



**ACFI Submission
to the
Committee to Review the functioning of the CIB&RC
and
Suggest Measures for its Improvement.**

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ACFI additional Inputs for consideration of the Committee to Review the functioning of the CIB&RC and Suggest Measures for its Improvement . Nov. 10, 2017.



Objectives

- To examine and document the current pesticide regulatory process under the Insecticides Act., 1968 & Insecticides Rules, 1971
- Identifying the gaps in the process of registration which could be:
 - **Collation of Database**
 - Policy Gaps,
 - Process/Administrative Gaps
 - Accountability and Transparency
 - Proposed Required Reforms
 - **Encourage Innovation**

Need of the hour:

A collaborative Approach by the Agrochemical Industry and Regulatory Authorities for Introducing timely availability of New Crop Protection Products into the Indian Market which will ultimately benefit our Farmers and contribute to the Hon'ble PMs vision:

“ Doubling the Farmers Income by 2022” in the country”.



Objectives

Collating Database

Sect. CIB&RC has no data base of the pesticide registrations granted u/s 9, which are still in force or inactive, withdrawn or cancelled

Neither is there any information maintained on the grant of Manufacturing licenses or related issues.

Innovation

Non adherence to Confidential Business Information

Non implementation of Data Protection for new innovative products that may be safer to use and have a reduced impact on the environment



The Central Insecticides Board u/s 4 of the Insecticides Act., 1968 & Insecticides Rules, 1971

The Registration Committee u/s 5 of the Insecticides Act., 1968 & Insecticides Rules, 1971

Issue regarding Metabolic Studies: Metabolic Data requirements for livestock should not be required, as the product is already registered u/s 9 (3) by an Original Registrant.

The Central Insecticides Laboratory (CIL) u/s 16 of the Insecticides Act., 1968 & Insecticides Rules, 1971

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ACFI Suggestive Measures



Administrative / Implementation of Procedural Guidelines

Let's Go Complete Digital and On-Line for Better Transparency & Accessibility

Need to Improve and Encourage Inter-disciplinary & Inter-Ministerial cooperation for Regulatory Approvals (**Manufacture, Import & Export**)

Capacity Development

Pesticides are the most Regulated Category of Chemicals in the World. Regulatory Experts need to be developed for (Agriculture & Non-Agricultural, Household & Public Health).

Regulatory Chemistry

Regulatory Entomology

Regulatory Plant Pathology

Regulatory Agronomy

Regulatory Toxicology

3 Tier Approach down the line to ensure constant availability of regulatory experts.

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ACFI Suggestive Measures contd.



Government should be supportive towards enhancing R&D facilities in support of the Pesticide Industry

MRL adherence for Export of Agri-commodities need be aligned along with International norms. Scenarios need be studied and evaluated.

Drafting of a National Pesticides Policy needs to be considered.

Post Registration Quality Enforcement

Scope of the Post registration sampling by Insecticide Inspectors (Central & State nominated) should be broadened to enroll companies apart from the common top 50 companies that remain in the market through out the year.

Definition of Spurious / Sub-standard pesticides need to be reasonably amended and need to be defined, as the charges believed to be imposed in the PMB 2017 are believed to be severe, if implemented.

Concerns regarding GLP Analytical certifications being challenged/ contested by Non GLP laboratory certifications need to be urgently addressed

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ACFI Suggestive Measures contd.



Better coordination amongst the Center & State Authorities for implementation of a standardized quality control mechanism to be implemented

Categorical introduction of GMP & GLP Norms to be well defined for pesticides and protocols/procedural details to be stated.

Data collation to be coordinated effectively with related departments i.e. customs, DGFT etc.

Protocols to be developed with a strict time frame for Chemistry, Bioefficacy, Toxicology & Packaging parameters to achieve consistency of data generated.

Issue a Vision Mission Statement for CIB&RC

Finalization of the Concepts of introducing Minor Changes for Pesticides, Crop Grouping, and harmonized pesticide labeling norms etc.

The Central Insecticides Laboratory, Regional Pesticide Testing Laboratories, & State Pesticides Testing Laboratories need to be GLP Certified.

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ACFI Suggestive Measures contd.



In cases wherein export samples have already qualified, but tend to be proven GLP/ NABL laboratories, the provision to have the sample counter tested by an GLP Laboratory need to be introduced.

Looking into the recent Maharashtra Issue on Pesticides, wherein Off Label Use has been identified as one of the culprits, wherein a product registered for use on Sugarcane was being recommended on Cotton. It is suggested that the Crop Grouping Guidelines need to be URGENTLY framed and implemented. This will help the industry to expand label claims and help reduce off label use of pesticides.

The time frame for grant of registration of pesticides should be time bound, i.e. 2 yrs from the date of submission.

Agriculture being a State subject, the Center & Regulatory Authorities need to to be empowered to monitor post registration compliance of a pesticide. GMP should be mandatory for pesticide manufacturing facilities, both technical & formulation. If any such facility lacks this requirement, it should not be allowed to operate as had been the case in the Pharma Industry.

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