TENTH JOINT CIPAC/FAO/WHO OPEN MEETING

(57th CIPAC Meeting and 12th JMPS Meeting)

Hotel 'Rus', Kiev, Ukraine

10 June 2013

Summary record of the meeting

Agenda

1. Opening and welcome

Dr László Bura, acting Chairman of Collaborative International Pesticides Analytical Council Ltd (CIPAC) and Chairman of the Joint Open Meeting welcomed all participants to the 10th Joint CIPAC/FAO/WHO Open Meeting. Special thanks were extended to Dr Vitaliy Chmil and his team from L.I. Medved`s Research Center of Preventive Toxicology, Food and Chemical Safety, Ministry of Heath, Ukraine for all their efforts in organizing the meeting.

Dr Bura introduced Madam Yong Zhen Yang, representing FAO and Dr Rajpal Yadav, representing WHO to the meeting. The special guests from Ukraine present at the opening of the meeting were Dr Anatoly Ponomerenko, Chairman of the State Sanitary Epidemiological Service, Ukraine, and Dr Mykola Prodanchuk, Head of the Ukrainian National Codex of Ukraine and Director of L.I. Medved's Research Center of Preventive, Toxicology, Food and Chemical Safety, Ministry of Health, Ukraine

Dr Ponomerenko informed the guests that it was an honour on behalf of the Ukrainian Government to welcome them to the ancient capital city of Kiev. The Chairman stated that the Open Meeting was not only important as a scientific event but it was also important as a socially significant event. The problems discussed by CIPAC are essential to protection from infectious diseases as well as to the protection of food growth. Equally important is the safe use of these pesticides for human health and the environment. In this regard, quality control of pesticides is extremely important and analytical methods are the main tool used for quality assurance. The Ukraine has a long tradition of being at the forefront of modern science – starting in the last Century, including the development and use of new pesticides while placing a particular attention to the safe use of pesticides. Based on studies conducted in Ukraine, the production and use of DDT was banned in Ukraine in the early 1970s. For the past 50 years, our scientists have been solving such problems by research in toxicology and chemistry. Their contribution to this work is held in high regard in Ukraine and the scientific analysis of pesticides in Ukraine is considered very important. Dr Ponomerenko's personal opinion would be to have no use of pesticides; however he acknowledged that the elimination of use of pesticides would be impossible because of the threat of a global food shortage and the need to prevent disease. He therefore considered it paramount to make pesticides safe for future generations and the environment. Dr Ponomerenko closed his speech by wishing all of the guests a bright future, a successful conference and welcoming them to Kiev and Ukraine!

Dr Mykola Prodanchuk gave a special welcome to all of those present from CIPAC, the WHO and FAO and stated that it was an honour to host the meeting in Ukraine. Dr Prodanchuk acknowledged that the work carried out by CIPAC, FAO and WHO is essential for human health and the environment on a global scale. The question regarding the safe use of pesticides was raised more than 50 years ago due to developments in agriculture leading to the widespread use of fertilisers and pesticides in Ukraine. Reliable toxicity testing and methods to enable quality control are needed, along with improvements in state registration of pesticides to implement international quality standards. The L.I. Medved Research Center has been focussing on these issues for the last 50 years. Agriculture is extremely important to Ukraine. In 2012, agricultural exports totalled 18 billion dollars. Ukraine ranks No. 1 in the world for exports of sunflower oil and is a world leader in the production of wheat, barley and corn therefore it is extremely

important to provide confidence in the products that we produce. Ukraine only uses validated CIPAC methods for the quality control of pesticides to ensure compliance with specifications, hence the importance of CIPAC methods to Ukrainian agriculture. Dr Chmil from our Research Center has been a member of CIPAC for 20 years. We hope that the meeting is productive and welcome you all to Ukraine.

Madam Yang (FAO) welcomed the meeting attendees on behalf of FAO and thanked the hosts and organisers for their hard work and great effort in organising the meetings. She also thanked the Ministry of Health for giving the Joint Open Meeting and pesticides quality control a high priority. She mentioned that the FAO celebrates the 50th anniversary of establishing FAO specifications for pesticides this year. It has been more than 10 years since the first joint FAO/WHO specifications of pesticides were established. As a scientific advisory body to FAO and WHO, the JMPS plays an important role in establishment of international pesticide specifications, on which national standards and registration measures are based. Countries and national authorities have benefitted greatly from the specifications and therefore the FAO still considers pesticide specifications as a high priority. FAO specifications not only contribute to food security and food safety by ensuring good quality of pesticide products used in agriculture production , but also to environment protection for future generations by reducing risk of pesticide use.
FAO will continue to support the work of pesticide specifications into the future. FAO acknowledges that CIPAC methods are essential for the pesticide quality control; the collaboration of JMPS with CIPAC is a very successful collaboration and long should it continue. Madam Yang wished participants a successful meeting.

Dr Yadav (WHO) welcomed the Ukrainian dignitaries, Madam Yang, Dr Bura and particularly Dr Dorit Nitzan, WHO Representative and Head of the WHO Country Office in Kiev. Dr Yadav emphasised that the meeting is essential to the work of the WHO. The use of public health pesticides for the control of vector borne diseases is on the rise as the diseases themselves are on the rise. This is due to wider travel across the globe and climatic changes. Dengue is now emerging in Europe. Vector control is therefore essential and pesticides play a vital role. The quality control of pesticides has always been on the WHO agenda at least for three reasons. Firstly, it is important to make sure that pesticide products are effective against vectors of disease; secondly they are used to reduce risks to users by ensuring their safe application, and thirdly to make best use of scarce resources ensuring that substandard products are not used. In that regard the JMPS is doing an immense job in setting up pesticide quality standards for public health and agriculture.

