

INTRODUCTION

On the 1st of January 2021, China enforced its new regulation on the management of chemicals – **Measures for the Environmental Management and Registration of New Chemical Substance** (MEE Order No.12). With the effect of this regulation, the previous regulation of MEP No.7 was repealed. Under this regulation, manufacturers /importers of those who want to research, produce, import or process new chemical substances within the territory of China have to register before carrying out their activities.

REGISTRATION TYPES

The registration procedures are divided into three types according to tonnage band:

Record filing	<ul style="list-style-type: none">Quantity below or equal to 1t/y2% polymer & PLC
Simplified Registration	Quantity between 1t/y and 10t/y
Regular Registration	<ul style="list-style-type: none">Quantity above 10 t/yNew Use Management

Additionally, Joint Registration and Series Registration is allowed. But Repeat Registration which is allowed under MEP Order No.7 was cancelled.

Registration Types	Document requirement
Record Filing	<ul style="list-style-type: none">Application formBusiness license, POA (overseas applicants), authorization letterDocuments regarding the necessity of CBI protectionOther in-hand information (test data, literature, known risk, etc.)
Simplified Registration	<ul style="list-style-type: none">Commitment letterSupporting documents for testing institutionsPhysical & chemical dataEco-toxicological data
Regular Registration	<ul style="list-style-type: none">Toxicological dataEnvironmental risk assessment report (CSR report)Socio-economic Benefits analysis report (Highly hazardous chemical substances)

KEY TERMS

Agent

Foreign applicant has to appoint a Chinese Agent to help them to finish the registration.

IECSC

IECSC is the official inventory maintained by the Ministry of Environment and Ecology of China (MEE). Currently, it contains 46,192 chemical substances.

Confidential Information

The Chinese Inventory is divided into two parts. For the public part, every can access it for free. While regarding the confidential part, a formal enquiry has to be provided and it costs 3,000 RMB.

New Use Management


Existing chemicals are exempted from registration obligation. But for those chemicals which is listed in the Inventory with specified purpose, it has to be notified when it has new use other than the one listed.


Joint Registration


For the same substance, different applicants can bring their applications together. For oversea applicants, they have to appoint the same agent.


Series Registration

For every single applicant, it can bring no more than 6 similar chemicals to register at the same time.

 IDEON Science Park (Beta 5)
Scheelevägen 17,
223 63 Lund, Sweden

 compliance@gpcregulatory.com

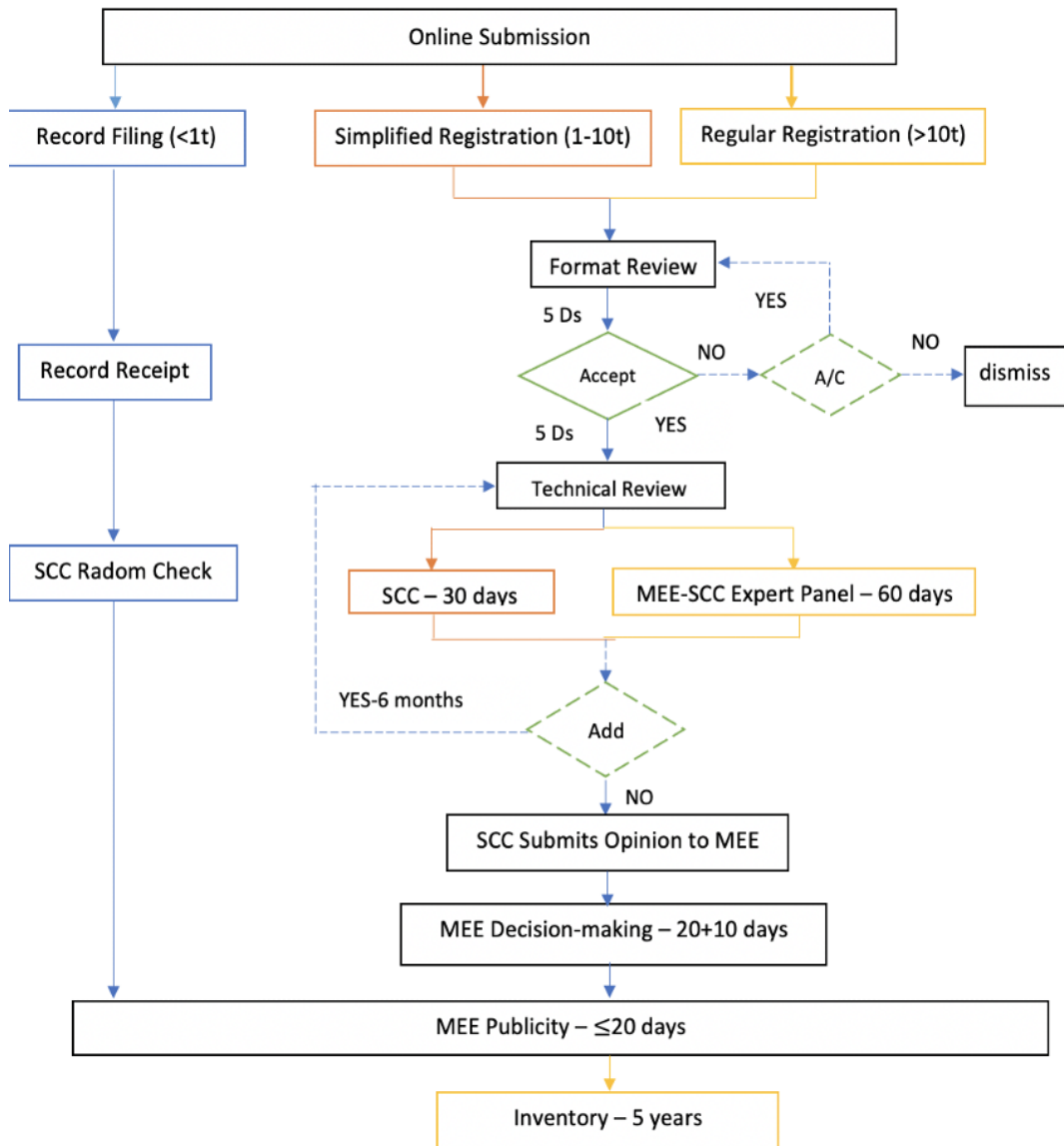
 Corporate Website:
www.gpcregulatory.com

 Regulatory Intelligence Portal:
www.gpcgateway.com

 Global Product Compliance (GPC)

REGISTRATION PROCEDURES

Once the dossier is prepared, applicants should submit their application to China MEE. Then MEE will conduct the following examination.



POST REGISTRATION OBLIGATIONS

1. Information communication
2. Data preservation
3. Information disclosure
4. Activity report
 - a. First activity report
 - b. Annual report
5. New hazardous information and environmental risk

LEGAL LIABILITIES

Upon failure to comply with relevant requirements, punishments may be imposed:

- **Monetary punishment**
The fine can amount to 30,000RMB.
- **Behavioral punishment**
This can be in the form of joint punishment on dishonest (loss in social credits) and not accepting application up to 3 years.
- **Disqualification**
This is normally imposed on members of expert panel and testing institutions