



Latest Update on India's Draft Chemical Regulation

March 22, 2022

Q & A Session

India CMSR

#	Question	Answer
1	When do we expect that "India reach" will be notified to WTO and their estimated implementation date?	There is no concrete information about the notification to the WTO. We understand that there is a certain delay in the implementation due to COVID pandemic and in part because new officials are taking place in the department. There is no specific date still, but we can expect major updates and changes in the following months.
2	Could a foreign manufacturer with a legal entity in India carry out notification?	Yes, since it is considered a legal entity in India you can perform the notification steps by yourself. Note that a leasing office alone is not considered a legal entity, and therefore must comply with the regulation via an Authorized Representative (AR).
3	As timeline for notification and registration is 1.5 yrs. Is there an exemption from notification if a substance has to be registered?	According to the rules, all substances manufactured or imported into the Indian market are subject to be notified when amounts exceed 1 ton per annum. Substances that are listed in Schedule II of the CMSR should be registered. The registration of a substance does not mean that the same substance is exempt from notification. The requirements are cumulative, i.e., the notification + the registration (when present in Schedule II).
4	Is the notification fee per substance?	Yes, the notification fee is per substance, and varies according to the company size and tonnage bands.
5	Do polymers need to be notified?	Yes, polymers are considered under the CMSR as substances, and must comply with same steps, including notification and registration.
6	Do substances in imported mixtures need to be notified?	Substances need to be notified if they amount over 1 TPA regardless of if it is a pure substance or a mixture of substances. The substances in mixtures shall follow the same logic and be

		notified when over 1 TPA. Such substances are also subject to be registered if necessary.
7	Which Software would be used for preparing dossier. e.g.: IUCLID?	Currently the Rules did not mention this in detail. ICLUD maybe a strong candidate system.
8	Will there be a list of Toxicological tests that needs to be performed as per tonnage band? For example, gextended one generation study for products above thousand tonnes for ECHA	The current draft did not elaborate about the data requirements for different tonnage bands. Currently, there is no difference, and all substances shall perform the same tests and assessments when required.
9	Do all notified substances (other than schedule II) should be registered?	No, substances to be registered are depicted on Schedule II. Substances subject to be notified are those imported or manufactured above 1 ton per year.
10	For registration of priority substances: How about mixtures containing priority substances, what is the threshold concentration limit that trigger the registration?	Although the CMSR scopes mixtures, there is no requirement to notify or register mixtures itself. The CMSR focuses substances present into mixtures, and consequently the same requirements apply to those, i.e., the notification or registration of the substance itself, when amounts are greater than 1 TPA, or the priority substances falls under special criteria (measured by w/w) – Schedule XI and XII for example.
11	On Schedule XVII, Labelling of Priority Substances, it showed "IN number". What exactly is the "IN number" and when is it issued?	The IN number is similar to the EC number in Europe, for example. It is a chemical identifier used in the Indian Chemical Inventory. The format of this has to be announced.
12	Schedule X: Hazardous Chemicals, Part I and Part II, was copied from the MSIHC Rules. Is the authority aware that Part I criteria on toxicity and flammability endpoints differ from UN GHS criteria? Will they be harmonized in the final version? Also, Part II has typo on the chemical substances name. Will these be corrected as well?	Since it is an inherited list, we believe that the application of GHS 8 revision will not occur retrospectively. In other words, only new added substances will follow the new GHS standard.
13	Could you please provide more information on SPECTRA?	Spectra is the structure information about a chemical, and it is very similar to the EU REACH.
14	If substances present in intermediates or mixture are notified, then the mixtures or intermediate also need to be notified or registered?	The CMSR scopes ingredients, i.e., chemical substances alone or in mixtures. All substances exceeding 1 TPA needs to be notified. However, only those present in Schedule II need to be registered.

15	On Slide 25, where does the classification come from? Self-Classification?	The classification mention refers to the GHS revision 8.
16	is there a list of exempted substances? and which are those?	According to the Rule 2, §1, item “ss” ICMSR does not apply to radioactive material, substance under customs supervision, substances in warehouses aimed to be re-exported, wastes, substances used as food or feeding stuff, substances meant for national defense, and cosmetics, pharmaceuticals, and pesticides complying with their respective legislations. Other exempted substances are also referred in Schedule IV.
17	Do ingredients for pharmaceuticals have to be registered?	There is an exemption criterion, and all such substances will be exempted from the obligation under ICMSR. However, exemption of the said substance will be only for such already identified exemptions. For any other use of the said substance, other than those mentioned in the Schedule IV will have to comply with ICMSR once into force.
18	Can you explain why we need so many data for the notification?	The data to be present in the notification is not much if compared to the amount of data to be present in the registration of a substance. The notification required only basic information about the substance. Th registration require same data of the notification plus many more detailed chemical information and assessment.
19	As we can verify EU REACH by testing for SVHC, is such way possible for India REACH? by the third party SGS like testing labs	According to the draft rules, substances are divided into priority list and hazardous substance list. So far, there is no list called SVHC under CMSR. Therefore, manufacturer and importers need to look into those lists cite above and comply with the specific requirements.
20	Are there any import notifications needed for mixtures containing hazardous substance now?	The CMSR does not deal with mixtures, but substances contained in mixture. These substances contained in mixtures are subject to the same conditions and criteria as substances alone.
21	Can we use our supplier's BIS license to import chemicals into India. Similarly, if we purchase for example styrene locally	<p>BIS certification is required by every manufacturer (Indian or foreign) of those who is manufacturing products under Compulsory Certification. It is important to check with your supplier if the product is BIS certified. For non-Indian companies, you can appoint an Indian representative.</p> <p>GPC services for BIS cover a complete package including hand holding to obtain the BIS certificate and its renewal.</p>

22	For Schedule X (Hazardous chemical) does foreign entities need to do registration?	<p>There is no specific registration required for hazardous chemical. The Schedule X is composed by registered substances that underwent an assessment, after the committee decided based on certain criteria which substance should be included.</p> <p>The correlation between Schedule II (registration of substances) and Schedule X (hazardous chemicals) still need to be clarified.</p>
23	Does the notification number base on the export country? For example, if this product is produced in EU, China, Malaysia, does it mean we have to do the notification 3 times since it has 3 different manufacture sources?	We understand that every overseas manufacturer needs to comply with the ICSMR. It means that each of manufacturer needs to do the notification for the same notification. The same is expected in case of registration is required.
24	if our customer is using our material in their product, can we represent them to cover their imported volumes?	Yes, manufacturers can comply with the ICMSR themselves and forward the documentation (notification/registration certificates) to their clients. The clients just need to show the same certificates when requested by the authorities.
25	Are pesticides or actives exempted from registration, since they are registered already under Pesticide Act 1968?	Yes, substances complying with their existing regulation will be exempt from the CMSR requirements.
26	for confidentiality, how does hiding of CAS# works?	The only case that you can hide the CAS number is applying for confidentiality of your substance (in case of novel chemicals). For that you need to justify the request for the authority and follow the established procedures for that. Every chemical claimed as confidential are subject to an application fee.
27	If the hazardous substance is not a priority substance, do we also need to do registration?	We believe that it will be clarified in the future. For now, only those substances present into Schedule II (List of Priority Substances required to be Registered) are required to be registered.