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(出國類別：出席國際會議)

出席『第四十七屆國際農藥分析聯合會年會』
(47th Session of CIPAC meeting)

報告書

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內容摘要: 第四十七屆國際農藥分析聯合協會年會(47th CIPAC Annunal Meeting) 及世界糧農組織農藥規格會議 (FAO Pesticide Specification) 及第二屆世界糧農組織及衛生組織農藥規格聯合會議 (Joint FAO/WHO Meeting on Pesticide Specifications (JMPS)) 合併於2003年6月8日至6月17日在羅馬尼亞布加勒斯特舉行。主辦單位為CIPAC、FAO、WHO及Romanian Ministry of Agriculture, Forestry and Food。CIPAC為「Collaborative International Pesticides Analytical Council」的簡稱，中譯為「國際農藥分析聯合會」。本會議計有CIPAC委員、國家代表、國際組織代表、農藥工業界代表共廿七國九十人出席。會議議程包括二天FAO農藥規格會議、一天JMPS會議、一天CIPAC Symposium 及三天CIPAC農藥成品分析方法討論會。本人以CIPAC Correspondents member身分出席，經費由藥毒所92年度公務預算支付。本年度世界糧農組織所負責之農藥規格會議依往例除討論現行之規格外，並對舊農藥每十年檢討一次。本次規格會議也包括第二次JMPS會議。CIPAC每年就農藥成品主成分及規格之分析方法，經過嚴謹之檢驗方法開發及實驗室間之認證過程，提出年會討論通過後才列入由CIPAC出版之「CIPAC Handbook」。本次為第四十七屆年會，計討論並作成結論有十七種農藥之成品主成分分析方法及五種理化性質檢驗方法。CIPAC所出版之「CIPAC Handbook」是世界採用之農藥主成分分析方法，目前已出版至第十冊「CIPAC Handbook J」(2000年出版)，本人名字(Mrs. Wong Sue Sun, Taiwan)也列在該冊”Members of CIPAC”中。

本文電子檔已上傳至出國報告資訊網

摘要

第四十七屆國際農藥分析聯合協會年會(47th CIPAC Annunal Meeting)及世界糧農組織農藥規格會議(FAO Pesticide Specification)及第二屆世界糧農組織及衛生組織農藥規格聯合會議(Joint FAO/WHO Meeting on Pesticide Specifications (JMPS))合併於2003年6月8日至6月17日在羅馬尼亞布加勒斯特舉行。主辦單位為CIPAC、FAO、WHO及Romanian Ministry of Agriculture, Forestry and Food。CIPAC為「Collaborative International Pesticides Analytical Council」的簡稱，中譯為「國際農藥分析聯合會」。本會議計有CIPAC委員、國家代表、國際組織代表、農藥工業界代表共廿七國九十人出席。會議議程包括二天FAO農藥規格會議、一天JMPS會議、一天CIPAC Symposium及三天CIPAC農藥成品分析方法討論會。本人以CIPAC Correspondents member身分出席，經費由藥毒所92年度公務預算支付。

本年度世界糧農組織所負責之農藥規格會議依往例除討論現行之規格外，並對舊農藥每十年檢討一次。本次規格會議也包括第二次JMPS會議。CIPAC每年就農藥成品主成分及規格之分析方法，經過嚴謹之檢驗方法開發及實驗室間之認證過程，提出年會討論通過後才列入由CIPAC出版之「CIPAC Handbook」。本次為第四十七屆年會，計討論並作成結論有十七種農藥之成品主成分分析及五種理化性質檢驗方法。

CIPAC所出版之「CIPAC Handbook」是世界採用之農藥主成分分析方法，目前已出版至第十冊「CIPAC Handbook J」(2000年出版)，本人名字(Mrs. Wong Sue Sun, Taiwan)也列在該冊”Members of CIPAC”中。

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目的

國際農藥分析聯合會(Collaborative International Pesticides Analytical Council, 簡稱CIPAC) 始於1954年在巴黎舉行之第三屆國際植物保護會議，會議中決議成立官方認定之農藥主成分標準檢驗方法委員會。1957年歐盟先行成立類似功能之組織，1960年代由CIPAC通過之農藥主成分分析方法尚歸類為世界糧農組織植物保護專刊，1970年出版第一冊 CIPAC Handbook 才奠定其在農藥成品規格分析上之權威地位。目前CIPAC除取得國際組織如FAO, WHO, AOAC, UNIDO及CLI 之肯定外，FAO農藥規格製備以CIPAC之結果為骨幹，AOAC也和CIPAC 取得協議彼此承認及引用對方研發之農藥成品主成分、不純分及其它理化性質之檢驗方法。CIPAC/FAO聯合年會所討論之分析方法結集成冊，不定期發行CIPAC Handbook 供各國農藥成品檢驗單位參考，2000年出版第十冊「CIPAC Handbook J」。CIPAC年會及FAO規格會議每年聯合舉行，2002年JMPS一併召開，使其成為農藥品質管理規範集大成之聯合會。大會所討論之農藥品質檢驗方法及規格認定為世界各國所重視及引用。

我國加入WTO後在農藥研發及品管上不論是農藥成品進出口或品質檢驗標準及流程均不可避免要與世界各國採取一致的作法，一方面可以對進口之農藥原體及成品作嚴格的把關，也可以保障國產農藥品質，強化農藥管理。且農藥品質之優劣間接影響農產品中之農藥殘留及安全品質，會對消費者造成隱憂。參加本會議可了解執國際農藥成品分析牛耳之CIPAC製訂分析方法之流程，並藉此維繫參與國際間實驗室聯合檢驗及認證之機會，將國內農藥品質管理推向國際化。由於出席聯合國組織之周邊會議常會有來自中國之關切。本人於1998年獲選為correspondent CIPAC member，得以台灣名義正式與會。也希望國內政府及民間農藥相關單位正視本會議之重要性。

過程

本報告所引用之會議單位及農藥劑型簡稱對照表見附件一。

一、議程

第四十七屆國際農藥分析聯合會年會(47th CIPAC Annual Meeting)、及世界糧農組織農藥規格會議(Meeting on FAO Pesticide Specifications)及第二次農藥規格專家會議 JMPS (Joint FAO/WHO Meeting on Pesticide Specifications) 於2003年6月8日至17日在羅馬尼亞布加勒斯特舉行。議程見表一。

表一、第47屆CIPAC年會及FAO農藥規格會議議程

日期	議程
6月8-9日	Meeting on FAO Pesticide Specifications
6月10日	2 nd Joint FAO/WHO Meeting on Pesticide Specifications
6月11日	CIPAC Symposium
6月12-13日	47 th CIPAC Annual Meeting
6月14-15日	CIPAC Technical Meeting
6月16日	CIPAC Management Meeting
6月17日	CIPAC Excursion

二、參加人員

本會議計有CIPAC委員、國家代表、國際組織代表、農藥工業界代表計九十人出席。分別來自Germany, Taiwan, USA, Australia, UK, Belgium, Denmark, Italy, Thailand, Japan, France, Switzerland, India, Spain, South Africa, Slovak Republic, Malaysia, The Netherlands, Brazil, Argentina, Romania, Cyprus, Slovenia,

Greece, Czech Republic, Ukraine, El Salvador, Hungary, Belgique 等廿七國。出席人員名單見附件二。

三、會議內容

(一)FAO 農藥規格會議(Meeting on FAO Pesticide Specifications)

FAO自1995年會議後已出版四本有關農藥規格專刊，並於1996年將FAO Manual 及Specifications放在國際網路上。另為加速農藥規格製備及評估之時效，上次會議決議以小組方式審查資料，如此每年至少可完成十五種農藥之作業。FAO於1997年3月在羅馬召開之農藥規格會議中制定新的農藥規格審查步驟，並建議比照FAO/WHO農藥殘留專家會議(JMPR)模式，成立FAO/WHO農藥規格專家會議(JMPS)，以討論農藥成品及不純物之毒理問題。該會議已於去年成立併入本會議。

(二)CIPAC年會(47th CIPAC Annual Meeting)

CIPAC會議討論重點包括農藥主成分檢驗方法及農藥理化性質試驗方法。要列入CIPAC Handbook之農藥主成分檢驗方法必須經過一連串的檢驗方法開發、實驗室間認證、聯合檢驗及提交大會審查。例行之程序為先由地區性或國內之農藥分析委員會(Pesticide Analytical Committees，簡稱PAC)就其區域內廠商開發之農藥選擇至少六個農藥檢驗實驗室進行方法比對及結果統計分析，結果提交CIPAC會議審查後依CIPAC制訂之Guideline進行國際間至少十五家實驗室間之比對，結果經審查通過後依其完成之程度歸類為「CIPAC Method」、 「Provisional CIPAC Method」或「Tentative CIPAC Method」。

本次會議進程序為：(1)主席致詞及確定議程：本次會議主席為Dr. M. Muller (Switzerland)。(2)各相關組織報告(Technical liaison with other organizations)：包括FAO、

