



FIRST JOINT CIPAC/FAO/WHO OPEN MEETING (48th CIPAC Meeting and 3rd JMPS Meeting)

Czech Republic, Brno, 8 June 2004

1. Opening and welcome

Dr Müller, CIPAC Chairman, opened the meeting and welcomed participants to the first Joint CIPAC/FAO/WHO Meeting, incorporating the 48th CIPAC Meeting and 3rd Joint Meeting on Pesticide Specifications (JMPS).

Mr. Zdeněk Trnka, Head of the Division of Plant Commodities of the Ministry of Agriculture of the Czech Republic welcomed CIPAC and JMPS participants to Brno.

Dr Vaagt, FAO Joint Secretary of JMPS, in his introductory remarks thanked the Ministry of Agriculture of the Czech Republic and especially Mr. Jindrich Foltýn and his team as the main organizer and initiator of the JMPS and CIPAC meetings here in Brno. He drew attention to changes and progress in the previous 12 months.

- EC directive 91/414, which is now the legal guiding document for pesticide authorisation and management in 25 European countries, includes in its Annex 6 the requirement for compliance with FAO pesticide specifications.
- The Working Group on Plant Protection Products of the EU had adopted the FAO/WHO procedure for the determination of equivalence, to be incorporated into the 91/414 amendments.
- The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade became official on 24 February 2004. The Stockholm Convention on Persistent Organic Pollutants (POPs) similarly became official on 17 May 2004. FAO Pesticide specifications have already proved to be a supportive element for the implementation of these Conventions. Examples include the FAO specifications for maleic hydrazide as an alternative control to the PIC Procedure and the reduction of HCB impurity levels in chlorothalonil specifications (HCB, hexachlorobenzene, is a POPs chemical). Dr Vaagt noted that the Czech Republic had already ratified these two conventions.
- The Revised Version of the International Code of Conduct on the Distribution and Use of Pesticides includes various references to the specifications and supports the Rotterdam and Stockholm Conventions.

Dr Zaim, WHO Joint Secretary of JMPS, in his introductory remarks thanked the Division of Plant Protection of the Ministry of Agriculture of the Czech Republic, and especially Mr Jindrich Foltýn, for their excellent support in facilitating the meeting, and for their warm hospitality.

Dr Zaim expressed his sincere thanks to the JMPS Panel Members for their invaluable technical support to the work of the two organizations for development of international standards for quality control of pesticides. He also extended his thanks

to CIPAC for their support and assistance in development of test methods in support of the pesticide specifications.

Dr Zaim noted that the promotion of availability of quality pesticide products is a priority activity for WHO and that they are very pleased to note the interest shown by the Member States as well as industry in the FAO/WHO harmonized procedures for development of pesticide specifications. He emphasized the need for continued and close collaboration with industry and Member Countries on promoting effective management of public health pesticides, including their quality control.

2. Arrangements for chairmanship and appointment of rapporteurs

Dr Müller, CIPAC Chairman, advised the meeting of the arrangements for this joint open meeting.

Chairmanship would rotate year by year beginning with CIPAC in 2004. Rapporteurs were appointed for the meeting: Mr Bura for CIPAC and Mr Hamilton for JMPS.

3. Adoption of the agenda

The agenda was accepted with the following modifications and amendments:

Add 9.3. Guidelines for TC/TK.

Treat items 11 and 12 together, i.e. the item becomes: *National and technical reports regarding CIPAC activities.*

Add:

- 14.1. Publication of test methods for impurities.
- 14.2. Method extension concept for impurities.
- 14.3. Clarification of procedure and timelines for adoption and publication of specifications following a JMPS review.
- 14.4. Report on closed Joint Meeting on Pesticide Specifications (JMPS).

4. Summary record of previous meetings

4.1 *47th CIPAC Meeting Technical Commission (12/13 June 2003, Bucharest, Romania)*

No comments. The Minutes of the 47th Annual Meeting as circulated by Mr L. Bura were accepted as correct without amendments

4.2 *Second JMPS Open Meeting (10 June 2003, Bucharest, Romania)*

No comments other than editorial. The Summary Records of the 2nd JMPS were summarized by Mr J. Pim and were accepted as correct.

5. Summary of actions taken after the 47th CIPAC and 2nd JMPS meetings

5.1 CIPAC

Dr. Müller summarized relevant CIPAC activities:

Eight information sheets had been sent out and the results will be discussed during this year's meeting. Several pilot studies are under way. In the meantime, the latest CIPAC Handbook, K, was published. It contains 22 new or extended methods for determination of pesticides and 6 new or extended MTs.

