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Key compliance issues under the New Cosmetics Regulations

Background: China has enacted several new regulations for the cosmetic industry in recent years and has gradually improved the legislation system in respect to cosmetics. This has established a regulatory foundation for enterprises engaged in cosmetic production and operation to refine their management, clarify their responsibilities, encourage innovation, and strengthen their supervision. With the emergence of the "Cruelty Free" concept in the global beauty industry, a series of laws and regulations in relation to animal testing have been gradually promulgated, which, to some extent, advance the legislative process relating to cosmetic products in China. In combination with the new cosmetic regulations and our relevant practical experience, this article aims to help enterprises engaged in the production and operation of cosmetics understand certain key compliance issues regarding the new regulations.

I. Brief introduction to the recent legislative process

The *Cosmetics Supervision and Administration Regulations* (the "**Regulations**") were formally promulgated on January 3, 2020 and came into effect on January 1, 2021. The Regulations replace the *Regulations on the Hygiene Supervision over Cosmetics* and establish the registration and filing management system for cosmetics and their raw materials. On December 31, 2020, the *Administrative Measures for the Registration and Record Filing of Cosmetics* (the "**Administrative Measures**") were approved by the State Administration for Market Supervision and provides specific implementation measures to the principle rules stipulated under the Regulations. On February 26, 2021, the National Medical Products Administration issued the *Administrative Provisions on the Registration and Filing Materials for Cosmetics* ("**Administrative Provisions for Cosmetics**") and the *Regulations on the Administrative Provisions on the Registration and Filing Materials for New Cosmetic Raw Materials* ("**Administrative Provisions for Raw Materials**") which further provide implementation rules for the Administrative Measures. The Administrative Measures and the above-mentioned two administrative provisions will come into effect on May 1, 2021.

II. Special safety supervision on the raw materials in new cosmetics

The Regulations implement risk classification management for raw materials in new cosmetics.

The registration requirement applies to the raw materials in new cosmetics such as those with anti-corrosion, sunscreen, coloring, hair dye, pigmentation, and whitening functions only, while the filing requirement applies to other raw materials in new cosmetics. The registered or filed raw materials in new cosmetics that are free from safety concerns within three years of first use shall be included in the catalog of used cosmetic raw materials. In practice, it is extremely difficult to obtain registration approval for raw materials in new cosmetics in recent years; the Regulations may change this. The Administrative Measures have established a safety monitoring system with a three-year safety monitoring period (calculated from the date upon the completion of the registration or filing of the cosmetics that use new raw materials; in the course of the safety monitoring period, the registrants and filing obligors of the raw materials for new cosmetics may use such new raw materials to produce cosmetic products). In addition, the Administrative Measures and Administrative Provisions for Raw Materials have established a continuous monitoring and evaluation system, refining the requirements for the registration and filing material management for new raw materials and the obligations on monitoring and reporting, and the specifications of technical material preparation on new raw materials.

III. Exemption of animal testing for imported cosmetics

As early as 2013, the *Notice on the Adjustment of Cosmetics Registration and Filing related Matters* promulgated by the China Food and Drug Administration no longer imposed compulsory animal testing for domestic non-special cosmetics whose risk evaluation results could fully reflect the product safety, which did not apply to imported cosmetics. In 2016 and 2018, certain exceptions for the retail and importation of cross-border e-commerce cosmetics were applied. The Administrative Provisions for Cosmetics explicitly exempts imported ordinary cosmetics from animal testing subject to certain conditions. In accordance with the Administrative Provisions for Cosmetics, for ordinary cosmetics (except for hair dyeing, hair perming, pigmentation and whitening, sunscreen, anti-hair loss cosmetics or cosmetics without a declaration of new functions), a manufacturer may be exempt from submitting a toxicology test report of such ordinary cosmetics if it has obtained the relevant qualification certificates in production quality management ("GMP certification") issued by the competent governmental authorities of the country (region) where they are located, and the product safety risk evaluation results can fully reflect the safety of such cosmetic products. However, the cosmetics shall meet the three "N" s: non-infant and non-child products, no use of new raw materials within the safety monitoring period and non-supervised products. Where animal testing exemption is available, the time for the qualified ordinary cosmetics manufacturers to complete the filing of imported ordinary cosmetics can be effectively shortened provided they have obtained the GMP certification acceptable to the National Medical Products Administration.

