

行政院及所屬各機關因公出國人員  
出國報告（出國類別：出席國際會議）

出席『第三十七屆國際農藥殘留標  
準委員會』報告書

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## 摘要

第三十七屆國際農藥殘留標準委員會(37<sup>th</sup> Session of Codex Committee on Pesticide Residues, 簡稱CCPR)於2005年4月18日至4月23日在荷蘭海牙(The Hague, 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三十八個會員國、一個會員組織及十三個國際組織代表計145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。

本會議計進行十七個議題,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。

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，成立於1963年，主辦國為荷蘭。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)、農藥容許量訂定之農作物分類(Commodities classification)、經取食安全評估值(Dietary Daily Intake Risk Assessment)等。本會議每年四至五月召開，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法典委員會((CAC)Codex Alimentarius Commission)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，因此備受各國重視。我國因非聯合國會員國，參與非開放性國際組織相關會議之機會很少，此聯合國組織下 intergovernment 會議也很難有機會出席，無法及時取得國際認同之資訊和同時反應國內的需求。對於我國參與國際活動及世界貿易組織談判上都是一種損失。本人取得國際純化學及應用化學學會(IUPAC)出席Codex相關會議之代表資格，除在會中報告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，參與議題討論，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，在農產品及食品之國際貿易上能引用國際準則而提高其競爭力。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

第三十七屆國際農藥殘留標準委員會（37<sup>th</sup> Session of CCPR）於2005年4月18日至4月23日在荷蘭海牙召開。主席Dr.Hans Jeuring（Senior Public health Officer of Food and Consumer Product Safety Authority, Netherlands），主要討論之十六項議題依序見表一。

表一、第三十七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 05/1
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 05/2
4	2004年JMPR報告一般性建議 Report on general considerations by the 2004 JMPR	2004 JMPR Reports
5	全球食品安全性取食評估報告GEMS/Food Porgress Report of Dietary Intake	CX/PR05/3
6	討論報告：利用統計計算MRLs運用於健康及貿易 Discussion paper on probabilistic modeling : MRLs health or trade limits	CX/PR 05/4
7	食品及動物飼料中農藥殘留標準 Draft and Proposed Draft MRLs in Foods and Feeds	CX/PR 05/5
8	安全性高農藥引用各國MRLs爲Codex MRLs暫行標準 Pilot project for the examination of national MRLs as interim Codex MRLs for safer replacement pesticides	CX/PR 05/6
9	加工或即食食品之MRLs Establishment of MRLs for processed or ready to eat foods	CX/PR 05/7

10	危機分析在農藥殘留標準制定上之運用 Risk analysis policies used by the committee in Establishing Codex MRLs for Pesticides	CX/PR 05/8
11	農藥殘留分析方法準則 Matters Related to Methods of Analysis for pesticide residues: a. Proposed draft guidelines on the use of mass spectrometry (MS) for identification, confirmation and qualitative determination of residues b. Proposed draft guidelines on the estimation of uncertainty c. The use and implications of measurement Uncertainty d. Proposed draft revision of the list of methods of analysis for pesticide residue analysis	CX/PR 05/9, CX/PR 05/10, CX/PR 05/11, CX/PR 05/12
12	農藥評估優先順序 Establishment of Codex Priority Lists of Pesticides a. Proposed draft criteria for prioritization process of Pesticides	CX/PR 05/13, CX/PR 05/14
13	Codex 殘留標準作物分類修正 Proposed draft revision of the Codex Classification of Foods and Animal Feeds	CX/PR 05/15
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	

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4月17日討論農藥評估優先順序，4月20日討論農藥殘留分析方法。另於4月22日召開 Friends of the JMPR.



## 二、參加人員

本屆會議計有60個Codex會員國、1個會員組織及14個國際組織代表共246人參加。參加國及國際組織代表人數見表二。本人以國際純化學及應用化學學會（IUPAC）代表身分與會。本會議參加國家及人數均有明顯增加。另因荷蘭宣佈將放棄主辦國之身分，韓國有意爭取，今年也加派人員出席。

表二、參加三十七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
Argentina	1	Ghana	5	Morocco	3	Uganca	1
Australia	6	Granada	1	Nepal	1	UK	1
Austria	2	Guinea-Bissau	1	<b>Netherlands</b>	11	USA	11
Belgium	3	Haiti	1	<b>New Zealand</b>	3	CPIUA	1
Brazil	7	Hungary	2	Niger	1	FAO	2
Burundi	2	India	3	Norway	2	FAO/IAEA	1
Canada	3	Iran	7	Poland	4	OIV	2
Chile	3	Ireland	1	Romania	2	WHO/OMS	3
China	6	Israel	1	Rwanda	1	CLI	24
Cyprus	1	Italy	1	Senegal	1	ECSP	1
Czech R.	2	Japan	7	<b>South Africa</b>	1	IBA	1
Denmark	2	Kenya	1	Spain	3	ICA	1
EC	3	Kiribati	1	<b>Switzerland</b>	3	IFU	1
Egypt	1	Korea R.	14	Sudan	3	IOSTA	2
Estonia	1	Lao, R.Dem	1	Surinam	1	ISC	1
Finland	3	Lesotho	1	Sweden	3	IUPAC	2
France	1	Malaysia	6	Tanzania	2	Sec.NZ	10
Germany	6	Mali	1	Thailand	6	Sec.Codex	3
Gabon	2	<b>Mauritania</b>	1	Tunesia	1		
Gambia	1	<b>Mongolia</b>	1	Turkey	2	合計	246

### 三、會議內容

本會議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Former Chief Inspector to the Dutch Food and Consumer Product Safety Authority Dr. W.J. Peters主持。開幕致詞藉由介紹荷蘭政府新完成之「Pesticides in food: assessing the risk to children」，說明農藥研究仍有很大之空間。各國應提昇研究之範圍，尤其注重農藥對神經系統、免疫系統及環境荷爾蒙等影響，並以調整safety factor來研訂適當之ADI值及Acute RfD值。

#### 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)

大會主席推舉美國代表 Dr. C.W. Cooper及紐西蘭代表 Dr. David W.Lunn為大會紀錄。

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

本屆會議CAC執行委員會決定每年開會討論各委員會之決議案。CCGP所定義之「Food Safety Objectives」因含生物性污染，不完全適用於CCPR。CCPFV希望CCPR能提供concentration factor以利其評估加工蔬果之安全性。本會決議只對有列食品類別之項目，以及Processing factor (PF)大於1者才考慮直接研訂加工食品之MRLs。

#### 議題四、2004年JMPR報告一般性建議( Report on general considerations by the 2004 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)。平均每年約評估廿五種農藥。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2004年JMPR之報告內容摘要如下：

1. Guidance on the establishment of acute reference doses (ARfDs)
2. Definition of "Overall NOAEL"
3. Interim acute reference dose
4. Progress report on the JMPR work-sharing pilot project on trifloxystrobin
5. Comparison of the JMPR recommendations and interim MRL recommendations from the CCPR pilot project.
6. Estimation of maximum residue levels of pesticides in or on spices on the basis of monitoring results
7. Revisited: MRLs for fat-soluble pesticides in milk and milk products.
8. Revisited: Dietary burden of animals for estimation of MRLs for animal commodities
9. Statistical methods for estimating MRLs
10. Application of the recommendations of the OECD project on minimum data requirements to the work of the JMPR.
11. Alignment of toxicological and residue evaluations for new and periodically reviewed compounds

## **議題五、全球食品安全性取食評估報告(GEMS/Food Progress Report of Dietary Intake)**

由WHO主導之GEMS /food Progress (Global Environment Monitoring System)利用1997-2001 FAO food balance sheet data完成十三個區域取食量資料，並已上網供各界引用。部分國家反應區域性資料對單一國家之代表性不

足，WHO代表Dr. Moy表示該取食量以主要作物為主，並歡迎各國提供充分之數據以便數據更新。

## **議題六、討論報告：利用統計計算（MRLs運用於健康及貿易 Discussion paper on probabilistic modeling : MRLs health or trade limits）**

經取食農藥暴露量評估結果影響風險決策管理，因此數據之完整性及規模大小，取食量數據，評估族群分類及可信度之選擇皆應列入考量。由荷蘭提供討論報告說明以統計評估模式來運用於Chronic and acute dietary assessments之可行性。本單元討論熱烈，政府單位、農藥業者及消保團體對於評估之認知差異大也引起許多建議。大會決議仍以單一作物與Codex MRL或Acute RfD相比，不得高於安全標準，否則應予銷毀。

