THIRD JOINT CIPAC/FAO/WHO OPEN MEETING
(50th CIPAC Meeting and 5th JMPS Meeting)

WHO/HQ, Geneva, 12 June 2006

Summary record of the meeting

Agenda

1. Opening and welcome

Dr Morteza Zaim, WHO Joint Secretary of JMPS, welcomed participants to the Third Joint CIPAC/FAO/WHO Open Meeting and noted WHO's pleasure in hosting the event for the first time.

Dr Markus Müller, Chairman of CIPAC, also welcomed participants and expressed satisfaction that the format developed for the meeting has evolved into a form that signals the mutual understanding between WHO, FAO and CIPAC. He explained that previously the open meeting was held in three parts, separately for CIPAC, FAO and WHO. The joint meeting was a good opportunity to strengthen the liaison between the three organizations. Dr Müller thanked WHO, Dr Lorenzo Savioli and Dr Morteza Zaim for hosting the event and wished a successful meeting.

Dr Gero Vaagt, FAO Joint Secretary of JMPS, welcomed participants to the open meeting held at WHO premises. He explained that the FAO and WHO are sister organizations with a long history of working together and sharing the coordination of this well recognized body for standard setting. This was the second CIPAC meeting held at WHO headquarters; the first was in 1988. Dr Vaagt extended thanks to Dr

Zaim for hosting the event and to all those involved in its preparation, especially Ms Avideh Denereaz and Dr Lorenzo Savioli. When the joint meeting was designed by the two organizations, It was considered that meetings be held every fifth year either at the FAO in Rome or at WHO/HQ in Geneva. Dr Markus Müller was thanked for his thoughtful input to the joint meeting and for presenting his beautiful country during the excursion.

The 5thJMPS was a very special meeting, with increased participation as well as increased interest from Latin America, India and other parts of Asia. This commitment signals the importance of pesticide quality and the impact of JMPS, with FAO and WHO specifications, to the issue. The relevance of JMPS is expanding and it is now recognized as a global standard setting body. Equivalence determination, as detailed in the FAO and WHO manual, is being adopted around the world with continuing increased interest in this approach. The quality of pesticides is very important to governments and it should be recognized that JMPS has an important role. However, as for all organizations, funding issues are becoming increasingly important and governments should therefore recognize the important role of JMPS.

Dr Lorenzo Savioli, Director, Department of Control of Neglected Tropical Diseases, welcomed participants to the meeting on behalf of WHO and thanked the Swiss Federal Research Station for Horticulture, Wädenswil, for its cooperation and collaboration in co-organizing the meeting. He noted the wide representation at the meeting from international organizations, pesticide registration authorities, national pesticide quality control laboratories, academia and research institutions and the pesticide industry.

Dr Savioli stressed the importance of the open meeting as a forum for exchange of information that sought the views of all interested parties on quality standards for pesticides and the test methods in support of pesticide specifications.

Many of the neglected tropical diseases, including sleeping sickness, schistosomiasis, river blindness, elephantiasis, dengue and blinding trachoma, rely on vector control and the application of insecticides as an essential cross-cutting activity. Dr Savioli noted the extent of substandard pesticide products on the market and reminded the meeting of the great challenges the national pest and vector control programmes and regulatory authorities face in their management.

Dr Savioli concluded by requesting international organizations to take coordinated action in support of Member States to build capacity for sound management of pesticides, including quality control. He reiterated the achievements and the global leadership of FAO and WHO in promoting international trade of quality-assured pesticide products five years after the signature of the Memorandum of Understanding between the two organizations on establishment of a joint programme on pesticide specifications.

2. Arrangements for chairmanship and appointment of rapporteurs

Dr Morteza Zaim explained that chairing of the open meeting is rotated among the three organizations and that this year facilitation of the meeting is with WHO and himself.

Dr Zaim pointed out that the Third Joint CIPAC/FAO/WHO Open Meeting coincides with the 5th JMPS Open Meeting and the 50th CIPAC meeting. He congratulated Dr Markus Müller and the CIPAC family for their excellent contribution to the science of pesticides.

Dr Zaim stated that the open meeting is a forum for exchange of information and an opportunity for industry, national authorities and all interested parties to provide comments/suggestions to the work of the three organizations on matters related to development of specifications for pesticides and their test methods. He therefore hoped for a good interactive meeting.

Mr Laszlo Bura (for CIPAC), Mr Jeff Pim (for FAO) and Dr Gitasri Mukherjee (for WHO) were nominated as rapporteurs of the open meeting.

3. Adoption of the agenda

The agenda was adopted without modification.

4. Summary record of the previous meeting

The summary record of the previous open meeting, held in Utrecht, the Netherlands, on 7 June 2005, had been published one month after the event. No comments on the report were made, and the report was adopted without amendment.

