Most Immediate

No. P. 15023/9/2004-PH(Food)
Directorate General of Health Services

Nirman Bhavan, New Delhi
Dated the 30th June 2004

OFFICE MEMORANDUM

Subject: ***Minutes of the Meeting held under the Chairpersonship of Ms. Rita Teaotia, Joint Secretary, Ministry of Health and Family Welfare on 14th June , 2004 at 2.30 PM in Room No. 146 'A', Nirman Bhavan, New Delhi-reg.***

A meeting was held under the Chairpersonship of Ms. Rita Teaotia, Joint Secretary, Ministry of Health and Family Welfare with the Pesticide Industry representatives to discuss and finalize about the Proforma/Checklist to be provided by the Industry/Manufacturers for fixation of MRLs by Ministry of Health and Family Welfare.

A copy of the minutes of the meeting and the proforma so finalized therein is enclosed for your kind perusal.

(Dr. R. K. Mahajan)
Assistant Director General (PFA)

Department of Agriculture
(Shri A.K. Singh, Additional Secretary)
Krishi Bhavan
New Delhi

Copy for information and further necessary action to:-

1. Dr. D. Kanungo, Additional DG (MS), Dte. G.H.S., West Block No.1, 1st Floor, R.K. Puram, New Delhi-110022
2. Dr (Mrs.) S. Kulshrestha, Secretary (RC&CIB), Directorate of Plant Protection, Quarantine and Storage , NH-IV, Faridabad-121001

Minutes of the Meeting held with Pesticide Industry Association held on 14th June 2004 at 2.30 P.M. , Nirman Bhavan, New Delhi

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A meeting was held under the Chairperson of Ms. Rita Teaotia, Joint Secretary, Ministry of Health and Family Welfare with the Pesticide Industry representatives to discuss and finalize about the proforma/checklist to be used by the Industry/manufacturers for fixation of MRLs by, the Ministry of Health and Family Welfare. The list of the participants is *Annexed.*

Ms. Rita Teaotia, Chairperson, welcomed the members of the Pesticide Industry. She explained details about the proforma to be used by the Industry for fixation of MRLs by Ministry of Health. She also explained that the Ministry of Health does not require the complete dossier of the data required for registration of pesticides. The Chairman, Crop Life India appreciated the efforts of the Ministry of Health and assured that Industry will fully cooperate with Ministry of Health and Family Welfare in generation of the data as required by Codex for fixation of MRLs. The following decisions were taken:-

1. The Industry members wanted certain clarifications on the proforma which were explained to them

2. It was agreed that the Secretary, RC&CIB will provide within a fortnight the list of pesticides which are being scrutinized by the RC for fixation of MRLs.

3. The Industry will provide list of pesticides for which data is generated on old guidelines to the Ministry of Health and Family Welfare and to RC.

4. The proforma will be applicable for the new molecules to be registered hereafter. The representative of the Industry mentioned that at present data on three seasons is being generated According to new guidelines data on multi-locational basis will be required to be generated from 1.4.2004. The Ministry of Health and Family Welfare agreed to consider the data on three seasons basis for the pesticides listed as per the point No. 2 and 3 of these minutes.

5. It was agreed that the Industry will provide data on pesticides that will be used for seed treatment for fixation of MRLs.

6. Some of the industry representatives raised a concern about the fixation of MRL for a compound which is already registered but comes for registration as it is to be manufactured through different manufacturing process and the resultant product has a different impurity profile (both quantitative and/or qualitative). In this regard it was agreed that if the impurity profile in technical grade product (both quantitative and qualitative) are same as those of earlier registered product for which MRL has been fixed, then there is no need for fixation of fresh MRL. However, in case of variation, the exercise for fixation or MRL is to be undertaken.

7. The industry's representative requested for exemption of fixation or MRL for pesticides to be used for floriculture. It was stated that since some of the floriculture products are used as a part of food either directly or indirectly, the pesticides used for floriculture have to have MRL. However, this is required to be considered on case-by-case basis in consultation with CIB/RC depending on its proposed use.

