



**FOURTH JOINT CIPAC/FAO/WHO OPEN MEETING  
(51<sup>st</sup> CIPAC Meeting and 6<sup>th</sup> JMPS Meeting)**

**UHMLANGA ROCKS, SOUTH AFRICA  
11 June 2007**

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Before opening the meeting, CIPAC, FAO and WHO remembered the three colleagues who had passed away since the last meeting:

- Louis van Dyk – from the Plant Protection Research Institute of South Africa was remembered for his great leadership and the managerial support he gave for 36 years to PPRI Division Pesticide Science as well as his leadership concerning "Pesticide Dynamics". Louis van Dyke was the first participant from South Africa in CIPAC and the FAO Panel of Experts on Pesticide Specifications. He had contributed to the preparations for this meeting to be held for the first time in South Africa.
- Robert Cashwell – the first AOAC correspondent to CIPAC, who fostered the collaboration between CIPAC and AOAC
- Michel Galoux – from the Pesticides Research Department of the Walloon Agricultural Research Centre, Belgium, and an active member of CIPAC. Dr Vaagt said that Dr Galoux would be missed not only a colleague but also as a friend and an active member of the FAO Panel for many years. Dr Zaim also expressed his sincere regret at the passing away of Michel Galoux, a long-standing member of the WHO Panel of Experts and an excellent scientist who had made his laboratory a centre of excellence for pesticide analysis and a WHO-designated Collaborating Centre.

One minute's silence was held in memory of these past members.

## **1. Opening and welcome**

Dr Ralf Hänel, the Chairman of CIPAC, opened the 4<sup>th</sup> Joint CIPAC/FAO/WHO Open Meeting. He welcomed Dr Bothle Michael Modisane, Chief Director of Food, Animal Health and Disaster Management of the Department of Agriculture of the Republic of South Africa, Dr Gero Vaagt, Senior Officer of the Pesticide Management Group of FAO, Dr Morteza Zaim, Manager of the WHO Pesticide Evaluation Scheme (WHOPES), Mr Denis Hamilton, the Chairman of the JMPS, and participants from JMPS, CIPAC, Government, the Agrochemical Industry, Academia and other interested parties. Dr Hänel expressed his pride at being designated to open the first joint meeting to take place in Africa - in Umhlanga Rocks - and wished the participants a successful meeting.

Dr Gero Vaagt, FAO Joint Secretary of the JMPS, welcomed participants to the 4<sup>th</sup> Joint CIPAC/FAO/WHO open meeting, the 6<sup>th</sup> JMPS and the 51<sup>st</sup> CIPAC meeting. He welcomed Drs Modisane, Zaim and Hänel and all other participants from the JMPS and CIPAC, government officials, representatives from the pesticide industry, multinational companies and generic manufacturers as well as their associations, the academic sector, public interest groups, intergovernmental organizations and other stakeholders to this first Meeting to be held in sub-Saharan South Africa. He hoped that all could work together on issues related to pesticide specifications and pesticide quality. He thanked in particular Dr Eric Sandmann for coordinating the event of more than 100 participants, and thanked him and all his team for their efforts.

He mentioned that many other initiatives had started in South Africa. At the meeting there were representatives from governments, industry and universities, and pesticide registrars from more than 10 neighbouring countries, thanks to Ms. Clarendon the FAO Regional Plant Protection Officer at the Regional Office for Africa. However, Dr Vaagt also expressed his concern at the lack of representation from the environment sector at this and previous meetings.

The importance of the environmental sector was growing, reflecting current concerns about climate change. Environmental issues affected the agricultural sector and involvement in environmental activities and work were of increasing importance. There had been talk of creating a new intergovernmental organization called the World Environment Organization. To obtain recognition for its work and interest, the agricultural sector should become more active in the area of environment.

The meeting venue in South Africa was linked to the “World Summit on Sustainable Development” which took place in Johannesburg in 2002, and had been attended by more than a thousand delegates and many political world leaders. The majority of decisions taken then were linked to environmental issues and some to human health. The outcome of the Summit had been the Johannesburg Plan of Implementation, which was a key political commitment.

This was also the basis for the development of the Strategic Approach to International Chemicals Management (SAICM), a multi-sectoral and multi-stakeholder approach, which was agreed upon at the “International Conference of Chemicals Management” (ICCM), held in Dubai in 2006. This approach included pesticides as reference was made to the *International Code of Conduct on the Distribution and Use of Pesticides* (hereinafter referred as the Code of Conduct). The next ICCM conference was scheduled to take place in 2009. Dr Vaagt emphasized that it was important to have close collaboration with colleagues in the environmental sector in order to avoid duplication of work at the national, regional and international level.

Another initiative in South Africa was the implementation of GHS, the globally harmonized system of classification and labelling of chemicals. Users needed to understand the new pictograms, and FAO would publish its revised *Guidelines on Good Labelling Practice*, probably in September 2007. The new guidelines would cover the current FAO/WHO-based labelling guidance as well as an introduction to GHS.

Dr Vaagt mentioned that the work of the meeting and reporting on pesticide quality issues were ahead of other groups, including industrial chemicals and pharmaceutical products. He highlighted again the need for the active engagement of the agricultural sector, which had a know-how not reflected in the environmental sector. He hoped that the meeting would contribute to advancement in the work on pesticides and product quality, and also urged participants to make use of such progress outside this forum. He thanked again Dr Eric Sandmann and all participants for coming to the “Rainbow Nation”.

Dr Morteza Zaim of WHO welcomed Drs Modisane, Hänel and Vaagt and all the participants to the 4<sup>th</sup> Joint CIPAC/FAO/WHO Meeting and to the 6<sup>th</sup> FAO/WHO Joint

Meeting on Pesticide Specifications. He thanked the Plant Protection Research Institute of the Agricultural Research Council of South Africa, and Dr Eric Sandmann, Division Manager of Pesticide Science, for their agreement to host the meeting, the excellent preparations and the warm hospitality.

Dr Zaim mentioned that the FAO/WHO Joint Programme on Pesticide Specifications had been established six years ago, and during that time a much wider adoption and application of WHO specifications for quality control of pesticides had been seen. He said that it was encouraging to see that WHO specifications were now widely used in international tenders and by major donors and institutional buyers. He thanked all present and their organizations for supporting WHO in developing these quality standards and promoting their use.

Dr Zaim added that quality control of public health pesticides was never seen as a separate subject by WHO; rather, it had been promoted through capacity building of WHO Member States in better regulation of pesticides and through the life-cycle approach to their sound management. He noted that such country support required close collaboration and cooperation with FAO and UNEP to ensure harmonized and coordinated responses to Member countries.

Dr Zaim informed the meeting that in March 2007, FAO and WHO had signed a Memorandum of Understanding on cooperation in a joint programme on pesticide management, and expressed the hope that, through this joint effort, WHO could further elevate the importance of pesticide management at the national level; further engage ministries of health in the sound management of pesticides; and optimize the use of limited resources in WHO Member States to address the important challenges they face in this field. He added that Code of Conduct would be the guiding document for sound management of public health pesticides, and integrated vector management would be the key strategy to ensure judicious use of pesticides in public health.

