European Parliament
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Committee on the Environment, Public Health and Food Safety

2017/2942(RPS)

11.12.2017

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 106(2), (3) and (4)(c) of the Rules of Procedure

on the draft Commission regulation on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials
(D052935/03 – 2017/2942(RPS))

Committee on the Environment, Public Health and Food Safety

Members responsible: Martin Häusling,

Guillaume Balas, Frédérique Ries and Sirpa Pietikäinen

B8-0000/2018

European Parliament resolution on the draft Commission regulation (EU) on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials

(D052935/03 – 2018/0000(RPS))

The European Parliament,

– having regard to the draft Commission regulation on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials (D052935/03),

– having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC[1], and in particular points (d), (e), (h), (i) and (j) of Article 5(1) and Article 23(3) and (4) thereof,

– having regard to the European Parliament Resolution of 6 October 2016 on the Implementation of the Food Contact Materials Regulation (EC) No 1935/2004[2];

– having regard to the opinion by the European Food Safety Agency adopted on 11 December 2014 and published on 21 January 2015[3],

– having regard to the decision of the Member State Committee of the European Chemicals Agency which voted unanimously in June 2017 to identify BPA as a substance of very high concern (SVHC) because 'it is a substance with endocrine disrupting properties for which there is a scientific evidence of probable serious effects to human health'[4],

– having regards to the decision of the standing committee on Plants, Food and Feed which delivered a positive opinion on 25 September 2017,

– having regard to Article 5a(3)(b) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[5],

– having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,

– having regard to Rule 106(2), (3) and (4)(c) of its Rules of Procedure,

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1 OJ L 338, 13.11.2004, p. 4.
2 P8_TA(2016)0384.
3 Scientific Opinion on the risks to public health related to the presence of bisphenol A in foodstuffs, available at http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.3978/epdf
4 https://echa.europa.eu/documents/10162/ac9efb97-c06b-d1a7-2823-5dc69208a238
5 OJ L 184, 17.7.1999, p. 23.

BPA in polycarbonates and epoxy resins

A. whereas bisphenol A (BPA) is used in the manufacture of polycarbonates and epoxy resins and as an additive in plastics; whereas polycarbonates are used in food contact materials such as reusable drinking bottles, infant feeding bottles, tableware (plates and mugs) and storage containers; whereas epoxy resins, in the form of varnishes and coatings, are used as internal protective linings for food and drinks cans and as a coating on metal lids for glass jars and bottles;

B. whereas BPA can migrate into food from the material or article with which it is in contact, resulting in exposure to BPA for consumers of those foods;

Measures set out in draft regulation

C. whereas the draft Commission regulation on the use of bisphenol A in varnishes and coatings ("the draft regulation") sets a specific migration limit (SML) of 0,05 mg of BPA per kg of food (mg/kg) from plastic materials and articles and from varnishes or coatings applied to materials and articles intended to come into contact with food; whereas the current SML for BPA, currently only applicable to plastic materials and articles, is 0,6 mg/kg;

D. whereas by derogation from the 0,05 mg/kg SML, the draft regulation specifies that 'no migration of BPA shall be permitted from varnishes or coatings applied to materials and articles specifically intended to come into contact with infant formula, follow-on formula, processed cereal-based food, baby food, food for special medical purposes developed to satisfy the nutritional requirements of infants and young children or milk-based drinks and similar products specifically intended for young children, as referred to in Regulation (EU) No 609/2013[1];

E. whereas Commission Implementing Regulation (EU) No 321/2011 placed a restriction on the use of BPA in the manufacture of polycarbonate infant feeding bottles which was introduced in 2011 on the basis of the precautionary principle; whereas the draft regulation, again on the basis of the precautionary principle, extends this restriction to drinking cups which 'due to their spill proof characteristics are intended for infants and young children';

Difficulties in verifying compliance

F. whereas 'no migration of BPA shall be permitted' de facto means that migration of BPA up to 0,01 mg/kg will be permitted[2]; whereas a migration-based approach still allows the use of BPA and tolerates a certain exposure, rather than avoid exposure altogether by

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[1] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181 29.6.2013, p. 35).