Dr Yadav also acknowledged the important role played by CIPAC in providing methods to develop quality control standards. WHO has a long and wide programme in pesticide management, which includes setting standards and helping Member States to increase capability for safe use of pesticides for public health. The FAO/WHO Joint Meeting on Pesticide Management due to take place this year in Geneva in October 2013 will continue to promote the activities for sound management of pesticides and developing necessary guidelines for use of pesticides in Member States.

Only a small number of pesticides are available for public health use compared to agriculture – the public health pesticides currently fall only within 4 classes. Therefore, the effective use of these pesticides by their proper management is essential and one aspect

of this is the use of a good quality product. This is why these meetings are so important. Dr Yadav wished the participants a successful and constructive meeting.

Dr László Bura declared the 10th joint FAO/WHO/CIPAC meeting officially open.

2. Arrangements for chairmanship and appointment of rapporteurs

Dr Bura noted that the Chairmanship of the Open Meeting rotates between the three organizations (FAO, WHO and CIPAC). This year it was the turn of CIPAC to facilitate the meeting, with himself as Chair.

Dr Bura proposed three rapporteurs for the meeting: Mrs Sonia Tessier (FAO), Dr Finbar Brown (WHO) and Dr Jim Garvey (CIPAC), and they were duly appointed. Rapporteurs were thanked for their support.

3. Adoption of the agenda

No changes were made to the agenda and the agenda was adopted.

4. Summary record of the previous meeting

Ninth Joint CIPAC/FAO/WHO Open Meeting; 56th CIPAC Meeting; and 11th JMPS Open Meeting, in Ireland

The summary record of the previous open meeting, held at Dublin Castle, Ireland on 11th June 2012 is available on the FAO/WHO web site.

There being no comments the Minutes of the last CIPAC/FAO/WHO Open Meeting (2012) were accepted.

5. Summary of actions taken after the 56th CIPAC and 11th JMPS meetings

5.1 FAO

Madam Yong Zhen Yang informed the meeting of the activities**,** meetings and events held by FAO since the previous Joint Open Meeting held in Ireland. In addition she informed the meeting of key points of a survey undertaken to gather experiences of countries in phasing out and banning Highly Hazardous Pesticides (HHPs) conducted in 2012. These meetings and workshops, documents and publications with additional information are listed as follows:

A. Training workshops and meetings

- Training workshop on data preparation and submission for the establishment of FAO/WHO specifications; November 2012, Haikou, China
- Regional training workshops on MRLs and risk assessment of pesticide residues in ASENA; January 2013, Vietnam
- FAO/WHO Joint Meeting on Pesticide Residues; September 2012, Rome, Italy

- FAO/WHO Joint Meeting on Pesticide Management; October 2012, Rome, Italy, the revision of Code of Conduct on Pesticide Management was discussed at the meeting.
- 45th CCPR; May 2013, Beijing, China. More that 300 Codex MRLs were adopted.
- Conferences of the Parties to the Basel, Rotterdam and Stockholm conventions; April and May 2013, Geneva. FAO organized two side events on catalyzing global action on HHPs and Sustainable synergies through sustainable agriculture.
- 146th FAO Council; April 2013, new Strategic Objectives and revision of Code of Conduct on Pesticide Management were adopted.

B. Documents and publications

- 2012 JMPR reports and evaluations (residue part)
- Pesticide specifications (see agenda Item 10)
- Three publications have been translated into Chinese in 2012:
    - Manual on development and use of FAO and WHO specifications for pesticides
    - FAO Manual on submission and evaluation of pesticide residues data for the estimation of MRLs in food and feed
    - FAO training manual on evaluation of pesticide residues data for the estimation of MRLs and calculation of dietary intake

C: Survey

FAO conducted a survey recently on Highly Hazardous Pesticides (HHPs). The results show that main information sources known and used for reaching regulatory decisions in surveyed countries are summarized as follows:

- WHO Classification of Pesticides by Hazard (Toxicity classes 1a or 1b & class II) 82%
- Stockholm Convention (Annexes A & B, paragraph 1 of Annex D, on POPs) 71%
- Rotterdam Convention (Annex III) and its PIC procedure 65%
- Pesticides that have shown high incidences of severe or irreversible adverse effects on human health (poisoning cases) or the environment 59%
- Registration status of product in countries with advanced registration systems (e.g. EU, US) 59%
- FAO/WHO Pesticide Specifications 53%
- Simple hazard and risk assessment and evaluation methods 41%
- Code of Conduct on Distribution and Use of Pesticides (guidance throughout the lifecycle of pesticides; MRLs; quality) 30 %
- Carcinogenicity Categories 1A and 1B of the GHS 18%
- Mutagenicity Categories 1A and 1B of the GHS 18%
- Globally Harmonized System on Classification and Labelling of Chemicals (GHS) 12 %
- Reproductive toxicity Categories 1A and 1B of the GHS 12 %
- Other information sources known and used 47%

Alternatives for the replacement of HHPs

- GAP and IPM strategies (41%)
- Biological control agents (35%)

- Natural pesticides (neem; oils) (35%)
- Selection of less hazardous replacement pesticide products (35%)
- Development of disease resistant varieties (12%)

Constraints

- Lack of funding > lack of training, capacity / knowledge gaps / missing access to information (71%)
- Illegal trade (smuggling) of mostly bad quality products (53%)
- Legislation (& policy guidance) inappropriate 30%
- More costly alternatives (30%)
- Farmers traditionally use chemical pesticide (24%)
- Storage facilities inappropriate (18%)
- Laboratories for quality-/residue control (18%)

D. Technical Projects

- FAO new projects on obsolete pesticides, container management and contaminated are sited in EECCA, Latin America (Paraguay, Bolivia) , Caribbean, and Africa (Malawi, Kenya, Eritrea, Botswana, Mozambique, Benin, Cameroon, Morocco, CILSS), Near East (Syria, Oman) and Afghanistan

Questions/Comments:
How widely spread is West Nile virus in the USA now? Dr Yadav responded that it is only recently been found to be present in some parts of USA but can be widely spread in some areas.

