REGULATORY MONITORING REPORT TEMPLATE

MAR 2022

Prepared for: ****

Prepared by: ChemLinked | REACH24H

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Monitoring Period	Mar. 1, 2022 – Mar 31, 2022
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Categories	Cosmetics

Part 1. Regulation Updates: China

Chapter 1. Notification / Registration Requirements

1.1 China NMPA Releases the 2021 National Cosmetics Supervision and Sampling Annual Report

- Issue date: 2022.03.21
- Source: Official Notice

On March 21, China NMPA released the 2021 National Cosmetics Supervision and Sampling Annual Report. In 2021, NMPA took risk-prone cosmetic types and places as the key sampling objects, and organized sampling testing for 11 cosmetic types including hair dyeing products, hair shampoos and conditioners, make-up products, sunscreens, products claimed to remove acne, facial masks, general skin care products claimed to moisturize & moisten, general skin care products claimed to tighten and anti-wrinkle, children cosmetic products, freckle-removing/whitening products and talcum powders, totaling 20,245 batches. 33 cosmetic inspection and testing institutions tested these products in accordance with Safety and Technical Standards for Cosmetics 2015, of which 19,847 batches of products met the standards, with a pass rate of 98.03%. Among the 11 types of cosmetics involved in the sampling test, the pass rate of 9 types, including talcum powder and freckle/whitening cosmetics, reached more than 98%.

Chapter 2. Ingredients

2.1 China NMPA Approves One New Cosmetic Ingredient

- Issue date: 2022.03.07
- Source: Official Notice

In March 2022, China National Medical Products Administration (NMPA) updated the notification information of one new cosmetic ingredient (NCI). The basic information of the new NCI is as follows:

Basic Information	
INCI Name	Chenopodium formosanum Extract
CAS No.	/
Purpose of Use	Skin protectant
Applicable Scope	All kinds of cosmetics
The Maximum Concentration	≤0.7%
Notifier	Baiyuet Biotechnology (Shanghai) Co., Ltd.

2.2 China NIFDC Consults on Limitation of Benzene in Cosmetics

- Issue date: 2022.03.10
- Deadline for comments: 2022.03.31
- Source: Official Notice

To strengthen the management of safety risk substances in cosmetics, on Mar. 10, 2022, China National Institutes for Food and Drug Control (NIFDC) released an announcement seeking public comments on **benzene** (CAS No. 71-43-2) limitation requirements. According to the risk assessment results, **the limit of benzene in cosmetics is proposed to be 2mg/kg**.

The limit of 2mg/kg proposed by China NIFDC is in line with the residue limits for benzene in pharmaceutical products set out in the *ICH Guidelines Q3C (R6) on Impurities: Guideline for Residual Solvents* of the European Medicines Agency. If the limit takes effect in the future, when benzene is present in cosmetics as an impurity, which during the production process cannot be technically avoided, the content shall not exceed 2 mg/kg. According to Inna Fu, Technical Lead of REACH24H Cosmetic Division, it may also be necessary to test for benzene levels or identify the hazards of benzene when conducting cosmetics safety assessment. According to Inna Fu, Technical Lead of REACH24H Cosmetic Division, it may also be necessary to test for benzene levels or identify the hazards of benzene when conducting cosmetics safety assessment.

2.3 China NIFDC Consults on Safety and Technical Standards for Cosmetics 2022

- Date: 2022.03.31
- Deadline for comments: 2022.04.30
- Source: Official Notice

On March 31, 2022, China National Institutes for Food and Drug Control (NIFDC) released a draft of the Safety and Technical Standard for Cosmetics 2022 (draft STSC 2022) for public comments. The consultation will end on April 30, 2022.

Compared with the 2015 version, the framework of the 2022 version remains basically unchanged. The draft STSC 2022 revises the content that is not suitable for the current supervision practice, retains the content that still applies, incorporates the previous approved revisions for STSC 2015 (they were issued as notifications), as well as standardizes and improves some terms and expressions.

