Food and Agriculture Organization of the United Nations

World Health Organization

14th JOINT CIPAC/FAO/WHO OPEN MEETING (61st CIPAC Meeting and 16th JMPS Meeting)

HQ, Rome, Italy
12 June 2017

Summary record of the meeting

Agenda

Contents

1. Opening and welcome

Madam Yong Zhen Yang, representing the Food and Agriculture Organization of the United Nations (FAO), and Chairperson of the Joint Open Meeting welcomed all participants to the 14th Joint CIPAC/FAO/WHO Open Meeting. Special thanks were extended to the FAO team for all their efforts in organizing the meeting.

Madam Yong Zhen Yang introduced Mr Rajpal Yadav, representing the World Health Organization (WHO), and Mr Laszlo Bura, representing the Collaborative International Pesticides Analytical Council (CIPAC), to the meeting.

Mr William Murray, Deputy Director of the Production and Protection Division of FAO, opened the meeting and welcomed delegates to the open meeting that had followed the 16th FAO/WHO Joint Meeting on Pesticide Specifications (JMPS) and taken place the previous week at FAO. He recalled that the last time this meeting had been held in Rome was in 2002. The 2017 meeting was being attended by more than 160 participants from 37 countries, almost half of which were from developing countries. This broad participation underlines the importance of the use of FAO/WHO specifications and the relevance of pesticide quality both to the developed and developing countries.

Mr Murray described the work of the Joint Meeting in the larger context. Agriculture has a major impact on the environment, while the environment and the services it provides are essential to the future of agriculture. The world's population is projected to reach 9.2 billion in 2050. This will require a 50% increase in global food production, some 80% of which will need to come from land that is already under cultivation. As a result, more food will need to be produced per unit of land – essentially by intensifying production. The adoption in 2015 by the United Nations General Assembly of the 2030 Agenda for Sustainable Development including the 17 goals for sustainable development as well as the Paris Agreement on climate change have put food security and agriculture at the centre of the global development agenda.

Clearly, agriculture in 2017 and beyond must produce more while at the same time protecting and enhancing the underlying natural resources on which it is based. The challenge is complicated because there is no "silver bullet" or one-size-fits-all solution to sustainably increasing agricultural production. Successful approaches are context specific and must be tailored to the needs of particular regions or communities. The approach to food production is moving from an input intensive approach to one that is knowledge intensive. The need for more varied, specialized and innovative approaches that draw on traditional knowledge and advances in science and technology will only be addressed though greater collaboration and cooperation at all levels. This includes cooperation within countries, between communities, ministries and agencies, and between countries through north–south cooperation – sharing knowledge, experience and expertise.

The availability of substandard and counterfeit pesticides represents a serious problem. Poor quality pesticides fail not only to serve their intended purpose, resulting in financial loss, but also present unacceptable risks to both human health and the environment. The quality of pesticides is thus of increasing importance in helping countries transition to more sustainable agriculture, in achieving food security and to improving food safety.

The Joint Meeting on specifications is a good example of cooperative action between two United Nations bodies. The specifications developed by the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS) provide an international point of reference for evaluating the quality of pesticide products, facilitating international trade while helping to promote the efficient use of pesticides, and protecting human health and the environment. The JMPS has made some impressive achievements; to date, about 1000 specifications have been developed for more than 400 active ingredients of pesticides. Additionally, the FAO/WHO procedure for determination of equivalence has been adopted by a growing number of countries worldwide. The demand for specifications continues to grow in response to increased international trade and a growing awareness among consumers of issues linked to food safety, human health and the environment.

The partnership between FAO and WHO was expanded in 2004 to include a joint meeting with CIPAC. CIPAC ensures that reliable methods of chemical analysis are available to facilitate implementation and compliance with the specifications. This meeting provides an open platform from which to share and discuss pesticide issues and promote control of pesticide quality and harmonization of pesticide regulation between countries. The tripartite cooperation of the three organizations is recognized as a successful example of a partnership that has evolved to meet the changing needs of countries in managing pesticides.

Mr Murray closed his welcoming remarks by noting that the FAO stands ready to strengthen the continued cooperation with WHO, CIPAC and other organizations in furthering the development and implementation of FAO/WHO pesticide specifications and the adoption of equivalence determination procedures at the national, regional and international levels. He wished all of the participants a successful meeting and a pleasant stay in Rome.

Mr Yadav welcomed the participants on behalf of WHO and thanked the hosts and organizers for their hard work and effort in organizing the meeting. Mr Yadav highlighted the great challenges being faced as a result of vector-borne diseases. Whilst malaria remains a disease of major public health importance, in recent years the Zika virus disease has appeared in the Americas and chikungunya has emerged in South-East Asia. The threat of dengue fever has increased in the Americas, African, South-East Asia and Western Pacific regions. Other vector-borne threats are more localized and WHO is investing resources as required.

The 70th World Health Assembly (22–31 May 2017) had adopted resolution WHA70.16 on a global vector control response, calling on Member States to increase awareness, funding and staff. The work required to support this

response will increase as vector control technologies increase. Joint collaboration among regulators, industry and laboratories has increased, contributing to a movement that has improved quality standards, prepared guidelines, advised Member countries, and thereby resulted in the development of high standards and high-quality products.

WHO has continued to evaluate new tools for vector control, including the evaluation of new products for which recommendations on public health policy are not available. Pesticides are the single biggest tool in the fight against vector-borne diseases. For example, it has been estimated that the numbers of cases and deaths from malaria have decreased by over 60% during 2000–2015 due to the use of insecticide-treated bed nets.

WHO has given greater importance to the development of quality standards by adopting the FAO/WHO pesticide specifications. Approximately 75% of the Member countries currently use these specifications, and many other countries use them as the basis for developing their own national standards. WHO focusses on providing guidance to stakeholders and countries via the WHO manual and training guidelines as well as other local guidance on standards and quality. The Organization also provides training courses in Member countries, and is developing guidelines and guidance for local staff to generate their own quality standards.

The WHO Pesticide Evaluation Scheme (WHOPES) has undergone some reforms. There have been two significant recent reforms. Since 1960, WHOPES has been the sole programme to evaluate public health pesticides, but faced with the low quality of some pesticides on the market it was essential that WHO put plans in place to increase standards of quality. In response, WHO has moved pesticide evaluation from WHOPES to its Prequalification of Medicines Programme. All new applicants for pesticide product evaluation must now work via the programme in order to screen their submissions in line with these revised standards. This work will involve factory site inspections, which will result in a quality assurance system working in close collaboration with industry. The expected outcome of this first reform is that any subsequent products which comply with the WHO criteria will be of high quality, enabling Member countries to rely on these products with greater confidence. For the second reform, WHOPES is working to help develop laboratories certified for good laboratory practice (GLP) to evaluate the efficacy of public health pesticides. The plan is to develop at least 17 such laboratories in collaboration with the Innovative Vector Control Consortium.

