SIXTH JOINT CIPAC/FAO/WHO OPEN MEETING

(53rd CIPAC Meeting and 8th JMPS Meeting)

Hotel Decameron Salinitas, El Salvador

8 June 2009

Summary record of the meeting

Agenda

1. Opening and welcome

Ms Elisabeth Aguila, representing the Minister of Agriculture or "Ministerio de Agricultura y Ganaderia (MAG), chaired the opening ceremony and introduced the special guests. These were Mr José Benites (FAO Representative El Salvador), Mr Allan Hruska (FAO Plant Protection Officer of Central America & the Caribbean), Mr Edwin M Aragon (Representative of the "Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA) in El Salvador) and Ms Priscilla Rivas-Loria (World Health Organization Representative in El Salvador).

Mr Edwin M Aragon (Representative of OIRSA in El Salvador) welcomed everyone and said it was a privilege to be here at the Open Meeting, where there is a gathering of more than 75 experts on specifications of pesticides here in Central America. He informed everyone about his organization OIRSA, which is an international organization, including Agricultural sanitation, plant and animal health, and food safety. It was founded in 1953, and is made up of 9 nations. OIRSA has connections with other organizations, all to benefit agriculture and sanitation. It also has established links with FAO and WHO, and Regional Organisations. Working with Elisabeth on pesticide specifications advances both the regions and countries analytical capability and Mr Aragon hopes you will have a good meeting. He thanked everyone for their support.

Mr José Benites (FAO Representative, El Salvador) welcomed everyone present to the meeting, on behalf of the FAO of the UN. He thanked the Government of El Salvador for hosting meeting, as well as Elisabeth de Aguila and her team for all their efforts. He mentioned that this meeting on pesticide specifications was the first one of its kind in Central America, so many participants from all over the world confirmed the importance of the FAO/WHO specifications and the relevance of pesticide quality. The issue of pesticide quality is of the highest relevance today for the farmers, for the consumers, for the development of the agricultural sector and for the protection of human health. The sub-standard quality of pesticides is of great concern to country regulators, and about 30% of pesticides do not meet the standards in the developing countries, and 14-27 % non-compliance pesticide products in industrialization countries. These substandard pesticides result in enormous financial losses and possible adverse effect for users and in term of efficacy and the environment. Since 1963, the FAO has contributed to pesticide quality. More than 300 FAO/WHO pesticide specifications have been established. Since 1992 the FAO equivalence procedure has assisted with the protection of human health and the environment. With the increase in international trade, more pesticide specifications are expected. The resolution of the FAO is a new commitment to fight against food insecurity, hunger and malnutrition. The FAO/WHO specifications make an important contribution to improve food availability and enhanced food safety. In this context, the work of JMPS is of ever increasing importance. Mr Benites further pointed out that FAO is very supportive of the JMPS. Pesticide quality control as well as the Code of Conduct is most important. FAO encourages that the FAO/WHO Manual be followed. FAO will continue working closely with WHO and CIPAC in improving the development and implementation of FAO/WHO Specifications and the adoption of equivalence determination pr ocedures at the national and regional level. This Open Meeting that is now in its 6th year is most unique. He hoped that this good collaboration would continue.

Dr Priscilla Rivas-Loria, the WHO Representative in El Salvador welcomed the participants to the 6th CIPAC/FAO/WHO Joint Open Meeting and to the 8th FAO/WHO

Joint Meeting on Pesticide Specifications. She thanked the Ministry of Agriculture and Animal Health for their kind agreement to host the meeting in El Salvador and for facilitating the meeting. She also extended the sincere thanks of WHO to Ms Elizabeth C. de Aguila of Pesticide Laboratory of the Ministry of Agriculture for her excellent preparations and for her warm hospitality.

Dr Rivas-Loria stated that capacity strengthening for sound management of pesticides is on WHO and the Pan American Health Organization (PAHO) high priority in the region, as well as in El Salvador, and the topic of this meeting which deals with standard setting for quality control of pesticides is of great importance.
She noted that vector-borne diseases such as malaria, Chagas disease, leishmaniasis and dengue are of public health significance in the region, and two of those (Chagas and dengue) are endemic in El Salvador and are often cause of outbreaks in recent years. In El Salvador, she noted, the use of insecticides has been the principal and preferred method for the prevention and control of vector-borne diseases. It is only recently with the implementation in 2004 of the Regional GEF-funded Project for Malaria Vector Control Without the use of DDT that the national authorities have initiated the use of alternatives and more environment friendly actions to control vector borne diseases.

Dr Rivas-Loria noted that a significant amount of insecticides is also used in agriculture in the region and their impact on human health and environmental safety is of great concern to WHO.

As a result, she added, WHO has intensified its support to the Member States, in recent years, for sound management of public health pesticides. Availability of good quality pesticide products is of significance to our efforts in minimizing the health risks associated with handling and use of these chemicals.

She also noted that WHO has strengthened its collaboration with FAO and with UNEP, in different areas of pesticide management at the global level, and that she hopes to see that the same inter-sectoral approach to management of pesticides, including their quality control is exercised at the country level. While collaboration between health, agriculture and environment sectors is of prime importance to management of pesticides, she noted, such collaboration is not adequate in many developing countries.

WHO has also intensified its country support for sound management of public health pesticides through mobilizing resources for comprehensive situation analysis and needs assessment in 12 priority countries, based on which a national action plan will be developed through a multi-stakeholder and multi-sectoral approach. Two of these countries are in the Americas. These are Ecuador and Guatemala. WHO hopes that the experiences gained in these countries and the positive outcome will attract further investment by donor agencies in this important area of work. WHO also hopes to share the lessons learnt from this activity with other Member States like El Salvador.

WHO wishes to thank the individuals and the organizations represented in the meeting for their valuable support to the work of the Organization as it relates to quality control of pesticides and to pesticide management in general. This includes, she added, the kind support of registration authorities in comparison of confidential data submitted to JMPS with that used for registration of pesticides in their country - which is greatly appreciated by WHO.

Dr Rivas-Loria wished participants a successful and productive meeting and a pleasant stay in El Salvador.

Mr Allan Hruska (Plant Protection Officer of Latin America & the Caribbean) welcomed everyone on behalf of the regional office of FAO. He introduced that the sub-regional office was established recently in Panama for strengthening the FAO work in this region. He highlighted the importance of this meeting, and that FAO, WHO and CIPAC could learn from the audience. This collaboration between the FAO, WHO, and CIPAC is very helpful to the Region for the quality control of pesticides, as well as for the enhancement of awareness of the commercial companies who are dealing with pesticides. As the Region is very challenged with pesticide registration, it is important to know how to take advantage of this collaboration and amplify it with more training events, etc from this wealth of expertise. and help those registration authorities with their processes. The Region has lots of challenges and there is more work to do. FAO has prepared to hold a sub-regional workshop in Panama in October on pesticide specifications, the determination of equivalency, and their use in pesticide registration. Mr Hruska hopes that the region can be benefit from this meeting in improving the implementation of the FAO/WHO specifications and JMPS principles.

Dr Ralf Hänel, Chairman of the Collaborative International Pesticides Analytical Council Ltd (CIPAC), welcomed everyone, and said that the Meeting was taking place for the first time here in El Salvador and in Central America. He mentioned that this Meeting would also improve everyone's understanding of the agricultural situation in Central America. He looked forward to the continuation of the co-operation in the development of analytical methods and pesticide specifications. Dr Hänel thanked the Minister of Agriculture of El Salvador and OIRSA, as well as Elizabeth de Aguila and her team for hosting the meetings.

Ms Elisabeth de Aguila, the National Co-ordinator of this meeting, welcomed everyone present and that the meeting in El Salvador will be very special. She said it was regretted that the Minister of Agriculture could not be here today, but he sent his apologies. Ms de Aguila said that she was addressing everyone on behalf of the Minister, and extended a warm welcome to everyone, hoping that this congress has satisfactory outcomes. She declared this meeting officially inaugurated and the 6th joint FAO/WHO/CIPAC meeting officially open.

2. Arrangements for chairmanship and appointment of rapporteurs

Dr Morteza Zaim, WHOPES, WHO, welcomed everyone to the 8th joint CIPAC/FAO/WHO Open meeting. He noted that the Chairmanship of the Open Meeting rotates between the three organizations (FAO, WHO and CIPAC). This year it was the turn of WHO to facilitate the meeting, with Dr Morteza Zaim as Chair.

Madam YongZhen Yang**,** FAO Joint Secretary of the Joint Meeting on Pesticide Specifications (JMPS), welcomed everyone and said it was good to see everyone again. She also welcomed her predecessor, Dr Gero Vaagt, the FAO representative in Nicaragua, who attended the meeting.

Dr Gero Vaagt thanked everyone for coming to this part of the world, Central America, for the meeting and said that this was important for the work of FAO and WHO. He also congratulated Elisabeth for organising the event.

Dr Zaim said that three rapporteurs were proposed: Mr Steve Funk (FAO), Mr Tony Tyler (WHO) and Dr Eric Sandmann (CIPAC), and they were duly appointed.

Rapporteurs were thanked for their support.