## **議題七、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MRLs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。

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。本次會議討論之藥劑及結論摘要如表三。

表三、食品及動物飼料中農藥殘留最高限量本會討論摘要

CodeNo	農藥名稱	決議事項
007	Captan 蓋普丹	1.修訂pome fruits MRLs 為15 mg/kg 2. MRL' s部分可進入step8
008	Carbaryl 加保利	1.重新評估acute RfD 0.2 mg/kg bw 2.MRL' s回至step6
017	Chlorpyrifos 陶斯松	修正部分MRLs
022	Diazinon 大利松	1.增訂cabbage head MRL 2. acute RfD 0.03 mg/kg bw
027	Dimethoate 大滅松	1. 修訂MRLs 2. 由EC進行取食評估
037	Fenitrothion 撲滅松	1. 取消穀類及加工品之MRLs 重新評估ADI及Acute RfD
041	Folpet福爾培	1. 所有MRLs回至step 5 2. EC評估variability factor
049	Malathion 馬拉松	1.肉品類MRLs回至step 5直至JMPR完成在動物用藥上之評估
057	Paraquat 巴拉刈	建議取消所有動物肉品之MRL' s值。
059	Parathion-methyl 甲基巴拉松	1. acute RfD 0.03mg/kg bw 2.取消MRLs for animal feeds
065	Thiabendazole 腐絕	1.修訂citrus, mushroom MRLs
072	Carbendazim 貝芬替	1.JMPR持續研訂acute RfD

CodeNo	農藥名稱	決議事項
074	Disulfoton 二硫松	1. 評估超過 acute RfD 0.003mg/kg bw 2. 建議修訂部分MRLs
084	Dodine多寧	1. 取消grapes, strawberries MRLs
085	Fenamiphos 芬滅松	1. 由於超過acute RfD值，取消grapes, pineapple, carrot之MRLs
086	Pirimiphos-methyl	1. 保留meat, eggs MRLs 四年 2. 取消其它所有作物之MRLs
090	Chlorpyrifos-Methyl	1. rice, barley, oats MRLs回至step 6
094	Methomyl 納乃得	1. 因acute RfD原因重新修正大部分作物MRLs
095	Acephate 毆殺松	1. 刪除大部分作物之MRLs 2. 保留動物肉品之MRLs
096	Carbofuran 加保扶	1. JMPR研訂acute RfD 0.009 mg/kg bw，許多國家認為太高，應予修訂
100	Methamidophos 達馬松	1. 修正大部分作物之MRLs。
101	Pirimicarb 比加普	JMPR 2004研訂Acute RfD，2006評估其毒理資料
103	Phosmet 益滅松	EC提供較JMPR acute RfD 0.002 mg/kg bw低之評估資料。
105	Dithiocarbamates 二硫代胺基甲酸鹽類	1. 不分別訂定propineb之MRLs 2. MRLs研訂應註明分析方法
112	Phorate	列入2005年JMPR評估藥劑

CodeNo	農藥名稱	決議事項
	福瑞松	
117	Aldicarb 得滅克	1. Banana, potato 因有急毒性顧慮重新評估
126	Oxamyl 毆殺滅	1. 修正部分MRLs 因有急毒性顧慮
133	Triadimefon 三泰芬	列入2006年JMPR評估藥劑
135	Deltamethrin 第滅寧	1. 葉菜類MRLs 重新評估並以單一作物為對象
142	Prochloraz 撲克拉	因acute RfD超量，取消mushroom MRL，重新修正大部分作物MRLs
145	Carbosulfan 丁基加保扶	JMPR評估完成結論安全，恢復所有MRLs。
149	Ethoprophos	1. 2004JMPR完成評估 2. 取消大部分 MRLs
151	Dimethipin	2004研訂Acute RfD，無安全顧慮
158	Glyphosate 嘉磷塞	1. 2004 JMPR修訂ADI值 2. 不需訂定Acute RfD
160	Propiconazole 普克利	1. 2004 JMPR研訂Acute RfD 2. 2007重新評估毒理資料
162	Tolyfluanid 甲基益發寧	修正lettuce MRL
166	Oxydemeton-methyl 滅多松	評估結果幼兒取食部分作物影響acute RfD，修訂大部分MRLs。
168	Triadimenol 三泰隆	2006年JMPR列入評估



CodeNo	農藥名稱	決議事項
172	Bentazone 本達隆	2004年JMPR評估結果無需訂定Acute RfD
188	Fenpropimorph	2004年JMPR評估訂定acute RfD
193	Fenpyroximate 芬普蟎	評估結果幼兒取食部分作物影響acute RfD，修訂部分MRLs。
194	Haloxifop 合氯氟	待2006年 JMPR進行risk assessment後評估
201	Chlorpropham	1. potato之 結果影響acute RfD，2005JMPR重新評估
203	Spinosad賜諾殺	增訂 milk MRL,刪除maize, sheep meat, sheep edible offal and sorghum之 MRLs
204	Esfenvalerate 益化利	保留所有MRLs之修訂直至fenvalerate完成轉換登記，Morocco提出進口之green tea常檢出殘留
207	Cyprodinil 賽普洛	所有MRLs至step 8
208	Famoxadone 凡殺同	所有MRLs至step 8
209	Methoxyfenozide	所有MRLs至step 8,保留spinach MRLs於step 6 由於acute RfD 考量
210	Pyraclostrobin 百克敏	所有MRLs至step5,注意grapes MRLs由於acute RfD 考量
211	Fludioxonil	所有MRLs至step5,不需研訂acute RfD
212	Metalaxyl-M 右滅達樂	所有MRLs至step5,不需研訂acute RfD

CodeNo	農藥名稱	決議事項
213	Trifloxystrobin 三氟敏	所有MRLs至step5,不需研訂acute RfD

### **議題八、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。美國今年提出Discussion paper，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，但只維持四年有效期並與codex MRLs有所區別。CI及EC則質疑其公平性、公開性、合法性及資料保密性。2003年大會建議工作小組就「安全農藥」定義明確，今年美國提出’safer’ and ‘reduced risk’ 定義為經由風險評估程序認定對人體健康、非目標生物及地下水體均可減少為害者。2005年CCPR也制定申請該類MRLs（即Interim MRL）之準則，詳見附件二。

### **議題九、加工或即食食品之MRLs (Establishment of MRLs for processed or ready to eat foods)**

上次會議決議由美國與EC製備Discussion paper供本會議討論，但並未完成。大會決議促請美國及EC加速完成方案提下次會議討論。

### **議題十、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。上次會議建議CCGP清楚定義區別risk assessment and risk management，並建議由主席及日本代表製備discussion paper，提交本次會議討論。該paper已完成，經討論後送CCGP討論後送CAC討論。詳見附件三。

## **議題十一、農藥殘留分析方法準則 (Matters Related to Methods of Analysis for Pesticide Residues)**

本議題為本次會議之主要討論重點，目前已完成單一實驗室標準分析方法建立 (Single Laboratory validation of methods and analysis) 及農藥殘留分析實驗室標準操作準則 (Guidelines on Good Laboratory Practice in residue analysis)。本次會議繼續討論以下三個議題。

1. Proposed draft guidelines on the use of mass spectrometry (MS) for identification, confirmation and qualitative determination of residues (詳見附件四)
2. Proposed draft guidelines on estimation of uncertainty of results (詳見附件五)
3. The use and implications of measurement Uncertainty
4. Proposed draft revision of the list of methods of analysis for pesticide residue analysis

## **議題十二、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JMPS建議之一部分。附件六為2005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。附件七為建議之評估準則。

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

現行Codex食品分類相對於熱帶蔬果分類太過粗糙，部分加工品、辛香料及 minor crop等作物也未含蓋，造成農產品國際貿易及作物安全標準擴大解釋上之困擾。上次大會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，並建議利用二國已建於網站上之作物分類電子檔作為Codex commodities修正之依據。本會議由荷蘭及日本負責依照附件八之proposal 製備circulate paper，收集與會各國及國際組織之意見修正後提本次會議討論。