IV. Quality and safety responsibilities of registrants and filing obligors

The Administrative Measures stipulate that the registrants and filing obligors of cosmetics and new cosmetic raw materials shall perform registration and filing obligations by law and be responsible for the quality and safety of the relevant products. For instance, cosmetic registrants and filing obligors shall specify the product standards and submit them to the relevant medical products administration authority during the application process for registration or filing; the applicants for cosmetics registration and filing shall entrust qualified institutions to conduct testing by law; registrants and filing obligors shall ensure the safety of the raw materials during the production of cosmetics with new cosmetics raw materials; registrants and filing obligors of the who use raw materials in new cosmetics in the

production shall (i) promptly report the use and safety of raw materials in new cosmetics to the registrants and filing obligors; and (ii) take immediate measures to control risks, notify the registrants and filing obligors of the raw materials for new cosmetics and perform reporting obligations when relevant adverse effects and/or safety problems occur. Overseas registrants and filing obligors shall appoint a domestic enterprise as the domestic responsible party; the domestically responsible party shall assume quality and safety responsibilities for the cosmetics and the raw materials for new cosmetics distributed in the domestic market in accordance with the agreements entered into with the registrants and filing obligors.

V. Conclusion and suggestions

As discussed above, we propose the following specific suggestions for relevant companies in the cosmetic industry to avoid compliance risks:

1. Study the relevant regulations such as the implemental rules of the Regulations, the Administrative Measures, Administrative Provisions for Cosmetics and Administrative Provisions for Raw Materials, as well as any further implementation rules to be issued by national and local authorities;

2. Carry out relevant registration, filing and other governmental procedures in time, abide by compliance requirements such as registration, filing for cosmetics and new cosmetics raw materials, undertake quality and safety and products risk assessment, and fulfill the relevant compliance obligations;

3. Ensure that the rights and obligations under the relevant laws and regulations are taken into account by overseas registrants or filing obligors whilst entering into the relevant agreements with the domestic responsible parties (in particular, clauses regarding quality control, safety monitoring, the adverse effect of cosmetics or raw materials and liabilities). If you need assistance in drafting or reviewing the relevant agreements, please contact us or your environmental legal counsel.

If you have any specific questions or need any assistance in the registration, filing and risk assessment for cosmetics and/or new raw materials for new cosmetics, or any additional relevant legal and compliance training, please contact us via email: ecoenvpro@junhe.com.

JunHe's EHS Legal Team: JunHe LLP, with over 930 professionals, is one of China's largest full-service law firms with an international reputation for providing high quality legal services. As one of the pioneers in the practice area of environment, health and safety production ("EHS") in China, JunHe's EHS team provides multinational enterprises with a full range of EHS legal services. These include industrial project development, the incorporation of joint ventures, M&A transactions, daily commercial operations, EHS related audit and compliance, government investigations, administrative punishments and reconsiderations and litigations.

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君合研究简讯

JUNHE

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环境健康与安全法律热点问题

环境健康与安全专题系列（十六）-- 化妆品新规项下的重点合规要点

导言：近年来，中国化妆品方面的新规相继出台，化妆品监管相关的法律法规体系日趋完善，已经为化妆品生产经营企业奠定了细化管理、明确责任、鼓励创新和强化事后监管的监管基调。同时，随着全球美妆界“零残忍”理念的兴起，我国非动物测试相关的法规逐步出台，一定程度上也促进了中国化妆品方面的立法进程。本文拟结合化妆品新规和相关实践经验，帮助化妆品生产经营企业了解与此相关的一些合规重点。

一、最新立法进程简介

2020年1月3日《化妆品监督管理条例》（以下简称“**《条例》**”）正式通过并于2021年1月1日起正式施行，取代《化妆品卫生监督条例》，确立了化妆品及其原料的注册备案管理制度。2020年12月31日，国家市场监督总局审议通过的《化妆品注册备案管理办法》（以下简称“**《管理办法》**”）对《条例》的原则性制度做出了细化规定。此后国家药品监督管理局于2021年2月26日发布《化妆品注册备案资料管理规定》（以下简称“**《化妆品管理规定》**”）和《化妆品新原料注册备案资料管理规定》（以下简称“**《新原料管理规定》**”），对《管理办法》规定进一步细化。《管理办法》与上述两部管理规定均将于2021年5月1日起施行。

