion 撲滅松	1. acute RfD 0.04 mg/kg bw 2.2003 JMPR評估藥劑 3.確認cereal grains MRLs
041	Folpet 福爾培	1.2004JMPR評估藥劑 2.需研訂acute RfD
049	Malathion 馬拉松	1.2003JMPR評估藥劑 2.需研訂acute RfD
053	Mevinphos 美文松	1. acute RfD 0.003 mg/kg bw 2.取消大部分作物之MRL's值
054	Monocrotophos 亞素靈	1. acute RfD 0.002 mg/kg bw 2. No longer support to use，取消所有 MRL's值。
055	Omethoate 歐滅松	No longer support to use，建議取消所有作物MRL's值
059	Parathion-Mehyl 甲基巴拉松	1. acute RfD 0.03mg/kg bw 2.取消MRLs for animal feeds
060	Phosalone 裕必松	1. acute RfD 0.3mg/kg bw 2.研訂pome 及stone fruits 之 MRLs
061	Phosphomidon 福賜米松	No longer support to use，取消所有 MRL's值

Code No	農藥名稱	決議事項
062	Piperonyl butoxide	1. 不需訂定acute RfD 2.應考慮其作為pyrethrins之增效劑而用於有機資材。
063	Pyrethrins 除蟲菊類	1.acute RfD 0.2mg/kg bw 2.2003JMPR評估藥劑,修訂部分MRLs
065	Thiabendazole 腐絕	建議修訂citrus, mushroom MRLs，取消melons, strawberries MRLs
072	Carbendazim 貝芬替	1.Residue定義為「sum of benomyl, carbendazim and thiophanate-methyl, expressed as carbendazim」2.2003JMPR評估藥劑
074	Disulfoton 二硫松	1. acute RfD 0.003mg/kg bw 2. 修訂部分MRLs
082	Dichlorfluanid 益發靈	建議取消不再推薦使用作物MRLs 如:blackberries, egg plant
084	Dodine多寧	1. acute RfD 0.2 mg/kg bw
085	Fenamiphos 芬滅松	1.acute RfD 0.003 mg/kg bw 2.重新評估所有作物之MRLs
087	Dinocap 白粉克	JMPR研訂二組Acute RfD供一般人(0.03mg/kg bw)及嬰幼兒(0.008mg/kg bw)評估用
090	Chlorpyrifos-Methyl	1. 不需訂定acute RfD 2.韓國代表建議向下修訂rice MRLs
094	Methomyl 納乃得	1. acute RfD 0.02 mg/kg bw 2.WHO代表指出dietary intake超出acute RfD 7000 % 3.重新評估大部分作物MRLs

Code No	農藥名稱	決議事項
096	Carbofuran 加保扶	1. acute RfD 0.009 mg/kg bw 2.暫停評估待重新計算acute intake
100	Methamidophos 達馬松	待2002JMPR評估毒理資料2003評估殘留完成後再討論MRLs。
103	Phosmet 益滅松	2002 JMPR研訂acute RfD 0.002 mg/kg bw，大會認為太低應重新研訂。
106	Ethephon 益收生長素	2002JMPR結論部分作物殘留影響幼兒安全，重新評估Acute intake
113	Propargite 毆蟎多	1.不需研訂acute RfD 2.考慮grape juice對孩童之risk
117	Aldicarb 得滅克	1. acute RfD 0.003 mg/kg bw 2.Banana,potato有急毒性顧慮 3.建議列入取食安全評估
126	Oxamyl 毆殺滅	1. acute RfD 0.05 mg/kg bw 2.2002JMPR建議取消之MRLs列入下會議
130	Diflubenzuron 二福隆	1.不需研訂acute RfD 2.修訂部分MRLs
135	Deltamethrin 第滅寧	1. acute RfD 0.05 mg/kg bw 2.2002JMPR建議取消之MRLs列入下會議
137	Bendiocarb 免敵克	No longer support，建議下次CXLs全部取消。
144	Bitertanol 比多農	保留apricot MRL為1 mg/kg
145	Carbosulfan 丁基加保扶	待2003JMPR研訂 acute RfD再議。

Code No	農藥名稱	決議事項
147	Methoprene 美賜平	1.不需研訂acute RfD 2.修訂部分MRLs
151	Dimethipin 獲萎得	1. acute RfD 0.02 mg/kg bw 2.修訂部分MRLs
161	Paclobutazol 巴克素	廠商no longer support，建議CXLs全部取消。
162	Tolyfluanid	1. acute RfD 0.5mg/kg bw 2.修訂部分MRLs
166	Oxydemeton-methyl減多松	保留2002及2004JMPR評估acute RfD及residue再議。
170	Hexaconazole 菲克利	1.廠商no longer support，建議CXLs全部取消。 2.EU建議保留，提下次討論
182	Penconazole 平克座	1.廠商no longer support，建議CXLs全部取消。 2.EU建議保留，提下次討論
187	Clethodim	1.修訂部分作物MRLs 2.分析方法已可區分clethodim及sethoxidam
193	Fenpyroximate 芬普蟎	2.保留修訂MRLs待2004JMPR訂定acute RfD
194	Haloxyfop 合氯氟	廠商將提供新的資料及新劑型(haloxyfop-R)供JMPR 重新評估
196	Tebufenozide 得芬諾	1. acute RfD 0.05mg/kg bw 2.廠商提供新資料以修正acute RfD
199	Kresoxim-methyl克收欣	修訂MRLs

Code No	農藥名稱	決議事項
201	Chlorpropham	1. acute RfD 0.05mg/kg bw 2.potato MRL太高，重新評估
202	Fipronil 芬普尼	1. acute RfD 0.003mg/kg bw 2.MRLs至5/8
203	Spinosad 賜諾殺	1.不需研訂acute RfD 2.修訂部分MRLs 3.EC,France認為milk MRL太高
204	Esfenvalerate 益化利	1. acute RfD 0.02mg/kg bw 2.因esfenvalerate及fenvalerate有相同之residue定義卻有不同之MRLs，保留所有MRLs之修訂
205	Flutolanil 福多寧	1.不需研訂acute RfD 2.修訂部分MRLs
206	Imidacloprid 益達胺	1. acute RfD 0.4mg/kg bw 2.修訂部分MRLs

2. EMRLs

EMRLs(外加殘留限量)指非施用農藥而是吸收存在於環境中之物質而來。定義須已禁用且有污染食品影響健康或國際農產品貿易者才要列入訂定EMRL之名單。訂定標準依各地區各項食品之調查報告(Monitoring Data)評估，以介於0.2-0.5%之超量率為標準。

上次會議討論畜肉（mammalian meat）中DDT之EMRL維持1999年會議依紐西蘭調查報告及建議所研訂之5 mg/kg (fat)。本次會議決定禽肉（paultry meat）中DDT之EMRL為0.3mg/kg。

議題八、危機分析在農藥殘留標準制定上之運用（**Risk Analysis Policies Used in Establishing Codex MRLs for Pesticides**）

風險分析為危害評估之標準操作程序，Codex Committee on General Principles（CCGP）在1997年訂定Codex風險分析準則，各食品標準委員會也相繼研擬其風險分析準則。上次會議決議交JMPR研究後提本次會議討論，但未完成。會議討論決議除建議CCGP評估完成後能清楚定義以區別risk assessment and risk management，並建議加入本會議各議題結論，以製備適合農藥殘留標準之危害評估之標準操作程序。

議題九、農藥殘留分析方法及取樣等相關準則（**Matters Related to Methods of Analysis and Sampling**）

本議題亦為本次會議之主要討論重點，包括六個討論案：

1.單一實驗室標準分析方法建立（**Single Laboratory validation of methods and analysis**）

分析方法確立一般需經實驗室間認証，但若單一實驗室依下列三個準則執行，則其建立之方法也可列為標準分析方法：

i.依CCPR或IUPAC guidelines

ii符合ISO 17025 standard or the principles of GLP

iii方法需具備証明準確之資料及數據如regular participation in proficiency schemes, calibration using certified reference materials, recovery studies等。

CCMAS並建議由IUPAC整合guidelines。

2.農藥殘留分析實驗室標準操作準則(**Guidelines on Good Laboratory Practice in residue analysis)**本準則建議進入step8報請Codex接受。整套文件包含Codex已公告之五個準則及新增之一個準則:

（1） Recommended method of sampling for the determination of pesticide residues

（2） Portion of commodities to which Codex Maximum Residue Limits apply and which should be analysed.