8. The Industry requested that meetings of the CCFS be held once in three months. The chairperson informed that it might not be feasible. However, she agreed to bring their suggestion to the notice chairman of CCFS.

9. It was agreed that Proforma/Checklist may be modified in the light of the discussions held in the meeting and sent to the Additional Secretary (Agriculture) for implementation. The modified proforma is enclosed and forms part of these minutes.

10. The proforma containing all technical information has to be submitted by the industry to RC along with its application for registration. RC shall send these proforma to Ministry of Health with due authentication of data which shall be used for fixation of MRL. The Ministry of Health shall prepare draft MRL's within 3 months from the date of receipt of proforma and authentication by RC of the data. Draft MRL's will be subjected to the approval by CCFS.

The meeting ended with vote of thanks to the chair.

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List of participants

1.	Ms. Rita Teaotia, Joint Secretary, Ministry of Health and Family Welfare, Nirman Bhawan New Delhi
2.	Dr. D.Kanungo Additional Director General (Medical Stores) Directorate General of Health Services. R.K.Puram New Delhi-110022
3.	Dr.(Mrs.) S.KKulshrestha Secretary CIB &RC Directorate of PPQS Fariadabad
4.	Dr.S.K.Handa, WHO, Consultant DGHS, Nirman Bhawan, New Delhi
5.	Shri.A.K.Shrivastav Deputy Additional Director General (PFA) Nirman Bhawan New Delhi
6	Dr.Pradip K.Mazumdar, Chairman, Crop Life India Mumbai-400020
7.	Dr.N.P.Agnihotri Director, Jai Research Foundation VAPI
8.	Shri P.A.Dave President PMFAI, Mumbai
9.	Shri Raj Kumar Singh PMFAI, New Delhi
10.	Dr.Uttam Gupta Crop Life India New Delhi

11	Dr.Amitava Sanyal Crop Life India New Delhi
12.	Shri. Thyagarajan Crop Life India New Delhi
13.	General Ravi Varma Executive Director Crop Care Federation of India New Delhi
14.	Shri S.S.Guleria (CCFI) C/o Crop Life India New Delhi
15.	Shri A.K.Ghoshal Pesticide Manufacturer & Formulation Association of India New Delhi

PROFORMA FOR SUBMITTING DATA ON RESIDUES AND TOXICITY BY THE APPLICANT SEEKING REGISTRATION OF NEW PESTICIDES FOR USE IN THE COUNTRY UNDER SECTION 9(3) OF THE INSECTICIDES ACT, 1968

GENERAL INFORMATION

IDENTITY

- ISO common name
- Chemical name
  IUPAC
  CAS
- CAS Registry No.
- CIP AC No.
- Synonyms and trade names
- Structural formula
- Molecular weight

Physical and chemical properties

Pure active ingredient

- Appearance
- Vapour pressure in mPa at stated temperature)
- Melting point
- Octanol-water partition coefficient (at stated pH and temperature)
- Solubility (water and organic solvents at stated temperatures)
- Relative density (at stated temperature)
- Hydrolysis (at stated pH and temperature)
- Photolysis
- Dissociation constant

Technical material

- Minimum purity (in %)
- Main impurities (range of amounts)
- Appearance
- Density
- Melting range
- Stability
- Reference to FAO specifications for TC of TK (TC, technical material, TK, technical concentrate)

Formulations

Provide a list of commercially available formulations.

