



## 13<sup>th</sup> JOINT CIPAC/FAO/WHO OPEN MEETING (60<sup>th</sup> CIPAC Meeting and 15<sup>th</sup> JMPS Meeting)

lino Hall & Conference Center, Tokyo, Japan

13 June 2016

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#### 1. Opening and welcome

Mr Ralf Hänel, Chairman of Collaborative International Pesticides Analytical Council Ltd (CIPAC) and Chairman of the Joint Open Meeting welcomed all participants to the 13<sup>th</sup> Joint CIPAC/FAO/WHO Open Meeting. Special thanks were extended to the Food and Agricultural Materials Inspection Center (FAMIC), and the Ministry of Agriculture, Forestry and Fisheries (MAFF), Japan for all their efforts in organizing the meeting.

Mr Hänel introduced Madam Yong Zhen Yang, representing FAO and Mr Rajpal Yadav, representing WHO to the meeting. The special guests from Japan present at the opening of the meeting were Mr T. Kawashima, Deputy Director from MAFF, and Mr Tsuneo Kobatake, Vice President of FAMIC in charge of agricultural chemicals inspection operations.

Mr Kobatake welcomed everyone to the 13th Joint CIPAC/FAO/WHO Open meeting, and noted that it was the first time that the CIPAC meeting was being held in Japan. On behalf of the Ministry of Agriculture, Forestry and Fisheries, he expressed special appreciation to Dr. Ralf Hänel, Chairman of CIPAC, for giving Japan the opportunity to host the CIPAC meeting with a long and distinguished history. His appreciation was also expressed to the Secretariat of CIPAC, and staffs of Food and Agricultural Materials Inspection Center and Japan Pesticides Analytical Council for their dedication to the preparation for the meeting.

He informed the Meeting that agricultural pesticides are indispensable for securing stable food production, for countries with warm and humid climate like Japan in particular. However, at the same time, as being designed to control organisms damaging crops, pesticides have the possibility to adversely affect the human health and the environment. In preventing such adverse effects, management of the quality of pesticide products is the very first and critical step. FAO and WHO have developed pesticide specifications, while CIPAC has standardized analytical methods to verify compliance with these specifications. In this regard, the activities of FAO, WHO and CIPAC have significantly contributed to the quality management of pesticides. MAFF believes it is extremely important work.

MAFF understands that along with the globalization of pesticide trade, international harmonization is becoming more and more important task for Japan. Currently, Japan MAFF is reviewing the pesticide registration system from the viewpoint of international harmonization. One of such examples is the introduction of specifications for technical grade of the active ingredients (TGAI) for improved management of the quality of pesticides, which is scheduled to take effect in the next year.

Japan has contributed to the global harmonization of pesticide regulation through several international fora, including JMPR, Codex and OECD, by sending experts, providing comments and scientific information. Japan is fully committed to continue such activities in the future, and take increasingly greater roles in the harmonization of pesticide specifications and analytical methods, a relevantly new area of activity for us.

He concluded by wishing everyone a fruitful and pleasant meeting.

Mr Kobatake welcomed everyone to Japan and expressed his honor in having the opportunity to give a welcome address on behalf of Food and Agricultural Materials Inspection Center, commonly called as FAMIC. The Vice President of FAMIC is in charge of agricultural chemicals inspection operations.

He expressed his desire to talk about missions of FAMIC and the current situation of agricultural chemicals in Japan.

FAMIC, under close cooperation with the Ministry of Agriculture, Forestry, and Fisheries, is entrusted with the mission of contributing to ensuring the safety and proper use of agricultural materials and improving the quality and labeling of food products.

For this mission, they carry out operations like scientific inspections and analysis of agricultural materials such as fertilizers, agricultural chemicals and feeds and food products by using our specialized knowledge and skills.

Originally, these operations had been conducted by three different governmental inspection organizations. However, through the administrative reform in 2001, all of them became transformed to incorporated administrative agencies respectively, and these three incorporated administrative agencies were integrated into one organization in 2007. That is FAMIC. Therefore, at present, the operations with respect to the review and evaluation of test data for registration of agricultural chemicals are carried out under the Agricultural Chemicals Inspection Station called ACIS, which is one of the departments of FAMIC.

For reference, a brochure of FAMIC was provided to meeting attendees.

Mr Kobatake then talked about the operations of ACIS. The Agricultural Chemicals Inspection Station called ACIS, which is now under FAMIC after the merger in 2007, had been established in 1947. Since then, ACIS has been the only inspection organization in Japan that carries out operations under the directions of the Ministry of Agriculture, Forestry and Fisheries relating to agricultural chemicals in an integrated fashion. Those operations include the review and evaluation of test data submitted by applicants for registration of agricultural chemicals. That is the main work of ACIS. Also, they conduct on-site inspections at agricultural chemical manufacturers, surveillance of proper use and residues of pesticide in crops at fields, compliance monitoring of GLP at test facilities that generate test data

required for registration, promotion of international harmonization with respect to regulations of agricultural chemicals, and research for the development and improvement of skills necessary for these inspections and analyses.

He informed the Meeting about the agricultural chemical registration system in Japan. The registration system of agricultural chemicals in Japan started when the Agricultural Chemicals Regulation Law was enacted in 1948 for the purpose of ensuring the proper quality, and safe and proper use of agricultural chemicals. Since then, the registration system has been improved and expanded in order to implement measures such as prohibition of pesticides with highly acute toxicity, regulations regarding pesticide residues, prevention of damages to aquatic animals and plants, applying of GLP to test data, and prohibition of manufacture, sale, and use of unregistered pesticides and so on.

When looking at the trend of pesticides abroad, the globalization of the products and their distributions and the international harmonization of registration system are proceeding. The Vice President considered that the activities of CIPAC are one of globalization and harmonization. FAMIC will continue to pay attention to the activities of CIPAC, FAO and WHO, and intend to incorporate necessary things into their registration system from the outcome of those activities.

Mr Kobatake referred to the excursion for Meeting attendees to the Nikko city, Tochigi prefecture. Nikko Toshogu Shrine enshrines Iyasu TOKUGAWA who established Tokugawa Shogunate in Edo, current Tokyo, in the seventeenth century. The current Tokyo is based on the historical townscape of Edo era. Nikko city is a town located in the north part of the Kanto Plain, where Tokyo is also situated. The area between Tokyo and Nikko holds a wide expanse of rice paddies and cultivated fields. Because Japan has a lot of rainfall and abundant water in Japan, there are many rice fields on flatlands to mainly grow paddy rice there. The total cultivated land in Japan is about 4.5 million hectares, of which paddy fields, equivalent to 2.45 million hectares, account for more than half (54%). The cultivated land has decreased in recent years.

On the other hand, because of the climate of high temperature and humidity in summer in Japan, problems of pests and weeds easily arise on cultivated lands. Therefore, agricultural chemicals are one of indispensable materials in order to stably produce agricultural crops.

Mr Kobatake informed the Meeting about the quantitative aspect of agricultural chemicals used in Japan. The annual shipping volume of agricultural chemicals within Japan for the period from October 2014 to September 2015 was about one hundred ninety thousand tons, and about three hundred forty billion yen or three billion euros on the monetary base. Over the past ten years, the shipping volume on quantitative basis tends to decline, but remains flat on the monetary basis. And when it comes to the shipping volume by use, insecticides and herbicides account for one third respectively, and fungicides take up one fifth, and mixture products of insecticide and fungicide represent one tenth.

Then, with regard to formulation types of agricultural chemicals, Wettable Powder including Suspension Concentrate accounts for the largest shipping volume, that is about 32 %. Then, it is followed by Granule which takes up 28 %. Dustable Powder and Emulsifiable Concentrate represent 9 % respectively, and the share of Water Soluble Liquid is 7 %.

Finally, he talked about some characteristics of use of agricultural chemicals in Japan. Since agricultural chemicals are mainly used in paddy fields in Japan, and in the circumstances of aging farming population and labor shortages, various unique innovative formulation types are being developed in Japan. For example, there is a formulation type used by throwing it directly into paddy fields, the merit of which is that no spraying apparatus is needed. Another example is a formulation type which is applied to seedling boxes and keeps effects long enough on targeted pests and diseases, which might arise in the seedlings' growing period,

after they are transplanted to paddy fields. The merit of this formulation type is that the laborsaving application and the long lasting residual effects are expected.