（3） Explanatory notes on Codex Maximum Limits for pesticide residues

（4） Recommendations for methods of analysis of pesticide residues

（5） Codex classification of food and animal feed

（6） Codex guidelines on good practice in pesticide residue analysis (新增)

Codex農藥殘留實驗室操作準則重點有三：（1） the analyst；（2） basic resources;（3） the analysis. 其它品保品管及實驗室管理可參考ISO/IEC 17025及OECD GLP Guidance documents.本草案見附件二。

3. Estimation of uncertainty of measurements；4. Multiple peaks for the estimation of uncertainty; 5. Revision of the list of methods of analysis for pesticide residues.以上三個議題因報告內容不足討論，大會責成FAO/IAEA TRC製備完整文件提下次會議討論。

5.熱帶蔬果新分類（**New tropical fruits and vegetable commodities**）本案考慮熱帶蔬果之獨特性包括其果型、食用方式及國際貿易價值，成立工作小組對其重新製訂與殘留標準相關之準則。

<u>議題十</u>、農藥評估優先順序**(Establishment of Codex Priority Lists of Pesticides)**

CCPR會議討論之農藥都經 JMPR先行評估，評估藥劑分為New Compounds(新藥劑)、Periodic Reevaluations(定期預先評估)及Evaluation(評估)三類。大會委請澳大利亞代表主持討論評估

順序。由於JMPR每年能評估之農藥有限，因此以資料完整者及有可能因無標準而易引起國際貿易爭議者如持久性污染物為優先。對於「較安全」之農藥之定義應包括降低作物中殘留、作業環境安全、保障大眾健康、維護生態環境安全及加速在環境中之降解等。另針對農藥規格所新成立之專家委員會JMPS (Joint FAO/WHO Meeting on Pesticide Specification) 其評估結論也會作為JMPR建議之一部分。附件三為2003至2012年之藥劑評估名單。

由於評估名單及順序常因故有所變動，因此與會人員要求訂定名單排訂準則。初步結論為資料完整且有國內或EU完整評估報告者優先。另考慮延長再評估時間自10年為15年。高污染物如DDT原應五年重評一次，因新環境調查資料取得不易也考慮延長再評估時間。

<u>議題十一</u>、安全性高農藥引用各國**MRLs**為**Codex MRLs**暫行標準（**Pilot project for the examination of national MRLs as interim Codex MRLs for safer replacement pesticides**）

由於Codex MRLs制訂程序嚴謹，且JMPR每年評估藥劑有限，因此對於新上市且安全性高之農藥或擴大作物範圍之Codex MRLs未能即時研訂，致使許多以Codex MRLs為國家標準者因無殘留標準而禁止檢出該等未有Codex MRLs農藥殘留之農產品或食品進口，造成國際貿易上非常大的困擾。大會委請美國及澳洲針對此問題成立工作小組以「國家容許量」作為Codex暫行標準（以step 8(I)標示）之可行性進行研究。因美國代表未出席，會議中本議題就正反意見提出充分討論。贊成者建議以具安全取代性之農藥、國際貿易及取食量上重要之作物由國家提供完整資料作為暫訂Codex標準，但有一定期限且非codex法定標準。反對者則對其公平性、公開性、合法性及資料保密性提

出質疑。大會決議由美國再召集工作小組並增加持反對意見之成員討論後提下次會議討論。

<u>議題十二</u>、辛香料殘留標準研訂 **(Elaboration of MRLs for Spices)**

上次會議南非及辛香料主要生產國提案因辛香料皆小面積種植，或間作於主要糧食作物間，很難依GAP之規範提出制訂Codex MRLs之完整殘留量資料。另如乾辣椒(dried chilli)應屬加工食品不適合引用新鮮辣椒之安全值。且因辛香料之取食量及取食比率皆偏低，農藥殘留不致影響人體健康，因此建議能以地區性之調查資料（monitoring data）作為制訂MRLs之殘留量資料。大會原則同意，並要求JMPR研擬以monitoring data作為殘留量資料之評估準則，及南非收集及提供各國主要辛香料中農藥殘留之調查資料。本會議討論中意見分歧，如對「辛香料」之定義及種類、新鮮及乾燥之殘留量轉換、DDT等殘留之定位等。中國代表提出茶也應適用此準則但被否決。大會責成南非及JMPR再修正報告提下次會議討論。

<u>議題十三</u>、**Codex殘留標準作物分類修正 (The Revision of the Codex Classification of Foods and Animal Feeds)**

由於目前分類對於開發中國家之主要作物尤其是熱帶及亞熱帶之蔬菜水果太過粗糙，部分加工品、辛香料、非主要作物（minor crop）等作物也未含蓋，對於農產品國際貿易及作物安全標準之擴大解釋上皆造成困擾。上次大會討論分類修正是否只作部分增訂或作大幅度修正，及應顧及熱帶及亞熱帶開發中國家之特殊作物之農藥使用及殘留問題。大多數國家代表包括美國及澳洲認同大幅度修正，包括類別定義、作物歸屬分類、MRLs之共用等，並建議利用二國之作物分類電子檔作為Codex commodities修正之依據。然本議題召集國荷蘭代表卻贊成小幅

度修正以免影響整個Codex MRLs之運作。大會決議各國與Codex秘書處收集與會各國及國際組織之意見，再作修正後提下次會議討論。

議題十四、加工或即食食品之**MRLs（MRLs for processed or ready to eat foods or feeds）**

本議題自1980年起即多次提出討論，但一直未能達成共識。部分成員包括消保團體贊成以raw commodities MRLs適用於加工或即食食品，部分則認為部分必需加工或專供加工用之作物其用藥及殘留情形均有差異，引用raw commodities MRLs會造成貿易障礙或對取食風險有錯誤之評估。會議決議由美國會同有興趣的國家參與討論提下次會議討論。

議題十五、排除**JMPR**額外之工作負擔（**Removal of an extraneous burden from the workload of the JMPR**）

美國書面報告建議取消環境代謝（environment fate）資料審查以減少JMPR資料審查之負擔。然反對意見認為環境代謝資料與農田輪作之殘留及長殘效污染物EMRL訂定有關，且對無法進行該類試驗之國家具參考作用。大會決議保留環境代謝資料之需求及審查。

議題十六、其它待辦事項（**Other business and Future Work**）

就減少資料需求之議題EC建議大會將OECD/FAO Zoing Steering Group及EC/OECD Workshop之資料置於相關網站供與會單位參考及列入討論。FAO參與JMPR秘書建議成立計畫就田間試驗重複數及加工影響等由專家進行評估提出討論。

議題十七、下次會議時間及地點**(Date and place on next session)**

下次（第三十六屆）CCPR會議將於2004年4月19日至4月24日於印度新德里召開。

<u>議題十八</u>、會議結論(**Adoption of the Report)**

會議最後一天由大會記錄及秘書作為會議結論，由與會人員討論報告內容及結論。會議結論將送2004年6月30日至7月5日在義大利羅馬召開之「Twenty-sixth Session of Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission」(CAC)討論。

心得

一、聯合國食品標準委員會之組織及運作

聯合國為保障消費者健康及建立食品國際貿易之公平性，於1962年由世界糧農組織及衛生組織聯合成立食品標準委員會(Codex Alimentarius Commission（CAC）)(中國譯為食品法典委員會)以制訂食品安全之相關標準及執行規範。CAC下設Execusive Committee負責業務推行，並依食品、任務及地區分設各類委員會討論規範，分別為General Subject Committees、Commodity Committees、 Regional Coordinating Committees、 ad hoc Intergovernmental Task Forces。詳列表四至表七。

表四、食品類別委員會(Commodity Committees）摘要說明

委員會名稱Codex Committee	主辦國	成立年
Codex Committee on Cocoa Products and Chocolate (CCCPC)	瑞士	1963
Codex Committee on Sugars （CCS）	英國	1964
Codex Committee on Fat and Oils（CCFO ）	英國	1964
Codex Committee on Processed Fruits and Vegetables （CCPFV）	美國	1964
Codex Committee on Fish and Fishery Products (CCFFP)	挪威	1966
Codex Committee on Natural Mineral Waters （CCNMW）	瑞士	1966
Codex Committee on Meat and Poultry Hygiene (CCMPH)	紐西蘭	1972
Codex Committee on Vegetable Proteins （CCVP）	加拿大	1980
Codex Committee on Cereal,Pulses and Lgumes （CCCPL）	美國	1980
Codex Committee on Fresh Fruits andVegetables （CCNMFFV）	墨西哥	1988
Codex Committee on Milk and Milk Products (CCMMP)	紐西蘭	1994

表五、共通議題委員會(General Subject Committees）摘要說明

委員會名稱Codex Committee	主辦國	成立年
Codex Committee on Food Hygiene 食品衛生委員會(CCFH)	美國	1964
Codex Committee on Food Additives and Contaminants 食品添加物及污染物委員會(CCFAC)	荷蘭	1964
Codex Committee on General Principles 一般準則委員會（CCGP）	法國	1965
Codex Committee on Food Labelling 食品標示委員會(CCFL)	加拿大	1965
Codex Committee on Methods of Analysis and Sampling 分析及採樣方法委員會(CCMAS)	匈牙利	1965
Codex Committee on Pesticide Residues 農藥殘留委員會(CCPR)	荷蘭	1966
Codex Committee on Nutrition and Foods for Special Dietary Uses 特殊食品及營養委員會（CCNFDU）	德國	1966
Codex Committee on Residues of Veterinary Drugs in Foods 食品中動物用藥殘留委員會(CCRVDF)	美國	1986
Codex Committee on Food Import and Export Inspection and Certification System 食品進出口檢驗及認証委員會(CCFICS)	澳洲	1992