WHO、AOAC、GCPF/ECPA、UNIDO、REN PAC、GTZ、ISO、IUPAC、EU、OECD、ASTM等報告與農藥品質管理技術相關成果或會議。(3) 專家報告 (Reports of expert witnesses)：由專家就各單一農藥檢驗方法或農藥成品規格檢驗方法進行小區域或大規模實驗室間比對檢驗結果提出報告。

(4) 國家報告 (National reports) 各出席國家代表報告各國農藥品質管理結果，本會議有廿二國代表報告。(5) 上次會議結論報告 (Minutes of the 46th meeting)。及(6) 決定下次會議時間及地點。

提交本次會議討論並作成結論之主成分檢驗方法農藥計有十七種，及五種規格檢驗方法。結論摘要列於表二。詳細討論內容見附件三。

表二、47th CIPAC會議討論結果摘要

CIPAC Code No	農藥名稱	檢驗對象	分析方法 (方法分類)
12	Malathion 馬拉松	TG, EC, EW, DP	Capillary GC method (Full CIPAC method)
221	Chlorpyrifos 陶斯松	UL	HPLC method (Full CIPAC method)
288	Chlorothalonil 四氯異苯晴腈		CIPAC/4187列入AOAC審查 (Provisional Method)
481	Esfenvalerate 益化利	TG, ULV	Capillary GC and HPLC (Full CIPAC method)
484	Fenoxypop-p-ethyl 芬殺草		CIPAC/4111 Chiral HPLC method(Provisional Method)
494	Tebuconazole 得克利	TG, Formulation	Capillary GC method (FullAOAC- CIPAC method)
510	Cycloxydim 環殺草	TK, EC	HPLC method (Full CIPAC method)
546	Tribenuron- methyl	DF, WG	CIPAC/4284HPLC method (Full CIPAC method)
582	Imidacloprid	SL, OD	HPLC method

CIPAC Code No	農藥名稱	檢驗對象	分析方法 (方法分類)
	益達胺		(Provisional CIPAC method)
734	Flufenzin		HPLC method (provisional CIPAC method)
740	Icaridin	TG, lotion	Capillary GC and HPLC (Full CIPAC method)
741	Transfluthrin	TG	Capillary GC and HPLC (Full CIPAC method)
741	Transfluthrin	VL	Capillary GC and HPLC (Provisional CIPAC method)
742	d-Allethrin 亞烈寧	CIPAC/4326 Provisional CIPAC method)	Capillary GC
203	Bioallethrin		
751	Esbiothrin		
MT-178.2	Attrition resistance of water dispersible granules		CIPAC method 178, CIPAC /4326 (Full CIPAC method)
MT 187	Particle size analysis by laser diffraction		CIPAC /4278 (Full CIPAC method)
MT188	Free a.i. in microencapsulated formulations of parathion-methyl		CIPAC MT method (Provisional CIPAC method)
MT189	Free a.i. in microencapsulated lambda cyhalothrin formulations		(Provisional CIPAC method)
MT190	Release properties of microencapsulated lambda cyhalothrin formulations		(Provisional CIPAC method)

國家報告 (National reports) : 本會議計有二十二個國家代表報告，分別為Australia: Paul Sethi (by Colin Cook) ; Belgium: Michel Galoux; Czech Republic: Jindrich Foltyn; Cyprus: Anna Kouppari; Denmark: Teddy Krongaard; El Salvador: Elisabeth de Aguila; Germany: Ralf Hänel; Greece: Ada Hourdaki; Hungary: Laszlo Bura; Italy: Roberto Dommarco; Japan: Ritsuko Furuta;

Netherlands: Ed van der Wal; Romania: Teodora; Iurascu Slovenia: Anna Gregorcic; Spain: Luis Manso; South Africa: Eric Sandman; Switzerland: Markus Müller; Taiwan: Sue Sun Wong; Thailand: Nuansri Tayaputch; Ukraine: Vitalij Chmil; United Kingdom: Richard Fussell; USA: Alan Hanks。本人所準備之Taiwan Report 書面報告見附件四。

本次會議宣告之十五種新CIPAC Code化合物名稱列於表三。

表三、47th CIPAC Meeting宣告之CIPAC Code化合物

CIPAC Code	Compounds	CIPAC Code	Compounds
747	Spiromesifen	755	Hydrogen peroxide
748	Bispyribac	756	Potassium phosphate
749	Dinotefuran	757	Sulfuryl fluoride
750	s-Bioallethrin	758	Penoxsulam
751	Esbiothrin	759	Cyflufenamid
752	Metrafenone	760	Acequinocyl
753	Paecilomyces lillacinus	761	d,d,-trans-cyphenothrin
754	Formic acid		

(三)第二屆世界糧農組織及衛生組織農藥規格聯合會議(Second JMPS meeting)

第二屆FAO/WHO 農藥規格專家會議由UK Dr. Alan Hill擔任主席。此會議之精神為將農藥及環衛用藥之管理統一化，並在規格制訂上考慮其對環境及人類之毒性影響。

2002年第一次JMPS會議即針對二十四種在毒性上引起關切之持久性污染物建議撤銷其規格。分別為anilazine, bromophos, camphechlor (toxaphene), chlorbenside, chlordane, demeton, demeton-S-methyl, DDT + its mixtures, HEOD (dieldrin), HEOD+mercury, dimefox, dinoseb, dioxathion, endrin, fenoprop, HHDN(aldrin), heptachlor, mehoxyethylmercury silicate, methoxyethylmercury chloride, monuron, nicotine, nicotine sulphate, schradan, 2,4,5-T.其中因DDT在環衛上還使用，故暫緩撤銷。Nicotine 類雖還有國家使用，但無廠商願提供規格資料，故仍撤銷。並決議重新整編FAO農藥規格手冊，更名為「Manual on Development and Use of FAO and WHO Specifications for Pesticides」，已於2002年底完成並公告於網站上。本手冊除了加入新的劑型規格，含環衛用藥、生物農藥、及特殊處理如防蚊纖維等，並統一FAO及WHO對農藥規格之要求。全書分九章及八個附錄，主要內容目錄見表四。本手冊已為EU及中南美洲OIRSA會員國列為農藥品質管理之依據。

表四、Contents of 「Manual on Development and Use of FAO and WHO Specifications for Pesticides, First Edition 2002」

1	Introduction
2	The process of developing FAO/WHO specifications
3	Requirements and procedures for development of FAO/WHO specifications

4	Aims, applicability, and requirements of specification clauses
5	Specification guidelines for technical materials and technical concentrates (except microbial TKs)
6	Specification guidelines for solid formulations
7	Specification guidelines for liquid formulated pesticides
8	Specification guidelines for pesticides formulated as, or in, devices for application
9	Specification guidelines for microbial pesticides
A	Guidelines for sampling
B	Supply and certification of reference substances
C	Glossary of terms
D	Coding of active ingredients, specifications and method status
E	CropLife International codes for technical and formulated pesticides
F	CIPAC codes for pesticides, in numerical order
G	CIPAC codes for pesticides, in alphabetical order
H	Declarations of interests and confidentiality by FAO/WHO experts

FAO 同時也完成「International Code of Conduct on the Distribution and Use of Pesticides」之修訂版，並有中文版本譯為「國際農藥供銷與使用行為守則」。此為一份自律性之行為守則，內容包括農藥的管理、檢測、減少健康和環境風險、管制與技術要求、供應與使用、供銷與貿易、信息交流、標籤包裝儲存及處理、廣告及守則之監督與遵守等。

FAO、WHO 及 JMPS 各自提供已完成審定之農藥規格如附件五。

本會議也討論四種新的農藥規格準則，分別為屬環衛用藥之含藥蚊帳（insecticide-incorporated mosquito nets），及農藥之CS與SC之混合劑型ZC、CS與SE之混合劑型ZE、CS與EW之混合劑型ZW，分別列於附件六至附件九。

2004及2005年FAO、WHO及/FAO/WHO預訂列入審查之農藥名稱列於附件十。

心得

一、國際農藥分析聯合會(CIPAC)之任務及作業程序

國際農藥分析聯合會(CIPAC) 主要任務為協助建立農藥成品規格及主成分之標準檢驗方法，而其公告之檢驗方法已成為世界各國對農藥管理及品質要求之基本檢驗方法。其制訂之規格也積極列為農藥產品國際貿易之合約內容之一以保障農藥品質。CIPAC年會進行實驗室聯合試驗結果之評估、規格製訂及規畫新農藥共同比對作業程序。大部分實驗室間共同比對(Collaborative Studies)由地區相對應之組織即「農藥分析協會」(Pesticide Analytical Council, 簡稱PAC)配合進行，依據「Guidelines for CIPAC Collaborative Study Procedures for the Assessment of Performance of Analytical Methods」循序完成檢驗。國際間實驗室比對應提出「CIPAC Information Sheets」由會議主辦人確定其準確性及再現性後才同意進行「Full-Scale Collaborative Studies」。檢驗結果經審查通過後依其完成之程度歸類為「CIPAC Method」、「Provisional CIPAC Method」或「Tentative CIPAC Method」。「CIPAC Method」為完成完整之國際性比對工作符合各項要求，分析方法之結果具高度之重覆性(repeatability)及再現性(reproducibility)。「Provisional CIPAC Method」為準CIPAC方法，須再補齊比對工作或分析方法不夠完美。「Tentative CIPAC Method」為未完成Full Scale Study，但因需要而接受其方法者。

