# ACTIONABLE SUMMARY
# CHINA MEE ORDER No.12

## 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 appealed. 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 | • Quantity below or equal to 1t/y<br>• 2% polymer & PLC |
| Simplified Registration | Quantity between 1t/y and 10t/y |
| Regular Registration | • Quantity above 10 t/y<br>• New 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** | • Application form<br>• Business license, POA (overseas applicants), authorization letter<br>• Documents regarding the necessity of CBI protection<br>• Other in-hand information (test data, literature, known risk, etc.) |
| **Simplified Registration** | • Commitment letter<br>• Supporting documents for testing institutions<br>• Physical & chemical data<br>• Eco-toxicological data |
| **Regular Registration** | • Toxicological data<br>• Environmental risk assessment report (CSR report)<br>• 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.

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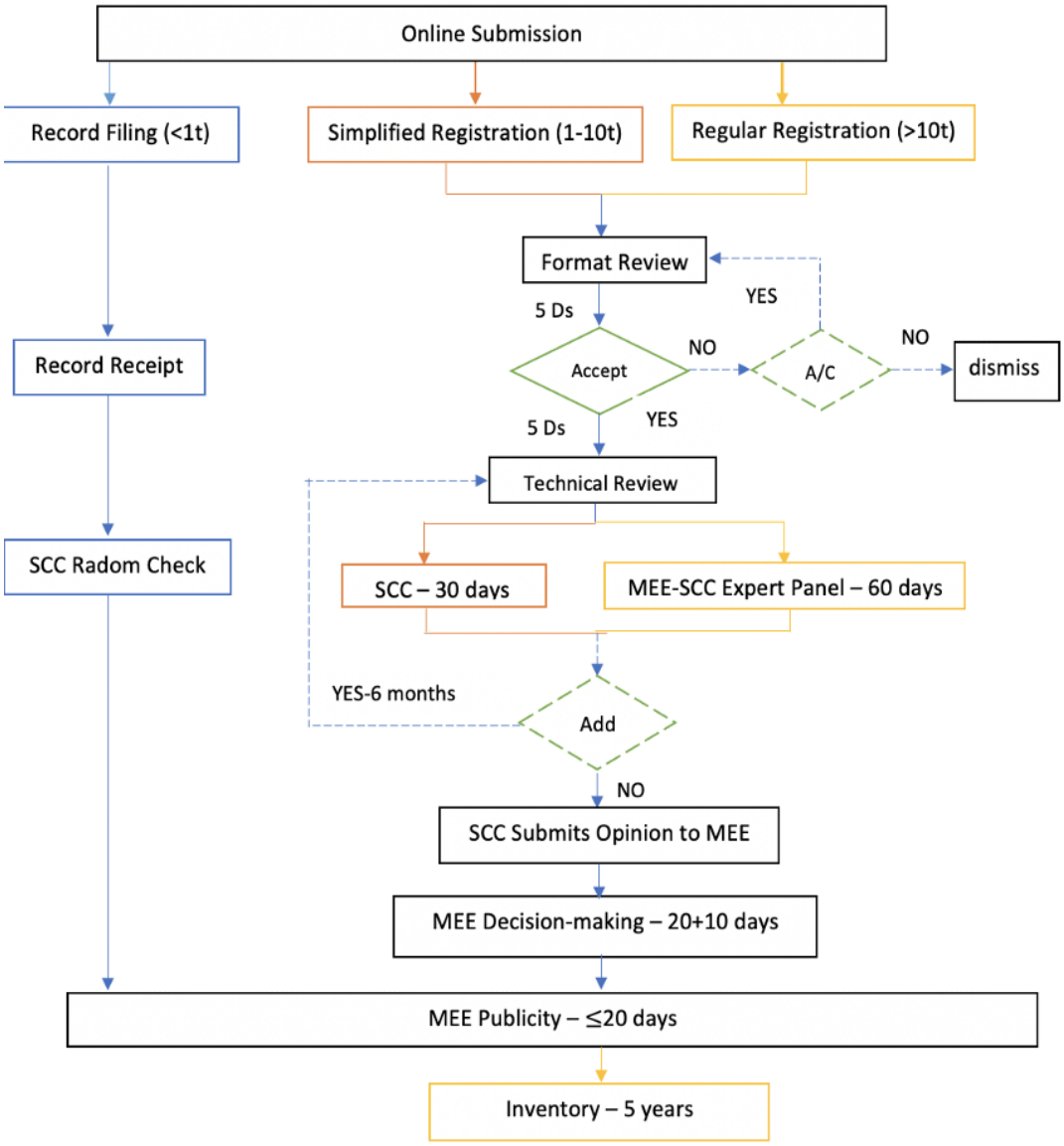
## REGISTRATION PROCEDURES

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.

