Comments from P. R. China on Notification

G/TBT/N/EU/1219

Amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances, including those classified as carcinogenic, mutagenic or toxic for reproduction

The People's Republic of China appreciates European Union for fulfilling the transparency obligation under WTO, as well as for the opportunities for other WTO Members to make comments on the notification G/TBT/N/EU/1219. According to Article 2.9.4 of the WTO/TBT Agreement "without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account", China would like to put forward the following comments on the notified regulations and hope EU take these comments into consideration. The detail comments as follows:

1. Regarding the Incomplete Scientific Assessment Basis for Newly Added Prohibited Substances: It is recommended that the EU publish the full set of SCCS assessment documentation and enhance regulatory traceability and transparency. The reasons are as follows:

This draft proposes to prohibit benzophenone-1, benzophenone-2, Basic Brown 16, Basic Blue 99, and prostaglandin analogues based on SCCS conclusions. However, the notification only announces the final conclusions, without disclosing the complete SCCS assessment reports, hazard identification data, human exposure risk verification, and the scientific basis for the prohibition decisions corresponding to the above substances.

A sufficient scientific basis and an open and transparent process are core prerequisites for technical regulations to comply with WTO/TBT rules. The absence of assessment documentation will prevent enterprises from precisely understanding risk determination criteria, making it difficult for them to efficiently carry out formulation adjustments and compliance upgrades, while also undermining the credibility and traceability of the regulation. It is recommended that the EU fully disclose the complete set of SCCS scientific assessment files for the above substances, clearly specify the core risk basis for the prohibition controls, and ensure that regulatory measures are scientifically justified and evidence-based.

2. Regarding the Regulatory Rules for Four Restricted Ingredients: It is recommended to refine the control requirements and unify compliance determination standards. The reasons are as follows:

This draft updates the regulatory rules for BHA, Butylparaben, CBD, and nano-hydroxyapatite, specifying that these substances may only be used under the specific safety conditions identified by the SCCS. However, it does not clarify the specific applicable scenarios, product scope, quantitative limits, or detailed restrictive conditions for the four substances.

Vague restrictive provisions will lead to non-uniform global compliance standards and inconsistent enforcement practices among EU Member States, increasing cross-border compliance costs and trade uncertainty for enterprises. It is recommended that the EU

supplement the final text with detailed usage specifications, applicable categories, boundary conditions, and compliance determination rules for the four restricted ingredients, so as to unify global applicable standards and enhance the operability of the regulation.

3. Regarding the Revocation of the Exemption for Mercury‑Containing Preservatives without Supporting Rules: It is recommended to improve the transitional implementation provisions to ensure a smooth regulatory transition. The reasons are as follows:

The draft proposes to revoke the exemption for mercury-containing preservatives, which constitutes a major regulatory adjustment. However, it currently only indicates the direction of revision, without accompanying provisions on the transitional arrangements between the old and new provisions, the rules for disposing of compliant products already in stock, the specific scope of application after the revocation of the exemption, or the transition period.

The lack of implementing details will leave industry actors without a clear basis for determining the compliance of products in production or in stock, potentially causing disruptions to normal trade. It is recommended that the EU supplement the draft with corresponding implementing rules, clearly define the regulatory switch-over date and the rules for handling existing stock, so as to ensure a smooth transition and minimise unreasonable impacts on international trade.

4. Regarding the Lack of Adaptation Basis for CMR Classification in Cosmetic Use Scenarios: It is recommended to add specific risk assessments for cosmetic scenarios to avoid over‑regulation. The reasons are as follows:

The core basis for this revision is the general industrial CMR classification criteria under Regulation (EU) 2025/1222. However, cosmetics have specific exposure characteristics involving direct, long-term, and frequent human contact, which are significantly different from the risk profile of industrial scenarios, and thus the general classification should not be directly applied.

The notification does not disclose the specific risk assessment basis for adapting the general classification criteria to cosmetic use scenarios, nor does it specify the corresponding CMR hazard categories for each controlled substance. It is recommended that the EU supplement the draft with a dedicated risk assessment report for cosmetic scenarios, clarify the basis for applying CMR classification, ensure that control measures are commensurate with the actual exposure risks of cosmetics, comply with the proportionality principle of the WTO/TBT Agreement, and strictly avoid over-regulation.

5. Regarding the Adaptation Period for Industry Compliance: It is recommended to optimise the implementation timeline and reserve sufficient buffer time. The reasons are as follows:

According to the official EU notification, this draft is tentatively scheduled for adoption in the fourth quarter of 2026, with entry into force 20 days after publication, and the CMR-related requirements becoming applicable on 1 February 2027. This revision covers a number of commonly used cosmetic ingredients, requiring the entire industry to carry out extensive work including formulation adjustments, safety re-evaluations, and compliance verifications, with broad impact.