CIPAC除於每年年會討論檢驗方法外，並負責規畫實驗室分析能力認證及國際性實驗室分析結果比對工作。不定期出版「CIPAC Handbook」，目前已發行十冊，「CIPAC Handbook J」於2000出版。中國大陸取得部分之中譯權，已譯成五冊。

二、農藥主成分分析及標準規格之重要性

我國農藥管理法中規定之農藥標準規格可分為原體、成品及增效劑之標準規格三種。原體規格中以有效成分含量及不純物含量為最重要，此與農藥原體合成方法及生產品管有關，常列為生產機密資料。主成分最低含量標準或不純物最高含量限制也常列為品管標準。成品農藥除主成分含量外，不同劑型有其理化安定性之標準及檢驗方法。

農藥原體及成品規格對農藥使用時之效果及使用後在作物上及環境中之殘留及副作用均有很大之影響。不純物的毒性若認定有致癌或畸胎性時常導致農藥被禁用，或要求廠商改變生產流程減少不純物產生。因此原體主成分檢驗方法有時必須包括不純物之檢驗。農藥成品之安定性、細度、懸浮率或分散性等都會影響農藥的效果，因此產品規格制訂及標準測試方法之建立非常重要。大陸各主要大學農學院中有農藥化學系，農藥工廠合成農藥的技術也很高明，農藥成本較低。唯品管不一，且忽視農藥專利權，其產品經各種管道行銷全世界，造成各國農藥管理上的困擾，在作物殘留及環境安全上也造成威脅。目前我方開放大陸原體進口，未來大陸生產之農藥成品在台上市為期不遠。台灣因農藥被社會大眾視為污染工業，農藥原體合成工廠很難生存，大部分為成品加工或分裝工廠，在成品規格檢驗方面也應加強。雙方若均遵循FAO及CIPA之農藥規格及檢驗方法，業者能支持政府以FAO及CIPA為基礎之相關農藥法規修正，相信對農藥品質保障及業者產品品管之提昇均有助益。

三、農藥與環衛用藥管理標準之一致性

FAO/WHO農藥規格專家聯合會議成立之目的為將農藥及環衛用藥之管理統一化，並在規格制訂上考慮其對環境及人類之毒性影響。此一精神可作為國內農藥及環衛用藥管理之參

考。農藥及環衛用藥主成分大部分一樣，但因管理機制不同可能造成原體及成品製造及使用成本之差異，若無完善且一致之管理制度及標準，恐易造成不肖業者將農藥用在環衛用藥上。尤其是在病蟲媒防治用藥對施藥者及環境之安全均應列入評估。

建議

一、重視農藥品質之管理

農藥原體合成過程會影響主成分含量及不純物種類及含量，因而影響產品品質及安全。成品之主成分含量、成品規格及其安定性則影響農藥的藥效、藥害及殘留量，因此農藥品質的管理非常重要。農藥原體合成過程牽涉到成本高低及專利權，因此除主成分含量管理外，毒性上值得考慮之不純物種類及含量也應列入管理。可由FAO公告之不純物種類及含量優先辦理。成分標示不明及品質不良之偽劣農藥常是造成作物上農藥殘留過量或藥害之原因之一，由榮總毒物中心的中毒案件中也常看到服食標示不明之農藥而導致急救發生困難的情形，此等皆會造成台灣農藥管理不善之印象。尤以本省農藥原體合成少，大陸農藥大量傾銷國外，台灣也是其市場之一，如何強化進口農藥原體品質之檢驗及修正國內成品農藥之檢驗項目有待農藥主管機關研究。此外對於國內廠商外銷至開發中國家的農藥也要信守農藥品質管制之原則，不要因開發中國家無能力作農藥品管檢驗或行政管理不夠嚴謹而傾銷不良品。

二、正視環衛用藥管理及對環境和消費者之安全

環衛用藥大部分主成分與農藥相同，唯劑型及使用方法因防治對象及地區而異。由於病蟲媒防治地區不是屋內即為生活社區，消費者與之接觸的機會和劑量較農藥為高。另在國際上DDT、BHC等有機氯烴劑在病蟲媒防治上仍有其防治效果及使用之必要性。合成除蟲菊類殺蟲劑為環衛用藥之主流，但其對水生生物的毒性強。該二類化合物均為疑似環境荷爾蒙，可能對生態及漁業養殖環境有影響，值得重視。

三、提昇國內農藥品質檢驗水準

國內參與農藥主成分或規格檢驗的單位除農藥成品之法定檢驗單位及農藥工廠之品管室外，研究單位及大學實驗室也可能進行農藥主成分檢驗。故除加速公告農藥主成分之國家標準檢驗方法外，建立實驗室檢驗能力認證及規畫標準的檢驗流程也是非常重要的工作。以農藥主成分標準檢驗流程為例，分析樣品包括分析級標準劑、內標準劑及待檢樣品。書面資料包括分析流程、各化學品基本理化性質說明及注意事項、每日分析步驟及結果計算公式及表格(Data Sheet)。附件十一為本會議建議之CIPAC發表格式，可供參考。另為建立我國檢驗水準之形象，有必要成立地區性農藥分析協會(PAC-Taiwan)，以進行實驗室檢驗能力認證、規畫標準檢驗流程、檢驗人員訓練、及負責接受國際間分析比對工作之聯繫，國內之品管結果能提交國際間流通，使國內的農藥品質分析技術及水準能更上一層樓。本所農藥化學組多年來即積極參與CIPAC Collaborative Study，並主動彙集出版「農藥標準規格與檢驗方法」，目前積極參與CNLA農藥成品檢驗實驗室認證。農藥管理當局及業界應肯定及支持其努力。

四、善用CIPAC資料和掌握及時資訊

農藥成品品質管制方法如主成分及理化性質試測方法CIPAC皆已建立很完善的檢驗制度，國內可參酌引用。另外國際網路上也可查到FAO所制定的農藥規格。直接進入FAO 首頁(fao.org.) 或進入FAO Pesticide Management首頁，其中與農藥成品相關的專刊如「FAO Specification for Plant Protection Products」及「Manual on the Development and Use of FAO and WHO Specifications for Pesticides」皆可載入，非常方便。另對

於新劑型之開發及運用也應隨時引進國內，以提昇國內農藥研發水準。

附件一、報告及農藥劑型簡稱對照表

PartI:

AOAC	Association of Analytical Chemists
CCPR	Codex Committee on Pesticide Residues
CIPAC	Collaborative International Pesticides Analytical Council
CLI	Crop Life International (formerly GCPF)
ECCA	Europe Crop Care Association
FAO	Food and Agricultural Organization
GCPF	Global Crop Protection Federation
ICRC	Interim Chemical Review Committee of the Rotterdam Convention
IPCS	International Programme on Chemical Safety
IR	infra-red
ISO	International Standards Organization
JMPR	Joint Meeting on Pesticide Residues
JMPS	Joint Meeting on Pesticide Specification
MRL	maximum residue limit
PIC	Prior Informed Consent
UNIDO	United Nations International Development Organization
WHO	World Health Organization

PartII *CIPAC Codes for Formulations*

CS	capsule suspension
DP	Dustable powders
DS	Powders for dry seed treatment
DT	Tablets for direct application
EC	emulsifiable concentrate
EG	Emulsifiable granules
EP	Emulsifiable powders
EW	emulsion, oil in water
FS	flowable concentrate for seed treatment
GR	Granule
LS	solution for seed treatment
MG	Microgranule
SC	suspension concentrate (= flowable concentrate)
SE	suspo-emulsion
SG	water soluble granule
SL	soluble concentrate
SP	Water soluble powders
ST	Water soluble tablets
TC	technical material
TK	technical concentrate
UL	ultra-low volume (ULV)
WG	water dispersible granule
WP	wettable powder
WS	water dispersible powder for slurry treatment
WT	Water dispersible tablets

附件二、47th CIPAC Meeting 出席人員名單

**List of participants of the 47th CIPAC Meeting
12 - 13 June 2003, Bucharest, Romania**

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附件三、47th CIPAC Meeting 各藥劑農藥規格討論內容

1 Acetamiprid -by Mr H. Muro (4320, 4321)

Dr. Muro presented the results of two small scale collaborative studies by JAPAC: the first on Technical Material (TC), and four formulations: a Wettable Powder (WP), a Water Soluble Powder (SP), Water Soluble Granules (SG) and Soluble Concentrates (SL) in which acetamiprid was determined by reverse phase HPLC, UV detection and the use of coumarin as internal standard. The second study for the EC formulations used normal phase HPLC, UV detection and p-nitroaniline as the internal standard. Five laboratories participated in each study. None of the outliers or strugglers were rejected and it was suggested that the results of all studies support testing the two methods by full collaborative trials. Mr Hill suggested the use of an alternative solvent to di-isopropyl ether for safety reasons. Mrs Hourdakos questioned the need for using different internal standards for different formulations and asked why coumarin could not be used for all formulations. The reason is the long retention time. Dr Müller asked for clarification on the role of the phosphoric acid in the mobile phase. It was confirmed that it served to control the pH in view of the fact that the retention time of an interfering peak could only be stabilised (and interference with the active ingredient peak avoided) under controlled pH conditions.