László Bura (CIPAC) summarized the work and purpose of CIPAC, which is to provide a platform for the development of methods not only to support FAO/WHO specifications for pesticides, but also to promote their use globally for the quality analysis of pesticide formulations. CIPAC maintains good collaboration with FAO and WHO and it is being globally recognized as a forum to promote good quality of pesticides. Mr Bura noted that JMPS was set up 16 years ago in Rome and that the number of attendees has increased over the years with many new attendees present at the 2017 meeting. The increase in attendance indicates the relevance and importance of the meeting.

Madam Yong Zhen Yang (FAO and Chair of the Open Meeting) remarked on the important role of CIPAC in the pesticide specification process and the excellent collaboration between the three organizations (FAO, WHO and CIPAC). She declared the 14th joint FAO/WHO/CIPAC meeting officially open.

2. Arrangements for chairmanship and appointment of rapporteurs

Madam Yang (FAO) explained that the Chair of the meeting was rotated each year among the three partner organizations. The meeting this year would be chaired by the secretariat of the FAO (Madam Yang). She proposed three rapporteurs for the meeting: Mr Axel Steer (for FAO and CIPAC), Mr Finbar Brown (for WHO) and Mr John Bewely as assistant rapporteur.

3. Adoption of the agenda

No changes to the agenda were proposed, which was then adopted as such.

4. Summary record of the previous meeting

4.1 13th Joint CIPAC/FAO/WHO Open Meeting; 60th CIPAC Meeting; and 15th JMPS Meeting, Tokyo, Japan

The summary record of the previous open meeting, held at the lino Hall & Conference Center, Tokyo, Japan on 13 June 2016 is available on the FAO/WHO website. There being no comments, the minutes of the last CIPAC/FAO/WHO Open Meeting (2016) were accepted.

5. Summary of actions taken after the 60th CIPAC and 15th JMPS meetings

5.1 CIPAC

Mr László Bura, Secretary of CIPAC, informed the meeting of the major activities carried out by CIPAC since the previous Joint Open Meeting. These were:

- Handbook O is in print and will be available soon.
- Review of the CIPAC guidelines has been initiated. First proposals will be made during the 2017 CIPAC meeting on technical material (TC).
- Review of the CIPAC handbook. The outcome will be published in summer 2017 for commenting.
- Participation at a CCPIA (China Crop Protection Industry Association) workshop in cooperation with experts of FAO, ICAMA (Institute for the Control of Agrochemicals, Ministry of Agriculture of China), JMPS and WHO to improve understanding on how FAO, WHO and CIPAC specifications and standards are developed and to increase the quality of technical materials and formulations.

Questions/Comments

No questions were asked.

5.2 WHO

Mr Rajpal Yadav informed the meeting of the major activities carried out by WHOPES within the framework of sound management of public health pesticides, since the previous Joint Open Meeting.

WHOPES and new pesticide evaluation procedures

The 20th WHOPES meeting (Geneva, 20–24 March 2017) had evaluated four new vector control products (Interceptor G2 LN, DawaPlus 3.0 LN, DawaPlus 4.0 LN and SumiLarv 2 MR used as a larvicide) and re-evaluated one product (Chlorfenapyr 240 SC for indoor residual spraying).

The new WHO pesticide evaluation procedures have been in place since January 2017. The evaluation of pesticide products for which a WHO policy recommendation is available has moved from WHOPES to the WHO Prequalification of Medicines Programme. It has been proposed that if the company involved does not have the data necessary to bring a product to market, the programme can help industry to determine if an authorization would be likely and identify the data requirements which must be addressed to achieve this authorization. The prequalification programme can be approached through the WHO website in the first instance and there is the potential to organize an initiation meeting to discuss the proposal and determine how much more data are likely to be needed if only a limited set is available. The evaluation of pesticide products will be overseen by a joint coordination committee of representatives from three WHO units: the Department of Control of Neglected Tropical Diseases (WHOPES); the Global Malaria Programme (Entomology & Vector Control) and the Prequalification of Medicines Programme. These units have entomology teams and are responsible for developing standard operating procedures, guidelines, quality standards and tools, among others. The normative functions (including policy, strategy, guidelines, standard operating procedures) will remain with the technical units, namely the Department of Control of Neglected Tropical Diseases (WHOPES) and the Global Malaria Programme.

Vector Control Advisory Group and evaluation of new vector control tools

The evaluation of innovative vector control products shall be under the remit of the Vector Control Advisory Group. Innovative vector control tools under development include *Wolbachia*; sterile insect technique in collaboration with the International Atomic Energy Agency; transgenic mosquitoes; attractive toxic sugar baits; eave tubes; and vector traps for surveillance.

Revision of equivalence determination procedures for formulated products

WHOPES convened a WHO consultation in 2016 that had led to some changes in the procedures for evaluation of generic long-lasting insecticidal nets, products for indoor residual spraying and mosquito larvicide products.

Guidelines and risk assessment models

FAO and WHO have jointly published the following guidelines since the 2016 Open Meeting:

- JMPM – highly hazardous pesticides
- WHO – field use of molluscicides in schistosomiasis control programmes: an operational manual for programme managers

The following guidelines are in preparation:

- Efficacy testing of molluscicides
- Guidelines for personal protective equipment
- Guidelines on registration of microbials, botanicals and semiochemicals

The following guidelines are being revised:

- Specifications for pesticide application equipment

- Guidelines for laboratory and field testing of long-lasting insecticidal nets
- Guidelines for testing insecticides for indoor residual spraying

Some risk assessment models are being either revised or developed with input and discussion between the chemical safety teams of WHOPES and WHO. The current models being revised are those for long-lasting insecticidal nets, indoor residual spraying, indoor and outdoor space spraying, and mosquito larval control. The model for aircraft disinfection is also available. These models shall be linked to the new FAO pesticide toolkit[1] so that people can benefit from the WHO guidance. The new risk assessment models being developed are for household insecticides, repellents for human skin and insecticide-treated clothing.

Research studies

A multi-centre study to determine insecticide discriminating concentrations for insecticide resistance monitoring against mosquitoes is planned for 2017–2018. Mr Yadav also gave an update on Zika virus disease, for which WHO had called an international expert meeting to review vector control options for its control (Geneva, 21–23 February 2017).

Update on roll out of good laboratory practice

The roll out programme for good laboratory practice (GLP) is an important part of WHO's reform for pesticide evaluation. On the basis of geographical representation, capacity and commitment and the ability to evaluate a range of products such as long-lasting insecticidal nets, 17 sites in five WHO regions have been selected in collaboration with the Innovative Vector Control Consortium. Many of these sites include institutes with which WHOPES has worked in the past for product evaluation. A summary of the institutions currently listed was provided, detailing the institutes across Africa, Pacific, Asia, America and Europe together with the key aspects they are focussing on. One laboratory in Africa has already been accredited by the South African regulatory authority. It was noted that the list does not include private organizations.