5. Summary of actions taken after the 49th CIPAC and 4th JMPS meetings

5.1 Collaborative International Pesticides Analytical Council (CIPAC)

Dr Müller provided background information on the status of CIPAC, an international non-profit and nongovernmental organization and a charitable company registered under British law. CIPAC's motto is to promote international agreement on the analysis and physical and chemical properties of pesticide technical materials and formulations. It also promotes inter-laboratory programmes, sponsors symposia in relevant areas, publishes standardized methods of analysis and collaborates with other organizations. CIPAC members are analytical chemists who are elected because of their expertise in the area of pesticides and their contribution to CIPAC goals. Others may be elected as corresponding members or observers depending on their contribution to CIPAC's work.

Dr Müller elaborated in detail on the modality of CIPAC operations and how the organization works. Methods proposed by companies are collaboratively tested by laboratories around the world. The results of the collaborative trials are evaluated at a CIPAC meeting against defined criteria and then considered for adoption and publication in the CIPAC handbooks. The work is organized by the use of the CIPAC information sheet. Once the preliminary work has proved that the method is robust

and suitable for testing in a full scale trial, the information sheet is sent out. The information sheets have a global distribution and provide information on the methods, including a summary of the equipment required and relevant contact details for the trial. All interested laboratories with the necessary equipment can participate. Once the trial is finished, the results are presented at the annual meeting. The adoption of the methods is then decided by a body comprising CIPAC members, correspondents, observers and selected industry representatives. CIPAC has published the decisions of the 49th meeting, CIPAC handbook L and CD ROM E to L. The CIPAC web site is continuously improved, facilitating access to CIPAC methods by online searching. Ongoing work includes the systematic review of CIPAC methods, reopening of the prepublication scheme for ordering individual methods and the independent laboratory validation of methods for relevant impurities.

Dr Müller explained, in response to a query from Dr Tom Woods about the independent laboratory validation of the impurity methods, that this was a request from industry for help in finding independent laboratories to undertake the work. CIPAC is happy to help with this and with the evaluation of the data and ultimate publication of the methods.

5.2 Food and Agriculture Organization of the United Nations (FAO)

Dr Gero Vaagt introduced the ongoing work of the FAO in this area. In August 2005, a regional conference on pesticide specifications was held for Andean countries in Bogota, Colombia. In September 2005, the JMPR meeting took place. In November 2005, a meeting to finalize the supplement of the FAO and WHO manual on pesticide specifications was held in Wädenswil, Switzerland. The Chinese version of the manual was launched at a national workshop in Beijing in November 2005. Another workshop on pesticide specifications and equivalence determination was held in Mexico City in March 2006. There will be an international Crop-Science Conference in July 2006 organized by the Pesticides Manufacturers & Formulators Association of India (PMFAI) at which the role of pesticide specifications will be addressed. The revised version of the manual on development and use of FAO and WHO specifications for pesticides is available in English on the FAO and WHO web sites. Translations of the original manual are available in Chinese and Spanish; an Arabic version will be available shortly.

The FAO are currently reviewing the availability of methods of analysis for impurities included in FAO specifications developed under the old procedure. The importance of coordinating the activities of the JMPS and the JMPR was explained. Specifications for technical material should be developed for a pesticide before it is evaluated by the periodic review programme of the CCPR and for new pesticides, but this should not delay evaluation of pesticides by the JMPR. FAO Specifications and Evaluations for Plant Protection *Products* include sections entitled “Hazard summary” and “Appraisal”, which cover toxicological information and an appraisal of the hazard potential of the compound. It is important to indicate whether these sections are based on existing national/regional or international evaluations. In the future, the JMPR will refer to available FAO/WHO specifications in the JMPR report. A new CropLife International publication on working with the JMPR and CCPR now includes the JMPS. It is also included in the FAO/WHO framework document on the Provision of Scientific Advice on Food Safety and Nutrition (prepared for Codex and FAO/WHO Member countries).

Dr Tom Woods queried the linkage between JMPS and JMPR and whether a product specification would become mandatory before consideration of the compound by the JMPR. This linkage was first considered in 2001 and discussed again at the CCPR in 2003 over possible concerns in delays in establishing Codex MRLs. The proposal for the moment is that a specification is not mandatory and should not delay the process of setting MRLs. The current practice will be observed and will be reviewed in the future for consideration at an appropriate meeting of the CCPR.

5.3 World Health Organization (WHO)

Dr Morteza Zaim outlined WHO activities and reported that it had published the specifications for 10 compounds. The revised version of the Manual on the Development and use of FAO and WHO specifications for pesticides is available on the WHO web site.

He also informed the meeting of publication of the joint CIPAC/FAO/WHO document *Quality control of pesticide products – Guidelines for national laboratories*, which is in line with article 4.3 of the *International code of conduct on the distribution and use of pesticides*, which requests international organizations to assist Member States in establishment of and/or strengthening their capacity for quality control of pesticides. He noted the different activities carried out by the organization under the general umbrella of pesticide management by which the use of FAO and WHO specifications and quality control of pesticide have been promoted. These include development of a resource tool on *Sound management of pesticides and the diagnosis and treatment of pesticide poisoning;* and training of trainers on judicious use of insecticides in malaria vector control for representatives of 10 Member Countries in Manila in 2005.