# ACTIONABLE SUMMARY
# TAIWAN TCCSCA

## BACKGROUND

The chemical law in Taiwan is **Toxic Chemicals and Concerned Substances Control Act (TCCSCA). It was amended on 16 January 2019. Under this Act, there is a** regulation on Chemical Substances Registration. From 1 January 2020, manufacturers or importers who manufacture or import any **Existing Chemical Substance** in an annual amount of 100 kilograms or more, should apply for the **Phase One Registration** within 6 months from the date of manufacturing/importing. Taiwan's EPA also issues a list of Priority Existing Chemicals (PECs) subject for Standard Registration. The first batch contains 106 PECs. Taiwanese manufacturers, importers and Third-Party Representatives (TPR) based in Taiwan can register substances under the TCCSCA.

Non-Taiwanese companies are not allowed to submit substance registrations directly and they cannot appoint a TPR to register substances on their behalf. The regulations only authorize Taiwanese importers or manufacturers to appoint a TPR to assume their chemical registration responsibilities.

Non-Taiwanese manufacturers not willing to disclose product compositions to their Taiwanese clients can ask the importers to nominate a TPR to do the annual reporting on behalf of the importers without disclosing product composition to the importers.

## CHEMICAL INVENTORY IN TAIWAN

Taiwan's Chemical substance Inventory (TCSI) was compiled jointly by two competent authorities, the Environmental Protection Administration and Ministry of Labor. The inventory contains more than 100,000 substances that have been circulated or placed in Taiwan between 1992 and 2014. The Inventory Chemical Substance Nomination and Notification (CSNN) is available online for search, via CAS no., English name, or Chinese name. Chemicals in the inventory are considered Existing Chemical Substances in Taiwan. Chemicals outside the inventory are considered New Chemical Substances.

## EXEMPTIONS

- Substances which occur in nature.
- Chemical substances in machines or equipment for test run purposes.
- Inseparable intermediates from chemical reactions in the reaction vessel or production process.
- Chemical substances for national security or national defense purposes.
- Chemical substances under customs supervision.
- Chemical wastes produced or released from industrial process.
- By-products or impurities that are of no commercial application.
- Mixtures; but individual constituents of mixtures shall not be applied to the Article.
- Articles
- Polymers that the 2% Rule is Applicable and listed on the inventory of existing chemical substances.
- Controlled chemicals defined by Occupational Safety and Health Act, Regulations Governing Designation and Handling Permission of controlled Chemicals (under evaluation)
- Concerned Chemical Substances defined by TCCSCA (under evaluation)

# SUBSTANCE REGISTRATION

| Existing Chemical Substance | New Chemical Substance |
|---|---|
| • Manufacturers / Importers, who manufacture/import existing chemical substances in an annual amount of 100 kilograms or more, should apply for the Phase One Registration within 6 months from the date of manufacture/import.<br>• Standard Registration is required for substances that are listed on the 106 PECs List with the tonnage band of more than 1 TPA.<br>• Joint registration of the same substance is recommended. | • Small quantity registration of those below 100 kg per year<br>• Simplified Registration between 100 kg and 1 ton per year<br>• Standard Registration for those above 1 ton per year |

## ANNUAL REPORTING

Annual Reporting takes place from April 1 to September 30. Information to be included in Annual Reporting:

- Substance name
- CAS Number
- Registration number for each substance
- Volume in the previous year
- Information on importer or manufacturer

## HOW CAN GPC HELP YOU?

- Supply Chain communication for Third Party Representative (TPR) Appointment
- Consortia communication (Joint Registration)
- Communication with competent regulatory authorities in Taiwan (TSCB and EPA)
- Existing Chemical Substance – Phase One Registration and Standard Registration support
- New Chemical Substance – Small quantity, Simplified Registration and Standard Registration
- Annual Reporting
- Review the compliance check communication and provide responses/justification
- Substance Sameness & Identification related follow up queries
- Member dossier update
- Certificate of compliance and tonnage coverage to the Buyers
- Manage Tonnage band compliance
- Update information on Registration as and when required
- Regulatory & compliance Submission to the IT system.