Last year a considerable improvement of the CIPAC web site was realised facilitating access by potential users of the methods and ordering of Handbooks. Furthermore, CIPAC now accepts credit card payment, which significantly enhances the processing of orders.

The CIPAC handbooks J and K were prepared as a CD-ROM, with searching facilities, and are offered as a package with an appropriate cost to cover the publication and handling charges. The preparation of the CD-ROM was achieved without delaying the publication of Handbook K.

For the first time, CIPAC offered to provide adopted but not yet published methods under the so called prepublication scheme (see www.cipac.org/prepublished methods). They are

available in a non-edited form. The method publication in a handbook no longer delays the publication of pesticide specifications.

5.2 FAO

Dr Vaagt summarized relevant FAO activities.

- The Manual on Development and Use of FAO and WHO Specifications for Pesticides has been translated into Spanish. French and Chinese versions will be available soon.
- JMPS has been established as a statutory body of FAO.
- Demand has risen to assist regulatory authorities and others with the procedure for equivalence determinations. Information has been disseminated at workshops, seminars and presentations:
 - July 2003: Workshop in Belize.
 - August 2003: Seminar in Kuala Lumpur, Malaysia.
 - October 2003: Seminar for representatives from CropLife Latin America, in Miami, USA.
 - November 2003: Presentation of the “new” procedure for the development of pesticide specifications during the International Conference of Pesticide Registration and Management, Beijing, People’s Republic of China.
 - December 2003: Presentation in Tokyo.
 - May 2004: Open presentation in Quito, Ecuador.

5.3 WHO

In order to assist the Member States in effective and sound management of public health pesticides, including their quality control, Dr Zaim summarized major activities carried out by WHO since the previous JMPS meeting.

- Held WHO Regional Workshops on the management of public health pesticides in Amman (December 2003) and Bangkok (April 2004) to develop regional strategies and national action plans.
- Initiated the development of "Quality control of pesticide products - Guidelines for national laboratories".
- Established a regional centre for quality control of pesticide in Africa, situated in Pretoria.

6. Technical liaison with other organizations

6.1 AOAC-International

Dr A. Hanks summarized the activities of the Committee on Pesticides and Disinfectant Formulations. It was pointed out that the fee required for validation studies has been a major concern and deterrent for those seeking collaborative validation. Methods for determining several herbicide active substances are continuing to be developed and improved, some with LC-MS technique. The study on acetanilide derived herbicides, glyphosate and pendimethalin formulations is continued and on hydrazine and maleic hydrazide will start.

6.2 CropLife International and European Crop Protection Association (ECPA)

Dr. T. Woods mentioned that CropLife International should not be abbreviated to CLI because CLI is already used for CropLife India.

He introduced and welcomed the representative of ECPA Secretariat, Ms D. Obierzynska and also recognized the the work of DAPF in method development and that of the specifications group.

6.3 American Society for Testing and Materials (ASTM)

Dr A. Viets made a short presentation on how ASTM is cooperating with CIPAC with respect to physical test methods.

6.4 European Crop Care Association (ECCA)

D. van Hoogstraten representing many generic manufacturers from EU, presented the activities ECCA proposed independently last year to the EU.

6.5 United Nations Industrial Development Organization (UNIDO)

Mr K. Ziller presented a report prepared by Mr. B.Sugavanam:

UNIDO in association with Nanshen Pesticide Formulation Centre and supported by the Government of China organized a workshop on "Cleaner Production in Agrochemical Industry -Seed Dressing Technology". The workshop dealt with the various developments of formulation technology the history and the present status of seed treatment technology, and technology transfer to less developed regions of Southwest and Northwest China. It also dealt with the seed pelleting and seed coating technology which would be very valuable for China. Papers also dealt with import/export of pesticides in China and the registration aspects in China for pesticides. The workshop was attended by more than 20 countries from Asia and Europe. The message from the workshop was to promote safe and effective seed dressing formulations in developing countries, proper application methods with suitable and well maintained machines and good quality control. It also stressed the importance of neem trees for rural and forestry development with potential in pest control and other areas.

