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ANNEX

Detailed explanation of the reasons for the differences accompanying the Draft COMMISSION REGULATION EU No .../.. of XXX amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") as regards chromium VI compounds, in accordance with its Article 73(1)

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Article 73(1)

- 1. Article 73(1) second subparagraph of the REACH Regulation stipulates that where the draft amendment diverges from the original proposal or if it does not take the opinions from the European Chemicals Agency ("ECHA") into account, the Commission shall annex a detailed explanation of the reasons for the differences.
- 2. The present detailed explanation therefore addresses the reasons for the differences between the original proposal of the Kingdom of Denmark ("Denmark"), as presented in the dossier conforming to the requirements of Annex XV to REACH ("Annex XV dossier"), and this draft Regulation. Although the Commission did take the opinions from the Agency into account, this detailed explanation also addresses the divergences between the restriction proposal as amended by ECHA Committees for Risk Assessment ("RAC") and for Socio-economic Assessment ("SEAC") and this draft Regulation.
- 3. The restriction proposed by Denmark on chromium (VI) compounds in leather articles was:
 - "Articles of leather, coming into direct and prolonged or repetitive contact with the skin, shall not be placed on the market if the leather contains chromium (VI) in concentrations equal to or higher than 3 mg/kg."
- 4. During the restriction process, both ECHA Committees, RAC and SEAC, agreed with Denmark in that there is a need to restrict placing on the market of leather articles containing chromium (VI). However, the wording of the suggested restriction was modified during the opinion forming of the Committees. RAC, in agreement with SEAC, extended the scope of the restriction, to cover all leather articles that come into contact with the skin. Therefore, the reference to "direct and prolonged or repetitive contact" with the skin, used in the original proposal, was removed.
- 5. RAC and SEAC suggested a modification of the initial proposal, as follows:
 - "Leather articles, or leather parts of articles, coming into contact with the skin, shall not be placed on the market if they contain chromium (VI) in concentrations equal to or higher than 3 mg/kg (0,0003%) chromium VI of the total dry weight of the leather."
- 6. The change suggested by RAC, and supported by SEAC, was justified by the Committees by:
 - a) considerations on enforceability of the restriction, based on the advice of the Forum on exchange of information on enforcement ("Forum") about

- enforceability and practicality of this restriction proposal (Forum 1st advice, May 2012), and the results of the public consultation; and
- b) considerations on better coverage of the exposure conditions by which chromium (VI) in leather articles can produce allergic contact dermatitis and thus to better reflect the nature of the risks posed.

As a result of this modification, this restriction would cover also some leather articles that would not have been covered by the initial proposal of Denmark, such as those for which an indirect, rather than direct, contact with the skin is foreseeable.

- 7. In addition, SEAC also suggested to include the transitional period of 12 months (already proposed by Denmark in the Annex XV dossier) into the entry, and to derogate from the restriction articles placed on the market for the first time before 12 months after the entry into force of this Regulation. For the latter, SEAC suggested a modification of the initial proposal, as follows:
 - "By way of derogation, the restriction shall not apply to leather articles placed on the market for the first time before [12 months after the amendment of the REACH Annex XVII enters into force]"
- 8. The draft Commission Regulation, after having taken into account the RAC and SEAC opinions, reads as follows:
 - "4. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003% by weight) of the total dry weight of the leather.
 - 5. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part.
 - 6. Paragraphs 4 and 5 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before [first day of the 13th month after the date of the entry into force]."
- 9. In addition, the Commission is proposing that the Regulation will start to apply 12 months after its entry into force.
- 10. As far as deleting of the reference to the "direct and prolonged or repetitive contact" with the skin is concerned, the Commission concurs with the RAC and SEAC opinions and the Forum advice, based on the grounds referred to in paragraph 6 above.
- 11. Paragraphs 4 and 5 of the proposed restriction fully correspond to the RAC and SEAC opinions on the suggested restriction. The division to two separate paragraphs was done for purely formal reasons, as it is articles that are being placed on the market under REACH, and not parts of articles.

- 12. Paragraph 6 introduces the derogation for the placing on the market of second-hand articles which were in end-use in the EU before the application date. The Commission, taking into account the SEAC opinion, considers that the restriction on the placing on the market of second-hand articles would impose a disproportionate burden on the consumers re-selling these articles. Furthermore, due to the nature of those transactions, such restriction would be difficult to enforce, as stated in recital (12) of the draft Regulation. The Commission did not consider appropriate to derogate also other articles which were already placed on the market, but still in the supply chain (including stocks), and not having reached the EU end-user yet at the time of entry into application of the measure. The Commission considers that the deferral of application of the Regulation of 12 months after its entry into force is sufficient to address SEAC concerns with regard to articles in the supply chain, as referred to in paragraph 7 above.
- 13. In conclusion, the draft Commission Regulation contains the following main changes compared to the restriction proposed in the Annex XV dossier submitted by Denmark:
 - The scope of the restriction was extended. It is not limited to articles (and parts of articles) that have strictly direct and prolonged or repetitive contact with the skin. It would further cover any leather articles and articles containing leather parts that, under normal or reasonably foreseeable conditions of use, come into contact with the skin, as explained in recital (5).
 - A derogation for placing on the market of second-hand articles which were in the end-use in the EU before this Regulation applies was introduced.

The draft Commission Regulation also slightly diverges from the opinion of ECHA Committees in limiting this derogation to second-hand articles which were in the end-use in the EU before this Regulation applies only, and not derogating all articles placed on the market for the first time before this Regulation applies.