Questions/Comments

Question 1: A question was asked in relation to GLP compliance from an industry perspective in relation to the WHO GLP compliance requirement. It was mentioned that a key part of the development process is validation of test substances, which could be considered a time limiting step because if many trials were needed then many samples would require analysis. Going forward, it would be useful to have a list of sites which industry could use, which have been recognized by WHO but which may not have already been considered compliant with GLP by WHO as the project is in its infancy. There are already a number of GLP accredited sites, which may not have been considered yet by WHO. Therefore, can industry use these sites or does WHO validation have to be completed first?

[1] http://www.fao.org/pesticide-registration-toolkit/en/

Answer 1: It was confirmed that the WHO process is expected to take approximately 2 more years to complete. Until then, industry can potentially use existing WHOPES collaborative institutions for pesticide evaluation work. The process would be to approach the WHO team with the test protocol being used for evaluation by the prequalification of medicines programme and to decide if the protocol complies with the WHO test guidelines. If so, then test institutions may be used even if at that point they may not have formally been certified as GLP laboratories.

Question 2: There was also a query regarding potential chemical analysis in the future. There are currently phases 1, 2 and 3 studies being conducted according to ISO 17025 accreditation. Some laboratories have been GLP certified for 20 years but with regard to this new form of WHO pre-qualification, would WHO accept in the future the chemical analysis data in accordance with ISO 17025 or will it insist on data from the GLP laboratories? In Belgium, CRA-W has both GLP and ISO 17025 certification. It was believed that the schemes are very similar in terms of the validation requirements for accuracy etc., but the ISO requirements are much faster with regard to generation of data, for example, they involve much less paperwork than GLP.

Answer 2: The situation needs further discussion within WHO. There is a belief that it would be logical to adhere to data from GLP rather than ISO certified laboratories. It is appreciated that it may be cheaper and faster to conduct in accordance with the ISO process but this needs further discussion.

5.3 FAO

Madam Yong Zhen Yang informed the meeting of the activities**,** meetings and events held by FAO since the previous Joint Open Meeting (Tokyo, 13 June 2016).

Training workshops and meetings

- FAO/WHO JMPR meeting (Rome, September 2016); more than 400 MRLs have been estimated for 35 pesticides

- FAO/WHO JMPM meeting (New Delhi, April 2017); two guidelines reviewed: (i) guidelines on personal protection when handling and applying pesticides and (ii) guidelines on the registration of microbials, botanicals and semiochemicals

- 49th CCPR (Beijing, April 2017); 488 Codex MRLs have been approved and the Codex classification for fruits and vegetables was adopted.

- Call for data for the convention of the old specifications issued in 2016; specifications are available for 56 pesticides in the 1st batch, and responses have been received for the support of 22 compounds.

- Training of trainers on FAO pesticide registration toolkit (Rome, November 2016)

- Webinar on FAO pesticide registration toolkit (Rome, November 2016)

- Training workshop on FAO/WHO specifications and CIPAC methods (Zhuhai, December 2016)

- Regional training workshop on application of the FAO Pesticide Registration Toolkit in Asia and the Pacific (Beijing, May 2017)

Documents and publications

- 2016 JMPR report and evaluations (residue monographs) http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/

- French and Spanish versions of the FAO/WHO manual on the development and use of pesticide specifications, 3rd version (2016) http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/manual/en/

- French and Spanish versions of the FAO manual on the submission and evaluation of pesticide residues data, 3rd edition (2016) http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/

- Case study on addressing highly hazardous pesticides in Mozambique http://www.fao.org/3/a-i5360e.pdf

- A quantitative approach to the socio-economic valuation of pollinator-friendly practices http://www.fao.org/3/a-i5481e.pdf

- Farmer Field School guidance document: planning for quality programmes http://www.fao.org/documents/card/en/c/d7d4db1f-826f-4d81-b097-44292ff7eeca/

Technical projects

- IOMC (Inter-Organization Programme for the Sound Management of Chemicals) toolbox for decision making in chemicals management; phase III under development

The project aims to:

(i) further develop and roll out the pesticide registration toolkit, with specific tools on (a) pesticide registration protection goals, registration criteria and thresholds, (b) identifying low risk alternatives to highly hazardous pesticides, and (c) ecosystem services and biodiversity in pesticide registration; and

(ii) run face-to-face capacity-building workshops at international, national and regional levels

- Projects on supporting the work of JMPR
  (i) GCP/GLO/798/CAN; contribution from the Canadian government to increase the frequency of the JMPR meeting, with an extraordinary meeting scheduled in 2019
  (ii) GCP/GLO/780/FRA; contribution from the French government to support the annual JMPR meeting.

Questions/Comments

No questions were asked.

6. Technical liaison with other organizations

6.1 AgroCare

Mr Hans Mattaar described AgroCare and its structure. AgroCare, a global organization that was founded in 2008, currently represents 865 generic pesticide manufacturers worldwide. The association provides an important voice for its members.

The association consists of four regional associations, namely:

- AgroCare Latin America (previously ALINA, Latin American Association of the National Agrochemical Industry);
- European Crop Care Association (ECCA);
- Pesticide Manufacturers and Formulators Association of India (PMFAI); and
- China Crop Protection Industry Association (CCPIA).

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 organizations such as CIPAC, FAO, WHO and WTO (World Trade Organization)
- AgroCare addresses the common issues that hamper the development and placing on the market of post patent products at the global level.

Generic/post-patent products

The generic/post patent pesticide products manufactured by members of AgroCare may be of a higher quality than the reference pesticide. This statement can be supported by the analysis results obtained by one of its members' own generic version of their product and comparing it with the reference product version.

One of the main areas of interest for AgroCare is the concept of equivalence. There are general concerns regarding current developments. For example, under very stringent regulatory authorities, equivalence seems a small part. However, as no global authorization system is in place it may be that more of the regulatory package is being incorporated into the equivalence package. AgroCare believes that this results in the repetition of studies composing the toxicological package. This is considered unnecessary and must be avoided.

