



2019/2843(DEA)

25.11.2019

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 111(3) of the Rules of Procedure

on the Commission delegated regulation of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation
(C(2019)07227 – 2019/2843(DEA))

Committee on the Environment, Public Health and Food Safety

Member responsible: Anna Zalewska

**European Parliament resolution on the Commission delegated regulation of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation
(C(2019)07227 – 2019/2843(DEA))**

The European Parliament,

- having regard to the Commission delegated regulation of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation (C(2019)07227),
 - having regard to Article 290 of the Treaty on the Functioning of the European Union,
 - having regard to Regulation (EC) No 1272/2008 of the European Parliament and of 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 1907/2006¹, and in particular Articles 37(5), 53(1) and 53a(6) thereof,
 - having regard to the principle of proportionality enshrined in Article 5 of the Treaty on European Union and Protocol No 2 on the application of the principles of subsidiarity and proportionality, annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union,
 - having regard to Rule 111(3) of its Rules of Procedure,
 - having regard to the motion for a resolution by the Committee on the Environment, Public Health and Food Safety,
- A. whereas titanium dioxide (TiO₂) is a widespread naturally occurring oxide of titanium existing in a number of crystalline forms, including rutile, brookite and anatase;
- B. whereas TiO₂ is an inert, thermally stable, non-combustible, insoluble compound, which is not classified as hazardous under the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals;
- C. whereas TiO₂, due to its ability to scatter light and absorb ultraviolet light has been extensively used as a colourant for more than a century creating a global market whose value is anticipated to be in excess of EUR 25 billion in 2025;
- D. whereas TiO₂ is commonly applied in a wide variety of sectors including cosmetics, medicines, ceramics, packaging, construction, automotive components and electric and electronic equipment;

¹ OJ L 353, 31.12.2008, p. 1.

- E. whereas at the 14th adaptation to technical progress of Regulation (EC) No 1272/2008 (the ‘CLP Regulation’), the Commission proposed a harmonized classification of TiO₂ as a category 2 carcinogen for mixtures in powder form, despite the supporting evidence providing an inadequate Klimisch data reliability score, firm opposition from many Member States citing concerns with the scientific evidence base, and the potential negative ramifications set by this precedent in the classification of other powder-based compounds;
- F. whereas Article 37(5) of the CLP Regulation states that the Commission shall without undue delay adopt delegated acts concerning the inclusion of the substance concerned together with the relevant classification and labelling elements in Table 3.1 of Part 3 of Annex VI, if it finds that the harmonisation of the classification and labelling of that substance is ‘appropriate’; the CLP Regulation therefore does not establish an obligation on the Commission to proceed with the harmonised classification, but instead provides that the Commission should also consider alternative solutions;
- G. whereas Article 5 of Protocol No 2 states, inter alia, that ‘Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved’;
- H. whereas the Risk Assessment Committee (RAC) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council²(the ‘REACH Regulation’) rejected 1A and 1B carcinogenicity classifications based on the fact that the adverse effects of TiO₂ on rat lungs, when overloaded, are not its intrinsic feature but are linked to its powder form which poses a risk following a long period of inhalation of extreme concentrations (250 mg/m³) for over 18 months, due to its low solubility in the lungs;
- I. whereas that conclusion was largely based on a study conducted on rats³; whereas the authors of that study and the RAC under the REACH Regulation stated ‘there is no convincing scientific evidence to question the human relevance of observed rat lung adenocarcinomas’; whereas some reputable contributors during the public consultation process in relation to the adaptation to technical progress, such as the German work accident insurance association, stated they have ‘no evidence of lung cancer cases in workplaces working with titanium dioxide’⁴; whereas workplace exposure standards for TiO₂ could be introduced by way of harmonised occupational exposure limits (OELs) within the framework of occupational health and safety legislation, as many Member States and other stakeholders have proposed;
- J. whereas there are potential downstream effects from this carcinogenicity classification for products containing TiO₂ in solid and liquid form which, despite being rigorously tested for their safety, may be stigmatised as potentially being unsafe; whereas this

² 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 (OJ L 396, 30.12.2006, p. 1).

³ K.P. Lee, H.J. Trochimowicz, C.F. Reinhardt, Pulmonary response of rats exposed to titanium dioxide (TiO₂) by inhalation for two years, *Toxicol. Appl. Pharmacol.*, 79 (1985), pp. 179-182.

⁴ https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-141469/feedback/F18258_en?p_id=352721

could mislead consumers and create business uncertainty;

- K. whereas the carcinogenicity classification is inconsistent with the prevailing innovation context existing in many scientific disciplines and could potentially end the use of TiO₂ in environmental applications for air and water purification, atmosphere cooling solutions and reducing the concentration of toxic and harmful substances⁵⁶⁷;
- L. whereas recycling and reuse in a circular economy could also be negatively affected as the classification would establish new obligations for the treatment and disposal of waste containing 1 % or more of TiO₂ (i.e. in plastics, wallpaper, paint residues, porcelain and furniture), as this would be classified as hazardous, even where there is no potential risk to human health; whereas there are at present no commercially viable alternatives that ensure a high level of protection of human health which also maintain the efficacy and functionality of TiO₂;
- M. whereas TiO₂ is being assessed in accordance with the REACH Regulation and this process will provide a more comprehensive and detailed evaluation;
1. Objects to the Commission delegated regulation;
 2. Considers that the Commission delegated regulation should not have been adopted in accordance with the CLP Regulation, given that it applies to substances that are hazardous due to their individual properties and a more comprehensive and detailed evaluation of TiO₂ is still in progress under the REACH Regulation;
 3. Considers that the Commission delegated regulation goes beyond what is necessary and proportionate to address possible health risks arising from workplace exposure to TiO₂ powder and risks stigmatising the substance in other forms as being unsafe;
 4. Calls on the Commission to withdraw the delegated regulation and to consider other options such as a harmonised occupational exposure limit (OEL) for TiO₂ within the framework of the occupational health legislation;
 5. Instructs its President to forward this resolution to the Commission and to notify it that the delegated regulation cannot enter into force;
 6. Instructs its President to forward this resolution to the Council and to the governments and parliaments of the Member States.

⁵ Radek Zouzelkaab, Radek Zouzelkaab, Photocatalytic abatement of NO_x pollutants in the air using commercial functional coating with porous morphology, J. Heyrovsky Institute of Physical Chemistry, University of Chemistry and Technology Prague.

⁶ W. R. Siah, N. A. Roslan, H. O. Lintang, M. Shamsuddin, L. Yuliaty, Photocatalytic Removal of 2,4-D Herbicide on Lanthanum Oxide-Modified Titanium Dioxide, Adv. Mater. Res. 2015, 1112, 168-171.

⁷ N. S. Alim, H. O. Lintang, L. Yuliaty, Photocatalytic removal of phenol over titanium dioxide-reduced graphene oxide photocatalyst, IOP Conf. Series: Materials Science and Engineering 2016, 107, 012001.