Commission Regulation (EU) 2016/2235 of 12 December 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bisphenol A (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/2235

of 12 December 2016

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bisphenol A

(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(1) thereof,

Whereas:

(1) On 6 May 2014, France submitted to the European Chemicals Agency ('the Agency') a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier'[(2)]), in order to initiate the restriction procedure set out in Articles 69 to 73 of that Regulation. The Annex XV dossier indicated a risk for workers (primarily cashiers) and consumers exposed to bisphenol A (BPA) by handling thermal paper receipts and proposed a restriction on the placing on the market of BPA in thermal paper in a concentration equal to or greater than 0,02 % by weight. More precisely, the population at risk was the unborn children of pregnant workers and consumers exposed to BPA contained in the thermal paper they handle.

(2) Thermal paper is composed of a base paper with at least one coating which may contain BPA. The coating changes colour when exposed to heat, allowing the printed characters to appear.

(3) France based its hazard assessment of BPA on the effects on several human health endpoints (the female reproductive system, the brain and behaviour, the mammary gland, metabolism and obesity). The effects on the mammary gland were considered the most critical endpoint, prevailing over the others. They were used to calculate the Derived No Effect Level (DNEL).

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/2235. (See end of Document for details)*

(4) During the opinion forming process of the Agency, the European Food Safety Authority (EFSA) published a new scientific opinion on BPA[(3)]. The Agency's Committee for Risk Assessment (RAC) discussed the assessment of BPA with EFSA in order to ensure consistency in the scientific evaluation and to base it on the most recent and updated scientific literature. The hazard assessment of RAC, as presented in its opinion, is consistent with the approach used by EFSA.

(5) RAC considered that the critical studies selected by France to calculate the DNEL did not allow quantification of the dose-response relationships and showed uncertainties. Therefore, for the purposes of calculating an oral DNEL, RAC selected the effects on the kidney and, as the available data indicated that these are not the most critical effects of BPA, applied an additional assessment factor of 6 to take account of effects on the female reproductive system, the brain and behaviour, the mammary gland, metabolism and obesity, and the immune system in the overall hazard assessment. Since the restriction proposal concerns the dermal route of exposure due to handling thermal paper, a DNEL for the dermal exposure route was also calculated for workers and the general population. As regards exposure, RAC refined the assessment and complemented it with new biomonitoring information on cashiers' exposure to BPA. Applying this methodology, RAC concluded that the risk for consumers is adequately controlled but confirmed the risk for workers.

(6) On 5 June 2015, RAC adopted its opinion, concluding that the proposed restriction is the most appropriate Union-wide measure to address the identified risks in terms of effectiveness in reducing those risks.

(7) Pursuant to the conclusion of RAC that the available data did not allow quantification of the dose-response relationship for the health effects of BPA, the Agency's Committee for Socio-Economic Analysis (‘SEAC’) could not use the benefit estimates in the French dossier and therefore performed a break-even analysis, on the basis of which it concluded that overall the estimated costs outweigh the potential health benefits of the proposed restriction. However, SEAC noted that the cost of the restriction amounts to a very small proportion of the total personnel costs or gross operating surplus of the affected sectors in the Union, and would only lead to a very small price increase if transferred to consumers through increased prices of consumer goods. Furthermore, SEAC noted that the restriction could lead to a more equitable distribution of impacts, considering that the sub-population of cashiers potentially at risk is disproportionately affected by the adverse health impacts, whereas the economic impact would be evenly shared by the wider Union population.

(8) On 4 December 2015, SEAC adopted its opinion and considered the proposed restriction unlikely to be proportionate in terms of comparing its socioeconomic benefits to its socioeconomic costs, but highlighted possible favourable distributional and affordability considerations. Furthermore, SEAC confirmed that a Union wide measure is justified and concluded that the proposed restriction is an appropriate measure to address the human health risks to workers.

(9) RAC and SEAC also concluded that the proposed restriction is implementable, enforceable, manageable and monitorable.

(10) The Agency's Forum for Exchange of Information on Enforcement was consulted during the restriction process and its recommendations were taken into account.

(11) On 29 January 2016, the Agency submitted the opinions of RAC and SEAC[(4)] to the Commission. Based on those opinions, the Commission concluded that there is an unacceptable risk to the health of workers who handle thermal paper containing BPA in a concentration equal to or greater than 0,02 % by weight. Taking into account SEAC's considerations on affordability and distributional effects, the Commission considers that the proposed restriction would address the identified risks without imposing significant burden on industry, supply chain or consumers. Thus, the Commission concluded that the restriction proposed by France is an appropriate Union wide measure to address the identified risks to the health of workers who handle thermal paper containing BPA. By regulating the placing on the market, the proposed restriction would also provide a greater margin of protection for consumers.

(12) Since test methods to measure the concentration of BPA in thermal paper are currently available, the restriction is enforceable. As confirmed by SEAC, the application of the restriction should be deferred in order to enable industry to comply with it. A period of 36 months seems reasonable and sufficient for that purpose.

(13) In its opinion, RAC noted that bisphenol S (BPS), the most likely substitute according to France, may have a toxicological profile similar to BPA and might cause similar adverse health effects. Therefore, in order to avoid that the adverse effects of BPA would simply be superseded by the adverse effects of BPS particular attention should be paid to an eventual substitution trend towards BPS. To that end, the Agency should monitor the use of BPS in thermal paper. The Agency should communicate any further information to the Commission so that it considers whether a proposal to restrict BPS under Regulation (EC) No 1907/2006 is necessary given that, contrary to BPA, the health risk associated to BPS in thermal paper has not yet been evaluated.

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

(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*.

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