[2] Article 11 of Regulation 2011/10 specifies that where no specific detection limits have been set for particular substances or groups of substances a detection limit of 0,01 mg/kg shall apply.

prohibiting its use; whereas the migration of substances is influenced by the different type of materials used for packaging as well as by the type of food and the temperature, making it impossible to exclude migration under all conditions,; whereas compliance will be extremely difficult to verify and could lead to inconsistencies based upon different laboratory detection limits; whereas it is far easier to measure content than migration;

G. whereas, in accordance with Article 4 of the draft regulation, business operators shall ensure that varnished or coated materials and articles are accompanied by a written declaration of compliance (DoC); whereas, as stated by the Parliament in 2016[1], the quality of DoCs is not always high enough to ensure that they are a reliable source of compliance documentation;

H. whereas verification of compliance with migration levels (the 0,05 mg/kg SML and 'no migration' limit) puts an unnecessary burden on national competent authorities given the technical complexities involved;

Health risks associated with BPA

I. whereas human studies have shown that most children, as well as adult men and women, including pregnant women, have measurable levels of BPA in body fluids and tissues sampled[2];

J. whereas a 2006 study found that recent trends in human diseases relate to adverse effects observed in experimental animals exposed to low doses of BPA with specific examples including an increase in prostate and breast cancer, uro-genital abnormalities in male babies, a decline in semen quality in men, early onset of puberty in girls, metabolic disorders including insulin resistant (type 2) diabetes and obesity, and neurobehavioral problems such as attention deficit hyperactivity disorder (ADHD)[3];

K. whereas, on 14 June 2017, the Member State Committee of the European Chemicals Agency (ECHA) voted unanimously to identify BPA as a substance of very high concern (SVHC) because 'it is a substance with endocrine disrupting properties for which there is a scientific evidence of probable serious effects to human health which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 REACH[4]';

L. whereas the ECHA classification concluded that on the basis of evidence available in relation to alteration of the reproductive function, mammary gland development, cognitive function and metabolism, BPA can be considered an endocrine disruptor for human health, that it is not excluded that BPA may also alter other physiological functions and that the

[1] European Parliament resolution on Implementation of the Food Contact Materials Regulation, paragraph 38: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bTA%2bP8-TA-2016-0384%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN

[2] http://www.loe.org/images/content/070803/Vandenberg%20Exposure%20Rep%20Tox%20resubmission.pdf

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2967230/

[4] https://echa.europa.eu/documents/10162/13638/svhc_msc_agreement_bpa_ii_en.pdf/ac9efb97-c06b-d1a7-2823-5dc69208a238

range of experimental effects induced by BPA in relation to its endocrine disruptor mode of action is predictive of serious health outcomes which are permanent and irreversible;

M. whereas the evidence used by ECHA shows significant uncertainties in establishing safe levels as well as a quantitative dose-response; whereas the European Food Safety Authority (EFSA) derived its recommendation of 0,05 mg/kg from a Benchmark Dose ($BMDL_{10}$) of 8960 µg/kg bw per day, which, in turn, was derived from mean relative kidney weight in a two generation study in mice; whereas the support document for the ECHA classification states that 'effects on the reproductive system have been observed at and below the range where kidney effects occur' and that 'a number of recent studies have confirmed that an alternation of cognitive performance is observed in the vast majority of studies below 9 mg/kg[1];

N. whereas a March 2017 study, peer reviewed by two eminent scientists[2], explains that pregnancy, childhood and adolescence are periods of brain development that are considered critically sensitive to toxic chemicals and rapid changes occurring during these life-stages render a child highly susceptible to environmental chemicals, with even small exposures at the wrong time altering the brain's developmental programming signals in an irreversible way;

O. whereas the same study states that impaired brain development may result in a broad range of human effects from altered reproduction, metabolism and stress response, to mental retardation, and subtle, subclinical intellectual deficiencies; whereas the study outlines that foetal and early childhood life stages are particularly sensitive to endocrine disruptors such as BPA, that there are likely to be no safe levels which can be set with sufficient certainty and that exposure to these chemicals via the food supply chain is a preventable cause of impaired brain development;