3. Adoption of the agenda

The following changes were made to the agenda, namely, in Item 6, changes were made to the order of presentation of the reports, and Item 11.5 "Other Matters" was added, originating from the JMPS Closed Meeting. There being no objections, the Minutes of the last CIPAC/FAO/WHO Open Meeting (2008) were accepted.

The minutes of this meeting (the 6th Open Meeting) should be published by the end of August.

4. Summary record of the previous meeting

4.1 Fifth Joint CIPAC/FAO/WHO Open Meeting; 52nd CIPAC Meeting; and 7th JMPS Open Meeting, Braunschweig, Germany

The summary record of the previous open meeting, held at the Federal Office of Consumer Protection and Food Safety (BVL) in Braunschweig, Germany on 9 June 2008, was published in August 2008 and is available on the FAO/WHO web site. By the end of August this year, the report on the 6th Open Meeting is expected to be available on the website. There being no objections, the Minutes of the last CIPAC/FAO/WHO Open Meeting (2008) were accepted.

Dr Zaim informed the meeting that in future no hard copy of the report of the open meetings will be made available at the meeting and that participants are requested to refer to the web site of the three Organizations for the report. He noted that the minutes of this meeting (the 6th Open Meeting) is expected to be published by the end of August 2009.

5. Summary of actions taken after the 52nd CIPAC and 7th JMPS meetings

5.1 CIPAC

Dr Hänel mentioned that Handbook M was to have been published in the second half of 2008, but due to some delays, should be published shortly. A review has been done on Handbooks 1A to E (see point 9.1) as well as on CIPAC methods on LN formulations.

A document on Guidelines of Relevant Impurities will be mentioned under item 9.3.

It is hoped that the harmonised washing method of LN formulations will soon come to an end (see item 10). The reason why it has taken so long was attributed to the issue of the calibration of the method, to be able to make use of the already generated data.

The review process of MT methods is ongoing, with good co-operation with ASTM.

Dr Hänel was happy to inform everyone of the existence since last year of the English-speaking PAC. The chairman of the ESPAC is Jim Garvey from Ireland.

5.2 FAO

Madam Yang informed the meeting of the activities and events that the FAO had participated in, documents which FAO had published and improvements in the management of pesticides for agricultural use by increased analysis of pesticides to assess compliance with the international specifications.

Meeting and Workshops

(i) 6-7 November 2008 - The 28th Japan Agricultural Formulation and Application Symposium; in Tsukuba;
(ii) 10-14 November 2008 - The 9th National Workshop on the Pesticide Quality Control and Analytical Technology of China, in Wuhan;
(iii) 24-26 November, 2008 - Workshop on Pesticide Management in GCC Countries, in Dubai UAE,
(iv) 29 March-3 April 2009 - Workshop on Pesticide Management in Moldova.

Documents and Publications

(i) Regular reference made in JMPR reports and evaluations to FAO/WHO specifications;.
(ii) Publication and distribution of the "Training Manual of development and use of FAO/WHO specifications";
(iii) Publication of the Russian version of the "Code of Conduct";
(iv) "Pesticide Management Update" is the regular information source for new FAO publications on pesticides.

GCP & TCP's

(i) GCP/ARM/003/GRE - "Support for pesticide quality control and residue monitoring in Armenia", for upgrading the national pesticide formulation control laboratory to analyse pesticide products in accordance with international specifications;
(ii) TCP/MOL/3103 - Set up the national pesticide formulation control laboratory to analyse pesticide products in Moldova;
(iii) TCP in Kyrgyzstan - Strengthening the laboratory for quality control of agrochemicals;
(iv) TCP/RAB/3101 - Development of regional one or two reference laboratories for pesticides residues analysis and quality control of pesticides products in GCC countries

Details are available on the FAO Website at http://www.fao.org/ag/agp/agpp/pesticid/

5.3 WHO

Dr Zaim informed the meeting that WHOPES attended several major meetings and events since the previous JMPS meeting held in Braunschweig, Germany. These were:

1. WHO Meeting on Sound management of pesticides - risk reduction, held in Bonn, Germany, 13-14 August 2008. The meeting was attended by representatives of 18 Member States, mainly from Eastern Europe, Caucasus and Central Asia. The meeting rrecommended actions to reduce risks associated with use of pesticides including inadequately stored obsolete stocks;
2. Second FAO/WHO Joint Meting on Pesticide Management, hosted and held in WHO/HQ, Geneva, 6-8 October 2008. The meeting addressed, among other issues highly hazardous pesticides and priority actions for risk reduction, as well as several guidelines in support of the International code of conduct on distribution and use of pesticides. This included guidelines for: (a) development of a reporting system for health and environmental incidents; (b) registration of pesticides; and (c) pesticide advertising;
3. First Intercountry Meeting of National Vector Control Focal Points, Amman, Jordan, 4-6 November 2008. The meeting identified challenges, constraints and opportunities to implement IVM in countries, as well as actions for sound management of public health pesticides;
4. Workshop on Risk Assessment in Area of Pesticide Residues, organized by the Institute for Control of Agrochemicals (ICAMA) - the pesticide registration authority of China, held in Beijing, 27-29 April 2009. Data requirements and procedures for toxicological and risk assessment of pesticides were presented at the meeting and estimation as well as development of the maximum pesticide residue limits in food and animal feed were discussed;
5. International Public Health Pesticides Workshop, 19-21 May 2009, a joint initiative by US EPA and Chartered Institute of Environmental Health, UK, in which new approaches and strategies for development of new public health pesticides were discussed and possibility of conducting global review of new public health pesticide products were investigated.

Dr Zaim also informed the meeting that since the previous JMPS meeting, WHOPES has completed the testing and evaluation of five pesticide products: four long-lasting insecticidal mosquito nets for malaria prevention and control, and a bacterial formulation for mosquito larvicide. The reports of the WHOPES Working Group Meetings, an advisory group to the Scheme, provide a critical review of existing literature as well as studies organized and supervised by WHOPES. The reports have been widely distributed among national control programmes, registration authorities and other stakeholders and are intended to facilitate their registration and use by the Member States. Dr Zaim noted that the WHOPES recommendations are prerequisite to publication of WHO specifications.

Dr Zaim also informed the meeting of the publication of the trial edition of a training package on the development of pesticide specifications in collaboration with FAO. The training manual provides a step-by-step approach to acquiring the knowledge and skills for basic decision-making on the development of pesticide specifications, including the determination of equivalence and has already been field tested by WHOPES in three countries. CropLife and ALINA have kindly agreed to provide technical support in

translation of the participant's guide into French and Spanish, respectively. The training package has been tested in three workshops organized by WHOPES, in collaboration with WHO Regional Offices, and additional 9 workshops are planned for the next 18 months, after which WHOPES would like to hold a small consultation to review and finalize the document.

Through the grants provided to WHO by the Bill and Melinda Gates Foundation for reduction of health risks through sound management of pesticides, WHOPES has supported 5 countries in situation analysis and needs assessment for management of public health pesticides, through inter-sectoral and multi-stakeholder approach, following WHO guidelines. WHOPES has also conducted three workshops on development of pesticide specifications, including principles of equivalence determination and have assessed the capacity of 2 national quality control laboratories. There are 12 priority countries participating in this Project and the same activities are planned to be carried out in the remaining countries in the next 18 months.

Dr Zaim also noted that several WHO evaluation reports and specifications have been published since the previous JMPS meeting as reported separately under agenda item 12.

6. Technical liaison with other organizations

Dr Zaim mentioned that CIPAC, FAO and WHO work with many regional and international organisations. He said that he has the pleasure to call on some of these organisations to present reports on the work that they are doing on the management and quality control of pesticides.

6.1 AgroCare

By way of introduction, Mr Héctor Di Loreto (ALINA) stated that AgroCare, as a global association, represents the independent post-patent (generic) crop protection industry. AgroCare was founded on April 28, 2008 in Brussels, Belgium, and it initiates operations with member associations from three continents, and is open to new member associations. Mr Di Loreto said that AgroCare fills a void, present in discussions at meeting with international organizations, where only the one-sided view of multinational companies has been heard on issues ranging from intellectual property to regulatory policies. The competition in the market place that AgroCare members generate reduces the production costs of farmers dramatically by lowering one of the most important cost items: crop protection products. AgroCare supports the right of generic agrochemical producers to play a crucial role in offering one of the needed solutions to face today's global challenges.

The current AgroCare members are ALINA **(**Asociación Latinoamericana de la Industria Nacional de Agroquímicos / Latin America), CCPIA (China Crop Protection Industry Association), ECCA (European Crop Care Association), and PMFAI (Pesticides Manufacturers & Formulators Association of India). Five founding members were also mentioned, as well as those on the current Board.