In the draft STSC 2022, the changes to cosmetic ingredients are mainly reflected in:

Chapter	STSC 2015	Draft STSC 2022
Chapter 2 Prohibited / Restricted Ingredients Used in Cosmetics	• 1290 prohibited ingredients • 98 prohibited plant (animal) ingredients • 47 restricted ingredients	• 1284 prohibited ingredients • 109 prohibited plant (animal) ingredients • 44 restricted ingredients
Chapter 3 Permitted Ingredients Used in Cosmetics	• 51 permitted preservatives • 27 permitted sunscreens • 157 permitted colorants • 75 permitted hair dyes	• 48 permitted preservatives • 26 permitted sunscreens • 156 permitted colorants • 73 permitted hair dyes

Chapter 3. Labeling / Claim / Packaging / Advertising

3.1 Children Cosmetics Logo is Not a Product Quality Certification Mark

- Issue date: 2022.03.07
- Source: Official Notice

On March 7, NMPA released a popular science article to help consumers correctly understand the meaning of the children cosmetic logo, Little Golden Shield. "Little Golden Shield" is a symbol that distinguishes children cosmetics from adult cosmetics, disinfection products, and toys. From May 1, 2022, children cosmetics that apply for registration/notification must be labeled with the logo. For those that applied for registration/notification before May 1, 2022, the registrant / notifier shall update the label before May 1, 2023. Non-children cosmetics shall not be labeled with this logo.

Labeling "Little Golden Shield" on the cosmetic packaging only indicates that the product belongs to children cosmetics, **but does not mean that the product has been approved by the regulatory authorities or certified for quality and safety**.

Chapter 4. Safety / Test Requirements

4.1 China NIFDC Consults on Safety and Technical Standards for Cosmetics 2022

- Date: 2022.03.31
- Deadline for comments: 2022.04.30
- Source: Official Notice

On March 31, 2022, China National Institutes for Food and Drug Control (NIFDC) released a draft of the Safety and Technical Standard for Cosmetics 2022 (draft STSC 2022) for public comments. The consultation will end on April 30, 2022.

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Regarding the safety and test requirements, the main changes in the draft STSC 2022 lie in:

Chapter	STSC 2015	Draft STSC 2022
Chapter 4 Physical and Chemical Test Methods	77 methods	67 methods
Chapter 6 Toxicological Test Methods	16 methods	24 methods
Chapter 8 Human Body Efficacy Evaluation Test Method	3 methods	5 methods

Chapter 5. Other Noteworthy Information

5.1 China NMPA Consults on the Inspection Points and Judgment Principles of Cosmetic Good Manufacturing Practices

- Issue date: 2022.03.30
- Deadline for comments: 2022.04.20

- Source: Official Notice

On January 7, 2022, China NMPA issued the finalized *Good Manufacturing Practices for Cosmetics* and will implement it on July 1, 2022. Cosmetics registrants, notifiers, and entrusted production enterprises shall organize the cosmetic production in accordance with the Practices. Following that, on March 30, 2022, NMPA released the draft of *Inspection Points and Judgment Principles of Cosmetic Good Manufacturing Practices* (the *Points*) for public consultation. Regulatory authorities across China will use the Points as a basis to determine whether the enterprise complies with GMP.

The *Points* introduces the classification of inspection, and lays down the principles for judging whether an enterprise complies with GMP in each inspection situation. According to the *Points*, the inspection can be classified into:

a) On-site inspection for issuing production license
b) On-site inspection after the production license is renewed
c) Routine supervision and inspection

The judgment principles are based on the severity and proportion of non-compliance items. It is worth noting that **if one core item is not compliant, the enterprise's production license will be revoked, or the enterprise will be punished**. The supervision for non-compliance behaviors will be more stringent.

Along with judging principles, detailed inspection points are also introduced in the *Points*. The inspection points are divided into two versions, one for manufacturing enterprises and the other for entrusting enterprises.

a) The inspection points for manufacturing enterprises cover six major parts: departments and personnel, quality assurance and control, plant facility and equipment management, material and product management, production process management, and product sales management;
b) The inspection points for the entrusting enterprises center on the person in charge of quality and safety, the quality management system and the quality control system.