Dr Zaim informed the meeting that last year his department at WHO had taken a strategic direction which would be reflected on later during the meeting. He noted that with recent WHO initiatives on further supporting Member States to control neglected tropical diseases, as well as capacity building for vector control in the context of integrated vector management, great opportunities existed to promote the availability of quality pesticide products, their regulation and quality control. These were issues of direct relevance to the meeting.

Dr Zaim wished participants a very productive and interactive meeting as well as a pleasant stay in Umhlanga Rocks.

Dr B.M. Modisane, representative of the Ministry of Agriculture, Department of Agriculture, welcomed Drs Hänel, Zaim and Vaagt, industry and other representatives on behalf of the "Rainbow Nation" and the South African Department of Agriculture. He mentioned that the Minister, Mr Lulu Xingwana, was unable to attend the meeting as he was participating in an international agricultural conference in Johannesburg. The Department of Agriculture thanked WHO, FAO and CIPAC for holding the meeting in South Africa and in particular thanked Dr Eric Sandmann for organizing the event.

Dr Modisane noted that the present era was characterized by public awareness of food safety and the environment and possible adverse effects of pesticide products on the environment. An international meeting had been held five years ago in Johannesburg to discuss their impact on the environment. He stressed the importance of using such products while at the same time safeguarding the environment. The specifications developed by the group were very important and were used worldwide by regulatory authorities, so it was essential to continue the work. It was important to improve production while safeguarding efficacy and controlling adverse aspects. Skills needed to be passed on to young South African scientists. There was large agrochemical production in South Africa and the experience from the meeting would be passed on to these scientists.

Dr Modisane wished the meeting fruitful deliberations, hoped they would enjoy the climate of Umhlanga and Durban, and trusted that the outcome would be of benefit to mankind.

## **2. Arrangements for chairmanship and appointment of rapporteurs**

Dr Ralf Hänel explained that chairing the open meeting rotated between the three organizations and this year the facilitation of the meeting lay with CIPAC, with himself as Chair.

Mr László Bura (CIPAC), Mr Steve Funk (FAO panel) and Mr Tony Tyler (WHO panel) were appointed rapporteurs of the Open Meeting.

Dr Eric Sandmann thanked the members of his committee and gave details of arrangements for the meeting.

## **3. Adoption of the agenda**

Dr. Vaagt proposed to include under item 13, Any other matters, to become agenda point 13.2 "Outcome of JMPS 2007 Meeting". This extra item was added to the agenda.

The agenda was adopted with the addition of the new agenda point.

## **4. Summary record of the previous meeting**

The summary record of the previous open meeting, held at WHO Headquarters in Geneva, Switzerland on 12 June 2006, had been published a month later. Dr Vaagt announced a post-meeting correction under item 11, chlorothalonil, and the name of the company Syngenta was added to the report. No other comments were made on the report, which was adopted without further amendments.

## **5. Summary of actions taken after the 50th CIPAC and 5th JMPS meetings**

### **5.1 CIPAC**

Dr Ralf Hänel presented an outline of CIPAC (Collaborative International Pesticides Analytical Council). He stated that CIPAC is an international, non-profit and non-governmental organization with the main aim of international agreement on methods, inter-laboratory programmes, sponsoring symposia, publishing standardized analysis methods and collaboration with other organizations. Daily business is run by a chairman, a secretary and a treasurer, all of whom are volunteers. CIPAC had 24 full members in 2006 which was a significant increase from the original seven members in 1957.

Dr Hänel noted that there were more than 400 methods for active ingredients, of which more than 200 for physical and chemical properties and also methods for reagents, published in handbooks and used for registration, pesticide quality control and for FAO and WHO specifications.

Dr Hänel said that CIPAC takes methods proposed by companies, collaboratively tested by laboratories all over the world, and evaluates these results at the CIPAC meeting against defined criteria. If adopted by CIPAC the methods are published in handbooks and recently also became available on CD-ROM. Since 2006, seven methods had been accepted as provisional, 11 provisional methods had been accepted as full methods and nine collaborative trials had been conducted.

Ongoing work included a systematic review of CIPAC Methods, a pre-publication scheme and the development of a guideline for independent laboratory validation for relevant impurities.

Mr Walter Dobrat mentioned that Dr Eric Sandmann was also the assistant secretary of CIPAC,

### **5.2 FAO**

Dr Vaagt gave a presentation on FAO activities in the last year, including various meetings and workshops held with respect to pesticides specifications, equivalence and revision of the pesticide manual.

Meetings and Workshops were held in: (i) July 2006 – International Conference on Pesticides and Trade organized by the Pesticides Manufacturers & Formulators Association of India (PMFAI) in Bangkok; (ii) October 2006 - ICAMA organized the 8<sup>th</sup> China Pesticide Quality Control and Analytical Techniques Workshop where issues related to product quality, equivalence determination and other issues related to pesticides were discussed, with participation also from Australia and USA; and (iii) January 2007 – the Regional Seminar and Workshop on FAO specifications, hosted by the Philippines with the participation of Indonesia, Thailand and Vietnam, organized the by Fertiliser and Pesticide Authority (FPA), which focused on pesticide specifications and determination of equivalence.

An Arabic version of the FAO Manual had been published owing to the strong interest in Arabic countries, in cooperation with the FAO Regional Office in Egypt.

The linkage between the JMPS and JMPR was outlined. The specifications are used in the assessment and evaluation of pesticide residues. All JMPR reports from 2006 onwards would contain the standard phrase “the specifications were established by the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS) and published as FAO/WHO specifications and evaluations for agricultural/public health pesticides” (Cyfluthrin,  $\beta$ -cyfluthrin, Cypermethrins, Pirimiphos methyl and Temephos). FAO has tried to keep track of the acceptance of the equivalence procedure in different countries. The FAO/WHO procedure for equivalence determination has been adopted in Argentina, Brazil, Costa Rica, European Community, Mexico and Paraguay and was also applied in South Africa.

Discussions were ongoing with ICAMA (PR of China), FPA (the Philippines), US-EPA, and within the OECD Working Group on Pesticides.

Dr Vaagt informed the meeting about the release of the “Pesticide Management Update”, published for the first time in January 2007. Through this tool, the FAO Pesticide Management Group informs all subscribers (ca.1300) on new publications, including the publication of new pesticide specifications, reports and forthcoming events deriving from its work.

FAO Global Minor Use Summit will be held from 3 to 5 December 2007, at FAO, Rome, organized in cooperation with USDA, US-EPA and IR4. Further information can be found on the website <http://www.fao.org/ag/agp/agpp/pesticid>

Dr Thomas Woods asked whether FAO also intended to translate the Manual into other languages. Dr Vaagt said that the translation into French had been initiated by WHO. He thanked CropLife International for reviewing the translations, in particular the Arabic version. A new version (2<sup>nd</sup> ed) of the full Manual would be published probably in five years' time.

Dr Zaim said that WHO had considered translating the FAO/WHO Manual into French. However, this was delayed due to lack of resources for translation. However, he pointed out that the revised version had been published and that the document would further evolve in future, so WHO was no longer considering the translation of the document.