### **議題十五、其它待辦事項 (Other business and Future Work)**

IAEA參與殘留分析準則及標準方法研擬工作，希望各國提供相關資料以隨時更新資料。IUPAC代表感謝Codex將最新之Codex MRLs公告於網站上。

### **議題十六、下次會議時間及地點 (Date and place on next session)**

下次（三十八屆）CCPR會議將於2006年4月於Brazil召開。

### **議題十七、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2005年7月4日至7月9日在義大利羅馬「28<sup>th</sup> Session of

Joint FAO/WHO Food Standards Programme Codex Alimentarius  
Commission」(CAC)討論。

## 心得

### 一、聯合國食品法典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法典準委員會(Codex Alimentarius Commission (CAC))以制訂食品安全之相關標準及執行規範。CAC下設Executive 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證委員會(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 Coordinating Committees) 摘要說明

委員會名稱Codex Committee	主辦國	成立年
FAO/WHO Coordinating Committee for Europe (CCEURO)	Slovak Republic	1965
FAO/WHO Coordinating Committee for Africa (CCAFRICA)	Uganda	1974
FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC)	Dominican Repub.	1976
FAO/WHO Coordinating Committee for Asia (CCASIA)	Malaysia	1977
FAO/WHO Coordinating Committee for North America and the Southwest Pacific (CCNASWP)	Canada	1990
FAO/WHO Coordinating 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169個會員國及EC會員組織。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，並證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，2005年為第三十七屆。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會議至今已完成三百餘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訂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。中央主管農藥部門相關人員既非專職專業，易可能因急功近利而導致修法無據，與國際無法接軌。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未能列入研究項目。一再顯示台灣的農藥管理之草率為之及研究不被重視。農藥登記相關試驗既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。

## 建議事項

### 一、有效運用聯合國食品法典委員會制定之準則

聯合國食品法典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、與農藥殘留標準委員會（CCPR）同步進行農藥殘留研究

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。另每年委託大學進行之農藥風險評估也應依循Codex Risk Analysis準則，應用有依據之評估數據及方法作客觀性評估及具體性建議，建立完善之國內農藥評估制度。

## 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、本會議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 Additives and Contaminants
CCGP	Codex Committee on General Principles
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CIPAC	Collaborative International Pesticides Analytical Council
CLI	CropLife International
CXL	Codex Maximum Residue Limit for Pesticide
CI	Consumer International
EMRL	Extraneous Maximum Residue Limit
EC	European Community
FAO	Food and Agriculture Organization
GAP	Good Agricultural Practice
GEMS	Global Environment Monitoring System
GLP	Good Laboratory Practice
IEDI	International Estimated Daily Intake
IESTI	International Estimated of Short-Term 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
NOEL	No Observed Adverse Effect Level
PHI	Pre-harvest Interval
PTDI	Provisional Tolerable Daily Intake
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
STMR	Supervised Trials Median Residue
TMDI	Theoretical Maximum Daily Intake
WHO	World Health Organization
WTO	World Trade Organization

## 附件二、

### PROPOSED REVISED INTERIM MRL ESTABLISHMENT PROCESS (2005 CCPR)

**Action 1.** The proposed chemicals and associated Interim MRLs must be nominated to the Chair, Ad Hoc Working Group on Priorities (WGP) by February 1<sup>st</sup>, for consideration at the next WGP meeting. The chemical must already be scheduled for review by the JMPR or be nominated simultaneously for consideration by the WGP. The nomination package should include (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

1. The nomination form, which is the same as the one submitted to the WGP in the standard process. The nominating country will only propose interim MRLs which are established in their country (or established in other countries from which they have *already obtained* the relevant national government information).
2. List of all of the established MRLs for nominated commodities in the countries where the chemical is registered (this may be the product of the manufacturer), together with the proposals for interim MRLs.
3. Dietary intake calculations based on the nominating country's ADI or ARfD, the nominated interim MRLs, and the JMPR methodology.
4. Justification for qualification as a new, safer, replacement pesticide:

**Action 2.** If the WGP (at its annual pre-CCPR meeting) agrees that the criterion for a new, safer, replacement pesticide is satisfied, then the nominations for Interim MRLs are to proceed to the CCPR for final decision.

**Action 3.** CCPR consideration and decision. CCPR may either decide to include the chemical on a list for consideration of interim MRLs at the next session or may decide to reject the chemical from further consideration in the Interim MRL Process.

**Action 4.** After the initial nomination process to the CCPR for a given chemical, and upon CCPR agreement, other national governments will have two months, until June 30, to supply the nominating country the relevant materials to nominate other uses of the approved chemical for interim MRLs or higher MRLs for commodities already nominated. Member countries wishing to add uses to the original list or support higher MRLs than those in the nominating country, should supply the nominating country with the following information, at a minimum (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

1. A summary table of the health intake values (ADI and ARfD) used in their country
2. A summary of residue trial data (not raw data) and an explanation of how the MRL was determined for the nominated commodities (see residue data requirements under Action 5 below)
3. Chronic and acute dietary intake risk assessments performed in their country

**Action 5.** The nominating government would then include these additional (or higher) interim MRL proposals in the detailed information package it sends to all member states for review. The detailed information packages would be provided to the Codex Secretariat for posting on the web; no later than August 1. The packages would be posted on the web no later than September 1. The complete detailed information package sent out for review and comment will include, at a minimum (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

1. Summary of the information contained in the package and where it was obtained; noting, for example, if any additional or higher MRLs have been added by member states since the original nomination to the WGP and approval by CCPR.
2. Summary of the reduced risk justification.

3. List of all of the established MRLs for nominated commodities in the countries where the chemical is registered (this may be a product of the manufacturer), together with the proposals for interim MRLs.

4. A summary table of the calculated dietary intake values from all countries where the chemical has been evaluated (this may be the product of the manufacturer).

5. Summary reports of the toxicology (equivalent to OECD Tier II summaries). These summary reports of the toxicology database should also contain “summary” and/or “discussion” sections which explain how the health intake values (ADI and ARfD) were set, document the safety factors used, and comment on whether they are likely to be conservative or not. For example, was the ARfD based on an endpoint in a repeat-dose study because there was no adequate acute study in the toxicological database? Or was the endpoint a critical endpoint from a developmental toxicity study? Discuss whether (a) a LOAEL is used instead of a NOAEL and thus warranted the application of an additional factor and (b) indicate when the endpoint selected originated from a developmental neurotoxicity study or from a study which shows sensitivity of the young. .

6. Summary reports of the residue chemistry. This would include summary evaluations for plant and animal metabolism, analytical methods (for enforcement), field trials (commodity, GAP, residue values in ranked order), and processing studies (as applicable), and a reasoned definition of residues for dietary intake calculation and for MRL enforcement.

7. The nominating national government’s assessment of the data in support of the interim MRLs. This would include the nominating national government’s dietary intake risk assessment and chronic and acute dietary intake assessments per JMPR methodology, using the nominating government’s health intake values and including all nominated commodities for all the regional diets considered by JMPR (FAO/WHO GEMS).

8. In the case that other member states supplied additional information (as noted in Action 4 above) this would also be included with the source clearly marked.

**Note:** Full reports should be available from the nominating country on request. In addition, if a member state requests actual study data the nominating country will work with the manufacturer to try and supply this information.

**Action 6.** Comments by member states are to be posted on the web site by December 31. The interim MRL Group<sup>iii</sup> will prepare and submit a report to the Chair of the WGP by February 1 for comment and subsequent distribution to member states for consideration at the next meeting of the WGP. Commentors should remember:

1. The commentor should explicitly state whether they support or oppose each specific proposed interim MRL.
2. As with a standard JMPR review, many countries will have different MRLs established, but the *highest nominated* Interim MRL that is *supported by an adequate set of field trial data* and that is *demonstrated to be safe*, would generally be selected as the interim Codex MRL. It is not necessary to list the MRLs established in the commentor’s country.
3. Comments should not be based on residue data that are not included in the detailed information package. No additional residue data (and resulting alterations in the proposed interim MRLs) can be considered in the review of the detailed information packages. The only opportunity to provide additional residue data and propose different MRLs is in Action 4.
4. Comments on the interpretation of the residue data provided in the detailed information packages and resulting suggested changes to interim MRLs are appropriate.

**Action 7.** The WGP, at its annual pre-CCPR meeting, will consider any technical issues raised and decide which Interim MRLs are proposed to CCPR for agreement at the plenary session.

**Action 8.** Proposed Interim MRLs agreed or refused by CCPR.

**Action 9.** Interim MRLs considered by the Codex Alimentarius Commission (CAC) for ratification at Step 8(I) or rejection.

