

Q&A

Draft Amendment to Taiwan’s New and Existing Chemical Substances Registration Regulation (June 17)

#	Questions	Answers
1.	Will the Taiwanese authority consider OR approach for registration?	<p>Currently, there is no Only Representative (OR) approach under Taiwan’s TCCSCA. Non-Taiwanese companies are not allowed to submit substance registrations directly. The regulation only authorize Taiwanese importers or manufacturers to appoint a TPR to assume their chemical registration responsibilities.</p> <p>Non-Taiwanese manufacturers who are unwilling to disclose product compositions to their Taiwanese clients can ask the importers to nominate a TPR to register the substance and do the annual reporting on behalf of the importers without disclosing product composition to the importers.</p>
2.	Is this similar to EU Reach?	<p>Taiwan’s TCCSCA is different from EU REACH. EU REACH requires substance registration of those above 1 TPA, while Taiwan’s TCCSCA only requires 106 PECS for substance registration.</p> <p>The OR system under EU REACH is not available in Taiwan.</p>
3.	Can a registrant outside Taiwan register their product or its proceeds only through importers?	<p>Registrants outside Taiwan cannot register their products/substances. They have to register it via Third Party Representative (TPR).</p> <p>Non-Taiwanese manufacturers who are unwilling to disclose product compositions to their Taiwanese clients can ask the importers to nominate a TPR to register the substance and do the annual reporting on</p>

		their behalf without disclosing product composition to the importers.
4.	Which substances require registration?	Currently, Taiwan's EPA requires 106 Priority Existing Substance (PECs) for standard registration. The list of 106 PECs can be downloaded from GPC's website https://gpcgateway.com/ . You can also contact us for further details: compliance@gpcregulatory.com
5.	What are the criteria for hazardous goods classification?	<p>Toxic chemical substances in Taiwan are divided into four classes.</p> <p>Class 1: Hard to break down in the environment, easily pollute the environment and endanger human beings health because of the bioaccumulation, bioconcentration, or biotransformation.</p> <p>Class 2: Has the ability to cause cancer, infertility, birth defects, genetic mutations, and other chronic diseases.</p> <p>Class 3: Human beings' health and environment will be endangered immediately after exposure to chemicals.</p> <p>Class 4: There is a risk to endanger human beings' health and the environment.</p> <p>For Class 1 to 3, the registrant will need to:</p> <ol style="list-style-type: none"> 1. Obtain the permit (manufacture, import, or sell toxic substances more than the large scale handling standard) 2. Obtain the registration (use, store, and dispose toxic chemical substance more than the large scale handling standard) - like reporting; 3. Obtain approval (manufacture, import, sell, use, store or dispose toxic chemical substance less than the large scale handling standard)
6.	Any new news for compliances of certification?	<p>Registrants will receive substance registration certification after they have submitted information items from 1 to 7. The rest can be submitted later.</p> <ol style="list-style-type: none"> 1. Information of the registrant and basic identification of substance



		<ol style="list-style-type: none">2. Information on manufacture, use, and exposure of the substance3. Hazards classification and labelling4. Safe use information5. Physical and chemical properties6. Toxicological information7. Ecotoxicological information8. Hazard assessment9. Exposure assessment
7.	What are all the requirements to continue our exports to Taiwan?	Comply with Taiwan's TCCSCA and if you need assistance for compliance, please contact us at: compliance@gpcregulatory.com