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

《化妆品新原料安全使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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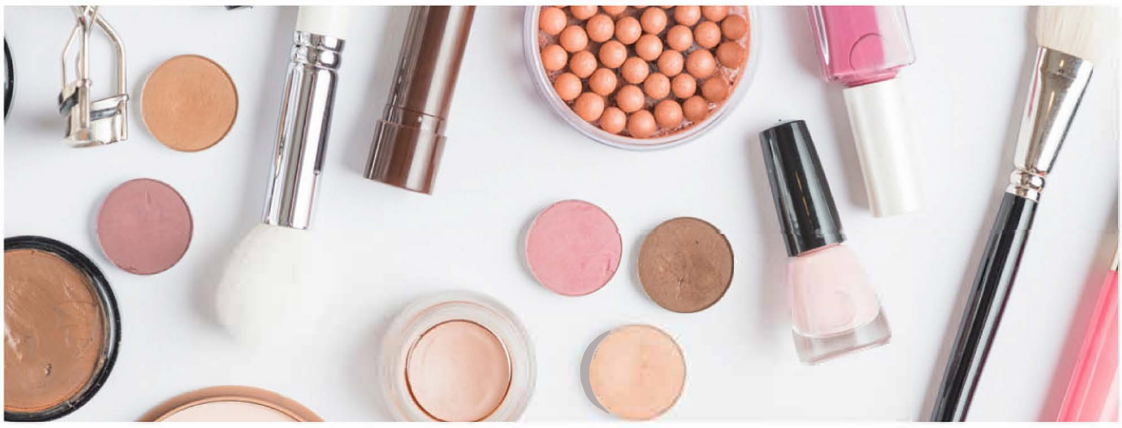

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Answers for Questions about the *Guidelines for Research and Determination of Safe Use History of New Cosmetic Ingredients (Trial)*

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 history of safe use in cosmetics 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 Use 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 use history related dossiers.

II. Do new ingredients to be registered or notified need to be completely consistent with the ingredients in the safe use history?

Registrants and notifiers of new ingredients shall conduct analysis on consistency of ingredients from the aspects of ingredient source, production technique, ingredient composition, quality specification, *etc.* For new ingredients with clear single chemical structures, consistency shall be ensured in terms of the molecular formula, structural formula and other key information. If the production technique is adjusted as a result of improvement of ingredient quality, environmental friendliness and other reasons, comprehensive analysis shall be conducted on the ingredient content (purity), impurity composition and other possible changes based on the technique adjustment. Other types of new ingredients, such as plant extracts, microbiological fermentation products, high-molecular polymers, *etc.*, shall be ensured that the ingredients in the cited proof materials of safe use history are consistent with the new ingredients to be registered or

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《化妆品新原料安全使用历史研究和判定指南（试行）》问答

一、《化妆品新原料安全使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，对于在化妆品中已有充足的安全使用历史的新原料，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《化妆品新原料安全使用历史研究和判定指南（试行）》（以下简称《指南》），为安全使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、拟注册备案新原料是否需要与安全使用历史中的原料完全一致?

新原料注册人、备案人（以下简称注备人）应从原料来源、生产工艺、原料组成、质量规格等方面进行原料一致性分析。对于具有明确单一化学结构的新原料，应确保分子式、结构式等关键信息一致；因原料质量提升、环境友好等原因对生产工艺进行调整的，应结合工艺调整情况，对原料含量（纯度）、杂质组成及其他可能产生的变化情况进行全面分析。对于其他类型的新原料，如植物提取物、微生物发酵产物、高分子聚合物等，则应确保所引用安全使用历史证明资料中原料与拟注册备案新原料一致。

此外，对于实际以复配形式进行销售的，应分析复配原料中其他成分对功效、安全等可能产生的影响，充分考虑作为拟注册备案新原料安全使用历史依据的科学合理性。

三、安全使用历史证明资料中的已上市化妆品有什么要求?

安全使用历史证明资料中的已上市化妆品应符合我国法规对于化妆品的定义范畴。当产品在境外不按照化妆品管理但符合我国化妆品定义时，应提供相关产品在境外的监管背景、法规要求以及产品功效、作用机理等相关资料，并对符合我国化妆品定义的有关情况进行分析说明。此外，已上市化妆品的原料使用浓度、使用部位、使用方法等应能够支持注册备案资料中填报的适用或使用范围、安全使用量等相关信息。

四、已上市化妆品的上市时间和使用数量有什么要求?

已上市化妆品上市时间应不少于 3 年，可以是同一款产品连续销售满 3 年及以上，或者多款产品累计连续销售满 3 年及以上。如产品上市时间较早，应充分考虑相关信息的可靠性和可追溯性。

此外，应确保相关产品具有足够的使用数量。原则上，如采用终端零售化妆品销售数量（即消费者实际购买数量），则 3 年累计销售数量不得低于 10000 件，其中每年不得低于 3000 件；如采用间接销售数据，如化妆品生产企业出厂量、分销商销售量等，则 3 年累计销售数量不得低于 100000 件，其中每年不得低于 30000 件。

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