表六、特殊任務委員會(ad hoc Intergovernmental Task Force）摘要說明

委員會名稱ad hoc Codex Intergovernmental Task Force	主辦國	執行期限
On Foods derived from Biotechnology（CCFBT）	日本	2000-2003
On Fruits and Vegetable Juices (CCFJ)	巴西	2000-2005
On Animal Feeding Practices (CCAF)	丹麥	2000-2003

表七、區域性合作委員會(Regional Coordinationg Committees）摘要說明

委員會名稱Codex Committee	主辦國	成立年
FAO/WHO Coordinationg Committee for Europe（CCEURO）	Slovak Republic	1965
FAO/WHO Coordinationg Committee for Africa （CCAFRICA）	Uganda	1974
FAO/WHO Coordinationg Committee for Latin America and the Caribbean（CCLAC）	Dominican Repub.	1976
FAO/WHO Coordinationg Committee for Asia （CCASIA）	Malaysia	1977
FAO/WHO Coordinationg Committee for North America and the Southwest Pacific （CCNASWP）	Canada	1990
FAO/WHO Coordinationg Committee for Near East（CCNEA）	Egypt	2001

聯合國食品標準委員會之會員為凡聯合國之會員國均可申請入會。目前計有162個會員國。會員國代表有權利參與會議及制訂各項準則。非會員國代表或其它國際組織若有興趣亦可申請以觀察員名義參加。然非會員國必須為聯合國之會員，國際組織則應事先申請，說明組織之性質與會議主題之相關性，並証明與會代表為該組織成員及其專業背景，始能與會。

CAC及各委員會之運作有其一定之作業流程。各項標準之制定或準則之研訂必須依一定之格式草擬內容及方案，並經八個程序審查後始能定案。對於各項名詞也有明確之定義，譬如其所討論之「食品（Food）」即指所有人類所食用之食物、飲料及口香糖包括原料、半成品及加工品，但不含藥品、化粧品及煙草。

食品標準之草案內容須包括以下items:

1. Name of the Standard
2. Scope

3. Description
4. Essential composition and quality factors
5. Food additives
6. Contaminants
7. Hygiene
8. Weights and measures
9. Labelling
10. Methods of analysis and sampling

二、國際農藥殘留標準委員會之任務及重要性

國際農藥殘留標準委員會(CCPR)於1966年在荷蘭海牙召開第一屆委員會，2003年為第卅五屆。國際農藥殘留委員會之主要任務有六：

1. 制訂農藥在單項食品或大類食品中之最高殘留限量。
2. 制訂農藥殘留在動物飼料中最高殘留限量，以涉及國際貿易及對人體健康有影響者為限。
3. 制訂化學性質與農藥相近之環境及工業污染物在食品中之最高殘留限量。
4. 制訂與作物及食品中農藥殘留安全標準相關之試驗規範，如分析準則、農作物分類等。
5. 決定JMPR評估農藥之優先順序。
6. 討論其它與農藥殘留有關之食品安全問題。

CCPR會議至今已完成近三百種農藥之毒理及殘留量評估，並制訂超過二千五百個最高殘留限量(MRLs)。本人與會多次之感想為會議過程嚴謹，議題事前之資料準備齊全，各會員國代表與會前作充分溝通，會議全程參與熱烈討論，而且對新的問題皆能即時回應並作出具體結論。據與前大會主席Dr. W.H. Van Eck交談得知其在會前一個月必須全力詳讀資料及作準備才

能完全控制會議進度。本會議結論提交聯合國食品安全委員會作為食品安全管制標準，並為世界貿易組織引用為農畜產品交易之當然約定標準。世界各國也都非常重視此一會議，以美國為例，每次與會代表超過十名，包括環境保護署、食品藥物管理局、農業部及廠商代表，在國內則成立Codex工作小組，每月集會一次，針對會議相關議題進行討論，本年因美伊戰爭安全顧慮未能與會，仍以書面資料表示意見。各國也利用每年一次集會的機會，在會場分送國內相關報告互作交流。近年來除農藥工業主要生產國如美、日、德、韓、中等派多位代表出席，許多開發中國家如泰國、巴西、印度等也逐漸在會議中增加出席人數及發言參與討論。本人代表IUPAC國際組織，IUPAC在農藥方面其撰寫之分析準則及acute RfD評估準則也是會中主要之參考依據，本人均為作者之一。每年在CCPR會中除介紹IUPAC Agrochemicals and Environment Commission之工作摘要、主要出版報告外，同時也把握機會與各國與會代表交換農藥殘留容許量研訂之準則及了解各國對進出口農產品農藥殘留管制之原則。

三、農藥殘留調查及整體性評估之運用

本次會議討論農藥殘留分析方法、農作物分類及各國農藥殘留調查及評估資料，都可能影響農產品國際貿易之成敗。因此各國對於國內之農藥殘留檢驗方法之標準化及是符合國際規範均非常重視。

藥試所對於國內容許量研訂一直非常積極參與，於民國七十年發表「食用作物中農藥最高殘留容許量之訂定方法」，研訂一百廿種農藥在登記使用作物上之殘留容許量。七十五年九月召開「農產品中農藥殘留容許量研訂方法研討會」，會議通過容許量之訂定原則及程序，由衛生署委託藥毒所研討後送交農委會函轉衛生署審查公告之。同年十二月衛生署公告殘留農

藥安全容許量，正式取代施行十二年之暫行標準。本研訂方法及程序延用至今，至九十二年九月共公告307種農藥計1287組安全容許量。同時為製備國內農藥最高殘留容許量，於1973年即開始計算各類農產品之取食量，並以作物分類之方式以含蓋各類作物，每五年更新一次。1998年依據衛生署於1997年完成之「國民營養健康狀況變遷調查1993-1996」（NAHSIT 1993-1996）以二十四小時飲食回顧法調查國人膳食資料分析整理所得，製備十三歲至六十四歲計十二組之取食量資料，並考慮進口之農產品。另藥試所於1993年以Codex建議之模式完成國民經取食農藥殘留暴露量安全評估報告，其模式與本次會議討論之方式幾近相同，1998年進行為期二年全省經口取食農藥暴露量評估計畫。2001年起衛生署委託藥試所進行為期五年之食品污染物國人總膳食調查計畫（Taiwan Total Diet Study），依本國國民之取食調查資料規畫採樣食物種類及烹調食譜，不同地區及季節採集生鮮食材或即食樣品，經食前處理後以食用狀態分析其中污染物之含量，再依不同年齡層及性別之國民取食量計算其檢出污染物中可能之暴露量，以評估國人經由攝食之危害風險。本計畫為衛生署食品衛生處大型計畫之一，計畫規畫時已參考Codex之準則，執行亦依國際標準規範進行，預期本研究成果不但可反應國人取食最接近事實之風險，並可作為運用於我國農產品之外銷諮商最具科學依據之談判資料。

四、由Codex MRLs制訂流程檢討國內農藥管理制度

Codex制訂之各項食品安全標準及準則所以可以在WTO及國際貿易上得到各國之重視，其嚴謹之製備流程是主要的因素。由CCPR所建立之農藥殘留最高限量每一個數值均須經一定的審查步驟，而提供每一農藥MRL's值之JMPR每年皆須以一個月的時間來進行毒理資料及殘留量資料的評估資料，對於每一項資料製備的標準流程也有準則可遵循。我國農藥管理法於

1972年公告實施，多年來為了扶持國內農藥產業及減輕廠商負擔，有關農藥登記所需提供之資料及田間試驗規範均與國際標準有相當之差距。我國成為WTO會員國後，中央農業主管人員參與國際談判後也體會到建立符合國際標準工作準則之重要性，開始要求國內各項試驗必要具有符合GAP或 GLP的實驗數據，然卻忽略了這些數據的產生不是一個公文一句命令就可以做到，是須要多年的扶持及相關政令的配合才能達到。中央主管農藥事務人員非專職專業，農藥研發及管理之經費嚴重不足，地方政府農藥管理為兼辦業務，「農藥」二個字因為「形象不好」在國科會的科技研究項目中連名字都消失了。再再顯示台灣的農藥管理及研究如何不被重視。農藥登記相關試驗非由廠商在提出申請前自行完成而是依法由政府單位完成；農藥毒理資料初步審查由研究人員兼辦，農藥技術諮議委員會委員遴選重視機關職位高低而輕視農藥專業素養；農藥殘留量田間試驗依附於藥效試驗下，無法以足夠的經費時間及人力製備完整之資料供 Codex 研擬我國主要作物之容許量。台灣農藥管理若無法由政策上進行全面改革，入關後門戶開放，各國品質不一之農藥充斥市面，農藥管理制度不易推行，農產品安全品質之提昇更會增加許多困難。

