

COMMENTS FROM THE EUROPEAN UNION CONCERNING NOTIFICATION

G/TBT/N/UKR/116

THE DRAFT RESOLUTION OF THE CABINET OF MINISTERS OF UKRAINE "ON APPROVAL OF THE TECHNICAL REGULATION ON COSMETIC PRODUCTS"

The European Union (EU) would like to thank the Ukrainian authorities for providing the opportunity to comment on the proposed draft Resolution *"On Approval of the Technical Regulation on cosmetic products"*.

The EU welcomes the effort of the Ukrainian authorities to *"establish basic requirements for cosmetics products developed on the basis of the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products"* (EU Cosmetics Regulation). In this regard, the EU would like to make the following remarks regarding some general issues as well as specific provisions.

General comments

The notified draft is intended to come into force 6 months after the date of its official publication. This transition period seems too short. A longer period would be necessary to allow the authorities and companies to implement the new requirements. Indeed, several new requirements such as compliance with the notification process, product safety evaluation and labelling requirements may disrupt the continuity of the business if manufacturers are not granted sufficient time to adapt their practice. When the EU moved from the old Directive (Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products) to the new EU Cosmetics Regulation, the text was published in November 2009 and more than three and a half years (until July 2013) were granted to national authorities and operators to comply with the new requirements. Whereas circumstances in Ukraine may not require a transition period similar to the one granted in the EU, the EU would like to request Ukraine to consider extending the transition period beyond the 6 months set out in the draft measure so as to ensure a smooth entry into application of the technical regulation and avoid trade disruption.

The EU would like to underline that when developing the EU Cosmetic Product Notification Portal (CPNP), the Commission and industry, together with IT professionals, collaborated intensively to ensure the robustness of the system and to guarantee a high security level for confidential information. Before the launch of the Ukrainian notification portal, companies should be able to test it to ensure a smooth transition.

The EU would also like to encourage the Ukrainian authorities to issue guidelines to support the enforcement regulation and to help the different actors to understand the process in practice. This could be done e.g. by direct reference to the relevant EU guidance or by specific guidelines to be elaborated by the competent Ukrainian authorities. In order to ensure legal certainty, such upcoming guidelines should be

mentioned in the notified draft together with clear indications on the matters they would cover.

The EU Cosmetics Regulation contains such commitments with clear deadlines and indications on the further guidance allowing operators to adjust their business processes accordingly.

Technical Comments regarding specific provisions of the notified draft

1) Paragraph 4

With regard to the "*definitions*", the EU has noted the absence of important definitions such as '*importer*', '*manufacturer*', '*distributor*' etc. in the notified draft. It is important that such definitions are either contained elsewhere in relevant legislation and referenced in the notified draft or integrated in the notified draft as they reflect the distribution of roles of different actors in the cosmetic sector.

2) Paragraph 29 item 4

According to this paragraph, "*the product information file shall be updated as necessary and contain the following information [...] - proof of the effects claimed for the cosmetic product*" (item 4). The EU would propose adding the following complement in this requirement '*where justified by the nature or the effect of the cosmetic product*'. Indeed, there is no requirement in the EU, e.g. to provide the proof that a lipstick colours the lips or a shampoo cleans the hair.

3) Paragraph 34

It seems as if the requirement on communication of information in this provision has been taken over from the EU Cosmetics Regulation. It was included in that Regulation with the purpose of informing poison centres in the Member State, where a cosmetic product was newly made available on the market, about the frame formula. Before the entry into application of the EU Cosmetics Regulation there was no central electronic notification portal and the notifications to poison centres had to be made on a national basis in each Member State. Since Ukraine is a single country with a future central notification portal, the aforementioned provision appears to be dispensable.