In order to fully fulfil WTO transparency obligations, accommodate global industry adaptation capacity, and ensure a reasonable period for comments and compliance adjustments by all Members, it is recommended that the EU fully take into account the comments of all Members before formal adoption, retain a sufficient compliance buffer period, and avoid industrial chain volatility and technical barriers to trade caused by an overly rapid schedule, thereby maintaining the stability and order of global cosmetics trade.

Comments in Chinese are in below:

中国对 G/TBT/N/EU/1219 通报的评议意见

中国赞赏欧盟履行 WTO 透明度义务，给予其他 WTO 成员评议 G/TBT/N/EU/1219 号通报的机会，根据 WTO/TBT 协定 2.9.4 条“无歧视地给予其他成员合理的时间以提出书面意见，并对这些书面意见和讨论的结果予以考虑”的规定，请欧盟对中方的评议意见予以考虑并作出答复，中方意见及论述如下：

1. 关于新增禁用原料科学评估依据不完整问题，建议公开全套 SCCS 评估资料、提升法规溯源透明度。理由如下：

本次草案基于 SCCS 结论，拟禁用二苯甲酮-1、二苯甲酮-2、碱性棕 16、碱性蓝 99 及前列腺素类似物。但通报仅公示最终结论，未公开上述物质对应的完整 SCCS 评估报告、危害识别数据、人体暴露风险验证及禁用决策科学依据。

科学依据充分、过程公开透明是技术法规符合 WTO/TBT 规则的核心前提。评估依据缺失将导致企业无法精准掌握风险判定标准，难以高效开展配方整改与合规升级，同时削弱法规公信力与溯源性。建议欧盟完整公开上述物质的全套 SCCS 科学评估文件，明确禁用管控的核心风险依据，确保监管措施有据可依、科学合规。

2. 关于四类限用原料监管规则，建议细化管控要求、统一合规判定标准。理由如下：

本次草案更新了 BHA、尼泊金丁酯、CBD、纳米羟基磷灰石的监管规则，明确上述物质仅可在 SCCS 认定的特定安全条件下使用，但未明确四类物质的具体适用场景、覆盖产品范围、量化限值及详细限定条件。

模糊的限制性条款将导致全球合规标准不统一、欧盟各成员国执法尺度偏差，增加企业跨境合规成本与贸易不确定性。建议欧盟在最终文本中补充细化四类限用原料的使用规范、适用品类、限制边界及合规判定细则，统一全球适用标准，提升法规可操作性。

3. 关于汞防腐剂豁免取消缺乏配套规则，建议完善过渡实施细则、保障监管平稳衔接。理由如下：

草案拟取消含汞防腐剂的禁令豁免，属重大监管调整。但目前仅明确修订方向，未配套公布新旧条款衔接规则、库存合规产品处置标准、豁免取消后的具体适用范围及过渡期安排。

实施细则缺失将导致行业在产、库存产品合规判定无据可依，易造成正常贸易阻滞。建议欧盟补充出台配套落地规则，明确监管切换节点与存量产品处置规范，确保法规平稳过渡，降低对国际贸易的不合理影响。

4. 关于 CMR 分类缺乏美妆场景适配依据，建议补充化妆品场景专项风险评估、规避过度监管。理由如下：

本次修订核心依据为欧盟 2025/1222 号法规的通用工业 CMR 分类标准。但化妆品具有直接、长期、高频人体接触的特殊暴露属性，与工业场景风险特征显著不同，不宜直接沿用。

通报未公开通用分类标准适配化妆品使用场景的专项风险评估依据，亦未明确各管控物质对应的具体 CMR 危害类别。建议欧盟补充化妆品场景专项风险研判报告，明确 CMR 分类适用依据，确保管控措施贴合化妆品实际暴露风险，符合 WTO/TBT 协定比例原则，杜绝过度监管。

5.关于产业合规的适配周期，建议优化实施周期、预留充足缓冲时间。理由如下：

根据欧盟官方通报，本草案拟定于 2026 年第四季度通过，发布后 20 日生效，CMR 相关要求于 2027 年 2 月 1 日正式适用。本次修订覆盖多款化妆品常用原料，需全行业完成配方调整、安全复核、合规验证等大量工作，影响范围广。

为充分履行 WTO 透明度义务，兼顾全球产业适配能力，保障各成员合理评议与整改周期，建议欧盟在正式采纳前充分吸纳各成员意见，保留充足合规缓冲期，避免因节奏过快引发产业链波动与技术性贸易壁垒，维护全球化妆品贸易稳定有序。