5.2 WHO

Dr Rajpal Yadav informed the meeting of the major activities carried out by the WHO Pesticide Evaluation Scheme (WHOPES) within the framework of sound management of public health pesticides, since the previous Joint Open Meeting. These were:

A. Meetings

- 6th FAO/WHO Joint Meeting on Pesticide Management, FAO, Rome, 8-12 October 2012.
- Documents in the pipeline
  - ***International code of conduct on the management of pesticides***
  - Guidelines on pesticide legislation
  - Guidelines on good labelling practice for pesticides
  - A generic risk assessment model for disinfection of aircraft with chemical insecticides

B. Documents and publications

- WHO Guidelines
  - Guidelines for laboratory and field-testing of long-lasting insecticidal nets
  - Guidelines for efficacy testing of spatial repellents
- FAO/WHO Guidelines
  - Guidelines on data requirements for registration of pesticides

- Specifications for pesticides: a training manual. Facilitator's Guide
- Specifications for pesticides: a training manual. Participant's Guide

C. Country support

- WHO African Region
  - Development of national policy for pesticide management in additional 6 countries
  - Training course on indoor residual spraying (IRS) in the Gambia,17–21 July 2012

- WHO American Region
  - Training Course on IRS, Mexico, 24–28 September 2012

- WHO Western Pacific Region
  - Training Course on IRS, Hanoi, Vietnam, August 6-9 2012

- WHO South-East Asia Region
  - Workshop on development of specifications, New Delhi, 10–12 April 2013)
  - Designation of National Institute of Malaria Research, New Delhi as a WHO Collaborating Centre
  - Training course on application of IRS, New Delhi, 10–15 September 2012
  - Regional course on Integrated Vector Management for dengue control, March 2013, Sri Lanka
  - Process initiated to designate Pesticide QC lab. of Dept. Med. Sci., Thailand as a WHO Collaborating Centre, December, 2012.

D. WHOPES product assessment

Application	Product	Manufacturer
Mosquito laviciding	*Spinosad GR and DT*	Clarke Mosquito Control, USA
Indoor residual spraying	*Chlorfenapyr SC*	BASF, France
	Pirimiphos-methyl CS	Syngenta, Switzerland
	Deltamethrin SC	Bayer, France
Long-lasting insecticidal nets	*Aka Net LN*	Kuse Lace Co, Japan
	*Duranet LN**	Shobikaa Impex, India
	*LifeNet LN**	Bayer, France
	MiraNet LN	A to Z Textile Mills, Tanzania
	*Netprotect LN**	Intelligent Insect Control, France
	Olyset Plus	Sumitomo Chemical, Japan
	Panda Net 1.0	Life Ideas Textiles, China
	Panda Net 2.0	Life Ideas Textiles, China
	*PermaNet 3.0 LN**	Vestergaard Frandsen, Switzerland

Kit for long- lasting treatment of mosquito nets	*Yahe LN*	Fujian Yamei Industry, China
	*ICON MAXX**	Syngenta, Switzerland

*WHOPES Phase III trials

Questions/Comments:
Do you anticipate that special repellents will need Quality Specifications in the future? Dr Yadav replied that for the WHOPES scheme every pesticide has to pass through 4 stages; 3 stages of efficacy testing and the 4th stage is development of specifications. These novel products will need to pass all 4 WHOPES stages.

5.3 CIPAC

Dr László Bura, acting Chairman of CIPAC, informed the meeting of the major activities carried out by CIPAC, since the previous Joint Open Meeting:

A. Meetings

- 56th CIPAC TC meeting, Wednesday 13 -14 June, 2012 at the Dublin Castle, Dublin
- ESPAC meeting (English Speaking PAC)
- JAPAC meeting (Japanese PAC)
- DAPA and DAPF meetings (German speak PAC for analytical methods and for formulations)

B. Documents and publications

- CIPAC handbook N and the CD-ROM E to N were published
- The review of the Handbooks is on-going.
    - The proposals for G and H will be placed on our website soon
- The work on a new MT handbook is unfortunately not yet finalised and still ongoing.
    - New comments can be made and will be considered

- CIPAC is going to review its Guidelines. A call for comments will be placed on the CIPAC website in the second half of the year

C. Collaborative trials

- Four full scale collaborative studies were initiated during the last year.
- The results will be presented at the technical meeting in Kyiv

Questions/Comments:
No questions or comments received.

6. Technical liaison with other organizations

Dr Bura mentioned that CIPAC, FAO and WHO work with many regional and international organisations. He called 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

Mr Roman Macaya representing AgroCare, informed the meeting that AgroCare is a global organization representing generic pesticide manufacturers consisting of 865 different companies and four regional associations: ALINA (Latin American Association of the National Agrochemical Industry), ECCA (European Crop Care Association), PMFAI (Pesticides Manufacturers and Formulators Association of India), and CCPIA (China Crop Protection Industry Association). All AgroCare Member Associations have expressed their support for the International Code of Conduct on the Distribution and Use of Pesticides. AgroCare supports science-based regulations and a balance in intellectual property rights that ensure fair market access of competitive post-patent products. Mr Macaya referred to AgroCare's number of global and regional initiatives, including the following:

- Annual participation in JMPM, JMPS, CODEX meetings, as well as other Regional initiatives
- AgroCare formed its Pesticide Specifications Group (PSG) in June 2010 as a technical group to address issues related to specifications

Specifically since the last Joint Open Meeting:

- Presented proposal to the JMPS Panel to resolve issues that bring FAO/WHO pesticide specifications in line with WTO guidelines on international standards of quality (JMPS 2012)
- Participation as Observer in JMPM (Rome, Italy) (October 2012)
- ECCA addressed the risks/costs of counterfeiting at the Informa Post-Patent Conference, Amsterdam (November 2012)
- Communication with the Regulatory Authorities of Peru and Colombia to discourage initiatives to allow importation without registrations
- Workshop with Regulatory Authority in Paraguay to advance the implementation of registrations based on equivalence
- Presentation to industry at Miami FCI Conference in August 2012 regarding the functionality and trends in registration systems in Latin America
- Workshop on Registrations by Equivalence in Guatemala (August 2012)
- Formal admission to CODEX under the status of Observer (September 2012)
- Workshop on counterfeit pesticides (Honduras) (November 2012)
- Presentation of results of the first Latin American Collaborative Inter-Laboratory Proficiency Evaluation Program (December 2012)
- Participation in 45th CCPR Meeting as Observer (Beijing, May 2013)
- International Crop Science Conference & Exhibition 2012 (Dubai, UAE)
    - Prospects for Biopesticides in MENA Region
    - Pheromones for Date Palm Weevil
    - Registration procedures in Iran, Saudi Arabia and Egypt
- International Crop Science Conference & Exhibition 2011 (Nairobi, Kenya)
    - Regulation of pest control products in Kenya
    - Registration procedures in Southern Africa

    - Biological pesticides
- Training programs for farmers regarding use, protection equipment and environmental issues
- Communication with Indian regulatory authority to eliminate registrations of formulated products without the prior registration of the Technical Grade
- Creation of a Tebuconazole Task Force in 2012 (CCPIA)
- Glyphosate Task Force has been very active in environmental control(CCPIA)
- Paraquat Social Responsibility Care Working Group (CCPIA)

Questions/Comments: No questions or comments received.

6.2 AOAC International

Adrian W. Burns, AOAC/CIPAC Correspondent and General Referee-CIPAC Studies, presented an update on AOAC International and the Official Methods Program.

AOAC International is an internationally recognized, proactive membership organization providing science-based consensus solutions for analytical performance criteria in several disciplines such as chemistry (formulations and residue); microbiology (efficacy testing for hospital/care giver/home products); fit for purpose (dietary supplements); and performance tested (test kits/food safety) methods. The ***OMA*** (***Official Methods of Analysis***) provides "official" methods that are scientifically credible and defensible worldwide. Established in 1894 the AOAC has over 3300 members representing more than 80 countries, academia, ministries, and other government organizations which include Industry, US Sates, Countries, Universities, Independent Labs, Non-profit and/or trade Associations, Publishers.

In 2011 the AOAC INTERNATIONAL Board of Directors (BOD) approved an alternative path to achieve Official Method (Official First Action) status for methods selected and reviewed using the AOAC volunteer consensus standards development processes. The traditional collaborative study process was shelved. 13 OMAs have been processed /approved with 13 more OMAs in the system since this came into effect

Methods for formulation are developed, in-house validated, and submitted as part of a regulatory registration process as the methods cannot be identified or determined by stakeholder panels due to confidential business concerns. At the 2012 AOAC International Annual Meeting in New Orleans, the BOD re-instituted and adopted the "traditional collaborative study process" for those methods that do not "fit" into the new pathway process. The methods must be funded and will be administered by and through the AOAC International's Research Institute.

In conclusion the traditional collaborative method process for formulations is alive and well and may be conducted through the AOAC International provided the methods are funded.

Questions/Comments No questions or comments received.

6.3 ASTM International

Dr Alan Viets presented an update on the work of ATSM International:

ASTM International (American Society for Testing & Materials) is one of the world's largest standards developing organizations, established in 1898. The ATSM is an internationally

recognised not for profit organisation, funded mainly through income from sales of their published standards, specifications, test methods and books. The HQ is in Philadelphia, USA.

- 34,165 members - leading experts in their fields
- 22,270 (65%) participate in standards development process
- Members from over 135 countries
- 141 main technical committees in over 100 industry sectors
- (E35.22 Agro) Mutual recognition agreement with CIPAC
- 12,150 standards, 114 manuals, 1,517 STP's
- 104,000 journal pages
- 3,200 changes to standards per annum (26%)
- 5,100 standards adopted by countries outside USA
- 45% of sales outside the USA

Dr Viets reminded the meeting that:

- ASTM is specifically concerned about physical test methods (115 Years)
- ASTM E35.22 - Agro began in 1978
- E35.22 has currently more than 100 active test methods. Methods are reviewed every 4-5 years to insure they are up-to-date.

ASTM-CIPAC Mutual Recognition:

- Cooperative work with DAPF began in 1994.
- At the 1995 Cyprus CIPAC meeting the ASTM compatibility test was suggested for use to fulfil EU 91-414 Compatibility testing requirements.
- In 2001 mutual recognition was established between CIPAC and ASTM

Since the last update ASTM has been working with the USDA on Organic Food - Although a small portion of US Food Production, USDA has devoted resources to address the Organic Food growers concerns. ASTM is now involved in writing definitions for claims. Each claim requires a confirmatory test. This is similar to what ASTM has done for Spray Tanks additives in the USA. EPA has no authority to regulate tank additives.

Global Round Robins including participation from members of ASTM and CIPAC undertaken:

- Inhalation Exemption method
- Laser Diffraction method
- VOC's tied up in Soil method

The next ASTM Symposium will be held from October 21 to 24, 2013 in Jacksonville, FL

Questions/Comments: No questions or comments received.

