

Food and Agriculture Organization of the United Nations



First Joint FAO/WHO Meeting on Pesticide Specifications (JMPS)

2002

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Tuesday 18 June 2002 Rome, Italy

OPEN MEETING

1. Opening Speeches (From CIPAC, FAO, Italian Ministry of Health and WHO)

Dr Mahmoud Solh, Director of the Plant Production and Protection Division, FAO, welcomed participants to the 1st Joint Meeting on Pesticide Specifications, and noted that it marked the beginning of a new era. Dr Solh thanked WHO for the assistance given and looked forward to FAO and WHO working together in the future. He also thanked the Italian Ministry of Health and noted that their participation demonstrated the importance of international standards on pesticides for Italy. Dr Solh thanked Dr Dobrat for the enduring and intense collaboration with CIPAC. Finally Dr Solh thanked participants for their attendance and for showing continued co-operation for the specification procedures.

Dr. Solh continued by stating that pesticide specifications were important for farmers, governments and industry, as they were quality standards that were internationally accepted. Dr Solh thanked the Panel of Experts and noted that their joint efforts meant that specifications were an international point of reference. Dr Solh stressed the importance of high quality pesticides and that these were the basis for the development of good agricultural practice to control pests and to protect the environment. High quality pesticides were important for both developing and developed countries.

Dr Solh noted that one of the key issues facing the meeting was the preparation of the new Manual and thanked Mr Alan Hill for his hard work to date. He hoped the new procedure would simplify the process with one standard for both WHO and FAO.

Dr Solh also informed the meeting that the recent roster call for new members had elicited an excellent response, with 80% of the applicants coming from developing countries.

Dr Solh concluded by reminding the meeting of the recent World Food Summit, which had the aim of reducing world hunger by 50%. He remarked that pesticides that are safe to human health and the environment are essential in helping to increase food production.

Dr Maria Neira, Director of Communicable Disease Control, Prevention and Eradication, WHO, welcomed participants to the 1st JMPS Open Meeting and said it was a pleasure to meet in Rome. She emphasised the global importance of vector-borne diseases and continued reliance on chemical control of vectors. She noted the decentralization of health services in many countries and the challenges to pesticide management. She also noted the inadequate resources and infrastructure for efficient registration of public health pesticides in most developing countries. Dr Neira stressed the lack of effective quality control measures in most developing countries to ensure availability of safe and effective products and remarked on the lack of adequate inter-sectoral collaboration at the national level and the challenges posed by agricultural use of insecticides in selection of resistance in major vector populations. She emphasised the importance of collaboration with FAO in assisting the Member States.

Dr Neira concluded by thanking the organisers and welcomed the exciting developments offered by the collaboration of WHO and FAO.

Dr Walter Dobrat, on behalf of CIPAC, expressed his gratitude for the opportunity to hold the 46th CIPAC meeting in the beautiful city of Rome. He explained that CIPAC is a mature, independent organisation established by a few chemists from a limited number of countries in 1957. He went on to say that CIPAC had evolved steadily to become a worldwide organisation with representatives from all continents. Dr Dobrat said it was an honour to be the chairman of the organisation.

Dr Dobrat noted that there had been close co-operation between CIPAC and FAO from the beginning and the first CIPAC methods were published in an FAO bulletin. The first meeting at FAO headquarters was held in 1982 and at WHO headquarters in Geneva in 1988. Dr Dobrat noted this was the first meeting of the JMPS and he hoped for continued co-operation between FAO/WHO and CIPAC and stated that CIPAC would provide the necessary test methods to support the joint specifications.

Dr Dobrat concluded by expressing his thanks to the meeting organisers, Dr Robert Dommarco, Dr Gero Vaagt and their staffs.

On behalf of the Italian Ministry of Health, Director General, Dr Romano Marabelli welcomed the participants and said he was very pleased that the Ministry of Health was participating in this important event. He went on to express that the Ministry was currently faced with difficult challenges regarding the need to ensure the use of safe and effective pesticides. No other agricultural issue was of such international prominence as food safety. For example, vegetable produce was vital to the prosperity of developing countries. A global evaluation of food safety was underway, therefore it was important to work together to control products in trade and to ensure an adequate relationship between all countries. He added that those working in the sphere of pesticides need to ensure that a permanent dialogue was maintained between countries to reassure consumers and increase confidence in food safety. Dr Marabelli commented that the general view of pesticides was not positive but added that we are now in a position to encourage Industry to produce even better products in order to ensure that farmers are better able to consolidate food production.