**Action 10.** Upon CAC ratification, interim MRLs recognized as MRLs at Step 8(I), with the following conditions:

1. The interim standard would have a four year lifetime. During the four years, the pesticide would be considered by the JMPR, and their recommendations would advance through the CCPR in the present Step fashion. The interim standard would be automatically withdrawn when the proposed standard in the normal process reaches Step 8.
2. The interim values would continue until supplanted by the advancement of the JMPR values to Step 8 regardless of the values recommended by the JMPR.
3. If JMPR makes unfavorable recommendations or cannot make MRL recommendations because of an insufficient data base, the subject interim MRLs will be automatically withdrawn at the next scheduled session of the CCPR.

**Action 11.** The adopted interim MRLs at Step 8(I) should be included in the annual listing (CX/PR) *Draft and Proposed Draft Maximum Residue Limits in Food and Feeds at Steps 7 and 4* or in whatever comprehensive, public listing that the Codex Secretariat may deem appropriate.

- i A new, safer, replacement pesticide is defined (CX/PR 03/14) as a pesticide that usually would have never had one or more Codex MRLs; would be shown to be an alternative to an existing pesticide or pesticide type within the Codex system; and would have demonstrated reduced acute and/or chronic risk to humans via dietary intake compared to the pesticide that it would supplant or compared to many other pesticides in its classification (insecticide, herbicide, fungicide).
- ii The CCPR must give clear direction to Codex to provide an interactive web space for the nominating country to post documents and for other countries to post responses.
- iii Membership of the Interim MRL Group, currently the Interim MRL Pilot Project Working Group, will need to be formalized if the pilot project is extended.

### 附件三、

## **PROPOSED DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES**

### **SCOPE**

1. This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and facilitates the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius<sup>1</sup>.

### **ROLES OF CCPR AND JMPR IN RISK ANALYSIS**

#### **Interaction between CCPR and JMPR**

2. In addressing pesticide residue issues in Codex, providing advice on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR while conducting risk assessment is the responsibility of JMPR.
3. CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.
4. CCPR and JMPR should continue to develop procedures to enhance communication between the two committees.
5. CCPR and JMPR should ensure that their contributions to the risk analysis process are scientifically based, fully transparent, thoroughly documented and available in a timely manner to Member States<sup>2</sup>.
6. JMPR, in consultation with CCPR, should continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments. These criteria should be used by CCPR in preparing its Priority List for JMPR. The JMPR Secretariat should consider whether these minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR.

#### **Role of CCPR**

7. CCPR is primarily responsible for recommending risk management proposals for adoption by the CAC.<sup>3</sup>
8. CCPR shall base its risk management recommendations, such as MRLs, to the CAC on JMPR's risk assessments of the respective pesticides.
9. In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific guidance is necessary, CCPR or CAC may make a specific request to JMPR to provide the scientific guidance necessary for a risk management decision.
10. CCPR's risk management recommendations to the CAC shall be based on JMPR's [quantitative] risk assessments and other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade.
11. CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors as described by JMPR.
12. CCPR shall consider maximum residue levels (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation including a quantitative risk assessment.
13. CCPR shall base its recommendations on the GEMS/Food regional diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food regional diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the consumption data provided by some member countries.
14. When establishing its standards, CCPR shall clearly state when it applies any non-science-based considerations in addition to JMPR's risk assessment and specify its reasons for doing so.
15. CCPR shall consider the following when preparing its priority list of compounds for

JMPR evaluation:

- CCPR's Terms of Reference;
  - JMPR's Terms of Reference;
  - The Codex Alimentarius Commission's Medium-Term Plan of Work;
  - The Criteria for the Establishment of Work Priorities;
  - The Criteria for Inclusion of Compounds on the Priority List;
  - The Criteria for Selecting Food Commodities for which Codex MRLs or EMRLs should be Established;
  - The Criteria for Evaluation of New Chemicals;
  - The Criteria for Prioritising Chemicals for Periodic Re-evaluation; and
  - A commitment to provide the necessary data for the evaluation in time.
16. When referring substances to JMPR, the CCPR shall provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.
17. When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.
18. CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

### **Role of JMPR**

19. JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions<sup>4</sup>. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/ registered uses.

20. JMPR should select scientific experts on the basis of their competence and independence, taking into account geographical representation where possible.

21. JMPR should strive to provide CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCPR's risk-management discussions. JMPR should continue to use its risk assessment process for

establishing ADIs and Acute Reference Doses where appropriate.

22. JMPR should provide CCPR with information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify

potential risks to populations of potentially enhanced vulnerability (e.g. children).

23. Recognizing that primary production in developing countries is largely through small and medium size enterprises, JMPR should strive to base its risk assessments on global data, including that from developing

countries. These data may include monitoring data and exposure studies.

24. JMPR is responsible for evaluating exposure to pesticides. When evaluating intake of pesticides during its risk assessment, JMPR should take into account the GEMS/Food regional diets used to identify

consumption patterns on a global scale. The GEMS/Food regional diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the consumption data as

provided by some countries.

25. JMPR should communicate to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR should provide CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.

26. JMPR should communicate to CCPR the basis for all assumptions used in its risk assessments.

### **ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR**

1. This part of the document addresses the risk management policy that is used by the Codex

Committee on Pesticides Residues (CCPR) when discussing the risk assessments, the exposure to pesticides and the proposals for MRLs which are the outcomes of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR).

#### **ESTABLISHMENT OF MRLs/EMRLs**

##### **Procedure for Proposing Pesticides for Codex Priority Lists**

2. CCPR has developed a policy document in relation to establishing a priority list of pesticides for evaluation or re-evaluation by JMPR.
3. Before a pesticide can be considered for the Priority List, it must:
  - be available for use as a commercial product; and
  - not have been already accepted for consideration.
4. To meet the criteria for inclusion in the priority list, the use of the pesticide must: give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.
5. When prioritising new chemicals for evaluation by the JMPR, the Committee shall consider the following criteria:
  - if the chemical has a reduced acute and/or chronic toxicity to humans compared with other chemicals in its classification;
  - the data nominated;
  - the date that data will be submitted; and
  - where possible, allocating new chemicals to be evaluated on at least a 50:50 basis with periodic re-evaluation chemicals to be evaluated.
6. When prioritising chemicals for periodic re-evaluation by the JMPR, the Committee shall consider the following criteria:
  - chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits;
  - the year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – not yet scheduled;
  - the date that data will be submitted and the availability of data;
  - if the intake and/or toxicity profile indicate some level of public health concern;
  - whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
  - if there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and
  - allocating periodic re-evaluation chemicals to be evaluated on a maximum ratio of 50:50 with new chemicals to be evaluated.
7. Once the JMPR has reviewed a chemical, three scenarios may occur:
  - the data confirm the existing Codex MRL, it remains in place, or
  - a new MRL is recommended or an amendment of an existing MRL. The new or amended proposal enters at Step 3 of the Codex procedure. The existing MRL remains in place for no more than four years or
  - insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, the manufacturer or countries may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years.The existing Codex MRL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

##### **MRLs for Commodities of Animal Origin**

8. Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or

commodities used in animal feed, in forage crops, or in plant parts that could be used in animal feeds. The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

9. If no adequate studies are available, no MRLs will be established for commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data.

Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation, MRLs at the LOQ must be established for animal commodities. MRLs should be established for all

mammalian species where pesticides on feeds are concerned and for specific species (e.g. cattle, sheep) where direct treatments of pesticides are concerned.

10. Where the recommended maximum residue limits for animal commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or JECFA and from residues in animal feed do not agree, the higher recommendation will prevail.

#### **MRLs for Processed or Ready-to-eat Foods or Feeds**

11. CCPR agreed not to establish MRLs for processed foods and feeds unless separate higher MRLs are necessary for specific processed commodities. However, this policy is under discussion at the moment.

#### **MRLs for spices**

12. CCPR agreed that MRLs for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

#### **MRLs for fat-soluble pesticides**

13. [Under discussion at the moment]

#### **Establishment of MRLs**

14. The CCPR is entrusted with the elaboration of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. The JMPR is using the WHO Guidelines for predicting dietary intake of pesticide residues (revised)(1997)<sup>6</sup>. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and periodic review compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the regional diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate.

15. When the ADI is exceeded in one or more regional diets, then the MRLs will not advance to Step 8

pending further refinement of the intake at the international level. If further refinement is not possible then MRLs (and CXLs) are withdrawn until the remaining MRLs and CXLs give no longer rise to intake concerns. This procedure should be reviewed at regular interval.