The following facts and issues were raised by Mr Di Loreto:

- The generic industry produces off-patent agrochemicals, which in 2009 represented about 70 % of the sales of agrochemicals out of a total world market of 25-30 billion USD.
- A strong generic industry is essential to ensure competition and therefore lowers prices of agrochemicals for agriculture, in a world where food insecurity is of major concern. If agrochemicals are too expensive, crop yields and product quality will drop due to pest-related damage.
- World food production at the farm level could be severely affected by an uncompetitive market for crop protection products that arbitrarily extends monopoly pricing against the welfare of farmers and consumers
- Crop protection products can represent more than 30% of the total production cost of many agricultural goods, especially in developing countries
- AgroCare strongly objects to the practice of protecting existing, old data – previously used in the EU or the USA – in countries of Latin America and East Asia that have updated their regulatory requirements. This practice of protecting old data must be considered "unfair commercial use", according to Article 39.3 of the TRIPS Agreement.
- AgroCare proposes that the FAO/WHO should not include in their Guidelines any reference to data protection, which is a matter dealt with in the TRIPS Agreement of the WTO, where article 39.3 deals with the protection of regulatory data against unfair commercial use, which is different from a right of "exclusive use". Countries should be free to use their sovereign right to define "protection data" as protection against commercial use, as defined in the Paris Convention.
- AgroCare acknowledges the interest of research-based industries to protect the investment in regulatory studies. Data protection of studies must be defined on a national level and be fair and transparent. Regulatory authorities may refer to studies for marketing approval of generic pesticides under the TRIPS Guidelines of protection against "unfair commercial use" as defined by the Paris Convention, Article 10 bis.
- AgroCare objects the customization of FAO/WHO specifications to a single manufacturer, since this eliminates the essence of a quality standard that can be met by different manufacturers.
- To avoid the unnecessary repetition of animal studies for the sake of animal welfare, access to protected vertebrate data must be ensured by arbitration (in countries where data protection is defined by exclusive use) in case that a data owner does not reach an agreement with a new registrant
- AgroCare acknowledges the work of FAO and WHO in the harmonization of the regulatory requirements. We encourage the mutual recognition of pesticide authorizations to avoid the unnecessary repetition of studies and evaluations

6.2 AOAC International

A report from Dr Adrian Burns was presented by Dr Hänel.

The re-organization of the AOAC International (AOACI) Official Methods Board (OMB) and the Official Method process was approved at last year's Annual Meeting and is

progressing through the various methods' Committees. To refresh everyone, the AOACI adopted a community concept to develop consensus standards and assistance in the development, validation, and collaboration of analytical methods. These communities consist of groups interested in specific scientific or analytical areas that network and engage the international, federal and state governments, industry, business organizations, and trade groups. Pesticides, particularly pesticide formulation analyses, are a major sub-community represented by the Agricultural Materials Community. The CIPAC and FAO/WHO JMPS are representative of the international pesticide community that works together to provide global policy and analytical method-based solutions regarding pesticides.

The Official Methods Board (OMB) revised and modified the Official Methods process in 2008 to better utilize and involve the Association's membership resources. In addition to providing oversight for the consideration, adoption, and Final Action approval to collaborated First Action methods, under the implemented re-organization, the OMB is now responsible for the establishment, and member approval (staffing) of the new "centric" committees being formed as individual methods or needs arise. Most of the past methods Committees have been phased out (retired) but as mentioned in the previous report, Committee A, Pesticide and Disinfectant Formulations has not due to our current activities.

The Pesticide and Disinfectant Formulations Committee A, activities include:

* AOAC Official Method 2007.07 - "Determination of Hydrazine in Maleic Hydrazide Technical and Pesticide Formulations by Gas Chromatography First Action". The method is so noted in the *Official Methods of Analysis* online at http://eoma.aoac.org/, and will be published as such in the next printed edition.

* Analyses of samples and statistical review of the data in the collaborative study for the method "Bifenthrin Analysis in Technical Material and Formulations by Capillary Gas Chromatography" have been completed. The study director is drafting the manuscript for publication in the Journal.

* Statistical data analyses of the results from the 6 laboratory 'mini-collaborative" round-robin study for the method "Determination of Mixed Phenols and Phenates in Formulated Products by Liquid Chromatography (LC) with Ultra-Violet (UV) Detection" was completed and is acceptable. A full collaborative study was approved and planned.

* Committee A's efforts to revise the packed columns with capillary columns in the GC methods in Chapter 7 of the *Official Methods of Analysis* (OMA) continues. The project is being approached and handled technology updates so as to require minimal additional collaborative work. AOAC Official Method 971.05 Captan in Pesticide Formulations Gas Chromatographic Method AOAC-CIPAC is being revised for approval by the Committee.

* All AOAC First Action Methods in Chapter 7, Pesticides and Disinfectant Formulations of the *Official Methods of Analysis* (OMA) have been brought forward and made Official Final Action.

6.3 ASTM International

Mr Alan Viets presented the "CIPAC update from ASTM". He stated that the ASTM is 111 years old and has been involved in method development over that time. Since 1995 there has been very good cooperation on analytical methods with CIPAC making the process more efficient. Many supporters from CIPAC have fostered this co-operation.

ASTM's tank mix compatibility test E1518-93 (now E1518-05) was presented in Cyprus.

Recent collaboration has included CIPAC and ASTM exchanging CDs of their methods. There is also mutual recognition through their web sites. ASTM has received the MT Method Descriptions. CIPAC has also received the ASTM E35.22 Method Descriptions. These Descriptions will be posted on the cooperating organizations' web sites.

One of the strongest links is through DAPF and ASTM is involved in the DAPF meetings. DAPF members continue to present papers at ASTM Symposia each year. This year 2 presenters will present 3 papers. A German speaking ASTM member has been present at DAPF meetings since 1995.

Concerning inerts under FQPA: ASTM has been involved in the work on Inerts under FQPA and on the EPA OECD 422 and nearly all EPA recommended OECD 422 are now complete. EPA is now pressing hard to complete all reports by August 2009, three years late. Recently requests from EPA for Dermal data have been received. The EPA is using I-DEEM modelling. Requests for percent limits in formulations have been coming from the EPA. There is no connection to use rate, grams per Hectare.

There are about 20 remaining Cluster Support teams (CST's) with Inert Supplier and Pesticide Producers members. EPA wants to regulate inerts by CAS numbers, whereas Industry wants to be sure that all correct CAS numbers are listed.

There was recent ASTM Method development concerning volatile organic compounds (VOCs) in California. The Soil Adsorption test passed ASTM final Ballot, Spring 2009. The method number will be issued soon. DPR's current TGA 115C testing is seen as a first tier test. The Soil Adsorption test can be used on products that have failed the TGA test as a second tier test. Foliar intercept will reduce the soil correction as all foliar intercepted application is assumed to be atmospherically available
Peter Green's Work at University of California at Davis shows that there is not enough NOx to react with O3 to form Ozone in the agricultural environment. With respect to VOC Calculations based on the new ASTM Soil method:

California Department of Pesticide Regulation (DPR) asked ASTM to calculate the impact of their data on some sample products. Examples – based on foliar intercept data (Linder 2000 IUPAC paper). Reductions: Baythroid 2 EC on Cotton (12% available VOC); Buctril EC on Corn (41% available VOC); Buctril EC on Onions (74% available VOC); DEF EC on Cotton (4% available VOC)

The new methods status is as follows:

Tank Additive Task Force stated that a second Humectancy Round Robin is planned for summer 2009, since the variation in results was too high in the first Round Robin.

Bob Goss will submit definitions to be balloted for Emulsion Spontaneity E1519, Water Conditioning Agent E1519, Spontaneity of WGs E609, Micro-emulsions, and Mini-emulsion E1519. Each of these will require defining test methods. Andrew Hewitt plans to have a draft test method for drift control adjuvants. In addition to the definitions in E1519 and E609, a new standard is planned for Seed Treatment terms. Most terms will require defining methods.

Concerning terminology used by the Adjuvants Task Force, "Invert Emulsion Suspension" was added to E609-05 as a result of Ballot discussions; and "Water Conditioning Agent" in E1519-06 was modified as a result of Ballot discussions.

The venues and dates of future meetings are:

- Atlanta, GA (1) Oct 19 – 23, 2009
- St. Louis, MO April 19 – 22, 2010
- San Antonio, TX (1) Oct 11 – 14, 2010
- Anaheim, CA April 11 – 14, 2011
- Tampa, FL (1) Oct 31 – Nov 2011

[Symposia (1)]

6.4 CropLife International and European Crop Protection Association (ECPA)

Mr John Dawson, Chairman of the CropLife International Specifications Expert Group (SEG), introduced the topic of the Group. He first described CropLife International, as a "Global federation", which represents the plant science industry in 91 countries. The main members are BASF, Bayer, Dow, DuPont, FMC, Monsanto, Sumitomo & Syngenta. Stewardship was defined as "the responsible and ethical management of a plant protection or biotechnology product throughout its life cycle". All elements of the lifecycle are covered, but CropLife's emphasis is at the field level. He went on to elaborate on their commitment to stewardship, with a network in 91 countries and CropLife associations delivering training programmes in over 40 countries around the world. CropLife has provided training to farmers and extension workers for over 20 years and trains 350,000 individuals each year

Container management programmes are found in 29 countries, collecting over 35,000 tonnes of used containers per year. Significant progress and contributions have also been made to the African Stockpiles Programme. Committed US $ 30 million to safe-guard and destroy obsolete stocks originally supplied by CropLife companies. Training and education are being provided on threats to good products due to increased number of counterfeit products in the market.

