



Brussels, **XXX**
[...](2013) **XXX** 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 Polycyclic aromatic hydrocarbons

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 68(2) thereof,

Whereas:

- (1) Benzo[a]pyrene, Benzo[e]pyrene, Benzo[a]anthracene, Chrysen, Benzo[b]fluoranthene, Benzo[j]fluoranthene, Benzo[k]fluoranthene and Dibenzo[a,h]anthracene, hereinafter referred to as polycyclic aromatic hydrocarbons (PAHs), are classified as carcinogens of category 1B in accordance with Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006².
- (2) These PAHs can be found in the plastic and rubber parts of a wide range of consumer articles. They are present as impurities in some of the raw materials used in the production of such articles, in particular in extender oils and in carbon black. They are not added intentionally to the articles and do not perform any specific function as constituents of the plastic or rubber parts.
- (3) These PAHs are banned for the sale to the general public as substances on their own or in mixtures by entry 28 of Annex XVII to Regulation (EC) No 1907/2006. Moreover, entry 50 of Annex XVII to that Regulation restricts the presence of PAHs in extender oils used for the manufacture of tyres.
- (4) Information submitted by Germany to the Commission indicates that articles containing PAHs may pose a risk to consumers' health by ingestion, dermal adsorption and, in some cases, by inhalation.

¹ OJ L 396, 30.12.2006, p. 1.

² OJ L 353, 31.12.2008, p. 1

- (5) The conclusion regarding the risk to consumers was based on the estimated dermal exposure to PAHs arising from the use of certain consumer articles, under realistic worst-case conditions of use. That exposure was found to exceed the Derived Minimal Effect Levels (DMEL)³ determined for benzo[a]pyrene, which was used as surrogate for the toxicity of the other PAHs.
- (6) The Commission evaluated the information provided by Germany and concluded on the existence of a risk to consumers posed by articles containing PAHs, indicating that a restriction would limit the risk. The Commission also consulted industry and other stakeholders on the impact of restricting the presence of PAHs in articles that could be used by consumers.
- (7) In order to protect the health of consumers from the risk arising from PAHs in articles, limits on the PAH content in the accessible plastic or rubber parts of articles should be set, and the placing on the market of articles containing any of the PAHs in concentrations greater than 1 mg/kg in those parts should be prohibited.
- (8) This restriction should only apply to those parts of articles that come into direct and prolonged contact with the human skin or the oral cavity under normal or reasonably foreseeable conditions of use. Articles or parts thereof which are only in short or infrequent contact with the skin or oral cavity should not be included within the scope of the restriction as the resulting exposure to PAHs would be insignificant.
- (9) Alternative raw materials containing low levels of PAHs have been identified in the Union market. Those include carbon black and oils meeting the requirements of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food⁴. There is uncertainty as to whether suitable low-PAH alternative raw materials are available for the accessible parts of the consumer articles within the scope of this restriction, in particular in technical applications including those demanding a high thermal or mechanical performance of the plastic or rubber materials.
- (10) The Commission should review the existing limit value adopted in this restriction in particular in the light of new scientific information, including information on the migration of PAHs from plastic and rubber materials of the articles covered, as well as the availability of alternatives.
- (11) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (12) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take the measures that may be required to comply with the measures set out in this Regulation.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

³ http://www.echa.europa.eu/documents/10162/13643/information_requirements_part_b_en.pdf
⁴ OJ L12, 15.01.2011, p. 1.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from *[24 months after the entry into force]*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission
The President*

ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

In Column 2 of entry 50, the following paragraphs 5, 6 and 7 are added:

	<p>5. Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct and prolonged contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0,0001 % by weight of this component) of any of the listed PAHs.</p> <p>Such articles include:</p> <ul style="list-style-type: none">- toys including activity toys such as swings and childcare articles- sport equipment such as bicycles, golf clubs, racquets- house-hold utensils, trolleys, walking frames- tools for domestic use- clothing, footwear, gloves and sportswear- watch-straps, wrist-bands, masks, head-bands <p>6. Paragraph 5 shall not apply to articles placed on the market for the first time before [2 years after date of entry into force].</p> <p>7. By [<i>insert date - 6 years after the date of entry into force of this Regulation</i>], the Commission shall review the limit value in paragraph 5 in the light of new scientific information, including migration of PAHs from the articles referred to therein, and the availability of alternatives and, if appropriate, modify that paragraph accordingly.</p>
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