### **5.3 WHO**

Dr Morteza Zaim outlined the major activities of WHO since the previous CIPAC/FAO/WHO Open Meeting in Geneva and gave a presentation entitled “Hidden Successes, Emerging Opportunities”. He noted that the previous year had been the year of strategic direction in WHO. During this period the Department of Control of Neglected Tropical Diseases had been re-orienting itself and, through strong advocacy, partnership and strategic planning, had attempted to identify opportunities to better serve the more than one billion people who are suffering from one or more neglected tropical diseases. The common denominators for all these diseases are poverty and neglected populations. The stigma, social isolation and

economic burden of these diseases are enormous, and included diseases such as Chagas disease, sleeping sickness, leishmaniasis, dengue, leprosy, guinea worm, elephantiasis and Buruli ulcer. Dr Zaim added that many of these diseases could be prevented, eliminated or even eradicated with improved access to the existing safe and cost-effective tools. This would require political will, partnership and mobilization of resources. He also noted that more than half of these disease are vector-borne and if malaria were added to the list, there would be a growing demand for quality insecticides, an issue which was of direct relevance to the discussions in the meeting.

Dr Zaim also added that WHO, through consultation with several of its Member States in the Eastern Mediterranean Region and in collaboration with UNEP and GEF, was able to develop a project proposal on demonstration of sustainable alternatives to DDT and strengthening of national vector control capacities in the Middle East and North Africa. This was a five-year project, expected to start later in 2007 in collaboration with FAO, which would be closely involved in issues related to pesticide management and the disposal of obsolete pesticide stockpiles .

Dr Zaim also mentioned that WHO, in collaboration with FAO and UNEP, had developed and submitted a four-year proposal to the Bill and Melinda Gates Foundation on strengthening the capacity of member states on sound management of pesticides. One of the main objectives of the proposal, which was of direct relevance to the meeting, was training on the use of WHO specifications and principles of determination of equivalence, as well as capacity building of national Quality Control laboratories in priority countries.

In 2006 WHO held the 5<sup>th</sup> meeting of the Global Collaboration for Development of Pesticides for Public Health (GCDPP). This is a unique public-private partnership established by WHO in 1997 and is represented by major manufacturers of pesticides and application equipment, government-supported agencies, research institutions and regional and international organizations. One of the key recommendations of the meeting was that WHO should develop a joint programme with FAO and UNEP on pesticide management to ensure complementary, harmonized and coordinated guidance and support to responsible bodies at the national level and to all stakeholders. The outcome of this recommendation was the signing of the Memorandum of Understanding between WHO and FAO on the joint programme mentioned earlier. The first meeting of the joint panel of experts of the two organizations on pesticide management is planned for October 2007.

Dr Zaim also noted another important activity during the past year on development of specification guidelines for major pesticide application equipment for use in public health.

Dr Zaim added that in 2006 the testing and evaluation of five pesticide products for use in vector control were finalized: two formulations of spinosad for mosquito larviciding; lambda-cyhalothrin CS for indoor residual spraying against malaria vectors; a treatment kit for mosquito nets which significantly increases the wash resistance of mosquito nets in the field; and finally a long-lasting insecticidal mosquito net for malaria prevention. WHO specifications for pesticides are only



published when the use of the pesticide product has been evaluated by the WHO Pesticide Evaluation Scheme.

Dr Zaim also informed the meeting of the submission of the Third Edition of the *Global use of pesticides for vector-borne disease control* for printing and noted that the document had been used as a reference for investment for development of alternatives, as well as development of guidelines and strategies for management of public health pesticides.

Mr Alan Viets asked if resistance was developed with pyrethroids, and if WHO had any plans to replace them. Dr Zaim stated that resistance to pyrethroids had already been developed and that was one reason why WHO was working with industry and other partners to increase the limited number of chemicals available for vector control. WHO was also assisting Member States in capacity strengthening for monitoring of insecticide resistance. However, he pointed out that prevention and management of resistance require close collaboration with the agricultural sector, because it has been demonstrated that in many instances the selection pressure for resistance in major disease vectors originates from agricultural use of pesticides. He also added that in the longer term the development of new active ingredients was essential.

Dr Vaagt commented that there had been close collaboration between organizations at the international level but close collaboration was also needed at the country level in the management of resistance. He added that the international guidelines on resistance management would be finalized.

Dr Zaim mentioned WHO's concern about some emerging and re-emerging vector-borne diseases, which called for capacity building for vector control at different levels.

## **6. Technical liaison with other organizations**

### **6.1 AOAC International**

Dr Adrian Burns represented AOAC International, the sister organization of CIPAC in promoting methods for PPPs. He noted that US state laboratories were involved in the analysis of pesticide products and collaborative studies. The turnaround time for collaborative studies for pesticide formulations would decrease progressively from five years to 10 months. The identification, solicitation and prioritization would be changed. Priorities would have actives and formulations registered in the USA. Methods would originate from Members, industries, government agencies and interested parties.

He added that AOAC had published the 18<sup>th</sup> edition of the methods. The referee responsible for the CIPAC methods would be responsible for incorporating them in the AOAC publications.

In theory, a collaboratively studied method grants first action. After the two years allowed for comments, a method can be promoted to final action. All the methods which were first action had now become final action. AOAC reviews OMA chapter 7

with regard to old methods where GC packed columns were used, or for LC old discontinued LC columns were used. 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. This project was initiated by CIPAC and he proposed to approach the CIPAC procedure. AOAC will try to see if, with minimum additional work, those methods can be adopted to the new technologies.

AOAC was running some collaborative trials and small-scale studies. The protocol of a mini collaborative study for phenols in surfactants used in pesticide formulations had just been completed. AOAC was looking at GC and LC procedures.

AOAC looked forward to working with CIPAC, FAO and WHO.

Dr Burns affirmed that AOAC would publish the brief report of this meeting and that he would be the general referee for CIPAC activities.

## **6.2 CropLife International and European Crop Protection Association (ECPA)**

Dr Ralf Eisert addressed the meeting on behalf of CropLife International/ECPA Specifications Expert Group (SEG). He thanked the three organizations and Dr Eric Sandmann for organizing the meeting.

SEG continues to prepare new specification guidelines for new products and proposes new and upgraded physical test methods to CIPAC, this year being dispersion to seeds. The group promotes the harmonization of physical test methods among ASTM, CIPAC, OECD and DAPF, and will continue to revise and issue new CropLife International Technical Monographs. The revised Technical Monograph 2 "Formulation Codes" and also Technical Monograph 19 will be published on CropLife International's website.

Dr Eisert mentioned that the Manual was a good source of information and a dynamic document, but there were items they considered needed further revision. They would submit these items for consideration prior to the meeting. SEG would prefer to have a single source of information, because it was difficult to follow many versions and modifications. Sometimes there could be differing interpretations, e.g. shelf life, where there are formulations which are stable for many years. The text does not propose more than two years, but this does not mean that it cannot be granted.

If the full version is a five-year issue their proposal would be to review the document and include changes on an annual basis. CropLife International would like to see an annual review of the document.

The specifications were valid for solo formulations and not for mixtures, therefore it would be useful to have a note to that effect.

