



BNAEOPC's Position on the Draft Ordinance on the organization of the certification process of good manufacturing practices for cosmetic products and the authorization of control officers (TRIS 2023/0537/FR)

BNAEOPC, the Bulgarian National Association Essential oils, Perfumery and Cosmetics, representing the essential oils, cosmetics, personal care and detergents industry in Bulgaria, expresses concerns about the Draft Ordinance submitted by France through the TRIS process under notification number 2023/0537/FR.

The Draft Ordinance introduces mandatory certification for good manufacturing practices (GMP) for certain establishments manufacturing and packaging cosmetics products in France. The Cosmetic Products Regulation does not mandate a GMP certificate but requires inclusion of GMP compliance statements in the product information file.

The Cosmetic Products Regulation does not require a certificate for demonstrating compliance with Good Manufacturing Practices (GMP). Article 11.2.(c) of the Regulation stipulates that a product information file containing a manufacturing method description and a statement on GMP compliance is sufficient. The Regulation does not prescribe a specific GMP method but establishes a presumption of compliance when manufacturing aligns with relevant harmonized standards published in the Official Journal of the European Union under Article 8(2).

In-market control, as outlined in Article 22 of the Cosmetic Products Regulation, enables Member States to monitor GMP compliance. However, new French certification requirements on GMP for establishments manufacturing cosmetic products are introduced through a Draft Ordinance. While the French State claims these measures apply only to establishments on French territory, it is argued that, in practice, it's challenging to separate requirements for establishments from those on products and supply chain actors regulated by the Cosmetic Products Regulation.

BNAEOPC cautions against the compulsory GMP certification in France. It emphasizes that any Member State system regulating GMP compliance should align with the self-declaration principle in Article 11.2(c). Member States should not impose specific GMP standards, as per Article 8, leaving the choice of GMP method to the manufacturer.

Concerns are raised about the compatibility of the proposed certification with Article 22, which requires GMP monitoring after products are placed on the market. Member States' power to regulate economic operators, outlined in Recital 56, must comply with EU law, including the Cosmetic Products Regulation and its GMP articles (Articles 8.2, 11.2.(c), and 22). The French Council of State clarified the scope of Recital 56 in 2017, emphasizing that while Member States can regulate economic operators, they cannot modify harmonized rules for the free circulation of cosmetic products in the Internal Market.