India's Draft Chemicals (Management and Safety) Rules: Know Your Compliance Obligations and Start Preparing

25 October 2021

Q & A Session

India CMSR

#	Question	Answer
1	When are you expecting the regulation being finalized and applied?	The 5th draft published in August 2020 has been circulated within the government authorities. It is assumed that the Rules would come into force in 2021 or early 2022. After one year of the enforcement, Initial Notification Period (INP) will start.
2	Is food and feed additives exempted under CMSR?	It is not directly mentioned but food and feed additives are exempted as far as they are used for only those applications. But for multiple use applications, notification will be required.
3	Are cosmetics exempted?	Cosmetics are considered finished products and are thus exempted from the ICSMR. Cosmetics have to comply with cosmetic regulation. However, substances used in cosmetics, for example cosmetic ingredients, would need to comply with ICSMR, e.g., substances included in Schedule II (registration).
4	How will fragrances be addressed? (they are proprietary mixtures)	Even though they are proprietary mixtures, the regulation is per substance and not per mixture. Therefore, you will have to notify substances in the mixture. Even though it is a proprietary mixture, the details may not be revealed while notifying it. There is no concern about proprietary mixtures, they will have to be notified.
5	Like Polymers, should we also notify Enzymes?	Several enzymes were registered in the EU REACH and enzymes will have to be notified. Once it has been notified, if it falls under Schedule II, the substance will need to be registered. Manufacturers or importers of Enzymes have notification obligation.

6	Please explain a little bit about tonnage band.	The ICMSR has a general requirement of notification for substance >1TPA. Some substances are required to comply to ICMSR depending on thresholds, e.g., in Schedule XI and XII (requirements vary by substance). The bands categories are 1-10, 10-100, 100-1000 and > 1000 ton/year and is used to calculate fees.
7	How will the Downstream user know if their use has been notified? Will it be visible in some open database?	The downstream user will have to make sure one shares the uses with the supplier and ask them to submit the uses when notifying. One can seek a declaration certificate from the supplier that it has been notified. At the initial stage, it won't be published on a database.
8	Can substances that are currently not listed in Schedule II be included later to the list or requested to register?	Yes, the authority may request a substance to be registered even after the legislation comes into force. If it is necessary to include or exclude a substance from Schedules, a public consultation is held for a period of 90 days.
9	What is the process of registration? Is there any tool launched or proposed by the Indian authority to complete registration? Do you think IUCLID could be used?	Registration is required for substances present in Schedule II above 1TPA. These substances must submit additional information including the technical dossier. All the activities will be performed through an online platform yet to be disclosed by the authorities. The acceptance of IUCLID is unclear for now.
10	India hasn't implemented GHS yet. How should Indian industry categorize their substances (whether they are priority or not) when there is no GHS?	According to the ICMSR draft, India is going to adopt GHS Rev 8. Priority substance in ICMSR will be categorized according to GHS Rev 8. Today, 750 substances are listed in Schedule II. Classification of other chemical substances during notification & registration will likely follow the GHS Rev 8 protocol.
11	Where can I find Schedule I and II? (Substances to be registered)	You can find all the information about the ICMSR on the following link: https://indianchemicalregulation.com
12	Can we use EU REACH data for registration?	According to the ICMSR, all existent data about the substances will be acceptable to the extent possible, including those used in other jurisdictions, for the purpose of registration.
13	What will be language for SDS and labels?	Labels and packing are required to be in English and Hindi. There is no specification about the SDS language to be used at the moment.
14	What will be the building blocks for SDS?	GHS will be implemented and this means that India would accept all the building blocks mentioned, unless there are further specification from the authority.