建議

一、 積極參與聯合國食品標準委員會會議及運用準則

聯合國食品標準委員會所制訂之各項食品安全標準及標示或管理準則雖未必與各國現行之食品安全衛生管理法相同，但參與起草及討論之會員國會將其國內之考量因素列入準則之規範中，且在食品進出口之協議上尤其是WTO會員國間Codex 標準一向被為視為共同遵守之準則。我國雖非Codex 之會員國但對Codex standard 草擬作業之方式及其進行之議題仍應如其它國家一樣重視。許多國家都設置National Codex Office，定期討論Codex之各項準則對國內食品管理及食品貿易間之利害關係及影響。我國在加入WTO以後，台灣廣大之消費人口是許多國家傾銷食品之重要市場，同時政府也應協助農民及食品工廠積極拓展外銷市場，Codex standard的分析及運用不論對進口食品之查驗檢疫管理，或對出口食品之品管文件及貿易談判之內容，均佔非常之角色。CAC所研擬之2003至2007年中長期策略方案即希望Codex Standard 對各國食品之生產、製造、管理及貿易達到最大之影響力，因此也針對消費者、食品業者及農民進行說帖呼籲其重視Codex standard 對其產業及生活之影響。我國在因應WTO之食品產業策略上應重視Codex standard之影響，應成立專責部門，對Codex各委員會之會議決議與國內之現行法令立即進行利益評估，且應將公告之Codex guidelines及 standard以中文版全文或摘錄之方式，介紹給政府相關單位、食品業者及生產者參考。

我國因中國強力阻撓及非聯合國會員國，因而無法參與許多以政府為與會主體之會議，長久以往容易導致政府及人民忽視國際間之重要會議及其協議，而使我國在國際市場之開拓及政府間之談判因不熟知國際通則而無法達到最有利之結果。現我國開放國內之食品市場，龐大的消費人口及消費能力是許多

國家如美國及澳洲的貿易目標。我國應利用此等貿易談判之機會，要求該等國家以Codex委員會主辦國及視我國為WTO會員國為前題，尋求出席聯合國食品標準委員會或參與各項議題討論之機會。或將我國對Codex準則之意見及立場在雙方談判時反應給對方，尋求共識及支持，以保障我國之權益。對於進口食品之安全品質查驗及管理應研究Codex準則以尋求對消費者健康達到最大之保障又不違反國際貿易之公平性。對出口之食品或農產品面臨進口國因與我國管理制度不同而造成之貿易障礙也應尋求利用Codex 之準則予以突破。使我國在進出口食品之管理及貿易上達到政府、業者及消費者最大利益及保障。

二、與**CCPR**同步研提農藥殘留研究重點

CCPR以研提及修正Codex MRLs及其相關議題為重點，每一個列入討論之農藥其討論重點及結論皆直接或間接反應該農藥之安全性及評估重點。每年討論議題更是農藥殘留管理不容忽視的一環。如許多農藥因原廠不再生產而無法提供再評估資料因而取消Codex MRLs者，在國內對該類農藥之品質及毒性及殘留管理則應提高警覺。又acute RfD二年來列入研訂重點，其運用及評估準則也由IUPAC製備完成，本人也是作者之一，在研究經費及人力許可之下應與世界同步進行acute RfD之評估。政府也該重視標準評估方法及準則之重要性，任由無取得國家或公信單位認可之方法四處橫行不予約束，以檢測急性毒性之名混淆視聽，製造消費者恐慌，誤導供銷者認定標準，損及生產者權益，實不容再忽視其對社會及國際形象之影響。

三、長期進行食品及環境中農藥安全評估工作

農藥為植物保護的資材，合法合理使用才能降低對環境生態及國民健康的威脅。農藥殘留最高容許量或最高殘留限量是食品安全的標準，食品衛生管理上可作為農產品例行安全檢驗

之法則。然農藥殘留是因使用而造成，因此市售農產品上之農藥殘留也因使用情形而異。以近來年藥檢局或藥試所蔬果農藥殘留抽檢結果，有農藥殘留者約佔40%，不符合容許量標準者約3%，遠低於每人每日可攝入量。為了解國民經取食可能受到農藥殘留的影響，及提供社會大眾一個合理的評估數據，成立長期性之食品污染物國人總膳食計畫，定期依國民取食農畜水產品之比率，依季節性及地區性進行市售樣品採集及經食前處理及烹煮後進行農藥殘留分析及安全評估。此等資料的建立除對國民食品安全品質作長期監測評估外，在食品安全管理上也是非常重要的國際性安全指標，應積極辦理。

四、善用農藥管理專責機構之人力資源及研究成果

我國為配合加入WTO之需要，將大量之人力及財力投入檢防疫體系。且為迎合消費者對有機農產品之迷思及避免接觸敏感之農藥殘留問題，政府對整個植物保護的方向完全偏向配合有機農業栽培及非農藥防治方法的研發，植物保護大部分人力及業務偏向檢疫及防疫而忽略檢驗之重要性。植物保護工作是農作物的醫療體系，值得政府成立專一的管理機關來作整體性的規劃，忽略農藥合理使用的研究或逃避繁雜體系的建立都不能使台灣農業得到永續的發展。目前農藥管理必須改進的地方很多，包括修訂農藥管理法規，健全登記資料審查制度，重新檢討田間試驗規範，成品農藥品質維護及農藥使用對農民及消費者之保障等。政府應增列預算增加人力，附於專責機構有足夠的資源建立完善的農藥管理體系。並應以尊重專業的心態正視其研究成果，畢竟專業人才養成不易，若不加以善用甚而引用外行打擊專業，對國家及個人都是一種損失。

附件一、本報告引用專有名詞簡稱說明

簡稱	說明
Acute RfD	Acute Reference Dose
ADI	Acceptable Daily Intake
CAC	Codex Alimentarius Commission
CCFAC	Codex Committee on Food Addititves and Contaminants
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CIPAC	Collaborative International Pesticides Analytical Council
CXL	Codex Maximum Residue Limit for Pesticide
EMRL	Extraneous Maximum Residue Limit
FAO	Food and Agriculture Organization
GAP	Good Agricultural Practice
GEMS	Global Environment Monitoring System
GLP	Good Laboratory Practice
IEDI	International Estimated Daily Intake
IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
MRL	Maximum Residue Limit
SPS	Sanitary and Phytosanitary Measures
WHO	World Health Organization
WTO	World Trade Organization

附件二、DRAFT REVISED GUIDELINES ON GOOD LABORATORY PRACTICE IN RESIDUE ANALYSIS

(At Step 8 of the Codex Procedure)

FOREWORD

The Guidelines are intended to assist in ensuring the reliability of analytical results in checking compliance with maximum residue limits of foods moving in international trade. Reliable analytical results are essential to protect the health of consumers and to facilitate international trade.

In addition to the present Guidelines, other relevant Codex recommendations elaborated by the Codex Committee on Pesticide Residues (CCPR) in the field of enforcement of Codex maximum limits for pesticide residues are as follows:

1. Recommended Method of Sampling for the Determination of Pesticide Residues (CAC/GL 33-1999, Vol.2A, part 1, 2nd Edition, Room, 2000)
2. Portion of Commodities to which Codex Maximum Residue Limits Apply and which should be analysed(CAC/GL 33-1999, Vol.2A, part 1, 2nd Edition, Room, 2000)
3. List of Codex Maximum Residue Limits for Pesticides (Codex Alimentarius, Vol.2, Pesticide residue in food, Room, 1993).
4. Recommend Methods of Analysis of Pesticide Residues(CAC/GL 33-1999, Vol.2A, part 1, 2nd Edition, Room, 2000)
5. Codex Classification of Food and Animal Feed(Codex Alimentarius, Vol.2, Pesticide residue in food, Room, 1993).

1. INTRODUCTION

It was considered that the ultimate goal in fair practice in international trade depended, among other things, on the reliability of analytical results. This in turn, particularly in pesticide residue analysis, depended not only on the availability of reliable analytical methods, but also on the experience of the analyst and on the maintenance of 'good practice in the analysis of pesticides

These guidelines define such good analytical practice and may be considered in three inter-related parts:

The Analyst (par. 2);

Basic Resources (par. 3);

The Analysis (par.4).
The requirements for facilities, management, personnel, quality assurance and quality control, documentation of results and raw data, and relevant subjects, which are considered as prerequisites for obtaining reliable and traceable results, are described in general in the ISO/IEC 17025 Standard (1999) and in a series of OECD GLP Guidance Documents, in the corresponding national laws and regulations. This Codex Guidelines, which are not exhaustive, outline the most essential principles and practices to be followed in the analysis of pesticide residues.