AgroCare's activities in 2016–2017 included the following:

New website, and the appointment of a Technical Director

- Participation in:
  - JMPM
    - Working Group Toolkit, physico–chemical properties
    - 10th JMPM meeting
  - JMPS
    - Industry workshop on biological section of the manual
    - Industry consultation specification guidelines on microbials

    - WHO
        - GCDPP meeting
        - Consultation on determination of equivalence for public health pesticides
        - PQT VCPAG Workshop dossier requirements and inspection protocol
    - CIPAC/JMPS
        - Joint CIPAC/FAO/WHO meeting (Rome)
- Participation in CCPR and LAPRW 2017 (Residue Workshop)
- Costa Rica: reform regulatory framework
- Guatemala: input into Central American common pesticide labelling guide
- Mexico: industry/authorities working group on substitution programme
- Argentina: input into Rotterdam Convention programme
- Training:
    - Good practice programmes in Costa Rica, Guatemala, Mexico, Honduras
    - FAO Code of Conduct
- Inter-laboratory proficiency test: 2016 edition 16 participating laboratories, 2017 edition in preparation
- ECCA/ECPA joint EU Regulatory Conference organization
- Participation in Zonal Steering Committee meetings
- EU PIC Designated Authorities meetings participation
- Intervention in legal action, supporting EU Commission against unrestricted access to confidential business information
- Contributions to EU Guidance Documents, procedure improvements for renewal of approvals and authorizations
- Introduction of new system of information dissemination to member companies
- Supporting fight against illegal and counterfeit pesticides
- Organized 11th International Crop Science Conference & Exhibition (ICSCE) in India (Goa, 10–11 November 2016)
    - Formulation developments
    - Workshops on
        - global registration and regulation
        - Latin America and China workshops
        - innovation in formulation and scope for R&D and patent
        - Technology R&D
    - Major Indian pesticide review:
        - 18 substances banned (15) or phased out (3) over 2–3 years
        - 46 substances revisited after 2 years
- HSE and Responsible Care programmes:
    - HSE training (> 300 staff), workshops, consulting and compliance checks
    - Since 2014: > 110 000 farmers trained
- Business services:
    - AgroChemEx organization (36 000 visitors from 80 countries)
    - Advisory/consulting services to formulators & packaging industry
    - Setting up QR-code system and programme for collection & processing of waste packaging.

- Contributed to Government programme on environmental protection and water pollution.
- New activities on:
  - pesticide/fertiliser issues: Committee to solve issues and aim at sustainable development
  - new Strobilurin Taskforce to solve common issues
  - setting up of CHIPAC (China Pesticide Advisory Committee)
  - stimulating and supporting Chinese manufacturers to introduce CIPAC methods and apply for FAO/WHO specifications.
  - organized "Advanced Training Class for the Development of FAO/WHO Specifications and CIPAC methods" for 77 participants from over 50 companies (December 2016)

Questions/Comments

Question 1: The statement made in relation to equivalence was wrong. It has never been the case that generic manufacturers are asked to manufacture a less pure form of technical material than is possible in order to comply with a reference specification.

Answer 1: The referral was in relation to formulated products that cannot be extended because they have different formulations compared to the reference and therefore different characteristics and therefore cannot rely upon the reference data package.

An additional comment was provided to the answer to Question 1: If the referral was related to a formulated product, then it should be noted that you cannot bridge the data to the reference product formulation anyway.

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

Mr Jean-Philippe Bascou, Chair of the CropLife International and European Crop Protection Association's Specifications Expert Group (SEG), gave a presentation on behalf of CropLife International and the European Crop Protection Association (ECPA). The focus of this year's presentation was on the SEG and not the CLI overall.

- The Specifications Expert Group (SEG) – who are we?
  - Comprised of member company representatives with expertise in
    - analytical, organic chemistry, physico–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 that aims
    - to enhance good specification quality (content, physico–chemical 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 five continents.
- The mission of the SEG includes:

- 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.
  - Provide discussion and feedback related to improvements and amendments in the FAO/WHO manual on specifications
    - annual comments,
    - revision of the EP and other comments in the general section
    - revision of chapter 9 on microorganisms
  - Is involved in providing workshop support to formulation specification training, quality, equivalence procedure and confidential business information (see activities with Regions)
  - Supported the Toolkit initiative for developing countries
  - Develop/Convert/Revise reference specifications safely assessed for good stewardship in spirit of transparency
    - Bacillus subtilis QST 713
    - d,d, trans-cyphenothrin
    - flupyradifurone
    - imidacloprid
    - methiocarb
    - transfluthrin
    - trifloxystrobin
    - triflumuron
  - Engage in and support the work of CIPAC
  - Coordinate our efforts with other expert groups (e.g. DAPF, DAPA, ESPAC, Phys-Chem Industry forum, OECD WG)
  - Play a leading role in introducing new or updated MT methods
    - MT 46.3 on storage stability for matrix release (N)
  - Annually introduce analytical methods to be used in specifications as reference methods, e.g.:
    - cyphenothrin EW
    - flupyradifurone TC, AL, EC, EW, FS, SL, WG
    - prothioconazole TC, EC, FS, SC
    - piperonyl butoxide EW
    - triflumuron TC, SCs
  - 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 (new revision from March 2017 published)
    - TM17, Guidelines for specifying the shelf life of plant protection products
    - TM19, Minor changes of formulants contained in formulations
  - Engage in and support OECD WG on Product Chemistry
    - Storage stability (guideline)
    - Analysed 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.
- SEG support workshop, training and regulations in:
    - Africa and the Middle East:
        - Egypt: Need to better understand the use of the FAO specification in particular on the use of the accelerated storage stability (If 14 days 54 °C does not pass).
        - Morocco: Revision of the Pesticide Act
        - Nigeria: New pesticide act has been drafted in order to transfer the responsibility for registration of pesticides from NAFDAC (regulation for drugs) to the Ministry of Agriculture as in most countries in the world.
    - Asia:
        - China: English translation and comments on the new Pesticide Act; English translation of the new GD on storage stability as well as English translation of the national coding system. It is much better aligned with the international system but alignment is still needed.
        - India: Workshop on data bridging concept, change of composition regulation, CBI and EP. Up to this point, India did not recognize this process.
        - Japan: GD 8147 from J-MAFF on equivalence procedure for AI used in agriculture is published: fundamental change in philosophy. The system now registers details of the specification itself rather than the previous system of registering the manufacturing process itself rather than the specification.

- SEG support workshop, training and regulations in:
    - EU: SANCO GD 3030 on Ministry of Agriculture validation for AS and impurities in TCs and FLs; guidelines for the generation of data on the physical, chemical and technical properties of plant protection products. Mixture of isomers management.
    - LATAM countries:
        - Chile: A new amended regulation was published (March 2016) as an internal guidance document for equivalence. Assessment is under preparation. SEG is supporting AFIPA in discussion with SAG.
        - Peru: New equivalence guideline published for Peru (Andean).
- Support scientific and risk-based approach
- Fosters innovation (New AI, FL types, MoA)
- Seeks harmonization improvement (Tolerances)
    - Fully support transparency concept as long as it does not endanger confidential business information; and data protection.

Questions/Comments

No questions were asked.

6.5 European Food Safety Authority (EFSA)

László Bura (EFSA) gave a presentation on the background, role and bilateral relationships that EFSA have within the European Union and on a global level.