Dr Zaim noted the finalization of WHOPES testing and evaluation of four insecticide products since the previous meeting and added that WHOPES testing is required before a WHO specification can be published. In contrast to this, it was pointed out that the FAO does not require efficacy studies. Therefore, if there are agricultural uses one may apply for specifications at the same time as application for a WHO specification.

Dr Zaim noted further strengthening of collaboration with FAO and UNEP on pesticide management and informed the meeting of several events that had taken place since the last meeting on this matter and in which WHO has been represented or has co-organized:

- FAO Regional Meeting on International Code of Conduct on the Distribution and Use of Pesticides: Implementation, Monitoring and Observance – Bangkok, 26-28 June 2005.

- WHO/UNEP Regional Induction Workshop on Reporting and Data Requirements for Countries that Use or Potentially Will Use DDT for Disease Vector Control – Bangkok, 7–9 November 2005.

- Launch of the Chinese Version of the Manual on Development and Use of FAO and WHO Specifications for Pesticides – ICAMA, Beijing, 13–14 December 2005.

- First Regional Committee Meeting of the WHO Eastern Mediterranean Region and Global Environmental Facility Project on Alternatives to DDT – Muscat, 6–8 March 2006.

- Second Conference of Parties to the Stockholm Convention – Geneva, 1–5 May 2006 – Country reporting and evaluation procedures on use of DDT for disease vector control.

6. Technical liaison with other organizations

6.1 AOAC International

Dr Adrian Burns presented the work of AOAC, an independent company that works in a transparent way and has well-established validation protocols. Expert volunteers review data, which are published in a peer reviewed journal. All of these factors support the credibility of the methods. The current activities of the AOAC community are to prioritize method needs, establish desired performance criteria, review and develop selected methods and perform method validation. It is also working on methods for dietary supplements, homeland security, general safety and security (with FDA, USDA, CDC, FBI, DOD, CIA, DHLS) and marine and fresh water toxins. In the agricultural community, it is working on the nutrient value of animal feeds, veterinary diagnostics, feed additives and contaminants, pesticide formulations and disinfectants. Collaborative studies are currently ongoing, with hydrazine in maleic hydrazide, bifenthrin isomers and glyphosate. AOAC is reviewing OMA chapter 7 with regard to old methods where GC packed or old LC columns were used. This is to update these methods to validate column replacements; consideration will need to be given to the amount of validation required. Once the work is done, the methods will be modified and published and this work would be coordinated with CIPAC.

6.2 CropLife International and the European Crop Protection Association (ECPA)

Dr Tom Woods introduced the topic of CropLife/ECPA Specifications Expert Group (SEG) – its mission and activities. The mission of SEG is to provide a forum for experts in matters of product quality and specifications, to discuss and resolve technical issues of importance to the global crop protection industry. There are currently 20 members from companies and countries around the world.

Current SEG activities include: provision of a global interface with FAO/WHO and the specification process; contribution to revisions of the Manual on Development and Use of FAO and WHO Specifications for Pesticides"; promotion of the proper use of FAO and WHO specifications by meeting with country regulators to support proper use initiatives; preparation of new specification guidelines for new products and proposal of new and upgraded physical test methods to CIPAC; And promotion of the harmonization of physical test methods among ASTM, CIPAC, OECD and DAPF.

The group will continue to revise and issue new CropLife International Technical Monographs relating to the finished product as well as Technical Monograph 2 "Formulation Codes". In addition, it will produce position papers on key issues, e.g. proper use of FAO specification.

The meeting was informed that the JMPS is a global initiative with universal participation by governments and companies. FAO/WHO specifications are gaining global significance, for example in the European Union, Latin America and Asia. Support to JMPS activities is consistent with industry's commitment to follow the FAO code of conduct. SEG provides a basis for discussions and development of a global consensus on JMPS issues.

6.3 ASTM International

ASTM International was not represented at the meeting.

6.4 European Crop Care Association (ECCA)

Dr David van Hoogstraten presented a report on the activities of ECCA. The Association has grown over the past year and now has 15 member companies with bases in Belgium, France, Germany, Ireland, Italy, Netherlands, Portugal, Poland, Slovenia, Spain and the UK. All of its members are producers of active substance and/or formulation and have their own registrations; no traders are involved. ECCA supports the new regulation that will replace Dir. 91/414/EC as it will result in a list of truly protected studies being made available and the expiry date of the data protection. Data protection will start from the moment of national product registration. The replacement of old studies with new ones will have to be justified and cannot be used as a way to gain extra data protection. ECCA has been collaborating with ALINA on joint issues such as those involving the World Intellectual Property Organization (WIPO). ECCA thanked FAO and WHO for setting equivalence guidelines.

ECCA members control every batch of material produced and certificates of analysis are provided. It is ensured that products meet FAO/WHO specifications. Controls are made randomly by external laboratories and authorities contact manufacturers periodically. All product labels list manufacturing and expiry dates and comply with local requirements. Exported products have labels in the local language and comply with local standards; local distributors are used. Member companies are involved in the development of solvent free formulations and are using United Nations packaging standards for all products. Colour coding of containers is being used to identify product type and label symbols are being used to indicate the crops on which the product can be used. A close watch is kept on advertising texts.