Dr Marabelli closed by saying the joint efforts of WHO, FAO and CIPAC were vital in this process and that the work would open trade to ensure a safe and plentiful food supply.

2. Appointment of Chairman and Rapporteurs

Mr Alan Hill was appointed as Chairman and Drs Jo Gillespie and Tan Soo Hian as rapporteurs.

3. Adoption of agenda

The agenda was adopted with the following amendments: Addition item 5.2 Links between JMPS, JMPR and CCPR Addition item 7.g Insecticide treated fabrics

4. Summary Record of the 31st Open Meeting of Pesticide Specifications (Bangkok, Thailand, 19 June 2001)

There were no amendments to the record of the meeting.

5. Summary of action taken after the 31st Meeting

5.1 Progress in revising the International Code of Conduct on the Distribution and Use of Pesticides

Dr Vaagt reported that a revision to the International Code of Conduct had been presented to the FAO Conference in 2001 and that discussion had centred on issues of data protection. It was decided that the matter should go to technical consultation and comments had been received from 40 governments. A revised text had been agreed upon and is to be considered for adoption at the FAO Council in November 2002. The Code now includes a section addressing the public right to information relating to human health and the environment. Dr Vaagt noted that the Code had made reference to TRIPS and had recommended a period of data protection but that this caused difficulties with the FAO Member States.

Dr Vaagt also reported that the principle for determination of equivalence as used under the specification procedure was now included in the Code and had been accepted by Conference.

Dr Thomas Woods, on behalf of Crop Life International, sought reassurance that the confidentiality of data would be maintained and the reassurance was provided by FAO and WHO.

It was also confirmed that the pesticide registration process and the specification process were separate matters.

5.2 Report from the Codex Committee on Pesticide Residues in relation to the JMPS programme.

It was proposed that an extant specification be a pre-requisite for a compound prior to consideration by JMPR and this was discussed at CCPR in 2001 and 2002. Dr Woods expressed concern that this could delay the JMPR process and that there should be co-ordination of the JMPR and JMPS programme. Manufacturers were encouraged to work together to ensure co-ordination of the programme.

5.3 Progress in Review Process of old specifications

FAO presented details of those pesticides which are identified under the POP scheme, which are identified as having toxicological concerns, or which are no longer traded. The following compounds were identified for withdrawal:

anilazine bromophos camphechlor (toxaphene) chlorbenside chlordane demeton demeton-S-methyl DDT + its mixtures* HEOD (dieldrin) HEOD + mercurydimefox dinoseb dioxathion endrin fenoprop HHDN (aldrin) heptachlor methoxyethylmercury silicate methoxyethylmercury chloride monuron nicotine nicotine sulphate schradan 2,4,5-T

* DDT has exemption for public health use

Members noted that nicotine was still in use in a number of countries but that no manufacturer had agreed to support the specification.

Members agreed that the listed specifications be withdrawn but that the use of DDT in public health applications be exempted from withdrawal.

It was confirmed that specifications considered under the old procedure would remain extant until reviewed.

5.4 Roster Call for Experts for JMPS by FAO

In March 2002 a note was circulated to all Member States to identify additional experts for JMPS and an announcement was included on the FAO web site to invite applications. FAO was very encouraged by the response and in total, to date, 67 applications had been received, of which 55 were from developing countries.

Letters would be sent to all candidates acknowledging receipt of their application and informing them that they could expect to receive further

information on the outcome of the evaluation of applications at the end of 2002 or the beginning of 2003. Evaluation of applications would be carried out by FAO, WHO and the Chair.

WHO noted that, in the past, most experts were located in Europe but that representation was required from all regions. The response to the roster call was welcomed and it was hoped to broaden participation.

5.5 Progress on the Manual on Development and Use of FAO and WHO Specifications for Pesticides

The Chairman presented a summary of the proposed changes to the manual incorporating the results of discussions with Industry and Experts.

He explained that the revision of manual was primarily driven by the need to harmonise the procedures between WHO and FAO.

