# GOVERNMENT INITIATIVES IN STANDARD SETTING FOR PESTICIDES

Dr. S. Kulshrestha

Secretary, CIB&RC

Dte. of PPQ&S

Faridabad

## Insecticides Act, 1968 & Rules (1971)

#### Regulates-

- >Import
- **≻**Manufacture
- > Sale
- >Transport
- **→** Distribution
- **Use**

The Act is administered by Ministry of Agriculture,

Deptt. of Agriculture & Cooperation

#### **OBJECTIVE OF THE ACT**

#### To make available

Safe, effective and quality

pesticide to farmers / users.

## Statutory bodies under the Act:

- 1. Central Insecticides Board
- 2. Registration Committee
- 3. Central Insecticides laboratory

#### CENTRAL INSECTICIDES BOARD

Constituted under Section 4 of the Insecticides Act

- to advice matters arising out of administration of the Act.
- to advice/specify on manufacture, classification based on toxicity, tolerance limit, PHI, shelf life and colourisation of highly toxic pesticides.

# REGISTRATION COMMITTEE (RC)

## CONSTITUTED UNDER SECTION 5 OF THE INSECTICIDES ACT, 1968

- Scrutinize The Formula Of Pesticide
- Verify Claims Regarding Efficacy And Safety To Human Beings And Animals
- Specify Dosage, Manner Of Use, Application Technique, Precautions Against Poisoning Etc To Be Printed On Label And Leaflet.
- Register Pesticides

## CENTRAL INSECTICIDES LABORATORY

Constituted under Section 16 of the Act

#### **Functions:**

- -To analysis samples received from Central/ State Govt.;
- -Analysis of samples of material for pesticide residue;
- -Verification of condition of registration;
- -Efficacy and toxicity testing.

#### STANDARD SETTING

- 3. Quality control:
- 4. Safety / Toxicity
- 5. Pesticide Residues: Maximum residue limit (MRLs) / Tolerance limits

### QUALITY CONTROL

- Specifications and method of analysis submitted by the applicants.
- Method of analysis verified in CIL
- Registrant submits the specification and method of analysis to BIS,
- BIS forms 'specifications' which are published and used for quality control.

# Classification of Pesticides on the basis of toxicity

Rule 19 (5) of the Insecticides Rules, 1971.

- 3. Extremely toxic
- 4. Highly toxic
- 5. Moderately toxic
- 6. Slightly toxic

Classification of the Insecticides	Medium lethal dose by the oral route acute toxicity LD 50 mg/kg body weight of test animals	Medium lethal dose by the dermal route dermal toxicity LD 50 mg/kg. Body weight of test animals	Colour of identificati on band on the label
Extremely toxic	1-50	1-200	Bright red
Highly toxic	51-500	201-2000	Bright yellow
Moderately toxic	501-5000	2001-20000	Bright blue
Slightly toxic	More than 5000	More than 20000	Bright green 11

- -GHS for labelling chemicals
- -WHO classification of pesticides by hazard under revision in view of GHS
- -India: considering revision of toxicity classification under the Insecticides Rules once WHO revises its pesticides classification

#### MRL (MAXIMUM RESIDUE LIMITS)

- Pesticides used on food crops may leave residues on these crops.
- MRLs are the levels of pesticides that can be ingested daily by man without appreciable risk
- This has been accomplished through the establishment of ADI (Acceptable Daily Intake)

#### Maximum Residue Limit

- MRLs are concentrations and are food specific
- MRLs are monitoring tools.
- Foods containing residues above an MRL are not inherently unsafe as long as any calculated acute reference dose is not exceeded.
- MRLs are set at levels at least low enough to ensure that even high-level consumers will not consume more that the ADI if they eat large quantities of every food type containing the residues at the MRL for that food type.

## Purpose For Setting MRL

#### (A) National Level

- To protect consumer health
- -MRLs provide a mechanism for enforcing (or measuring / ensuring compliance with Good Agricultural Practices *i.e.* authorised uses.

## Purpose For Setting MRL

(B) Codex Alimentarius Commission:

 In the framework of codex, MRLs are set to protect the health of the consumers and

- To ensure fair practice in food trade.

#### SOME OTHER FACTS

- MRLs once fixed are not forever.
- Re-evaluation / re-setting may be required based on –

- Availability of new toxicological / safety data
- Availability of monitoring data on pesticide residues

#### ADI (Acceptable Daily Intake)

It is an estimate of the amount of a pesticide, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk.

#### **Determination of ADI**

- Total toxicology data base (to determine NOAEL)
- Application of appropriate 'safety factor' (usually 100)
- TADI (3-5 years) JMPR

## MRL Calculated based on

- ADI (Toxicological data)
- Terminal residues left on treated crops (residue trials as per GAP)
- Body weight (60 kg international,
   50 kg India)
- Daily Dietary Intake of treated commodity (Indian diet unique)

#### In India:

Tolerance limits (MRLs) for pesticides are notified under the Rules framed under Prevention of Food Adulteration Act, 1954. The PFA Act is administered by Ministry of Health & Family Welfare.