6.6 International Union of Pure and Applied Chemistry (IUPAC)

Mr D Hamilton reported that IUPAC information is available at www.iupac.org. Recently published papers and progress reports on current projects of the *IUPAC ADVISORY COMMITTEE ON CROP PROTECTION CHEMISTRY* are available from the internet. An IUPAC workshop on crop protection chemistry in Latin America is scheduled for 14-17 Feb 2005 in Costa Rica and the next IUPAC International Congress on Pesticide Chemistry will be held in Kobe, Japan from 6-11 Aug 2006.

6.7 European Commission (EC)

Nobody from the EC attended the meeting

6.8 European Food Safety Authority (EFSA)

Mr R. Hänel gave a description of the history of the establishment of EFSA and a short description of the organizational structure. The EFSA was established because of a succession of food scares in Europe (e.g. BSE and dioxins), the creation of national food safety agencies and dissension within the EU over risk assessments. EFSA will provide scientific advice in the form of risk assessments and risk communication, but it is not responsible for risk management decisions. EFSA's web page: www.efsa.eu.int

6.9 Organization for Economic Co-operation and Development (OECD)

Dr. G. Vaagt informed the meeting that the OECD is interested in maintaining an information exchange with CIPAC and JMPS.

6.10 International Programme on Chemical Safety (IPCS)

Dr. M. Zaim reported that Dr. A. Aitio will represent IPCS

6.11 International Organization for Standardization (ISO)

No representative

7. Status, review and publication of CIPAC methods

Dr. M. Müller informed the meeting about the new guideline proposal on "method migration", which will be discussed during the CIPAC technical meeting. The aim is to withdraw the old CIPAC methods, which are not in line with the requirements of the guidelines on chromatographic methods or which are otherwise obsolete, without leaving a data gap. CIPAC will try to speed up the process.

8. Review and publication of FAO and WHO specifications for pesticides

8.1 Status of FAO Specifications

Dr Vaagt provided a progress report on previously evaluated pesticides.

Manufacturer	Product	FAO spec	Status
Agro Chemie	Difluidazin (Flufenzine) TC, TK, SC	new	Specification and evaluation report published
Bayer CropScience	Cyfluthrin TC, WP, EW	new	In progress
	Imidacloprid TC, DT, FS, GR, PR, SC, SL, UL, WG, WS	new	In progress
	Iprodione TC, WP, WG, SC	new	In progress
Chlormequat Task Force (Nufarm, BASF, Ciba Specialty Chemicals, UCB SA)	Chlormequat chloride TK, SL	new	In progress
Drexel, Crompton, Fair Products	Maleic Hydrazide TC, SL, SG, SP, PD	new	Evaluation report published- publication of specifications subject to validation of analytical methods
DuPont	Hexazinone TC, WG, SP, GR	new	Evaluation report published – publication of specifications subject to validation of methods for the relevant impurity
	Chlorsulfuron TC, WP, WG	new	Ready for publication
Nufarm	Butralin	new	Was rescheduled for 2004, but withdrawn
Syngenta	Paraquat TC, TK, SG, SL	new	Specification (TK) and evaluation report published. Publication of formulation specifications is subject to validation of methods for impurities.
Trifolio M, EID Parry Fortune Biotech	Azadirachtin EC, TK	new	In progress, on 2004 agenda.

Dr Woods (CropLife International) noted that specifications were being held up by method requirements for relevant impurities and requested notification as early as possible about decisions on relevant impurities. Ideally, validation data should be provided at the time of data submission but companies could not always anticipate JMPS decisions on relevant impurities.

8.2 Status of WHO Specifications

Dr Zaim (WHO) reported that data submissions were received for 14 compounds in 2002-3, 7 of which were for joint FAO/WHO specifications and 7 specifically as WHO specifications. WHO aims to publish evaluation reports in the same year as the JMPS evaluation is completed.

The progress to publication is summarized in the tables below.

JMPS year	Compound	Proposer	WHO publication of evaluation report	specification
2002	d-allethrin	Sumitomo	yes	yes
2002	d-phenothrin	Sumitomo	yes	
2002	prallethrin	Sumitomo	yes	
2002	transfluthrin	Bayer Environmental Science		
2003	esbiothrin	Sumitomo		
2003	bioallethrin	Sumitomo		
2003	trans-cyphenothrin	Sumitomo		

8.3 Status of Joint FAO/WHO Specifications

JMPS year	Compound	Proposer	WHO publication of evaluation report	specification
2002	nicosamide	Bayer	yes	yes

JMPS year	Compound	Proposer	WHO publication of evaluation report	specification
2002	chlorpyrifos	Dow AgroSciences, Makhteshim	yes	
2003	lambda-cyhalothrin	Syngenta	yes	yes
2003	cyfluthrin	Bayer CropScience		
2003	propoxur	Bayer CropScience		
2003	novaluron	Makhteshim	yes	
2003	malathion	Cheminova		

9. Proposed new/amended specification guidelines

9.1 Guidelines for mixed formulations ZC, ZE and ZW

New codes and specifications for mixed formulations of CS and SC (ZC), CS and SE (ZE) and of CS and EW (ZW) were introduced at the 2003 meeting.