16. The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term

dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of

the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the acute RfD.

17. When the ARfD is exceeded for a given commodity, then the MRLs will not advance to Step 8



pending further refinement of the intake at the international level.

18. When a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns if possible.

19. If further refinement is not possible then MRLs (and CXLs) are withdrawn. More sophisticated methodologies such as probabilistic approaches are under investigation at the moment.

20. The estimate of the short-term dietary intake requires substantial food consumption data that currently are only sparsely available. Governments are urged to generate relevant consumption data and to submit these data to the WHO.

### **Establishment of EMRLs**

21. The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of the pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity or animal feed.

22. Chemicals for which EMRLs are most likely to be needed are persistent in the environment for a relatively long period after uses have been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

23. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data<sup>7</sup>.

24. The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to the CCPR.

25. Because residues gradually decrease, CCPR evaluates every 5 years, if possible, the existing EMRLs, based on the reassessments of the JMPR.

26. The CCPR generally agreed at the 30th Session on the potential elements for inclusion in a set of criteria for estimation of EMRLs while it also agreed not to initiate a full exercise of criteria elaboration.

### **Periodic Review Procedure**

27. The Committee agreed on the Periodic Review Procedure, which was endorsed by the CAC and attached to the list of MRLs prepared for each session of the CCPR. Those Codex MRLs confirmed by JMPR under the Periodic Review shall be distributed to member countries and interested organizations for comments.

### **DELETING Codex MRLs**

28. Every year new compounds are introduced. These compounds are often new pesticides which are safer than existing ones. Old compounds are then no longer supported/produced by industry and existing Codex MRLs (CXLs) can be deleted.

29. If information is delivered between two sessions of CCPR, that a certain compound is no longer supported, this information will be shared during the first coming session ( $t=0$ ). The proposal will be to delete the existing CXLs at the following session ( $t=0+1$  year).

30. It may happen that compounds are no longer supported in Codex, but are supported in some selected countries. If there is no international trade in commodities where the active compounds may have been used, CCPR will not establish MRLs.

### **MRLs AND METHODS OF ANALYSIS**

31. JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and

enforcement methods.

32. If no methods of analysis are available for enforcing MRLs for a specific compounds, no MRLs will be established by CCPR.

#### 附件四、

## **PROPOSED DRAFT GUIDELINES ON THE USE OF MASS SPECTROMETRY (MS) FOR IDENTIFICATION, CONFIRMATION AND QUANTITATIVE DETERMINATION OF RESIDUES**

### **Confirmatory Tests**

When analyses are performed for monitoring or enforcement purposes, it is particularly 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.

Analysis of pesticide residues with multi-residue methods generally consists of two phases: screening and confirmation. The process is schematically depicted in Fig. 2. The first phase comprises establishment of those pesticide residues that are likely to be present from interpreting the raw data, avoiding false negatives as much as possible. The second phase is the confirmation, which focuses on the pesticides found in phase 1. The use of the results to be reported, and consequent management decision determines the efforts put in the confirmatory process. The choice of the technique used for confirmation depends on their availability, time and cost. They are based on, either further interpretation of chromatographic and mass spectrometric data, or alternative methods using different physico-chemical properties of the compound, the combination of various separation and detection methods. Some alternative procedures for confirmation are given in Table 6.

Whenever chromatographic techniques are used in screening or confirmation proper settings of the retention time windows is pivotal. Care should be taken that the instrument is adjusted correctly before starting the analysis, a system suitability test should be performed prior to each batch of analysis<sup>1</sup>. Retention times data base should be adjusted for the current conditions<sup>2</sup>. In phase 1 tolerance intervals of 1.5 to 3% of the absolute retention time may be applied for capillary GC depending on the peak shape. For confirmation of the retention time the absolute tolerance intervals will increase at higher retention time. The tolerance interval should be less than 1 sec for an RT less than 500 sec. For retention times

between 500 and 5000 sec. An interval of 0.2% RRT is recommended. For higher retention times 6 sec. is a suitable interval.

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.

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 number of randomly selected results should be confirmed. Where "blank" samples are available, these should be used to check the occurrence of possible interfering substances.

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.

### **Gas Chromatography/Mass spectrometry (GC/MS)**

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 is also used commonly for residue screening purposes (phase 1). 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 abundance data simultaneously. Quantitative transmission of labile analytes through the chromatographic system is subject to problems similar to those experienced with other detectors. 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 ratio.

When using selected ion monitoring (SIM), tolerance intervals of ion ratios and retention times based on injection of pesticide standard in pure

solvent at the concentration close to critical level should have been established at this point. The tolerance intervals for the ion ratios should be within the limits of  $\pm 30\%$  of absolute ion abundances ratios. When 2 (or 3) selected ion ratios are within the established tolerance intervals the residue is confirmed<sup>3</sup>. For a small number of pesticides the mass spectrum may only exhibit one specific ion. In this case alternative confirmation should be sought.

When the ions detected still indicate the possible presence of a residue the result may be reported as tentatively identified. However, when the result would lead to regulatory action, further confirmation of analyte identity shall be sought. This can be achieved with the same GC-MS equipment, by injecting matrixmatched standards of the suspected analyte, in order to compensate for matrix influence on ion ratios. In this case subsequent injections of matrix matched standard and suspected sample has to be made. The deviation of RRT of analyte in standard and suspected peak in sample should typically be less than 0.1 %. Two ion ratios measured in a sample should be within the tolerance interval calculated based on the ion ratios in matrix-matched standard. The residue is considered to be confirmed if it complies with the general rule stated above. If the ion ratios are not within the tolerance intervals, additional confirmation of identity may be obtained by the use of alternative analytical techniques, examples are listed in Table 6.

Further confirmation by mass spectrometry can be accomplished by acquisition of the “complete electronimpact mass spectrum (in practice generally from  $m/z$ 50 to beyond the molecular ion region. The absence of interfering ions is an important consideration in confirming identity. Additional confirmation of identity may be obtained by (i) the use of an alternative chromatographic column; (ii) by the use of an alternative ionisation technique (eg chemical ionization); (iii) by monitoring further reaction products of selected ions by tandem mass spectrometry (MS/MS or MS<sup>n</sup>); or (iv) by monitoring selected ions at increased mass resolution.

Mass spectrometric determinations should satisfy similar analytical quality control criteria to those applied to other systems.

### **HPLC and HPLC-MS**

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. LCMS/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 (Table 6).

### **Thin Layer Chromatography (TLC)**

In some instances, confirmation of gas chromatographic findings is most conveniently achieved by TLC. Identification is based on two criteria, R<sub>f</sub> value and visualisation reaction. Detection methods based on bioassays (e.g. enzyme -, fungal growth 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<sup>4,5</sup>. The scientific literature contains numerous references to the technique<sup>6</sup>. 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 R<sub>f</sub> 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 nonrepeatability of R<sub>f</sub>. 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.

### **Derivatisation**

When selecting ions for GC/MS confirmation based on a derivative, the selected ions must be structurally significant for the residue and not only represent fragments of the derivatizing agent. Whereas derivatisation

might be a valuable way to confirm the identity of a residue, it should be taken into account that it will also add an extra element to the uncertainty of a quantitative confirmation .

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 may be 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

<sup>1</sup> Soboleva E. Ambrus A., Application of system suitability test for

quality assurance and performance optimization of a gas chromatographic system for pesticide residue analysis, *J. Chromatogr. A.* 1027. 2004. 55-65.

<sup>2</sup> Lantos J., Kadenczki L., Zakar F., Ambrus A. Validation of gas chromatographic Databases for qualitative identification of active ingredients of pesticide residues in Fajgelj A. Ambrus A. (eds) *Principles of Method Validation*, Royal Society of Chemistry, Cambridge, 2000, pp 128-137.

<sup>3</sup> Soboleva E. Ahad K. Ambrus A. Applicability of some MS criteria for the confirmation of pesticide residues, <http://www.iaea.org/trc>

<sup>4</sup> Ambrus<sup>1\*</sup> Á., Füzesi<sup>2</sup> I.; Susán<sup>2</sup> M.; Dobi<sup>3</sup> D., Lantos<sup>4</sup> J., Zakar<sup>5</sup> F., Korsós<sup>4</sup> I., Oláh<sup>3</sup> J., Beke<sup>3</sup> B.B., and L. Katavics<sup>5</sup> A cost effective screening methods for pesticide residue analysis in fruits, vegetables and cereal grains, *J. Environ Sci. Health B39* **2004** *accepted for publication*.