Following the request to supply study reports, Dr Eisert said that CropLife International would like to continue to reference where a registration is carried out.

Dr Gero Vaagt thanked him for his comments which the JMPS has discussed. Mr Hamilton would report on the issues under agenda item 13. In relation to the extension of the shelf life beyond two years, Dr Vaagt explained that FAO did not want farmers to buy cheap products and store them for a long time; their intention was to encourage farmers to buy pesticides only on an as-needed basis. The reasons behind the two-year shelf life included therefore also pest management issues. He mentioned that the Code of Conduct recommends to show also the release date, i.e., from the time when the product is put into the market the company guarantee lasts two years.

Dr Zaim mentioned that there were exceptions to what Dr Vaagt said, for example LNs; however, WHO fully agreed with FAO on the basic principle.

Dr Hänel confirmed his agreement with the two-year shelf life.

### **6.3 ASTM International**

Mr Alan Viets mentioned that since 1998 the American Society for Testing Materials (ASTM) had an application and formulation group. Collaboration with CIPAC started in 1995 during a meeting in Cyprus. ASTM would proceed with mutual recognition of methods and links are now appearing on the Websites. CIPAC and ASTM have now exchanged CDs containing methods.

Mr Viets gave a presentation on the current and future work of ASTM: EPA recommended OECD 422 repeat dose developmental and reproductive studies for Inerts; atmospheric availability of VOCs as alternative to TGA testing – working with the California Government to produce an ASTM method as the TGA method is fairly inappropriate. California DPR accepted the ASTM proposal to work on a solvent basis instead of a formulation basis, which greatly reduces the workload and allows ASTM to carry out in-depth studies on solvents. VOCs from pesticides have been reduced due to DOT and warehouse regulations. Alternative methods look promising and reflect reality better than the current TGA method. TGA results are predictably based on the composition of the formulation.

ASTM is developing an adsorption/desorption soil testing method of pesticides sprayed. Future meetings from 2007 to 2009 and symposia were mentioned

### **6.4 European Crop Care Association (ECCA)**

Mr David Van Hoogstraten presented a report on the activities of ECCA, which represents the generic manufacturers in the EU. ECCA had attended many FAO conferences on pesticide specifications and guidelines, and meetings dealing with the new proposal for pesticide regulation in the EU. [He mentioned that the ECCA website was used for distributing information.]

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

Dr Roman Macaya gave an introduction on ALINA, the Latin American Association of National Agrochemical Industries. ALINA represents the generic agrochemical industry in Latin America (generic companies from 16 countries in three regions).

ALINA promotes the cost competitiveness and sustainability of small farmers by promoting competition of high quality crop protection products, the most important cost item in most crops grown in developing countries. This has become increasingly relevant due to the proliferation of “North-South” Free Trade Agreements where small farmers in developing countries must compete with subsidized agriculture in developed countries. This relates to sustainability.

To illustrate this point, Dr Macaya presented the cost structure of many horticultural crops, rice, sugar cane, maize and other crops in Guatemala and Costa Rica. In almost all crops, pesticides are one of the major, if not the most important, production cost item. Data showed that, by 2005, when generic formulations had entered the market the total cost had dropped for both non- and generic products. Dr. Macaya stressed that one of the important objectives of this group (CIPAC-FAO-WHO) should be to ensure that agrochemicals on the market are of high quality and acceptable risk. However, one should not forget that decisions made by this group affect the livelihood of millions of small farmers in developing countries. Therefore, a balance needs to be reached in which a system is implemented that ensures not only quality and relative safety, but also market access to generics.

Dr Macaya stated that ALINA supports registrations by equivalence and listed the international activities ALINA has organized or participated in to support the FAO Code of Conduct and the implementation of functional registration systems. These activities include internal and external workshops, as well as speaker participation in India and China to encourage similar organizations to adopt functional registration systems by equivalence.

Despite the promise of clear, transparent and technically justified requirements for registering generic products by equivalence, the result has been a complete paralysis in most countries which have attempted to implement such a system.

Several countries have not registered a single generic product in several years, with one notable exception: Argentina.

Certain critical details determine whether or not a registration system by equivalence is functional:

- How products already on the market are treated when the system changes
- How the “reference product” (comparison product) is defined
- What is required of formulated products

Therefore, it is of the utmost importance that the registration authorities in developing countries implement registration systems by equivalence in such a manner that they are operational.

FAO has an important role to play in ensuring that countries following its advice to implement registration systems by equivalence achieve functional systems. Otherwise, the side-effect is commercial monopolies and higher costs to small farmers. ALINA proposes that an *ad hoc* committee be formed to discuss and finalize a comprehensive registration document encompassing all registration types, which ensures not only quality and relative safety, but also the necessary market access to generic agrochemicals without arbitrary barriers.

FAO-CIPAC-WHO should create a committee to work on guidelines. Draft Registration Guidelines had already been distributed by FAO prior to the November meeting of the FAO Panel of Experts on Pesticide Management for consideration. The next step should be the discussion of such Guidelines with all involved parties.

With regard to the equivalence of patents by ALINA, Dr Macaya stated that intellectual property would be covered by legal systems in that country but technical aspects needed to be covered.

Dr Vaagt and Dr Zaim confirmed the interest of FAO and WHO, where resources permitted, to assist Member States in capacity building for registration of pesticides, including principles of determination of equivalence.

Asked if equivalence covered technical products or the formulations, Dr Zaim referred participants to the Manual and stated that where the technical materials were equivalent and the specifications for formulated products the same, formulation equivalence could be given. However, there were exceptions for some formulated products, e.g. LNs, as noted in the header notes to the specifications.

## **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)**

Mr Denis Hamilton represented IUPAC and the IUPAC Advisory Committee on Crop Protection Chemistry. He reported on current projects being undertaken by IUPAC:

- Bioavailability of xenobiotics in the soil environment
- Impact of transgenic crops on use of agrochemicals and the environment
- Global availability of information on agrochemicals
- Crop Protection Chemistry in Latin America
- Glossary of pesticide-related terms
- Development of simplified methods and tools for ecological risk assessment of pesticides
- Critical review of available methods to predict VOC emission potentials for pesticide formulations

He also informed the meeting that a Glossary of Terms had been published which was also available on the IUPAC website.

The 3<sup>rd</sup> International Symposium on Pesticide and Environmental Safety and the 7<sup>th</sup> International Workshop on Crop Protection Chemistry and Regulatory Harmonization would be held in Beijing, PR China in October 2007. The six main topics for discussion were:

- Global views and harmonized approaches to pesticide regulation
- Pesticide residues in food and international trade standards
- Environmental safety assessment of pesticides
- Pesticide quality, manufacturing, specifications
- New pesticide discoveries and synthesis
- Formulation and application techniques

He reported that under the topic “Pesticide quality, manufacturing, specifications” the main discussion would be on: relevant impurities; equivalence; public health pesticides; FAO and WHO specifications; and industry perspectives.

### **6.8 European Food Safety Authority (EFSA)**

Mr Jeff Pim gave an outline of EFSA activities. He noted 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 to this there was some dissension within the EU over risk assessment.