6.5 Asociación Latinoamericana de la Industria Nacional de Agroquímicos (ALINA)

Mr Juan M. Perez reported that the main constraint faced by ALINA is the non-availability of a reference profile/specification in many of the countries, even though the active ingredient is approved. This means that ALINA member companies are unable to get their product on the market. The FAO expressed concern over this issue and stated that counties could write to FAO and WHO so that they can help resolve these issues if possible. The FAO considered that a manufacturer should not be allowed to hold back a specification as this should be a standard part of a registration. CropLife International stated that the registration holder should provide the regulatory authority with the reference specification. If, of course, the registration of the original source had lapsed, then the regulatory authority would have to take

this into account. Again, the FAO invited countries to write to FAO for further guidance on these issues and wished to support the countries involved.

6.6 United Nations Industrial Development Organization (UNIDO)

UNIDO was not represented at the meeting.

6.7 International Union of Pure and Applied Chemistry (IUPAC)

Dr Denis Hamilton reported that the IUPAC Committee on Crop Protection Chemistry will meet this year in August, so no progress reports on projects are available. The 11th IUPAC Congress on Pesticide Chemistry will be held on 6–11 August 2006 in Kobe, Japan (http://www.iupac2006.jtbcom.co.jp/). A topic on formulations and application technology is included in the programme. For those planning ahead, the 12th IUPAC International Congress on Pesticide Chemistry will be held in Melbourne, Australia, in 2010.

6.8 European Food Safety Authority (EFSA)

Mr Ralf Hänel explained that EFSA was set up because of a number of food scares, e.g. BSE and dioxins, and the creation of some national food safety agencies. In addition, there was some dissension within the European Union over risk assessment. EFSA is tasked with providing independent scientific advice on all matters with a direct or indirect impact on food safety, covering all stages of food production and supply, from primary production to the safety of animal feed to the supply of food to consumers. It also carries out scientific based assessments of risks to the food chain and on any matter having a direct or indirect effect on the safety of the food supply, including matters relating to animal health, animal welfare and plant health. EFSA gathers information on emerging issues and monitors new developments in science. It interacts with experts and decision-makers at all levels, shares findings and listens to the views of others through networking. Issues are communicated directly with the public through the EFSA web site (www.efsa.europa.eu).

EFSA work covers both risk assessment and risk communication; it has no responsibility for risk management. The EFSA organigram was displayed; a new Executive Director, Catherine Geslain-Lanéelle, will assume her post on 1 July. EFSA has an International and Institutional Affairs department whose main duty is liaison with the European Parliament, Council and the Commission on regulatory matters relevant to EFSA's work; it also liaises with other major organizations, e.g. FAO and WHO. In the area of pesticides there are two groups. The PPR panel provides EFSA opinions to questions from the Commission, Member States and European Parliament as well as self tasking. The PRAPeR (Pesticide risk assessment peer review) undertakes peer review of Draft Assessment Reports prepared by European Union Member States. The PPR panel is made up of external experts who deal with questions including "Is dinocap eye toxicity seen in a dog study relevant to man?". It also provides opinions on the acceptability of new guidance documents or new Directives. The PRAPeR team consists of 21 EFSA staff with 15 scientific experts.

6.9 International Programme on Chemical Safety (IPCS)

The IPCS was not represented at the meeting.

6.10 Joint FAO/IAEA Division

Apologies were received from the FAO/IAEA Division. Dr Gero Vaagt provided some information on their behalf. He explained that this Joint FAO/International Atomic Energy Agency division is a very unique cooperation between two United Nations agencies. The unit is involved in monitoring the use of radiation in the treatment of agricultural commodities and in the use of radioisotopes. It possesses laboratories involved in training for residue and formulation analysis and also acts as a reference point for pesticide analysis.

6.11 Association of Producers of Biological Plant Protection Products (of German speaking countries) – APBPPP

Mr Hubertus Kleberg presented the APBPPP, which has about 15 member companies that are in contact with a similar group in China. APBPPP is a member of International Biocontrol Manufacturers Association. Mr Kleberg informed the meeting of the International Neem Conference to be held in China. Dr Zaim expressed his hope in a possible future collaboration of the APBPPP with FAO/WHO/CIPAC.

7. National reports regarding CIPAC activities and reports from official quality control laboratories

The following reports were presented: Argentina, Belgium, China, Cyprus, Czech Republic, Denmark, El Salvador, France, Germany, Greece, Hungary, India, Ireland, Japan, Netherlands, Romania, Slovak Republic, Slovenia, Spain, South Africa, Switzerland, Thailand, Ukraine, United Kingdom, USA.

