Commission Regulation (EU) No 1272/2013 of 6 December 2013 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)

COMMISSION REGULATION (EU) No 1272/2013

of 6 December 2013

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)

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/EC[(1)], 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 1907/2006[(2)].

(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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 1272/2013. (See end of Document for details)*

(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.

(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 exposure to 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) Taking into account the vulnerability of children a lower limit value should be established. Therefore the placing on the market of toys and childcare articles, containing any of the PAHs in concentrations greater than 0,5 mg/kg in their accessible plastic or rubber parts, should be prohibited.

(9) This restriction should only apply to those parts of articles that come into direct as well as prolonged or short-term repetitive 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 and 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. Further guidance in this respect should be developed.

(10) 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 food[(4)].

(11) The Commission should review the existing limit values 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 on alternative raw materials. The availability and reliability of testing methods should also be considered in this review of new scientific information.

(12) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(13) 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.

(14) A restriction on the placing on the market of second-hand articles and articles that are in the supply chain at the date of entry into application of this Regulation could pose difficulties for enforcement. Therefore, the restriction should not apply to articles placed on the market for the first time before that date.

(15) 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.

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 27 December 2015.

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

Done at Brussels, 6 December 2013.

For the Commission

The President

José Manuel BARROSO