5.2 China NMPA Answers Key Questions on Cosmetic Supervision and Administration

- Issue date: 2022.03.10
- Source: Official Notice

On March 10, 2022, China NMPA issued an announcement, answering frequently asked questions about ingredient safety information, efficacy claim evaluation and sample retention.

1. Ingredient's Safety Information

With the launch of the cosmetic ingredients safety information submission platform (the submission platform), the ingredient enterprises can easily submit the ingredient's safety information uniformly, and obtain the

ingredient submission codes. Cosmetic registrants and notifiers just need to fill in the ingredient submission code provided by the ingredient manufacturers, then the platform will help match the ingredients' safety information documents. If any ingredient currently has no submission code, cosmetic registrants and notifiers can submit relevant ingredient safety information on the cosmetics registration and notification information service platform

2. Efficacy Claim Evaluation

For the major efficacy claims of cosmetics on the market, which can be directly recognized by vision, smell or other senses or function through physical covering, adhesion, friction, etc., they can be exempted from efficacy evaluation. Only for a few claims, which have strong functions and are strictly managed as drugs or quasi-drugs in most countries and regions, the human body efficacy evaluation test is required. For other efficacy claims, the evaluation can be based on literature review, research data analysis, or cosmetic efficacy claim evaluation tests as appropriate.

For cosmetics that have been registered and notified before May 1, 2021, if the content of the efficacy claim involved in the product name or label cannot be supported by the evaluation result, a change application can be filed before **May 1, 2021**.

3. Sample Retention

NMPA has given a reference to the sample retention quantity of 10 categories of products for cosmetics registrants and notifiers. According to this reference, the quantity of retained samples shall not be less than three packages, while the number of milliliters of retained samples may vary according to its category. For other types of products, cosmetics registrants and notifiers shall determine the sample retention quantity by themselves according to regulatory requirements.

Cosmetics registrants and notifiers involved in entrusted production shall retain samples in their respective domicile or main business premise, or in other business premises where their respective domicile or main business premise is located. If the responsible person in China keeps the retained samples, the selection of the location for retained samples shall follow the provisions above. The selection of the sample retention site shall meet the requirements of laws and regulations, as well as the product storage requirements indicated on labels.

Part 2. Regulation Updates: South Korea

Chapter 1. Notification / Registration Requirements

No updates

Chapter 2. Ingredients

No updates

Chapter 3. Labeling / Claim / Packaging / Advertising

3.1 MOE discloses the Notice on Submitting the Delivery and Import Records of Recycled Package

- Issue date: 2022.03.29
- Source: Official Notice

On March 29, 2022, the Ministry of Environment (MOE) published the notice on submitting the delivery and import records of recycled packages and products. Enterprises whose products and packaging are subject to recycling shall submit the delivery and import records of 2021 via the EPR online system before **April 15, 2022**.

The notice specifies the data to be submitted as well as the situations of exemptions from data submission. For producers obligated to recycle, they shall submit records of delivered or imported quantity of the products and packing materials subject to recyclability, and other required documents. For enterprises eligible for exemption from data submission, they shall submit the "Confirmation Form of the Exception from Recyclability Obligation" and other required documents. The exemption situations are:

<table>
<tr><th>Category</th><th>Entity</th><th colspan="5">Exemption Situations</th></tr>
<tr><td rowspan="5">Packing Materials [including the five kinds of films (except the PVC film)]</td><td rowspan="5">Manufacturer or importer of the products whose packaging materials are subject to recyclability or the five kinds of films</td><td colspan="2">Types</td><td>Paper packs, metal cans, synthetic resin materials</td><td>Foamed synthetic resin materials</td><td>Glass bottles</td></tr>
<tr><td rowspan="2">Manufacturer</td><td>Sales amount</td><td colspan="3">Less than 1 billion won (about 822 thousand dollars)</td></tr>
<tr><td>Delivery quantity</td><td>Less than 4 tons</td><td>Less than 0.8 tons</td><td>Less than 10 tons</td></tr>
<tr><td rowspan="2">Importer</td><td>Import amount</td><td colspan="3">Less than 300 million won (about 247 thousand dollars)</td></tr>
<tr><td>Delivery quantity</td><td>Less than 1 ton</td><td>Less than 0.3 tons</td><td>Less than 3 tons</td></tr>
</table>

Products	Manufacturer or importer of the products subject to recyclability	-

Regarding the products and packing materials subject to recyclability obligation, MOE also provided a clarification in the notice. According to MOE, **cosmetics, medicine and quasi drugs in paper packs, glass bottles or metal cans are subject to recyclability obligation**.