Summary table of national reports of official quality control laboratories

Region	Reporting laboratory	No. samples tested	Non-compliance	
			No.	%
Africa	South Africa	225	16	7
Americas	Argentina	897	23	3
	El Salvador	688	41	6
Europe	Belgium	124	20	16
	Czech Republic	57	0	0
	Cyprus	105	2	2
	Denmark	37	10	27
	France	40	2	5
	Germany	151	8	5
	Greece	303	8	3
	Hungary	1013	51	5
	Ireland	5	0	0
	Netherlands	31	0	0
	Romania	555	106	19
	Slovakia	170	16	9
	Slovenia	17	1	6
	Spain	276	14	5
	Switzerland	276	14	5
	UK	53	5	9
	Ukraine	19	0	0
Asia	China	700	97	14
	Thailand	4464	109	2
TOTAL		**10206**	**543**	**5**

8. Proposed new/amended specification guidelines

Dr Woods informed the meeting that there were no new proposed guidelines.

8.1 Revision of guidelines for TC/TK introduction of TG

The proposal to replace TC and TK with technical grade (TG) was introduced by Mr Alan Hill (see Annex 1).

It was questioned that the introduction stated that material can contain only a small amount of solvent, which would then exclude TK. It was agreed that this matter required further consideration. Lengthy discussion ensued regarding Table 2.2 of the specification and how some of the different concentration issues relating to TC/TK type materials would be dealt with. The matter would be considered further and worked examples will be looked at. It was suggested that if a material had two forms, e.g. a solid and a liquid, it could be covered in the same specification, but that if this proved difficult, two TG specifications could exist. The specification description should also state that it was for ease of handling. However, it was considered that this was already covered in the phrase "safe handling". Industry considered it a good

proposal in general, but would need time to consider it further. The question was then raised as to what will happen with existing TC and TK specifications. The situation will be clarified and FAO/WHO will manage the changeover. The chairman informed participants that when the JMPS reconvenes its closed meeting after the open meeting it will discuss the proposal further. However, opinion/comments shall be sought on the issue from governments and industries through wide circulation. The deadline would be the end of October 2006. It was further pointed out by industry that preferably tolerance limits can be kept as +/– g and not as %.

9. Status, review and publication of CIPAC methods

Mr Laszlo Bura presented the position paper in detail, informing participants that the identification of obsolete methods has been an issue for many years. Handbook one was published in 1970, and since then science and technology have moved on. The systematic review process that was agreed in Utrecht has been adopted and will now be implemented. This will take into account the existing FAO/WHO methods, origin and year of adoption, techniques used, including availability of solvents and consumables, and current usage of the active ingredient. Initially, such product information shall be tabled as per format. The review will start with the oldest book. A priority list of methods, both analytical and MT, will be ranked from obsolete to state-of-the-art, discussed with FAO/WHO and industry and regularly updated. Once the obsolete methods are identified, they will be listed in a negative list of CIPAC methods that are no longer supported. For these, no method extension would be possible but they could still be used for special purposes. The job will be undertaken by a task force of CIPAC members who will draw up the list for consideration within CIPAC TC and council meetings followed by presentation in the JMPS meetings.

10. Proposed new/extended CIPAC analytical and physical test methods

The principle of the CIPAC code number system was explained in response to the query raised by Dr Hamilton and Dr Woods. (for details see www.cipac.org; "What are CIPAC code numbers?"). In addition, the intention of the "8000er" numbers was clarified.

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

From 2002 to 2006, the JMPS has considered at total of 86 compounds: 41 FAO, 19 WHO and 26 joint. Details are presented below.

11.1 Status of FAO specifications

COMPOUND	MANUFACTURER	STATUS
Azadirachtin	Fortune	Ready for publication
Bensulfuron-methyl TC, WP, WG	Dupont	Published 2002
Dicamba TC, WG, SL (SG)	Syngenta, BASF, Gharda	Published 2001
Flufenzine TC,TK (see Diflovidazin)	Agro-Chemie	Published 2003
Glyphosate SL	Syngenta	Published 2005
Maleic hydrazide TC, TK, SL,SG	Crompton	Evaluation only
Methomyl TC, SP, SP-SB, SL	Dupont	Published 2002
Quinclorac TC, WP, WG, SC	BASF	Published 2002
Tribenuron methyl TC, WG	Dupont	Published 2002
Azadirachtin	Trifolio	Published 2006
Chlormequat chloride TC, TK, SL	BASF; NUFARM, UCB, Ciba Speciality Chemicals	Published 2005
Chlorsulfuron TC, WG, WP	Dupont	Published 2003
Flufenzine TC,TK (see Diflovidazin)	Agro-Chemie	Published 2003
Hexazinone TC, SP, WG, GR, SL	Dupont	Published 2006
Imidacloprid	Bayer	Published 2006
Iprodione	Bayer	Ready for publication
Maleic hydrazide	Drexel; Fair Products	Published 2004
Paraquat TK, SL, SG	Syngenta	Published 2003
Clofentezine TC, SC	Makhteshim	Postponed to 2006
Chlorothalonil	Caffaro SpA, Vischim Srl, SDS Biotech K.K.	Published 2005
Copper , cupric hydroxide and oxychloride (to include copper calcium oxychloride), Bordeaux mixture, tribasic copper sulphate and cupric oxide	European Union Copper Task Force	In progress
Cymoxanil	CymoxanilOxon	Published 2006
Diquat dibromide, SL	Syngenta	Ready for publication
Ethofumesate TK,SC,EC,SE,OD	Bayer CropScience	In progress
Nicosulfuron TC, WG	Dupont	Published 2006
Propanil	Propanil Task Force (Dow AgroSciences; Riceco)	JMPS 2006
Pendimethalin TC,TK,EC	Industria Prodotti Chimici	To be rescheduled
Rimsulfuron TC, WG	Dupont	Published 2006

