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'I/A' ITEM NOTE

From: General Secretariat of the Council

To: Permanent Representatives Committee/Council

No. Cion doc.: ST 6871/21 + ADD 1 - D071732.01

Subject: Commission Regulation (EU) .../... of XXX amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products
- Decision not to oppose adoption

1. On 4 March 2021, the Commission submitted the above draft Regulation to the Council which amends Annexes II and III of Regulation (EC) No 1223/2009¹, in accordance with its Article 31(1).
2. It is necessary to add a new entry in Annex III, concerning the use of the substances Deoxyarbutin and Dihydroxyacetone.

¹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59); Current consolidated version: 03/12/2020;

Deoxyarbutin, which is currently not regulated in Regulation (EC) No 1223/2009, results in the release of Hydroquinone, which Annex II of the same Regulation includes among the substances prohibited for use in cosmetic products. The use of up to 3% Deoxyarbutin in face creams cannot be considered safe and should be prohibited in cosmetic products, and added to the list of prohibited substances in Annex II.

Dihydroxyacetone is an ingredient in skin conditioning and tanning, and is currently not regulated under Regulation (EC) No 1223/2009. According to the opinion of the Scientific Committee on Consumer Safety, a certain level of concentration of the above ingredient is considered safe when used as a hair colouring ingredient and in self-tanning products. It is therefore necessary to add a new entry in Annex III of the above Regulation that will allow for a restricted use of Dihydroxyacetone.

3. The Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of Regulation(EC) No 1223/2009.
4. Under the procedure in Articles 5 and 5a of Council Decision 1999/468/EC, before being formally adopted by the Commission, such draft measures are submitted for scrutiny to the European Parliament and the Council. If neither the European Parliament nor the Council oppose the measures, the Commission shall adopt the draft Regulation by 4 June 2021.
5. On 22 February 2021, the Committee voted unanimously in favour in accordance with Article 5a(2) of the above Council Decision.
6. On 9 March 2021, delegations were asked by 16 April 2021 to indicate their possible opposition to the draft Regulation. No delegation raised any grounds for opposition.
7. Against this background, the Permanent Representatives Committee is invited to recommend to the Council to confirm its non-opposition to the draft Regulation, as set out in document ST 6871/21 + ADD 1 as an item without discussion at one of its forthcoming meetings.