METABOLISM AND ENVIRONMENTAL FATE

Information is required on:

- **Animal metabolism studies -** Animal studies are required when pesticide is directly applied to livestock and animal premises or where significant residues remains in crops or commodities used in animal feed or in any plant parts that could be used in animal feeds
- **Plant metabolism** – identification and Quantification of the metabolies on the registered crop and on similar crops are required.
- **Environmental fate in soil**
- **Environmental fate in water-sediment systems.**

Details	Season I	Season II	Season III
Location Name and address of the institute / Location where residue trial has been carried out. Name and address of the institute where residue analysis has been carried out APPLICATION DATA Date of Crop planting / sowing Description of the plot plan / crop layout / cropping system Plot size			

Number of plants per plot / unit area Number of plots per treatment Method of application and equipment No. of applications and application dates. Application details Dose rate Spray volume	Untreated control standard dose a.i. / has Double dose a.i. / ha	Untreated control standard dose a.i. / has Double dose a.i. / ha	Untreated control standard dose a.i. / has Double dose a.i. / ha
CLIMATE CONDITIONS Av. Min. Temperature (^{0}C) Av. Max. Temperature (^{0}C) %relative humidity % relative humidity Rainfall (mm) Av. Relative humidity % Other pesticides applied to trial plots with relevant details			

Growth stage at last treatment of present pesticides			
SAMPLING DATA Date of sampling with time No. of samples taken per test / treatment Sample weight and preparation Interval between last application and sampling storage conditions before analysis			
METHOD OF ANALYSIS Analytical methods should include all residue components needed for residue definitions for compliance with the MRL The individual studies should be summarized and clearly outline the compounds determined, the commodities for which the method is recommended, specificity, repeatability of the method, the LOQ and the range of residue levels for which the method has been validated, the mean recovery and the relative standard deviation of recoveries at each fortification level including the LOQ, etc. The analytical method should include procedure in detail including a precise description of the portion of sample analysed, tests to prove the efficiency of extraction, recoveries at various levels, LOQs, limits of detection, chromatograms of samples and controls and a description of how the limits of quantification and detection were derived. **Storage stability tests** The results of storage stability test for residues in stored analytical samples of			

representative substrates should be provided for samples held in storage before analysis.

Residues data

In case of cereals, oil seeds, pulses, which are harvest my be given as follows: -

RESIDUES	**RESIDUES ESTIMATED AT HARVEST**		
Control	Ag. Pro. / Soil	Ag. Pro. / Soil	Ag. Pro. / Soil
Replication 1			
Replication 2			
Replication 3			
Mean			
Standard dose a.i., /ha			
Replication 1			
Replication 2			
Replication 3			
Mean			
Double dose a.i./ha			
Replication 1			
Replication 2			
Replication 3			
Mean			

In the case of fruits and vegetables the residue data should be submitted as follows: -

Days	**Normal Dose Residue (mg /kg)**				**Double dose Residue (mg /kg)**			
0	**R1**	**R2**	**R3**	**Mean± SD**	**R1**	**R2**	**R3**	**Mean± SD**
1								
3								
5								
-								
-								
-								
-								

Effect on normal processing on the fate of residues – Processing studies are not required –

- when the plant material is eaten as raw
- only simple physical operations such as washing and cleaning are involved
- if no residues occur above the LOQ

Proposed waiting period

Proposed MRLs limit

Prescribed MRL registered crop in others countries

MRLs of pesticides on other crops

Use pattern

The use patterns should be summarized from two aspects, (1) biological efficacy and (2) formulation and application. The biological efficacy should be given in the *format I* and information and formulation and application should be summarized in the *format II*

GAP information

The information should be given in the *format III*.

Residues resulting from supervised trials on crops

The information should be given in the *format IV*. To ensure the availability of all detailed information necessary for evaluation, copies of the complete original reports on the supervised trails must be submitted.