11.2 Status of WHO specifications

JMPS (year)	COMPOUND	MANUFACTURER	PUBLICATION
2002	D-ALLETHRIN	SUMITOMO	March 2004
2002	D-PHENOTHRIN	SUMITOMO	October 2004
2002	PRALETHRIN	SUMITOMO	November 2004
2002	TRANSFLUTHRIN	BAYER	Evaluation only (January 2005)
2003	ESBIOTHRIN	SUMITOMO	October 2004
2003	BIOALLETHRIN	SUMITOMO	May 2005
2003	TRANS-CYPHENOTHRIN	SUMITOMO	September 2005
2004	BACILLUS THURINGIENSIS	VALENT	--
2004	DELTAMETHRIN LN	VESTERGAARD	--
2004	ICARIDIN	BAYER	October 2004
2005	IR3535	MERCK	February 2006
2005	PERMETHRIN LN	SUMITOMO	--
2005	S-BIOALLETHRIN	SUMITOMO	March 2006
2005	PERMETHRIN/S-BIOALLETHRIN	BAYER	Evaluation only (Feb. 2006)
2005	TEMEPHOS	BASF	--

11.3 FAO/WHO joint specifications

JMPS (year)	COMPOUND	MANUFACTURER	PUBLICATION
2002	NICLOSAMIDE	BAYER	January 2004
2002	CHLORPYRIFOS	DAS, MAKHTESHIM	October 2004
2003	DELTAMETHRIN	BAYER	April 2005
2003	LAMBDA-CYHALOTHRIN	SYNGENTA	January 2004
2003	CYFLUTHRIN	BAYER	November 2004
2003	PROPOXUR	BAYER	October 2005
2003	NOVALURON	MAKHTESHIM	December 2004
2003	MALATHION	CHEMINOVA	September 2004
2004	BIFENTHRIN	FMC	--
2004	DELTAMETHRIN	BAYER	April 2005
2004	DIFLUBENZURON	CROMPTON	April 2005
2004	DIMETHOATE	CHEMINOVA	APRIL 2006
2004	FENTHION	BAYER	--
2004	PIRIMIPHOS-METHYL	SYNGENTA	April 2006
2005	ALPHA-CYPERMETHRIN	BASF/TAGROS	April 2006
2005	DELTAMETHRIN	TAGROS/ARGOS	April 2006
2005	PERMETHRIN	SUMITOMO/TAGROS	--
2005	PYRIPROXYFEN	SUMITOMO	--
2005	SPINOSAD	DAS	January 2006 (WHO- Evaluation only)

11.4 Revision of the manual

Mr Alan Hill presented the detailed changes that have been incorporated into the manual on the development and use of FAO and WHO specifications for pesticides, revised first edition, March 2006. Full details of the revisions, which are highlighted in grey, can be found in the manual. The revised manual is only available on the Internet and can be downloaded from the following links:

http://whqlibdoc.who.int/publications/2006/9251048576_eng_update2.pdf;
http://www.fao.org/ag/AGP/AGPP/Pesticid/Default.htm

11.5 Further changes to FAO/WHO manual

Some further changes were presented that change the header notes on the specification, the change being required for legal reasons (see Annex 2). It was questioned why the new header does not state that the specifications can be used as a quality criteria for all products. It was made clear that this statement was in the manual but that it has never been in the header. It was further explained that some authorities misunderstand this and it would be better if it was in the header. The FAO explained that they do not wish it to be in the header but it will be in the disclaimer. This was acceptable to all parties.

It was then explained that the JMPS had been discussing the toxicology requirements for equivalence and it had been considered that perhaps acute toxicity data are not the best data to ask for. For this reason, the JMPS, FAO and WHO considered that a review should be conducted after consultation with industry, regulatory authorities and other interested parties. There was some discussion over the deadline, which was finally agreed as the end of October.

One further new requirement explained was that there will be a completeness check of data before a compound is added to the list for the following year.