Chapter 4. Safety / Test Requirements

No updates

Part 3. Regulation Updates: Thailand

Chapter 1. Notification / Registration Requirements

No updates

Chapter 2. Ingredients

2.1 Thailand Updates Cosmetic Ingredients Lists

- Issue date: 2022.02.28
- Effective date: 2022.03.01
- Source: Official Document

On February 28, 2022, Thailand's Ministry of Public Health (MOPH) announced to amend the cosmetic ingredient standards in *Cosmetic Act B.E. 2015*.

Details of the amendments are as follows (*strikethrough indicates removal from the previous standards*):

1. List of Prohibited Ingredients for Use in Cosmetics

The exception conditions for the following two prohibited ingredients have been reduced from two to one.

Entry No.	Before Amending	After Amending
221	Mercury (CAS No. 7439-97-6) and its compounds, except: ~~a) The object specified in the List of Restricted Ingredients for Use in Cosmetics. (E.g. Thiomersal used as a preservative.)~~ b) Contaminants in finished products that is no more than 1 ppm or 1 mg/kg.	Mercury (CAS No. 7439-97-6) and its compounds, except for the contaminants in finished products that is no more than 1 ppm or 1 mg/kg.
289	Lead (CAS No. 7439-92-1) and its compounds, except: ~~a) The object specified included in the List of Restricted Ingredients for Use in Cosmetics. (E.g. Lead acetate used in hair products.)~~ b) Contaminants in finished products that is no more than 20 ppm or 20 mg/kg.	Lead (CAS No. 7439-92-1) and its compounds, except for the contaminants in finished products that is no more than 20 ppm or 20 mg/kg.

Seven prohibited ingredients have been newly added. They are:

a) Paraformaldehyde (CAS No. 30525-89-4)
b) Methanediol; methylene glycol (CAS No. 463-57-0)
c) 1,2,4 -Trihydroxybenzene (CAS No. 533-73-3), when used as a substance in hair dye products
d) 4-Amino-3-hydroxytoluene (CAS No. 2835-98-5) when used as a substance in hair dye products
e) 2-[(4-Amino-2-nitrophenyl)-amino]-benzoic acid (CAS No. 117907-43-4) when used as a substance in hair dye products
f) Formaldehyde (CAS No. 50-00-0)

The amendments to above-mentioned nine ingredients are subject to a **grace period until August 28, 2022**.

2. List of Restricted Ingredients for Use in Cosmetics

The maximum concentration limit for the ingredient Piroctone Olamine in leave-on products has been raised from 0.1% to 0.5%. The entries of Formaldehyde (CAS No. 50-00-0) and Lead Acetate have been removed from the *List of Restricted Ingredients for Use in Cosmetics*, and cosmetic stakeholders who have manufactured, imported, or sold products that contain these two ingredients before March 1, 2022, shall comply with this new requirement **within 180 days thereafter**.

In addition, two new restricted ingredients having been added with use restriction:

	Substances		Conditions	

Entry No.	Chemical Name	Name of Common Ingredients Glossary	CAS No.	Field of application and/or use		Warnings on the label
202	2-Hydroxyethyl Methacrylate	HEMA	868-77-9	Nail Products	Professional use only	a) Can cause an allergic reaction b) For professional use only
203	11,14-Dioxa-2,9-diazaheptadec-16-enoic acid, 4,4,6,16-tetramethyl-10,15-dioxo, 2-[(2-methyl-1-oxo-2-propenyl) oxy]ethyl ester	DI-HEMA TRIMETHYLHEXYL DICARBAMATE	41137-60-4 / 72869-86-4	Nail Products	Professional use only	a) Can cause an allergic reaction b) For professional use only
Grace period: February 28, 2023 (12 months)						

3. List of Preservatives Allowed for Use in Cosmetics

Three entries of ingredients from the *List of Preservatives Allowed for Use in Cosmetics* have been deleted and their labeling requirements were abolished accordingly. This amendment is subject to **a grace period of 6 months until August 28, 2022**.