EFSA is tasked with providing independent scientific advice on all matters with a direct or indirect impact on food safety and carrying 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.

He noted that EFSA carries out risk assessment and risk communication but not risk management.

EFSA consists of two groups: (i) the PPR panel which provides EFSA opinions to questions from the Commission, Member States, European Parliament as well as self-tasking, and (ii) the PRAPeR - Pesticide risk assessment peer review - which peer reviews Draft Assessment Reports prepared by Member States of the European Union. Fifty substances have been dealt with but 144 more need to be done by the end of 2008. Details of EFSA’s work are available on the EFSA website at [www.efsa.europa.eu](http://www.efsa.europa.eu) and for PRAPeR the website is [www.efsa.europa.eu/en/science/praper.html](http://www.efsa.europa.eu/en/science/praper.html)

### **6.9 International Programme on Chemical Safety (IPCS)**

Dr Antero Aitio presented information on PCS, the programme within the WHO for the promotion of chemical safety. He referred to a number of international conventions of relevance. PCS is involved in a range of areas including:

- WHO drinking water guidelines
- Poison information and acute poisonings
- Risk assessment

- JMPS
- Joint FAO/WHO Expert Committee on Food Additives (JECFA)
- WHO classification of pesticides by hazard
- Preparations for emergencies of a microbiological nature (now expanded to incorporate emergencies related to chemical substances)

He added that the International Programme on Chemical Safety (IPCS), established in 1980, is a joint programme between WHO, International Labour Organization (ILO) and UNEP, implementing activities related to chemical safety. WHO is the Executing Agency of the IPCS, whose main role is to establish the scientific basis for safe use of chemicals and to strengthen national capabilities and capacities for chemical safety.

#### **6.10 Pesticide Manufacturers and Formulators Association of India (PMFAI)**

No representative was present at the meeting.

#### **6.11 Other**

No other organization offered a report.

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

The following country reports (see Annex 1), including any collaborative studies in which they participated, were presented:

Argentina, Belgium, P.R. China, Czech Republic, Denmark, El Salvador, France, Germany, Greece, Hungary, Ireland, Italy, Japan, the Netherlands, Romania, Slovak Republic, Slovenia, Spain, South Africa, Switzerland, Thailand, Ukraine, United Kingdom and USA.

Questions and comments:

1. The report of quality control laboratories in the USA is prepared by each State separately and there is no compiled report. CIPAC studies - the USA participated in the dodine collaborative study.
2. Romania asked about the possibility to use collaborative trials also for checking laboratory performance as accreditation bodies require participation in proficiency tests. The question will be the initiation of a discussion on collaborative trial at the CIPAC meeting on Wednesday.
3. Dr Zaim discussed the statistics on data presented by national laboratories at the meeting and on the number and range of non-compliances shown by the data.

## **8. Proposed new/amended specification guidelines**

### **8.1 Revision of guidelines for TC/TK**

Dr Vaagt presented the background of the proposal to replace TC and TK with Technical Grade (TG) introduced by Mr Alan Hill in the previous meeting. The members of JMPS had suggested to FAO and WHO to continue using the existing definitions in the Manual.

### **8.2 Determination of equivalence**

Mr Denis Hamilton gave a summary presentation on how the JMPS sees the issue and made a proposal: "How can we improve the process".

Mr Hamilton referred to the Code of Conduct which defines equivalence broadly as: "the determination of the similarity of the impurity and toxicological profiles, as well as of the physical and chemical properties, presented by supposedly similar technical material originating from different manufacturers, in order to assess whether they present similar levels of risk."

He noted that the idea was to determine:

- if a second technical material contains no new impurities and no existing impurities at significantly higher levels than in the reference profile; and
- if its toxicological and ecotoxicological properties were within tolerance of the existing profiles.

He added that the issues to be addressed were:

- Whether the new material meets the existing specification
- In the manufacturing process, whether the by-products were expected to be similar in the two processes
- Comparison of the manufacturing specification limits determines if the impurity profiles are equivalent. If differences exceed stated tolerances (> +3 g/kg or > +50%, whichever is the greater), there may still be reasons for deciding that the technical materials are essentially equivalent
- Relevance or non-relevance should be determined for new impurities appearing at concentrations exceeding 1 g/kg, and for any at <1 g/kg if they present an exceptional hazard

Mr Hamilton added that the considerations applied to synthetic organic materials and that other approaches might be needed for biologicals, botanicals and inorganic substances.

He added that as the JMPS meets once a year, the evaluation must be such as to proceed without a tiered process and the data package must contain all required documentation at the time of submission. He pointed out that transparency of process, scientific judgment and common sense should operate in company with general guidelines. Animal toxicity testing should be no more than absolutely necessary. High consideration should be given to data validity and data quality (GLP).



Mr Hamilton also noted the following considerations:

- From the process of synthesis, the anticipated or expected list of impurities.
- Basis for the QC limits – recent or long-term experience, one or more than one manufacturing site.
- Five-batch analysis – it was necessary to clarify when the batches were produced and the quality of data was sometimes not evident.
- Toxicity testing must reflect the toxicity properties of what is present. It may also be used to confirm that there are no unidentified “surprise” significant impurities.
- Toxicity testing is imprecise. It is less useful if active ingredient is highly toxic.

Mr Hamilton proposed that equivalence determination should be made primarily on the basis of chemical composition and mutagenicity testing, and that the following information should be provided on the composition of the technical material:

- a) List of impurities expected from the synthesis procedure and the starting materials (and their impurities). Sometimes impurities are in the starting materials;
- b) Which compounds were looked for and not found (and LOQ);
- c) Basis for the manufacturing QC limits;
- d) Analytical data on five batches, reasons for choice of those five batches, quality and validity of five-batch analysis data.

It should be recognized that, for specific cases, animal toxicity testing may be necessary.

Dr Eisert thanked him for the presentation and pointed out that industry still understood it as a tiered approach; it might happen that more time was needed as one year might not be sufficient. If analytical data were not equivalent there was a need for more toxicity data which may not be available. Mr Hamilton said that the intention was to be ready for one shot.

Mr Hamilton confirmed that equivalence determinations had to go through a JMPS meeting and discussion in the meeting was needed to ensure consistency.

If sufficient data were presented it should go through the process in one year and it would go through in one shot, without the need for more toxicity testing. It has already been through a national registration process so it should go through equivalence in one shot.

Dr Woods noted that Mr Hamilton’s proposal was basically consistent with the CropLife International proposal. He asked whether a statement would be requested if the synthetic pathway might lead to the formation of toxic compounds.

Mr Hamilton confirmed that it would, but toxic compounds may also arise as impurities from the starting material, not only from the synthetic pathway. Sometimes the impurities were strange and not really explainable from the reaction scheme.

Mr Viets asked about compounds looked for but not found. Mr Hamilton said that the starting materials and the synthetic pathway suggested possible impurities. The

results of analyses for such impurities should be reported if such analyses were done.

Mr van Hoogstraten suggested a similar completeness check to that carried out by the registration authorities, so that the evaluation could be completed in the same year.