In closing, he hoped that the Meeting would bring about a meaningful and fruitful outcome for everyone, for further developments in CIPAC, FAO and WHO, and everyone's good health.

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. Madam Yang recognised Japan's excellent contribution to FAO, Codex, JMPR and JMPS work areas, in addition to international pesticide guidelines. She noted that the Joint Open Meeting is an open platform for sharing pesticide issues, and significantly contributes to pesticide quality, international trade and the harmonisation of pesticide regulation between countries.

UN countries adopted a set of goals to end poverty, protect the planet, and ensure prosperity for all as part of a new UN Sustainable Development Agenda. Each of the 17 goals included in the agenda has specific targets to be achieved over the next 15 years. One of the most important goals of the agenda, is to reduce hunger, but in a sustainable way. In this regard, it is envisaged pesticides will play an important part by reducing food loss responsibly. The JMPS and CIPAC work therefore will make a significant contribution to achieving this goal, by securing food safety and food security.

The FAO will continue to provide support to the important work carried out by JMPS and CIPAC. She concluded her remarks by thanking the government of Japan for its continued contribution to international work in the area of pesticide standards.

Mr Yadav (WHO) welcomed the two Japanese dignitaries, and fellow participants to the Meeting. He referred to the importance of the Memorandum of Understanding that exists between the WHO and FAO. WHO and FAO had signed a Memorandum of Understanding in 2001 for a joint collaboration in pesticide specifications that has been renewed in 2015 for another 6 years.. When working together, the two expert Committees set up are known as the FAO/WHO Joint Meeting on Pesticides Specifications (JMPS) and Joint Meeting on Pesticide Management. He said that CIPAC play an important role in ensuring that the reliable methods of chemical analysis are available to support the FAO/WHO specifications.

The WHO has significantly contributed to the achievement of the Millennium Development Goals by reducing the burden of vector-borne diseases. He noted that there was a 35% reduction in malaria cases, and a 40% decrease in mortality due to malaria. The use of long-lasting insecticide nets and indoor residual spraying of insecticides have mainly contributed to reduction in the burden of malaria since 2000. The global strategy for malaria control relies upon the responsible use of effective pesticides. Apart from dengue, Zika virus disease has caused a great concern in many parts of the world, and the emergency response team in the WHO are advising affected countries in dealing with the emerging problem. Pesticides play a significant role in controlling mosquito vectors of these diseases. It is important that only high quality pesticide products are manufactured to ensure effective vector control.

Mr Hänel mentioned that even at the first JMPS Meeting in 2002, it was obvious that the Japanese colleagues were very active in the area of pesticides, and noted that there has been a Japanese CIPAC member for the past number of years and they are proving to be very important and useful with regards to the work of CIPAC.

Mr Hänel declared the 13<sup>th</sup> joint FAO/WHO/CIPAC meeting officially open.

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

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

Mr Hänel proposed three rapporteurs for the meeting: Mr Axel Steer (FAO), Mr Finbar Brown (WHO), and Mr Jim Garvey (CIPAC) and they were duly appointed. Rapporteurs were thanked for their support.

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

Only one change was made to the Agenda 6, Technical liaison with other organisations, i.e the FASA will not be making a presentation this year. No other changes were made to the agenda, which was then adopted.

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

#### **4.1 12<sup>th</sup> Joint CIPAC/FAO/WHO Open Meeting; 59<sup>th</sup> CIPAC Meeting; and 14<sup>th</sup> JMPS Meeting, Athens, Greece**

The summary record of the previous open meeting, held at the Royal Olympic Hotel, Athens, Greece on 15<sup>th</sup> June 2015 is available on the FAO/WHO web site. There being no comments, the Minutes of the last CIPAC/FAO/WHO Open Meeting (2015) were accepted.

### **5. Summary of actions taken after the 59<sup>th</sup> CIPAC and 14<sup>th</sup> 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 Athens.

##### *Training workshops and Meetings*

- FAO/WHO Joint Meeting on pesticide residues, September 2015, Geneva, Switzerland
- FAO/WHO Joint Meeting on Pesticide Management, October 2015, Nanjing, China
- 48th CCPR, April 2016, Chongqing, China, > 300 Codex MRLs approved
- Special session of the 2016 JMPR meeting, 9-13 May, Geneva, Switzerland, re-evaluation of diazinon, glyphosate and malathion
- Technical working group meeting on ground and surface water risk assessment (Toolkit) in Rome. 8-10 December 2015
- National workshop on the Pesticide Registration Toolkit in Yangon, Myanmar. 4-7 April 2016
- Regional workshop for SADC member countries on HHPs and including parts of the Toolkit in Johannesburg, South Africa. 25-29 April 2016

##### *Documents & publications*

- 2015 JMPR report and evaluations (Residue monographs)  
<http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/>
- FAO/WHO guidelines on Highly Hazardous Pesticides  
<http://www.fao.org/3/a-i5566e.pdf>
- FAO/WHO Manual on development and use of specifications for pesticides  
<http://www.fao.org/3/a-i5713e.pdf>

- FAO/WHO Guidelines on pesticide legislation  
<http://www.fao.org/3/a-i5008e.pdf>
- FAO/WHO Guidelines on good labelling practice for pesticides  
<http://www.fao.org/3/a-i4854e.pdf>
- Draft guidelines under development
  - Microbial and botanic pesticides
  - Personal protection when working with pesticides

### *Pesticide Registration Toolkit*

- Toolkit for pesticide regulators on-line, FAO supports informed decision-making for the authorization of pesticides <http://www.fao.org/pesticide-registration-toolkit/en/>
  - it is a web-based handbook intended for day-to-day use by pesticide registrars to support several of their regular tasks: finding data requirements, evaluating human health and environmental risks, determining appropriate risk mitigation measures, and accessing pesticide-specific information, such as registrations in other countries, scientific reviews, hazard classifications, maximum residue limits (MRLs) and pesticide properties
  - it provides assessment methods at different levels of complexity, from generic methods requiring limited resources, to more locally specific risk and efficacy assessment methods

### *Technical projects*

- Pesticide Field Projects
  - FEM GCP/INT/147/GFF(Disposal Of Obsolete Pesticides Including POPs And Strengthening Pesticide Management Of The Comité Permanent Inter-Etats De La Lutte Contre La Secheresse Dans Le Sahel (CILSS) Member States)  
17 countries in CILSS-UEMOA-ECOWAS, US\$ 38 million, 4 years objectives:
    - Strengthen the regulatory framework and institutional capacity for sound management of pesticides;
    - Promote alternatives to POPs and other conventional hazardous chemical pesticides;
    - Implement management systems for empty pesticide containers; and
    - Safely dispose of POPs and other obsolete pesticides and remediate heavily pesticide-contaminated sites ;
    - Develop and implement a communication strategy on pest and pesticide management.
  - Capacity-Building Related to Multilateral Environmental Agreements in ACP Countries – Phase 2 (GCP / INT / 153 / EC), EUR 4.23 million, 2 years  
Objective: elimination of obsolete pesticides, pesticides management and sustainable pest management; and implementation of MEAs related to Chemicals and Waste, through specific field project activities
  - Target countries: Africa Angola - Benin - Botswana - Burkina Faso - Burundi - Cameroon - Cape Verde - Central African Republic - Chad – Comoros - Congo (Brazzaville) - Congo (Kinshasa) - Cote d'Ivoire - Djibouti - Eritrea - Ethiopia - Gabon - Gambia - Ghana - Republic of Guinea - Guinea-Bissau - Equatorial Guinea - Kenya - Lesotho - Liberia - Madagascar - Malawi - Mali - Mauritania - Mauritius - Mozambique - Namibia - Niger - Nigeria - Rwanda - Sao Tome and Principe - Senegal - Seychelles - Sierra Leone - Somalia - South Africa - Sudan - Swaziland - Tanzania - Togo - Uganda - Zambia - Zimbabwe
  - Caribbean: Antigua and Barbuda - Belize - Bahamas - Barbados - Cuba - Dominica - Dominican Republic - Grenada - Guyana - Haiti - Jamaica - St. Kitts and Nevis - St. Lucia - St. Vincent and the Grenadines - Suriname - Trinidad and Tobago

- Pacific: Cook Islands - Fiji - Kiribati - Marshall Islands - Micronesia - Nauru - Niue - Palau - Papua New Guinea - Solomon Islands - Samoa - Timor Leste - Tonga - Tuvalu - Vanuatu

## Questions/Comments

None.