<sup>5</sup> Ambrus Á.; Füzesi I.; Lantos J.; Korsos I.; Hatfaludi T. Repeatability and Reproducibility of Rf and MDQ Values with Different TLC Elution and Detection Systems. *J. Environ Sci. Health B39* **2004** *accepted for publication*.

<sup>6</sup> IUPAC Report on Pesticides (13) (Bátora, V., Vitorovic, S.Y., Thier, H.-P. and Klisenko, M.A.; *Pure & Appl. Chem.*, 53, 1981, 1039-1049



**Table 6. Detection methods suitable for screening (Phase 1) and confirmation (Phase 2) of residues.**

		Phase 1 - Screening							
		GC with capillary column – ECD, NPD, FPD, PFPD	GC-MS	LC-MS	LC-DAD or scanning UV	LC-UV/VIS (single wavelength)	LC-fluorescence	GC with packed column – ECD, NPD, FPD	TLC – enzyme -, fungal growth or chloroplast inhibition
Phase 2. confirmation	GC-capillary column - ECD, NPD, FPD, PFPD	x	x <sup>1</sup>	x	x	x	x	x	x
	GC-MS	x	x <sup>12</sup>	x	x	x	x	x	x
	GC-MS	x	x		x	x	x	x	x
	LC-MS	x	x	x	x	x	x	x	x
	Full scan techniques	x	x	x	x	x	x	x	x
	(MS)n, HRMS, alternative ionisation techniques	x	x	x	x	x	x	x	x
	LC-DAD or scanning UV	x	x	x		x	x	x	x
	LC-UV/VIS (single wavelength)	x	x				x	x	x
	LC-fluorescence	x	x		x	x		x	x
	TLC – enzyme, fungal growth or chloroplast inhibition	x	x	x	x	x	x	x	x <sup>2</sup> <sub>3</sub>
	Derivatisation	x	x	x	x	x	x	x	x
Specific isomers profile	x	x	x	x	x	x	x		

1 – Either the column of different polarity, which results in different elution order of the residues and

contaminants eluting in the vicinity to the peak of interest, or another specific detector shall be used.

2- The same GC-MS technique can be used for the phase 2 (confirmation) if different ions are selected or

tolerance intervals are established based on matrix matched solutions.

3 – Mobile or stationary phase of different polarity shall be used.

## 附件五、

# PROPOSED DRAFT GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS

## 1. INTRODUCTION

According to the CCMAS guidelines on measurement uncertainty at step 5 of the Codex procedure, it is a requirement under ISO/IEC 17025 that laboratories determine and make available the uncertainty associated with each analytical method and result. To this end, food laboratories operating under Codex guidelines should have available considerable data derived from method validation /verification, inter-laboratory studies and in-house quality control activities, which can be applied to estimate the uncertainties particularly for the routine methods undertaken in the laboratory.

### 1.1 CONCEPT AND COMPONENTS OF UNCERTAINTY

Measurement uncertainty refers to the ‘uncertainty’ associated with data generated by a measurement process. In analytical chemistry, it generally defines the uncertainty associated with the laboratory process but may also include an uncertainty component associated with sampling and qualitative confirmation.

The uncertainty ‘estimate’ therefore describes the range around a reported or experimental result within which the true value can be expected to lie within a defined level of probability. This is a different concept to measurement error which can be defined as the difference between an individual result and the true value. The reporting of uncertainty is intended to provide a higher level of confidence in the validity of the reported result.

Contributions to data uncertainty are manifold and described in detail in Tables 1 and 2. The evaluation of uncertainty ideally requires an understanding and estimation of the contributions to the uncertainty of each of the activities involved in the measurement process.

## 2. IDENTIFICATION OF UNCERTAINTY SOURCES

In general, the uncertainty of measurements is comprised of many components, arising from activities involved with the sample. The uncertainty of an analytical result is influenced by three major phases of the determination:

□ External operations: sampling ( $S_s$ ), packing, shipping and storage of samples<sup>1</sup>;

- Preparation of test portion: sample preparation and sample processing ( $S_{Sp}$ );
- Analysis ( $S_A$ ): extraction, cleanup, evaporation, derivatisation, instrumental determination

The combined standard ( $S_{Res}$ ) and relative ( $CV_L$ ) uncertainty may be calculated according to the error propagation law:

If the whole sample is analysed the mean residue remains the same and the equation can be written as:

## 2.1 ERRORS IN ANALYTICAL MEASUREMENTS

In most measurements we can distinguish between three types of errors: gross, random and systematic errors.

**Gross errors** refer to unintentional/unpredictable errors while generating the analytical result. Errors of this type invalidate the measurement. Laboratory quality assurance procedures should minimize gross errors. It is not possible or desirable to statistically evaluate and include the gross errors in the estimation of uncertainty. They need no further discussion in this document.

**Random errors** are present in all measurements, and cause replicate results to fall on either side of the mean value. The random error of a measurement cannot be compensated for, but increasing the number of observations and training of the analyst may reduce the effects.

**Systematic errors** occur in most experiments, but their effects are quite different. The sum of all the systematic errors in an experiment is referred to as the bias. Since they do not sum to zero over a large number of measurements, individual systematic errors cannot be detected directly by replicate analyses. The problem with systematic errors is that they may go undetected unless appropriate precautions are taken. In practice, systematic errors in an analysis can only be identified if the analytical technique is applied to a reference material, the sample is analysed by another analyst or preferably in another laboratory, or by reanalyzing the sample by another analytical method. However, only if the reference material matches identically in terms of analyte, matrix, and

concentration does it meet the ideal conditions for determining the bias of the method. The bias of a method may also be investigated by recovery studies. However, recovery studies assess only the effects of analysis ( $S_A$ ) and do not necessarily apply to naturally incurred samples, or components of the bias that may be introduced prior to the analytical step. In pesticide analysis, results are not normally corrected for the recovery, but should be corrected if the average recovery is significantly different from 100%. If the result has been corrected for recovery, the uncertainty associated with recovery should be incorporated in the uncertainty estimation of the measurement.

Some examples of sources of errors are illustrated in Tables 1 and 2 It should be noted that not all sources mentioned have to be evaluated in the uncertainty estimation. Some sources are already incorporated in the overall uncertainty, while others are negligible and may be disregarded. However, it is important to recognise and assess all sources before elimination. Further information may be obtained from published documents<sup>2,3</sup>

<sup>1</sup> Packing, shipping, storage, and laboratory preparation of samples may have significant influence on the residues detected, but their contribution to the uncertainty can often not be quantified based on the current information. Examples of such errors are eg selection of sampling position, time of sampling, Incorrect labelling decomposition of analytes or contamination of the sample

<sup>2</sup> EURACHEM Guide to Quantifying Uncertainty in Analytical Measurements, 2nd ed. 1999, <http://www.measurementuncertainty.org>

<sup>3</sup> Ambrus A. Reliability of residue data, Accred. Qual. Assur. 9, pp. xx. 2004

**Table 1: Sources of error in preparation of the test portion**

	Sources of systematic error	Sources of random error
<b>Sample preparation</b>	The portion of sample to be analysed (analytical sample) may be incorrectly selected	The analytical sample is in contact and contaminated by other portions of the sample
		Rinsing, brushing is performed to various extent, stalks and stones may be differentially removed
<b>Sample processing (SSp)</b>	Decomposition of analyte during sample processing, cross contamination of the samples	Non homogeneity of the analyte in single units of the analytical sample
		Non homogeneity of the analyte in the ground/chopped analytical sample
		Variation of temperature during the homogenisation process
		Texture (maturity) of plant materials affecting the efficiency of homogenisation process

**Table 2: Sources of error in analysis (SA):**

	Sources of systematic error	Sources of random error
<b>Extraction / Clean up</b>	Incomplete recovery of analyte	Variation in the composition (e.g. water, fat, and sugar content) of sample materials taken from a commodity
	Interference of co-extracted materials (load of the adsorbent)	Temperature and composition of sample/solvent matrix
<b>Quantitative determination</b>	Interference of co-extracted compounds	Variation of nominal volume of devices within the permitted tolerance intervals
	incorrect purity of analytical standard	Precision and linearity of balances
	Biased weight/volume measurements	Incomplete and variable derivatisation reactions
	Operator bias in reading analogue instruments, equipment	Changing of laboratory-environmental conditions during analysis
	Determination of substance which do not originate from the sample (e.g. contamination from the packing material)	Varying injection, chromatographic and detection conditions (matrix effect, system inertness, detector response, signal to noise variation etc.)
	Determination of substance differing from the residue definition	Operator effects (lack of attention)
Biased calibration	Calibration	

### **3. PROCEDURES FOR ESTIMATING MEASUREMENT UNCERTAINTY**

Whilst there are a number of options available to laboratories for the estimation of measurement uncertainty, there are two preferred procedures described commonly as the ‘bottom up’ approach and the ‘top down’ approach.