Mr Hamilton agreed that this was possibly a good idea, but the answer should be given by FAO/WHO as it was difficult for somebody who was not a chemist to judge. Probably this issue could be covered by the list of studies to be submitted.

Mrs Hourdakís pointed out that these questions were not points for initial checking, but cropped up during the evaluation.

Dr Macaya asked if the mutagenicity data would be included as additional information required or whether they would have to be submitted with the five-batch, as he had not seen the methods. He was informed that toxicity data supplied with five-batch analyses, mutagenicity perhaps later, and the question of methods is hidden under the quality of data.

It was questioned whether the proposal was adopted. This would be discussed at the closed meeting after the open meeting. No decision had been taken and the result would be communicated to interested parties.

## **9. Status, review and publication of CIPAC methods**

### **9.1 Handbooks and pre-published methods**

No new handbook had been published in 2006 nor would there be one in 2007. The pre-published method scheme would be available very shortly.

### **9.2 CIPAC method review process (information)**

Dr Markus Müller presented the review process carried out by CIPAC in identifying the obsolete methods. The use of such methods is no longer encouraged by CIPAC, and the criteria for calling a method obsolete are, e.g., where the columns, reagents were no longer available, or where the a.i. was on the PIC list, or for which no more FAO/WHO specifications exist. The topic would be discussed in more detail during the CIPAC technical meeting on Wednesday 13 June 2007.

Outcome of review 2006 – Handbook 1B.

There were 25 obsolete methods, and of the compounds only amitrole and chlorpropham were in use. These methods were possible candidates for a renewal.

Twenty-six compounds had no FAO specifications, but several such as brodifacoum (AOAC based on HPLC), captan (normal phase HPLC) and bromoxynil-octanoate were still in use. Methods for PIC compounds and mixtures were obsolete.

A list of obsolete methods from handbooks 1B and 1C was available on the CIPAC website.

AOAC gave CIPAC the lead and so 14 methods were declared obsolete, 17 compounds with methods referred to in FAO specifications, from alachlor to thiophanate-methyl were up for review and metolachlor(-S) as candidates for renewal.

Obsolete methods would be listed in a negative list of CIPAC method and classified “no longer supported”. The next steps were to (i) publish the obsolete list, with explanatory notes and (ii) Handbook E to be reviewed in 2008.

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

### **10.1 Proposal for a CIPAC Guidance document for LN formulations (information)**

Dr Markus Müller presented a CIPAC Guidance document for LN formulations. A document was needed as in the last two years there had been an increasing number of LN types proposed for specifications. There was a gap between LN guidelines and CIPAC guidelines and it was difficult for companies with a textile background to understand these guidelines. The document would be discussed in detail during the CIPAC meeting, and comments and proposals were welcome.

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

### **11.1 Status of FAO Specifications**

Dr Gero Vaagt provided an overview of the status of the FAO specifications. His presentation focussed on those specifications which were finalized in 2006 and 2007, those close to finalization and those for which certain information was still outstanding (for further details see Annex 3).

### **11.2 Status of WHO Specifications**

Dr Zaim noted that, since the establishment of the FAO/WHO Joint Meeting on Pesticide Specifications in 2002, about 108 submissions had been made to the JMPS under the new procedure. Almost half have been for the development of FAO specifications and use in the agricultural sector, the remainder being for joint or WHO specifications only.

He added that the majority of compounds and products submitted for WHO specifications during 2002-2005 had been finalized and published (see Annex 4). This included the more recent publication of the evaluation report and specifications for *Bacillus thuringiensis israelensis*. He also noted that the evaluation report on temephos was ready for publication, but the specifications would not be published until the analytical method for impurities had been validated. The evaluation report and the specifications for alpha-cypermethrin LN were pending.

### **11.3 FAO/WHO Joint specifications**

Dr Zaim noted that, except for bifenthrin which was reviewed in 2004 and the evaluation report and the specifications which were still pending, all other compounds for joint FAO and WHO specifications submitted during 2002 and 2005

had been completed and published. He also noted that the evaluation report and specifications for the majority of compounds submitted in 2006 were expected to be finalized by the end of summer 2007 (see Annex 5).

Dr Zaim also noted that over half of the submissions to the JMPS during the period 2002-2007 had been by the leading companies of CropLife International (i.e. BASF, Bayer, DOW, Dupont, FMC, Sumitomo and Syngenta). The number of submissions from other manufacturers had also reached significant levels.

#### **11.4 Withdrawal of FAO Specifications**

FAO specifications developed under the old procedure, for which methods for the determination of impurities for a specification could not be provided, would be withdrawn due to the lack of the necessary information for quality control of the product.

FAO had announced the procedure for withdrawal of specifications and had written to ALINA, CropLife International, ECCA, ICAMA and PMFIA about its intention and included the list of the 31 active ingredients with the respective impurities.

Information had been received from CropLife International and WHO for five compounds - diazinon, fenitrothion, lindane, metolachlor and profenofos.

If no further information were obtained FAO would withdraw the 26 compounds listed in Annex 6. This would also be announced through AGROW, Crop Protection Handbook, Pesticide Management Update, etc. There were two ways to proceed:

- Companies would come forward with the applicable methods for the impurities of the specifications, or
- Companies would propose the development of specifications under the new procedure, which would be the preferred option for FAO.

Mr Ed van der Wal asked if these specifications had been withdrawn because no methods were available for the impurities of the active ingredients, what about the formulations. FAO will withdraw not only the TC specifications, but also the specifications for the formulations containing the active ingredients and the impurities.

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

Drs Zaim and Vaagt presented the *DRAFT* priority list for JMPS 2008 (see Annex 2) in three different categories: (1) original proposer; (2) subsequent proposer(s); (3) specification for formulation. They stated that there were 10 submissions as primary proposers, eight for FAO specifications and two for FAO/WHO Joint Specifications. There were also eight submissions for determination of equivalence (subsequent proposers), two for FAO specifications, one for WHO specifications and the rest for

FAO/WHO Joint Specifications. There was also one submission for establishment of WHO specifications for formulated product.

Dr Zaim noted that FAO and WHO would write to the listed companies requesting them to provide the list of studies in support of their submissions, before the submissions and the list of compounds/products for JMPS 2008 were finalized. From 2009, however, FAO and WHO would only accept proposals for inclusion in the work of JMPS if the list of studies had been submitted with the request at the beginning. In addition and from 2008, the reports for all physio-chemical studies should be submitted.

CropLife asked if it would be possible to see the list as it developed through the year. This would be taken into consideration. Industry was requested to keep FAO and WHO informed of its priorities.

### **12.1 Proposal for the FAO/WHO Programme**

Dr Vaagt stated that the proposals for FAO/WHO programmes were normally made by the pesticide manufacturers, but could also be initiated by JMPS, FAO or WHO. They could also be initiated by governments for equivalence determination, or on specific requests, e.g. formulations sold in a country where no specifications were available and it was impossible to judge in the absence of an independent international reference. The basic idea was to make this known to government authorities and to make the process more interactive with national governments. The data submission rests always with the manufacturer(s). The proposal would be available for observation and comment.