## 5.2 WHO

Mrr 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.

The WHO organised two recent WHOPES meetings:

- 18th WHOPES meeting, 29 June–1 July 2015, which recommended 4 new vector control products ;
- 19th WHOPES meeting, 8–11 February 2016, which recommended 4 new vector control products.

The reports of these meetings are available on the WHOPES website.

FAO/WHO collaborations continue to take place and included the following activities:

### a. Pesticide standards & management:

- FAO/WHO Manual, 3rd revision, 2016. The Manual is being regularly reviewed. Further amendments will be published separately to the Manual, until a 4<sup>th</sup> revision takes place.
- Guidelines on highly hazardous pesticides
- Guidelines on licensing of pest control operators
- Guidelines on pesticide legislation
- Guidelines on good labelling practice for pesticides

### b. Use of malathion in public health:

- FAO/WHO JMPR organized an extraordinary meeting, Geneva, 9–13 May 2016, to review the hazard and risk assessments of glyphosate, dieldrin and malathion.
- WHOPES organized a meeting in Geneva, 16–17 May 2016 to review the human health risk of malathion used in vector control including malaria, Zika and dengue. The meeting recommended that malathion can be continued to be used provided health of operators is monitored (see full report available at: [http://apps.who.int/iris/bitstream/10665/207475/1/9789241510578\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/207475/1/9789241510578_eng.pdf)).

### c. Guidelines – work in progress:

- Efficacy testing of molluscicides since snail control is required to control schistosomiasis in some regions of Africa and China.
- Guidelines for personal protective equipment.
- Revision of the guidelines for specifications for pesticide application equipment
- Revision of the guidelines for laboratory and field testing of LLINs.
- Revision of the guidelines for indoor residual spraying
- Test procedures for insecticide resistance testing.

d. Zika virus disease: Zika is a huge problem in the American region. The only method for Zika control currently available is the control of vector mosquitoes. WHO have responded by setting up an emergency response team, providing, technical support on vector control and

publication of Vector Control Operators framework for Zika virus (<http://www.who.int/entity/csr/resources/publications/zika/vector-control/en/index.html>).  
Innovative vector control tools - *Vector Control Advisory Group (VCAG)*:

d. A VCector Control Advisory Group on new vector control tools was set up 3 years ago. It is a group that helps industry develop new technologies that helps bring this technology to the market. The group has evaluated new tools such as Wolbachia, Sterile Insect Technique (in collaboration with IAEA), transgenic mosquitoes, attractive toxic sugar baits (ATSB), eave tubes, and vector traps for surveillance.

e. WHO reforms: WHO initiated reforms in vector control product evaluation system since 2015. The reform will improve efficiency, transparency, and lead to devolution of pesticide product evaluation functions from WHOPEs to the WHO prequalification unit (PQ Unit). Details of this change will be placed on the WHOPEs website. The normative functions will remain with WHOPEs and WHO Global Malaria Programme. WHOPEs in collaboration with IVCC is currently developing a quality management system leading to GLP accreditation of test sites. There are no GLP laboratories currently involved in vector control. Therefore, WHO and IVCC have identified about 14 institutions to build GLP capacity. The aim is for Industry to be able to go to these labs, and to request their products tested.

## **Questions/Comments**

Question 1: Will malathion exposure be a problem?

Answer: Maximum adsorption of malathion is through skin, therefore operators need protective clothing. Malathion results in lowering cholinesterase enzyme in red-blood cells, so if the operator wears protective clothing, and the enzyme level is periodically monitored, malathion use does pose undue risk to the operators. Certain relevant impurities in malathion manufacturer need to be controlled, which requires quality control checks.

Question 2: What about bystanders? Is it possible for bystanders to be sprayed outdoors.

Answer: Space spraying was best used indoors instead of on the streets. However, malathion is only recommended for outdoor space spraying, not for indoor use. There is a difficult balance between different risks. You need a balance between risk to malathion exposure and risk of exposure to the Zika virus. When applied under recommended conditions of use, outdoor levels of malathion exposure are considered to be within the acceptable levels.

## **5.3 CIPAC**

Mr Ralf Hänel, Chairman of CIPAC, informed the meeting of the major activities carried out by CIPAC, since the previous Joint Open Meeting:

- There is a new CIPAC website. <http://www.cipac.org/>
- CIPAC has asked for comments on the hallmark vale for using collaborative trials.
- The Review of methods and handbooks are ongoing. The review is on time.

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

### **6.1 AgroCare**

Mr Jürgen Wenzel gave a presentation on behalf of AgroCare and its structure.

- AgroCare is a global organization that was founded in 2008. AgroCare currently represents 865 generic pesticide manufacturers, split up into four regional associations, namely:
  - AgroCare Latin America (previously 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).

*AgroCare's Mission is:*

- AgroCare members abide by the FAO/WHO Code of Conduct.
- AgroCare also provides a uniform and clear voice at international level organisations such as the CIPAC, the FAO, the WHO, and the WTO.
- The AgroCare mission is to support the generic producers' right to play a crucial role in offering one of the most needed solutions to face today's global food security and public health challenges. Generic companies offer innovative, high-quality solutions to address farmers and public hygiene needs.

He gave an explanation of the term "generic". AgroCare informed the meeting that off patent products can sometimes be improved copies of the original, therefore the equivalence process that is carried out by JMPS is a very important part of the process in ensuring these generic products reach the market.

*Activities in 2015-2016 include:*

- AgroCare supports and actively contributes to the work of JMPM, JMPS, JMPR, CIPAC and WHOPEs.
- Specifically, AgroCare contributed to the following areas:
  - JMPM: Dissemination of Code of Conduct.
  - JMPM: Development of Registration Toolbox, Inclusion of the equivalence concept.
  - JMPM: Statement on HHP (with CLI).
  - JMPS: Discussion the standards setting process and terminology in the Manual.
  - JMPS: Gembloux meeting on specifications for microbial pesticides.
  - JMPR: AgroCare LA.
  - CIPAC: AgroCare observer.
  - WHOPEs: Informational meeting on bio-equivalence of end-use products in public hygiene vector control.

*He described that:*

- Setting standards is very important for a functioning (global) economy, but it can also be used as a tool to disrupt competition.
- WTO Principles for Standards include transparency, impartiality, consensus, effectiveness and relevance
- To avoid the misuse of standards in international exchange of goods the WTO passed certain rules for both, standards and the standard setting process.

*FAO/WHO JMPS Process. He explained AgroCare's understanding of the process for overview of the technical grade active ingredients (TGAI) as under:*

- Manufacturer produces at least 5 representative batches of TGAI.
- The Manufacturer analyses for purity/impurity profile.
- The Manufacturer proposes the Manufacturing specification (published part containing active substance and relevant impurities, and the undisclosed part containing impurities of  $\geq 1$  g/kg).

- The JMPS evaluates Manufacturers proposal.
- A Reference Profile and FAO/WHO Evaluation Report are produced, containing the FAO/WHO Specification (published), an undisclosed part (confidential), and the hazard profile and phys-chem. properties published as summaries.

AgroCare expressed their concerns with the JMPS process, in relation to:

- Mixing up “FAO/WHO specification“ with “Reference profile“.
- The unilateral revision of standards takes place behind closed doors, and conflicts with WTO rules & distortion of competition.

*AgroCare expectations of JMPS include:*

- Transparency
- Impartiality and Consensus
- Effectiveness and Relevance
- The Manual has to be unambiguously clear as to the definitions of “FAO/WHO specification” (= international point of reference and standard) and “Reference profile”.
- AgroCare requests JMPS to give up the unilateral modification of international standards. All stakeholders shall be informed and invited to participate in the review.
- In terms of Effectiveness some hurdles have been removed (equivalence of confidential data submitted to FAO/WHO, compared to confidential data submitted to a national authority were a registration has been obtained).
- We shall follow the forthcoming modifications in the Manual and are ready to further contribute to its improvement.