Data on Toxicity

Whether information on the following provided: -

i) Acute Oral rat

LD 50: Dosage: - Signs: -
NOEL: - in each dose

ii) Acute Oral mice

LD 50: Dosage: - Signs: -
NOEL: - in each dose

iii) Acute dermal

LD 50: Dosage: - Signs: -
NOEL: - in each dose

iv) Acute inhalation

LD 50:

v) Mutagenicity

Name of tests Dose used Result

vi) Teratogenicity

Rat

Rabbit

vii) Effect on reproduction (Rat) NOEL Maternal
Fetal
Description of toxicity

viii) Carcinogenicity (Rat / mice)
NOEL
LOAEL
Tumors Seen
Any other Pathological adversity

ix) ADI

x) National maximum residues limits on other registered crops:

xi) Residue definition – Pesticide Residue means any specified substance in food, agricultural commodities or animal feed resulting form the use of a pesticide. The term includes any derivatives of a pesticide such as conversion products, metabolites reaction products and impurities considered to be toxicological significance . For example residue definition of endosulfan includes endosulfan alpha, endosulfan Beta and endosulfan sulfphate and residue definition of parathion methyl include parathion methyl and paraoxon methyl.

xii) Labels and Leaflets – To be submitted

Format 1
Information on pests and diseases controlled by [pesticide]

Crop	**Pests/diseases controlled**	**Timing of application (s)**
Banana (example)	Aphids, corm borer, corm weevil, nematodes	2-4 times per year
Cotton (example)	Soil pest, wireworms	Furrow treatment at planting

Format 2
Registered uses of [pesticide] on vegetables and cereals

Crop	**Country**	**Formulation**	**Application**				**PHI Days**
			Method	**Reate kg ai/ha**	**Spray conc., kg ai/hl**	**Number**	
Beans (example)	Greece	WP 800 g/kg	Foliar	0.6-1.5	0.1-0.25	3-4	7
Lettuce (example)	France	SP 800 g/kg	Foliar	0.64			21

Format-III SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES.

(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address): Date:

Pesticide(s) (common name(s)): Page:

CCPR No(s).: Country:

Trade name(s):

Main uses, e.g. insecticide, fungicide:

Use Pattern

Crop and/or situation (a)	F or G (b)	Pest or group of pests) controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (k)	Remarks (1)
			Type (d-f)	Conc. of ai (i)	method, kind (f-h)	growth stage (j)	number (range)	kg ai/hl	water l/ha	kg ai/ha		

Explanatory notes: (these explanatory notes are needed only on page 1 of a multi-page GAP summary)

Include only the information provided on the label.

(a) In case of group of crops the Codex classification should be used

(b) Outdoor or field use (F), or glasshouse application (G)

(c) e.g. biting and sucking insects, soil borne insects, foliar fungi

(d) e.g. wettable powder (WP), emulsifiable concentration (EC), granule (GR)

(e) Use CIPAC/FAO Codes where appropriate

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants

(i) g/kg or g/l

(j) Growth stage at last treatment

(k) PHI = Pre-harvest interval

(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications)

Format IV. RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS

(Application on agricultural and horticultural crops)

Active ingredient:
Responsible body for reporting (name, address):
Country:
Content of ai (g/kg or g/l):
Formulation (e.g. WP):
Commercial product (name):
Producer of commercial product

Crop/crop group:
Submission date:
Page:
Indoor/outdoor:
Other ai in formulation:
(Common name and content):
Residues calculated as:

Report-No.: Location incl. Postal code	Crop Variety	Date of (1) Sowing or planting; (2) Flowering or (3) Harvest (b)	Application rate per treatment			Dates of treatment(s) or no. of treatments and last date	Growth stage at last treatment or date	Commodity, Portion analysed (a)	Residues (mg/kg)	PHI days) (d)	Remarks (e)
			kg ai/ha	water l/ha	kg ai/hl						

Explanatory notes: (these explanatory notes are needed only on page 1 of a multi-page residue data summary)

(a) According to Codex Classification/Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
Note: All entries to be filled in as appropriate

CHECK LIST FOR SUBMISSION OF INFORMATION FOR FIXATION OF MRLs FOR NEW PESTICIDES

For fixation of MRLs complete information / details on various parameters of residues and toxicology of pesticide are essential in the enclosed proforma by Ministry of Health and Family Welfare. The Registration Secretariat may ensure that the information received from the registrants is complete from all aspects so that MRLs are fixed correctly and without any delay.

