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Committee on the Environment, Public Health and Food Safety

2017/0000(RPS)

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DRAFT MOTION FOR A RESOLUTION

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

on the draft Commission regulation amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
(D047219/03 – 2017/0000(RPS))

Committee on the Environment, Public Health and Food Safety

Member responsible: Julie Girling

B8-0000/2017

European Parliament resolution on the draft Commission regulation amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
(D047219/03 – 2017/0000(RPS))

The European Parliament,

– having regard to the draft Commission regulation amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (D047219/03),

– 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 Articles 2(5)(a), 58 and 131 thereof,

– having regard to Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy[2],

– having regard to Article 5 of the Treaty on European Union,

– having regard to Article 168 of the Treaty on the Functioning of the European Union,

– 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[3],

– 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,

A. whereas draft Commission regulation amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (D047219/03) notes that the substance group 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated are substances which through their degradation have endocrine disrupting properties for which there is evidence that discharges result in probable serious effects on the environment;

B. whereas the substance group 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated is used

[1] OJ L 396, 30.12.2006, p. 1.
[2] OJ L 226, 24.8.2013, p. 1.
[3] OJ L 184, 17.7.1999, p. 23.

primarily in the manufacture of paints, resins and emulsions, as well as in a product known under the trade name “Triton X-100”;

C. whereas one industrial use of Triton X-100 is its use in the life sciences sector, including in biopharmaceuticals, blood plasma, medical devices, *in vitro* diagnostic medical devices and laboratory and clinical chemistry sectors for viral inactivation and to remove protein impurities from biotech medicinal products and processes in order to ensure patient safety;

D. whereas the Commission has authorised the use of Triton X-100 in the manufacture of medicinal products used in many therapy areas including cancer, diabetes, influenza vaccines, blood plasma, and veterinary medicines; whereas plasma protein therapies are classified as ‘Essential Medicines’ by the World Health Organisation (WHO)[4]; whereas the use of Triton X-100 is referenced in both European Medicines Agency (EMA)[5] and WHO[6] Guidance;

E. whereas there has been no impact assessment or risk management option analysis carried out to assess the impact on the life science sector of listing the substance group 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated in Annex XIV of Regulation (EC) No 1907/2006 (REACH);

F. whereas according to point (a) of Article 2(5) of REACH, “the provisions of Titles II, V, VI and VII shall not apply to the extent that a substance is *used in* [emphasis added] medicinal products for human or veterinary use”[7]; whereas this derogation is not extended to substances *used in the manufacture* of active ingredients used in those medicinal and veterinary products;

G. whereas the standard duration of an authorisation under REACH is seven years, which can be extended to 12 years under certain conditions[8];

H. whereas the duration of an authorisation should take into account the practical availability of alternatives, and the life cycle of the products in question; whereas the regulatory life cycle of medicinal products is a unique length and the clinical trials phase alone can exceed 12 years[9];

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[4] “19th WHO Model List of Essential Medicines”, WHO, 2015, Annex 1.
[5] “Guideline on plasma-derived medicinal products”, EMA, 2010, point 8.2.4
[6] WHO Technical Report Series 924, 2004, Annex 4.
[7] Within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
[8] “Setting the review period with RAC and SEAC give opinions on an application for authorisation”, ECHA, 2013, https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf
[9] “How long a new drug takes to go through clinical trials”, Cancer Research UK, http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/how-clinical-trials-are-planned-and-organised/how-long-it-takes-for-a-new-drug-to-go-through-clinical-trials

I. whereas the substitution of Triton X-100 will require the identification of a suitable alternative which can offer equal levels of patient safety, whereas its substitution may also require modifications to existing marketing authorisations granted by EMA, and further clinical trials and animal testing may be necessary to prove equivalent efficacy and patient safety;

J. whereas the use of Triton X-100 as a viral inactivation agent and the degradant of concern, 4-tert-OP, are regulated under other pieces of Union legislative acts, including Directive 2000/60/EC of the European Parliament and of the Council[10] (the Water Framework Directive); whereas measurements undertaken by the UK Environment Agency of 4-tert-OP in UK waters (2000-2008) showed that 99,9% of the samples were below the Annual Average Environmental Quality Standard (AAEQS) set for 4-tert-OP[11];

K. whereas some life sciences sectors which use Triton X-100 in their manufacturing processes operate a capture system which is intended to limit any release into the environment to safe levels;

L. whereas the listing of substance group 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated will have an impact on the manufacture of medicinal products, medical devices and *in vitro* diagnostic medical devices in the Union where Triton X-100 is used, but will not have an impact on the placing on the market of medicinal products manufactured using Triton X-100 imported from outside the Union;

M. whereas in the framework of Directive 2013/39/EU, the Commission had a legal obligation to develop a strategic approach to water pollution by pharmaceutical substances by the end of 2015; whereas to date, no such strategic approach has been developed;

1. Opposes adoption of the draft Commission regulation;

2. Considers that the draft Commission regulation is not compatible with the aim of Regulation (EC) No 1907/2006 to ensure a high level of protection of human health and the environment, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation;

3. Considers that the draft Commission regulation fails to respect the principle of proportionality concerning the use of Triton X-100 in the biopharmaceutical and wider life sciences sector;

4. Calls on the Commission to withdraw the draft regulation and submit a new one to the committee which takes adequate account of the specific circumstances of the biopharmaceutical and wider life sciences sector and the significance of this sector for public health and patient safety;

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[10] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p.1).

[11] Responses to Comments Document (RCOM) on ECHA's Draft 5th Recommendation for 4 (1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)) (EC number:), ECHA, 2014.

5. Calls on the Commission to include in the new draft regulation an extension of the sunset date for the substance group 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated, in order to allow for a sector-specific risk management option analysis and an impact assessment on the implications for the biopharmaceutical and wider life sciences sector to be carried out;

6. Calls on the Commission to consider exempting the use of Triton X-100 by those parts of the life science sector operating a capture system where it can be demonstrated that emissions of Triton X-100 from manufacturing are below the relevant predicted no-effect concentration (PNEC) for 4-tert-OP;

7. Calls on the Commission to consider the issue of substances used in the manufacture of active pharmaceutical ingredients (APIs) and life science products as part of the REACH REFIT evaluation; calls on the Commission to also re-commit to developing a strategic approach to water and environmental pollution by pharmaceutical substances;

8. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.