15	Finished Goods - Cosmetics, Drugs etc. are all exempted from registration/ notification, right? Even if they contain some hazardous chemicals?	Finished products are not part of the ICMSR but substances are, i.e., substances must comply with the rules and notify/register when necessary. Finished products containing hazardous chemicals must comply with their respective regulations.
16	Does the latest draft specify the requirement for testing? Can it only take place in Indian GLP labs?	No official statement was made until now, therefore, according to ICMSR 5th version, all studies should be from NABL or GLP accredited lab.
17	Is the Authorized Rep in India responsible for annual volume reporting?	Annual reporting is required for all notified substances. Foreign manufacturers can notify substances only through an Authorized Representative (AR). On behalf of the foreign manufacturer, AR has the responsibility to fulfill CMSR obligations which include annual reporting.
18	For classification data of substances that are not available on public domain, and in cases where different companies have notified different classification, will there be a harmonized classification approach?	An official substance classification list (based on GHS Rev. 8) is expected to be published after the ICMSR comes into force.
19	For active ingredient and other raw materials/adjuvants used in pesticide which have been registered to Indian CIB & RC already, do they also require notification & registration under Indian CMSR?	All manufacturers and importers who have registered a substance under any other Indian Acts, Rules or Regulations that are currently in force, shall notify the Division in accordance with Rule 8 except sub-rule 12 and 13. Such substances are exempted from Registration, Chemical Safety Assessment and Evaluation and Restriction. Rules 10, 13 and 16 will also not apply in such cases.
20	How will Paints & Coatings be addressed under CMSR?	All the ingredient substances need to be notified under the ICMSR, including pigments and dyes. There is no requirement to notify mixtures, but there is need to notify substances in mixtures. If these ingredients/substances are further classified as hazardous, restricted, or prohibit, then additional obligations are applicable.
21	Could you clarify the GHS implementation in India?	India has not ratified GHS, however, India is a full signatory for UNGHS and thus through implementing these rules, it will be beneficial to meet the requirements mentioned in UNGHS. Thus, the GHS Rev. 8 is being adapted via the proposed rules and this is being implemented as a regulation for SDS, Classification and Labelling requirements.
22	Is there a plan by Indian Government Authorities to release Guidance for compliance with ICMSR clauses alike the one published by EU REACH?	It is expected that the National Chemical Authority will issue a guide for compliance after official enactment of the ICSMR. There is no official timeline though. Probably this

		guide will be published before the notification period starts, or even in parts (a guideline for notification, another for registration, and so on, respecting the implementation periods).
23	If you have a company working as a toll manufacturer for you, who is supposed to apply for the Reach Certification?	The manufacturer/importer that is placing the product in the market need to comply with ICMSR. Therefore, if an Indian company is getting a substance from a toll manufactured within India and is placed in the market under its own name, it will be their responsibility to comply. Nevertheless, if the toll manufacturer also manufactures the same substance and is placing them directly in the market then they also need to comply with the ICMSR. The toll manufacturer has to comply with the supplier responsibility additionally.
24	Regarding Quality Control orders, what's the deadline and can you also briefly tell us the workflow particularly if the material is manufactured outside India certifications?	There is no one single order of quality control, it is chemical specific. Each of those 70 chemicals will come as separate orders each time. There is no specific timeline. Currently, about 35 -40 orders are already notified to WTO and with upcoming compliance deadlines. From July or August, there will be some deadlines as the order is already implemented. You have 6 months to comply once an order comes into force. Foreign manufacturers can proceed via BIS certification application through their ARs (Authorized Representatives).
25	Can you please clarify the information exchange from different authorities, will that be allowed?	According to the ICMSR, all existent data about the substances will be acceptable to the extent possible, including those used in other jurisdictions for the purpose of registration.
26	If an authorized representative notifies or register a substance, do the downstream customer or importer in India need to also register the same substance?	If an AR notifies a substance on behalf of a foreign manufacturer/importer, the foreign party do not need to notify/register the same substance again. The downstream user of such notified substance has no further obligation unless the use of the notified substance is not included in its notification. In such a case, the downstream user shall notify the authorities and submit an updated safety data sheet (SDS).