Mr Dawson explained that the SEG comprised member company representatives with expertise in analytical, physical-chemical issues, regulatory and formulation Sciences, with ad-hoc members from other expert areas e.g. toxicology and ecotoxicology. SEG is a technical resource for CropLife and ECPA. The mission of SEG is to provide a Forum comprised of experts in matters of product quality and specifications for discussion and resolution of technical issues of importance to the Crop Protection Industry. SEG provides an industry interface with FAO/WHO and specifications process, promotes the FAO/WHO specification process as the principal globally recognized system for maintaining high quality plant protection products, prepares new specification guidelines for new product or

formulation types, supports the work of CIPAC, co-ordinates efforts with other expert groups (e.g. DAPF, DAPA etc), provides Industry input to other new guidelines, the Industry position papers and technical monographs, and comment / review on new and/or revised OECD methods on phys-chem properties.

Specifications Expert Group (SEG)
The SEG is comprised of member company representatives with expertise in Analytical, Physical-chemical, Regulatory and Formulation Sciences. Ad-hoc members are from other expert areas e.g. toxicology, ecotoxicology, etc. SEG is a technical resource for CropLife and ECPA

The aim of the SEG is the responsible and ethical management of a plant protection or biotechnology product throughout its lifecycle. The mission of SEG is to provide a forum comprised of experts in matters of product quality and specifications for discussion and resolution of technical issues of importance to the crop protection industry:

- Provide Industry Interface with FAO/WHO and Specifications Process
- Provide discussion and feedback relating to improvements to the FAO/WHO Manual on Specifications
- Provide e.g. input and comment to proposals from JMPS on changes to equivalency and phys-chem requirements for FAO/WHO specification process
- Promote FAO/WHO specification process as the principal globally recognized system for maintaining high quality plant protection products
- Support proper use of FAO/WHO Specifications, such as training offers to National Authorities
- Support and expert input to the new training manual on FAO/WHO Specification process
- Prepare new specification guidelines for new product or formulation types
- Engage in and support the work of CIPAC
- Provide input to proposal on peer review process for relevant impurities
- Co-ordinate SEG efforts with other expert groups (e.g. DAPF, DAPA, phys-chem Industry forum, etc)
- Provide Industry input to other new guidelines
- Provide e.g. input to proposed new guidelines on EU product chemistry and analytical methods (technical and formulations)
- Provide Industry position papers and Technical Monographs
- Recently revised TM17, shelf-life of formulations and this update will be published by CropLife in the near future
- Provide comments and review new and/or revised OECD Methods on phys-chem properties

The CropLife website can be found at http://www.croplife.org/, and the Farming First website at http://www.farmingfirst.org/

6.5 European Food Safety Authority (EFSA)

Mr László Bura described the tasks of the one branch of EFSA, namely, the PRAPeR Group (Pesticide risk assessment peer review):

These include activities in the framework of Directive 91/414/EEC concerning the placing of plant protection products on the market, as well as activities in the framework of Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feeds of plant and animal origin. Dr Bura referred to Pesticides in the EU and risk assessment in the European food safety system is conducted independently from risk management. EFSA is the risk assessor, providing sound independent scientific advice. EU Commission and Member States are the risk managers and take decisions following legally defined procedures on whether or not to include an active substance in Annex I.

Concerning Directive 91/414/EEC, and the assessment of active substances, Dr Bura mentioned the review programme of all active substances which were on the market within the EU before July 1993 (existing active substances (EAS), the assessment of existing active substances which are re-submitted following a non-inclusion decision is being done, and the assessment of new active substances (NAS) (a.s. not included in products on the European Union market on or before 25 July 1993)

Mr Bura described EFSA's involvement in the review programme for EAS, involving 4 stages, and those which have been re-submitted, as well as EFSA's involvement in the review programme of new active substances (NAS).
Concerning work sharing at EU level, he described the "Tiered approach of evaluation of active substances". Dr Bura also referred to the EU pesticides review process and phases to address the remaining issues.

Concerning the conclusion on risk assessments, various risks were described, such as the risk to those that apply the pesticide, the risk to consumers, the risk to the environment, and the potential contamination of ground water. With respect to risk assessments, the aims of PRAPeR peer review is to promote consistency and technical quality in risk assessment, and to ensure that the risk assessment is maintained as a transparent sound scientific process separated from risk management.

Future developments / challenges include the implementation of new guidance documents on risk assessment developed by the PPR panel, the introduction of the new regulation (when finalised) on the authorisation of plant protection products, and the reassessment of substances included in Annex I following a period of 10 years of inclusion. For further information, please consult: http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_PRAPER.htm

6.6 International Programme on Chemical Safety (IPCS)

Dr Antero Aitio, Toxicologist (JMPS) and IPCS, a former member of WHO/PCS, gave a presentation on the collaborative work between the WHO and IPCS.

The work involves the evaluation of risks of chemicals and the development of risk assessment methods. Unit names mentioned here are not completely accurate as the WHO is undergoing change and some of these organisations will have different names. IPCS is a tri-partite effort.

Specific Programs - WHO/ILO/UNEP
These comprise two programmes, namely, the WHO Programme on Chemical Safety, and the International Programme on Chemical Safety, involving the WHO, ILO, and UNEP.

International Policy Drivers
These are the United Nations Conference on Environment & Development (UNCED, 1992), the World Summit on Sustainable Development (WSSD), 2002, the Strategic Approach to International Chemicals Management (SAICM, 2006), including WHA Resolution 59.15 (2006) on SAICM, which requested WHO to facilitate health-sector implementation. Finally, the last driver refers to the Multilateral Environmental Agreements, e.g. Rotterdam Convention, Stockholm Convention

For some time IPCS has been active in Stockholm and it participates by being involved in other safety agreements.

WHO Chemical Safety Activities
Chemical safety is based on risk assess and information and the development of risk assessment methodologies. WHO provides guidance on how risk assessment should be done:

- Evaluation of risks of chemicals to human health
- Development of risk assessment methodologies
- Preparedness, alert & response for chemical emergencies & incidents (for microbial and contagious disease outbreaks and including chemical emergencies e.g. release of benzene into river from one country into another).
- Prevention & management of toxic exposures (INTOX Programme)

Pesticides and Food Additives
Pesticides and food additives are dealt with by the Joint FAOWHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meeting on Pesticide Residues &Specifications JMPR /JMPS, and the WHO Classification of Pesticides by Hazard

Other Risk Assessments and Publications
These assessments and publications are in the form of Environmental Health Criteria (EHC), Concise International Chemical Assessment Documents (CICADs), and International Chemical Safety Cards (ICSC)

Use of WHO assessments in support of Convention requirements
The WHO/IPCS risk assessments are extensively referenced in Rotterdam Convention Decision Guidance Documents (DGD). In addition, an IPCS report provided the basis for initial Stockholm Convention POPs, and such reports continue to be used.

Guidelines for drinking water quality
These guidelines provide guideline values for chemicals in water supply, and are backed up by monographs on each chemical listed. They assist risk assessment after chemical contamination of water sources. More information can be obtained from the WHO website: www.who.int/water_sanitation_health/dwq/guidelines/en/index.html

Pesticides hazard management activities
This comprises sound management of pesticides and the diagnosis and treatment of pesticide poisoning (CD); WHO classification of pesticides by hazard, as well as the International Chemical Safety Cards on pesticides.

6.7 International Union of Pure and Applied Chemistry (IUPAC)

Mr Denis Hamilton mentioned that the IUPAC Advisory Committee on Crop Protection Chemistry deals with pesticides issues, which may be found on the following website: http://agrochemicals.iupac.org/index.php?p=home

Properties Database A to Z list of Pesticide Active Ingredients was shown on the website with comments on actives and you can find the metabolites by searching the actives.

Regarding future IUPAC-sponsored Conferences:

- IUPAC RIO 2009. It is the 3rd International Workshop on Crop Protection Chemistry in Latin America: Environment, Safety and Regulation, from 9-12 November 2009 in Rio de Janeiro, Brazil. (Please see www.iupacrio2009.org)
- 12th IUPAC International Congress of Pesticide Chemistry, with the co-organizer being the Royal Australian Chemical Institute, from 4-8 July 2010 in Melbourne, Australia http://www.iupac.org/web/act/Melbourne_2010-07-04

The Programme objective is that "Chemistry for a sustainable world" will provide an opportunity for the scientific community to present cutting-edge research which provides solutions towards sustainability.

As part of a project sponsored by IUPAC and CropLife Latin America, work is nearing completion on a Spanish language version of the world-renowned text of the book called "Pesticides and the environment" by Gerald R Stephenson and Keith R Solomon. It is being updated also to include Latin American interests and agricultural considerations in the region. (For further details, please contact Prof. Elizabeth Carazo at the University of Costa Rica at email ecarazo@cariari.ucr.ac.cr)

6.8 Other organizations

There were no other organizations present who wished to give a report.

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

The following country reports, including any collaborative studies in which they participated, were presented: Argentina, Austria, Belgium, Czech Republic, Denmark, El Salvador, France, Germany, Greece, Hungary, Ireland, Japan, Panama, Romania, Slovenia, South Africa, Spain, Switzerland, Ukraine, and the UK, (Annex 1). The reports are obtainable on the CIPAC web-site (http://www.cipac.org/datepla.htm) as long as they are electronically available.