#### **The bottom-up method:**

The bottom up or component-by-component approach incorporates an activity-based process whereby the analyst breaks down all the analytical operations into primary activities. These are then combined or grouped into common activities and an estimate made of the contribution of these activities to the combined uncertainty value of the measurement process. The bottom up approach can be very laborious and requires a detailed knowledge of the whole analytical process. The benefit to the analyst is that this approach provides a clear understanding of the analytical activities which contribute significantly to the measurement uncertainty and which therefore may be assigned as critical control points to reduce or manage measurement uncertainty in future applications of the method.

#### **The top-down method:**

The top down approach is based on method validation and long-term precision data derived from laboratory control samples, proficiency testing results, published literature data and/or inter-laboratory collaborative trials. Uncertainty estimates based on inter-laboratory studies may also take into account the betweenlaboratory variability of the data and is likely to provide the most reliable estimate of the method performance and the uncertainty associated with its application. It is important to acknowledge however that collaborative studies are designed to evaluate the performance of a specific method and participating laboratories. They normally do not evaluate imprecision due to sample preparation or processing as the samples generally tend to be highly homogenized.

Pesticide residue analytical laboratories normally look for over 200 residues in numerous commodities that lead to practically infinite number of combinations. Therefore it is recommended that, for estimating the uncertainty associated with multi residue procedures, laboratories use a properly selected range of analytes and sample matrices which represents the residues and commodities to be analysed in terms of physical chemical properties and composition according to the relevant parts of the

*Revised Guidelines on Good Laboratory Practice* instead of establishing the uncertainty for each method/analyte/matrix combination.

In summary, laboratories should use either their own long-term precision data or the activity-based procedure (component by component calculation) to establish and refine the uncertainty data.

In certain situations it may also be appropriate to estimate the uncertainty contribution due to sample variability. This will require an understanding of the analyte variability within the sample lot and is not readily available to the laboratory or the analyst. The values obtained from the statistical analysis of over 8500 residue data (Table 4) provide currently the best estimate. These estimates can be incorporated into the combined uncertainty value.

Likewise it may be necessary to take into consideration the stability of analytes during sample storage and processing if these are likely to result in analyte variability between analysts and laboratories.

### **3.1 UNCERTAINTY ESTIMATES OF RESULTS INVOLVING ANALYSIS OF MULTICOMPONENTS**

The estimation of uncertainty of results for multi-component residues arising from the application of technical mixtures including structural and optical isomers, metabolites and other breakdown products may require a different approach particularly where the MRL has been established for the sum of all or some of the component residues. The assessment of the random and systematic errors of the results based on the measurements of multiple peaks is explained in detail in a recent publication and should be consulted where necessary.

### **4. GUIDANCE VALUES FOR ACCEPTABLE UNCERTAINTIES**

The establishment of the standard deviation of a series of tests run by a single laboratory, as a measure of standard uncertainty, requires the results a large data-set that is not always available. However, for smaller amounts of data the true standard deviation can be estimated as follows:

Depending on the number of observations ( $n$ ), the relation of the true ( $\sigma$ ) standard deviations, calculated ( $S$ ) standard deviations, and the expected range of the mean value ( $\bar{x}$ ) at 95% probability are illustrated in Table 3. The multiplying factor,  $f$ , provides the link between the estimated and true values as the function of the number of measurements.

**Table 3 The values of  $f$  for calculation of expected ranges of standard deviation and mean values**

n	$S_{\min}=f_1\sigma$	$S_{\max}=f_2\sigma$	$x = \pm f_3S$
	$f_1$	$f_2$	$f_3$
5	0.35	1.67	1.24
7	0.45	1.55	0.92
15	0.63	1.37	0.55
31	0.75	1.25	0.37
61	0.82	1.18	0.26
121	0.87	1.13	0.18

The guidance values for standard uncertainty, given in Table 4, are based on a large number of data and can be used to assess the reality of the estimated uncertainty in a laboratory in order to avoid an unreasonable high or low value.

In addition to the estimated uncertainties made by the individual laboratories, regulatory authorities and other risk managers may decide on a default expanded uncertainty of measurements which can be used in judging compliance with MRLs (See section 5) based on between-laboratories reproducibility values. For instance, a 50% expanded uncertainty for CVL is considered to be a reasonable default value.

## 5. USE OF UNCERTAINTY INFORMATION

If required, the result should be reported together with the expanded uncertainty,  $U$ , as follows

$$\text{Result} = x \pm U \text{ (units)}$$

The expanded uncertainty,  $U$ , may be calculated from the standard combined uncertainty ( $S_{Res}$ ) with a coverage factor of 2 as recommended by EURACHEM or with the Student  $t$  value for the level of confidence required (normally 95%) where the effective degree of freedom is less than 20. The respective calculations for the expanded uncertainty are as follows

$$U = 2S_{Res} \text{ or } U = t_{v,0.95}S_{Res}$$

The numerical value of the reported results should follow the general rule that the last digit can be uncertain. Rounding the results should be done only when the final result is quoted since rounding at the initial stages of calculation may introduce unnecessary bias in the calculated values.



**Table 4. Typical expected uncertainties of major steps of pesticide residue analysis**

<b>Procedure</b>	<b>Relative uncertainty</b>	<b>Comments</b>
<b>Sampling of commodities of plant origin.</b>	Medium and small commodities. (Sample size $\geq 10$ ) <sup>a</sup> : 26-30% <sup>b</sup>	For testing compliance with MRLs, the sampling uncertainty is 0, as the MRLs refer to the average residues in bulk samples.
Reflects the variation of mean residues being in composite samples taken randomly from a lot. It does not incorporate the errors of follow-up procedures.	Large commodities. (Sample size $\geq 5$ ) <sup>a</sup> : 36-40% <sup>b</sup>	
<b>Sampling of animal products</b>	The relation between the number of samples (n) to be taken for detection of a specified percentage of violation ( $\beta p$ ) with a given probability ( $\beta t$ ), is described by <sup>a</sup> : $1 - \beta t = (\beta p)^n$	The primary samples should be selected randomly from the whole lot.
<b>Sample processing</b> Includes the physical operation performed for homogenizing the analytical sample and subsampling, but excludes decomposition and evaporation of analytes.	Largely varying depending on sample matrix and equipment. No typical value can be given. The analysts should try to keep it <sup>2</sup> below 8-10%.	It may be influenced by the equipment used for chopping / homogenising the sample and the sample matrix, but it is independent from the analyte.
<b>Analysis</b> It includes all procedures performed from the point of spiking of test portions.	Within laboratory reproducibility: 16-53% for concentrations of 1 $\mu\text{g}/\text{kg}$ to 1 $\text{mg}/\text{kg}$ <sup>c</sup> . Average between-laboratories reproducibility within 0.001-10 $\text{mg}/\text{kg}$ : 25% <sup>d</sup>	The typical CVA can be conveniently determined from the recovery studies performed with various pesticide/commodity combinations on different days and during the use of the method.

Notes:

(a) Codex Secretariat. Recommended method of sampling for the determination of pesticide residues for compliance with MRLs,

[ftp://ftp.fao.org/codex/standard/en/cxg\\_033e.pdf](ftp://ftp.fao.org/codex/standard/en/cxg_033e.pdf).