6.4 CropLife International and European Crop Protection Association (ECPA) SEG

Mr Jean-Philippe Bascou, Chair of the CropLife International/ECPA, Specifications Expert Group (SEG) noted that in addition to main member companies, CropLife represents plant science industry in 91 countries and has *ca.* 1000 members (large and small companies) through their affiliation with CropLife's regional and national organisations. Between them, CropLife members have the largest share of so-called generic or off-patent market. Thus, CropLife speaks for the entire spectrum of the industry, not just the research and development-based (multinational) industry. He highlighted the importance of research and development in Crop protection following on from the results of a survey conducted by Phillips McDougall:

- Average cost associated with discovery, development & registration of a new plant protection agent is 189 million Euros
    - A rise of 68.4% in a decade (1995-2005)
    - Expected to increase a further 26.4% by 2012
- Average time between early stage research & authorisation of a new agrochemical molecule is 10 years
- Need for agricultural innovation remains urgent and crucial in face of call to increase food production 70% by 2050
- Without advanced pest management ca. 50% of today's food production would be destroyed by pests and disease

Mr Bascou outlined the role and activities of the Specifications Expert Group (SEG). The group is comprised of member company representatives with expertise in analytical, phys-chem, regulatory and formulation Sciences, along with ad-hoc members from other expert areas e.g. toxicology, ecotoxicology. The SEG is a technical resource for CropLife and ECPA established to enhance good specification quality and to promote consistency and harmonization in registration requirements. The mission of the 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 and to promote harmonisation.

The Key activities of SEG include:

- Industry interface with FAO/WHO and Specifications process
    - Provide discussion and feedback related to improvements and amendments in the FAO/WHO Manual on Specifications
    - Is involved in providing workshop support to formulation and specification training (Kenya, Morocco, Tunisia)
    - Continue to provide support to JMPS process (Industry guidance document "Working with the JMPS to establish an FAO/WHO specification: A Manual for the Pesticide Industry")

- Engage in and support the work of CIPAC.
    - Co-ordinate our efforts with other expert groups (e.g. DAPF, DAPA, ESPAC, phys-chem Industry forum, etc)
    - Play a leading role in introducing new methods or updated MT methods
    - Annually introduce analytical methods to be used in Specifications as reference methods

    - Provide comment on new or revised OECD Methods on phys-chem properties

- Provide Industry Technical Monographs.
    - TM1, Use of Tolerances in the Determination of Active Ingredient Content in Specifications for Plant Protection Products
    - TM2, Catalogue of pesticide formulation types and international coding system
    - TM17, Guidelines for Specifying the Shelf Life of Plant Protection Products
    - TM19, Minor Changes of Formulants contained in Formulations

- Support to ECPA and CLI Regulatory Teams on
    - Formulation changes – management at zonal level
    - Opinion on SANCO document on Method validation
    - Support CropLife Latin America on equivalence training…

Questions/Comments: No questions or comments received.

6.5 European Food Safety Authority (EFSA)

Mr László Bura presented *EFSA today: priorities and challenges*

The European Food Safety Authority was established in 2002 and scientific work began in 2003. The EFSA guiding principles consist of scientific excellence, independence, openness, transparency and responsiveness. Currently the EFSA has over 450 staff, of which 60% are engaged directly in science. More than 3300 scientific outputs, including 2330 scientific opinions from the EFSA have been produced since its beginning covering a wide remit including food and feed, nutrition, animal health and welfare and plant health. The EFSA's principle roles are

- Provide independent scientific advice and support for EU law/policies on food and feed safety
- Provide independent risk communication
- Promote scientific cooperation
    - Networking
    - Monitoring

The EFSA relies upon scientific expertise across Europe, providing impartial scientific advice. EFSA publish their own journal, have scientific colloquia, and cooperate internationally. As well as within Europe the EFSA works with national food safety organisations outside Europe:

- USA: FDA, USDA APHIS, USDA FSIS, ARS, EPA
- Health Canada
- Food Safety Commission of Japan
- Food Standards Australia
- New Zealand Food Safety Authority

And with international organisations such as:

- WHO
- FAO
- OiE (World Organisation for Animal Health)
- Codex Alimetarius Commission

The EFSA's future challenges include:

- Improve mid term planning
- Reinforce risk assessment capacity (scientific cooperation)
- Optimise internal scientific expertise
- Risk assessment training
- Integrated multi-disciplinary advice
    - meat inspection
    - nutrition
    - antimicrobial resistance…
- Development of harmonised methodologies
- Collection and analysis of high-quality data

Questions/Comments No questions or comments received

6.6 Other Organisations (Global Fund)

Dr Joelle Daviaud, Quality Assurance Specialist from The Global Fund presented *The Global Fund experience in the procurement of pesticides.* Dr Daviaud informed the meeting that The Global Fund is a unique, public-private partnership between governments, civil society, the private sector and affected communities dedicated to attracting and disbursing additional resources to prevent and treat HIV and AIDS, TB and malaria. The Global Fund's model is based on a country ownership concept, i.e. people in countries implement their own programs based on their priorities and on performance-based funding i.e. the Global Fund provides financing on the condition that verifiable results are achieved.

The Global Fund has supported more than 1,000 programs in 151 countries:

- 4.2 million people receiving antiretroviral treatment
- 9.7 million new cases of infectious tuberculosis detected and treated
- 260 million malaria drug treatments (cumulative data for the last 3 years),
- 310 million insecticide-treated nets were distributed to protect families from transmission

The Global Fund's procurement principles are:

- Procure quality assured products
- Conduct procurement processes in a transparent and competitive manner
- In the most adequate form to support adherence (Fixed dose combinations, children forms)
- At the lowest possible price

- Adhere to National and International Laws

On average, 37% percent of funds are used for medicines and health products procurement. LN's represent 42% in value of the budget spent for the core products – Between June 2009 and December 2012 orders totalling 123 million insecticidal nets (US$ 549 million) were made, with 33 million nets ordered in 2012 alone.