2. THE ANALYST

2.1 Residue analysis consists of a chain of procedures, most of which are known, or readily understood, by a trained chemist, but because the analyte concentrations are in the range ug/kg to mg/kg and because the analyses can be challenging, attention to detail is essential. The analyst in charge should have an appropriate professional qualification and be experienced and competent in residue analysis. Staff must be fully trained and experienced in the correct use of apparatus and in appropriate laboratory skills. In addition, each analyst using the method for the first time should complete the tests specified in sections 4.4.5 of Table 4 to demonstrate that they can use the method within the expected performance parameters established during method validation prior to analysis of samples. They must have an understanding of the principles of pesticide residue analysis and the requirements of Analytical Quality Assurance (AQA) systems. They must understand the purpose of each stage in the method, the importance of following the methods exactly as described and of noting any unavoidable deviations. They must also be trained in the evaluation and interpretation of the data that they produce. A record of training and experience must be kept for all laboratory staff.

2.2 When a laboratory for residue analysis is set up, the staff should spend some of their training period in a well established laboratory where experienced advice and training is available. If the laboratory is to be involved in the analysis for a wide range of pesticide residues, it may be necessary for the staff to gain experience in more than one expert laboratory.

3. BASIC RESOURCES

3.1 THE LABORATORY

3.1.1. The laboratory and its facilities must be designed to allow tasks to be allocated to well-defined areas where maximum safety and minimum chance of contamination of samples prevail. Laboratories should be constructed of, and utilise, materials resistant to chemicals likely to be used within them. Under ideal conditions, separate rooms would be designated for sample receipt and storage, for sample preparation, for extraction and clean-up and for instrumentation used in the determinative step. The area used for extraction and clean-up must meet solvent laboratory specifications and all fume extraction facilities must be of high quality. Sample receipt, storage and preparation should be handled in areas devoted to work at residue levels. Maintenance of sample integrity and adequate provisions for personal safety are priority requirements.

3.1.2 Laboratory safety must also be considered in terms of what is essential and what is preferable, as it must be recognised that the stringent working conditions enforced in residue laboratories in some parts of the world could be totally unrealistic in others. No smoking, eating, drinking or application of cosmetics should be permitted in the working area. Only small volumes of solvents should be held in the working area and the bulk of the solvents stored separately, away from the main working area. The use of highly toxic solvents and reagents should be minimised whenever possible. All waste solvent should be stored safely and disposed of both safely and in an environmentally friendly manner taking into account specific national regulations where available.

3.1.3 The main working area should be designed and equipped for utilisation of an appropriate range of analytical solvents. All equipment such as lights, macerators and refrigerators should be "spark free" or "explosion proof". Extraction, clean-up and concentration steps should be carried out in a well ventilated area, preferably in fume cupboards.

3.1.4 Safety screens should be used when glassware is used under vacuum or pressure. There should be an ample supply of safety glasses, gloves and other protective clothing, emergency washing facilities and a spillage treatment kit. Adequate fire fighting equipment must be available. Staff must be aware that many pesticides have acutely or chronically toxic properties and therefore, great care is necessary in the handling of standard reference compounds.

3.2 EQUIPMENT AND SUPPLIES

3.2.1 The laboratory will require adequate, reliable, supplies of electricity and water. Adequate supplies of reagents, solvents, gas, glassware, chromatographic materials, etc., of suitable quality are essential.

3.2.2 Chromatographic equipment, balances, spectrophotometers etc. must be serviced and calibrated regularly and a record of all servicing/repairs must be maintained for every such item of equipment. Calibration is essential for equipment performing measurements. Calibration curves and comparison with standards may suffice.

3.2.3 Regular calibration and re-calibration of measuring equipment must be done where the possible change in nominal value may significantly contribute to the uncertainty of the measurement. Balances and automated pipettes/ dispensers and similar equipment must be calibrated regularly. The operating temperatures of refrigerators and freezers should be continually monitored or be checked at specified intervals. All records should be kept up-to-date and retained.

3.2.4 Equipment used must be fit for purpose.

3.2.5 All laboratories require pesticide reference standards of known and acceptably high purity. Analytical standards should be available for all parent compounds for which the laboratory is monitoring samples, as well as those metabolites that are included in MRLs.

3.2.6 All analytical standards, stock solutions and reagents whose integrity could be influenced by degradative processes must be clearly labelled with an expiry date and stored under proper conditions. "Pure" reference standards must be kept under conditions that will minimise the rate of degradation, e.g. low temperature, exclusion of moisture, darkness. Equal care must be taken that standard solutions of pesticides are not decomposed by the effect of light or heat during storage or become concentrated owing to solvent evaporation.

4. THE ANALYSIS

The methods applied for the determination of pesticide residues should generally satisfy the criteria given in Table 3.

4.1 AVOIDANCE OF CONTAMINATION

4.1.1 One of the significant areas in which pesticide residue analysis differs significantly from macro-analysis is that of contamination and interference. Trace amounts of contamination in the final samples used for the determination stage of the method can give rise to errors such as false positive or false negative results or to a loss of sensitivity that may prevent the residue from being detected. Contamination may arise from almost
anything that is used for, or is associated with, sampling, sample transport and storage, and the analyses. All glassware, reagents, organic solvents and water should be checked for possible interfering contaminants before use, by analysis of a reagent blank.

4.1.2 Polishes, barrier creams, soaps containing germicides, insect sprays, perfumes and cosmetics can give rise to interference problems and are especially significant when an electron-capture detector is being used. There is no real solution to the problem other than to ban their use by staff while in the laboratory.

4.1.3 Lubricants, sealants, plastics, natural and synthetic rubbers, protective gloves, oil from ordinary compressed air lines and manufacturing impurities in thimbles, filter papers and cotton-wool can also give rise to contamination.

4.1.4 Chemical reagents, adsorbents and general laboratory solvents may contain, adsorb or absorb compounds that interfere in the analysis. It may be necessary to purify reagents and adsorbents and it is generally necessary to use re-distilled solvents. Deionised water is often suspect; re-distilled water is preferable, although in many instances tap water or well water may be satisfactory.

4.1.5 Contamination of glassware, syringes and gas chromatographic columns can arise from contact with previous samples or extracts. All glassware should be cleaned with detergent solution, rinsed thoroughly with distilled (or other clean) water and then rinsed with the solvent to be used. Glassware to be used for trace analysis must be kept separate and must not be used for any other purpose.

4.1.6 Pesticide reference standards should always be stored at a suitable temperature in a room separate from the main residue laboratory. Concentrated analytical standard solutions and extracts should not be kept in the same storage area.

4.1.7 Apparatus containing polyvinylchloride (PVC) should be regarded as suspect and, if shown to be a source of contamination, should not be allowed in the residue laboratory. Other materials containing plasticizers should also be regarded as suspect but PTFE and silicone rubbers are usually acceptable and others may be acceptable in certain circumstances. Sample storage containers can cause contamination and glass bottles with ground glass stoppers may be required. Analytical instrumentation ideally should be housed in a separate room. The nature and importance of contamination can vary according to the type of determination technique used and the level of pesticide residue to be determined. For instance contamination problems which are important with methods based on gas chromatography or high performance liquid chromatography, may well be less significant if a spectrophotometric determination is used, and vice versa. For relatively high levels of residues, the background interference from solvents and other materials may be insignificant in comparison with the amount of residue present. Many problems can be overcome by the use of alternative detectors. If the contaminant does not interfere with the residue determination, its presence may be acceptable.

4.1.8 Residues and formulation analyses must have completely separate laboratory facilities provided. Samples and sample preparation must be kept separate from the all residue laboratory operations in order to preclude cross contamination.

4.2 RECEPTION AND STORAGE OF SAMPLES

4.2.1 Every sample received into the laboratory should be accompanied by complete information on the source of the sample, on the analysis required and on potential hazards associated with the handling of that sample.

4.2.2 On receipt of a sample it must immediately be assigned a unique sample identification code which should accompany it through all stages of the analysis to the reporting of the results. If possible, the samples should be subject to an appropriate disposal review system and records should be kept.

4.2.3 Sample processing and sub-sampling should be carried out using procedures that have been demonstrated to provide a representative analytical portion and to have no effect on the concentration of residues present.

4.2.4 If samples cannot be analysed immediately but are to be analysed quickly, they should be stored at (1 - 5°C), away from direct sunlight, and analysed within a few days. However, samples received deep-frozen must bekept at under -16 oC until analysis. In some instances, samples may require storage for a longer period before analysis. In this cases, storage temperature should be approximately - 20 °C, at which temperature enzymic degradation of pesticide residues is usually extremely slow. If prolonged storage is unavoidable, the effects of storage should be checked by analysing fortified samples stored under the same conditions for a similar period. Useful information on storage stability of pesticide residues can be found in the annual publications of FAO titled: Pesticide Residues - Evaluations prepared by the FAO/WHO JMPR, and in the information submitted by the manufacturers for supporting the registration of their pesticides.

