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Guidelines for Research and Determination of Safe Consumption History of New Cosmetic Ingredients (Trial)

化妆品新原料安全食用历史研究和判定指南（试行）

National Institutes for Food and Drug Control

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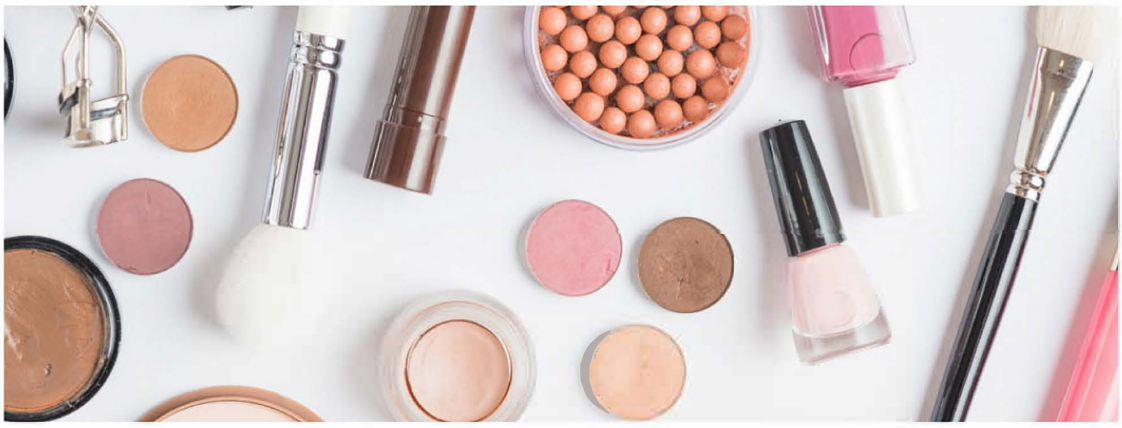

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Attachment 2

Guidelines for Research and Determination of Safe Consumption History of New Cosmetic Ingredients (Trial)

National Institutes for Food and Drug Control

I. Overview

New ingredients are classified into different situations based on their characteristics, functions, use history, consumption history, *etc.*, in the *Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers* (hereinafter referred to as the *Dossier Provisions*), and corresponding toxicological test item requirements are proposed based on risk management concepts. New ingredients with a safe consumption history may be exempted from corresponding toxicological test items as their safe consumption history can to some extent serves as available data information on toxicological endpoints of systemic toxicity. In safety assessment, the use safety of new ingredients in cosmetics can be analyzed and assessed by combining the safe consumption history and relevant data adopted.

For the purpose of standardizing the research and evaluation of new cosmetic ingredients, guiding the collection, determination and application in safety assessment of safe consumption history dossiers of ingredients, and leading registrants and notifiers to reasonably choose corresponding situations when applying for registration or handling notification of new ingredients, these guidelines are hereby formulated in accordance with the requirements of the *Cosmetic Supervision and Administration Regulations* (*CSAR*), *Administrative Measures on Cosmetic Registration and Notification*, *Dossier Provisions* and relevant regulations.

These guidelines are formulated based on current regulations and standards, and level of scientific understanding, and the applicability thereof shall follow the principle of specific analysis of specific issues. In addition to the forms specified in these guidelines, registrants and notifiers of new ingredients may choose other scientific and effective data information depending on actual situations, but shall provide scientific and reasonable basis and fully describe that the new ingredients to be registered or notified have a sufficient safe consumption history. Adjustment will be made to these guidelines in a timely manner with the updating and improvement of regulations and standards, and development of science and technology.

II. Application Scope

These guidelines apply to the research and determination of safe consumption history of

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+ Cosmetic formula and label compliance review
+ EDI Notification
+ Cosmetic QC test service
+ Functional cosmetic registration
+ Ingredients registration by ICID

+ Marketing license application
+ Cosmetics notification
+ Ingredients analysis and full ingredient list translation
+ Cosmetic test service
+ Label & advertisement review

+ Responsible Person (RP) service in the EU & UK
+ Cosmetic Product Notification Portal (CPNP)
+ Cosmetic Product Safety Report (CPSR)
+ Preparation of Product Information File (PIF)

+ Cosmetic formula and label compliance review
+ FDA Voluntary Cosmetic Registration Program (VCRP)
+ California Safe Cosmetics Program (CSCP)
+ Toxicological Risk Assessment (TRA)
+ INCI application

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附件 2

化妆品新原料安全食用历史

研究和判定指南（试行）

中国食品药品检定研究院

一、概述

在《化妆品新原料注册备案资料管理规定》（以下简称《资料规定》）中，根据原料特性、功能、使用历史、食用历史等情况，将新原料分为不同情形，并基于风险管理理念提出相应毒理学试验项目要求。其中，对于具有安全食用历史的新原料，其安全食用历史能够一定程度上作为系统毒性相关毒理学终点的可用数据信息，从而减免相应的毒理学试验项目。在安全评估中，可结合所采用的安全食用历史及相关数据，对新原料在化妆品中使用时的安全性进行分析和评估。

为规范化妆品新原料研究和评价，指导原料安全食用历史相关资料的收集、判定以及在安全评估中的应用，引导注册人、备案人（以下简称注备人）在新原料申请注册或进行备案时合理选择对应情形，根据《化妆品监督管理条例》《化妆品注册备案管理办法》《资料规定》及相关法规要求，制定本指南。

本指南是在现行法规和标准以及当前科学认知水平下制定，其适用性应遵循具体问题具体分析原则。除本指南明确的形式外，新原料注备人可根据实际情况选用其他科学有效的数据信息，但应具有科学合理的依据，并能够充分说明拟注册备案新原料具有充足的安全食用历史。随着法规和标准更新完善，以及科学技术发展，将适时进行调整。

二、适用范围

本指南适用于化妆品新原料安全食用历史的研究和判定。

化妆品新原料注备人应在遵循相关法规和技术标准的前提下，使用本指南。如同时符合其他技术指南或指导原则适用范围的，还应同时参考相关技术要求。

三、一般原则

注备人应对新原料安全食用历史开展全面、充分的研究，应采用最新依据资料和研究数据，特别是对于安全风险较高、食用安全性存在一定争议的原料，应对原料毒性信息进行全面研究。在此基础上，结合拟注册备案新原料的实际情况进行合理分析和安全评估。

经研究，如能够获得充足、确切的安全食用历史证明资料，且能够支持拟注册备案新原料的安全评估，可按照《资料规定》中的对应情形申请注册或进行备案，同时应按照《资料规定》要求，提交相应的安全食用历史、毒理学试验和安全评估等相关资料。相关资料的真实性、准确性、完整性和可追溯性由新原料注备人负责。

四、安全食用历史证明资料基本要求

安全食用历史的证明材料应来源于相关领域监督管理部门或权威技术机构，注备人应结合拟注册备案新原料进行具体分析，确保原料或制备该原料的原材料有可安全食用的特性，

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