A small group met in York, U.K. in February 2002 to agree upon the revised text of the new Manual. A second draft was circulated recently. Some technical details were still to be incorporated and further work was required on household pesticides and microbial larvicides. It was hoped the new Manual would be available before the end of 2002. The following points were discussed:

- New and revised CIPAC methods have been included and obsolete methods withdrawn;
- New formulation guidelines have been included e.g. emulsifable granules;
- Public health formulation guidelines have been incorporated, including new formulation guidelines where appropriate;
- Guidelines on data submission have now been included as a new chapter rather than as an Appendix;
- Proposers must identify the link, if any, between the tox and ecotox data and the impurity profile;
- When the Manual is posted on the Internet, proposers will also be able to download templates for specifications;
- In the UL guideline, agreement to remove the clauses for kinematic viscosity and volatility has been discussed because the methods were not

available to provide meaningful data for consideration. It was emphasised that these data were still important but, without a meaningful method, interpretation would be difficult. Kinematic viscosity will move to a footnote;

- The Disclaimer will be strengthened to advise against misuse;
- Two options for letters of access:
 i) Authorising the evaluator to access the registration data;
 ii) Authorising the evaluator (or FAO/WHO) to send the data to a regulatory authority for their assessment;
- Methods for relevant impurities will be appended to the specification;
- Manual will contain a new Appendix H addressing declarations of interest and Confidentiality Agreement;
- Proposers will be asked to round data submitted to one or two significant figures;
- WHO recommendations for use, based on efficacy evaluation, may be used to support registration;
- A summary of the history of the development of specifications will be inserted.
- Outstanding issues included:

i) The distinction between TC and TK;

ii) Certain specification clauses for aerosols which are problematic;

iii) Bacterial larvicides - Certain clauses and "Notes" in the specification guidelines for bacterial larvicides require clarification or reconsideration.

The Chairman thanked Industry and Panel Members for their efforts.

Dr. Woods, on behalf of Industry, also thanked and congratulated those involved in the preparation of the manual.

It was proposed that the temperature of measurement of physical properties should be performed at $23 \pm 2^{\circ}$ C but it was agreed that $30 \pm 2^{\circ}$ C be retained because it was considered to be more practical to maintain the latter temperature in the majority of laboratories in the world.

It was confirmed that the revised method for attrition resistance to WG to be presented to CIPAC in 2002 would be considered. [Post-meeting note. The JMPS agreed that this method would not be used to support a corresponding clause in guidelines for WG, SG and EG. Clauses for dustiness appear to provide a more meaningful indication of quality with respect to dust content but this method does not determine the potential for generation of respirable dust. Industry is therefore requested to develop a more definitive method.]

6. Review and publication of specifications

6.1 Status of FAO and WHO Specifications

On behalf of FAO, Dr. Vaagt stated that the principal means of publication for specifications would be on the Internet. The review procedure was on going. The old specifications, previously only available as hard copy, would be available through the internet.

Dr. Morteza Zaim, speaking for WHO, reported that there were currently 30 compounds and 78 products for which WHO specifications were available and a further 14 interim specifications. There had been a call for review of existing specifications and manufacturers had identified an interest in 7 compounds and 23 products.

It was specified that WHO specifications were available only through the Internet.

6.2 Status of pending FAO Specifications

FAO reported the publication of specifications considered by the Panel of Experts from 2000. Specifications for some compounds were awaiting final comment by the proposers.

FAO expressed concern over compounds for which proposers had requested inclusion in the agenda but where no data were presented. This had the effect of limiting the number of compounds which could be considered by the JMPS and delayed the consideration of others. It was urged that Industry only request inclusion in the agendas of those compounds where the data were available for submission within the agreed time scale.

7. New Specification Guidelines

Guideline specifications were proposed for:

- a. Dispersible Concentrates
- b. Emulsifiable Granules
- c. Emulsifiable Powders
- d. Oil Based Suspension Concentrates
- e. Household insecticide products
- f. Bacterial larvicides
- g. Insecticide impregnated fabrics

Insecticide treated nets are effective in reducing malaria mortality and morbidity. However, it is estimated that less than 5% of nets currently used in Africa have been properly re-treated. Responding to this challenge, WHO has intensified its collaboration with industry and scientists on development of long-lasting insecticidal nets. These are ready-to-use pre-treated mosquito nets which require no further re-treatment during their life span. One such net has successfully passed WHOPES evaluation and another one is under field testing. Interim specifications which contain clauses relating to physical properties of the fabric, as well as specifications relating to the active ingredient and physical properties of the insecticide, the release rate and storage stability, are in preparation. Other types of insecticidal fabrics are also in development and under evaluation. WHO invited industry to assist in development of guideline specifications for all such products.