The deleted preservatives are:

a) Formaldehyde (CAS No. 50-00-0) and Paraformaldehyde (CAS No. 30525-89-4)
b) Thiomersal (CAS No. 54-64-8)
c) Phenylmercuric salts, including borate (CAS No. 62-38-4 / 94-43-9)

Chapter 3. Labeling / Claim / Packaging / Advertising

No updates

Chapter 4. Safety / Test Requirements

No updates

Part 4. Regulation Updates: Indonesia

Chapter 1. Notification / Registration Requirements

No updates

Chapter 2. Ingredients

2.1 Indonesia Releases Draft Amendments to Cosmetic Ingredient Use Requirements

- Issue date: 2022.03.29
- Deadline for comments: 2022.04.01
- Source: Official Notice

On March 29, Indonesia BPOM released the second draft amendments to *Technical Requirements for Cosmetics Ingredients* for public consultation. The main amendments include:

1. **Revising the general requirements for prohibited cosmetic ingredients and adding 230 prohibited cosmetic ingredients**

In the new draft, the following changes to the scope of prohibited cosmetic ingredients are made (changes are marked in red):

- Ingredients listed in Appendix II, III and IV not used as the colorant, preservative and sunscreen agent, and do not comply with the requirements listed in Appendix II, III and IV;
- Colorants not listed in Appendix II, except for hair dyes only for dyeing hair.

In addition, the prohibited cosmetic ingredients in Appendix V are increased from 1,375 to 1,605, with 230 ingredients newly being added.

2. **Revising the use requirements of other ingredients and natural ingredients**

If business actors intend to use other ingredients or natural ingredients in cosmetics, in addition to scientific or empirical evidence, **a policy recommendation on ingredient safety / efficacy / quality issued by Directorate of Standardization of Traditional Medicines, Health Supplements and Cosmetics is newly required**.

To apply for a policy recommendation, business actors need to submit the following documents:

a) The application letter for the issuance of a policy recommendation on ingredient safety / efficacy / quality;
b) Supporting data on ingredient safety / efficacy / quality.

3. Adding 5 restricted ingredients to and deleting 1 restricted ingredient from Appendix I

In Appendix I, the restricted ingredient Formaldehyde (50-00-0) was deleted, and five ingredients were newly included. The newly included restricted ingredients are:

a) Tagetes minuta flower extract (CAS No. 91770-75-1); Tagetes minuta flower oil (CAS No. 91770-75-1 / 8016-84-0);
b) Tagetes patula flower extract (CAS No. 91722-29-1); Tagetes patula flower oil (CAS No. 91722-29-1 / 8016-84-0);
c) Tagetes erecta flower extract (CAS No. 90131-43-4); Tagetes erecta flower oil (CAS No. 90131-43-4);
d) Hydroxyethyl Methacrylate / HEMA (CAS No. 868-77-9);
e) 11,14-Dioxa-2,9-diazaheptadec-16-enoic Acid, 4,4,6,16-tetramethyl-10,15-dioxo, 2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl ester / Di-HEMA Trimethylhexyl Dicarbamate (CAS No. 41137-60-4 / 72869-86-4)

4. Adding 2 permitted sunscreens in Appendix IV

No.	Ref No. in ACD	Substance	Maximum Authorised concentration	Other limitations and requirements
31	30	3,3-(1,4-Phenylene) bis (5,6-diphenyl-1,2,4-triazine) Phenylene Bis-Diphe-nyltriazine (INCI) CAS No. 5514-22-2	5%	Not to be used in application that may lead to exposure of the end user's lungs by inhalation.
32	31	2-ethoxyethyl (2Z)-2-cyano-2-[3-(3-methoxypropylamino) cyclohex-2-en-1-ylidene]acetate Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate CAS No. 1419401-88-9	3%	- Not to be used in application that may lead to exposure of the end-user's lungs by inhalation. - Maximum nitrosamine content: 50µg/kg (in raw material terms); - Kept in nitrite-free containers.

