How does India's latest draft of its overarching chemicals law compare with REACH?

The Indian government released the fifth draft of the Chemicals (Management & Safety) Rules in August. Kozue Ohsawa of knoell Germany outlines the latest changes – and the draft regulation's similarities and differences with REACH

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Once India's new chemicals regulation – the Chemicals (Management & Safety) Rules (CMS Rules) – is implemented, it will apply to all substances, including in mixtures and intermediates that are manufactured in, or imported into, the country.

The fifth and final draft (dated 24 August) of the CMS Rules has been a long time coming. India's first chemicals regulation was established in the 1980s by the Ministry of Environment & Forests. Unlike REACH, only hazardous chemicals were regulated under this. Then in 2014, the first draft of India's new chemicals law was created, with the expectation that it would be adopted by the government within six months. Since then there has been almost no update on this topic. Then this year, discussions on the creation of the CMS Rules progressed rapidly, resulting in several updates.

At the outset, the rules were considered to have many similarities with REACH. However, the latest draft of the regulation contains many aspects which are quite distinct. The most important sections are summarised below, as are the main differences from REACH.

Outline of the chemicals rules

The latest draft of India's new chemicals regulation consists of six chapters and 19 schedules. The chapters contain the basic rules and the schedules contain detailed information on them, such as requirements for notification and registration, and lists of priority and restricted or prohibited substances.

Chapter III on substance notification, registration and restrictions on use, and Chapter V on labelling and packaging, are the most important for business since they directly affect companies manufacturing substances in, or importing them into, the country.

Notification and registration

'Existing substances' are defined in the CMS Rules as those manufactured, imported, supplied to or used in India, or which have already been placed in its territory prior to the end of the initial notification period. The latter is scheduled to start one year from the date of the enforcement of the rules, and end 180 days after their commencement. After this period, any substance not notified will be considered a new substance.

New substances imported or manufactured above one tonne/year (t/y) must be notified prior to the date they are placed in Indian territory. The deadline was set initially at a minimum of 90 days prior, but then shortened to 60 days in the latest draft. Companies will need to plan well in order to meet this short timeframe.

The notification requirements are described in Schedule V. In addition to the details of the notifier, substance information and other general facts, the name of the top three known downstream users, as well as actual quantity per year, must be provided.

Once notification is completed, companies need to update the information annually, no later than 60 days after the end of each calendar year. This must include information on the actual quantities of substances in the previous year. A fee is applicable for both notification and annual updates.

Registration is required only for defined hazardous substances within 18 months of their inclusion in Schedule II. Currently, 750 substances are listed there and companies may register them jointly.

Chemical safety reports will be required for substances listed in Schedule II in quantities greater than ten t/y. Substances listed in quantities between one to ten tonnes will only need exposure scenarios.

Authorised representative

Foreign entities will be able to notify and register substances, using an authorised representative responsible for all obligations under the new regulation – like under REACH. However, the fifth draft of the rules now indicates such a person must have a "minimum average net worth of ten times the average value of substances handled during the last calendar/financial year" – a large barrier to taking on the role and requiring more explanation. Previously they were defined as an "Indian natural or juristic person with sufficient knowledge in the practical handling of the substances and information related to them".

Animal testing as the last resort

The Indian government has finally included the principle of animal testing as a last resort. Several years after the implementation of REACH, many companies have access to existing data and this should ease the registration process.

Reduced requirement for special cases

Thanks to the implementation of the principle on animal testing, there are also reduced requirements for some special cases.

The first is for substances registered under another law in India. They are excluded from the scope of full registration because data on them has already been submitted to the authorities. However, companies will still need to notify them.

Moreover, where possible, the authorities will accept data on the same substance that has been submitted to foreign regulators in other jurisdictions for the purpose of registration. The draft states:

- to avoid repeated testing, existing test data must be considered prior to new testing; and
- all efforts should be made to derive the required data using alternative methods recommended by the OECD.

By actively using existing data, the government is trying to reduce the financial burden on industry and avoid new animal testing.

Update of the list of restricted or prohibited substances
The list of restricted or prohibited substances is also updated in the latest draft. Currently only one substance, phosgene, is restricted. Some previously listed are now in the list of priority substances which require registration.

An authorisation request must be submitted to use a restricted substance. The government will decide whether to grant this for an initial period of no more than four years. This can only be extended for the same period after reapplication.

Substance sameness

Correct identification of substances is one of the essential steps in registration, just as it is under REACH. The fifth draft of the CMS Rules outlines the meaning of the 'same substance' principle as follows:

Mono constituent: all substances containing the same main constituent at a concentration of more than 80% (w/w) and not containing any other constituent listed in Schedule II at a concentration of 10% (w/w) or more; and
Multi constituent: substances containing more than one main constituent with concentrations between 10% (w/w) and 80% (w/w) may be considered as the same substance if they have the same composition.

In the case of substances of unknown or variable composition, complex reaction products or biological materials (UVCBs), the sameness will be decided by the competent division. A structural representation of the constituents, reaction scheme and process output, must be provided.

Labelling and packaging

India has yet to implement the Globally Harmonized System (GHS) of classification and labelling of chemicals. However, Chapter V in the final draft explains these requirements, and states that companies shall ensure that all product identifiers, hazard statements and pictograms, signal words and precautionary statements shall be in

accordance with the eighth revision of the GHS. So it is expected that India will finally officially adopt this law.

Timeline to implementation

While there are many improvements in the fifth draft, there still remain some uncertainties and challenges. In particular, there are unanswered questions over the notification and joint registration procedures, for example:

- how to check the list of existing substances;
- how to find other registrants of the same substance; and
- how to jointly submit a registration.

This should be clarified and revised prior to implementation of the new regulation. However, due to the ongoing Covid-19 pandemic, it remains unclear when the final draft will be accepted, and some companies have already requested postponement of its obligations.

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