*AgroCare’s global activities include the following:*

- Europe (ECCA activities 2015-2016)
  - Participation to different Stakeholder platforms:
    - European Commission:
      - DG SANTE Advisory Group
      - DG Environment PIC Meeting
      - Expert Working Groups
      - Zonal Steering Committee meetings
      - Technical workshops
      - Procedural Workshops
    - EFSA stakeholder platforms
  - Conferences
    - Chairing ECCA-ECPA Regulatory Conference
    - ECCA speakers at other conferences
  - Intervention in Legal Case
    - ECCA intervening in support of the EU Commission’s No to access for NGOs to business confidential information.
  - SANTE Advisory Group & PIC meetings:
    - General presence, expressing industry position where required, vigilance re. specific generic interests
  - Operation Silver Axe (Oct-Nov 2015)
    - ECCA participation in preparation of joint operation of European enforcement agencies and Europol, in fight against illegal trade & counterfeit pesticides. 190 Tons of illegal product seized.
- Latin America (AgroCare LatinoAmerica 2015-2016)
  - Promotion and dissemination of the FAO/WHO Code of Conduct among partner organisations.
  - Participation in CCPR48 – Chongqing, China:

- Revision of ISTIE – International Estimate of Short-term Intake.
  - Draft guidance on performance criteria for methods of analysis for determination of pesticides residues.
  - CODEX schedules and priority lists of pesticides.
  - Monitoring and counselling in programs of collection and handling of empty pesticide containers.
  - Implementation of IV Interlaboratory Proficiency Testing 15 laboratories of 7 countries participated.
  - Commenting on HorRat CIPAC criterion for reproducibility in collaborative trials.
  - Argentina Meeting national Codex authorities in preparation of CCPR48
  - Brazil Consultation for a new registration law. Risk Assessment training for industry in partnership with IBTox – Brazilian Institute for Toxicology. Establish a positive list of co-formulants Working group with ANVISA.
  - Costa Rica Design a new policy framework for agrochemicals registration.
  - Mexico Support VAT exemption or imports of pesticide active ingredients.
- India (PMFAI activities 2015-2016)
- Defend generic competition in several court cases supporting the Indian government's new and balanced guidelines.
  - Support the Indian government's Compulsory Licensing Patents Act and Price fixing of Pesticides.
  - Promote sound science vs. "media hype" in the Indian review of 66 pesticides.
  - Adopt fair and transparent data protection clauses in the forthcoming new Pesticides Management Bill 2008.
  - Promote standardisation in the FAD committee to the Bureau of Indian Standards (BIS).
  - Define rules for minor changes in pesticide formulations in amendment of local regulations (with CLI).
  - Improve pesticide labels and leaflets in amendment of local regulations (with CLI).
  - Promote safe pesticide use in the Agriculture Skill Council of India (ASCI).
  - Environmental impact assessment of pesticides in rice cropping systems (Partnership with Krishi Vigyan Kendra and the National Centre for Integrated Pest Management).
- China (CCPIA activities 2015 – 2016)
- Responsible Care & Safe Use
- Responsible Care is a global, voluntary initiative developed autonomously by the chemical industry. It stands for the chemical industry's desire to improve health, safety, and environmental performance.
  - Responsible Care alliance grew by 13 to 30 members.
  - Trained >500 staff in 3 professional training seminars.
  - Assisted 4 companies to pass the HSE certification.
  - Started an MBA program Agrochemical HSE with Nanjing Tech University. 14 MBA students recruited in 2015.
  - CCPIA's Committee of Using Pesticide Safely & Scientifically held 186 trainings with >32,000 farmers.

- Organized 4 conferences on integrated crop protection in potato, rice, citrus, and vegetables, reaching >3'000 participants to realise the “Pesticide and Fertiliser Zero Increase Policy by 2020”.
- CCPIA’s “Non-agricultural Pesticide Use Committee” explores the safe use of pesticides in the public health area.

#### Industry services 2015-2016

- 15<sup>th</sup> AgroChemEx (ACE) attracted >600 exhibitors and >30'000 visitors from >80 countries.
- CCPIA published 1180 articles. Followers increased by 122%.
- CCPIA maintains 14 industry task forces (e.g. Imidacloprid review task force, Phorate safe use task force).
- CCPIA arranged for foundation of CHIPAC (analogue German DAPA and Japanese JAPAC) with the guidance and support of ICAMA, to help companies implement CIPAC methods.
- CCPIA assists local producers to apply for extension of FAO/WHO specifications to local sources.
- CCPIA project for the coding of pesticide packs for the proper identification and container collection and recycling purposes.
- CCPIA contributed to a CCTV broadcast “*Pesticide’s Secret*” to inform the public about the research and development, the production process of the usage of pesticide products.

#### *Overall, the take away message from AgroCare*

- Generic products comprise high-quality, modern and innovative solutions to customer needs with patent free a.s.
- Standards and standard setting bodies should respect the WTO rules in the best interest of all stakeholders (consumers, governments, industry) within its business domain AgroCare supports all international activities that promote a healthy food, life and environment.

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

Mr Jean-Philippe Bascou, Chair of the CropLife International and European Crop Protection Association’s Specifications Expert Group, gave a presentation on behalf of CropLife International and the European Crop Protection Association (ECPA).

### *CropLife International*

- CropLife International is a global federation that represents the plant science industry in 91 countries worldwide.

- CopLife has six regional associations:

- CropLife America
- CropLife Latin America
- CropLife Africa Middle East
- ECPA (Europe)
- JCPA (Japan)
- CropLife Asia

- CropLife International company members are: BASF, Bayer , Dow, DuPont, FMC, Monsanto, Sumitomo & Syngenta.

- CropLife members have largest share of so-called generic or off-patent market.

- In addition to main member companies, CropLife has ca. 1000 members (Companies large and small) through their affiliation to Regional and County association.

### *The European Crop Protection Association (ECPA)*

- ECPA acts as the ambassador of the crop protection industry in Europe and represents the industry's European regional network.
- ECPA promotes modern agricultural technology in the context of sustainable development.
- ECPA represent Crop Protection industry in relevant European forums towards the major stakeholders and the wider public.
- ECPA endeavour to listen and learn from the stakeholders and the public, and seeks to understand their interests, views and perspectives.
- ECPA advocates policies and legislation which represent a scientific and risk-based approach, fosters innovation, protects intellectual property and rewards the introduction of new technologies and practice

### *The Specifications Expert Group (SEG)*

- Comprised of member company representatives with expertise in
  - Analytical, Organic Chemistry, Physical-chemical, Regulatory and Formulation Sciences
  - Ad-hoc members from other expert areas e.g. toxicology, ecotoxicology, Bio Control Agent, etc.
- SEG is a technical resource for CropLife International as well as for the regional and country associations
  - to enhance good specification quality (Content, phys-chem properties, and analytical methods for technical ingredients and formulations)
  - to promote consistency and harmonization in registration requirements
- The SEG has 23 full members from 10 countries from 5 continents.
  - The Mission of the SEG include:
    - 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
    - Promote Harmonization

### Key activities of the SEG:

- SEG is an Industry Interface with FAO/WHO and the Specifications Process.
  - Provides discussion and feedback related to improvements and amendments in the FAO/WHO Manual on Specifications
    - Annual comments, not done this year due to the preparation of the new version
    - Input into the revision of the manual
    - Specifications for new formulation codes
    - Deep involvement in revision of Chapter 9 on microorganisms
  - Involved in providing workshop support to formulation specification training, Quality, equivalence procedure and Confidential Business Information
    - Product Chemistry Workshop at WenZhou China
  - Continue to provide support to JMPS process (Industry guidance document on JMPS procedure on CLI web site)