Chapter 3. Labeling / Claim / Packaging / Advertising

3.1 Indonesia Unveils New Halal Label Logo

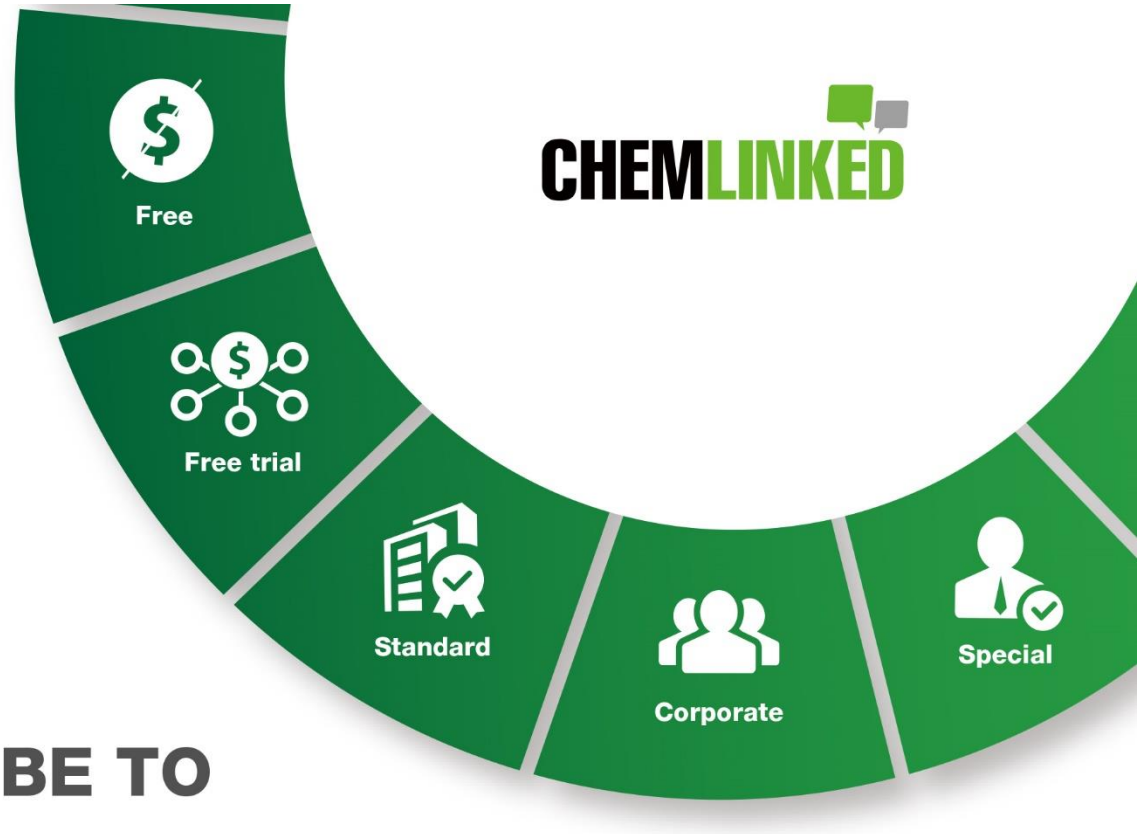
- Issue date: 2022.03.13
- Effective date: 2022.03.01
- Source: Official Notice

On March 13, 2022, Indonesia Halal Product Guarantee Agency (BPJPH) announced to set a new halal label logo, which is stipulated in *BPJPH Number 40 of 2022 regarding the Determination of Halal Labels*. The new halal logo has been applied nationally and must be shown on the product packaging as a sign of product halalness from **March 1, 2022**. For halal-certificated products in stock, which were manufactured and packaged with the former halal logo before the implementation of the new logo, they are allowed to be sold first.

In Indonesia, the halal logo must be contained on halal label to show the halalness of the product and ensure it is easier for consumers to identify halal products. Halal certification started on a voluntary basis for cosmetic products on Oct. 17, 2021 and will **become mandatory since Oct. 17, 2026**. The certification applies to both domestic and imported products.

Chapter 4. Safety / Test Requirements

No updates



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