



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies

Directorate-General for Environment
Circular Economy and Green Growth

Directors

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NOTE FOR THE ATTENTION OF MR G. DANCET, EXECUTIVE DIRECTOR ECHA

Subject: Request to the European Chemicals Agency to review entries 63 (Lead) and 50 (PAH) of Annex XVII to REACH in the light of new scientific information

Pursuant to paragraph 6 of entry 63 of Annex XVII to REACH, the Commission must review the current restriction for lead in jewellery articles by 9 October 2017. Similarly, by 27 December 2017, the Commission must also review the limits in paragraphs 5 and 6 of entry 50 of Annex XVII, relative to maximum polycyclic aromatic hydrocarbon (PAH) content in rubber and plastic components of articles placed on the market for supply to the general public.

Lead in jewellery articles

Paragraph 1 of entry 63 establishes a maximum concentration limit of 0.05% (w/w), for lead in jewellery articles defined in a non-exhaustive manner in paragraph 2. Exemptions from paragraph 1 are provided for in paragraphs 3, 4 and 5.

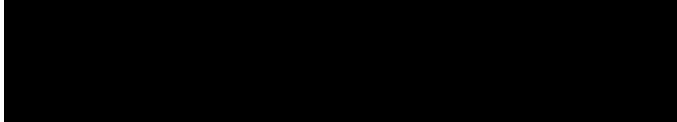
In order to enable the Commission to conduct the required review of the restriction, the Agency is requested to investigate the state of the art of scientific information in terms of available analytical methodologies to determine migration of lead from the different materials used in jewellery as well as the availability of alternatives to these materials and to those exempted by paragraph 4.

Timing

ECHA should deliver to the Commission an evaluation report, reflecting the assessment described above, no later than 30 September 2017. Based on this report the Commission will consider whether to request ECHA to prepare an Annex XV dossier in accordance with Article 69(1) to launch the procedure to amend the current restriction including, potentially, modifying paragraph 1 to include maximum lead migration limit.

PAHs in articles placed on the market for supply to the general public

Paragraphs 5 and 6 of entry 50 of Annex XVII establish maximum content limits for each of the listed carcinogenic polycyclic aromatic hydrocarbons (PAHs) in rubber and plastic



components of articles placed on the market for supply to the general public, including specific (lower) limits on toys and childcare articles.

In order to enable the Commission to conduct the required review of the restriction, the Agency is requested to investigate the state of the art of scientific information in terms of available analytical methodologies to determine:

1. the content of the individual PAHs listed in entry 50
2. the migration of each of the individual PAHs listed in entry 50

from plastic and rubber materials relevant to the scope of the restriction, paying particular attention to the availability of validated methodologies and to their associated analytical performance parameters, particularly their limit of quantification. ECHA should take into consideration the work currently being carried by the JRC, at the request of DG GROW, in the development of a PAH migration methodology for plastic and rubber. The availability of such methodologies in commercial national and international laboratories and their practicality and cost should also be investigated and documented.

The Agency should also review the current market situation in terms of the availability of suitable alternative low-PAH raw materials, particularly carbon black and extender oils, used to manufacture rubber and plastic components and should advise the Commission, in the light of new scientific information, on the possible reduction in the PAH(s) content limits in articles covered by paragraph 5 as well as in toys and childcare articles (Paragraph 6).

Timing

ECHA should deliver to the Commission an evaluation report, reflecting the assessment described above, no later than 30 November 2017. Based on this report the Commission will consider whether to request ECHA to prepare an Annex XV dossier in accordance with Article 69(1) to launch the procedure to amend the maximum PAH content limits in paragraphs 5 and 6 of entry 50 including, potentially, introducing a maximum PAH migration limit, as an alternative to determine compliance with the restriction.

Yours sincerely,

(e-signed)

Carlo Pettinelli
DG Internal Market, Industry,
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(e-signed)

Kestutis Sadauskas
DG Environment