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# ACTIONABLE SUMMARY: KKDIK

## WHAT IS KKDIK?

KKDIK (aka Turkey REACH) came into force on 23 June 2017 and has replaced three existing regulations on chemicals and mixtures with the purpose of regulating the chemical inventory, enforcing secure usage, and risk management on hazardous substances, and promoting alternatives to hazardous substances or procedures. The provisions of KKDIK are very similar to EU REACH.

**The KKDIK registration period started on 1st January 2021.** Exporters who wish to enter into Turkish market but missed the pre-registration deadline can still pre-register. They should do so as soon as possible to be able to benefit from the advantages of joint registration and to participate in the KKDIK Substance Information Exchange Forum (SIEF).

Unlike under EU REACH, the registration deadlines are not affected by the tonnage bands under KKDIK.

**The deadline for final registration under KKDIK is 31st December 2023.**

***We have already set up an Only Representative (OR) facility in Turkey, 'GPC Turkey', to assist our existing and new clients in complying with their obligations under KKDIK!***


## WHO IS CONCERNED?

- **Turkey-based manufacturers and importers of chemical substances**
  Importers and manufacturers must register chemical substances before placing them on the market.
- **Non-Turkey-based manufacturers who wish to export chemical substances to Turkey**
  Exporters may appoint a Turkey-based OR to carry out the pre-registration/registration

## WHAT IS THE PURPOSE OF KKDIK?

- To regulate the administrative and technical procedures and principles regarding the registration, evaluation, authorisation and restriction of chemical substances.
- To ensure a high level of protection of human health and the environment.
- To promote the use of alternative methods for the assessment of hazard substances while enhancing competitiveness.


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## Which documents do I need to submit for registration purpose?

| Documents | 1 – 10 t/y | 10-100 t/y | 100-1000 t/y | 1000+ t/y |
|---|---|---|---|---|
| Technical dossier including main information as registrant's identification, Substance ID, guidance on safe use, classification and labelling | ✓ | ✓ | ✓ | ✓ |
| Exposure assessment | ✓ | | | |
| Exposure scenario | | ✓ | ✓ | ✓ |
| Chemical Safety Report and Chemical Safety Assessment | | ✓ | ✓ | ✓ |
| Safety Data Sheet (if the substance is under harmful criteria) | ✓ | ✓ | ✓ | ✓ |
| Physiochemical Properties | ✓ | ✓ | ✓ | ✓ |
| Toxicological information | ✓* | ✓ | ✓ | ✓ |
| Ecotoxicological information | ✓* | ✓ | ✓ | ✓ |

*If the substance is hazardous

### Q&As – KKDIK

1. **What are the obligations of non-Turkish companies under KKDIK?**
   Non-Turkish companies that are exporting substances to Turkey are not obliged to register unless they appoint an OR to accomplish the obligations of importers.

2. **What is the role of an OR?**
   An OR is a natural person or legal entity established physically in Turkey, equipped with sufficient knowledge in the practical handling of the substances and information related to them. ORs are appointed by a mutual agreement with a manufacturer, formulator or article producer, established outside Turkey. They are responsible for complying with the legal requirements for importers under KKDIK.

3. **Is KKDIK applicable to substances with manufactured/imported tonnage below 1 ton per year?**
   Under KKDIK registrants have obligations regardless of tonnage. These include restriction, authorization and communication within the supply chain (such as the provision of Safety Data Sheet.) The one ton and above per year threshold applies to registration only.