(b) Ambrus A. Soboleva E. Contribution of sampling to the variability of residue data; [www.iaea.org/trc](http://www.iaea.org/trc)

(c) Codex Secretariat, Revised Guidelines on Good Laboratory Practice in Residue Analysis [ftp://ftp.fao.org/codex/alinorm03/al03\\_41e](ftp://ftp.fao.org/codex/alinorm03/al03_41e)

(d) Alder L., Korth W., Patey A., van der Schee and Schoeneweis S., Estimation of Measurement Uncertainty in Pesticide Residue Analysis, *J. AOAC International*, 84, 1569-1578, 2001

**附件六、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 2006 to 2012

**2006 JMPR**

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

**2007 JMPR**

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

**2008 JMPR**

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

**2009 JMPR**

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

**2010 JMPR**

<b>Toxicological evaluations</b>	<b>Residue evaluations</b>
<i>Periodic re-evaluations</i>	<i>Periodic re-evaluations</i>
Dithianon (028) Fenbutatin oxide (109)	bioresmethrin (93) buprofezin (173)

	chlorpyrifos-methyl (090) hexythiazox (176)
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**2011 JMPR**

<b>Toxicological evaluations</b>	<b>Residue evaluations</b>
<i>Periodic re-evaluations</i>	<i>Periodic re-evaluations</i>
	Amitraz (122) Bifenthrin (178) Cadusafos (174) Chlorothalonil (081)

**2012 JMPR**

<b>Toxicological evaluations</b>	<b>Residue evaluations</b>
<i>Periodic re-evaluations</i>	<i>Periodic re-evaluations</i>
	Etofenprox (184) Fenpropathrin (185)

## 附件七、

### **DRAFT REVISED CRITERIA FOR PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR**

**To be submitted to the Committee on General Principles and subsequent adoption by the Commission**

#### **1. GENERAL CRITERIA**

##### **1.1 CRITERIA FOR INCLUSION OF COMPOUNDS ON THE PRIORITY LIST**

Before a pesticide can be considered for the Priority List it:

- i must be registered for use in a member country;
- ii must be available for use as a commercial product;
- iii must not have been already accepted for consideration; and
- iv must give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

##### **1.2 CRITERIA FOR SELECTING FOOD COMMODITIES FOR WHICH CODEX MRLS OR EMRLS SHOULD BE ESTABLISHED**

The commodity for which the establishment of a Codex MRL or EMRL is sought should be such that it may form a component in international trade. A higher priority will be given to commodities that represent a significant proportion of the diet.

###### **Note:**

Before proposing a pesticide/commodity for prioritization, governments are recommended to check if the pesticide is already in the Codex system. Pesticide/commodity combinations that are already included in the Codex system or under consideration are found in a working document prepared for and used as a basis of discussion at each Session of the Codex Committee on Pesticide Residues. Consult the document of the latest session to see whether or not a given pesticide has already been considered.

#### **2. CRITERIA FOR PRIORITISATION**

##### **2.1 New Chemicals**

When prioritizing new chemicals for evaluation by the JMPR, the Committee will consider the following criteria:

1. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);
2. The date nominated to the Chair, Priorities Working Group;
3. Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;
4. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
5. Allocating new chemicals to be evaluated on at least a 50:50 basis, if possible, with periodic reevaluation chemicals to be evaluated.

###### **Note**

In order to satisfy the criterion that the proposed new chemical is a “safer” or “reduced risk” replacement chemical, the nominating country is required to provide:

- i the name(s) of the chemicals for which the proposed chemical is likely to be an alternative;
- ii a comparison of the acute and chronic toxicities of the proposed chemical with other chemicals in its classification (insecticide, fungicide, herbicide);
- iii a summary of acute and chronic dietary exposure calculations encompassing the range of diets considered by CCPR; and
- iv other relevant information to support classification of the proposed chemical as a safer alternative chemical.

##### **2.2 Periodic Re-Evaluation**

When prioritizing chemicals for periodic re-evaluation by the JMPR, the Committee will consider

the following criteria:

1. If the intake and/or toxicity profile indicate some level of public health concern;
2. Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;
3. The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – Not Yet Scheduled;
4. The date that data will be submitted;
5. Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
6. If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and
7. The availability of current labels arising from recent national re-evaluations.

### **2.3 Evaluations**

When prioritizing proposed toxicological or residue evaluations by the JMPR the Committee will consider the following criteria:

1. The date the request was received;
2. Commitment by the sponsor to provide the required data for review with a firm date of submission;
3. Whether the data is submitted under the 4-year rule for evaluations; and
4. The nature of the data to be submitted, and the reason for its submission; for example, a request from CCPR.

#### **Note:**

Where a pesticide has already been evaluated by the JMPR and MRLs, EMRLs or GLs have been established, new evaluations may be initiated if one or more of the following situations arise:

- i New toxicological data becomes available to indicate a significant change in the ADI or ARfD.
- ii The JMPR may note a data deficiency in a Periodic Re-evaluation or New Chemical evaluation. In response, national governments or other interested parties may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy to the Chair of the Working Group on Priorities. Following scheduling in the JMPR tentative Schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR.
- iii The CCPR may place a chemical under the four-year rule, in which case the government or industry should indicate support for the specific CXLs to the FAO Joint Secretary of the JMPR, with a copy to the Chair of the Working Group on Priorities. Following scheduling in the JMPR tentative schedule, any data in support of maintenance of the CXL(s) would be submitted to the FAO Joint Secretary of the JMPR.
- iv A government member may seek to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some CXLs already exist for other commodities. Such requests should be directed to the FAO Joint Secretary of the JMPR and copied to the Chair of the Working Group on Priorities. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.
- v A government member may seek to review a CXL due to a change in GAP. For example a new GAP may necessitate a larger MRL. In this case the request should be made to the FAO Joint Secretary with a copy to the Chair of the Working Group on Priorities. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.
- vi The CCPR may request a clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant Joint Secretary will schedule the request for the next JMPR.
- vii A serious public health concern may emerge in relation to a particular Codex pesticide. In such cases government members should notify the WHO Joint Secretary of the JMPR promptly and provide appropriate data to the WHO Joint Secretary.

附件八、

## **PROPOSALS TO INCLUDE OF NEW COMMODITIES IN THE CODEX CLASSIFICATION**

### **FRUITS**

**FC Citrus fruits**

**FP Pome fruits**

**FS Stone fruits**

**FB Berries and other small fruits**

**FT Assorted tropical and sub-tropical fruits – edible peel**

### **VEGETABLES**

**VA Bulb vegetables**

**VB Brassica (cole or cabbage) vegetables, Head cabbages, flowerhead  
brassicas**

**VC Fruiting vegetables, Cucurbits**

**VO Fruiting vegetables, other than Cucurbits**

**VL Leafy vegetables (including Brassica leafy vegetables)**

**VP Legume vegetables**

**VD Pulses**

**VR Root and tuber vegetables**

**VS Stalk and stem vegetables**

**GC Cereal grains**

**TN Nuts and seeds**

**CO Oilseed**

**HH Herbs**

**HS Spices**

**DT Teas**

## **PROPOSAL FOR REGROUPING COMMODITY GROUPS**

### **FC Group 1 Citrus fruits**

- Small citrus fruits (e.g. lemons, limes, mandarins)
- Big citrus fruits (e.g. oranges, shaddocks, pomelos)

### **FB Group 4 Berries and small fruits**

- 4-1 Cane berries (e.g. blackberries, raspberries, dewberries)
- 4-2 Bush berries (e.g. blueberries, currants and gooseberries)
- 4-3 Other small fruited berries (e.g. grapes, strawberries)

### **VA group 9 Bulb vegetables**

- 9-1 Bulbs (e.g. onions, shallots)

- 9-2 Whole bulb vegetables (e.g. spring onions) (whole plants without roots)

#### VB group 10 Brassica vegetables

- 10-1 Flowerhead cabbages (e.g. cauliflower, broccoli)
- 10-2 Head cabbages (e.g. cabbage, white, red)
- 10-3 Leafy Brassicas (codes from Leafy vegetables e.g. Chinese cabbage, mustard greens) kohlrabi?

#### VC group 11 Fruiting vegetables, Cucurbits

- 11-2 Edible peel (e.g. cucumber, courgette)
- 11-2 Inedible peel (e.g. melon, pumpkins)

#### VO group 12 Fruiting vegetables, other than Cucurbits

- 12-1 Solanaceae (e.g. tomatoes, peppers)
- 12-2 Mushrooms

#### VL group 13 Leafy vegetables (including Brassica leafy vegetables) change in Leafy vegetables, except Brassica leafy vegetables

#### VR group 16 Root and tuber vegetables

A new group is proposed for the foliage of root and tuber vegetables or the tops or leaves should be added to the leafy vegetable group and to the animal feeds (sugar beet tops).

#### GC group 20 Cereal grains

- 20-1 Small grains (e.g. millet, teff)
- 20-2 Grains (e.g. wheat, barley, rice)
- 20-3 Immature grains (e.g. sweet corn)