NGO Platform: How animal testing in India can be further reduced for chemicals

The country has incorporated several measures to reduce tests on animals in its draft overarching chemical framework. But there is still scope to truly minimise the practice says Dr Ankita Pandey, research associate for Peta India

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The need for a suitable legislative framework to regulate the manufacture, import and use of industrial chemicals in India has long been recognised. Earlier this year, the Department of Chemicals and Petrochemicals, under the Ministry of Chemicals and Fertilizers, released its draft Chemicals (Management and 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; and evaluation and authorisation for restricted use or prohibition of chemicals, depending on the risks they pose.

Furthermore, they mandate a hazard-communication system and a chemical-accident prevention programme.

The ministry's objective with the rules is "to ensure a high level of protection to human health and the environment". They require the registration of all priority substances, which include carcinogens, mutagens and reproductive toxicants (category 1 or 2) (CMRs); specific target organ toxicants (repeated or single exposure, category 1 or 2); and any substances that fulfil the criteria as (very) persistent, bioaccumulative and toxic (PBTs). The generation of relevant physico-chemical and (eco) toxicological information where it does not already exist will also be required. This will result in a significant increase in animal testing, which will be exacerbated if all possible steps are not taken to minimise it.

The REACH Regulation in the European Union includes many provisions intended to ensure testing on animals is undertaken only as a last resort – for example, through the promotion of non-animal methods, the requirement that registrants share in vivo data, the adaptation of data requirements, and the examination of, and public consultation on, testing proposals. However, despite these measures, the estimated total number of animals used in REACH testing exceeded 2.3 million in 2019, almost double the 2016 figure, and is predicted to increase further in the future. It is crucial that the Indian government learns from the animal death toll in Europe and goes further in modernising its chemical legislation so ensuring that tests on animals are in fact minimised and that the letter and spirit of such provisions are honoured.

Following recommendations from Peta India, several opportunities to reduce tests on animals have already been incorporated in the draft rules, but there is still scope for further reductions. So far, they mandate testing on vertebrate animals only as a "last resort". Several mechanisms have been introduced to ensure that this is achieved – for example, through the use of internationally

validated non-animal testing approaches and acceptance of data submitted for the registration of substances in foreign jurisdictions.

To avoid repeat testing, all existing information will be considered as part of a weight-of-evidence assessment prior to the submission of a testing proposal. Registrants will be required to 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 before proposing any new tests.

They will also have to propose a testing strategy for the Chemical Regulatory Division (CRD) to formally evaluate first. The draft rules promote a 'risk-based' assessment, as opposed to hazard-based, meaning the CRD will consider the hazard of actual exposure in its overall decision. This approach is common in other jurisdictions such as the US, scientifically supported and can result in reduced testing on animals.

These provisions will help to avoid the duplication of toxicity data generated using animals and reduce the resources registrants and regulators need to register and assess priority chemicals. Furthermore, the use of efficient, cost-effective and relevant non-animal testing methods will facilitate better identification of the potential risks of chemicals – and can offer better protection of human health and the environment than that offered by tests on animals.

What else is needed to minimise testing on animals?

The Indian Prevention of Cruelty to Animals Act, 1960, requires that "experiments on animals are avoided wherever it is possible to do so" (Section 17(2)(d)). To help meet this, the country should make mandatory a 'one-substance, one registration' system and the sharing of (eco)toxicological data generated using animals among registrants. Importantly, this would streamline the process, as regulators would not be required to consider multiple registrations of the same substance. Furthermore, it would reduce data generation and registration costs and avoid duplication of tests on animals.

The draft rules should permit the adaptation of data requirements where testing does not appear scientifically necessary, is technically not possible, or can be omitted based on exposure scenarios. Third-party consultations on testing proposals should be conducted to allow stakeholders to provide valid scientific information and recommendations for alternative approaches that could enable data gaps to be addressed, thus avoiding additional tests on animals.

The establishment of a non-animal methods unit could help the CRD to review testing proposals and evaluate joint registrations, as well as ensuring data sharing among registrants. Reviewers would need to maintain expertise in non-animal testing approaches, so regular training is needed. The unit could provide this to CRD dossier assessors and industry representatives to ensure consistent acceptance of the most up-to-date non-animal technology. It could help with forums for researchers and regulators to discuss case studies and emerging fit-for-purpose approaches. Furthermore, balanced representation in stakeholder engagement (including animal protection groups) in several decision-making activities of the CRD would assist effective information flow and oversight.

To encourage knowledge and data sharing, the CRD should regularly update its digital platform to include information collected on the hazardous properties of substances. This may help future registrants to identify existing data, facilitate read-across, encourage data sharing and enable further development of computational prediction methods. Information dissemination through regular training opportunities, such as workshops, meetings, or webinars, with participation from industry stakeholders, contract research organisations and NGOs, should be routinely undertaken.

To encourage the use of non-animal testing methods, the department should offer speedier review and reduced fees for registrants that use non-animal approaches to satisfy data requirements. Moreover, a significant proportion of the notification or registration fees should be invested in their development, validation and implementation.

This is an unparalleled opportunity for the Indian government to redirect its economic and intellectual resources towards more reliable and relevant non-animal chemical safety assessments. To achieve this, it should commit to promote these approaches in the rules and liaise with experts on new methods both in India and around the world. The goal should be to phase out the use of animals for chemical safety assessments, matching and surpassing the US EPA's aim:

- to eliminate all funding of, and requests for, tests on mammals by 2035;
- reduce such testing by 30% by 2025;
- direct funds towards non-animal method development; and
- hold annual conferences to discuss advancing non-animal testing.

In the Netherlands, the government has declared its ambition to be a world leader in animal-free innovation. The National Committee for the Protection of Animals Used for Scientific Purposes has advised on making this transition and identified regulatory safety testing as an area in which it could be phased out in the near future. To achieve its goal, the government has initiated the Transition Programme for Innovation Without the Use of Animals (TPI), bringing together regulators, scientists, funding bodies and industry representatives and offering them a platform for identifying and developing innovative activities within their fields that will increase the pace of change.

Opportunities to shape the Chemicals (Management and Safety) Rules 20XX

The Department of Chemicals and Petrochemicals has taken tangible steps to reduce testing on animals in its draft rules. However, to reap the maximum benefits from the perspective of animal welfare, and efficiency while ensuring the protection of human health and the environment, they must incorporate the recommendations I have made. Implementation of these provisions would also help achieve alignment with international chemicals legislation that promotes the use of non-animal methods, such as the Toxic Substances Control Act in the US.

An updated draft will soon be published on the WTO website and notified in The Gazette of India, opening the public consultation period. This is an excellent opportunity for all stakeholders to encourage the government to invest in, and implement, systems that will best protect humans and the environment by relying on valid, fit-for-purpose, non-animal testing approaches that can efficiently and effectively assess chemical risk.

The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch

FURTHER INFORMATION

CFE. Number of animals used in EU chemical tests doubles. 24 June 2020

NCad. Transition to non-animal research: On opportunities for the phasing out of animal procedures and the stimulation of innovation without laboratory animals. 2016.

Peta International Science Consortium Ltd. Alternative methods validated for regulatory use

Draft Chemicals (Management and Safety) Rules, 20XX.