2 d-Allethrin by Mrs. R.Furuta (4326, 4327)

3 Bioallethrin by Mrs. R.Furuta (4328, 4329)

4 S-Bioallethrin by Mrs. R.Furuta (4331)

5. Esbiothrin by Mrs. R.Furuta (4330)

Mrs. Furuta presented the results of a CIPAC collaborative study on the determination of the active substances in d-allethrin, bioallethrin, s-bioallethrin and esbiothrin technical materials and d-allethrin liquid vaporizer formulations. For the technical materials a capillary GC method was used with FID detection and using m-terphenyl as the internal standard. Results were submitted by eleven laboratories. JAPAC proposed the method to be accepted as Provisional CIPAC method. A study for the applicability of the CIPAC draft method for d-allethrin, bioallethrin, and esbiothrin to mosquito coils and vaporizing mats was also presented. Hexane is used in sample preparation for MC formulations instead of acetone to reduce the amount of coextracted coformulants interfering in the determination.

6. Dinotefuran by Mrs T. Kumeta (4322, 4323)

Mrs Kumeta presented a small scale Collaborative study by JAPAC for the determination of dinotefuran in one technical material, and four formulation (two wettable powders and two water soluble granules) samples. Five laboratories participated in the study. Mr Bura asked if there is a special reason for using a C8 HPLC column instead of a C18 column. It was used in order to get better symmetry of the peak of the a.i. Dr Müller asked if it was necessary to use a "Symmetry" column or if any equivalent C8 column could be used instead. Mrs Kumeta answered that it is possible to use equivalent column. Mr. Schreuder made a remark concerning the sample preparation: first dissolve in methanol, add water and mix and fill to volume.

7 Flufenzin (SZI-121) by Mrs. Á. Hegedüs (4324, 4325)

Mrs Á. Hegedüs presented a Collaborative study for the determination of flufenazine in two technical materials, and two SC formulation samples by reverse phase HPLC using a C18 column and UV detection. Ten laboratories participated in the study, but only nine results arrived in time and were included in the calculation. The results of the tenth laboratory were well fitting in the range of results of the other laboratories. Mr Hill asked what were the criteria for rejecting the outliers and asked for them to be included, since there was no reason to exclude them, and in order to give a more representative picture of the performance of the method. Mrs Á. Hegedüs agreed to this.

8 Parathion-Methyl, free a.i. by Mrs.E.Sørensen (4318, 4319)

Mrs. E.Sørensen noted that it was the fifth time that she was presenting a collaborative study for measuring free parathion methyl in capsule suspensions by HPLC. Four samples were sent to eleven laboratories and results were received from only eight of them. The method was suggested for acceptance as a provisional CIPAC method. Mr Hill sought clarification on the saturation concentration of the a.s. in the extraction solution with surfactant. Mrs.E.Sørensen replied that the method can measure up to 10% parathion methyl concentration in the formulation. It was proposed to include this information in the method description. Dr Müller asked if the active ingredient could be determined by NMR. Mr. Bjornholm replied that they tried, but this was not possible.

9 Release properties and "free ai" in microencapsulated formulations by Mr. R. Parker (4315, 4316)

Mr. Parker presented a CIPAC collaborative study on the method of measurement of the release properties and "free a.i." in CS formulations for public health applications of lambda- cyhalothrin. Data were available from a total of 14 laboratories each of which tested 4 formulations. Each formulation was tested 4 times with 2 independent replicate samples being tested on each of 2 separate days. 4 measurements were recorded on each sample: Free AI and three release property measurements taken at 15, 30 and 180 minutes. Two laboratories were completely eliminated from the evaluation of results due to significant deviation from the test protocol (use of rollers of much slower speed). It was noted that one laboratory had used a rotary evaporator instead of a roller and still received satisfactory results but that was not recommended for future use. Mr. Hill commented that it appears to be a good method for a wide range of capsules for the free a.i. determination but not so much for assessing the release rate.

Other matters

1 Imidacloprid method extension by Mr.T. Werner (4332/R)

Mr.T. Werner presented a proposal for an extension of the scope of CIPAC method 582 for the imidacloprid determination to the SL and OD formulations. For this purpose the existing method was tested by standard additions to blank formulations. The results obtained were satisfactory and it was proposed to extend the existing CIPAC method for the SC formulation to the SL and OD formulation types. Mr. Werner announced that the Company intends to initiate a new trial on deltamethrin, because the old method is using hexane. The new method will be a NP HPLC method and the small scale study will be initiated through DAPA.

2 glyphosate, alternative method by titration by Mr. H. Di Loreto (4335/R)

Mr Héctor Di Loreto presented an alternative method for the determination of glyphosate in SL formulations and technical products. In this method, glyphosate is

extracted from the sample and then dissolved in water and titrated with sodium hydroxide. This is a very cheap, simple and CIPAC time efficient method compared to the traditional official CIPAC method. Mr Dommarco asked if there was any information on any possible acidic impurities that may interfere with the active ingredient determination. Mr Di Loreto replied that there are no such impurities in IPESA's products. Mr Hill commented that cheaper analytical techniques are always welcomed and suggested to elaborate a CIPAC guideline how to validate such alternative methods. The chairman replied that CIPAC will consider this matter.

3 Transfluthrin, stereospecific identity test by Mr.T. Werner (4333/m)

Mr. T. Werner presented a stereospecific identity test for transfluthrin in response to the requirement, discussed at the 46th CIPAC Meeting in Rome, for the verification of the selectivity of the CIPAC method 741 for transfluthrin. Dr Müller asked if the technical material in which the stereoisomers are present at known concentrations could be available as a reference material for checking the performance of the GC column. Mr Werner replied that this could be arranged. Mr Fussel enquired about the commercial availability of stereoselective GC columns: it was confirmed that such columns are available.

4 MT 31 Determination of acidity and alkalinity by Mr.R.Grohs (4342)

Mr. R.Grohs presented a proposal for a revised CIPAC Method for the determination of acidity and alkalinity. At present there are three sub-methods. The electrometric method appears to be the method of choice and so a modification of this method that would allow more flexibility and minimize the sample preparation required was proposed. Mr Hill commented on the justification for the inclusion of an acidity/alkalinity clause in the FAO/WHO specifications and then welcomed the development of a more reliable method of measurement of the acidity/alkalinity that could contribute to the assessment of the quality of the product considered. Mr Krongaard said that in the EU, the classification of the active ingredient depends on its acidity/alkalinity characteristics but Dr Grohs clarified that the present presentation relates to the formulations and is not at all a reflection of the acidity/alkalinity of the active ingredient. Mr Hill added that such a clause in the FAO/WHO specifications is only justified when it does not relate to the acidity/alkalinity of the active ingredient.

5 Azadirachtin small scale study using HPLC isocratic and gradient method

Mr. E. Sandman informed the meeting that a study will be presented at next years CIPAC Meeting. It will be based on reverse phase HPLC and will include both isocratic and gradient technique.

6 Fenoxaprop-P-ethyl by Mr. T. Werner

Mr. T. Werner presented a study on the safe use of the HPLC chiral column specified in the official CIPAC method for the determination of fenoxaprop-p-ethyl. He proposed the addition of the set of rules presented as a note in the CIPAC method. Mr Hill commented that his laboratory had encountered problems with the commercial columns and asked if the column suppliers would be willing to provide additional loose column material in order to enable the testing laboratories to maintain the quality of the columns. With this study the long-term stability of the column, which worked well, was demonstrated and not really the availability of columns with continuous good quality. Dr Müller added that he was also concerned about this matter. Mr Werner replied that he was optimistic that the column suppliers would be willing to do so. Mr Foltyn asked if there is a maximum limit for the water content in the eluent solvent and received a positive reply.