- EFSA is based in Parma, Italy and deals with the risk assessment for pesticides. It is an independent organization under the European Commission, not a regulatory authority.
- EFSA works with a selection of stakeholders, including individual experts, representatives of national food safety institutes, delegates from the 28 European Member States (and Iceland and Norway), other European Union agencies and research institutes.
- EFSA is requested by DG Santé to support the work of CODEX and its Committees.
- Outside the European Union, EFSA has developed relationships with partner bodies such as WHO, FAO, EPPO and risk assessment bodies in various countries such as Canada, Australia and New Zealand. It has also established cooperative relationships with the Russian Federation, South Korea, India, various Asian countries and also countries which are pre-accession to the European Union.
- EFSA have been involved in investigating levels of contaminants in food, researching opportunities to coordinate with other bodies and sharing data to avoid duplication with the work and requirements of WHO/FAO. This includes consideration of ways to harmonize the risk assessment for exposure to such components as food additives, contaminants and pesticide veterinary drugs (e.g. Joint FAO/WHO meetings on TTC (threshold of toxicological concern) and on methods for the acute dietary intake of pesticides).
- EFSA have bilateral relations with EU Enlargement (IPA) and Neigh Neighbourhood (ENP) countries:
  - Lumpy skin disease (LSD) ENP/IPA workshop organized by EFSA and EU COM (Brussels, May 2016)
  - EFSA multi-country workshop to enhance cooperation between the Mediterranean countries on emerging risks in the food chain (Zaragosa, 7–8 March 2017)
- Partner countries with which EFSA has signed a cooperation agreement:
  - 5th meeting with the Food Safety Commission of Japan (FSCJ).
  - Bilateral meeting with China.
- Established cooperation with countries which are developing risk assessment capacity, i.e. the Asean risk assessment Centre in South East Asia, India and Taiwan.
- EFSA have working relations with 400 institutes worldwide.

The EFSA plan for the future is going global together.

Questions/Comments

No questions were asked.

6.6 American Federation of Agrichemical Societies (FASA)

There was no presentation from FASA at this year's meeting.

6.7 Other organizations

No other organizations made presentations.

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: Austria, Belgium (two reports for agriculture and public health), China, Czech Republic, Denmark, El Salvador, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Panama, Romania, South Africa, Spain, Switzerland, Thailand (two reports for agriculture and public health), Ukraine and the United Kingdom.

Questions/Comments

Question 1: In relation to the results provided by China (ICAMA), a participant asked if the out of specification results as reported were out of specification according to FAO limits or the ICAMA limits (national limits)?

Answer 1: According to the national limits.

Question 2: In relation to the results provided by CZ, the CZ representative was asked why CZ did not do an analysis for xylene? Is xylene banned in CZ or is there an upper limit?

Answer 2: CZ check for xylenes because there have been very high amounts found previously in some products in CZ.

8. Status, review and publication of CIPAC methods

It was noted that publication of CIPAC Handbook O is now in progress and can be ordered via the CIPAC webpage. The intention is now to update all handbooks from series E to O and it is hoped that these will be available in the autumn of 2017. All of the pre-published methods will now be included in Handbook O.

Questions/Comments

No questions were asked.

9. Subjects from the 16th JMPS Closed Meeting of 2017

- The major issues of general importance identified in the Closed Meeting were:
  - Use of CIPAC methods
  - Revision of reference specifications for TC and formulations
  - Revision of Section 9 of the manual on microbial pesticides
  - Further amendments to the manual
  - Revision of the Tier-2 equivalence procedure
  - Communication of data proposers with evaluators and the Joint Secretariat
  - Updated list of companies with details on contact person

- Changes in data requirements for determination of (biological) equivalence for public health pesticide products.

- Use of CIPAC methods:
  - CIPAC methods have to be followed as closely as possible in studies supporting FAO/WHO specifications because they are fully collaboratively tested or peer-validated.
  - CIPAC methods for active ingredients and relevant impurities have to be used also for equivalence.
  - A method validation according to e.g. EU SANCO/3030 is not acceptable.
  - If an in-house method is presented and used, then a bridging study with the CIPAC method used to demonstrate equivalence will be required.
  - If there are deviations from the CIPAC method, then a reason should be provided and justified by the proposer and not by the evaluator (e.g. replacement of a toxic solvent, HPLC column no longer available, adaptation of the mobile phase for a better resolution, etc.).

- Revision of reference specifications for TC and formulations:
  - A stepwise approach is in place
    - Initially, a proposal is made to revise a reference specification.
    - The proposal is then evaluated and any revisions are adopted.
    - A data call in for manufacturers of equivalent materials then follows.
    - Non-equivalent products are subsequently identified, supporting data packages are evaluated, and revised reference specifications and validation reports are published.
  - The proposed changes to the reference specification must be explained and considered by the JMPS.
    - Any change to a clause (e.g. higher purity, removal or addition of a specification clause, lowering or widening of a specification limit) must be explained and justified.
    - Any consequences on the equivalent products are considered by the JMPS.

- Revision of Section 9 of the Manual relating to microbial pesticides:
  - FAO/WHO JMPS and industry (AgroCare, CropLife International, IBMA) consultation in Gembloux and Geneva (January and October 2016)
  - Methods of identification for bacteria, virus, yeast and fungi
    - at the strain level
    - one identification method sufficient (published or full description)
  - Methods for quantification: GLP not necessary, independent laboratory validation when possible
  - Minimum limit in TK for content, higher limit in case of hazard concern
  - Primary or secondary metabolites and compounds may be defined as AI or relevant impurity
  - Most of the relevant physico–chemical properties as described in the manual are applicable, but limits may be less stringent (e.g. suspensibility, dispersibility, wet sieve test)
  - Cold temperature storage stability may not be required and should be considered when physical stability and biological activity are affected. Storage conditions to be stated on the product label.
  - Accelerated storage stability test not applicable

- Minimum content to be considered carefully.
- Expiry date to be included on the label.
- Relevant impurities: biological and chemical impurities, OECD guidance document 65 not applicable for all microorganisms, IBMA paper to be sent to JMPS for consideration
- Specification templates for TK, GR, WP, WG, SC, FS, OD and WT
- Introduction to chapter 9:
  - in line with JMPM document on registration of microbial
  - pesticides and IBMA paper on relevant impurities
  - limits for physico–chemical properties may be less stringent
  - data on long-term stability
  - EU, EPA data requirements to be followed for tox/eco-tox data
  - Equivalence not to be considered now
- Structure of section 9 of the manual on microbial pesticides:
  - Section 1 (introduction) remains valid for microbials and does not need adaptations
  - Section 2 (process of developing specifications) needs some amendments for subsection 2.9 (acceptability of analytical test methods)
  - Section 3 (data requirements) needs major amendments and possibly no equivalence for microbial pest control agents due to their particular nature
  - Section 4 (aim, applicability, specification clauses) has to be rewritten, including relevant impurities (4.4) and 4.6 (storage stability)
  - Section 5 (specification guidelines) will be a completely new section with introductory text and seven new templates, two of which already exist (on TK and WG); the others to be developed, no further division into solid and liquid formulations
  - The new or amended dedicated sections will be subsections of new section 9. After public consultation, the new section 9 will be published as a “trial edition” and stand-alone document, until being revised and then integrated into the main text body of the manual.
- Deadlines:
  - January 2018: drafting of the new section 9 of the manual
  - February 2018: consultation with AgroCare, CLI and IBMA
  - April 2018: updated version available
  - June 2018: review by the JMPS.