P. whereas a study published in August 2017[3] found that the BPA effect on testosterone in foetal human tissues was multiplied by 10 when combined with 7 other chemicals and 'provides direct evidence that co-exposure should be considered when evaluating the risk of a single chemical'; whereas many other studies also show how small doses of different chemicals acting together can produce a cocktail effect[4];

Q. whereas ECHA changed its classification of BPA as toxic to reproduction from 2 (suspected) to 1B (presumed) in July 2016;

R. whereas a joint assessment in 2015 by ECHA's Committee for Risk Assessment (RAC)

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[1] See page 165 of ECHA support document. https://echa.europa.eu/documents/10162/19cadd97-452f-8901-000f-04930c8531d4 9mg is equivalent to 8960µg.

[2] http://www.chemtrust.org/brain/

[3] Pierre Gaudriault, Séverine Mazaud-Guittot, Vincent Lavoué, Isabelle Coiffec, Laurianne Lesné, Nathalie Dejucq-Rainsford, Martin Scholze, Andreas Kortenkamp, Bernard Jégou, "Endocrine Disruption in Human Fetal Testis Explants by Individual and Combined Exposures to Selected Pharmaceuticals, Pesticides, and Environmental Pollutants", *Environmental Health Perspectives,* vol.125 issue 8, August 2017: DOI:10.1289/EHP1014 https://ehp.niehs.nih.gov/ehp1014/#tab1

[4] Some examples can be seen here http://www.nature.com/articles/ncomms9089, http://www.foodpackagingforum.org/news/carcinogenicity-of-cocktails-highlighted and http://www.food.dtu.dk/english/News/Nyhed?id=ED25058B-D02C-4CF2-B1AB-20E0D8054290

and Committee for Socio-economic Analysis (SEAC) on restrictions on BPA states that bisphenol S (BPS) may have a toxicological profile similar to BPA and is suspected of having many of the same adverse health effects, and therefore advises against substitution of BPA with BPS[1];

Measures taken at Member State level and by retailers and industry

S. whereas some Member States have already put in place restrictions on BPA in food contact materials (FCM)[2]; whereas a French ban on the use of BPA in all FCM came into force in 2015;

T. whereas many companies have already committed to going BPA free[3]; whereas many retailers across Europe have or will be banning BPA from their products[4];

U. whereas a 2013 report by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) highlighted that there is no one-size-fits-all replacement for BPA but identified at least 73 possible alternatives[5]; whereas while the safety of some alternatives may need to be fully verified, there is no risk identified when it comes to the use of glass, silicone or ceramics as replacements; whereas safer alternatives to BPA in epoxy-based coatings for the inside of food and drinks cans already exist on the market[6];

V. whereas in France, there is a portal on BPA to help companies with substitution[7]; whereas ECHA signposts companies who are looking for information on alternatives to BPA towards this portal[8];

W. whereas the adoption of this draft regulation would topple existing bans and restrictions in FCM already in place at national level; whereas Member States who would like to bring in

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[1] https://echa.europa.eu/documents/10162/9ce0977b-3540-4de0-af6d-16ad6e78ff20

[2] Countries which have put in place restrictions include Denmark (https://chemicalwatch.com/5782/denmark-stands-firm-on-bpa-ban), Sweden (https://www.chemistryworld.com/news/sweden-bans-bpa-in-food-packaging-for-under-threes/5013.article) and Belgium (https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Belgium%20bans%20use%20of%20Bisphenol%20A_The%20Hague_Belgium-Luxembourg_1-15-2013.pdf)

[3] Examples include Nestle and Heinz (http://www.independent.co.uk/life-style/health-and-families/health-news/major-producers-to-ditch-bpa-from-packaging-2121837.html) as well as Campbell's (https://www.campbellsoupcompany.com/newsroom/press-releases/campbell-to-remove-bpa-from-packaging-by-mid-2017/)

[4] For example, the Basque consumer co-operative Eroski does not use BPA in any of its own-branded products, the Danish Coop has banned BPA and other bisphenols in June 2016, replacing them with epoxy lacquer in cans in co-operation with the Danish packaging industry association and the Finnish consumer co-operative SOK is in the process of replacing all own-brand packaging materials containing BPA and the complete substitution will be finalised by 2018 (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4140854/feedback/F6886_en)