Purchasing is guided by the Global Fund Quality Assurance for Health Products which for LNs and IRS procurement includes WHOPES recommendations and WHO specifications. Grant funds may only be used to procure long-lasting insecticidal nets that are recommended for use by the WHO Pesticide Evaluation Scheme. Even with these quality standards in place there are still issue with procuring LNs and IRS. Dr Daviaud presented three case studies highlighting the challenges faced when procuring LNs and IRS

Case 1: Post Marketing Quality Control of LNs in one country

- 5 brands of LN that had been ordered and were still in stock were sampled by an independent party, and analysed for Quality Control Tests by ISO 17 025 certified Reference Laboratory for WHOPES , according to the WHOPES recommended methods for each concerned insecticide.
    - Brands 1 and 2: 100% samples tested were consistent with the results expected
    - Brand 3: 95% of nets tested were not impregnated with any insecticide
    - Brand 4: 70% of samples tested showed an insecticide content inferior to content specifications
    - Brand 5: 33% of samples tested showed an insecticide content inferior to the specifications.

- Only 2/5 brand show 100% of compliance with specifications for insecticide content even before the LNs were distributed to the users
- All the districts "tested" are impacted by quality problem of LNs tested

Case 2: Pre-shipment quality control of IRS

- Early 2012: UNDP reported to the Global Fund that eight orders of insecticides for IRS out of eight tender processes were not compliant with WHOPES standards

Country/ case reference	Product	Total batches produced	Total batches failed	% of failures
1	A	105	27	34.5 %
1	B	3	3	100%
1	B	1	1	100%
1	A	55	o	0%

2	C	3	3	**100%**
3	D	2	2	**100%**
4	E	1	1	**100%**
5	F	3	3	**100%**

- The manufacturers agreed to replace the sub-standard batch by a compliant one. However this lead to
  - significant delay in the supply of IRS insecticides to national malaria programs
  - serious concern as it may have great public health significance, in particular by contributing to insecticide resistance.

Country/ case reference	Product	Total batches produced	Total batches failed	% of failures
1	A	16	10	63%
		Discussion between the manufacturer and WHOPES lab on methods used		
		10	0	0%
2	A	14	14	0%
	B	6	3	50%
		23	23	100%
		Investigation and exchange between the manufacturer and WHOPES lab on methods used		
		23	0	0%

Case 3: VPP pre-shipment testing of IRS in 2012

Lessons learned from this case were that a thorough review of manufacturers QC methods with WHOPES laboratory can prevent future failures. There is a seed for a strict application by manufacturers of the WHOPES published methods on all the parameters.

The Global Fund has proposed several options to prevent such quality issues in the future:

1. Increase Pre shipment QC of Pesticides: the Global Fund Secretariat is developing a plan for systematic pre-shipment quality control of pesticides, by WHOPES QC laboratory
    - Procure from WHOPES recommended sources
    - Systematic Manufacturers CoA review at pre-shipment level
    - All parameters listed in WHOPEs published methods to be reported
    - Random pre-shipment testing by an independent QC laboratory, ISO 17025 certified
    - According to WHOPES published Methods and Specifications
    - Sampling to be done by an independent sampling agent

2. Urgent need to address regular quality testing failure
    - Enhanced collaboration with manufacturers producing WHOPES recommended insecticide products and WHOPES laboratory

3. Need for additional quality control (QC) laboratories with recognized capacity to test pesticides products.

4. Need for more WHOPES recommended pesticides products on the market to allow additional choice for the countries, decrease the risk of shortage, increase the competition and certainly decrease the cost.

Dr Daviaud concluded that the safe use and efficiency of the pesticides is critical - the lack of pesticides quality has delayed the use of LNs and IRS by countries, in some cases for more than one year leading to no spraying before the raining season and contributing to insecticide resistance. The quality of pesticides cannot be compromised: The Global Fund

is increasing the quality monitoring of pesticides, including its control on pesticides at pre and post shipment level. The Global Fund is working in close collaboration with WHO and Partners and Manufacturers to identify solutions for increasing the access to additional assured quality pesticides.

Questions/Comments

In animal health we have seen similar problems with quality control of insecticidal ear tags.

6.7 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, Australia, Belgium, Peoples Republic of China, Czech Republic, Denmark, El Salvador, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Netherlands, Panama, Romania, Slovakia, Slovenia, South Africa, Spain, Switzerland, Thailand #1-Department of Agriculture, Thailand #2- Ministry of Public Health, Ukraine and the UK. Annex 1 contains a summary of the reports.

National reports which were provided electronically are available on the CIPAC web-site (http://www.cipac.org/datepla.htm).

Questions/Comments:

The National reports are very helpful; however we are unable to clearly see the year on year trend if the results for random monitoring and the result of analysis “for cause” are reported tighter. It would be useful if the National country laboratories could report these results separately

8. Status, review and publication of CIPAC methods

Mr Bura observed that information on the most recent CIPAC publications had been discuses under Agenda Item 5.3.

Mr Jim Garvey reported the results of the ESPAC review of Handbooks F & G. He noted that many of the methods were packed column methods and therefore have been identified as either obsolete or due for an update. These will be discussed further during the CIPAC meetings.

Further information is available on the website www.cipac.org

9. Subjects from JMPS Closed Meeting

The following points on significant issues, advanced from previous meetings and also on new matters, were raised in discussions held in the JMPS Closed Meeting. These were presented by Dr Muller, Chairman of JMPS to the FAO/WHO/CIPAC Open Meeting.