- 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, OECD WG, etc.)
  - Play a leading role in introducing new or updated MT methods
    - ....
    - MT 46.5 on Storage stability for Matrix Release
  - Annually introduce analytical methods to be used in Specifications as reference methods, e.g.:
    - Chlorantraniliprole full scale collaborative study
    - Flupyradifurone small scale trial
    - Clothianidin WP method extension
- Provide and Maintain Industry Technical Monographs (TM)
  - 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 (under revision with addition of 3 new formulation types: MR, LB, GD)
  - TM17, Guidelines for Specifying the Shelf Life of Plant Protection Products
  - TM19, Minor Changes of Formulants contained in Formulations
- Support all Crop Life Regulatory Teams on
  - Formulation changes – management at zonal level
- Engaged in and support OECD Working Group on Product chemistry.
  - Storage stability (guideline)
  - Analyzed the results in the survey on the data requirements for registration in Product chemistry
  - Ready to contribute to any Guidance on data requirements for registration which would be needed.
- Support CropLife in workshop/training and regulation review:
  - Africa and Middle East:
    - Egypt: Workshop on Pesticide quality and specifications
    - Nigeria: New pesticide Act ongoing
  - Asia:
    - China: - Workshop on Product Chemistry
      - ready for commenting the new draft regulation
    - India: - Change of composition regulation
      - Equivalence procedure, CBI & data bridging concept
    - Japan: - a draft guidance document on equivalence procedure for AI used in agriculture is circulating
  - Latin America:
    - Chile: - A new amended regulation published (March 2016)
      - an internal guidance document for equivalence assessment is under preparation SEG is supporting AFIPA in discussion with SAG
    - Peru: - New equivalence guideline for Peru (Andean)

*Remaining actions from the SEG meeting in Kiev are:*

- Global industry survey on the acceptance of FAO/WHO tolerances on AI content in the formulated products:
  - Feedback from company regulatory teams
  - ~ 120 country information were compiled
  - Almost all countries accept FAO tolerances
  - USA: have their own specific tolerances. However US-EPA allows registrations according to the FAO tolerances. It is industry responsibilities responsibility to ensure harmonization.
  - Mexico: do not have defined tolerances in the regulation. In practice, until recently FAO tolerances were accepted. However,  $\pm 5\%$  is now required, independent from the concentration for new registrations.
  - China: Although current regulation requirements are in agreement with the FAO tolerances, China requests % w/w for solid or g/L and % for liquid. In practice they request the value in % w/w and to round to the integer value: e.g.: 5.4% would require rounding to 5%.
  - India: BIS (Bureau of Indian Standards) define different tolerances again.

*Overall, the SEG:*

- Support scientific and risk-based approach
- Fosters innovation (New AI, FL types, MoA)
- Is looking for harmonization improvement (e.g., Tolerances)
  - Fully supports the transparency concept as long as it doesn't endanger confidential Business Information and Data Protection

## Questions/Comments

Question 1:

Why are there differences in the FAO and US-EPA tolerance system??

Answer 1: CropLife answered that they do not know, but maybe the differences are historical. The tolerance limits are probably from the 1980's.

## 6.3 European Food Safety Authority (EFSA)

Mr László Bura provided a presentation with regards to EFSA's technical liaison with other organisations.

EFSA is:

- A key factor in the EU food and feed safety system.  
Covers the entire food chain (from farm to fork)
- Committed to excellence in risk assessment.  
EFSA are the EU reference body for risk assessment part of a constellation of bodies that are responsible for food safety.
- Open, transparent and independent
- Sustained by a robust governance
- An advocate of scientific cooperation
- Leading on risk communications
- Constantly evolving to meet new challenges

Three main goals for EFSA:

- Promote scientific cooperation
- Provide independent scientific advice and support for EU law/policies on food and feed safety
- Provide independent, timely risk assessment

Independent Scientific advice provided by EFSA in the form of:

- External scientific reports
- Scientific Opinions
- Guidance documents

The EFSA Pesticides Unit has 5 major activities:

- Peer-review of active substances
- MRL related work
- Support the PPR Panel
- Outsourced projects
- Development of EFSA guidance
- 

Communication:

- EFSA communicates with clear target audiences such as –
  - Risk assessors (e.g. MS and beyond)
  - Risk Managers (EC, EP and MS)
  - Stakeholders (Environment, consumer health, NGOs, Industry)
  - Media (Food, Health, EU Affairs)
  - Stakeholders (Scientists/Academics)
  - Policy Makers (EU and beyond)
  - The General Public
  - Concerned individuals (more and more frequently)
- Advisory Forum Working Group on Communications
  - Set up in November 2013
  - Is a network of communications units from EFSA, MSs and EU Commission
  - Key to promoting coherence in communications
  - Co-ordination of risk communications; exchange information; evaluation of efforts; development of best practices
  - Early warning on emerging/topical issues
  - Pre-notification of press releases
- EFSA website  
The EFSA website is used for communication and contains publications from its scientific journal. All of these outputs are published. The website has a relatively new Glossary of Terms.

Scientific cooperation:

- Need for scientific cooperation
  - Appropriate allocation of resources against priorities
  - Better co-ordination of work to avoid duplication of activities
  - Increased coherence in scientific risk assessment methods
  - Information and harmonised data collection and appraisal
  - Early identification and analysis of emerging risks
- Objectives
  - Support of EU in its international commitments
  - Optimise the use of risk assessment capacity in EU/Internationally
  - Develop and harmonise risk assessment methodologies and approaches
  - Strengthen the scientific evidence for risk assessment and risk monitoring
  - Strengthen the scientific evidence for risk assessment and risk monitoring
  - Promote coherence in risk communication

- Scientific cooperation activities
  - Provision of scientific and technical support to EU COM in Codex Alimentarius related activities
  - Multilateral activities with International organisations like FAO, WHO, OIE
  - Bilateral meetings with delegations and RA organisations from non-EU countries
  - Implementation of IPA and ENP Programmes
- Provision of scientific and technical support to EU
  - Joint Events organised with WHO and FAO
  - Information exchange in support of EFSA or FAO/WHO activities
- EFSA's cooperation with FAO and WHO comprises:
  - Contributions to calls for data and experts from Codex and JECFA/JMPR/JEMRA
  - International harmonisation of methodologies and tools for RA and risk comm.
  - Training and capacity building initiatives of FAO, WHO and EFSA
- Multilateral activities:
  - APEC – Asian Pacific Economic Cooperation – Food Safety Cooperation Forum
  - FAO – Food and Agricultural Organization of the UN
  - GCRSR – Global Coalition for Regulatory Science Research
  - IFCSLG – International Food Chemical Safety Liaison Group
  - OECD – Organisation for Economic Cooperation and Development
  - WFF – World Food Research & International Forum
- Bilateral relations:
  - US: FDA, USDA (ARS, APHIS, FSIS), EPA
  - Canadian Food Inspection Agency, Health Canada
  - Food Safety Commission of Japan
  - Food Standards Australia and New Zealand
  - New Zealand Ministry of Primary Industries
  - China Food and Drug Administration
  - Chilean Food Quality and Safety Agency
  - India FSSAI
  - Taiwan Food and Drug Administration
- EFSA cooperation with EU Pre-Accession (IPA) countries
  - IPA – Instrument for Pre-accession Assistance (IPA)
  - EC financed tool
  - EU supports reforms in the 'enlargement countries' with financial and technical help.
  - October 2015 – started IPA II – programming period 2014-2020
- EFSA cooperation with EU Neighbourhood partner (ENP) countries
  - Cooperation since 2009 (first training seminar on EU food safety in Brussels)
  - Since February 2014 – EC financed under the European Neighbourhood Policy Instrument
- Mechanism for Scientific Cooperation
  - Harmonisation with international RA bodies (e.g. WHO, FAO, OIE)
    - Specific topics in risk assessment and data collection (e.g. TTC, weight of evidence, risk communication guidance, exchanging exposure assessment data)
  - Thematic events: international workshops/seminars, e.g. on
    - Trends and developments in risk assessment (EFSA@EXPO 2015)

- Best practices in risk communication
- Knowledge transfer
  - Visits of third country delegations
  - Scientists visiting EFSA and staff visiting international partners
- EFSA's experts/staff assigned for short-medium tasks
  - Scientific support to EU delegation at Codex
  - Participating in JECFA/JMPR meetings

### **Questions/Comments**

Question 1: What is OIE?

Answer 1: World Organisation for Animal Health.

#### **6.4 American Federation of Agrichemical Societies (FASA)**

There was no presentation from FASA at this years meeting. Change to the original agenda.

#### **6.5 Other organisations**

No other organisation gave a presentation.

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

The following country reports, including any collaborative studies in which they participated, were presented: Belgium (two reports for agriculture and public health), China, Czech Republic, Denmark, El Salvador, Germany, Greece, Hungary, Ireland, Italy, Japan, Netherlands, Panama, Slovenia, Spain, Switzerland, Thailand (two reports for agriculture and public health), United Kingdom and the Ukraine.