4.2.5 When samples are to be frozen it is recommended that analytical test portions be taken prior to freezing in order to minimise the possible effect of water separation as ice crystals during storage. Care must still be taken to ensure that the entire test portion is used in the analysis.

4.2.6 The containers must not leak. Neither the containers used for storage nor their caps or stoppers should allow migration of the analyte(s) into the storage compartment.

4.3 STANDARD OPERATING PROCEDURES (SOPS)

4.3.1 SOPs should be used for all operations. The SOPs should contain full working instructions as well as information on applicability, expected performance, internal quality control (performance verification) requirements and calculation of results. It should also contain information on any hazards arising from the method, from standards or from reagents.
4.3.2 Any deviations from a SOP must be recorded and authorised by the analyst in charge.

4.4 VALIDATION OF METHODS1

4.4.1 Guidelines have been published for validation of analytical procedures for various purposes. The principles described in this section are considered practical and suitable for validation of pesticide residue analytical methods. The guidance is not normative. The analyst should decide on the degree of validation required to demonstrate that the method is fit for the intended purpose, and should produce the necessary validation data accordingly. For instance, the requirements for testing for compliance with MRLs or providing data for intake estimation may be quite different.

4.4.2 An analytical method is the series of procedures from receipt of a sample to the production of the final result. Validation is the process of verifying that a method is fit for the intended purpose. The method may be developed in-house, taken from the literature or otherwise obtained from a third party. The method may then be adapted or modified to match the requirements and capabilities of the laboratory and/or the purpose for which the method will be used. Typically, validation follows completion of the development of a method and it is assumed that requirements such as calibration, system suitability, analyte stability, etc., have been established
satisfactorily. When validating and using a method of analysis, measurements must be made within the calibrated range of the detection system used. In general, validation will precede practical application of the method to the analysis of samples but subsequent performance verification is an important continuing aspect of the process.
Requirements for performance verification data are a sub-set of those required for method validation.
Proficiency testing (or other inter-laboratory testing procedures), where practicable, provides an important means for verifying the general accuracy of results generated by a method, and provides information on the betweenlaboratory variability of the results. However, proficiency testing generally does not address analyte stability or homogeneity and extractability of analytes in the processed sample.
Where uncertainty data are required, this information should incorporate performance verification data and not rely solely on method validation data.

4.4.3 Whenever a laboratory undertakes method development and/or method modification, the effects of analytical variables should be established, e.g. by using ruggedness tests, prior to validation. Rigorous controls must be exercised with respect to all aspects of the method that may influence the results, such as: sample size; partition volumes; variations in the performance of the clean-up systems used; the stability of reagents or of the derivatives prepared; the effects of light, temperature, solvent and storage on analytes in extracts; the effects of solvent, injector, separation column, mobile phase characteristics (composition and flow-rate), temperature, detection system, co-extractives etc. on the determination system. It is most important that the qualitative and quantitative relationship between the signal measured and the analyte sought are established unequivocally.

4.4.4 Preference should be given to methods having multi-residue and or multi-matrix applicability. The use of representative analytes or matrices is important in validating methods. For this purpose, commodities should be differentiated sufficiently but not unnecessarily. For example, some products are available in a wide range of minor manufactured variants, or cultivated varieties, or breeds, etc. Generally, though not invariably, a single variant of a particular commodity may be considered to represent others of the same commodity but, for example, a single fruit or vegetable species must not be taken to represent all fruit or vegetables (Table 5). Each case must be considered on its merits but where particular variants within a commodity are known to differ from others in their effects on method performance, analyses of those variants are required. Considerable differences in the accuracy and precision of methods, especially with respect to the determination step, may occur from species to species.

4.4.4.1 Where experience shows similar performance of extraction and clean-up between broadly similar commodities/sample matrices, a simplified approach may be adopted for performance validation. A representative commodity may be selected from Table 5 to represent each commodity group having common properties, and used for validation of the procedure or method. In Table 5, the commodities are classified according to the Codex Classification2.

- Some examples of how far the validation data may be extended to other commodities are: cereals, validation for whole grains cannot be taken to apply to bran or bread but validation for wheat grain may apply to barley grain or wheat four;
- animal products, validation for muscle should not be taken to apply to fat or offal but validation for chickenfat may apply to cattle fat;
- fruit and vegetables, validation for a whole fresh product cannot be taken to apply to the dried product but validation for cabbages may apply to Brussels sprouts.

4.4.4.2 Similarly representative analytes may be used to assess the performance of a method. Compounds may be selected to cover physical and chemical properties of analytes that are intended to be determined by the method. The selection of representative analytes should be made based on the purpose and scope of analysis taking into account the following.

(a) The representative analytes selected should:

(i) possess sufficiently wide range of physico-chemical properties to include those ofrepresented analytes;

(ii) be those which are likely to be detected regularly, or for which critical decisions will bemade based on the results.

(b) As far as practicable, all analytes included in the initial validation process should be those which will have to be tested regularly and which can be determined simultaneously by the determination system used.

(c) The concentration of the analytes used to characterise a method should be selected to cover the accepted limits (AL, see Glossary) of all analytes planned to be sought in all commodities. Therefore the selected representative analytes should include, among others, those which have high and low ALs. Consequently, the fortification levels used in performance testing with representative analytes/representative commodities may not necessarily correspond to the actual ALs.

4.4.5 Where appropriate data are already available, it may not be necessary for the analyst to perform all the tests. However, all required information must be included or referred to in the validation records. Table 1 provides an overview of parameters to be assessed for method validation according to the status of the method to be validated. Specific parameters and criteria to be assessed are listed in table 2. Parameters to be assessed should be restricted to those that are appropriate both to the method and to the purpose for which the particular method is to be applied. In many cases, performance characteristics with respect to several parameters may be obtained simultaneously using a single experiment. Test designs where different factors are changed at the same time (factorial experiment designs), may help to minimise the resources required. The performance of the analytical method should be checked, both during its development and during its subsequent use as indicated in section 4.5, according to the criteria given in Table 3.

4.4.6 Individual (single residue) methods should be fully validated with all analyte(s) and sample materials specified for the purpose, or using sample matrices representative of those to be tested by the laboratory.

4.4.7 Group specific methods (GSM) should be validated initially with one or more representative commodities and a minimum of two representative analytes selected from the group.

4.4.8 MRMs may be validated with representative commodities and representative analytes.

4.5 PERFORMANCE VERIFICATION

4.5.1 The main purposes of performance verification are to:

- . monitor the performance of the method under the actual conditions prevailing during its use;
- ttake into account the effect of inevitable variations caused by, for instance, the composition of samples, performance of instruments, quality of chemicals, varying performance of analysts and laboratoryenvironmental conditions;
- demonstrate that the performance characteristics of the method are broadly similar to those established at method validation, showing that the method is under "statistical control", and the accuracy anduncertainty of the results are comparable to those expected of the method. For this purpose, data obtained during method validation may be updated with data collected from performance verification during the regular use of the method.

The results of internal quality control provide essential information on the long term reproducibility and other performance characteristics of the method including the analytes and commodities which were incorporated during the extension of the method.
The basic performance characteristics to be tested and the appropriate test procedures are described in Table 2.
For effective performance verification, analyse samples concurrently with appropriate quality control analyses (blank and recovery determinations, reference materials, etc.). Control charts may be used to check for trends
in performance of the method and to ensure that statistical control is maintained.

4.5.2 Construction and use of control charts.

4.5.2.1 Control charts may be a useful tool for demonstrating the performance of a method and the reproducibility of its selected parameter. One example for that is the control chart for recoveries. Its application depends on the tasks of the laboratory. When a large number of the same type of sample is analysed for the same active ingredients the control chart is based on the mean recovery and its standard deviation obtained during
the regular use of the method. When small numbers of each of a large

variety of samples are analysed for a great number of analytes with a multi-residue procedure the control charts cannot be applied in the usual way. In such cases, initially a control chart is constructed with the average recovery (Q) of representative analytes in representative matrices and the typical within-laboratory reproducibility coefficient of variation (CVAtyp), obtained as described below. . When the average recovery data and their coefficient of variation obtained during method validation for individual analyte/sample matrices are not statistically different, each can be considered as an estimate of the true recovery and precision of the method, and with their appropriate combination the typical recovery (Qtyp) and coefficient of variation (CVAtyp) of the method can be established and used for constructing the initial control chart. The warning and action limits are Qtyp+-2*CVAtyp*Q and Qtyp+-3*CVAtyp*Q, respectively.