8. Proposed new/amended specification guidelines

8.1 CropLife proposal - Specifications for mixtures - formulations with more than one active ingredient

This was presented by Dr Rodler (Syngenta) on behalf of CropLife International.

FAO/WHO Manual (March 2006)
The section on mixtures in the FAO/WHO Manual was quoted. Formulation specifications normally refer only to a single active ingredient. Where two or more active ingredients are co-formulated, the specification for each active ingredient is expected to apply. Manufacturers should therefore ensure that the limits provided in proposed specifications are mutually compatible. In exceptional cases (for example, if special controls are required where active ingredients are co-formulated), a specification may be accepted for a co-formulated product but the manufacturer must explain the basis for the requirement. FAO/WHO specifications do not apply to mixtures prepared in the spray tank, etc.

Active ingredient Identity and Content
Dr Rodler said the mixtures of two or more active ingredients were causing the industry difficulties. Analytical methods can often not be applied, even with modifications, to the testing of mixed formulations e.g. interferences are a problem with GC, HPLC, and IR. Nobody can predict what new active ingredients are being developed and what their analytical properties will be. Not all possible mixtures with existing active ingredients are checked either.

Relevant Impurities
These are present in small amounts in a complex matrix and need a specific detector with GC, and LC instruments.

Physical Properties
The interpretation of physical properties for formulations with more than one active ingredient is difficult. We refer to previous discussions (CIPAC 2008) on mixtures and the challenges produced by mixtures will be the subject of a presentation at CIPAC symposium. Annex 4 of the summary record of the 5th Joint CIPAC/FAO/WHO Open meeting was quoted and presented. Annex 4 presents a table of physical properties where decisions, conflicts or compromises were required to set the physical properties for mixtures, with comparisons to the properties for individual active ingredients. At the CIPAC meeting in 2008, comments were presented from the following:

- Mr. Hamilton said that the JMPS would want the best possible specification values while still allowing for the normal compromises required to produce good formulations. It is our aim to revise the manual so specifications for products with two (2) active ingredients could apply to compounds in same formulations.
- Dr Zaim (WHO) reminded participants that the purpose of the FAO/WHO specifications is to provide the highest quality formulations in trade.

CropLife International companies share these goals.

Formulation Development
Scope and Limitations: When developing new formulations, companies are faced with many challenges, which increase even more if more than one A.I. is present in a formulation.

CropLife Proposal
A change was requested to the text in the FAO/WHO Manual as follows:

Formulation specifications normally cover only a single active ingredient. Where two or more active ingredients are co-formulated, the analytical methods referred in the specifications may no longer apply without modification. For the physical properties where recommended limits are given in this Manual, these limits are expected to apply. In exceptional cases (for example, if special controls are required where active ingredients are co-formulated), a specification may be accepted for a co-formulated product but the manufacturer must explain the basis for the requirement. FAO/WHO specifications do not apply to mixtures prepared in the spray tank, etc.

Suggestion: Replace the term “requirements” in the Manual (pp. 44-58) by “recommended limits” (as in p. 43)

A comment was made that there is a global trend towards having more than one active ingredient in formulations and this makes it complicated. Another speaker concurred with this, saying that this worldwide trend is towards mixtures with more than one active ingredient, particularly mixtures with herbicides. This is because of e.g. advantages concerning resistance.

In addition, an example on co-formulated materials is in the Manual and we need to take note that “Safeners are always co-formulated”, and never the only active ingredient in a product.

9. Status, review and publication of CIPAC methods

Dr Ralf Hänel gave an explanation and definition of CIPAC, or the Collaborative **I**nternational Pesticides Analytical Council. It is an international, non-profit and non-governmental organisation, established in 1957. Daily business is run by a chairman, a secretary and a treasurer (voluntary work) with funding through the sale of Handbooks and CD-ROMs. There are 24 full CIPAC members (2009), up from 7 in 1957.

According to the Constitution, CIPAC aims are to promote:
- international agreement on methods
- inter-laboratory programs
- to sponsor symposia
- to publish standardised methods of analysis
- to collaborate with other organisations

It was explained how CIPAC works:
- Methods are proposed by companies and are collaboratively tested by laboratories all over the world (using *CIPAC Information sheets*)

- Evaluation of the results at the CIPAC meeting against defined criteria and possible adoption of methods by CIPAC
- The adopted methods are published in CIPAC Handbooks

Concerning CIPAC publications, CIPAC Handbooks range currently from 1A (1980) to L (2006)

Regarding CIPAC-tested Methods, there are about 250 methods for the pesticide active ingredient (M-series), about 200 methods for physical and chemical properties (MT-series), as well as methods for reagents etc (R-series)

CIPAC Methods are used for:
- pesticide registration
- official post-registration control
- FAO and WHO Specifications

Most information is available on www.cipac.org , with online searching and ordering.

9.1 Review process analytical methods (Handbooks 1A to E)

CIPAC Handbooks were reviewed. The presentation demonstrated the CIPAC webpage and the site layout was also shown. Latest news and updates are available on the home page of the CIPAC website at www.cipac.org.

The website page "CIPAC Methods and Publications" was presented, the published methods page showing the index was shown including reference to "Guidelines for LN methods". In addition, the "methods not supported" page lists those methods no longer supported by CIPAC. The webpage "CIPAC guidelines" which shows a series of "guidelines for preparing collaborative studies" and related documents containing instructions and formats – this should assist any industry in developing analytical methods or in preparing to run collaborative studies to validate these.

9.2 Review MT methods (Handbook F)

Last year the concept was introduced but regrettably the process of review has slowed down a bit for various reasons, but will be available next year. However, CIPAC invited any comments regarding the MT methods. CIPAC is grateful for the continuing work of DAPF to develop, update and improve MT methods.

9.3 Guideline for analytical methods for the determination of relevant impurities

Everyone was thanked for their many comments for next edition of the Guideline. The amendments and clarifications are related to the scope, criteria accuracy, criteria repeatability, LOQ – in terms of definition of the LOQ, number of laboratories involved in the independent validation? These were the reasons for the changes and further discussions on relevant impurities were to be held at the meeting on Wednesday, 10th June, 2009

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

10.1 Proposal for a washing method for LN-formulations

This was presented by Dr Markus Müller, with Dr Olivier Pigeon as collaborator. The question was asked why a wash method should be used. CIPAC is an organisation dealing with pesticides, formulations and analysis methods. CIPAC has never been restricted to agricultural pesticides; it was always also concerned with pesticides required for human use. LN is a slow release form of pesticide use and for these nets we need to determine how much ingredient is left and the best method for this is by washing. Wash methods are something we cannot directly validate so we need to test these indirectly. Chemical methods can be done in this way, but physical methods cannot be and must be tested indirectly.

The indirect validation of a wash method was described. There are two net types, namely, coated and incorporated, both of which will be tested for comparative purposes. The insecticide used for these tests is the synthetic pyrethroid, α-cypermethrin. The IEC detergent A is to be used. A method suitable for determination of retention or release index was needed. The method is to wash and analyse the net to test for the decrease of pesticides concentration present.

The aims of method development for the wash method are to:

- Ensure wash steps 2 and 3 are representative
- Determine if triplicate samples are adequate
- Check the reproducibility of the wash steps
- Develop acceptance criteria for analysis
- Check if the detergent solution is stable
- Determine the best practice for data evaluation

Timelines proposed for the method development are:

Summer 09 - Calibration of detergent & method
Fall 09 - Participating laboratories selected, run trial
Early 10 - Compile results from laboratories
Apr 2010 - Present results at DAPF meeting
2010 - Results presented to CIPAC meeting

Dr Müller stated that as soon as the recommendation has been received, the draft method will be published on the CIPAC website. He and Dr Pigeon will first look at small collaborative trials and after they have seen the results they can go to a full collaborative trial perhaps. Regarding status of wash method, an LN will be eligible for FAO/WHO specifications provided the retention index is based on the WHO wash method.

11. Subjects from JMPS Closed Meeting

The JMPS asked for comments on the following topics, which they discussed resulting in these proposed changes.

11.1 Revision of requirements for physical and chemical properties

Mr Hamilton presented the reasons why the JMPS requires the physical and chemical properties of active ingredients to support the specifications and proposed changes to the section in the Manual.

The JMPS in 2007 requested that industry should provide detailed studies with the specifications data package:

- Physical-chemical studies should be submitted
- Data should be checked against the full studies

The JMPS, in 2008 provided details on the requirement for each of the properties

- Required properties for pure active ingredient are, namely:
  - Vapour pressure
  - Melting point
  - Temperature of decomposition
  - Water solubility
  - Octanol-water partition coefficient
  - Dissociation characteristics
  - Hydrolysis characteristics
  - Photolysis characteristics

    Required properties for technical grade are melting point and solubility in organic solvents

Solvent Solubility

Most regulatory authorities request solvent solubility tests to be performed on technical grade material. Solvent solubility is usually measured on technical material because otherwise it could require large amounts of (expensive) pure material.

Available information should be provided on the solubility of pure active ingredient or technical active ingredient in organic solvents. For the property of "solvent solubility" the pure active ingredient is preferred to the technical material.