Annex 1 contains a summary of the reports.

National reports that were provided electronically are available on the CIPAC website (<http://www.cipac.org/index.php/meetings/national-reports/2016>)

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

Mr Ralf Hänel, Chairman of CIPAC gave an overview of the organization.

- What is CIPAC?
  - International association of official chemists (currently 24 full members), established in 1957
  - Non-governmental and non-profit organisation, organised as company limited by guarantee under British Law
  - Funded by the sale of CIPAC Handbooks
  - Daily business is run by a chairman, a secretary and a treasurer on a voluntary basis
  - An Editorial team (3 – 4 persons) is dealing with the publications and the CIPAC website on a voluntary basis
- Aim:
 

CIPAC's aim is to promote agriculture in the field of pesticides for the benefit of the community.

  - This is primarily done by promoting international agreement on:
    - (i) Methods for the analysis of pesticide products and other products

(ii) Methods for the determination of physical, chemical and technical properties of pesticide formulations.

- Platform:

CIPAC provides a platform for conducting collaborative trials according to certain criteria

- The accepted methods are published in Handbooks (available as print out or electronically on CDs)
- CIPAC does not conduct trials itself!
- CIPAC is not in the position to require from companies the performance of CIPAC trials for certain substances or properties (however you need CIPAC or AOAC methods for FAO/WHO specifications)

- Guidelines: CIPAC provides guidelines for preparing collaborative trials

- Guidelines for the design of chromatographic analytical methods intended for CIPAC collaborative study
- Format for the presentation of the summary of the results of collaborative studies
- Instructions for writing CIPAC methods
- Guidelines on method validation to be performed in support of analytical methods for agrochemical formulations
- CIPAC guidelines for collaborative study procedures for assessment of performance of analytical methods
- Extension of the scope of methods
- Extension of scope of methods Flow chart
- CIPAC Guideline for analytical methods for the determination of relevant impurities referred to in FAO and/or WHO specifications for pesticide technical grade active ingredients and formulations
- Work flow for integration of anal analytical and physical-chemical methods for LN into related CIPAC methods for corresponding active ingredients

The above Guidelines can be found on the CIPAC website (<http://www.cipac.org/index.php/guidelines>)

- Publications:

- The methods which have been evaluated by collaborative tests and accepted as CIPAC Methods are published in regular intervals in CIPAC Handbooks. These Books are named with Roman letters, with Handbook N, being the last published in 2012 and the next planned to appear in the year 2016.
- You can order these publications on the CIPAC website (<http://www.cipac.org/index.php/methods-publications>)
- CIPAC's pesticide advisory committees (PAC):
  - Prepares and discusses the methods for collaborative trials
  - Conducts a small scale trial, if necessary

For the moment 4 PACs

- DAPA (German speaking WG of the BVL for analytical methods)
- DAPF (German speaking WG of the BVL for physical methods)
- ESPAC (English speaking PAC)
- JAPAC (Japanese PAC)

- Organisations CIPAC interacts with:

- AOAC International
- ASTM International
- FAO and WHO (JMPS)

- EFSA
- AgroCare (China, India, Europe, Latin America)
- CropLife International (SEG)
- FASA (Latin and South America, USA)
- 
- FAO/WHO
  - The availability of CIPAC methods are a key component to the development of FAO/WHO specifications.
  - According to the Manual on development and use of FAO and WHO specifications for pesticides (November 2011, 2nd revision) –
  - Section 1.3.1 of the 2010 Manual refers to CIPAC and AOAC. The section states that
  - “Wherever practicable, the test methods cited in FAO/WHO specifications should have been evaluated by inter-laboratory trials.
  - CIPAC and AOAC published methods of analysis have been accepted after collaborative testing...Methods to be used in support of FAO and WHO specifications may be validated by other organizations but, with few exceptions.....”
    - Relevant impurities –
      - The FAO and the WHO invited CIPAC to consider independent laboratory validations for relevant impurities in the scope of its activities
      - CIPAC agreed
      - The method validation and development should be handled in principle as CIPAC methods
      - Adopted methods, if necessary with remarks from CIPAC, will be made available on the CIPAC website
      - The methods will not be covered by CIPAC copyright (do not form part of the published handbooks and are freely available on the CIPAC website). (<http://www.cipac.org/index.php/methods-publications/In-methods>)

## 9. Subjects from the 15<sup>th</sup> JMPS Closed Meeting of 2016

Major issues of general importance identified in Closed Meeting:

- Publication of the 3rd revision of the FAO/WHO Specifications Manual
- Adopted revision of equivalence process: Tier-2
- Major revision of Section 9 on microbials
- Revision of reference specifications with transition period before publication
- Review of old procedure FAO specifications – status and way forward
- 1st amendment to the 3rd revision of the Manual
- Omission of question/answer sessions with industry

Publication of the 3rd revision of the FAO/WHO Specifications Manual:

- Version March 2016
- Integrates all changes discussed and adopted up to June 2015
- Numerous editorial corrections
- New formulation guidelines included
- Glossary of terms revised and extended
- Sampling section removed

Adopted revision of Tier-2 equivalence process:

- Proposal to have a strengthened Tier-2 based on acute
  - dermal irritation
  - dermal sensitization

- eye irritation
- 28 or 90 days repeated dose study in rodents
- Tier-2 case study
  - Nicosulfuron – comparison of 2 TC qualities with their tox studies
  - 28 and 90 days repeated dose studies on two different TC
  - proven predictive power of OECD 407 (28 days) and 408 (90 days repeated dose)
  - Comparative evaluation for NOAEL and “critical effects” (e.g. weight, neurotox, blood status, organ functions)
- New Tier-2 data requirements:
  - Draft amendment to the 3rd revision of the Manual, available for commenting
  - Final version planned end of 2016, for new proposals 2018 onward

Major revision of Section 9 on microbials include:

- Gembloux workshop Jan 2016 industry/JMPS/IBMA
- Drafting of data requirements for FAO and WHO specifications for microbiological actives (bacteria, fungi, viruses etc)
- Data requirements harmonized with JMPM Microbials Guideline and OECD documents
- Still open and controversial: storage stability
- Workshop for resolving storage stability issues needed and planned (Nov 2016)
- Final version expected to be available in 2018 as new Section 9 in the Manual

Revision of reference specifications with equivalent products:

- New paragraph in Manual on procedures
- More precise or tightened reference specification possibly render hitherto equivalent products off-spec!
- Before publication of the revised reference specification, producers of equivalent products shall be informed with data call-in (transition period)
- Reasonable deadline for submission of new data to show compliance
- Procedure envisaged –
  - Step 1: Proposal for revision of reference specification
  - Step 2: Evaluation and adoption of revision of reference specification
  - Step 3: Data call in for manufacturers of equivalent products
  - Step 4: Non-equivalent products are identified
  - Step 5: Evaluation of data packages and publication of revised reference specification and evaluation reports
- Objectives of the transition period from “old” to “new” reference specification –
  - To avoid undue disadvantages for equivalent products in tenders and national registration
  - To avoid future off-spec products becoming obsolete
  - While ensuring an open, timely and transparent revision process

Note: Monitoring of annual work programme of JMPS by data proposers will become even more important!

Review of “Old Procedure” FAO Specifications:

1<sup>st</sup> Edition of the FAO Manual was published in 1971 - basis for ca. 360 specifications “old procedure” (much less for WHO!).

