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Answers for Questions about Guidelines for the Research and Determination of the 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）》问答

National Institutes for Food and Drug Control

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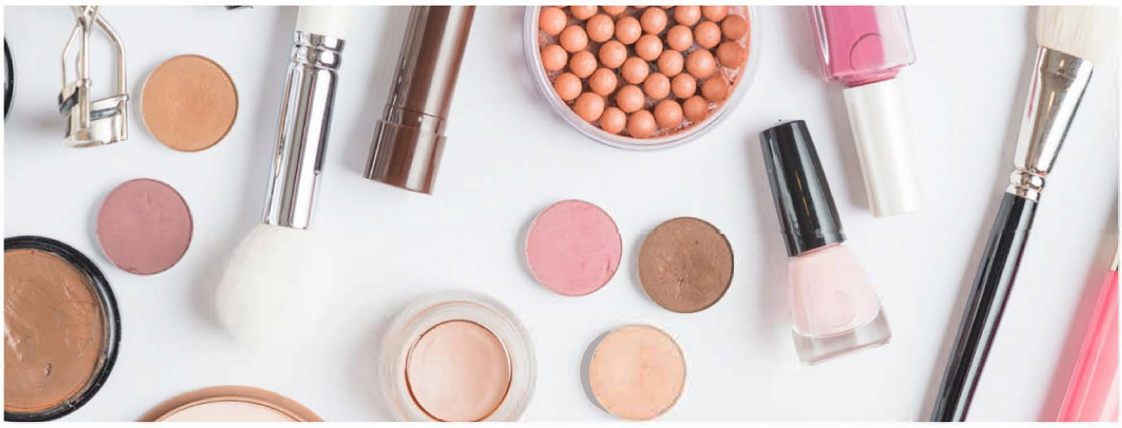

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Answers for Questions about the *Guidelines for Research and Determination of Safe Consumption History of New Cosmetic Ingredients (Trial)*

I. What is the background of formulation of the *Guidelines*?

According to the *CSAR*, application for registration or handling of notification of new cosmetic ingredients shall submit safety assessment dossiers for the new ingredients. New ingredients with a sufficient safe consumption history may be exempted from some toxicological test items.

In order to implement the *Provisions on Supporting Innovation in Cosmetic Ingredients* published by the National Medical Products Administration and strengthen the utilization of existing data, the National Institutes for Food and Drug Control has organized the formulation of the *Guidelines for Research and Determination of Safe Consumption History of New Cosmetic Ingredients (Trial)* (hereinafter referred to as the *Guidelines*), providing technical guidance for the collection, determination and application in safety assessment of safe consumption history related dossiers.

II. What are the requirements for the source of proof materials of safe consumption history?

The proof materials of safe consumption history shall come from supervision and administration departments in the fields of food, agriculture, health, *etc.*, or technical institutions with functions or technical capabilities related to food safety risk assessment. Such materials shall have certain authority and generally be publicly released data information (e.g., announcements, notices, technical standards, *etc.*). The above-mentioned supervision and administration departments shall refer to those at the ministerial and provincial level or above in China, and national level abroad; the technical institutions shall refer to the internationally recognized authoritative institutions or organizations.

In addition, at the time of using the proof materials of safe consumption history, comprehensive analysis shall be conducted on the background and specific contents of the cited materials, as well as relevant food safety administration requirements, fully describing the relevant situations of safe consumption.

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《化妆品新原料安全食用历史研究和判定指南（试行）》问答

一、《化妆品新原料安全食用历史研究和判定指南（试行）》的制定背景是什么?

根据《化妆品监督管理条例》，申请化妆品新原料注册或者进行化妆品新原料备案时，应当提交新原料安全评估资料。其中，对于具有充足的安全食用历史的新原料，能够减免部分毒理学试验项目。

为落实国家药监局《支持化妆品原料创新若干规定》，加强已有数据利用，中检院组织制定《化妆品新原料安全食用历史研究和判定指南（试行）》（以下简称《指南》），为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提供技术指导。

二、安全食用历史证明资料来源有什么要求?

安全食用历史证明资料应来源于食品、农业、卫生等相关领域的监督管理部门，或具有食品安全风险评估相关职能或技术能力的技术机构，应具有一定权威性，且一般应是公开发布的数据信息（如公告、通知、技术标准等）。其中，我国监督管理部门应为省部级及以上；国外监督管理部门应为国家级；技术机构应为国际公认的权威机构或组织。

此外，在采用安全食用历史证明资料时，应同时对引用资料背景、具体资料内容、食品安全监管相关要求等进行全面分析，充分说明可安全食用的有关情况。

三、拟注册备案新原料与安全食用历史中载明的食品原料应有何一致性或相关性?

拟注册备案新原料应与安全食用历史证明资料中载明的食品原料具有一致性或相关性，新原料注册人、备案人（以下简称注备人）应结合安全食用历史证明资料以及拟注册备案新原料有关情况进行分析。

需要指出的是，如加工方式与食品食用加工方式不一致（如使用其他溶剂提取等），应结合具体的工艺类型，对组成成分及富集情况、残留溶剂等进行分析；对生物发酵类新原料，应提供最终获得的发酵产物可安全食用的相关证明资料。

四、常见的安全食用历史证明资料有哪些?

常见的安全食用历史主要来自普通食品原料、地方特色食品原料、新食品原料、药食同源原料、保健食品原料等。为指导新原料注备人收集和利用相关信息，在《指南》中列举了部分常见证明资料及其基本要求。

其中，考虑到部分普通食品原料可能缺少官方发布的相关依据，新原料注备人可说明相关情况，提供已在我国境内作为普通食品原料上市销售的相关证明材料，并对安全食用情况等进行分析说明。所提供证明资料应具有关联性、可追溯性，并能够准确体现与拟注册备案新原料的一致性或相关性。

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