[5] https://www.anses.fr/en/content/potential-alternatives-bisphenol

[6] https://marketplace.chemsec.org/Alternative/valPure-V70-the-first-next-generation-coating-technology-with-epoxy-like-performance-28

[7] https://substitution-bp.ineris.fr/en

[8] https://echa.europa.eu/regulations/substituting-hazardous-chemicals/examples-from-real-life/safer-alternatives-for-bisphenol-a

stronger measures in the future to protect their populations would not be able to do so if this draft measure is adopted;

Failure to take on board the concerns of Parliament

X. whereas in October 2016 the European Parliament called on the Commission to ensure that harmful substances phased out under REACH are also phased out in FCMs, to extend the concept of vulnerable groups to pregnant and breastfeeding women and to include the potential effects of low-dose exposure and non-monotonic dose responses in the risk assessment criteria; whereas the European Parliament also called for a ban of BPA in all FCM[1];

Failure to secure a high level of protection of human health

Y. whereas the purpose of Regulation (EC) No 1935/2004 is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health;

Z. whereas Article 14 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[2] states that in determining whether any food is injurious to health, regard shall be had, inter alia, not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;

AA. whereas the multiple EFSA evaluations over the last decade have not effectively addressed all health concerns; whereas the fact that EFSA is regularly reviewing safe limits says something in itself about the uncertainty surrounding the effects of the substance;

AB. whereas the sole basis for the draft regulation is the EFSA opinion which was adopted in 2015; whereas that EFSA opinion does not take into account the 'cocktail effect' of chemicals to human health; whereas the draft regulation does not take into account the latest science nor the 2017 ECHA classification of BPA as a substance with endocrine disrupting properties for which there is a scientific evidence of probable serious effects to human health; whereas, in accordance with Article 6 of Regulation (EC) No 178/2002, the Commission as risk manager shall take into account, in addition to EFSA's opinion, other legitimate factors as well as the precautionary principle;

AC. whereas the failure of the Commission to extend the ban on BPA beyond polycarbonate drinking cups in the draft regulation is inconsistent with the need to protect vulnerable groups such as pregnant women and their unborn children, and fails to secure a high level of protection of human health;

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[1] See paragraphs 30, 20 and 32 in Parliament's 2016 resolution: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bTA%2bP8-TA-2016-0384%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p.1).

AD. whereas, in relation to the 'no migration' limit, food and drink for young children and infants, as defined by Regulation (EU) No 609/2013, only covers children up to three years old; whereas infants and children of all ages consume food and drink from containers that are not specifically intended for them;

AE. whereas given the potential damage which may accrue for children later in life, meaningful action is long overdue; whereas regulatory action should be taken on the basis of the precautionary principle; whereas the costs of any remaining uncertainty about the safety of such a dangerous endocrine disruptor should not be borne by future generations;

AF. whereas only a full ban on BPA in FCM can fulfil the purpose of Regulation (EC) No 1935/2004; whereas only a full ban will be effective and enforceable; whereas only a full ban can provide certainty for both consumers and industry;

1. Opposes adoption of the draft Commission regulation;
2. Considers that the draft Commission Regulation is not compatible with the aim and content of Regulation (EC) No 1335/2004;
3. Calls for a ban on BPA in all plastic material and articles, as well as in varnishes and coatings, intended to come into contact with food, and that this ban should enter into force without delay;
4. Calls on the Commission to withdraw the draft regulation and submit a new one to the committee in accordance with Paragraph 3;
5. Calls on the Commission to urgently assess whether BPA is present in other FCM, and if so, to put measures in place to also ban these uses;
6. Calls on the Commission to follow the ECHA Risk Assessment Committee's analysis of BPA and BPS, and to advise industry not to substitute BPA with BPS;
7. Calls on the Commission to urgently assess whether, in addition to BPA, any other bisphenols have similar endocrine disrupting properties; if this cannot be excluded, they should also be subject to a ban in FCM;
8. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.