Purity and Composition

We need to clarify the points on (1) purity and (2) "where the composition is different from the composition of the reference material"

Purity - It is difficult to prescribe a percentage purity that would always be a suitable dividing line between pure and not pure. For present purposes, the purity required is that of material suitable for use as an analytical standard.

Composition - The composition of pure active ingredient is accepted as the same in reference material and the equivalence-proposed material when it is:

- a single non-chiral compound;
- a single enantiomer; or
- a chiral compound as a racemate of an enantiomeric pair.

If the pure active ingredient is a mixture, apart from being a racemate of an enantiomeric pair, the composition of the pure active ingredient is presumed to be different in the

reference material and equivalence-proposed material without evidence that the compositions are the same.

Solvent Solubility
Solvent solubility can now be discussed in relation to the purity and composition of the material used to perform the test.

If solvent solubility is available for the pure active ingredient of the reference material, solvent solubility data should not be needed for the pure active ingredient of the equivalence-proposed material, provided it is the same composition.

If solvent solubility data for pure material are already recorded in the evaluation supporting the reference specification, such data are not required for the pure (or technical) active ingredient of the equivalence-proposed material, provided it is the same composition as the reference pure material.

Proposed revision to the text
This revision comes from the JMPS and the first 4 items are what was discussed last year. The JMPS invited comments and the JMPS Closed Meeting has considered these with the following recommendations:

Changes prompted by the comments have been added to the proposed text revision from 2008.

The result of changes made during 2007-2009 was that:
- Requirements have been brought up to date.
- Requirements for studies on pure or TC material have been clarified.
- Requirements for physical and chemical properties of an equivalence-proposed material are more explicit.

Regarding evidence that the compounds are the same, e.g. considering variation in a compound with 8 isomers, it depends on what property is being measured.

The differences between doing the tests with the technical and pure material is like the case with an analytical standard. Scientists accept those differences in materials as good enough for an analytical standard and we would accept these in this case (for analytical use), but physical properties such as vapour pressure can be affected by very small differences in composition.

11.2 Determination of relevant impurities

Dr Antero Aitio, representing WHO on Chemical Safety, gave a presentation on section D, of the FAO/WHO manual on pesticide specifications - the “Determination of the relevant or non-relevance of impurities”. The changes proposed by the JMPS were outlined in the document and reasons for these changes were given.

Dr Aitio said that: when it has been decided that an impurity is relevant, if there is nothing better available, then the calculation method for relevant impurities must be used. The limits for relevant impurities adopted are based on the “GHS guideline values for the

labelling of mixtures". These are the substantive changes that JMPS has considered and has now proposed for to be made to the Manual.

The complete document, Relevant Impurities – Revision 8th June, 2009, is attached as Annex 7.

Dr Aitio also stated the relevance of impurity is not determined by analytical capabilities or advances in technology

The main principle in the JMPS is the relationship of the toxicity of the active ingredient to the toxicity of the other impurity. The active ingredient is the driving force as far as human toxicity is concerned. It is the ratio of the active ingredient and the relevant impurity that decides the relevance.

11.3 Determination of equivalence

Mr Hamilton gave a presentation on the determination of equivalence, with comments provided by JMPS toxicologist Dr Aitio.

Determination of equivalence – revisited 2009

In 2007, the Chair of JMPS and the FAO and WHO agreed to prepare a proposal for comment by JMPS, which would then be circulated for wider consultation. The proposal used as its basis Dr Aitio's paper, taking into consideration CropLife International and ALINA's proposals.

In 2007, the proposal was made by the JMPS that equivalence determination should be made primarily on the basis of chemical composition and mutagenicity testing. A report was prepared for discussion at the 2008 meeting

In 2008, the recommendations were that:

1. The determination of equivalence is to operate as a two-tiered system with Tier 1 based on the manufacturing process, manufacturing QC limits and batch analysis data.
2. The batch analysis data should be produced under GLP control.
3. The electronic template for data submission should be revised.
4. Comments were requested before 2009.

Comments received (and response to the comments):

1. A "tiered" system for determination of equivalence is supported because it allows for the evaluation of safety and risk while reducing duplicated animal toxicity testing.
2. Physical and chemical properties are usually measured on the pure compound, so should not be necessary for a follow-on source seeking an equivalence determination.
3. In an equivalence determination, the proposal states that studies and data on the physical and chemical properties are required for an active ingredient where its composition is different from the composition of the reference material but is not clear what is meant by difference in composition.
4. Mutagenicity testing could be transferred to the second tier.

5. Mutagenicity testing, e.g. Ames testing, should not be included in Tier 1 and should be required in Tier 2 only when suggested by differences in impurity concentrations between the reference and equivalence-proposed materials or when the possible presence of potentially new and toxic impurities could not be excluded.
6. GLP should not be a requirement for laboratory generated data, but the following of GLP principles is desirable.
7. Margins of variation for toxicity values between reference and equivalence-proposed material should be maintained as in the Manual – 2X for toxicity and 5X for ecotoxicity.
8. For toxicity testing procedures that produce a classification system (e.g. non-irritant, mild irritant or irritant), the classification system result should prevail, i.e. there are no tolerances on such a system.
9. Equivalence determination should focus on making best use of data comparing the chemical composition of technical materials. Removal of acute toxicity testing from Tier 1 is supported.
10. Requirements for toxicity testing in Tier 2 should depend on a case-by-case assessment of impurity profile differences.
11. Detailed procedures were suggested for the establishment of the reference material for equivalence determination and for Tier 1 and Tier 2 evaluations.
12. Comparisons required in the equivalence procedure are highly demanding, and they must be conducted with care by experts experienced in the appropriate areas of chemistry, toxicology and ecotoxicology.

Discussion

- The implications of a tiered system in JMPS have yet to be fully seen. JMPS meets only once per year and the aim should be to finalise an equivalence determination at one meeting.
- Consequently, it would be in the interests of the data submitter to submit only the Tier-1 data in those situations where there was a high probability that Tier-1 was sufficient for a decision.
- In other situations, the data submitter would likely submit Tier-2 data as well as Tier-1 data, especially if the Tier-2 data were already generated and available because of national registration requirements.
  - Three conclusions are possible after a Tier 1 assessment:
    1) equivalence,
    2) non-equivalence,
    3) insufficient information to reach conclusions 1 or 2.
  - A Tier 2 assessment should be needed only in the third case.
  - Data requirements for physical and chemical properties of the pure active ingredient – see previous agenda item.
  - Mutagenicity testing (bacteria, *in vitro*) should be seen as a check for the presence of unidentified "surprise toxic impurities" in the test material. Mutagenicity tests are *in vitro* tests and are not of animal welfare concern. Mutagenicity testing should remain as a part of Tier 1 requirements.
  - JMPS should expect that most recent batch-analysis studies designed to be submitted to registration agencies will be GLP studies. Older batch-analysis studies should also be accepted and assessed on their merits.
  - Recent 5-batch studies will be required to be GLP studies.
  - For equivalence determination, a letter of authorization granting access to registration data has not been required. In practice, it has usually been arranged.

The JMPS, in 2008, recommended that confirmation of registration by a National Authority was required.
- The procedures for data evaluation in a two-tiered system require changes in the Manual.
- The electronic template for data submission has been revised. See later agenda item.

Regarding what would be the cut-off date for all these studies, Industry would need to understand and expect that the only GLP studies will be acceptable soon.

11.4 Revision of Proposer data entry form

Mr Hamilton said that the previous template originating from about 2000 was edited in the light of experiences and changes since that time and was then circulated in February 2009 to JMPS members for comment.

Important changes
- Manufacturing process: include a flow diagram.
- A separate reference list for studies in the confidential section is required.
- Study reference identification numbers are to be included in tables of data for physical and chemical properties, toxicology and ecotoxicology.
- Purity of test material is to be provided in a specific column in each table.
- Revised requirements for physical and chemical properties are included.
- Solubility in organic solvents are now included in physical and chemical properties.
- Revised text for the FAO Manual relating to Sections 3.1 (data requirements, reference specification) and 3.2 (data requirements, equivalence) are included as an Annex to the data entry form.

Post-meeting note
The revised proposer data entry form is now available at:
WHO: http://www.who.int/whopes/quality/en/Proposer_data_entry_form_July09.pdf
FAO: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/manual/en/:

11.5 Items from closed meeting

The following points on significant issues, advanced from previous meetings and also on new matters, were raised in discussions held in the Closed Meeting

11.5.1 – Implementation of Items 11.1; 11.2 & 11.3
Implementation of these items will be done when the report is published:
- 11.1 Physical and chemical properties
- 11.2 Relevant impurities
- 11.3 Determination of equivalence
    - Introduced in 2007 and 2008.
    - Subject to a round of comments
    - Time for implementation is at the time of publication of the Report of the 2009 Open Meeting.
    - Incorporate into next edition of the Manual.