## **13. Any other matters**

**3.1 Requirement: list of studies** – it was discussed whether the list of studies should be provided with the data package on the compound.

**13.2 Communication regarding confidential information** – confidential information was to be sent in hard copy and electronically (CD-Rom).

### **13.3 Default or low values for physical and chemical properties**

Mr Hamilton informed the meeting of the JMPS's concern that in many recent draft specifications proposed by industry the lowest acceptable limits (the default values) for physical properties of formulations had been proposed.

He emphasized that the proposed values for physical properties should be derived from measured values and supported by relevant data. He reiterated that the specification values should be "as good as reasonably achievable" and noted that some proposers were not carrying out tests but just simply using the default values.

Dr Woods remarked that the reason why the worst case was selected was because the JMPS did not accept competitive ones, but he welcomed the proposal.

Mr Hamilton said that there are many specifications where default values were not proposed.

Mr Jean-Philippe Bascou said he felt uncomfortable with the proposal because there might be difficulties with the authorization bodies.

Dr Eisert said that companies were faced with the dilemma that the specification should cover many products, sometimes older ones and new ones, and if the specifications were tightened, they might need to revisit them more frequently. Croplife wanted the specifications to be broader to allow for any future changes and for new products to be introduced.

Dr Zaim noted that it was impossible to accommodate the requirements of all registration authorities. FAO and WHO wished to set the highest possible standards for pesticides and encourage national authorities to adopt them. He reiterated that there was no justification for always using default values.

Dr Grohs said that it was in the interests of both industry and the JMPS to set a certain standard. It was necessary to recognize that major improvement in quality had shifted to the a.i, and the formulation no longer seemed so important. Under the old procedure, the formulation was the important consideration. He questioned what was gained by high limits. Where specifications were recognized or were part of the registration process, it was counter productive in the EU to have an FAO specification.

Dr Macaya said that there were two balancing arguments, one economic, the other qualitative. He suggested that there was a danger of it becoming a specification to have the best specification and that written comments should be requested.

Mr Viets said that the persistent foam test did not match field conditions. He stated that foam in the laboratory did not mean the same thing as foam in the field and noted that the foam test was rather poor.

Mr Hamilton said that it was a compromise between what is achievable and what is acceptable, but the recent tendency seemed to be towards the default values.

Mr. Hamilton thanked people for comments but thought that the tendency for many specifications to be proposed at default values was not ideal. He suggested that the issue should be sent out to companies and other parties for comment.

There was a general comment that some properties were not very useful.

#### **13.4 Mixtures, how to address these in the future**

Mr Hamilton gave two examples of specifications that did not seem to make sense for a single compound, e.g. technical material existing as a suspension and an emulsion:

Suspo-emulsions - Description: The material shall consist of a suspension of fine particles of technical material in the form of a suspension, combined with an

emulsion of fine droplets of technical material in an aqueous phase, together with other suitable formulants.

Oil-based suspension concentrate (OD) – Description: The material shall consist of a stable suspension of technical material in a non-aqueous fluid together with suitable formulants.

It is understood that these formulations are intended for mixed active ingredients. So the question is - What is the way forward?

Dr Vaagt said industry was invited to make comments. Proposals should be received by 31 October 2007, which would help in the preparation of the next meeting. An invitation to make comments on the improvement of the Manual was extended to all members involved, academia and others.

Dr Woods noted that it was understood that after the proposals for the equivalence, industry would have the possibility of discussing the proposals with the JMPS.

The JMPS decision would be communicated to stakeholders and if necessary discussions initiated, as was the case of the Wädenswil meeting. It would be appreciated if comments were received by end of March 2008. In addition, proposals for JMPS discussion should reach the Secretariat by 15 March 2008.

### **13.5 Retirements**

Dr Vaagt announced the retirement of two JMPS members: Mr Rudolf Schreuder and Mr Günter Menschel. He thanked them for their contributions to the work of the JMPS and for their efforts on the development of specifications and methods for use all over the world and presented them with an FAO Medal.

Dr Zaim also thanked them for their distinguished contribution and said that it had been an honour to have worked with them.

Dr Vaagt and Dr Zaim also expressed their thanks for the excellent work and friendship of Dr Thomas Woods who retired this year from CropLife International. He would be missed by all.

### **14. Date and venue of next meeting**

Dr Ralf Hänel invited everyone to the next meeting which was scheduled to take place from 5 to 13 June 2008, in Braunschweig, Germany

**Annex 1. Summary table of national reports of official quality control laboratories**

REGION	REPORTING LABORATORY	NO. OF SAMPLES TESTES	NON-COMPLIANCE	
			No.	%
Africa	South Africa	133	9	7
Americas	Argentina	1021	22	2
	El Salvador	627	13	2
Europe	Belgium	106	15	14
	Czech Republic	57	13	23
	Denmark	68	7	10
	France	74	20	27
	Germany	215	42	20
	Greece	302	27	9
	Hungary	906	80	9
	Ireland	37	1	3
	Netherlands	31	0	0
	Romania	558	58	10
	Slovakia	120	11	9
	Slovenia	20	0	0
	Spain	218	40	18
	Switzerland	94	58	62
	UK	70	20	29
Ukraine	342	46	13	
Asia	China	800	120	15
	Thailand	5180	74	1
<b>Total</b>		<b>10979</b>	<b>676</b>	<b>6</b>



**Annex 2. Programme for development of FAO and WHO Specifications for pesticides**

<b>Year</b>	<b>Products</b>	<b>Proposer(s)</b>
<b>2008</b>	<b>FAO:</b> Carbosulfan 1-methylcyclopropene Cyprodinil Fipronil TC, TK, EC, FS, SC, UL and WG Haloxypop-P-Methyl TC, EC Indoxacarb Mefenpyr-diethyl Nicosulfuron Pendimethalin	(1) FMC (1) Rohm and Haas France SAS (1) Syngenta (1) BASF/Bayer; (2) Gharda Chemicals (1) DAS (1) DuPont (1) Bayer (2) ISK Biosciences Europe (1) Finchimica
	<b>WHO:</b> Lambda-cyhalothrin coated LN Deltamethrin incorporated LN Temephos TC, EC, GR	(3) Syngenta (3) Intelligent Insect Control (2) Gharda Chemicals
	<b>FAO &amp; WHO:</b> Alpha-cypermethrin TC, SC, WP  Bifenthrin TC, WP Chlorpyrifos TC, EC Deltamethrin Deltamethrin TC, SC, WP Lambda-cyhalothrin TC Permethrin TC, EC	(2) Gharda Chemicals; Meghmani Organics (1) FMC (2) Gharda Chemicals (1) Bayer (2) Gharda Chemicals (2) Heranba (2) Tagros; Gharda Chemicals

(1) Original proposer; (2) Subsequent proposer(s); (3) Specification for formulation