12. FAO/WHO priority list and programme for development of FAO and WHO specifications for pesticides

Year	Products	Proposer(s)
2007	**FAO:**	
	Azoxystrobin TC,SC,WG	Syngenta
	Deltamethrin LN	Vestergaard Frandsen
	Fenoxaprop-p-ethyl	Bayer
	Fluazinam	ISK Biosciences Europe
	Flusilazole	Dupont
	Glyphosate	JSC Trans Oil
	Lufenuron TC,EC	Syngenta
	Nicosulfuron	ISK Biosciences Europe
	Oxamyl	Dupont
	Propanil TC	Proficol SA
	Thiacloprid TC,SC,SE,OD,WG	Bayer CropScience
	WHO:	
	Alpha-cypermethrin LN	Clarke Mosquito Control Products
	Bendiocarb TC,WP	Bayer, Argos
	Deltamethrin LN	Intelligent Insect Control
	Deltamethrin LN	Tana Netting; Netto Group; Hiking Group Shandongtex Genfont; Yorkool
	Lambda-cyhalothrin LN	Syngenta
	Spinosad DT	DAS
	FAO & WHO:	
	Alpha-cypermethrin TC	Heranba
	Cyromazine TC,WP	Syngenta
	Fenitrothion TC, EC,WP	Sumitomo
	Lambda-cyhalothrin TC	Heranba
	Permethrin TC, EC	Sumitomo
	Pyrethrum TK, EC	Pyrethrum Board of Kenya

In order to develop the final programme for 2007, and to ensure the completeness and the availability of the required data, FAO/WHO will request the proposer to provide a list of study references for the data submission to meet the requirements described in the manual.

It was noted that oxamyl was omitted from the list. It was confirmed that this was a mistake that had been rectified. CropLife International asked if it would be possible to see the list as it develops throughout the year. This request will be taken into consideration. Industry was asked to keep the FAO and WHO informed of its priorities and to provide a draft list prior to each JMPS.

13. Any other matters

13.1 Persistant organic pollutants (POPs) as relevant impurities

The topic was presented by Dr Martin Rodler of the CropLife Specifications Expert Group. A POP chemical is defined through the Stockholm Convention. It has the potential to bioaccumulate in living organisms, so even low-level exposure can result in toxic levels being reached after perhaps decades because of its persistent nature. The presentation stated that standard toxicity and ecotoxicity testing do not completely address the toxicity of these compounds. Thus, it was considered that the accumulation issue calls for measures to reduce their release into the environment below levels that would be justified on purely toxicology and ecotoxicology grounds. It was considered by the speaker that this justified the introduction of a different class of relevant impurities, namely POPs. The Stockholm Convention requests that each country takes measures to eliminate or reduce the release of these chemicals. One consideration is that best available techniques must be used to eliminate these compounds in chemical production.

As the FAO and WHO definition of relevant impurities does not specifically address POPs, it was suggested that the following definition should be used:

> "Those by-products of the manufacture or storage of a pesticide which, compared with the active ingredient, are toxicologically significant to health or the environment, are phytotoxic to treated plants, cause taint in food crops, affect the stability of the pesticide, or cause any other adverse effect. By-products that are listed as persistent organic pollutants in the Stockholm Convention are also considered relevant impurities. The establishment of appropriate limits follows the rationale laid down in the convention."

The FAO/WHO response was that the Stockholm Convention is always taken into account when relevant impurities are considered. It is not only the Stockholm convention that is taken into account but also other international agreements, for example the Montreal agreement on ozone depleting substances. It was stated that the argument on best available techniques can be applied only if these techniques are made available to all. If not it is very difficult to apply. The FAO/WHO will follow the progress on this issue and consider it further.

13.2 Safeners

Dr Ralf Grohs of Bayer CropScience gave a brief explanation of safeners and the need for specifications. The requirements of regulatory bodies are very different; in the European Union they are as for PPPs. It was also explained this was a proposal of Bayer CropScience and not of CropLife International. FAO noted with interest the presentation of Dr Grohs and advised that this topic needs to be discussed further at the next JMPS meeting.

14. Date and venue of next meeting

6–15 June 2007, Umhalanga Rocks, near Durban, South Africa.
The meeting gave a warm goodbye to Alan Hanks and Alan Hill who retire this year from the JMPS. They will be missed by all.

ANNEX 1.

5. **SPECIFICATION GUIDELINES FOR TECHNICAL GRADE ACTIVE INGREDIENTS** (except microbial TGs[1])

Introduction

A technical grade (TG) active ingredient is a relatively pure form of the active ingredient, prior to its incorporation into a formulation. Although TG contains no formulants specifically intended to aid distribution of active ingredient during application by the end-user, it may contain small proportions of added solvent, stabilizer, etc., if essential to facilitate handling of the TG or avoid degradation prior to preparation of formulations.

Separate specifications may be required for TGs of the same active ingredient prepared in different chemical forms. For example, if the active ingredient is an acid which may be incorporated into formulations as the free acid, the potassium salt, or the ethylhexyl ester, TG specifications may be developed for each of the three forms. On the other hand, if TGs in the same chemical form can be either a dry solid or a concentrated solution, both forms may be encompassed by a single TG specification.

Where an active ingredient is defined as specific salt/complex or other derivative which is not directly measured as such, a quantitative/semi-quantitative method must be provided to determine the nature and approximate quantity of the counter-ion/ligand, etc., present, to ensure that the calculated value for content of the intact molecule is valid.

In most cases, TGs are traded between manufacturers but, exceptionally (e.g. certain UL products), the TG may be supplied to the end-user. In these unusual cases, the product should comply with the formulation specification appropriate to its physical state and intended use.