- SEG/ DAPF proposals for future amendments to the manual
  - All typographical errors in the 3rd version of the manual accepted by JMPS
  - Proposals for clarification of certain points which are already described in other subsections are not needed, to avoid duplication.
  - Free active ingredient content only applicable for slow release CS. To be further discussed whether feasible for fast release CS.
  - Harmonization of the test temperature at 25 ± 5 °C is in progress with DAPF and CIPAC. In the meantime, temperatures are those used in the CIPAC method.
  - Flowability should be specified for all granules. GR specification template to be updated.

- Request for splitting the two-in-one SP-SB and SG-SB model specification into the respective formulation specifications. Industry is kindly invited to send a proposal to JMPS.
- Laser diffraction probably not applicable for liquid formulations to be dispersed in water (SC, FS, CS, OD, ZC, ZW, ZE). Further discussion needed within CIPAC, ESPAC and JMPS to have more feedback and better understanding.
- Flammability clause for LN recently updated by CITEVE. To be still clarified for better understanding.
- The proposal to change the intended use of MR as direct application into water needs further explanation and possible re-consideration by SEG.

– Revision of Tier-2 equivalence procedure
  - 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:
    - Weedosulfuron – comparison of two TC qualities with their toxicology 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, neurotoxicity, blood status, organ functions)
  - New Tier-2 data requirements:
    - Extended draft amendment to the 3rd revision of the manual (January 17) sent to AgroCare and CropLife SEG for comments
    - Comments received and carefully considered
  - Outcome
    - CropLife: minor revision and clarifications in the Tier-2 amendment
    - AgroCare: major concern with Animal Health & Welfare for acute and repeated dose testing. Suggested that the tests be replaced by in-silico tox: (Q)SAR and TTC.
  - JMPS conclusions on Tier-2
    - CropLife: minor revision and clarifications mostly adopted
    - AgroCare: in-silico toxicity for impurities not predictive and reliable enough.
    - The EFSA opinion on (Q)SAR and TTC was noted and quoted by JMPS:
      “The approach (TTC, QSAR) is ready for use, but it is anticipated that on many occasions the outcome of the assessment scheme will be that further testing is needed to reach a firm conclusion on the toxicological relevance of the metabolite.
      However, the benefit of applying the approach is that it will allow prioritisation of metabolites for subsequent testing.”
  - JMPS 2017 conclusions on Tier-2

- CropLife: minor revision and clarifications mostly adopted
- AgroCare: in-silico tox for impurities not predictive and reliable enough[1]
    - if Tier-1 data package is inconclusive:

- tier-2 will only be requested and upon advice from JMPS (no combined Tier-1 and former Tier-2 data packages accepted) from 2018 onwards.

– Communication of data proposers with evaluators and the Joint Secretariat
    - Data proposers are kindly reminded to:
        - always copy communication with the assigned evaluator and the FAO/WHO secretariat
        - to respect the timelines for submission of data as set in the timelines of the manual
        - to raise any points of contention in the evaluation with the FAO/WHO secretariat, 3 weeks before the JMPS meeting, who will dispatch the notion immediately to the evaluator
        - not send data requested by evaluator or secretariat later than 2 weeks before the meeting
        - not exert pressure of any kind on the evaluator expecting immediate response on data submitted on data sent later than 2 weeks before the closed meeting or during the JMPS meeting.

– Updated list of companies with details on contact person
    - JMPS acknowledges mergers and acquisitions in the crop protection industry. However as pesticide specifications are linked to companies producing and supporting these products, FAO and WHO must be notified when company names and focal persons change.
    - FAO/WHO should be notified when upon:
        - company name change
        - change of focal person(s) or contact detail
        - sale or acquisition of compounds
        - manual, section 2.7
          “Specifications are published on the basis that information on the manufacturing process (...), impurity profiles (...), the hazard data available to FAO/WHO, and the manufacturer’s name and address remain valid.
          Proposers have a responsibility to inform FAO/WHO of changes in this information. Where the validity of this information is in doubt, the specification(s) may be scheduled for review by the JMPS.”

– Changes in data requirements for determination of (biological) equivalence for public health pesticide products:
    - Based on recommendations of a WHO consultation (Geneva, 17–18 October 2016).
    - Four products were considered:

[1] Scientific Opinion on Evaluation of the Toxicological Relevance of Pesticide Metabolites for Dietary Risk Assessment, EFSA PPR Panel, EFSA Journal 2012;10(07):2799.

- long-lasting insecticidal nets (LNs or LLINs)
- products for indoor residual spraying (IRS)
- mosquito larvicides
- space spray products

- Additional tests for generic products
  - LLINs: to better predict the wash resistance of equivalent LLINs under field conditions, conduct additional bioassays in laboratory of 20x washed nets using the “Phase II wash procedure” compared with a reference LN.
  - IRS products:
    - laboratory (Phase I) efficacy and residual activity on relevant substrates – compare with reference
    - the insecticidal efficacy of generic products should be higher or similar; residual activity should be the same as or longer than the reference product
    - concurrent QC testing of both products.
  - Mosquito larvicides: include simulated efficacy evaluation under laboratory conditions
  - Space spray products – no change in test procedures.

Questions/Comments

Question 1: In relation to Tier 2 data requirements, the presentation stated that the toxicity data packs did not always give the correct answers. Please provide examples.

Answer 1: The example of fluazinam was used in the case study where it was the first compound – the famous impurity 5 – but it would never be detected because it has no acute toxicity action and this would not be observed following a single dose exposure. There are other examples; however, this is considered to be one of the most significant.

Question 2: Follow-on question from Answer 1. Would this not just show up in QSAR?

Answer 2: QSAR is based on chemical similarity and is limited, and this is why EFSA came to their conclusion in their published opinion and why FAO/WHO are in full agreement with the findings. The metabolites must be considered in vivo or order to estimate the relative contribution and because the contribution of QSAR and TTC is very limited. QSAR can be used, therefore, but only to prioritize. QSAR can still be used but the QSAR predictions will often need to be supported by further testing.