### Annex 3. Status of publication of FAO specifications

JMPS (year)	COMPOUND	MANUFACTURER	STATUS
2002/2003	Azadirachtin	Fortune	Partly published
	Azadirachtin	Trifolio	Published 2006
	Hexazinone TC, SP, WG, GR, SL	Dupont	Published 2006
	Imidacloprid	Bayer	Published 2006
	Iprodione	Bayer	Published 2006
	Maleic hydrazide TC, TK, SL,SG	Crompton	Evaluation only
	Imidacloprid	Bayer	Published 2006
2004/2005	Clofentezine TC, SC	Makhteshim	Published 2006
	Copper , cupric hydroxide and oxychloride (to include copper calcium oxychloride), Bordeaux mixture, tribasic copper sulphate and cupric oxide	European Union Copper Task Force	To be finalized for publication
	Diquat dibromide, SL	Syngenta	Published 2006
	Ethofumesate TK,SC,EC,SE,OD	Bayer CropScience	Published 2006
	Pendimethalin TC,TK,EC	Industria Prodotti Chimici	Rescheduled to JMPS 2008
	Prochloraz TC, EC, SC	Makhteshim	To be finalized for publication
	2006	Carbaryl TC, WP, SC	Bayer
Clodinafop propargyl TC, EC, WP		Syngenta	To be finalized for publication
Chlorothalonil TC		Sipcam Agro USA, Inc	To be finalized for publication
Clofentezine TC, SC		Makhteshim	Published 2007
Fosetyl-AI TC, WG, WP		Bayer	Pending information from company
Propanil TC		Proficol, S.A	Rescheduled for 2007
Propaquizafop TC, EC		Makhteshim	Evaluation only to be published
2007	Deltamethrin	Agros-Tagros/ Bayer CropScience/ Herbanda/ Vestergaard Frandsen	Published 2007
	Pirimphos Methyl	Syngenta	Published 2007

#### Annex 4. Status of publication of WHO specifications

<b>JMPS (year)</b>	<b>COMPOUND</b>	<b>MANUFACTURER</b>	<b>PUBLICATION</b>
2002	D-ALLETHRIN	SUMITOMO	March 2004
	D-PHENOTHRIN	SUMITOMO	October 2004
	PRALETHRIN	SUMITOMO	November 2004
	TRANSFLUTHRIN	BAYER	November 2006
2003	ESBIOTHRIN	SUMITOMO	October 2004
	BIOALLETHRIN	SUMITOMO	May 2005
	TRANS-CYPHENOTHRIN	SUMITOMO	September 2005
2004	BACILLUS THURINGIENSIS	VALENT	June 2007
	DELTAMETHRIN LN	VESTERGAARD	July 2006
	ICARIDIN	BAYER	October 2004
2005	IR3535	MERCK	February 2006
	PERMETHRIN LN	SUMITOMO	July 2006
	S-BIOALLETHRIN	SUMITOMO	March 2006
	PERMETHRIN/S-BIOALLETHRIN	BAYER	November 2006
	TEMEPHOS	BASF	June 2006
2006	ALPHA-CYPERMETHRIN LN	BASF	--

## Annex 5. Status of publication of joint FAO and WHO specifications

JMPS (year)	COMPOUND	MANUFACTURER	PUBLICATION
2002	NICLOSAMIDE	BAYER	January 2004
	CHLORPYRIFOS	DAS, MAKHTESHIM	October 2004
2003	DELTAMETHRIN	BAYER	April 2005
	LAMBDA-CYHALOTHRIN	SYNGENTA	January 2004
	CYFLUTHRIN	BAYER	November 2004
	PROPOXUR	BAYER	October 2005
	NOVALURON	MAKHTESHIM	December 2004
	MALATHION	CHEMINOVA	September 2004
2004	BIFENTHRIN	FMC	--
	DELTAMETHRIN	BAYER	April 2005
	DIFLUBENZURON	CROMPTON	April 2005
	DIMETHOATE	CHEMINOVA	APRIL 2006
	FENTHION	BAYER	December 2006
	PIRIMIPHOS-METHYL	SYNGENTA	April 2006
2005	ALPHA-CYPERMETHRIN	BASF/TAGROS	April 2006
	DELTAMETHRIN	TAGROS	April 2006
	PERMETHRIN	SUMITOMO/TAGROS	--
	PYRIPROXYFEN	SUMITOMO	July 2006
	SPINOSAD	DAS	January 2006
2006	CHLORPYRIFOS	CHEMINOVA	--
	DELTAMETHRIN	HERANBA	--
	DIMETHOATE	JSC TRANS OIL	--
	ETOFENPROX	MITSUI	--
	RS-METHOPRENE	BABOLNA	Evaluation only (February 2007)

## Annex 6. Withdrawal of FAO Specifications developed under the old procedure

Specification	Year of publication	Methods not available from FAO
acephate	1996	Methamidophos O,O,S-trimethyl phosphorothioate Acetamide
aldicarb	1988	Aldicarb Oxime Methyl Isocyanate Trimethylamine Aldicarb Nitrile Dimethylurea + Trimethylbiuret
aluminium phosphide	1990	Arsenic
bifenox	1994	Dichlorophenol Dichloroanisole
captan	1990	Perchlormethylmercaptan
carbosulfan	1995	Carbofuran
cyanazine	1988	(4-amino-6-chloro-1,3,5-triazin-2-ylamino)-2-methyl propionitrile (4,6-dichloro-1,3,5-triazin-2-ylamino)-2-methyl propionitrile Simazine Inorganic chloride Loss on drying at 70 <sup>0</sup> C (under vacuum) to constant weight Chloroform insolubles
dichlorprop	1994	Free phenols Triethanolamine insolubles
dichlorprop + MCPA	1984	NO TECHNICAL BUT AQUEOUS SOLUTIONS
dichlorprop + mecoprop	1984	NO TECHNICAL BUT AQUEOUS SOLUTIONS
dicofol	1995	DDT and DDT-related impurities
dinobuton	1984	Loss on drying Potassium chloride
edifenphos	1995	3.1 O,O-diethyl S-phenyl phosphorothioate 3.2 Thiophenol
fenoprop + mecoprop	1979	Free phenols
fentin acetate	1988	Inorganic tin
fentin hydroxide	1988	Inorganic tin
magnesium phosphide	1990	Arsenic
MCPA	1994	Triethanolamine insolubles
MCPA + MCPB	1984	NO TECHNICAL BUT AQUEOUS SOLUTIONS

Specification	Year of publication	Methods not available from FAO
MCPB	1984	Free phenols
mecarbam	1984	Ethyl-N-methyl-N-chloroacetylcarbamate Ethyl-N-methyl carbamate Methyl oxazolid-2,4-dione S-Triethylphosphorothiolothionate 0,0-Triethylphosphorothionate
mecoprop	1984	Free phenols Triethanolamine insolubles
metam-sodium	1979	NO TECHNICAL BUT AQUEOUS SOLUTIONS
monocrotophos PIC	1988	Trimethyl Phosphate
Propargite	1984	Active Ingredients
propineb	1980	Arsenic
thiodicarb	1997	Methomyl
thiophanate- methyl	1995	2,3-diaminophenazine 2-amino-3-hydroxyphenazine
triadimefon	1995	4-chlorophenol
triflumoron	2000	N,N'-bis-[4-(trifluoromethoxy)pheny] urea Water (MT 50.5, CIPAC I, to be published)
trifluralin	1988	N-nitroso-di-n-propylamine