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[1] For information on specifications for microbial pesticides, see section 9.

5.1 **TECHNICAL GRADE (TG)**

Note for preparation of draft specifications. Do not omit clauses or insert additional clauses, nor insert limits that are more lax than those than given in the guidelines, without referring to section 4. From the "Notes" provided at the end of this guideline, incorporate only those which are applicable to the particular specification.

TECHNICAL GRADE ..... [ISO common name]

[CIPAC number]/TG (month & year of publication)

1 **Description**

The material shall consist of …… [ISO common name] together with related manufacturing impurities, in the form of ..... (see Section 4.2), and shall be …… [physical description] free from visible extraneous matter and added formulants or modifying agents, except for a diluent, stabilizer or other additive essential for the safe handling/storage of the active ingredient, if required.

2 **Active ingredient**

2.1 **Identity tests** (Note 1)

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

2.2 **..... [ISO common name] content** (Note 1)

The …… [ISO common name] content shall be declared (g/kg) and, when determined, the average measured content shall not differ from that declared by more than the appropriate tolerance, as follows.

Declared content in g/kg	Tolerance
up to 25	± 15% of the declared content
above 25 up to 100	± 10% of the declared content
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 5% of the declared content
above 500 up to 900	± 25 g/kg or g/l
above 900 up to 1000	the minimum content, only, is declared
Note In each range the upper limit is included	

2.3 **Any other clause** (Note 1), if required

Such as isomer ratio.

3 **Relevant impurities**

3.1 **By-products of manufacture or storage** (Note 2), if required

Maximum: .....% of the …… [ISO common name] content found under 2.2.

3.2 **Water** (MT 30.5) (Note 3), if required

Maximum: ..... g/kg.

3.3 **Insolubles** (Notes 3 & 4), if required

Maximum: ..... g/kg.

4 **Physical properties**

4.1 **Acidity** and/or **Alkalinity** (MT 191) or **pH range** (MT 75.3) (Notes 3 & 4), if required

Maximum acidity: ..... g/kg calculated as H_2SO_4.

Maximum alkalinity: ..... g/kg calculated as NaOH.

pH range: ..... to .....

4.2 **Any other clause** (Note 4)

Such as a sieve test, kinematic viscosity range, specific gravity, etc.

Note 1 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.

If the active ingredient is defined as a salt, a complex or some other derivative, and only a moiety of the defined compound is determined by the primary method of analysis, a quantitative or semi-quantitative method must be provided for the counter-ion, ligand, or whole molecule, so that the calculated value for the defined form of active ingredient may be checked.

The corresponding value for g/l at 20 ± 2°C may also be given but the referee value for content is in g/kg and the tolerance range(s) is/are based on g/kg values.

The approach to tolerances at >900 g/kg is intended to encourage manufacture of TG with the highest possible purity. Within the 900-1000 range, any increase in active ingredient content represents a negligible increase in hazard from the active ingredient but a significant decrease in the amount of impurities which would otherwise be needlessly distributed into the environment.

Note 2 This clause should include only relevant impurities and the title should be changed to reflect the name of the relevant impurity. Method(s) of analysis must be peer validated.

Note 3 Clause to be included only if appropriate to the material.

Note 4 The method to be used shall be stated. If several methods are available, a referee method shall be selected.

ANNEX 2.

PROPOSED NEW HEADER NOTES FOR FAO/WHO SPECIFICATIONS

The new headers have been developed with the objective to better clarify the scope and application of the specifications, i.e.

(1) FAO and WHO specifications are developed to enhance confidence in the purchase and use of pesticides and to contribute towards better pest control, sound agricultural production, effective vector control measures and improved user, public and environmental safety. The FAO and WHO specifications provide an international point of reference against which products can be judged either for regulatory purposes or in commercial dealings. The specifications are standard quality criteria, not intended to describe the products of any particular manufacturer, and not an endorsement of a product or a company.

(2) Under the "new procedure", the names of manufacturers who have shown to FAO/WHO that they are able to meet with the appropriate requirements and quality standards for a given pesticide product are mentioned in the evaluation report, to inform national regulatory authorities, pest/vector control programmes and other buyers.

Proposed new header notes:

TC/TK
This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (xx/yy/zzzz). It should be applicable to TC/TK produced by this manufacturer but it is not an endorsement of it, nor a guarantee that it complies with the specification. The specification may not be appropriate for TC/TK produced by other manufacturers. The evaluation report xx/yy/zzzz, as PART TWO, forms an integral part of this publication.

Formulated products
This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (xx/yy/zzzz). It should be applicable to relevant products of this manufacturer, and any those of other formulators who use only TC/TK from the evaluated source(s). The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of manufacturers who use TC/TK from other sources. The evaluation report xx/yy/zzzz, as PART TWO, forms an integral part of this publication.

Specific formulated products, e.g. LN, CS
This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (xx/yy/zzzz). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers, irrespective of the source of TC/TK. The evaluation report xx/yy/zzzz, as PART TWO, forms an integral part of this publication.