- “Old Procedure FAO Specifications”
  - See <http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/ps-old/en/>
  - All manufacturers should comply with their products
  - No hazard evaluation
  - No appraisal
- Review of old procedure FAO specifications – objectives

- Identify compounds apparently no longer in use (ca. 60 %) - -----withdraw specifications
- Identify compounds still broadly produced, traded and used in agriculture (ca. 40 %) -----candidates for update into “new procedure” specifications
- Recommendations: action plan
  - 1) Collate and publish a priority list for renewal for commenting by industry
  - 2) Develop a 5-year working plan according to the prioritization
  - 3) Withdraw some old specifications, but keep it somewhere for reference.
    - Challenges expected for the renewal of old specifications in fulfilling all the data requirements under the new procedure
    - Proposal of a compromise requirement for toxicology data for renewal of old specification for “orphan compounds”
- Main obstacles expected
  - Many compounds divested by original companies
  - Generics may afford to prepare a data package for chemistry and acute tox, but not for chronic, mutagenicity and repro studies
- Way forward
  - Bridging of published chronic, mutagenicity and reprotox studies with actual manufacturing specification through comparison of 28 or 90 days repeated dose studies using the criteria of proposed Tier-2 process!
- Publication of specifications
  - Will become new reference specification
  - Updated data package for formulations (chemistry/phys-chem props) required
  - New Tier-2 tox
  - Background and bridging of tox should be explained in appraisal

1st amendment to the 3rd rev of the Manual:

- After 2016 JMPS, to appear ca. Nov 2016
- Contains:
  - New Tier-2 equivalence process
  - Data requirement changes for 1<sup>st</sup> and subsequent proposers: Letter of access and registration certificate are usually sufficient
  - Revised Glossary (clarification of some points)

Questions to companies concerning their products under evaluation:

- Questions re products under evaluation were discussed with proposers in “Questions & Answers” sessions at end of Closed Meeting
- But - time and effort spent is disproportionate with the feedback – majority of answers provided in writing
- Starting 2017, all questions will be dealt with in writing

## Questions/Comments

Question 1: The question and answer session between industry and JMPS is very useful for industry.

It IS a very good way of operating compared to how the JMPS operates.

Under the JMPS procedure, companies receive questions too late in order to make the JMPS deadline. Therefore, the new JMPS proposal causes a concern for industry.

Answer 1: JMPS always allows a reasonable deadline, especially in the case of requesting more data. The benefit is disproportionate to the effort spent on organising the question and answer session.

JMPS and JMPS are different. JMPS have to conclude there and then in that year with respect to the evaluation.

JMPS do not have to conclude that same year. JMPS can discuss the evaluation again the next year.

Question 2: Will getting rid of the question and answer session speed up the process? Why doesn't the Evaluator communicate his questions to the company in advance of the JMPS, and then JMPS can just sign off on the Evaluator's evaluation, so the company will have an answer in advance of the meeting??

Answer 2: The process that you described happens already, however there may always be the possibility of additional questions being raised in the JMPS meeting by additional JMPS panel members. The timelines are outlined in the Manual.

Question 3: Two specific questions

- (i) Reference specification: Can you explain what the reference specification means, is it different from reference profile?

Answer 3 (i)- Reference specification is used in the main body of the Manual. Reference specification consists of the unpublished and published part of the specification.

- (ii) Higher predictive power of OECD 407 and 408

These do not have higher predictive power, they provide different information, not actually the same information.

Answer 3 (ii)– The higher predictive power has already been explained as part of the presentation.

Question 4: The proposal for reviewing "Old" specifications under the "new procedure" is a major issue. When do JMPS intend to start this process – will it be in the next version of the Manual? The proposal is a fundamental change – therefore the change and process needs to be included in the Manual.

Answer 4: There will be a transition period – the proposal will not have to be included in the new version of the Manual.

More consultation will have to be carried out with stakeholders to provide more information and to receive your comments before inclusion in a revised version.

It is better to have some information on the FAO website showing that the specification has been updated under a new procedure as opposed to having old specifications which are no longer representative.

Question 5: "Orphan products" may be supported by a very limited data package. You cannot evaluate and publish these specifications under a new procedure before the new process is agreed and published in the Manual.

Answer 5: Good point. If there is no repeated dose study from original manufacturer, then the specification is then eliminated. If it does not compare with the 28 or 90 day study, then we write a short Evaluation Report and the specification is removed. With such a limited data set, JMPS cannot say any real statement about the hazard profile about the hazard criteria and therefore the specifications cannot be supported. We have the same case where we have an equivalence. We are in a new Tier 2 – we compare hazard profile to the original profile. We check for the published literature for toxicity data. We will only have to have 5-batch data and methods from the original manufacturer. It is essential that we have the one process for updating the old to the new procedure. The new procedure will be included with the updated Tier 2 data requirements.

Question 6: There will be a cost and time issue with respect to moving from an acute oral to sub-chronic. There are about 360 old specifications. Ca 60% of those products will be out of use you have estimated. Industry would like to have this list that JMPS has developed.

Answer 6: The list is an internal document – but you can make the comparison for yourself using the criteria as outlined – national registration web bases to see if it is registered, e.g. Mancozeb registered in all the countries checked. The Codex list will also be cross-checked with our proposed list – we are aware of most of them which are not registered. Industry is welcome to put forward their proposals and information. We won't be circulating a list which needs more development.

## **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 (Annex 3). It was noted that the failure to have used/developed CIPAC methods of analysis for active ingredients can cause a delay in the process in some cases.

### **10.2 Status of WHO Specifications**

Mr Yadav presented the status of WHO specifications (Annex 4). It was noted that some Proposer's are not following the data requirements as outlined in the Manual prior to submission, and in other cases are not even providing a response to a request for data, which can result in withdrawal after initial submission in some cases.

### **10.3 Status of Joint FAO/WHO Specifications**

Mr Yadav presented the status of joint FAO/WHO specifications shown as tables (Annex 4).

### **10.4 FAO/WHO Manual 3rd revision, 1st edition (March 2016)**

Issues relating to the 3rd revision of the FAO/WHO Specifications Manual were discussed as part of Agenda Point 9.

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

Mr Yadav presented the list of priorities for JMPS 2017 (Annex 2) in four different categories: (1) original proposer; (2) subsequent proposer(s); (3) specification for formulation; and (4) revision of specification.

## **12. Any other matters**

A list of meeting participants can be distributed to those who request them.

## **13. Date and venue of the next JMPS and CIPAC/FAO/WHO-meetings**

At the request of the Chairperson, Madam Yang (FAO) announced that the CIPAC/FAO/WHO Annual Meeting in 2017 will be held in Rome, Italy from the 6 – 15<sup>th</sup> June. A presentation was given on the next venue for the meeting.

Further details will be available in due course on the CIPAC website (<http://www.cipac.org/index.php/meetings>)

## **14. Closing of the 13<sup>th</sup> Joint CIPAC/FAO/WHO Open Meeting**

Mr Ralf Hänel, Chairperson of the meeting, declared the meeting closed and thanked the organizers for their hard work in organizing the meeting, Mr Yadav and Madam Yang for their continued collaboration, the participants for their attendance and the rapporteurs for their work. He declared the meeting closed.

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

Region	Reporting laboratory	No. Of samples tested	Non-compliance	
			No.	%
Americas	El Salvador	616	14.0	2.3
	Panama	109	2.0	1.8
Asia	Japan	24	0	0
	P.R of China	4639	735	15.8
	Thailand (DMSc)	373	74	19.8
	Thailand (DOA)	3404	4.0	0.1
Europe	Belgium (AFSCA)	82	1	1.2
	Belgium (CRA-W)	281	45	16.0
	Czech Republic	85	27.0	31.8
	Denmark	33	1.0	3.0
	Germany	261	3.0	1.1
	Greece	264	5.0	1.9
	Hungary	1110	29	2.6
	Ireland	82.0	3.0	3.7
	Italy	7295	22	0.3
	Netherlands	20	0	0
	Slovenia	30	2.0	6.7
	Spain	330	0	0
	Switzerland	27	16	59.3
	UK	66	13.0	19.7
<b>Total</b>		<b>19198</b>	<b>1003</b>	<b>5.2</b>

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

- (1) Original proposer; (2) Subsequent proposer(s); (3) Specification for formulation;  
 (4) Revision of specification