4) Paragraph 38

This paragraph contains a list of substances which shall not be contained in cosmetic products, notably "*colorants, except those listed in Annex IV*" In this respect, the EU would like to underline that hair dyes are not yet included in Annex IV of the EU Cosmetics Regulation as some of them are still being assessed by the Scientific Committee for Consumer Safety (SCCS). Therefore, the EU would propose that the notified draft should provide for an exception for hair colouring products and would suggest adding '*except for hair colouring products referred to in paragraph 2*' after the sentence '*colorants, except those listed in Annex IV to this Technical Regulation and colorants, which are listed in Annex IV to this Technical Regulation but not used in accordance with the relevant conditions laid down in that Annex*'.

Moreover the EU would like to propose adding the following subparagraph as provided for in the EU Cosmetics Regulation: '*2. Subject to a decision of the Ministry of Health to extend the scope of Annex IV to hair colouring products, such products*

shall not contain colorants intended to colour the hair, other than those listed in Annex IV and colorants intended to colour the hair which are listed there but not used in accordance with the conditions laid down in that Annex.'

5) Paragraph 45

This provision provides the obligation for the responsible person to submit the identical data required for the notification of nanomaterials as in the EU. However, neither the safety assessment procedure, nor the creation of a scientific committee such as the SCCS (which provides opinions on the safety of nanomaterials before national authorities approve their placement on the EU market) are laid down in the draft. To avoid technical barriers to trade, the EU would recommend aligning with the corresponding processes arising from the EU Cosmetics Regulation until Ukraine has developed its own harmonized processes – e.g. the default recognition of new nanomaterials used in cosmetics products placed on the Ukrainian market if they have been notified and recognised at EU level.

6) Paragraph 48

With regard to the list of prohibitions laid down in this paragraph, the EU would like to suggest completing the following sentences (corresponding provisions are provided in the EU Cosmetics Regulation): Paragraph 48, 3) and 4): Add '*within the Ukrainian territory*' after '*the performance*'. At the end of 4) add '*or in Annex VIII to this Technical Regulation*'.

As it is provided in the EU Cosmetics Regulation, the EU considers it important that the following derogation is added at the end of paragraph 48:

'In exceptional circumstances, where serious concerns arise as regards the safety of an existing cosmetic ingredient, a Central executive healthcare authority may grant a derogation from paragraph 48.

A derogation shall be granted only where:

- (a) the ingredient is in wide use and cannot be replaced by another ingredient capable of performing a similar function;*
- (b) the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation'.*

7) Paragraph 54

The EU greatly supports the intention to apply INCI labelling of ingredients as it is a worldwide practice ensuring the free movement of goods and high safety standards for cosmetic products. The EU would like to point out that any requirement to translate INCI names into Ukrainian would create a technical barrier to trade under the World Trade Organization rules and would go against the international technical and regulatory convergence objective pursued by Ukraine.

8) Paragraph 58

With respect to the obligation to notify serious undesirable effects, the EU would like to underline that, in the EU, the communication of serious undesirable effects is limited to those that occurred in the EU Members States. In this regard, the EU would like to suggest the following modification:

In the event of serious undesirable effects that occurred in Ukraine, the responsible person and distributor shall without delay notify the following to the state market surveillance bodies: [...]

Furthermore, the EU would like to stress that the EU Cosmetics Regulation has been developing dynamically following the innovations and scientific knowledge of the fast growing cosmetic sector. Since the entry into force of the Regulation, over 20 amendments have been made, including new ingredients listed in its Annexes II-VI.

In this context, the EU would like to encourage the Ukrainian authorities to consider the possibility of developing a specific procedure for amending the Annexes of the notified draft allowing the alignment with the Annexes of the EU Cosmetics Regulation where appropriate. In this regard, the EU would suggest adding a specific paragraph to the notified draft regarding the process for amending the Annexes in the future.

In this respect, the EU would like to recall Article 2.2 of the TBT-Agreement which states *"Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create"*.

In the light of the above concerns, the EU would be grateful if these comments could be taken into account and would welcome receiving a reply.