11.5.2 Data entry template, implementation of Item 11.4

A revision of the entry template was recommended in 2008, with editorial changes, such as “FAO/WHO” to replace “FAO”, “CropLife” to replace “GCPF”, etc. The template has been revised, for implementation on data submissions in 2009 for evaluation by JMPS 2010

Post-meeting note
The revised proposer data entry form is now available at:
WHO: http://www.who.int/whopes/quality/en/Proposer_data_entry_form_July09.pdf
FAO: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/manual/en/:

11.5.3 Timeliness of submissions
Concerning the timeliness of submissions:
- Some compounds are taking too long in the process from first data submission to publication of the specification.
- Data submitters are requested to provide relevant data in the prescribed format by the time suggested in the Manual.
- Some data submitters do an excellent job, so it is possible.

11.5.4 Tracking and progress of Specifications
Timelines, tracking system, additional data requirements and collation of supplementary data is needed. Tracking & progress of draft specifications is important in managing the process of evaluation & publication of specifications. Evaluators have not always followed the timetable suggested in the Manual. Essentially completed specifications have not been sent for publication for the following reasons:
- pending the submission of additional data
- awaiting a data submission from another data submitter
- awaiting the answers to questions
- A tracking system has been suggested for timely monitoring what stage has been reached and who is currently responsible for further progress?
- Expected additional data or answers to questions - are identifying whether they are critical or supplementary, otherwise proceed to publication if no critical points remain.

11.5.5 Generic descriptions in specifications for formulations
The aim (see p. 34, Manual) is “To provide a brief clear description of the technical grade active ingredient or formulation, which can be checked by simple inspection …..”. Generic descriptions are being proposed for formulation specifications that cover the current formulations and future possibilities. However, generic descriptions do not seem to meet the aim. “The description should include physical state, colour and odour…..”. For the WG: “..it is recommended that information about the form (e.g. irregular shape, nearly spherical, cylindrical, ..) is added and the nominal size range stated.” Suggestions on how to meet the aim of the description were requested from participants as well as their comments on what should be included in the description paragraph**.**

11.5.6 Fungal (microbial) pesticides
China is developing specification guidelines for fungal pesticides (microbial pesticides). In the Manual, new sub-sections which will be allocated to microbial (fungal) pesticides as detailed below:

9 .Specification guidelines for microbial pesticides
9.1 BACTERIAL PESTICIDES
9.2 FUNGAL PESTICIDES

9.21 Fungal pesticide technical concentrates TK
9.22 Fungal pesticide powders DP
9.23 Fungal pesticide wettable powders WP
9.24 Fungal oil miscible flowable concentrates (OF)
9.25 Fungal pesticide baits RB

This document of the proposed draft specification guidelines for "microbial fungal pesticides" is based on The China National Standard Guidelines on Drafting Specifications of Fungal Pesticides (GB/T21459.1~5-2008). It is the aim of JMPS to evolve these to FAO/WHO pesticide specifications. These draft specification guidelines were jointly developed by Prof. Yiyan Wang, Ms. Xiangqun Nong from The Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA), and Institute of Plant Protection, Chinese Academy of Agricultural Sciences (IPPCAAS). The contact email that can be used is: wyyicama@yahoo.com.cn

Dr Zaim stated that just responses to ICAMA are not only desirable but also welcomed anyone interested from industry, national governments, other organisations to become involved in taking the Chinese initiative forward to develop the specification for fungal pesticides for FAO and WHO.

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

12.1 Status of FAO Specifications

Madam Yang presented the current status of publication of the specifications in the FAO list of compounds. About 60% of the FAO specifications reviewed by the JMPS 2002-2008 have been published. However, she commented on the timeline to publication – it is sometimes much too long, from both the Secretariat and company point of view, to progress specifications forward to publication. It is important to reduce the time between the JMPS meeting and publication. The actual publication status of the FAO specifications is detailed in the Annex 3.

12.2 & 12.3 Status of WHO Specifications and Status of Joint FAO/WHO Specifications

Dr Zaim presented the current status of the WHO and Joint FAO/WHO specifications. All specifications reviewed before 2006 are now published, but the 2006 & 2007 LNs are not yet published, but soon an interim specification for LNs will be published.

Since the establishment of JMPS in 2002, more than 150 submissions have been considered by the JMPS. Except for the pesticide products listed in Annexes 4 and 5, and for few products that have been withdrawn since 2002 due to major data gaps, the assessment of all those submitted for the development of WHO specifications or that for joint FAO/WHO specifications during this period have been finalized and the evaluation report and specifications have been published on the web sites of FAO and WHO.

12.4 Withdrawal of WHO specifications

Dr Zaim informed the meeting that WHO specifications for Deet is considered obsolete and will be withdrawn by the Organization, as recommended by 2009 JMPS Closed Meeting.

13. FAO/WHO priority list and program for development of FAO and WHO specifications for pesticides

Madam Yang presented the priority list for JMPS 2010 (see Annex 2) in three different categories: (1) original proposer; (2) subsequent proposer(s); (3) specification for formulation. She stated that the schedule for the 2010 JMPS is quite full, and the demand of determination of equivalence has been increased rapidly in recent years. There were 3 submissions as primary proposers for FAO specifications and 12 submissions for determination of equivalence (subsequent proposers). Among them, 5 were for FAO specifications, 3 for WHO specifications and the rest for FAO/WHO Joint Specifications. There were also submissions (2) for the establishment of WHO specifications (1) and Joint specifications for formulated products (1).

14. Any other matters

Dr Gero Vaagt would like to encourage a translation of the FAO/WHO Manual into Spanish. In turn, Mr John Dawson welcomes the proposal for a revised Manual and encourages Industry to get involved.

The lack of reference profiles in Central and South America is still a major problem for registration, and it was asked if there was any progress in this regard. Decision taken last year was that this will be dealt with on a case-by-case basis. The point is that the procedure as described in the Manual should not be changed. However, it is a known fact that developing countries are struggling concerning the general lack of reference profiles required for equivalence determinations. The FAO/WHO would be happy to assist if resources are available regarding the definition of reference profiles.

There were no other matters for discussion.

15. Date and venue of next meeting

CIPAC/FAO/WHO invited everyone to the next meeting, which was scheduled to take place on 2-10 June 2010 (with the 9th JMPS meeting on 2-5 June) at the Kmetijski Inštitut in Ljubljana, Slovenia. A presentation video was shown of the meeting venue.

Closing of the 5th Joint CIPAC/FAO/WHO Open Meeting

Dr Zaim (WHO), Chairperson for the Meeting, declared the meeting closed. Madam Yang and Dr Ralf Hänel thanked Dr Zaim for chairing the meeting and thanked the rapporteurs.

ANNEX 1.
SUMMARY TABLE OF NATIONAL REPORTS OF OFFICIAL QUALITY CONTROL LABORATORIES

Region	Reporting laboratory	No. Of samples tested	Non-compliance	
			No.	%
Africa	South Africa	31	5	16
Americas	Argentina	1075	10	1
	El Salvador	622	22	4
	Panama	127	0	0
Europe	Austria	22	6	27
	Belgium	440	68	15
	Czech Republic	39	9	23
	Denmark	64	2	3
	France	66	40	61
	Germany	144	29	20
	Greece	238	20	8
	Hungary	863	3	0
	Ireland	162	7	4
	Romania	355	16	5
	Slovenia	25	0	0
	Spain	197	11	6
	Switzerland	44	4	9
	Ukraine	223	37	17
Asia	Japan	34	0	0
Total		**4820**	**294**	**6**

ANNEX 2.
PROGRAMME FOR DEVELOPMENT OF FAO AND WHO SPECIFICATIONS FOR PESTICIDES

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

Year	Products	Proposer(s)
2010	**FAO:**	
	Flazasulfluron TC and WG	(1) ISK Japan
	Fosthiazate TC, FG and EC	(1) ISK Japan
	Fipronil	(2) Tagros
	Metsulfuron-methyl, TC and WG	(2) Cheminova A/S
	Nicosulfuron, TC and (SC or OD)	(2)&(3) Cheminova A/S
	Thifensulfuron-methyl, TC and WG	(2) Cheminova A/S
	Tribenuron-methyl, TC and WG	(2) Cheminova A/S
	Triflumuron TC, WP and SC	(1) BCS
	WHO:	
	Deltamethrin (coated) LN	(2) Tianjin Yorkool, China
	Spinosad EC	(3) DAS/Clarke Mosquito Control
	Temephos	(2) Coromandel Fertilisers Ltd.
	FAO & WHO:	
	Chlorpyrifos	(2) Meghmani Organics
	Deltamethrin	(2) Meghmani Organics
	Lambda-cyhalothrin	(2) Meghmani Organics
	Permethrin	(2) Meghmani Organics
	Permethrin EC	(3) Tagros

ANNEX 3.
STATUS OF PUBLICATION OF FAO SPECIFICATIONS

FAO specifications reviewed in 2002-2005

Product	Manufacturer	Status
Maleic hydrazide TC, TK, SL,SG	Chemtura Drexel Fair Products	Published 2009
Copper, cupric hydroxide and oxychloride Bordeaux mixture, and cupric oxide	European Union Copper Task Force	To be finalized for publication
Diquat dibromide, TK, SL	Syngenta	Published 2008
Paraquat dichloride TK, SC, SG	Syngenta	Published 2008
Prochloraz TC, EC, SC	Makhteshim	Published 2009