#### **PFA Act**

- \*CCFS (Central Committee for Food Standards).
- \*CCFS has various subcommittees
- -Pesticide Residue Sub Committee; (recently nomenclature changed to Sub- Committee on Pesticide Residues and Antibiotic Residues ) advises CCFS on tolerance limits fixation.

#### Tolerance limits notified under PFA Act.

➤ Before enaction of Act, pesticides were in

use: Deemed registered pesticides status – No MRL

- Later MRLs for some have been fixed.
- Presently MRLs for 120 pesticides notified under the PFA Act.

## GOVT. EFFORTS IN STANDARD SETTING

- No registration of new molecules without fixation of tolerance limits since 2002-03
- No registration granted for any pesticides for which tolerance limits not prescribed under PFA Act.

- Deemed registered pesticides (DRP): pesticides which were being used in the country before enactment of the Act
- ❖ Public notice issued through DAVP on dated 18.11.1998 and 24.9.1999 for 76 pesticides.
- To compile and examine data an Expert Group constituted.

#### Based on the recommendations of the Expert Group

Draft Gazette notification [S.O.1747(E)] issued on 12.12.2005 for –

- \* withdrawal of following 7 pesticides:
  - 1.Dalapon

5. Para-dichlorobenzene

2.Ferbam

6. Simazine

3. Formothion

7. Warfarin

- 4. Nickel Chloride
- deletion of 128 crops for 31 pesticides.

Data / information w.r.t following DRP pesticides sent to Ministry of Health & Family Welfare for fixation of MRL:

1	Alpha Naphthyl Acetic Acid
2	Oxydemeton methyl
3	Captan
4	Carbaryl
5	Chlormequat chloride
6	Dimethoate
7	Dichlorvos
8	Dicofol
9	Dinocap
10	Endosulfan
11	Ethion

12	Lindane
13	Malathion
14	Monocrotophos
15	Mancozeb
16	Methyl parathion
17	Phosphamidon
18	Phorate
19	Phosalone
20	Parquat dichloride
21	Quinalphos
22	Zineb
23	2,4-D

- ❖ Public notice issued on 27.8.2005 to submit data / information in prescribed proforma within 6 months to the registrants of 64 pesticides for the crops for which tolerance limited are not fixed
- ❖Data / information for 45 pesticides has been received in the Sectt. of CIB&RC which is under scrutiny.

Present procedure for registration of pesticides / expansion of label claims:-

- Data submitted by the applicant along with duly filled proforma prescribed for MRL fixation to the Sectt. of CIB&RC
- MRL proforma scrutinized for verification w.r.t. data from chemistry, efficacy and toxicity.
- ➤ If found complete, sent to Ministry of Health & Family Welfare for fixation of MRLs.

- PFA Sectt. Ministry of Health & Family Welfare scrutinizes proforma
- Calculate tolerance limit based on residue data, ADI (derived from toxicity data), body weight and dietary intake.
- The calculated 'tolerance limit' put up to PRSC for approval.
- Then circulated to CCFS members for approval.
- Registration of pesticides issued once approval of CCFS received.

## Summary of MRL status

Sl.No.	Status	Total
1.	MRL fixed	66
2.	MRL partially fixed	69
3.	MRL not fixed	17
4.	MRL not required	35
5.	Product withdrawn	7
6.	Label claim withdraw	n 1
7.	Total	195

### Government Efforts (contd.)

#### Standard for packaged drinking water:

Notification issued on 18<sup>th</sup> July 2003 Effective w.e.f. 01.01.2004

- vi) Pesticides residues Not more than considered individually 0.0001 mg/litre
- ix) Total pesticide residue
- Not more than 0.0005 mg /litre

### Government Efforts (contd.)

#### Standard carbonated water

(1)Standard for carbonated water have been amended vide notification GSR 451 (E) dated 15.7.2004 whereby it has been made mandatory that water conforming to the standards prescribed for packaged drinking water under PFA Rules, 1955 shall be used for manufacture of carbonated water

### Government Efforts (contd.)

• Deptt. Of Health has also identified the National Level Experts to examine the issue relating to laying down the MRLs in carborated water and other food beverages

## GOVERNMENT EFFORTS (CONTD.) PESTICIDE RESIDUE MONITORING SCHEME:

 Government of India has initiated a scheme of Rs.24 crore in Ministry of Agriculture, Department of Agriculture with a view to achieve the long term objective of reorienting our production/processing standards to ensure safety for human beings, animals and plants, the prioritized activities are as follows: 36

- To monitor pesticide residues in Regions/States known to use pesticides extensively / indiscriminately so that intensive campaigns would be launched in such areas to generate awareness about safe and judicious use of pesticides amongst the farmers as a component of IPM.
- To monitor pesticide residues in market yards in major consumption areas so that consumer awareness about pesticide residues in commodities forces vendors, processors and farmers to reduce pesticide residue levels by adopting appropriate measures

• To strengthen testing/certification facilities at export centers like quarantine stations at ports, production areas, processing and packaging houses by developing appropriate inter linkage between production, marketing, processing, export and certification centres in order to provide A-Z monitoring / certification of residues levels in export sensitive commodities.

### THANK YOU