Following the suggestion of Mr Hill a clause for stability during storage at 0°C or during freeze-thaw cycles was introduced as it is necessary for CS type formulations. After the introduction of this additional clause the new guidelines were accepted by the meeting and are attached in its final version as annex 1. FAO and WHO will publish these new guidelines on their website.

9.2 Guidelines for long lasting insecticidal nets.

The draft guidelines specifications for long-lasting insecticidal nets (LN) was presented by industry. Mr Hill requested the inclusion of "free from damage (such as splitting or tearing)" in the description. After the introduction of this additional clause the new guidelines were accepted by the meeting and are attached in its final version as annex 2.

9.3. Guidelines for TK.

Dr Grohs (Bayer CropScience) suggested that the concept and definition of TK could be extended to include salts or complexes of the active ingredient as well as just the active ingredient with residual moisture or solvents from the production process. The definition of TK could be amended by adding the words "or salt or complex of the active ingredient". Proposed amended definition (underlined words are added).

TK Technical concentrate. A material resulting from a manufacturing process comprising the active ingredient, or salt or complex of the active ingredient, together with associated impurities. This may contain small amounts of necessary additives and appropriate diluents. A note would be added at the end of paragraph 5.2.2.2 of TK specifications stating ". (Note 2): In the case of salts or complexes only a minimum content (not less than.... g/kg) needs to be declared. "

The Meeting was concerned about the consequences, which were not all immediately clear, of extending the meaning of TK and, at least at this time, declined to make a change. . Mr Hill proposed alternative definitions of TC and TK and industry representatives agreed to consider them.

10. Proposed new/extended CIPAC analytical and physical test methods and CIPAC workplan for 2004/5

Dr. M. Müller informed the meeting that there are several MT and analytical methods under revision and development.

11 and 12. National and technical reports regarding CIPAC activities

The following reports were presented:

Argentina – H. di Loretto in the name of SENASA

Australia – P. Sethi
 Belgium – M. Galoux
 Brasil – M. Fuentes Piedade
 Czech Republik – J. Foltýn
 Cyprus - written report by A. Kashouli-Kouppari
 Denmark – T. Krongaard
 El Salvador – E. de Aguila
 France – A. Venant
 Germany – G. Menschel
 Greece – A. Hourdaki
 Hungary – L. Bura
 India – G. Mukherjee
 Ireland – J. Garvey
 Italy –R. Dommarco
 Japan - T. Fujita
 Korea – K. Oh
 Netherlands – E. van der Wal
 P.R.China – J. Ying
 Romania – T. Iuraşcu
 Slovenia – A. Gregorčič
 Slovakia – written report by J. Schlosserova
 Spain – L. Manso
 South Africa – S. Marais
 Switzerland – M. Müller
 China, Province of Taiwan – S.-S. Wong
 Thailand – N.Tayapuch
 Ukraine – V. Chmil
 United Kingdom – R. Fussell
 USA – V. Goodwin

The following national laboratories reported on their participation in CIPAC collaborative studies and provided a summary of quality control analysis carried out on pesticide samples during 2003-2004:

Region	Reporting laboratory	No. of samples tested	Non-compliance	
			No.	%
Africa	South Africa	12	3	25
Americas	El Salvador	662	83	13
	Indiana, USA	262	21	8
Europe	Czech Republic	29	4	14
	Cyprus	84	6	7
	Denmark	45	7	16
	France	80	16	20
	Germany	13	1	8

	Greece	158	5	3
	Hungary	1585	81	5
	Italy	298	9	3
	Romania	2494	50	2
	Slovakia	197	9	5
	Slovenia	11	2	18
	Spain	518	48	9
	UK	102	10	10
Asia	China, Taiwan	1240	250	20
	China	710	130	18
	Thailand	4589	100	2

	Total	13089	835	6.4
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13. FAO/WHO priority list for the development of specifications (2005-2007)

Dr Vaagt provided the priority list of specifications for evaluation in 2005 and a tentative list for 2006. It was suggested that the permethrin/S-bioallethrin combination is not used in agriculture and may not require an FAO specification.