	<b>Product</b>	<b>Manufacturer</b>
<b>FAO specifications</b>		
1	Teflubenzuron TC	(1) Simonis, Netherlands
2	Tribenuron-methyl TC	(1) Jiangsu Agrochem, China
3	Clodinafop-propargyl TC	(2) Zhejiang Bosst CropScience Co., Ltd., China
4	Fenoxaprop-P-ethyl TC	(2) Hangzhou Udragon Chemical Co., Ltd., China
5	Azoxystrobin TC	(2) Hebei Veyong Biochem Co- Ltd, China
6	Zeta-cypermethrin TC	(1) FMC Corp., USA
7	Pyriproxyfen TC, EC	(2) Rudong Zhongyi, China
<b>WHO specifications</b>		
1	Diflubenzuron TC, GR, WP & DT	(2) Gharda Chemicals, India
2	DawaPlus 3.0 (deltamethrin coated sides+PBO incorporated top) LN	(3) Tana Netting, UAE
3	DawaPlus 4.0 (deltamethrin+PBO incorporated) incorporated LN	(3) Tana Netting, UAE
4	Bendiocarb CS	(3) Landcent (China) Ind Dev Co. Ltd, China
5	CMP123-003 UL	(3) Clarke International LLC, USA
6	Novaluron GR (Mosquiron 2 GR)	(3) Control Solutions USA (Adama, Israel formerly Makhtesim, Israel)
7	Dinotefuran TC; ATSB bait station (treated device)	(1) Mitsui Chem; (3) Westham Ltd., Israel
8	Flupyradifurone+transfluthrin EW	(3) Bayer CropScience
9	Bioxlin LN (bifenthrin+pyriproxyfen+PBO)	(3) VK Polymers, India
10	S-methoprene TC + 2 formulations (?)	(1) Babobna Bio Ltd., Hungary
11	DEET TC	(1) SCJ (to be confirmed)
12	DEET formulation (to be decided)	(3) SC Johnson, USA
13	Paraffin oils (CAS 64742-46-7; 72623-86-0)	(1) Total Fluides, France
<b>FAO/WHO specifications</b>		
1	Imidacloprid TC (with revision of FAO spec)	(4) Bayer CropScience, Germany
2	Imidacloprid TC	(2) UPL Ltd, India
3	Flupyradifurone TC	(1) Bayer CropScience
4	Pyriproxyfen TC	(2) Symbiont, China
5	Deltamethrin TC	(2) Yangnong, China
6	Lambda-cyhalothrin TC	(2) Jiangsu Huifeng Agrochemical Co., Ltd., China

**ANNEX 3.**  
**STATUS OF PUBLICATION OF FAO SPECIFICATIONS**

<b>Product</b>	<b>Manufacturer</b>	<b>Status</b>
Deltamethrin LB	Vestergaard frandsen	Published
Chlorpyrifos TC	Bharat	Published
Prochloraz TC, EW	Jiangsu Huifeng	Published
Pyriproxyfen TC	Tagros	Published
Permethrin TC 40:60	Yangnong	Published
Brodifacoum TC, Bait	BCS	Published
Chlorothalonil TC	Rotam	Published
Diflubenzuron TC	Arysta/Helm	To be published
Copper compounds	European Union Copper Task Force	To be published (method for heavy metals missing)
Thiacloprid TC, SC	Chemnova	To be published (pending confirmation from the authority)
Bifenthrin TC	Bharat	To be published
Hexazinone WG	Nutrichem	To be published
Bifenthrin TC	Rotam	Pending data from company
Clethodim TC, EC	Arysta	Pending data from company
Trifloxystrobin TC, EC, WG, SC	BCS	Re-evaluate in 2016 JMPS
Clothianidin TC, FS, W	BCS	Re-evaluate in 2016 JMPS
Niclosamide-olamine T	Sichuan Academy	Pending data from company
Triflumuron TC,WP, SC	BCS	Re-evaluate in 2016 JMPS

**ANNEX 4.****STATUS OF PUBLICATION OF WHO AND FAO/WHO JOINT SPECIFICATIONS\******Specifications published***

<b>JMPS*</b>	<b>Compound/product</b>	<b>Manufacturer</b>	<b>Month/yr of publication</b>	<b>Spec.</b>
2013	Yahe (delta coated) LN	Fujian Yamei, China	Nov-15	WHO
2013	PandaNet 2.0 (delta incorp.) LN	Lifeldeas, China	Sept-15	WHO
2013	Permethrin 25:75 TC	Bayer, Germany	Jul-15	WHO
2013	S-bioallethrin+permethrin +PBO EW	Bayer, Germany	Jul-15	WHO
2013	Chlorpyrifos TC	Baharat Rasayan, India	Aug-15	FAO/WHO
2014	Lambda-cyhalothrin TC	Jiangsu Yangnong, China	Aug-15	FAO/WHO
2014	SafeNet (alpha-cyper coated) LN	Mainpol GmbH, Germany	Aug-15	WHO
2014	MiraNet (alpha-cyper incorporated) LN	A to Z Mills, Tanzania	Feb-15	WHO
2014	Veeralin (alpha-cyper+PBO incor) LN	VC Innovations, India	May-16	WHO
2014	B. sphaericus+Bti (VectoMax) GR	Valent BioSciences, USA	May-16	WHO
2015	Permethrin 40:60 TC	Yangnong, China	Sep-15	FAO/WHO
2015	1R-trans-phenothrin TC	Sumitomo Chem, Japan	Sep-15	WHO
2015	Bendiocarb WP-SB 400g/kg	Bayer, Germany	Nov-15	WHO
2015	Pyriproxyfen TC, 0.50% GR	Tagros Chem, India	May-16	WHO
2015	Transfluthrin TC	Tagros Chem, India	May-16	WHO

\*Year of original submission to JMPS.

***Pending WHO and FAO/WHO specifications***

<b>Compound/product</b>	<b>Manufacturer</b>	<b>Spec</b>
Bactivec SC	Labiofam, Cuba	WHO
Bifenthrin TC, EC	Rotam & Bharat	FAO/WHO
Diflubenzuron TC	Helm AG & Chemtura	FAO/WHO
Metaldehyde TC	Xuzhou Nuote, China	FAO/WHO
Nicosamide-olamine TC	Sichuan Academy, China	FAO/WHO
Akanet LN	Kuse Lace Co., Japan	WHO
Interceptor G2 LN	BASF, Germany	WHO
Propoxur TC, WP	Tagros Chemical	FAO/WHO

**Terminated/withdrawn**

(1) Original proposer; (2) Subsequent proposer(s); (3) Specification for formulation;  
(4) Revision of specification

Compound/product	Manufacturer	Spec.
DawaPlus 2.0 (deltamethrin coated) LN - extn to 150D yarn	(4) Tana Netting, UAE	WHO
Deltamethrin (polyester coated) LN (Christiansen LN)	(3) Christiansen Sarl, France	WHO
Zinc borate TC (Borogard ZB)	(1) Rio Tinto Minerals, USA	WHO
Alphacypermethrin +PBO incorporated LN	(3) DCT, USA	WHO
Alphacypermethrin incorporated LN (HILNet)	(3) HIL, India	WHO
Bifenthrin TC	(2) Jiangsu Huifeng, China	FAO/WHO
Lambda-cyhalothrin TC	(2) Jaangsu Huifeng, China	FAO/WHO

**New WHO and FAO/WHO specifications reviewed by JMPS, June 2016**

Compound/product	Manufacturer	Spec
Sumilarv 2MR (pyriproxyfen 20 g/kg MR)	(3) Sumitomo Chemical, Japan	WHO
Clothianidin 500+ deltamethrin 62.5 WP-SB (Fludora Fusion)	(3) Bayer CropScience, Germany	WHO
Clothianidin TC	(1) Bayer CropScience, Germany	WHO
Transfluthrin TC (revision of WHO spec)	(4) Bayer CropScience, Germany	WHO
Bendiocarb TC	(2) Saerfu AgroChem., China	WHO
Pyriproxyfen TC	(2) NTGC Fine Chemical Co. Ltd, China	WHO
Alphacypermethrin+PBO (Duranet Plus) LN	(3) Shobikaa Impex, India	WHO
Alphacyper+pyriproxyfen incorporated LN (Royal Guard)	(3) DCT, USA	WHO
DawaPlus 2.0 (deltamethrin coated)LN - extn to 150D yarn	(4) Tana Netting, UAE	WHO
Yahe LN (deltamethrin coated) LN - extn to 50 and 100D yarn	(4) Fujian Yamei Industry, China	WHO
Deltamethrin SC-PE	(4) Bayer, Germany	WHO
Pirimiphos-methyl	(4) Syngenta, Switzerland	WHO
Deltamethrin WG-SB	(3) Gharda Chemicals, India	FAO/WHO
Deltamethrin TC, SC, WP	(2) Sharda Cropchem, India	FAO/WHO
Deltamethrin TC (revision of FAO & WHO spec)	(4) Bayer CropScience, Germany	FAO/WHO