Unlocking a New Paradigm for Pesticide Toxicity Assessment in India

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PETA INDIA

Ankita Pandey, PhD
People for the Ethical Treatment of Animals (PETA) India
ankitap@petaindia.org

Background

GOVERNMENT OF INDIA
MINISTRY OF AGRICULTURE & FARMERS WELFARE
DEPARTMENT OF AGRICULTURE & FARMERS WELFARE
DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE

सत्यमेव जयते

Central Insecticides Board → **Provides technical advice**

Registration Committee → **Reviews registration dossiers to verify claims related to efficacy and safety**

- Chemical pesticides (conventional pesticides)
- Biopesticides (microbial pesticides, botanical pesticides, and semio-chemicals/pheromones)

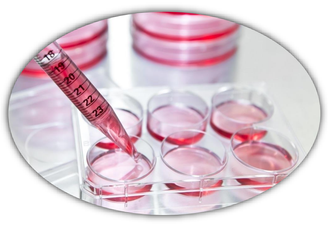
The Central Insecticides Board and Registration Committee (CIB&RC) requires a battery of toxicity tests to evaluate potential toxicity to humans, wildlife, and the environment and satisfy registration requirements for pesticides. These include tests to assess local toxicity (e.g., skin and eye irritation/corrosion and skin sensitisation) as well as acute systemic toxicity tests and longer-term effects (e.g., reproductive toxicity and carcinogenicity).

Here, we present on our efforts to advance the uptake of reliable and relevant non-animal approaches by **analysing current regulatory flexibility** to use non-animal approaches and providing **recommendations to support their increased uptake within the Indian regulatory framework**.

Current regulatory landscape

In its 2023 guidelines, CIB&RC adopted non-animal approaches for the safety evaluation of chemical pesticides and biopesticides. CIB&RC now considers replacement and reduction methods recognised by the OECD and other regulatory bodies and waivers based on a weight on evidence approach incorporating existing information, read-across, and use and exposure.

❑ **Acceptance of data from non-animal approaches**

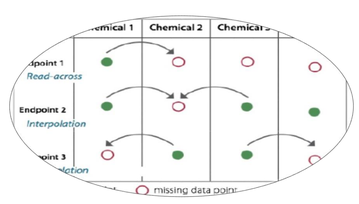


In chemico, *in vitro,* and *ex vivo* approaches

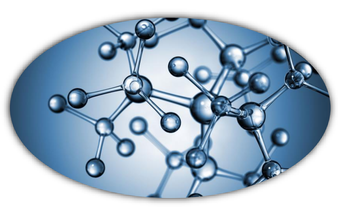
Computational models

❑ **Acceptance of scientifically justified waivers based on**

Existing information



Read-across/data bridging from structurally and biologically related pesticides



Physiochemical/biological properties

Use and exposure patterns

- Redundant testing is no longer required for new registration of existing pesticides in India.
- An additional species is no longer required for acute oral toxicity study and acute avian toxicity study for microbial pesticides.
- For microbials, the requirement for toxicity data can be exempted based on genetic similarity with an already registered strain (minimum 98%).

Transitioning to a new paradigm

Opportunities within the current regulatory framework to advance the use of reliable and relevant non-animal approaches that can better protect human health and the environment in India:

Global harmonisation

As an OECD mutual acceptance of data signatory since 2011, India has adopted OECD test guidelines for chemical toxicity testing. Regulators and industry together should strive for harmonising global policies and practices and adopt available and newly developed OECD and other valid non-animal approaches.

Expert committee on non-animal approaches

CIB&RC, industry, and experts (including animal protection groups) should establish regular discussions on the availability and technological readiness of non-animal approaches and steps to integrate them in a regulatory context.

Capacity building

Industry, regulators, and other stakeholders should expand infrastructural capacity and provide trainings through webinars and hands-on workshops on the use and interpretation of data from non-animal approaches. For example, the US Environmental Protection Agency (EPA) co-organizes webinars for this purpose: www.thepsci.eu/epicwebinars

Stronger legislation

Regulators should mandate that non-animal approaches are used wherever applicable and that tests on animals are conducted only as a last resort. It is a legal requirement in the European Union (EU) that vertebrate animal tests must not be conducted where valid alternative methods are available and can reliably be used.

Removing requirement for redundant toxicity data generation

Leveraging chemical equivalence data, regulators should remove the default requirement for new data when a technical is imported from a new source or a technical already registered for import is indigenously manufactured in India. As required in the EU, registrants should avoid duplicating testing by sharing data.

Clarifying method acceptance

To provide clarity and build confidence, CIB&RC should establish a webpage of available non-animal approaches and waiver opportunities that could be used for regulatory decision making. For example, the US EPA maintains webpages on strategies to replace and reduce the use of animals in testing: epa.gov/chemical-research/epa-new-approach-methods-efforts-reduce-use-vertebrate-animals-chemical-testing

Pre-submission consultations

Prior to testing, CIB&RC and registrants should engage in dialogue to clarify toxicity data needs and discuss relevant testing strategies allowing maximal use of non-animal approaches. The US EPA, European Food Safety Authority, Health Canada, Australian Pesticides and Veterinary Medicines Authority, and other agencies have implemented measures to meet this need.

Conclusion

These recommendations may be adopted in the form of a national strategy or roadmap enabling India to embrace a regulatory framework that relies on modern, effective science.

As more global regions work towards reducing and replacing animal testing for regulatory purposes, including the assessment of pesticides, India should ensure that the best science that does not rely on animal testing is used to protect human health and the environment.