Question 3: A further question in relation to new Tier 2 requirements. I do not understand the Tier 2 in Tier 1 splitting.

Answer 3: The main concern from AgroCare was animal testing. The majority of cases that JMPS receive have Tier 1 and 2 acute toxicity data and Tier 2 was not used in most cases. Therefore, in order to prevent this from happening, the Tier 1 submission will be used by itself as the start.

Question 4: Acute toxicity data sets are requested from certain regulatory authority but they are the most brutal animal studies of all and are unnecessary in some cases.

Answer 4: JMPS agrees that these tests are the most brutal tests and that is why they have proposed the current changes to Tier 2.

Question 5: Is the LN flammability test available to industry?

Answer 5: Yes, the flammability test is available.

Question 6: Why is flowability proposed in GR?

Answer 6: Flowability was included for WG and other granules and therefore it was important also for all granule formulations to show that they are flowing easily, not just those dispersed in water.

Question 7: Is there no wettability test for GR?

Answer 7: The wettability test is only for granules dispersed in water (WG and SG). Flowability refers to packaging, and the flowability shows that the granules can still flow after packing and being compacted. It is therefore applicable to whatever kind of granules.

Question 8: A statement was made about AgroCare's position, which was misunderstood. The main argument is that there is no stringent regulatory authority in the world that requires multi-dose studies for equivalence standards. Why would JMPS have a more stringent position than any other regulatory authority in the world? Multi-dose studies have rarely ever been required. Multi-dose studies should not be the standard. What is the JMPS plan? Will it be the case of fluazinam, where it will be required in nearly all cases?

Answer 8: It will be a standard part of the evaluation in cases where JMPS cannot come to a conclusion on Tier 1. The reason for JMPS to propose the 90 day study was that in the case of the increased use of the acute studies, it only gives a very large range and not points, and therefore it does not give any method for comparing the two products for equivalence. If there is uncertainty, the 28 day study is required – it gives confidence and is a doable study.

Question 9: CIPAC method slides – AI content require CIPAC method. But what about physico–chemical clauses?

Answer 9: Slide includes CIPAC requirement for active ingredient content and physico–chemical methods. However, where the CIPAC method is not applicable a different method can be used (e.g. not suitable for the solvent), but the reasons must be justified.

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 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 submission of data dossier, which may result in withdrawal of the products from JMPS evaluation after initial submission.

10.3 Status of Joint FAO/WHO specifications

Madam Yang presented the status of joint FAO/WHO specifications (Annex 3).

Questions/Comments

No questions were asked.

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

Mr Yadav presented the list of products prioritized for evaluation by JMPS in June 2018 (Annex 2) in four different categories: (1) original proposer; (1a) revision of old procedure specification; (2) subsequent proposer(s); (3) specification for formulation; and (4) revision of specification.

Questions/Comments

No questions were asked.

12. Any other matters

No other matters were proposed for discussion.

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

Madam Yang (FAO) announced that the CIPAC/FAO/WHO Annual Meeting in June 2018 will be held in Panama City by the Ministry of Agricultural Development (MIDA), National Plant Protection Direction, Panama City. A presentation was given on the 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 13th Joint CIPAC/FAO/WHO Open Meeting

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

ANNEX 1. PROGRAMME FOR DEVELOPMENT OF FAO AND WHO SPECIFICATIONS FOR PESTICIDES

Year		Product	Manufacturer
	(1) Original proposer; (1)* Revision of old procedure specification, (2) Subsequent proposer; (3) Specification for formulation; (4) Revision of specification		
2018		***FAO specifications***	
	8.1	2,4-D TC	(1)* Jiangxi Tianyu Chemical Co., Ltd,
	8.2	Azoxystrobin TC	(2) Taizhou Bailly Chemical Co., Ltd
	8.3	Chlorothalonil TC	(2) Jiangyin Suli Chemical Co., Ltd
	8.4	Diflubenzuron TC	(2) Taizhou Bailly Chemical Co., Ltd.
	8.5	Ethephon TC	(1)* Shaoxing Eastlake High-tech CO., LTD
	8.6	Fluazinam TC	(2) Taizhou Bailly Chemical Co., Ltd. Jiangsu Yangnong
	8.7	Hexazinone TC	(2) Jiangsu Lanfeng Biochemical Co. Ltd.
	8.8	Iprodione TC and SC	(2) Rotam
	8.9	Mancozeb TC	(1)* Mancozeb Task Force; Limin Chem Co (2017)
	8.10	Phenmendipham TC, EC, SE, OD	(1)* Bayer
	8.11	Phosmet TC	(1) Govan (rep. by SCC GmBH)
	8.12	Propiconazole TC & formulations	(1)* Syngenta
	8.13	Propineb TK, WP, WG	(1)* Bayer; Limin Chemical Co., Ltd.
	8.14	Tebuconazole TC	(1)* Jiangsu Sevencontinent Green Chemical
	8.15	Thiamethoxam TC, WG, FS	(2) Rotam
	8.16	Tribenuron-methyl WG	(2) Jiangsu Agrochem Laboratory
	8.17	Zeta-cypermethrin TC	(1) FMC
		WHO specifications	
	9.1	Bioxlin LN (bifenthrin + indoxacarb + PBO)	(3) VK Polymers, India
	9.2	DurActive LN (equiv. to PermaNet 2.0)	(3) Shobikaa Impex
	9.3	M-Kito Net LN (equiv. to PermaNet 2.0)	(3) Life Ideas Biological Tech. Co. Ltd
	9.4	Yorkool G2 LN (Chlorpyrifos ethyl + deltamethrin)	(3) Tianjin Yorkool
	9.5	Malathion 440 EW	(3) Tagros Chemicals
	9.6	Bendiocarb 20% CS - change in spec	(4) Landcent
		FAO/WHO specifications	
	10.1	Permethrin TC (40:60 *cis:trans*)	(2) Gharda Chemicals
	10.2	Malathion TC	(2) Tagros Chemicals
	10.3	Clothianidin TC, WG(equivalence for new production site)	(1),(3) Sumitomo Chemical

ANNEX 2. STATUS OF PUBLICATION OF FAO SPECIFICATIONS

FAO Specifications reviewed before 2016

Amicarbazone TC, SC	Arysta	Evaluation report to be published
Clethodim TC, EC	Arysta	Pending response to the data gap
Diflubenzuron TC	Arysta, Helm	Published, to be published
Fenazaquin TC, EC, SC	Gowan	Pending response to Open points, evaluation report to be published
Flucarbazone TC, SC, WG	Arysta	Pending response to the data gap
Hexazinone WG	Nutrichem	WG specification drafted. TKI to be contacted
Prochloraz TC, EW	Jiangsu Huifeng	Published
Thiacloprid TC, SC	Cheminova	Open points, specifications and evaluation report to be finalized by the evaluator and to be sent to FAO for editing
Trifloxystrobin TC, EC, WG, SC	Bayer	Specifications and evaluation delayed waiting the EU approval