FAO specifications reviewed in 2006

Product	Manufacturer	Status
Clodinafop propargyl TC, EC, WP	Syngenta	Published 2009
Chlorothalonil TC, WP, WD, SC	Sipcam Agro USA, Inc	Published 2009
Fosetyl-Al TC, WG, WP	Bayer	Pending information from company
Propanil TC	Rice. Co	To be finalized and published
Propaquizafop TC, EC	Makhteshim	Evaluation only to be published, pending information from company

FAO specifications reviewed in 2007

Product	Manufacturer	Status
Azoxystrobin TC, SC, WG	Syngenta	Published 2008
Deltamethrin	Bayer CropScience Herbanba Tagros/Agros	Published 2009
Fenoxaprop-P-ethyl	Bayer	To be finalized for publication
Flusilazole	Dupont	Published 2008
Lufenuron TC, EC	Syngenta	Published 2008
Oxamyl	Dupont	Published 2008
Pirimiphos Methyl	Syngenta	Published 2007
Thiacloprid TC, SC, SE, OD,WG	Bayer CropScience	Pending reply from company for finalizing

FAO specifications reviewed in 2008

Product	Manufacturer	Status
Carbosulfan	FMC	Pending information from the company
1-methylcyclopropene	Rohm and Haas France SAS	Pending CIPAC method
Cyprodinil, WG, EC, TC	Syngenta	Published 2009
Fipronil TC, TK, EC, FS, SC, UL and WG	(1) BASF/BCS (2) Gharda Chemicals	To be finalized for publication
Fluazinam	ISK Biosciences Europe	Pending CIPAC method
Haloxyfop-P-Methyl TC, EC	DAS	Pending response from the national authority
Imidacloprid GR	Cheminova	To be finalized for publication
Indoxacarb TC, TK, WG, SC, EC	DuPont	To be finalized and published
Mefenpyr-diethyl TC, WG, EW, EC, OD	BCS	Pending response from the company
Pendimethalin	Finchimica	To be finalized for publication

ANNEX 4.
STATUS OF PUBLICATION OF WHO SPECIFICATIONS

List of pending WHO specifications

Year of submission	Product	Proposer
2006	Alpha-cypermethrin (coated) LN	BASF
2007	Alpha-cypermethrin (incorporated into filament) LN	Clarke Mosquito Control
2007	Deltamethrin (incorporated into filament) LN	Intelligent Insect Control
2008	Temephos	Gharda

ANNEX 5.
STATUS OF PUBLICATION OF FAO AND WHO SPECIFICATIONS

List of pending FAO/WHO joint specifications

Year of submission	Product	Proposer
2004	Bifenthrin	FMC
2007	Cyromazine	Syngenta
2007	Fenitrothion	Sumitomo
2008	Alpha-cypermethrin	Gharda*
2008	Lambda-cyhalothrin	Heranba - Withdrawn
2008	Permethrin	Gharda*

*Under final review and editing by FAO & WHO Secretariat

ANNEX 6.
RELEVANT IMPURITIES - REVISION 8TH JUNE 2009

This document contains changes to section D in the manual proposed by JMPS in 2009.

D. **Determination of the relevance or non-relevance of impurities**

D.1 **Principles**

Any impurity capable of creating an adverse effect, above or beyond that of the active ingredient, is potentially relevant and may therefore have to be controlled by the specification. The adverse effects may reflect toxic or non-toxic hazards (see definition of relevant impurity in the glossary of terms, Appendix C). However, relevance is not determined only by the hazards presented by an impurity. A potentially relevant impurity may be designated as non-relevant if the available evidence indicates no significant likelihood of its hazards being manifested in practice.

Impurity concentration thus has a bearing on risks but risks are application-dependent. So, for the purposes of determining the relevance of impurities, the JMPS considers impurity concentration in terms of its contribution to the overall hazard of a product. In this respect, JMPS procedure is similar to that of GHS guidelines[1] for mixtures of substances. Broadly, the principles adopted by the JMPS follow those of the GHS guidelines but there are some differences.

In GHS terminology, “substance” (corresponding to TC, or a TK without diluent) is the starting point for hazard classification purposes and therefore limits are recommended for “substances”. In contrast, an important function of FAO/WHO specifications is to restrict the hazards of a “substance” (TC or TK) to those of the active ingredient, by limiting the content of relevant impurities.

The specification limits of the GHS guidelines apply to both substances (alone) and “mixtures” of substances (corresponding to formulations or TKs with diluent). In contrast, FAO/WHO specifications for relevant impurities are normally based on the active ingredient content, to ensure that formulations are prepared from a good quality TC or TK.

Relevance is dependent upon the relative hazards of the active ingredient and impurity and therefore an impurity which happens to occur in two different active ingredients may be

[1] Globally Harmonized System of Classification and Labelling of Chemicals, United Nations, New York and Geneva, 2003, http://www.unece.org/trans/danger/publi/ghs/ghs_rev00/english.

designated as relevant in one and non-relevant in the other, or may have different maximum acceptable limits applied.

D.2 Criteria for designating impurities as relevant or non-relevant

The decision on the relevance of an impurity is the result of case-by-case scientific judgement.

Criteria are applied separately to each hazard (toxic and/or non-toxic [including ecotoxicity]) of the impurity, in the following sequence.

D.2.1 Available information on hazards

(a)The impurity is known to present the same type of hazard as the active ingredient (the toxicities being considered additive →**D.2.2**

(b)The impurity is known to present a different type of hazard to those of the active ingredient → **D.2.2**

(c)There is strong evidence from chemical structure, or some other consideration, that the impurity hazards may be in category (a) or (b)

→ **D.2.2**

(d)Impurity hazards unknown and there is no reason to suspect that it may be in category (a) or (b) **decision: non-relevant**

D.2.2 Occurrence of the impurity

(f) The impurity has occurred at least once at detectable levels[2] in production batches of TC/TK before or after storage → **D.2.3**

(g)The impurity has occurred at least once but only in formulations, before or after storage

decision for TC/TK: non-relevant

formulations D.2.3

(h) The impurity does not occur at quantifiable levels in TC/TK or formulations

→ **D.2.4**

[2] the default requirement would be a detection limit of 1 g/kg, but this depends on the toxicity or expected toxicity of the impurity.

D.2.3 Assessment of hazard contribution

Note: concentration values utilized in calculations are derived from manufacturing specifications.

(j) The calculated[3] worst-case-possible contribution to hazard exceeds the threshold for negligible contribution (see Appendix J)

decision: relevant

(k)The worst-case-possible contribution to hazard cannot be calculated[4]:

decision: relevant

(l) The calculated[1] worst-case-possible contribution to hazard does not exceed the threshold for negligible contribution (see Appendix J)

decision: non-relevant

D.2.4 Assessment of non-quantifiable levels

(m)The impurity occasionally occurs in production batches but its levels are rendered non-quantifiable by blending batches

D.2.3, utilizing pre-blending limit for calculation

(n) Evidence or experience indicates that the impurity could occur in manufacture of the active ingredient but:

- it has never occurred at detectable levels in the product being evaluated, or
- it is unlikely to be formed by the process used, or
- it could be derived from starting materials but does not occur in those used by the manufacturer whose data are evaluated

decision: non-relevant but cautionary note to be appended to the specification[5]

D.3 Allocation of limits for relevant impurities

The limits adopted are the result of case-by-case scientific judgement and advice from WHO/PCS and any other source will always be taken into account in deciding the most appropriate limit for toxic relevant impurities.

D.3.1 Maximum acceptable limits

[3] The calculation may be based on data derived from the impurity itself, or involve extrapolation from analogous compounds.

[4] The calculation may be impossible, for example, because: the data required are not available; or the hazard in question does not lend itself to calculation of the contribution; or a threshold for negligible contribution cannot be estimated. This will often be the case when the impurity presents toxicity that is qualitatively different from that of the active ingredient.

[5] The cautionary note will identify the impurity and limit of quantification and state that, although it was considered unnecessary to include it in the specification, the impurity could occur at quantifiable levels in other manufacturers' products.

In the absence of data or other information permitting a more refined approach, the JMPS will normally adopt the GHS guideline values for the labelling of mixtures as default maximum acceptable limits for relevant impurities[6]. The GHS acknowledges that deviations from the guidelines may be necessary or justifiable in some cases. Where the data required are available to the JMPS, a maximum acceptable limit, corresponding to a negligible contribution to the overall hazards, will be estimated by the JMPS and used in preference to the GHS limit.

For impurities posing a similar type of toxic hazard to that of the active ingredient [additive effects], the maximum acceptable limit adopted by the JMPS normally corresponds to a concentration which would lead to a calculated 10% increase in the overall hazard presented by the active ingredient. The cut-off value of 10% is arbitrary but is considered to represent a negligible increase in hazard. Example calculations are given in Appendix J. Where effects are not considered to be additive the calculations, if any, will be made on a case-by-case basis.

D.3.2 Specification limits for relevant impurities If a limit below the maximum acceptable for the relevant impurity has been shown to be practical for routine manufacturing (Section 3.1, paragraphs A.5 or A.6), the JMPS will normally adopt it in preference.

[6] This will often be the case when the impurity presents toxicity that is qualitatively different from that of the active ingredient.