### ACTION POINTS

1. Compile a list of substances that you would like to place on the Turkish market and submit the list to your OR.
2. Get in touch with a Turkey-based OR facility, such as **GPC Turkey**.
3. **GPC Turkey** will assist you in carrying out KKDIK pre-registration/registration as well as CLP notification.
4. Keep in mind that substances not registered after 31st December 2023 will be kept out of the Turkish market.
5. Keep yourself updated on KKDIK developments at www.gpcgateway.com

# ACTIONABLE SUMMARY
# Poison Centre Notification

## WHAT IS A POISON CENTRE NOTIFICATION (PCN)?

**Legal Background**

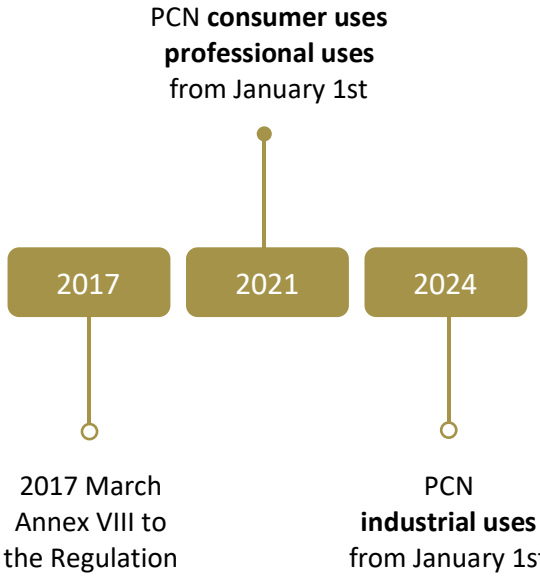
According to **Article 45 of the Classification, labelling & Packaging (CLP) Regulation**, companies placing hazardous mixtures on the market are obliged to provide information about certain hazardous mixtures to the relevant national bodies. Duty holders under Article 45 are defined as importers and downstream users placing hazardous mixtures on the market. It is also important to consider that fulfilment of the notification obligation is a pre-condition for placing the mixture on the market – this may be important in cases where placing on the market is not performed by the importer or downstream user.

## WHO CAN SUBMIT INFORMATION?

- Legal entities on behalf of duty holders, such as consultant, mother company, i.e. 'Foreign user'
- Importers or downstream users of mixtures out of scope i.e. a voluntary submission
- Legal representative of non-EU suppliers can also submit through the EU legal entity

## TIMELINE FOR COMPLIANCE

Notifications must comply with the harmonised requirements according to the use type of the mixture (see figure)




## COMPLIANCE STRATEGY

- **Step 1:** Identify & verify if you are manufacturing / exporting Mixtures or Mixtures in Mixtures (MiMs)
- **Step 2**: Prepare an inventory of the mixtures along with its ingredients manufactured and exported to EU
- **Step 3:** Verify & compile the classification of the mixtures as per CLP notification and verify available SDS

## IS PCN APPLICABLE TO YOUR MIXTURES?

- Check applicability of your mixtures for PCN on our Free **PCN Compliance Advisor**.
- Just submit your CAS details and get free compliance requirements to check for PCN.

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## HOW TO DO A PCN IN 3 EASY STEPS:

**Step 1:**

**Identify and Verify your Product Detail for PCN!**

Request our PCN quote by submitting your product details **here**. This includes product identification details with the product category, packaging and COA details along with uses and composition information

**Step 2:**

**Complementary Detailed PCN Requirement Assessment!**

We will do a complimentary detailed assessment of your products and its constituents and provide you with your customized complete obligations for PCN.

**Step 3:**

**PCN Submission!**

Upon your acceptance of our PCN quote within 2 weeks we will do the PCN for your product and provide you with a confirmation.

## HOW CAN GPC HELP YOU?

1. Guidance on PCN requirements
2. Assess the portfolio to identify the
   - Notification Requirements
   - Trade names and Brand
   - Country specific variations
   - Use specific variations
   - Components specific variations
3. Possibility to group and optimize the Notifications
4. Generate the UFI core for the Mixture
5. Verify the UFI in cases of Mixture (external) in Mixtures
6. Inventorize data to support classification & Labelling of Mixture
7. Guidance on Packaging – type, and size requirements
8. Update SDS to harmonized with Poison Centre Notified information
9. Revised and updated PCN Notification submission
10. Portfolio management in PCN portal