附件四、47th CIPAC Meeting Country Report 台灣報告

Taiwan Report to 47th CIPAC Meeting
Bucharest Romania, 7th -15th June 2003

1. TACTRI Participation in CIPAC collaborative studies.
2002-2003

12 Malathion: Capillary GC Method (Technical, EC, EW, DP)

740 Icaridin: Capillary GC Method (Technical, lotion formulation)

741 Transfluthrin: Capillary GC Method (Technical, Vaporizer solution)

487 Parathion-methyl: free ai in CS

463 lambda-Cyhalothrin: free ai in CS

2. TACTRI Publications on Pesticide Specifications

Pesticide Specification and Official Analysis Method Vol. 1 (2000)
(in Chinese) 168pp ISBN 957-02-7412-3

Pesticide Specification and Official Analysis Method Vol. 2 (2000)
(in Chinese) 207pp ISBN 957-02-7413-1

Pesticide Specification and Official Analysis Method Vol. 3 (2000)
(in Chinese) 96pp ISBN 957-02-7414-X

Pesticide Specification and Official Analysis Method Vol.4 (2002)
(in Chinese) 132pp ISBN 957-01-0327-2

Pesticide Specification and Official Analysis Method Vol.5 (2003)
(in Chinese) 190pp ISBN 957-01-0563-8

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附件五、FAO、WHO 及 JMPS 完成審定農藥規格之名單

1. Status of FAO Specifications

Manufacturer	Product	FAO specification	Status
Dupont	Bensulfuron-methyl TC, WP, WG	New	Specification and Evaluation report published
	Methomyl TC, TK, SL, SG	Revised	Specification and Evaluation report published
	Tribenuron- methyl TC, WG	New	Specification and Evaluation report published
BASF	Quinclorac TC, WP, WG, SC	New	Specification and Evaluation report published
Syngenta	Glyphosate SL	Extension of specification	Extended specification and amended evaluation published
BASF; Gharda; Syngenta	Dicamba TC, SL, WG	Revised	Specification and Evaluation report published
Crompton Corp. (Uniroyal)	Maleic hydrazide TC, TK, SL, SG	New	Evaluation report published – publication of specifications subject to validation of analytical methods
Fortune; Godrej; Trifolio M	Azadirachtin (TC), TK, EC	New	In progress, scheduled again for 2003

Manufacturer	Product	FAO specification	Status
Agro-Chemie	Flufenzine (diflovidazin) TC, TK	New	In progress, scheduled again for 2003
	Beta-Cypermethrin	New	Insufficient data, removed from the programme
Bayer CropScience	Iprodione TC, SC, WG, WP	New	Withdrawn, rescheduled for 2003
Nufarm	Butralin	New	Withdrawn, rescheduled for 2004

2. Status of WHO Specifications

Manufacturer	Product	WHO specification	Status
Sumitomo	d-allethrin TC	New	Evaluation report published – publication of specification subject to validation of analytical methods
	d-phenothrin TC	New	Evaluation report published – publication of specification subject to validation of analytical methods
	Prallethrin TC	New	Evaluation report finalised – publication of specification subject to validation of analytical methods

Bayer	Transfluthrin TC	New	Evaluation report finalised – publication of specification subject to validation of analytical method
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3. Status of FAO/WHO Specifications

Bayer	Niclosamide TC, WP, EC	Revised/Joint	Evaluation report and specifications finalised – await decision by JMPS and Industry on definition of TC/TK
Dow AgroScience, Makhteshim & Gharda (withdrew)	Chlorpyrifos TC, EC	Revised/Joint	Evaluation report published - publication of specifications subject to validation of analytical method for the relevant impurity

附件六、Draft Guideline for Specifications of Long Lasting Insecticidal Net

Long-lasting insecticidal netting [CIPAC number]/LN

1. Description

The product shall consist of netting, formed from [type and mono-/poly-filament] fibres, treated with technical [ISO common name] complying with WHO specification, together with any necessary stabilizers, plasticisers, other formulants and synergists, if required. The product shall be suitable for use as an insecticidal net and shall have long-lasting activity (Note 1).

2. Active ingredient

2.1 Identity tests (Note 2)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply at least one additional test.

2.2 Total content of active ingredient (Note 2)

The [ISO common name] content shall be within the range to g/kg and, when determined, the average content shall not differ from that declared by more than \pm g/kg or \pm 15% (homogenous product) or \pm 25% (heterogeneous product) if the declared content is lower than 25 g/kg.

2.3 Any other relevant clause

Such as isomer ratio or synergist content, if relevant.

2.4 Initial surface concentration of active ingredient on yarn (Note 3)

The initial surface amount of [ISO common name] on the yarn, determined by the method described in Note 2, shall be not less than mg/g of netting.

2.5 Release index or durability to washing (Note 4)

The [ISO common name] release index or durability to washing, when determined by the method described in Note 3 shall be within the range to

3. Relevant impurities

3.1 By-products of manufacture or storage [insert common name and/or chemical name]

If required,
Maximum: % of the [ISO common name] content found under 2.2.

4. Physical properties

4.1 Fibre composition (Note 5)

The fibres shall be of atype.
If required, melt index shall be in the range to

4.2 Netting mesh size

The mesh size shall be uniform and with a minimum of complete holes per square inch.

4.3 Dimensional stability of netting to washing (Note 6)

The dimensional stability (length and width) shall be $\pm 10\%$ of initial dimensions.

4.4 Mass per m² of netting (Note 7)

The mass/m² shall be ... \pm g/m².

4.5 Bursting strength (Note 8)

The minimum bursting strength shall be

5. Storage stability

5.1 Stability at elevated temperature (MT 46.3, CIPAC J, pp.128-130)

After storage at 54 ± 2 °C for 2 weeks, the determined total active ingredient content shall not be lower than% relative to the determined average content found before storage (Note 9) and the product shall continue to comply with clauses for:
isomer ratio (2.3),
initial surface concentration (2.4),
release index (2.5)
dimensional stability (4.3) and
bursting strength (4.5).

- Note 1 Long-lasting insecticidal netting is expected to retain its insecticidal activity during its lifespan and through a given number of washes. The long-lasting insecticidal effect may be produced by incorporation or coating of pesticide in/on the yarn. Although flammability of the product is not part of this specification, it should be measured by 16CFR Part 1610 and the result presented on the package.
- Note 2 Sampling. Cut out at least one full-width strip, at least 20 cm wide, across the shortest dimension and not less than 100 cm from the end of the longest dimension of a net or the netting. Roll up the strip(s) and place it/them in a labeled, new, clean aluminium foil prior to analysis. Sub-samples for testing should be taken as described in each test method.
- Note 3 Methods must be CIPAC, AOAC or equivalent and an appropriate reference to the method must be provided.
- Note 4 A full description of the method for determination of initial surface concentration must be provided or, if the method has been published, an appropriate reference must be given. The method is expected to distinguish good and bad products of the same type, using an extraction procedure designed for the product. For this reason, a method intended for impregnated nets must not be used with coated nets, or *vice versa*, and the method may be specific to a particular product.
- Note 5 A full description of the method for release index or durability to washing must be provided or, if the method has been published, an appropriate reference must be given. The method is expected to distinguish good and bad products of the same type, using an extraction procedure designed for the product. For this reason, a method intended for impregnated nets must not be used with coated nets, or *vice versa*, and the method may be specific to a particular product.
- Note 6 The melt index should be determined according to the method of ISO (1997).
- Note 7 The dimensional stability should be determined according to the method of ISO 5077 (1984).
- Note 8 The mass/m² should be determined according to the method of ISO 3801 (1977).
- Note 9 The minimum bursting strength must be measured according to ISO 93938-2 (1999), using a 7.3 cm² sample.
- Note 10 Samples of the product taken before and after the storage stability test should be analyzed concurrently in order to reduce the analytical error.

附件七、Mixed formulation of CS and SE (ZE)

Introduction

A mixed formulation of CS and SE is a stable dispersion of microcapsules and a mixture of active ingredient(s) dispersed in an aqueous solution, where one (or more) of the active ingredients is in suspension form and one (or more) of the active ingredients is in emulsion form. The formulation is normally intended for dilution with water before use. In the case of microcapsules, the active ingredient is present inside discrete, inert, polymeric microcapsules. The formulation is intended for dilution into water prior to spray application. Mixtures of active ingredients one of which is encapsulated are used to provide a broader spectrum of pest control. Formulating the active ingredients together eliminates the need for tank mixing (which can lead to incompatibilities). Like other aqueous liquid formulations, ZE formulations are easy to handle and measure, dust free, nonflammable and offer good miscibility with water.

Different reasons for the encapsulation of active ingredient may exist, for instance

- To increase the residual biological activity.
- To reduce the acute toxicity.
- To obtain a physical or chemically stable water-based formulation.

This purpose determines whether the “release rate” is a relevant property of a specific product.

Mixed formulations of CS and SE are not stable indefinitely and therefore it is necessary to ensure that, after transportation and storage, the formulation remains suitable for use.

Quantification of the following parameters, particularly after high and low temperature stability tests, serves this purpose.

- Active ingredient, determined and expressed as “total” and “release rate” (“total” is required in all cases and “release rate” is dependent upon the intended application).
- Pourability test.
- Dispersion stability, wet sieve and persistent foam tests (to ensure the sprayability of the diluted ZE formulation).
- Rate of release. In assessing performance of a capsule, the rate of release of the active ingredient after application may be considered an important property (see above).

Information about other properties may also be given, e.g. mass per milliliter

and flash point (if relevant), but these parameters do not normally constitute essential parts of the specification. However, some other physical properties, especially particle size distribution and viscosity, are excluded from the specification for the following reasons.

- Particle size distribution (CIPAC MT 185).
- Viscosity. Although viscosity is a very important property, it cannot be described simply, as most ZE formulations show non-Newtonian flow characteristics. In the specification, the pourability and water dispersibility adequately described the flow (rheological) properties.

[ISO Common name] Mixed formulation of CS and SE

[CIPAC number]/ZE

1.1. Description

The material shall consist of an emulsion of fine droplets of technical [ISO common name] complying with the requirements of the FAO/WHO specification..., in the form of (section 4.2), and a suspension of fine particles of technical [ISO common name] complying with the requirements of the FAO/WHO specification..., in the form of (section 4.2), combined with a suspension of microcapsule of technical [ISO common name] complying with the requirements of FAO/WHO specification..., in the form of ... (section 4.2), in an aqueous phase together with suitable formulants. After gentle agitation the material shall appear homogeneous (Note 1) and be suitable for dilution in water.

