Summary of Registration of New Cosmetic Ingredient in China

By Chemical Inspection and Regulation Service

Strictly speaking, a cosmetic ingredient that is not listed on IECIC must be registered with the CFDA prior to being used in cosmetics in China. If a new cosmetic ingredient is to be imported into China on its own or in finished cosmetic products, the manufacturer of the new ingredient or finished cosmetic products must register the new ingredient with the Chinese CFDA. Usually, a Chinese responsible agent needs to be appointed for the registration work.

The following documents are required for the registration of a new cosmetic ingredient in China according to the guidelines for the registration and technical review of new cosmetic ingredients published in 2011.

- Application form for hygiene license for new cosmetic ingredient;
- A research & development report consisting of the following information:
  - Background of research, R&D process and relevant technical files;
  - The source of ingredient, physio-chemical properties, molecular structure, molecular structure, molecular weight;
  - Purpose in cosmetics, supporting proof, scope and extent of use in cosmetics;
- Brief description and diagram of production process;
- Standards for quality and safety control of ingredient (including qualitative and quantitative test methods and specifications for the ingredient and impurities, etc);
- Toxicology safety assessment data including safety assessment of risk substances;
- Power of Attorney in case of using an agent;
- Other information which are helpful to review;

Required Toxicology Data and Exemptions

In general, the following toxicology data is required. If test report is conducted in overseas labs (GCP or GLP is preferred), original full study report or certified copy is required.

1. acute oral and acute dermal toxicity;
2. skin and eye irritation/corrosion;
3. skin sensitisation;
4. skin phototoxicity and photosensitivity (required if the ingredient is used as UV-filters);
5. mutagenicity (should at least include a gene mutation test and a chromosome aberration test);
6. sub-chronic oral and dermal toxicity;
7. teratogenicity;
8. chronic toxicity/carcinogenicity;
9. toxicokinetics and dynamics;

Some data endpoints listed above can be exempt based on the properties and use of the new ingredient. For example, if the new ingredient is structurally similar to an existing ingredient and shares the similar property with the existing ingredient, some tests can be waived. More exemptions are listed in the following table.

Exemption Criteria	Exempt endpoints
(1)The ingredient is not used as a preservative, sun block agent, colorant or hair dye; and (2)The ingredient does not need to be added to restricted substances list in hygienic standard of cosmetics from the safety point of view.	7, 8, 9, sub-chronic oral or dermal toxicity depending on exposure route
(3)The ingredient has met criteria (1)+(2) and the ingredient has been included the inventory of existing ingredients in overseas authoritative organization for more than 4 years; and (4) The ingredient is not found to be hazardous in public literature when used.	6,7,8,9
(5) The ingredient is proven to have a history of safe use as food ingredient by government or authoritative organizations.	1,5,6,7,8,9
(6)Polymer with average molecular weight above 1000 Daltons;	1,3,5,6,7,8,9 and photosensitivity
(7)Risk assessment of the cosmetic ingredient has been carried out by overseas authoritative organizations and the conclusion is that the ingredient is safe to be used in cosmetics.	1,2,3,4,5,6,7,8,9

Usually, if a new ingredient meets criteria 5, 6 or 7, it will be easier and less expensive to get approved in China.

Safety Assessment of Ingredient and Risk Substances

When registering a new cosmetic ingredient, safety assessment of the ingredient and risk substances is crucial. China CFDA has shifted the responsibilities of risk assessment from government to registrants. Risk substances are the components (impurities or additives) that may cause potential harm to human health resulted from raw materials or brought in during the production process.

Toxicology safety assessment data required by China SFDA usually consists of three parts: safety assessment report of the ingredient, necessary toxicology test reports and the safety

assessment of risk substances in the ingredient. If there are no risk substances in the ingredient, a letter of commitment shall be provided.

The required safety assessment report shall include the following contents:

- Ingredient characterization through relevant physico-chemical data, purity and profile of impurities or additives ;
- Source of the ingredient(like synthesis, animal source or plant extract);
- Data on pesticide residues and other impurities brought in during the extraction process in case of ingredient extracted from plant;
- Toxicological profiles of the ingredient and risk substances(including whether a substance has been regarded as a carcinogen by IRAC);
- Summary of the restriction of risk substances in cosmetic ingredient, finished cosmetics, food, air, water(if available) found in public literature or international regulations;
- The concentration of risk substances in the ingredient and finished cosmetics, qualitative and quantitative testing methods and relevant public literature;
- Hazard characterization, dose-response assessment(calculation of NOAEL if appropriate) and exposure assessment;
- Calculation of safety or exposure margins (as appropriate) for the ingredient and risk substances;

The new guidelines for risk assessment of cosmetic ingredient and cosmetics are consistent with those used in EU and US.

Cost

The best case scenario is that an ingredient has been assessed by international authoritative organizations and has been proved to be safe; China does not require toxicology assessment data any more. However, a dossier, risk assessment report, conclusions, approval document and relevant documents need to be provided. This case costs approximately 80,000-120,000RMB, which includes consultancy fee.
The worst case scenario is that all toxicology tests are required. Under this case, the cost is approximately between 800,000-1,000,000RMB which includes both testing fee and consultancy fee.

Administrative Procedure for the Approval of New Ingredient

It takes 5 days for CFDA to issue an acceptance notice since all required documents have been submitted, 90 days for CFDA to conduct the technical review of the new ingredient and 20 days to issue an approval notice or an opinion letter to the registrant to request more documents