I. Name of the Pesticides and the crop on which the MRLs is to be fixed

II. Date on which application was received by Registration Secretariat.

III. Date on which application with data is sent to the Ministry of Health and Family Welfare.

IV. General Information

i)	Identity	Yes	No
ii)	Physical and Chemical Properties	Yes	No.
iii)	Technical Material	Yes	No
iv)	Formulation	Yes	No.
v)	Metabolism and Environmental fate	Yes	No
vi)	Whether the pesticide is registered in other countries	Yes	No

V. Application Data on supervised trials

Information in respect of following is provided or not

i)	Trial conducted	Yes	No
ii)	Commodity	Yes	No
iii)	Name of the Institute(s) where supervised trials were carried out	Yes	No

iv)	Name of the institute where residue analysis was carried	Yes	No
v)	Crop planting / sowing data	Yes	No
vi)	Plot size is mentioned	Yes	No
vii)	Number of plants per plot	Yes	No
viii)	Number of treatments provided	Yes	No
ix)	Method of application and equipment	Yes	No
x)	No. of applications and dates	Yes	No
xi)	Dose rate	Yes	No
xii)	Spray volume	Yes	No
xiii)	Growth stage at last treatment	Yes	No

VI. Sampling Data

i)	Details of No. of samples taken per test	Yes	No
ii)	Details of samples weight and preparation	Yes	No
iii)	Date of sampling with time	Yes	No
iv)	Interval between last application and sampling	Yes	No
v)	Has the data on the following aspects	Yes	No
	a) waiting period	Yes	No
	b) Pre-harvest interval	Yes	No

VII. Method of Analysis

i)	Complete method of anlaysis as per BIS format	Yes	No
ii)			
iii)	Results of recovery experiments indicating level of fortification	Yes	No
iv)	Details of equipment is provided	Yes	No
v)	Limit of determination is indicated	Yes	No

VIII. Climatic Conditions

Whether details on the following provided: -

i)	Average Min. Temperature (^{0}C)	Yes	No
ii)	Average Max.. Temperature (^{0}C)	Yes	No
iii)	Percentage relative humidity provided	Yes	No
iv)	Percentage relative humidity	Yes	No
v)	Rainfall (mm)	Yes	No
vi)	Average Relative humidity %	Yes	No
vii)	Other pesticides applied to trial plots with relevant details	Yes	No
viii)	Growth stage at last treatment	Yes	No

IX. Data on Toxicity

Whether information on the following provided: -

i)	Acute Oral rat LD 50:	Yes	No
ii)	Acute Oral mice LD 50:	Yes	No
iii)	Acute dermal LD 50:	Yes	No
iv)	Acute inhalation LD 50:	Yes	No
v)	Mutagenicity Name of tests Dose used Result	Yes	No

vi) Teratogenicity

Rat — Yes / No

Rabbit — Yes / No

vii) Effect on reproduction (Rat) — Yes / No

viii) Carcinogenicity (Rat / mice) — Yes / No
NOEL

ix) Toxicity to livestock (animal name_____) — Yes / No
NOEL

x) ADI — Yes / No

xi) Basis of calculation of ADI — Yes / No

X. Has the pesticide reviewed by JMPR or any other international organization? — Yes / No

If so? Whether details have been provided?

XI. Has the proposed MRLs of the pesticide in crop been given? — Yes / No

XII. Has MRL fixed by other countries on the proposed food commodity been submitted? — Yes / No

XIII. Has the MRLs of pesticide on other crops been submitted? — Yes / No

XIV. Has the results of residues analysis for three seasons / multilocation trials been submitted? — Yes / No

XV. Have you given information on use pattern? — Yes / No

XVI. Have you given information on GAP information? — Yes / No

XVII. Have you given information on Residues resulting from Supervised trials on crops? — Yes / No

XVIII. Have you given information on National Maximum Residues Limit? — Yes / No

XIX. Have you given information on Residues Definition? — Yes / No