1.2. Active ingredients

1.2.1.1. Identity test(Note 2)

The active ingredients shall comply with identity tests and, where an identity remains in doubt, it shall comply with at least one additional test.

1.2.1.2. [ISO common names] content

1.2.1.3. Total content (No. 2)

The [ISO common names] content shall be declared (g/kg or g/l at 20 ± 2 °C, Note 3) and, when determined, the average contents measured shall not differ from those declared by more than the appropriate tolerances, given in the table of tolerances, section 4.3.2.

1.2.1.4. Release rate (if relevant, see introduction)

1.3. Relevant impurities

1.3.1.1. By-products of manufacture or storage (Note 4)

Maximum: ... % of the [ISO common name] content found under 1.2.2.1.

1.4. Physical properties

1.4.1. Acidity or alkalinity (MT31) or pH range (MT 75.3) (Note 5)

Maximum acidity: ... g/kg calculated as H₂SO₄
Maximum alkalinity: ... g/kg calculated as NaOH
pH range: ... to ...

1.4.2. Pourability (MT 148.1)

Maximum "residue": %

1.4.3. Dispersion stability (MT 180) (Note 6)

The formulation, when diluted at 30 ± 2 °C (Notes 7 and 8) with CIPAC Standard Waters A and D, shall continue to comply with the following:

Time after allowing the dispersion to stand	Limits of stability
0 h	initial dispersion complete
0.5 h	"cream", maximum: ... ml "free oil", maximum: ... ml sediment, maximum: ... ml
24 h	Re-dispersion complete
24.5 h	"cream", maximum: ...ml "free oil", maximum: ...ml sediment, maximum: ...ml

1.4.4. Wet sieve test (MT 185) (Note 9)

Maximum: ... g/kg of the formulation shall be retained on a ... micro m test sieve, at the dilutions specified.

1.4.5. Persistent foam (MT 47.2) (Note 10)

Maximumml after 1 min

1.5. Storage stability

1.5.1.1. Stability at elevated temperature (MT 46.3)

After storage at $54 \pm 2^\circ\text{C}$ for 14 days (Note 11), the determined average total active ingredient content must not be lower than ... % relative to the determined average content found before storage (Note 12) and the formulation shall continue to comply with the clauses for: free active ingredient content (1.2.2.2.), (an increase in the free [ISO common name] content shall be allowed to an extent of ... % (absolute) of that found under 1.2.2.1., by-products of manufacture or storage (1.3.1.), acidity/alkalinity/pH range (1.4.1), pourability (1.4.2), dispersion stability (1.4.3.), and wet sieve test (1.4.4.), as required.

Note 1 All physical and chemical tests listed in this specification are to be performed with a laboratory sample taken after the recommended homogenization procedure.

Before sampling to verify formulation quality, inspect the commercial container carefully. On standing ZE formulations usually develop a concentration gradient from the top to the bottom of the container. This may result in the appearance of a clear liquid on the top and/or sediment on the bottom. Therefore before sampling, the formulation must be homogenized according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example by inverting the closed container several times).

After this procedure the container shall not contain a sticky layer of non-dispersed matter at the bottom (if the ZE has flocculated it may not be possible to re-disperse this sticky layer). A suitable and simple method of checking for a non-dispersed sticky layer "cake" is by probing with a glass rod or similar device adapted to the size and shape of the container.

Note 2 Method(s) of analysis must be CIPAC, AOAC or equivalent. If the methods have not yet been published then full details, with appropriate method validation data, must be submitted to FAO/WHO by the proposer.

Note 3 Unless homogenization is carried out carefully, it is possible for the sample to become aerated. This can lead to errors in the determination of the mass per millilitre, and in calculation of the active ingredient content (in g/l), if methods other than MT 3.3 are used. If the buyer requires both g/kg and g/l at 20°C , then in case of dispute the analytical results shall be calculated as g/kg.

Note 4 This clause should include only relevant impurities. Method(s) of analysis must be peer validated.

Note 5 The method to be used shall be stated. If several methods are

available, a referee method shall be selected.

- Note 6 The test will normally be carried out after the stability at elevated temperatures test (7.41.5.2). The test should be carried out at the highest and lowest recommended rates of use.
- Note 7 Unless another temperature is specified.
- Note 8 The formulation should be tested at 2% dilution or, alternatively, at the highest and lowest rates of use recommended by the supplier.
- Note 9 This test detects coarse particles (e.g. oversize capsules, crystals) or agglomerates (of capsules or from crust formation) or extraneous materials that could cause blockage of spray nozzles or filters in the spray tank.
- Note 10 The mass of sample to be used in the test should be specified at the application rate of use recommended by the supplier.
- Note 11 Unless other temperatures and/or times are specified. Refer to section 4.6.2 of this Manual for alternative storage conditions.
- Note 12 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

附件八、Mixed formulation of CS and SC (ZC)

Introduction

A mixed formulation of CS and SC is a stable suspension of microcapsules of the active ingredient and fine particles of active ingredient(s) in fluid, normally intended for dilution with water before use. In the case of microcapsules, the active ingredient is present inside discrete, inert, polymeric microcapsules. The formulation is intended for dilution into water prior to spray application. Mixtures of active ingredients one of which is encapsulated are used to provide a broader spectrum of pest control. Formulating the active ingredients together eliminates the need for tank mixing (which can lead to incompatibilities). Like other aqueous liquid formulation, ZC formulations are easy to handle and measure, dust free, nonflammable and offer good miscibility with water.

Different reasons for the encapsulation of active ingredient may exist, for instance

- To increase the residual biological activity.
- To reduce the acute toxicity.
- To obtain a physical or chemically stable water-based formulation.

This purpose determines whether the “release rate” is a relevant property of a specific product.

Mixed formulations of CS and SC are not stable indefinitely and therefore it is necessary to ensure that, after transportation and storage, the formulation remains suitable for use.

Quantification of the following parameters, particularly after high and low temperature stability tests, serves this purpose.

- Active ingredient, determined and expressed as “total” and “release rate” (“total” is required in all cases and “release rate” is dependent upon the intended application).
- Pourability test.
- Dispersion stability, suspensibility, re-suspensibility, wet sieve and persistent foam tests (to ensure the sprayability of the diluted ZC formulation).
- Rate of release. In assessing performance of a capsule, the rate of release of the active ingredient after application may be an important property (see above).

Information about other properties may also be given, e.g. mass per milliliter and flash point (if relevant), but these parameters do not normally constitute essential parts of the specification. However, some other physical properties, especially particle size distribution and viscosity, are excluded from the specification for the following reasons.

- Particle size distribution (CIPAC MT 185).
- Viscosity. Although viscosity is a very important property, it cannot be described simply, as most ZC formulations show non-Newtonian flow characteristics. In the specification, the pourability and water dispersibility adequately described the flow (rheological) properties.

[ISO Common name] Mixed formulation of CS and SC

[CIPAC number]/ZC

1.5. Description

The material shall consist of a suspension of fine particles of technical [ISO common name] complying with the requirements of the FAO/WHO specification..., in the form of (section 4.2), combined with a suspension of microcapsule of technical [ISO common name] complying with the requirements of FAO/WHO specification..., in the form of ... (section 4.2), in an aqueous phase together with suitable formulants. After gentle agitation the material shall appear homogeneous (Note 1) and be suitable for dilution in water.

1.6. Active ingredients

1.6.1.1. Identity test(Note 2)

The active ingredients shall comply with identity tests and, where an identity remains in doubt, it shall comply with at least one additional test.

1.6.1.2. [ISO common names] content

1.2.2.1. Total content (No. 2)

The [ISO common names] content shall be declared (g/kg or g/l at $20 \pm 2^\circ \text{C}$, Note 3) and, when determined, the average contents measured shall not differ from those declared by more than the appropriate tolerances, given in the table of tolerances, section 4.3.2.

1.2.2.2. Release rate (if relevant, see introduction)

1.7. Relevant impurities

1.7.1.1. By-products of manufacture or storage (Note 4)

Maximum: ... % of the [ISO common name] content found under 1.2.2.1.

1.8. Physical properties

1.4.1. Acidity or alkalinity (MT31) or pH range (MT 75.3) (Note 5)

Maximum acidity: ... g/kg calculated as H_2SO_4
Maximum alkalinity: ... g/kg calculated as NaOH
pH range: ...to...

1.4.2. Pourability (MT 148.1)

Maximum "residue":%

1.4.3. Dispersion stability (CIPAC MT 180)

The formulation, when diluted at 30 ± 2 °C (Notes 7 and 8) with CIPAC Standard Waters A and D, shall continue to comply with the following:

1.4.5. Wet sieve test (MT 185) (Note 8)

Maximum: g/kg of the formulation shall be retained on a ... μ m test sieve, at the dilutions specified.