Compounds to be evaluated by JMPR (Joint Meeting on Pesticide Residues) in 2006 should have been previously evaluated by JMPS. However, national governments have tended to treat residue issues as the priority, so the 2006 requirement will be treated as voluntary.

Products	Proposer(s)
2005	
FAO	
Clofentezine TC, SC	Makhteshim
Chlorothalonil	Caffaro SpA, Vischim Srl, SDS Biotech K.K.
Copper, cupric hydroxide and oxychloride (to include copper calcium oxychloride), Bordeaux mixture, tribasic copper sulphate and cupric oxide.	European Union Copper Task Force
Diquat dibromide, TC, SL	Syngenta
Ethofumesate TK, SC, EC, SE, OD	Bayer
Nicosulfuron TC, WG	Dupont
Pendimethalin TC, TK, EC	Industria Prodotti Chimici
Rimsulfuron TC, WG	Dupont
WHO:	
IR3535	Merck
Permethrin long-lasting insecticidal net	Sumitomo
Temephos	BASF
FAO & WHO:	
Alpha-cypermethrin TC, SC, WP	BASF, Tagros
Bendiocarb TC, WP	Agros
Deltamethrin TC, WP	Agros
Deltamethrin TC, SC, WT, WG, WP, EC	Tagros
Permethrin TC	Sumitomo
Permethrin TC, EC	Tagros
Pyriproxyfen TC, GR	Sumitomo

Products	Proposer(s)
Spinosad TC, GR, SC	DAS
Permethrin/S-bioallethrin TC, EW	Bayer
2006 Tentative	
FAO	
Oxamyl TK, SL, G	Dupont
Propaquizafop	Makhteshim
FAO & WHO:	
Lambda-cyhalothrin TC, CS, WP	Tagros

14. Any other matters

14.1. Publication of test methods for impurities.

Peer validation of methods to determine relevant impurities in technical material and in formulations: a proposal for development of guidelines for and organization of, peer validation studies through CIPAC. Proposal to publish such methods by CIPAC

14.2. Method extension concept for impurities.

JMPS asked CIPAC to develop guidelines for extension of methods for impurities

14.3. Clarification of procedure and timelines for adoption and publication of specifications following a JMPS review.

The Meeting discussed the timing for publication of specifications. It was suggested that a formal process be established to keep the proposer aware of progress and obstacles that have cropped up.

14.4. Report on closed Joint Meeting on Pesticide Specifications (JMPS).

Mr Hill (Chairman of JMPS) summarized the discussions on general items in the 2004 JMPS.

- In updating evaluations and specifications, editorials and minor changes will be introduced as date-controlled corrigenda. New information that may impact on decisions or recommendations will be put on the agenda of a JMPS for consideration. Borderline cases, e.g. receipt of expected method validation data, may be circulated by email for consideration by JMPS Panel members.
- If the specification 'description' clause states the identity and quantity of a stabilizer, it becomes part of the specification and a validated analytical method is needed for stabilizer analysis and identification. If the specification 'description' clause refers to a NOTE about the stabilizer, it is not part of the specification and an analytical method is not required.
- When isomer composition is specified for TC or TK, it will also be specified for formulations. Isomer composition does not need to be specified if the ISO name already defines the isomer composition.
- Products from different manufacturers may be substantially different even though having the same active ingredient and being covered by the same technical or formulation code, i.e. TC, SC, CS, LN, etc. The differences mean that there could be more than one TC, TK, etc specification for the same active ingredient. This situation can occur for traditional synthetic chemicals, but is likely to occur more frequently for botanicals, microbials and products such as LN (long-lasting insecticidal nets). The JMPS is considering how to handle this situation and how to identify different specifications that have the same nominal identifying code. The views of industry were also sought.
- The Manual includes a definition for relevant impurities and a process for the determination of equivalence. The JMPS, in the light of experience, is developing more detailed guidelines on deciding on whether or not an impurity is relevant. A delay in the process may occur if JMPS decides that an impurity is relevant, but the proposer had not anticipated the decision and had not validated an analytical method suitable for the

formulations as well as the technical material. The FAO and WHO Secretaries should keep the proposer informed of the situation to minimize delays in publishing the specifications.

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15. Date and Venue of next meeting

The Netherlands is the likely venue for the 2005 JMPS-CIPAC meetings.