

China Chemical

1. Q: Do essential oils count as "naturally occurring substances" as they are extracted from plant parts?

A: For "Naturally Occurring Substances", it is defined as below per MEE Order 12.

- Unprocessed substances or substances physically processed only by manual, mechanical or gravitational means, or by dissolution in water, by flotation or by heating solely to remove water, etc;

- Substance extracted from air by any means;

- Natural polymers that have not been chemically processed;

- Living substances that have not been chemically processed to change their chemical structures, such as ribonucleic acid, deoxyribonucleic acid, proteins and other biomacromolecules.

Therefore, if the essential oil meets any one of above situations, it can be exempted from MEE Order 12.

2. Q: Does inorganic substance have persistence property?

A: It is always difficult to have the inorganic substance to do Ready biodegradability. Therefore, according to the authority, if you cannot provide further information or evidence to prove it can be degradable, then you cannot exclude the persistence property for inorganic substance.

3. Q: What are the requirements for the testing institutes that generate GPC and other spectra for the application of regular/simplified registration of polymers?

A: The requirements for such institutes are the same as the qualification requirements specified in the Guidance on Environmental Management Registration of New Chemical Substances (hereinafter referred to as the Guidance) for the domestic and overseas testing institutes engaged in testing of physicochemical properties.

China Cosmetic

Q1: CSAR registration platform for ingredient raw materials for cosmetics: I've heard that there are reduced requirement for fragrances. Is this correct? If so, what are those reduced requirements?

A: No, there is no reduced requirement for fragrances currently. In fact, different from other types of raw materials, fragrances shall choose 'fragrance' in 'Basic attribute'. Besides, no additional or reduced requirements.

Q2: A lot of cosmetic raw material suppliers completed Annex 14 forms before the platform was set up and running. Is this enough or is a submission code still required?

A: Annex 14 is a way to fulfill the requirement of the finished products registration and notification. While in the long run, it is recommended to obtain the ingredient code, as mentioned in the presentation, it would be more advantageous.

Q3: What does it means "typical/target value" for a compound ingredient? Why is it needed to be indicated? Which kind of ingredients (synthetic, hemi synthetic, vegetable) needs target values (mandatory)?

A: The "typical/target value" can be a theoretical value, or an average one obtained by monitoring over a long period of time, or a representative one. For the compound ingredient obtained by physical mixing, the "typical/target value" is needed. And for the mixture obtained by production or other reason, the percentage range is accepted.

China Pesticide:

Q1: Are pheromones considered a pesticide?

Yes, pheromones are under the pesticide regulation and should be registered in China.

Q2: It is mandatory to register the TC/TK? How does this work when the TC/TK is already registered in the Country? This applies to the bio-pesticides?

“For new pesticides, the first applicant must register the TC/TK and formulation together, and other companies can only register one of them. For the chemical pesticide and bio-pesticide, if the TC/TK is still within the 6-year new pesticide protection period, other companies need to register according to the new pesticide requirements. If it has been registered for more than 6 years, it can be registered according to the me-too TC/TK requirements.”

Q3: To register Proprietary TC (Technical grade material)in China, is it necessary to conduct Carcinogenicity study and Reproduction study just for export outside China. The TC is not used for formulation in China.

If this proprietary TC is a new TC in China, carcinogenicity test data and reproduction test data are required when applying for export-only registration, and you can also use foreign data in this part. Otherwise, carcinogenicity test data and reproduction test data are not required when applying for export-only registration.

China Fertilizer:

Q1. Which fertilizers are just requested to be recorded in China, other than registration?

A: They are water-soluble macronutrient fertilizers, water-soluble fertilizers containing calcium and magnesium, water-soluble fertilizers containing micronutrients, magnesium potassium sulfate for agriculture, magnesium potassium chloride for agriculture.

Q2. What's the difference between fertilizer recording/filing and fertilizer registration?

A: The timeline of fertilizer recording is normally around 3-6 months (depending on the efficiency of legalized documents preparation in foreign countries) and the documents required for recording are also much less than product registration.

No test requirements for product recording, compared with the quality analysis and field trial of registration.

The timeline for product registration would be normally 9-14months based on fertilizer type. For example, if it's a water-soluble fertilizer containing organic matter (non-standard product), there are only May/Oct. evaluation meeting each year.

Q3. What are the documents required to prepare from the country of origin?

- A: 1. Business Registration Certificate
2. Certificate of production and sales of registered products
3. Original foreign label

These documents are required to be legalized in the Chinese Embassy of the local country.

China FCM

Q1 : Can rPET be used as food contact materials in China?

A1: At present, recycled PET is not allowed to be used in the field of food contact materials in China.

Q2: Any labeling requirements for food contact packaging materials

A2: Label requirements are set under GB 4806.1 section 8 and specific product standard.

Q3: What are the costs for getting a new substance assessed and approved?

A3: The rough total project cost will be 80,000 USD to 150,000 USD consisting of consulting fees and experimental expenses. The cost of the project varies from case to case. Before we start the new substance application project, we provide the Data Gap Analysis service to pre-analysis the data gap for the application and will help our customers have a rough understanding of the application plan, fee, and period of this project. If you need any help with China new food contact substance application, please feel free to contact us.