4.5.2.2 When the method is applied for regular analysis of various analyte/matrix combinations represented during the validation of the method, the individual recoveries are plotted on the chart. The reproducibility of the method during its normal use may be somewhat higher then obtained at the validation of the method. Therefore, if some of the recoveries are outside the warning limits or occasionally the action limits, but they are within the ranges calculated from the CVA values specified in Table 3, no special action is required.

4.5.2.3 Based on the additional 15-20 recovery tests performed during the regular use of the method, as part of performance verification, the mean or typical recovery and the CVA shall be recalculated and a new control chart constructed which reflects the long term reproducibility of the application of the method. The new parameters established must be within the acceptable ranges specified in Table 3.

4.5.2.4 If this is not achievable, for example in the case of particularly problematic analytes, results from samples should be reported as having poorer accuracy or precision than is normally associated with pesticide residues determination.

4.5.2.5 During the regular use of the method, if the average of the first >=10 recovery tests for a particular analyte/sample matrix is significantly different (P=0.05) from the average recovery obtained for the representative analyte/sample matrices, the Qtyp and CVtyp are not applicable. Calculate new warning and action limits for the particular analyte/sample matrix, applying the new average recovery and the CV values measured.

4.5.2.6 If performance verification data repeatedly fall outside the warning limits (1 in 20 measurements outside the limit is acceptable), the application conditions of the method must be checked, the sources of error(s) identified, and the necessary corrective actions taken before use of the method is continued.

4.5.2.7 If performance verification data are outside the refined action limits established according to 4.5.2.1 to 4.5.2.3 section, the analytical batch involved (or at least samples in which residues found are >=0.7 AL or 0.5 AL, for regularly and occasionally detected analytes, respectively) should be repeated.

4.5.2.8 Re-analysis of analytical portions of positive samples is another powerful way of performance verification. Their results can be used to calculate the overall within-laboratory reproducibility of the method (CVLtyp) in general or for a particular analyte/sample matrix. In this case, the CVLtyp will also include the uncertainty of sample processing, but will not indicate if the analyte is lost during the process.

4.6 CONFIRMATORY TESTS

4.6.1 When analyses are performed for monitoring or enforcement purposes, it is especially important that confirmatory data are generated before reporting on samples containing residues of pesticides that are not normally associated with that commodity, or where MRLs appear to have been exceeded. Samples may contain interfering chemicals that may be misidentified as pesticides. Examples in gas chromatography include the responses of electron-capture detectors to phthalate esters and of phosphorus-selective detectors to compounds containing sulphur and nitrogen. As a first step, the analysis should be repeated using the same method, if only one portion was analyzed initially. This will provide evidence of the repeatability of the result, if the residue is confirmed. It should be noted that the only evidence supporting the absence of detectable residues is provided by the performance verification data.

4.6.2 Confirmatory tests may be quantitative and/or qualitative but, in most cases, both types of information will be required. Particular problems occur when residues must be confirmed at or about the limit of determination but, although it is difficult to quantify residues at this level, it is essential to provide adequate confirmation of both level and identity.

4.6.3 The need for confirmatory tests may depend upon the type of sample or its known history. In some crops or commodities, certain residues are frequently found. For a series of samples of similar origin, which contain residues of the same pesticide, it may be sufficient to confirm the identity of residues in a small proportion of the samples selected randomly. Similarly, when it is known that a particular pesticide has been applied to the sample material there may be little need for confirmation of identity, although a randomly selected results should be confirmed. Where "blank" samples are available, these should be used to check the occurrence of possible interfering substances.

4.6.4 Depending upon the initial technique of determination, an alternative procedure which may be a different detection technique, may be necessary for verification of quantity. For qualitative confirmation (identity) the use
of mass-spectral data, or a combination of techniques based on different physico-chemical properties, is desirable (see Table 6).

4.6.5 The necessary steps to positive identification are a matter of judgement on the analyst's part and particular attention should be paid to the choice of a method that would minimise the effect of interfering compounds. The technique(s) chosen depend(s) upon the availability of suitable apparatus and expertise within the testing laboratory. Some alternative procedures for confirmation are given in Table 6.

4.7 MASS SPECTROMETRY

4.7.1 Residue data obtained using mass spectrometry can represent the most definitive evidence and, where suitable equipment is available, it is the confirmatory technique of choice. The technique can also be used for residue screening purposes. Mass spectrometric determination of residues is usually carried out in conjunction with a chromatographic separation technique to provide retention time, ion mass/charge ratio and ion abundance data simultaneously. The particular separation technique, the mass spectrometer, the interface between them and the range of pesticides to be analysed are usually interdependent and no single combination is suitable for the analysis of all compounds. Quantitative transmission of labile analytes through the chromatographic system and interface is subject to problems similar to those experienced with other detectors. The most definitive confirmation of the presence of a residue is the acquisition of its "complete" electron-impact ionisation mass spectrum (in practice generally from m/z50 to beyond the molecular ion region). The relative abundances of ions in the spectrum and the absence of interfering ions are important considerations in confirming identity. This mode of analysis is one of the least selective and interference from contaminants introduced during the production or storage of extracts should be scrupulously avoided. Mass spectrometer data systems permit underlying interference (eg column bleed) signals to be removed by "background subtraction" but this technique must be used with caution. Increased sensitivity can usually be achieved by means of limited mass range scanning or by selected ion monitoring but the smaller the number of ions monitored (especially if these are of low mass), the less definitive are the data produced. Additional confirmation of identity may be obtained (i) by the use of an alternative chromatographic column; (ii) by the use of an alternative ionisation technique (eg chemical ionisation); (iii) by monitoring further reaction products of selected ions by tandem mass spectrometry (MS/MS or MSn); or (iv) by monitoring selected ions at increased mass resolution. For quantification, the ions monitored should be those that are the most specific to the analyte, are subject to least interference and provide good signal-to-noise ratios. Mass spectrometric determinations should satisfy similar analytical quality control criteria to those applied to other systems.

4.7.2 Confirmation of residues detected following separation by HPLC is generally more problematic than where gas chromatography is used. If detection is by UV absorption, production of a complete spectrum can provide good evidence of identity. However, UV spectra of some pesticides are poorly diagnostic, being similar to those produced by many other compounds possessing similar functional groups or structures, and co-elution of interfering compounds can create additional problems. UV absorption data produced at multiple wavelengths may support or refute identification but, in general, they are not sufficiently characteristic on their own. Fluorescence data may be used to support those obtained by UV absorption. LC-MS can provide good supporting evidence but, because the spectra generated are generally very simple, showing little characteristic fragmentation, results produced from LC-MS are unlikely to be definitive. LC-MS/MS is a more powerful technique, combining selectivity with specificity, and often provides good evidence of identity. LC-MS techniques tend to be subject to matrix effects, especially suppression, and therefore confirmation of quantity may require the use of standard addition or isotopically-labelled standards. Derivatisation may also be used for confirmation of residues detected by HPLC (paragraph 4.6.5.4).

4.7.3 In some instances, confirmation of gas chromatographic findings is most conveniently achieved by TLC. Identification is based on two criteria, Rf value and visualisation reaction. Detection methods based on bioassays (e.g. enzyme -, fungal groth or chloroplast inhibition) are especially suitable for qualitative confirmation as they are specific to certain type of compounds, sensitive and normally very little affected by the co-extracts. The scientific literature contains numerous references to the technique, the IUPAC Report on Pesticides (13) (Bátora, V., Vitorovic, S.Y., Thier, H. -P. and Klisenko, M.A.; Pure & Appl. Chem., 53, 1039-1049 (1981)) reviews the technique and serves as a convenient introduction. The quantitative aspects of thin-layer chromatography are, however, limited. A further extension of this technique involves the removal of the area on the plate corresponding to the Rf of the compound of interest followed by elution from the layer material and further chemical or physical confirmatory analysis. A solution of the standard pesticide should always be spotted on the plate alongside the sample extract to obviate any problems of non-repeatability of Rf. Over-spotting of extract with standard pesticide can also give useful information. The advantages of thin layer chromatography are speed, low cost and applicability to heat sensitive materials; disadvantages include (usually) lower sensitivity and separation power than instrumental chromatographic detection techniques and need for more efficient cleanup in case of detections based on chemicals colour reactions.

4.8 DERIVATISATION

This area of confirmation may be considered under three broad headings.

(a) Chemical reactions

Small-scale chemical reactions resulting in degradation, addition or condensation products of pesticides, followed by re-examination of the products by chromatographic techniques, have frequently been used. The reactions result in products possessing different retention times and/or detector response from those of the parent compound. A sample of standard pesticide should be treated alongside the suspected residue so that the results from each maybe directly compared. A fortified extract should also be included to prove that the reaction has proceeded in the presence of sample material. Interference may occur where derivatives are detected by means of properties of the derivatising reagent. A review of chemical reactions which have been used for confirmatory purposes has been published by Cochrane, W.P. (Chemical derivatisation in pesticide analysis, Plenum Press, NY (1981)). Chemical reactions have the advantages of being fast and easy to carry out, but specialised reagents may need to be purchased and/or purified.

