



The Changing Face of Chemicals Legislation In India: Opportunities to Minimise Testing on Animals



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INTRODUCTION

In 2020, the Indian Ministry of Chemicals and Fertilizers released the draft Chemicals (Management & Safety) Rules, 20XX. The draft rules provide for:

- the creation of a national chemicals inventory
- notification of all chemical substances marketed in India in quantities above 1 tonne per year
- registration of priority substances
- evaluation and authorisation for restricted use or prohibition of chemicals, depending on the risks they pose

International chemicals legislation, such as the Registration, Evaluation, Authorisation and Restriction of Chemicals regulation in the European Union (Regulation (EC) No 1907/2006) and the Toxic Substances Control Act in the United States include requirements to avoid the use of animal tests wherever possible, and India must implement similar requirements to align with international standards.

METHODOLOGY

Modernisation of the chemicals legislation provides India with an opportunity to use the most scientifically advanced non-animal assessment strategies, thereby ensuring better protection of humans and the environment. Therefore, PETA India made recommendations to the Indian government highlighting several opportunities for using reliable and relevant non-animal testing approaches.

RESULTS

To register priority substances (carcinogens, mutagens, reproductive toxicants and specific target organ toxicants (category 1 or 2), that are (very) persistent, bio-accumulative and toxic)

Acceptance of data submitted for the registration of substances in foreign jurisdictions

Use existing scientific evidence (examine all available data from human epidemiological surveys, from animal and *in vitro* studies, information on the physico-chemical properties of the substance, quantitative structure–activity relationship (QSAR) models and read-across)

Following our recommendations, several opportunities to reduce tests on animals have been incorporated in the draft Rules (Figure 1) that enable the following:

- ✓ Avoid duplication of toxicity data generated using animals by allowing the use of existing scientific information
- ✓ Reduce resources and time spent on data generation by registrants
- ✓ Facilitate better identification of the potential risks of chemicals (through use of human relevant methods) – allowing for better protection of human health and the environment

THE WAY FORWARD

To further minimize animal testing, we also recommend:

- Mandating data sharing among applicants for registration of the same chemicals, to further ensure that tests using animals are not duplicated
- Allowing stakeholders to share existing data and recommendations for use of non-animal methods through public consultations on testing proposals
- Establishing a non-animal methods unit to support the Chemical Regulatory Division
- Instating faster reviews and reduced fees for applicants registering chemicals using non-animal methods
- Investing a significant proportion of notification and registration fees in the development, validation and use of non-animal methods

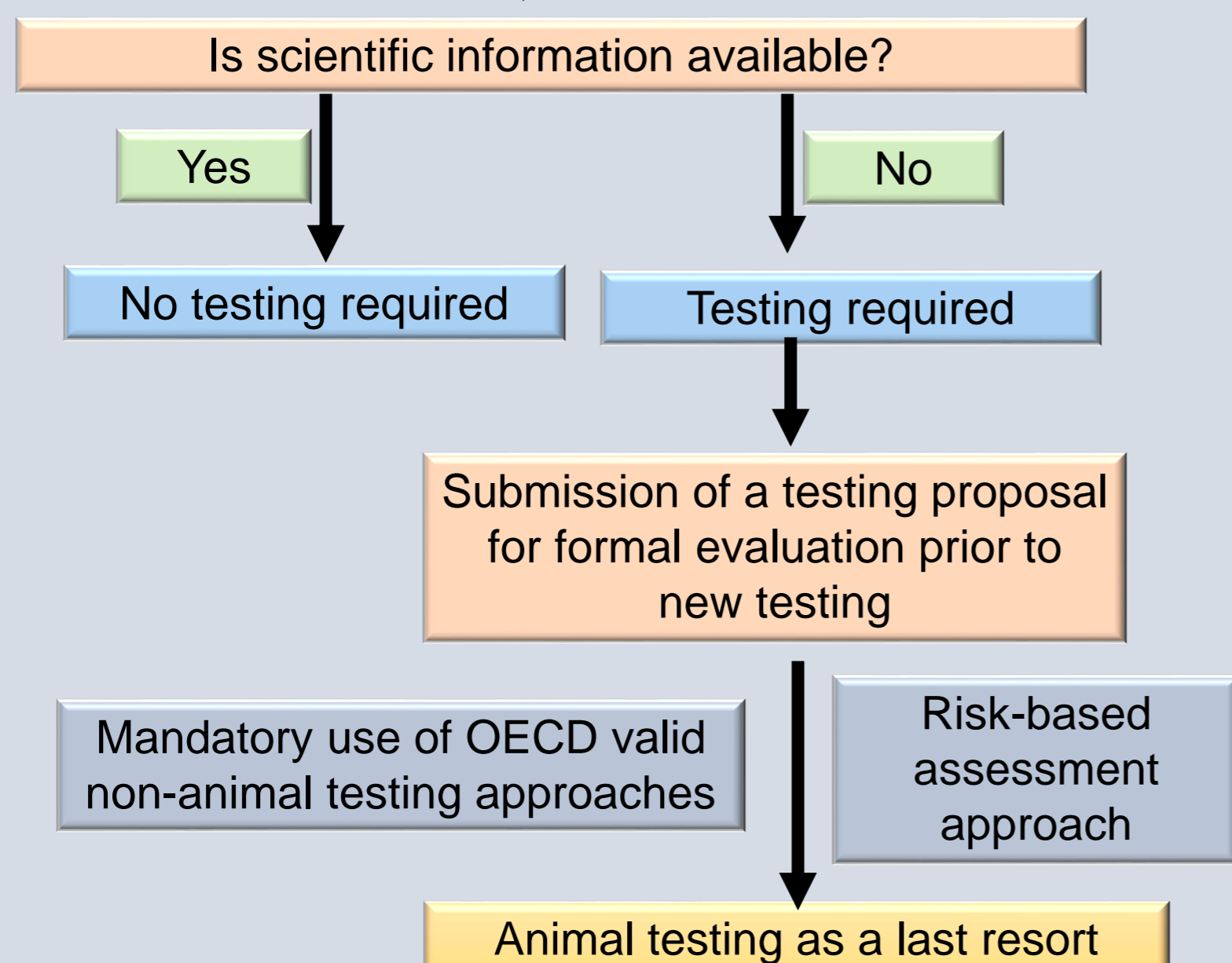


Figure 1: Flow-chart depicting recommendations by PETA India that were incorporated into the draft Chemicals (Management & Safety Rules) 20XX