1.4.6. Persistent foam (MT 47.2) (Note 9)

Maximum ml after 1 min

1.6. Storage stability

1.6.1.1. Stability at elevated temperature (MT 46.3)

After storage at 54 ± 2 °C for 14 days (Note 10), the determined average active ingredient content must not be lower than ... % relative to the determined average content found before storage (Note 11) and the formulation shall continue to comply with the clauses for: free active ingredient content (1.2.2.2.), (an increase in the free [ISO common name] content shall be allowed to an extent of ... % of that found under 1.2.2.1., by-products of manufacture or storage (1.3.1.), acidity/alkalinity/pH range (1.4.2), pourability (1.4.3), spontaneity of dispersion (1.4.4.), suspensibility (1.4.5.), and wet sieve test (1.4.6.), as required.

Note 1 All physical and chemical tests listed in this specification are to be performed with a laboratory sample taken after the recommended homogenization procedure.

Before sampling to verify formulation quality, inspect the commercial container carefully. On standing mixed formulation of CS and SC usually develop a concentration gradient from the top to the bottom of the container. This may result in the appearance of a clear liquid on the top and/or sediment on the bottom. Therefore before sampling, the formulation must be homogenized according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example by inverting the closed container several times).

After this procedure the container shall not contain a sticky layer of non-dispersed matter at the bottom (if the ZC has flocculated it may not be possible to re-disperse this sticky layer). A suitable and simple method of checking for a non-dispersed sticky layer "cake" is by probing with a glass rod or similar device adapted to the size

and shape of the container.

- Note 2 Method(s) of analysis must be CIPAC, AOAC or equivalent. If the methods have not yet been published then full details, with appropriate method validation data, must be submitted to FAO/WHO by the proposal.
- Note 3 Unless homogenization is carried out carefully, it is possible for the sample to become aerated. This can lead to errors in the determination of the mass per ml, and in calculation of the active ingredient content (in g/l), if methods other than MT 3.3 are used. If the buyer requires both g/kg and g/l at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.
- Note 4 This clause should include only relevant impurities. Method(s) of analysis must be peer validated.
- Note 5 The method to be used shall be stated. If several methods are available, a referee method shall be selected.
- Note 6 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent-extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of the chemical assay method. In case of dispute, the chemical method shall be the "Referee method".
- Note 7 Unless another temperature is specified.
- Note 8 This test detects coarse particles(e.g. oversize capsules, crystals) or agglomerates (of capsules or from crust formation) or extraneous materials which could cause blockage of spray nozzles or filters in the spray tank.
- Note 9 The mass of sample to be used in the test should be specified at the application rate of use recommended by the supplier.
- Note 10 Unless other temperatures and/or times are specified. Refer to section 4.6.2 of this Manual for alternative storage conditions.
- Note 11 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

附件九、Mixed formulation of CS and EW (ZW)

Introduction

A mixed formulation of CS and EW is a stable dispersion of microcapsules and active ingredient(s) in an emulsion form, normally intended for dilution with water before use. In the case of microcapsules, the active ingredient is present inside discrete, inert, polymeric microcapsules. The formulation is intended for dilution into water prior to spray application. Mixtures of active ingredients one of which is encapsulated are used to provide a broader spectrum of pest control. Formulating the active ingredients together eliminates the need for tank mixing (which can lead to incompatibilities). Like other aqueous liquid formulation, ZW formulations are easy to handle and measure, dust free, nonflammable and offer good miscibility with water.

Different reasons for the encapsulation of active ingredient may exist, for instance

- To increase the residual biological activity.
- To reduce the acute toxicity.
- To obtain a physical or chemically stable water-based formulation.

This purpose determines whether the “release rate” is a relevant property of a specific product.

Mixed formulations of CS and EW are not stable indefinitely and therefore it is necessary to ensure that, after transportation and storage, the formulation remains suitable for use.

Quantification of the following parameters, particularly after high and low temperature stability tests, serves this purpose.

- Active ingredient, determined and expressed as “total” and “release rate” (“total” is required in all cases and “release rate” is dependent upon the intended application).
- Pourability test.
- Dispersion stability, wet sieve and persistent foam tests (to ensure the sprayability of the diluted ZW formulation).
- Rate of release. In assessing performance of a capsule, the rate of release of the active ingredient after application may be an important property (see above).

Information about other properties may also be given, e.g. mass per milliliter and flash point (if relevant), but these parameters do not normally constitute essential parts of the specification. However, some other physical properties, especially particle size distribution and viscosity, are excluded from the

specification for the following reasons.

- Particle size distribution. (CIPAC MT 185).
- Viscosity. Although viscosity is a very important property, it cannot be described simply, as most ZW formulations show non-Newtonian flow characteristics. In the specification, the pourability and water dispersibility adequately described the flow (rheological) properties.

[ISO Common name] Mixed formulation of CS and EW

[CIPAC number]/ZW

1.9. Description

The material shall consist of an emulsion of fine droplets of technical [ISO common name] complying with the requirements of the FAO/WHO specification..., in the form of ... (section 4.2), combined with a suspension of a microcapsule of technical [ISO common name] complying with the requirements of FAO/WHO specification..., in the form of ... (section 4.2), in an aqueous phase together with suitable formulants. After gentle agitation the material shall appear homogeneous (Note 1) and be suitable for dilution in water.

1.10. Active ingredients

1.10.1. Identity test(Note 2)

The active ingredients shall comply with identity tests and, where an identity remains in doubt, it shall comply with at least one additional test.

1.10.2. [ISO common names] content

1.10.2.1. Total content (No. 2)

The [ISO common names] content shall be declared (g/kg or g/l at 20 ± 2 °C, Note 3) and, when determined, the average contents measured shall not differ from those declared by more than the appropriate tolerances, given in the table of tolerances, section 4.3.2.

1.10.2.2. Release rate (if relevant, see introduction)

1.10.3. Relevant impurities

1.10.4. By-products of manufacture or storage (Note 4)

Maximum: ... % of the [ISO common name] content found under 1.2.2.1.

1.10.5. Physical properties

1.4.1. Acidity or alkalinity (MT31) or pH range (MT 75.3) (Note 5)

Maximum acidity: ...g/kg calculated as H₂SO₄
Maximum alkalinity: ...g/kg calculated as NaOH
pH range: ...to...

1.4.2. Pourability (MT 148.1)

Maximum "residue": %

1.4.3. Dispersion stability (MT 180) (Note 6)

The formulation, when diluted at 30 ± 2 °C (Notes 7 and 8) with CIPAC Standard Waters A and D, shall continue to comply with the following:

Time after allowing the dispersion to stand	Limits of stability
0 h	initial dispersion complete
0.5 h	"cream", maximum: ... ml "free oil", maximum: ... ml sediment, maximum: ... ml
24 h	Re-dispersion complete
24.5 h	"cream", maximum: ... ml "free oil", maximum: ... ml sediment, maximum: ... ml

1.4.4. Wet sieve test (MT 185) (Note 9)

Maximum: g/kg of the formulation shall be retained on a ... micro m test sieve, at the dilutions specified.

1.4.5. Persistent foam (MT 47.2)(Note 10)

Maximum ml after 1 min

1.7. Storage stability

1.7.1.1. Stability at elevated temperature (MT 46.3)

After storage at 54 ± 2 °C for 14 days (Note 11), the determined average active ingredient content must not be lower than ... % relative to the determined average content found before storage (Note 12) and the formulation shall continue to comply with the clauses for: free active ingredient content (1.2.2.2.), (an increase in the free [ISO common name] content shall be allowed to an extent of ... % of that found under 1.2.2.1., by-products of manufacture or storage (1.3.1.), acidity/alkalinity/pH range (1.4.1), pourability (1.4.2), dispersion stability (1.4.3.), and wet sieve test (1.4.4.), as required.

Note 1 All physical and chemical tests listed in this specification are to be performed with a laboratory sample taken after the recommended homogenization procedure.

Before sampling to verify formulation quality, inspect the commercial container carefully. On standing mixed formulation of CS and SC usually develop a concentration gradient from the top to the bottom of the container. This may result in the appearance of a clear liquid on the top and/or sediment on the bottom. Therefore before sampling, the formulation must be homogenized according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example by inverting the closed container several times).

After this procedure the container shall not contain a sticky layer of non-dispersed matter at the bottom (if the ZC has flocculated it may not be possible to re-disperse this sticky layer). A suitable and simple method of checking for a non-dispersed sticky layer "cake" is by probing with a glass rod or similar device adapted to the size and shape of the container.

Note 2 Method(s) of analysis must be CIPAC, AOAC or equivalent. If the methods have not yet been published then full details, with appropriate method validation data, must be submitted to FAO/WHO by the proposer.

Note 3 Unless homogenization is carried out carefully, it is possible for the sample to become aerated. This can lead to errors in the determination of the mass per millilitre, and in calculation of the active ingredient content (in g/l), if methods other than MT 3.3 are used. If the buyer requires both g/kg and g/l at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.

Note 4 This clause should include only relevant impurities. Method(s) of analysis must be peer validated.

Note 5 The method to be used shall be stated. If several methods are available, a referee method shall be selected.

Note 6 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent-extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of the chemical assay method. In case of dispute, the chemical method shall be the "Referee method".

Note 7 Unless another temperature is specified.