二、化妆品新原料实行特殊安全监管

《条例》对化妆品新原料实行风险分类管理，即仅具有防腐、防晒、着色、染发、祛斑美白功能的化妆品新原料实施注册管理，而对其他化妆品新原料实施备案管理。经注册、备案的化妆品新原料投入使用后3年内未发生安全问题的化妆品新原料，纳入已使用化妆品原料目录。实践中，近年来化妆品新原料注册审批通过难度较大，该规定有望突破现状。《管理办法》明确实行安全监测制度，设置了3年安全监测期限（自首次使用化妆品新原料的化妆品取得注册或者完成备案之日起算；安全监测期限内，化妆品新原料注册人、备案人可以使用该化妆品新原料生产化妆品）。此外，《管理办法》和《新原料管理规定》建立了新原料的持续监测和评价体系，细化了新原料注册和备案管理资料和监测报告义务的要求，规范了新原料技术性相关资料的编制等方面的要求。

三、进口普通化妆品免除动物测试

早在2013年，国家食品药品监督管理总局颁布了《关于调整化妆品注册备案管理有关事宜的通告》，对风险评估结果能够充分确认产品安全性的国产非特殊用途化妆品不再强制要求进行动物试验，但此规定对进口化妆品并不适用。2016年及2018年我国在跨境电子商务零售进口方面做出了一些例外规定。《化妆品管理规定》则明确有条件地豁免进口普通化妆品进行动物测试。根据《条例》和《化妆品管理规定》，普通化妆品（染发、烫发、祛斑美白、防晒、防脱发或宣称新功效以外的化妆

品）生产企业已取得所在国（地区）政府主管部门出具的生产质量管理体系相关资质认证（简称“**GMP认证**”），且产品安全风险评估结果能够充分确认产品安全性的，可免于提交该产品的毒理学试验报告，但须满足三“非”，即非婴幼儿和儿童产品、未使用监测期内新原料的产品和非监管对象。普通化妆品生产企业取得动物测试豁免能够有效缩短完成进口普通化妆品备案的时间，而其前提在于取得国家药品监督管理局认可的GMP认证。

四、注册人、备案人的质量安全责任

《管理办法》规定了化妆品、化妆品新原料注册人、备案人依法履行产品注册、备案义务，对质量安全负责（例如：化妆品注册人、备案人应明确产品标准并在申请注册或者进行备案时提交药监部门；化妆品注册申请人、备案人应委托有资质机构依法检验；化妆品注册人、备案人应在使用化妆品新原料生产化妆品时保证使用原料的安全性；使用化妆品新原料生产化妆品的化妆品注册人、备案人，应当及时向化妆品新原料注册人、备案人反馈化妆品新原料的使用和安全情况；出现可能与此相关的不良反应或者安全问题时，立即采取措施控制风险，通知化妆品新原料注册人、备案人并依法履行报告义务）；如果注册人、备案人在境外的应指定境内企业作为境内责任人；境内责任人按照与注册人、备案人的协议，对投放境内市场的化妆品、化妆品新原料承担相应的质量安全责任。

五、结语与建议

基于前述讨论，我们为化妆品行业相关企业提供如下具体建议，以避免合规风险：

1、 学习相关规定，尤其是作为《条例》之细化规定的《管理办法》、《化妆品管理规定》和《新原料管理规定》，以及未来国家和地方层面出台的配套规则；

2、 及时开展相关注册、备案等政府程序，遵守相关化妆品和化妆品新原料注册、备案，质量安全和产品风险评估等合规要求，并履行相关合规义务；

3、 确保境外注册人或备案人在与境内责任人签订相关协议时通盘考虑相关法律法规项下各自的权利与义务，尤其注意化妆品/原材料的质量控制、安全监测、不良反应及责任承担等方面的约定。如需协助起草或审阅相关协议的，请联系我们或您的环境法律师。

如您有任何具体问题，需要化妆品/化妆品新原料注册、备案和产品风险评估等方面的服务或化妆品相关法律或合规培训的，欢迎邮件联系我们：ecoenvpro@junhe.com。

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