FAO Specifications reviewed in 2016

Azoxystrobin TC	Jiangsu Sevencontinent, Nutrichem	Published
Bacillus subtilis QST 713 TC, TK, SC, WP	Bayer	Data requirements
Bifenthrin TC, EC	Bharat	Published
Beta-cyfluthrin TC	Bayer	Published
Dicamba TC	Jiangsu Yangnong	Published
Fluazinam TC	Nutrichem	Reconsidered in 2017
Flumioxazin WP-SB	Sumitomo	To be published
Methiocarb TC, FS	Bayer	Specifications and evaluation report to be finalized for editing/publication
Propiconazole TC	Jiangsu Fengdeng	Data requirements
Pyraoxystrobin TC, SC	Shenyang Sciencreat Chemical	Published
Silthiofam TC, FS	Monsanto	To be finalized for publication

FAO Specifications reviewed in 2017

1	**Tribenuron-methyl TC**	**(1) Jiangsu Agrochem**
2	**Clodinafop-propargyl TC**	**(2) Zhejiang Bosst CropScience**
3	**Fenoxaprop-P-ethyl TC**	**(2) Hangzhou Udragon Chemical**
4	**Azoxystrobin TC**	**(2) Hebei Veyong Biochem**
5	**Mancozeb TC, WP**	**(1) Limin Chemical Stock**
6	**Pyriproxyfen EC**	**(2) Rudong Zhongyi**
7	**Flupyradifurone EC, EW, FS, SL**	**(3) Bayer CropScience**
8	**Imidacloprid SL, WG, GR**	**(4) Bayer CropScience**
9	**Metsulfuron-methyl TC, WG**	**(2) Rotam Agrochemical**
10	**Deltamethrin TC**	**(2) Jiangsu Yangnong**

Review of the old FAO specifications

Call for data for the convention of the old Specifications issued in 2016, specifications for 56 pesticides in 1st batch, responses for support 22 AIs

Compound	Comments	Response
2,4-D	acid, salts, esters	Jianxi Tianyu, 2018 2,4-D Task Force, 2019
Ametryn		Syngenta, 2019-2020
Atrazine		Syngenta, 2019-2020
Bromoxynil	Free phenol and esters (phenol and esters: Bromoxynil Octanoate, Bromoxynil Octanoate-Heptanoate)	Bayer, 2019; Nufarm, 2019
Captan		Yingde Greatchem, 2019
Diflufenican		Bayer, 2020
Dichlorprop	racemic and P (Dichlorprop-P and Diclorprop-P EHE)	Nufarm, 2019
Ethephon		Shaoxing Eastlake High-tech 2018; Bayer, 2020
Folpet		Yingde Greatchem, 2019
Mancozeb		Limin, 2017; Mancozeb Task Force, 2018
MCPA	free acid, salts, and esters (MCPA Acid, Salts, Esters)	EU MCPA Renewal Task Force, MCPA Task Force Three, 2020
MCPB		Nufarm, 2019
Mecoprop	racemic and P (Mecoprop-P)	Nufarm, 2019
Metolachlor	racemic and S (S-metolachlor)	Syngenta
Metribuzin		Bayer, 2019; Nufarm, 2019
Propiconazole		Jiangu Fengdeng, 2016; Syngenta, 2018
Propineb		Bayer, 2018; Limin, 2018
Phenmedipham		Bayer, 2018; Limin, 2018
Sulfomrturon methyl		DuPont?
Tebuconazole		Jiansu Sevencontinent, 2018
Terbuthylazine		Syngenta, 2019-2020
Thiodicarb		Bayer 2021
Triflumuron		Ongoing

ANNEX 3. STATUS OF PUBLICATION OF WHO AND FAO/WHO JOINT SPECIFICATIONS

	Product	Manufacturer		Status
Pending specifications				
7.2	Bactivec SC	Labiofam		Data requirements
7.3	Bifenthrin TC, EC	Rotam		Withdrawn
7.3	Bifenthrin TC, EC	Bharat		Published
7.5	Diflubenzuron TC	Helm		Specification and evaluation report drafted by FAO and sent to WHO for editing
7.9	Metaldehyde TC	Xuzhou Nuote		Withdrawn
7.10	Niclosamide-olamine TC	Sichuan Academy		Withdrawn
7.11	Permethrin (incorporated LN) AkaNet	Kuse Lace Co. Ltd		Withdrawn
7.13	Alpha-cypermethrin + chlorfenapyr (coated LN) Interceptor G2	BASF		Specification and evaluation report drafted. Await for adoption of the CIPAC method for alpha-cypermethrin and chlorfenapyr
7.14	Propoxur TC, WP, WP-SB	Tagros		Published
WHO specifications				
9.1	Alpha-cypermethrin + PBO (incorporated LN) Duranet Plus	Shobikaa Impex		Data requirements
9.2	Alpha-cypermethrin + pyriproxyfen (incorporated LN) Royal Guard	Disease Control Technologies		Specification and evaluation report drafted. Await for adoption of the CIPAC method and successful evaluation by WHOPES
9.3	Bendiocarb TC	Saerfu AgroChem		Specification and evaluation report to be finalized by the evaluator and to be sent to WHO for editing
9.4	Clothianidin + deltamethrin WP-SB (Fludora Fusion)	Bayer		Specification and evaluation report sent to WHO for editing. Await successful evaluation by WHOPES
9.5	Deltamethrin (coated LN) Yahe LN	Fujian Yamei		Published
9.6	Pyriproxyfen TC	NTGC Fine Chemicals Co. Ltd		Data requirements
9.7	Pyriproxyfen 20 /kg MR	Sumitomo		Specification and evaluation report edited and sent to Sumitomo for final check

	Product	Manufacturer		Status
9.8	Transfluthrin TC (revision)	Bayer		Data requirements. New finding for toxicological evaluation. MoA for relevant impurity to be peer-validated
9.9	Pirimiphos-methyl TC, EC, CS	Syngenta		Published
9.10	Deltamethrin SC-PE	Bayer		Open points, specification and evaluation report to be finalized and edited by WHO
Joint FAO/WHO specifications				
10.1	Deltamethrin WG-SB	Gharda		Published
10.2	Deltamethrin TC, SC, WP	Sharda		Specifications for TC and WP, and evaluation report to be finalized by the evaluator and to be sent to FAO/WHO for editing. Data requirements for SC
10.3	Deltamethrin TC (revision)	Bayer		Data received from Gharda, Heranba, Isagro, Rotam and Tagros. Specification and evaluation report to be finalized by the evaluator and to be sent to FAO/WHO for editing