8. Priority list for development of specifications and three-year programme (2003-2005)

see annex 1

WHO reported that a review of public health specifications for malathion was requested by one manufacturer but that this did not include the WP, which is made by other manufacturers. If a new specification for TC were to be adopted, the existing TC specification would have to be withdrawn and, as a direct consequence, all existing formulation specifications would also be withdrawn (because these must refer to the TC specification). The implication of the withdrawal of the WP formulation could have serious consequences for public health uses and co-operation was requested from industry to ensure that a new specification for WP could be developed in parallel with the new specifications for TC and other formulations.

9. Requests by Governments to FAO/WHO for workshops on Pesticide Specifications

Two workshops have taken place - in 2001 in Argentina and in 2002 in Brazil. FAO noted that specification procedures, and especially the determination of equivalence, were important in Registration. FAO and WHO had received requests from countries and from regions for assistance in procedures and were happy to respond as far as possible. It would be preferred if this could be organised on a regional rather than a national basis.

10. Any other matters

There were no other matters not covered by the agenda. The Chairman closed the meeting by thanking the organisers, the rapporteurs and the meeting participants.

PROGRAMME FOR DEVELOPMENT OF

FAO AND WHO SPECIFICATIONS FOR PESTICIDES

Year	Products	Proposer(s)	
2002	FAO:		
	Azadirachtin	Godrej; Fortune	
	Bensulfuron-methyl TC, WP, WG	Dupont	
	Beta-cypermethrin TC, TK	Agro-Chemie	
	Butralin (withdrawn)		
	Dicamba TC, WG, SL (SG)	Syngenta; BASF; Gharda	
	Flufenzine TC,TK	Agro-Chemie	
	Glyphosate SL	Syngenta	
	Maleic hydrazide TC, TK, SL,SG	Uniroyal	
	Iprodine (withdrawn)		
	Methomyl TC, SP, SP-SB, SL	Dupont	
	Quinclorac TC, WP, WG, SC	BASF	
	Tribenuron methyl TC, WG	Dupont	
	WHO:		
	d-allethrin TC	Sumitomo	
	d-phenothrin TC	Sumitomo	
	Prallethrin TC	Sumitomo	
	Transfluthrin TC	Bayer	
	FAO & WHO:		
	Chlorpyrifos TC, EC, UL, WP	Dow; Makhteshim; Gharda	
	Niclosamide TC, TK, EC, SC, WP	Bayer	
2003	FAO:		
	Azadirachtin	Godrej; Trifolio; Fortune	
	Chlormequat chloride	BASF	
	Chlorsulfuron	Dupont	

	Flufenzine TC, TK	Agro-Chemie	
	Hexazinone	Dupont	
	Imidacloprid	Bayer	
	Iprodine	Bayer	
	Maleic hydrazide	Drexel; Fair Products	
	Paraquat TK, SL, SG	Syngenta	
	Propanil	Riceco; Dow	
	WHO:		
	Bioallethrin TC	Sumitomo	
	Cyfluthrin TC, EW, WP	Bayer	
	Esbiothrin TC	Sumitomo	
	Trans-cyphenothrin TC, EC	Sumitomo	
	FAO & WHO:		
	Deltamethrin TC, DP, SC, UL, WG, WP, WT	Bayer	
	Lambda-cyhalothrin TC, CS, EC, WP	Syngenta	
	Malathion TC, DP, EC*	Cheminova	
	Novaluron TC, EC, WG	Makhteshim	
	Propoxur TC, WP	Bayer	
2004	FAO:		
Tentative	Butralin	Nufarm	
	Guazatine TC, LS	Makhteshim	
	Prochloraz TC, EC, SC	Makhteshim	
	WHO:		
	Icaridin	Bayer	
	FAO & WHO:		
	Pirimiphos-methyl TC, EC	Syngenta	

* Existing WHO specifications for malathion WP (WHO/SIF/10.R7) may be withdrawn when new specifications for malathion TC is established, unless data package on TC & WP is received from other manufacturer(s), for determination of "equivalence" under the new procedure.