- Note 8 The formulation should be tested at 2% dilution or, alternatively, at the highest and lowest rates of use recommended by the supplier.
- Note 9 This test detects coarse particles(e.g. oversize capsules, crystals) or agglomerates (of capsules or from crust formation) or extraneous materials which could cause blockage of spray nozzles or filters in the spray tank.
- Note 10 The mass of sample to be used in the test should be specified at the application rate of use recommended by the supplier.
- Note 11 Unless other temperatures and/or times are specified. Refer to section 4.6.2 of this Manual for alternative storage conditions.
- Note 12 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

附件十、PROGRAMME FOR DEVELOPMENT OF FAO
AND WHO SPECIFICATIONS FOR PESTICIDES

Year	Products	Proposer(s)
2004	<p>FAO:</p> <p>Azadirachtin Butralin</p> <p><i>Chlorothalonil TC,SC,WG,WP</i></p> <p><i>Cymoxanil TC,WP,WG</i></p> <p><i>Guazatine TC, LS</i> Picloram</p> <p><i>Prochloraz TC, EC, SC</i> Propanil</p> <p>WHO:</p> <p><i>Bacillus thuringiensis israelensis</i> TK, WG</p> <p>Deltamethrin long-lasting insecticidal net Icaridin (KBR 3023)</p> <p>FAO & WHO:</p> <p>Bifenthrin TC, WP Deltamethrin TC, DP, SC, UL, WG, WP, WT Diflubenzuron TC, WP Fenthion TC, EC, WP Pirimiphos-methyl TC, EC, WP</p>	<p>Fortune Biotech Nufarm</p> <p><i>Syngenta</i></p> <p><i>Dupont</i></p> <p><i>Makhteshim</i> DAS</p> <p><i>Makhteshim</i> Propanil Task Force (DAS; Riceco)</p> <p>Valent BioSciences</p> <p>Vestergaard Bayer</p> <p>FMC Bayer</p> <p>Crompton Corp. Bayer Syngenta</p>
2005 tentative	<p>FAO:</p> <p><i>Azimsulfuron</i></p> <p><i>Nicosulfuron</i></p>	<p><i>Dupont</i></p> <p><i>Dupont</i></p>

WHO:

Permethrin long-lasting insecticidal net Sumitomo

FAO & WHO:

Permethrin TC *Sumitomo*

Pyriproxyfen TC,GR *Sumitomo*

附件十一、

FORM OF CIPAC PUBLICATIONS - HANDBOOKS, ELECTRONIC OR BOTH

Introduction

The various possibilities for publishing CIPAC methods were considered under item 6.2 of the agenda of the joint Thirtieth Management Committee meeting and the 35th Council meeting in Granada on 3 June 2000 (CIPAC/CM+M/181).

The Chairman invited a number of members to report on various aspects of such publications. This report examines the potential use of the Internet for CIPAC publications.

Advantages and disadvantages of publishing on the internet

Shaw and Elliot (1998) reported some of the advantages and disadvantages for Internet publishing.

1. Speed of publication and access
2. Rapid retrieval of related papers
3. Accessibility from a wide variety of locations with minimum time constraints
4. Non-availability of a universal browser and the many different software packages in use that are not all mutually compatible
5. Copyright issues and intellectual property rights of authors are not easily resolved

Costs of electronic publishing

The American Geophysical Union reported on the experience of learned society publishers in providing online editions of their publications; the additional cost of online access was in the range of 20-30% (Shaw and Elliot, 1998). This includes the cost of providing access to and maintaining a digital archive. The term 'archiving' denotes not only the storage of materials but the systematic organisation and provision of access to these materials. Libraries have traditionally maintained archives of published books, but with electronic publication the costs of archiving will tend to fall on the publisher.

A problem for electronic publications is the wide variety of formats in use and the resources required to update the archival material when new formats are introduced. A former editor for the American Institute of Physics concluded that the addition of an electronic version to an established print-on-paper journal increases costs (Shaw and Elliot, 1998). An alternative electronic journal could be produced for about the same cost as a printed version.

CIPAC methods - what are the needs of users?

At CIPAC's annual meetings, results of collaborative studies are evaluated, and the status of the methods is decided.

Once a method has been accepted it may be classified as a CIPAC Method, a Provisional CIPAC Method, or a Tentative CIPAC Method.

CIPAC Methods are methods that have been investigated in accordance with internationally accepted rules and have given results falling within the accepted ranges for repeatability and reproducibility.

Provisional CIPAC Methods are either candidate CIPAC Methods, which may become full after a certain period, or methods with minor imperfections. Tentative

CIPAC Methods have usually not been tested in a full-scale study but are still accepted because there is a certain need for them.

The needs of a user for a CIPAC analytical or test method are somewhat different from the needs for information in a paper published in a scientific journal.

The status of the methods will influence the needs of users. A full CIPAC method is valuable to laboratories in official accreditation or quality assurance systems. The value lies in the fact that the method has been properly tested, is published (CIPAC Handbook) and is unlikely to change at short notice. The published handbook, as a perpetual public record of the method from the date of publication to the date it is replaced by another published method, is valuable to quality systems.

If CIPAC methods were to be published in electronic form only, the costs of archiving would fall on CIPAC. From a user perspective an archive maintained by a single publisher is not as secure as published handbooks held by a number of libraries.

Provisional methods open for comment have some possibility for change in the near future, even if some of the changes are rather minor or editorial. In this case the electronic copy and immediate access to suggested changes are important.

However, in practice it is not just provisional methods that are subsequently modified.

In fact provisional methods seem to be modified fairly rarely before they become "full". The last few years have seen several modifications of "full" methods, and perhaps more would be forthcoming if they could be introduced without (hidden) cost. The modifications are adopted as provisional but how does the user of the full method in the handbook know that a modification has been introduced? Having it temporarily on the internet be helpful if the user happens to look at that time but, otherwise, the "grapevine" may be the only source of such information.

CIPAC should ensure that its procedures for issuing and publishing revisions are readily compatible with quality systems.

Needs of CIPAC

CIPAC needs to sell its publications to remain viable. It also must find ways to best serve its clients.

Needs of FAO and WHO

The initial discussion on internet publication was linked to the desire for FAO and WHO to publish (or have links to) CIPAC methods on the web. Both organizations have indicated a willingness to provide some kind of financial support in return for this. We accept the management committee's argument that they do not wish to become too closely linked with FAO and WHO, because of the risks this entails. Is it possible to continue printing handbooks and publish on the internet at the same time, if we accepted some financial support from FAO and WHO. There should be little need to worry about being left with piles of unsold books: the costs of printing 1000 books seems to be covered when we have sold 2-300 of them, so why not sell them at a quarter of the price so that even internet users could afford the hard copy. Internet users could pay for internet access to the methods either as one-offs or by subscription.

Both WHO and FAO are willing to negotiate for internet access to CIPAC methods. One option is for internet access to be exchanged for sufficient cash to enable hard copies to be produced at roughly the same price as now (that is, subsidised as required by the FAO/WHO support) for those who want/need them. The option needs to be considered in terms of its financial feasibility and whether CIPAC would become

dependent on FAO and WHO.

Practicalities - methods, procedures and costs

Information on the possibility of electronic publishing of CIPAC methods was provided by a staff member of Wageningen University and Research Publishing (WUR).

The two possibilities are:

* Preparing the method as a Web page. A problem is that re-edition has to be done because a number of scientific symbols are not recognised and had to be programmed. This is expensive due to the working time;

* The easiest way it to convert the method in a PDF format. The needed time for the WUR employee is very limited. For the printing of such a PDF format an Acrobat Reader program (free of charge) is required. The document could be printed preferable on A4.

The method has to be submitted to the WUR by the CIPAC secretary after the final copy has been prepared.

Then for the first method some development work has to be done. For later methods only a very limited time is needed for each method.

The title of the methods will be visible on the CIPAC Web Pages. After selecting the desired method(s), the user is redirected to a secure server and is presented with different payment options such as credit cards. After a successful payment transaction the method(s) will be visible and can be downloaded or printed.

A rough estimation has been made, but an offer could be made.

Lay out first method 1160 guilders or GBP332

Server costs p.m.

Over head (management etc.) Yearly costs 250 guilders or GBP72

Lay out each method 30 guilders or GBP9

Internet payment for each (handling) 2 guilders or GBP0.6

According to the WUR there are two possibilities for submitting methods.

The preferable one for ease of use is sponsoring. Then the method is directly available for the chemist if he has access to the Internet.

Due to the independent character of CIPAC, this may not be an acceptable solution.

The other one is the pay per view. The cost are low only fl 2.- for each action.

This form of payment is safe. WUR has contacted a specialised company for this financial transaction and has sufficient confidence in this method of payment.

Recommendations

1. Make provisional methods available on the Internet. The electronic system provides immediacy and accessibility. Archiving and the associated costs are not necessary for this application.

2. Continue to publish the final methods in Handbooks protected by copyright. When a method moves from provisional to full method it should be removed from the Internet.

3. Examine how revisions and modifications of full methods may be issued in a systematic way that will better satisfy quality systems.

Reference

Shaw, D.F. and Elliot, R.J. 1998. ICSU Press workshop on the economics, real costs and benefits of electronic publishing in science - a technical study. Available from the

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