Harmonization of CropLife Monograph Nr. 2 and FAO/WHO Specification manual

- JMPS follows CropLife formulation coding (Annex E, FAO/WHO Manual)
- Sometimes, special formulations need a code extension with a suffix:
    - WG packed in water sol. bag WG-SB
- For the insecticide as SC with residual activity: JMPS propose SC-PE (polymer-enhanced)

- Certain types of specifications seem no longer in use – no longer in Mon. 2 or no proposals e.g.
    - SS (Water soluble powders for seed treatment)
    - ES (Emulsion for seed treatment)
    - DP (Dustable powder)
    - CG (Coated granules)
- These formulations seem no longer be used and the corresponding model specs could be deleted in a future revision of the Manual?

- Model specifications for WP- and WG-SB are a “two-in-one” approach with cross-references to clauses that apply for SB
    - rather difficult to understand for user
- Conclusions JMPS:
- Two separate specifications in case of SB-packed WG or WP (editorial)
    - easier to understand for user

Data package for submission for reference and equivalence:

- Specification Manual has caused difficulties with for subsequent manufacturers not clearly understanding the data requirements
- A check list is now available

Confidential data, 1st and subsequent manufacturers

Sometimes the information provided is basic and light on detail e.g.

- Outline of the route of manufacture, summarizing the conditions and solvents employed

    - Reaction:
    - Intermediate “A” + Intermediate “B” → „C“ technical

This information not sufficient for evaluator, as solvents, reagents, catalysts, purification conditions etc. often are missing

- Section A3 to be revised/extended

- More guidance (operational) what information is needed to enable evaluator and Panel to understand TC impurity profile and specification
- Plausibility check

CropLife Specification Expert Group comments – Revision of the Manual

JMPS thank SEG for their valuable comments – many of the comment were editorial; in addition the following technical points were discussed...

- Test temperatures for determination of most physical properties have been harmonised at 30±2°C
  - Recently CIPAC has started to apply 25±°C ad standard temperature range therefore we propose the manual is changes to reflect this.
  - JMPS concluded: Partially agree because some methods are still applies at 30±2°C and the impact of changing the temperature on all tests has not yet been fully studied.

- Adhesion to seed.
  - The manual states that this should be tested after storage. We propose that this does not need to be tested or should only be tested if the physical parameters of the formulation that are relevant for seed treatment application change after storage.
  - JMPS conclusion: We disagree, however would propose that the note should be modified to explain that the test after storage should be performed on one representative crop only.

Amendments to the Manual and future revised edition

- Amendments grow year by year
- More difficult to cross-reference
- FAO and WHO plan to incorporate the amendments into a revised & consolidated version of the Specification Manual in due time

Review Process of Published New Procedure Specifications

- As announced at the Joint Open Meeting 2012
- The JMPS identified, when extending some published specifications, inconsistencies like references to obsolete methods etc.
- JMPS propose a regular review and, if necessary, update published specifications (editorial process) and will establishment of priority list for review
- In 2013 the JMPS concluded that some new procedure specifications are frequently extended. Some of these then sit for many years untouched....
- Propose that specifications for those compounds to be included in a published priority list

Questions/ comments:

We noted you proposed a four letter code e.g. WG-SB. Will four letter codes become officially used by JMPS as this may cause problems for the Industry that use 2 letter codes.

Is there an official procedure for proving comments or remarks for an already published CIPAC method? Mr Bura replied that anybody who is using a CIPAC method can comment by sending remarks to the CIPAC secretariat in writing or by raising them for discussion at the CIPAC TC meeting. He remarked that CIPAC are always pleased to receive comments particularly if someone has concerns or difficulties with a published method.

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

10.1 Status of FAO Specifications

Madam Yang presented the status of FAO specifications as tables, shown in Annex 3.

10.2 Status of WHO Specifications

Dr Yadav presented the status of WHO specifications as tables, shown in Annex 4.

10.3 Status of Joint FAO/WHO Specifications

Dr Yadav presented the status of Joint FAO/WHO specifications as tables, shown in Annex 4.

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

Dr Yadav presented the priority list for JMPS 2013 (see Annex 2) in three different categories: (1) original proposer; (2) subsequent proposer(s); (3) specification for formulation.

He remarked that although there are 21 proposals; only 3 are for new reference specifications.

Mr Jean-Philippe Bascou informed the meeting that there would be a presentation on methods for deltamethrin discussed at the CIPAC TC meeting. He commented that it may therefore be necessary to reconsider the current specifications for deltamethrin – should this be considered as editorial changes only or should this also be added to the programme for next year? Dr Yadav remarked that if there are any additions needed to the list this can be done before the list is finalised although it should be remembered that the last date for expressing interest and confirming the future development of a specification each year is end of May.

Madam Yang commented that companies should be aware of the deadlines for submissions. Late submission of data and proposals puts pressure on the panel members and secretariat of the JMPS. She added that the late withdrawal of proposals also makes forward planning difficult and wastes the time and resources of the panel members.

12. Any other matters

There were no other matters discussed.

13. Date and venue of next meeting

Dr Olivier Pigeon announced that the CIPAC/FAO/WHO Annual Meeting in 2014 will be held in Liege, Belgium and will be co-organised with Walloon Agricultural Research Centre (CRA-W) in collaboration with Federal Agency for the Safety of the Food Chain (FASFC). A presentation was shown of the meeting venue.

Provisional dates for the JMPS and CIPAC meetings were announced as 18th to the 26th of June, 2014. Dr Olivier Pigeon stated he was looking forward to welcoming all participants to Liege next year.

Further details are available on the CIPAC website (http://www.cipac.org/datepla.htm).

Closing of the 10th Joint CIPAC/FAO/WHO Open Meeting

Dr László Bura, Chairperson for the Meeting, declared the meeting closed and thanked the participants for their attendance and the rapporteurs for their work.