(b) Physical reactions
A useful technique is the photochemical alteration of a pesticide residue to give one or more products with a reproducible chromatographic pattern. A sample of standard pesticide and fortified extract should always be treated in a similar manner. Samples containing more than one pesticide residue may give problems in the interpretation of results. In such cases pre-separation of specific residues may be carried out using TLC, HPLC
or column fractionation prior to reaction.

(c) Other methods
Many pesticides are susceptible to degradation/transformation by enzymes. In contrast to normal chemical reactions, these processes are very specific and generally consist of oxidation, hydrolysis or de-alkylation. The
conversion products possess different chromatographic characteristics from the parent pesticide and may be used for confirmatory purposes if compared with reaction products using standard pesticides.

4.9 THE CONCEPT OF LOWEST CALIBRATED LEVEL (LCL)

4.9.1 When the objective of the analysis is to monitor and verify the compliance with MRLs or other ALs, the residue methods must be sufficiently sensitive to reliably determine the residues likely to be present in a crop or an environmental sample at or around the MRL or AL. However, for this purpose it is not necessary to use methods with sufficient sensitivity to determine residues at levels two or more orders of magnitude lower. Methods developed to measure residues at very low levels usually become very expensive and difficult to apply. The use of LCL (see Glossary) would have the advantage of reducing the technical difficulty of obtaining the data and would also reduce costs. The following proposals for LCLs in various samples may be useful in enabling the residue chemist to devise suitable methods.
4.9.2 For active ingredients with agreed MRLs, the LCL can be specified as a fraction of the MRL. For analytical convenience this fraction will vary and could be as follows:

MRL (mg/kg)	LCL (mg/kg)
5 or greater	0.5
0.5 up to 5	0.1 increasing to 0.5 for higher MRLs
0.05 up to 0.5	0.02 increasing to 0.1 for MRLs
less than 0.05	0.5 x MRL

When the MRL is set at the limit of determination of the analytical method, the LCL will also be at this level.

4.10 EXPRESSION OF RESULTS

For regulatory purposes, only confirmed data should be reported, expressed as defined by the MRL. Null values should be reported as being less than lowest calibrated level, rather than less than a level calculated by extrapolation. Generally results are not corrected for recovery, and they may only be corrected if the recovery is significantly different from 100%. If results are reported corrected for recovery, then both measured and corrected values should be given. The basis for correction should also be reported. Where positive results obtained by replicate determinations (e.g. on different GC columns, with different detectors or based on different ions of mass spectra) of a single test portion (sub-sample), the lowest valid value obtained should be reported. Where positive results derive from analysis of multiple test portions, the arithmetic mean of the lowest valid values obtained from each test portion should be reported. Taking into account, in general, a 20-30% relative precision, the results should be expressed only with 2 significant figures (e.g.: 0.11, 1.1, 11 and 1.1x102). Since at lower concentrations the precision may be in the range of 50%, the residue values below 0.1 should be expressed with one significant figure only.

附件三、PRIORITY LIST OF CHEMICALS SCHEDULED FOR EVALUATION AND RE-EVALUATION BY JMPR

The following are the tentative schedules to be evaluated by the FAO /WHO Joint Meeting on Pesticides Residues (JMPR) from 2003 to 2012

2003 JMPR

Toxicological evaluations	**Residue evaluations**
New compound	***New compounds***
cyprodinil famoxadone methoxyfenozide pyraclostrobin	cyprodinil famoxadone methoxyfenozide pyraclostrobin
Periodic re-evaluations	***Periodic re-evaluations***
carbosulfan (145) paraquat (057) terbufos (167) to be clarified	acephate (095)/methamidophos(100) fenitrothion (037) lindane (048) pirimiphos-methyl (086) dodine(084)
Evaluations	***Evaluations***
pyrethrins (063) dimethoate (027) - acute toxicity malathion (049) - acute toxicity tebufenozide – acaute toxicity	carbendazim(072)/thiophanate-methyl(077) carbosulfan(145) dimethoate (027) dicloran (083) pyrethrins (063)

2004 JMPR

Toxicological evaluations	**Residue evaluations**
New compounds	***New compounds***
Fludioxinil trifloxystrobin	fludioxinil trifloxystrobin
Periodic re-evaluations	***Periodic re-evaluations***
Cyhexatin(067)/azocyclotin(129) glyphosate (158) phorate (112) pirimicarb (101) triadimefon (133) {should be evaluated triadimenol (168) {together	ethoprophos (149) metalaxyl-M paraquat (057) prochloraz (142) propineb
Evaluations	***Evaluations***
Captan(007)-acute toxicity fenpyroximate (193) – acute toxicity folpet (041)-acaute toxicity guazatine (114) haloxyfop (194) phosmet (103) –acute toxicity chlorpyrifos – acute toxicity bentazone(172)-acute toxicity dimethipin (151)-acute toxicity fenpropimorph(188)-acute toxicity	chlorpyrifos (017) dithiocarbamates (105) guazatine (114) malathion (047) methomyl (094) oxydemeton-methyl (166) folpet (041) carbofuran (096)

2005 JMPR

Toxicological evaluations	Residue evaluations
New compounds	*New compounds*
dimethenamid-P fenhexamid indoxacarb novaluron	dimethenamid-P fenhexamid indoxacarb novaluron
Periodic re-evaluations	***Periodic re-evaluations***
benalaxyl (155) clofentezine (156) propamocarb (148) propiconazole (160)	Alpha and zeta cypermethrin Cypermethrin (118) cyhexatin (067)/ azocyclotin (129) endosulfan (032) methoprene (147) glyphosate (158) phorate (112) terbufos (167)
Evaluations	***Evaluations***
ethoxyquin (035) imazalil (110)-acute toxicity thiaendazole (65) – acaute toxicity chlorpropham (201) – acute toxicity carbendazim (72) – acute toxicity	ethoxyquin (035) methiocarb (132) spinosad (203)

2006 JMPR

Toxicological evaluations	Residue evaluations
New compounds	*New compounds*
Bifenazate Pyrimethanil Dimethomorph	Bifenazate Pyrimethanil Dimethomorph
Periodic re-evaluations	***Periodic re-evaluations***
cyromazine (169) flusilazole (165) procymidone (136) profenofos (171)	pirimicarb (101) triazophos (143) triadimefon (133) {should be evaluated triadimenol (168) {together

2007 JMPR

Toxicological evaluations	Residue evaluations
Periodic re-evaluations	***Periodic re-evaluations***
azinphos-methyl (002) cyfluthrin (157)/beta cyfluthrin fentin (040) vinclozolin (159)	clofentezine (156) permethrin (120) fpropamocarb (148) propiconazole (160) triforine (116)

2008 JMPR

Toxicological evaluations	**Residue evaluations**
Periodic re-evaluations	***Periodic re-evaluations***
bioresmethrin (93) buprofezin (173) chlorpyrifos-methyl (090) hexythiazox (176)	benelaxyl (155) cyromazine (169) *lambda*-cyhalothrin replacement of cyhalothrin flusilazole (165) procymidone (136) profenofos (171)

2009 JMPR

Toxicological evaluations	**Residue evaluations**
Periodic re-evaluations	***Periodic re-evaluations***
Bifenthrin (178) Cadusafos (174) Chlorothalanil (081) Cycloxydim (179)	azinphos-methyl (002) cyfluthrin/beta cyfluthrin (157) fentin (040) vinclozolin (159)

2010 JMPR

Toxicological evaluations	**Residue evaluations**
Periodic re-evaluations	***Periodic re-evaluations***
Dithianon (028) Fenbutatin oxide (109)	bioresmethrin (93) buprofezin (173) chlorpyrifos-methyl (090) hexythiazox (176)

2011 JMPR

Toxicological evaluations	**Residue evaluations**
Periodic re-evaluations	***Periodic re-evaluations***
	Amitraz (122) Bifenthrin (178) Cadusafos (174) Chlorothalonil (081)

2010 JMPR

Toxicological evaluations	**Residue evaluations**
Periodic re-evaluations	***Periodic re-evaluations***
	Etofenprox (184) Fenpropathrin (185)

ANNEX I

CANDIDATE CHEMICALS FOR PERIODIC RE-EVALUATION –NOT YET SCHEDULED (confirmation of support required by November 2003)

Aldicarb (117) Bromopylate (070) Dichlorvos (025) Dicofol (026)	Diquat (031) Etofenprox (184) Fenpropathrin (185)

ANNEX II

CHEMICALS PROPOSED FOR PRIORITY LISTING BUT FOR WHICH FURTHER CONSIDERATION IS REQUIRED BEFORE A DECISION CAN BE MADE.

DDT (EMRLs)

gentamicin; oxytetracycline hydrochloride

MRLs for various pesticides on spices based on monitoring data