Annexes

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

Annex 2. Programme for development of FAO and WHO specifications for pesticides

Annex 3. Status of publication of FAO specifications

Annex 4. Status of publication of WHO and joint FAO and WHO specifications

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	2489	102	2.9
Americas	Argentina	1553	47	3.0
	El Salvador	503	16	3.2
	Panama	171	3	1.8
Asia	Japan	25	0	0
	P.R of China	4909	567	11.6
	Thailand	7268	191	2.6
Australasia	Australia	10	0	0
Europe	Belgium	276	88	31.9
	Czech Republic	63	21	33.3
	Denmark	50	2	4.0
	Germany	277	27	9.7
	Greece	405	3	0.7
	Hungary	1380	24	1.7
	Ireland	162	3	1.9
	Italy	290	1	0.3
	Netherlands	14	1	7.1
	Romania	374	88	23.5
	Slovakia	125	4	3.2
	Slovenia	10	0	0
	Spain	426	16	3.8
	Switzerland	32	8	25.0
	Ukraine	132	7	5.3
	UK	71	10	14.1
Total		**22015**	**1229**	**5.6**

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)
2014	**FAO:**	
1.	Clodinafop propargyl TC	(2) Bharat Rasayan Ltd
2.	Flumioxazin TC, WP	(1) Sumitomo
3.	Chlorothalonil TC and 720g/l SC	(2) Rotam Agrochemical Co., Ltd.
4.	Imadocloprid TC	(2) Helm
	WHO:	
1.	Alpha-cypermethrin (coated) LN	(3) Mainpol GmBH, Germany
2.	Alpha-cypermethrin (incorporated LN)	(3) VC Innovations, India
3.	Alpha-cypermethrin (incorporated) LN (Mira net)	(3) A-Z Mills, Tanzania
4.	Deltamethrin (coated) LN (Fonyi)	(3) Hangzhou, China
5.	Permethrin (incorporated LN) (Aka net)	(3) Kuce Lace Co., Japan
6.	Bendiocarb WP40-SB	(3) Bayer, France
7.	Deltamethrin WG25-SB	(3) Tagros Chemicals, India
8.	Icaridin TC (to be confirmed)	(2) Saltigo GmbH, Germany
9.	S-methoprene TC, WG	(1) Novartis, Switzerland
10.	*B. sphaericus+Bti* (Vectomax) FG	(1) Valent BioSciences, USA
11.	Bifenthrin (incorporated) LN	(3) VC Innovations, India
	FAO & WHO:	
1.	Lambda-cyhalothrin TC	(2) Youth Chemicals, China
2.	Bifenthrin TC	(2) Youth Chemicals, China
3.	Deltamethrin TC	(2) Sulphur Mills, India
4.	Lambda-cyhalothrin TC	(2) Sulphur Mills, India
5.	Permethrin TC (40:60::cis:trans)	(2) Gharda Chemicals, India

ANNEX 3.
STATUS OF PUBLICATION OF FAO SPECIFICATIONS

Product	Manufacturer	Status
Alpha-cypermethrin TC	Meghmani	Published
Fosetyl-aluminium TC	Helm	Published
Lambda-cyhalothrin TC	Bharat	Published
Dinotefuran TC	Mitsui	Published
Flazasulfuron TC, WG	ISK	Published
Picloram TC	Nutrichem	Published
Propamocarb hydrochloride TC	Bayer CropScience	Published
Azoxystrobin TC	Helm	To be published
Glyphosate TC	Helm, Monsanto	To be published
Imidacloprid	Cheminova	To be published
Carbosulfan TC	FMC	Report to be published
Nicosulfuron TC	Cheminova	To be published
Fluazinam TC SC	ISK	To be published
Diazinon TC	Makhteshim	Report to be published
Clothianidin TC, FS, WS	Bayer CropScience	Pending review of 2013 JMPS
Fosthiazate TC, GR	ISK	Pending CIPAC method
Thiamethoxam TC, WG, SC, FS	Syngenta	Pending CIPAC method
Cyazofamid TC, SC	ISK	Pending CIPAC method
Chlorfenapyr TC, SC	BASF	Pending CIPAC method
Diflubenzuron TC	Helm	Pending review of 2013 JMPS
Triflumuron TC, WP, SC	Bayer CropScience	Pending CIPAC method

ANNEX 4.
STATUS OF PUBLICATION OF WHO AND FAO/WHO SPECIFICATIONS

Year	Product	Manufacturer	Spec.	Status
2011	Alpha-cypermethrin LN	Disease Control Tech.	WHO	Sep-11
	Alpha-cypermethrin LN	VKA Polymers	WHO	Sep-11
	Bacillus thuringiensis GR	Valent BioSciences	WHO	2011
	Deltamethrin LN	Bayer	WHO	Sep-11
	Pirimiphos-methyl CS	Syngenta	WHO	Finalized
	Alpha-cypermethrin TC	Bharat Rasayan	FAO/WHO	2012
	Chlorfenapyr TC, SC	BASF	FAO/WHO	Finalized
	Deltamethrin EC, EW	Bayer	FAO/WHO	2012
	Deltamethrin SC	Bayer	FAO/WHO	Finalized
	Lambda-cyhalothrin TC	Bharat Rasayan	FAO/WHO	2012
	Permethrin (40:60 cis/trans) TC	Tagros	FAO/WHO	Finalized
2012	Alpha-cypermethrin WG, WG-SB	Tagros	WHO	Finalized
	Malathion EW	Cheminova	WHO	Published
	Permethrin+PBO LN	Sumitomo	WHO	Published
	Spinosad DT, CG	Clarke/Dow AgroSciences	WHO	Finalized
	Temephos TC	Fersol	WHO	Pending
	Deltamethrin, TC, EC	Isagro	FAO/WHO	Published
	Diflubenzuron TC	Helm	FAO/WHO	Pending

Note: Specifications marked as finalized are awaiting a satisfactory WHOPES assessment and report.