



Brussels, 4.10.2019  
C(2019) 7227 final

**COMMISSION DELEGATED REGULATION (EU) .../...**

**of 4.10.2019**

**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**

(Text with EEA relevance)

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE DELEGATED ACT

The objectives of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) are to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles. These objectives are fulfilled, *inter alia*, by establishing a list of substances with their harmonised classifications and labelling elements at Union level. Article 37 of Regulation (EC) No 1272/2008 empowers the Commission to include substances in Table 3.1 of Part 3 of Annex VI (Table 3.1 has been renamed Table 3, following the deletion of Table 3.2).

Based on the opinions issued by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as on the comments received from the parties concerned, it is appropriate to introduce, update, delete or leave unchanged the harmonised classification and labelling of certain substances and amend Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 accordingly.

In addition, it is appropriate to include harmonised Acute Toxicity Estimates (ATE) values for certain substances in the entries listed in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008, in order to facilitate the harmonisation of the classification of mixtures and to provide support for enforcement authorities.

Moreover, it is necessary to correct the harmonised classification and labelling for the substance pitch, coal tar, high temp., before 1 December 2019, which is the applicability date of Commission Regulation (EU) 2018/669, as that Regulation amends erroneously the harmonised classification and labelling of that substance.

### 2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 37(4) of Regulation (EC) No 1272/2008, ECHA has performed a public consultation for each substance, before the adoption of the respective opinions on the proposals for harmonised classification and labelling of substances by its Committee for Risk Assessment. In addition, the Commission held a public consultation on the draft legal text adding those substances to Annex VI to CLP, from 11 January to 8 February 2019.

This Commission Delegated Regulation was initially drafted in the form of a Commission Regulation that was subject to the Regulatory Procedure with scrutiny. In that framework, the draft Regulation has been submitted for discussion to the Committee established by Article 133 of Regulation (EC) No 1907/2006. Subsequently, in accordance with Regulation (EU) 2019/1243<sup>1</sup>, which covers, *inter alia*, Regulation (EC) No 1272/2008, the initial draft Regulation has been redrafted as a Commission Delegated Regulation.

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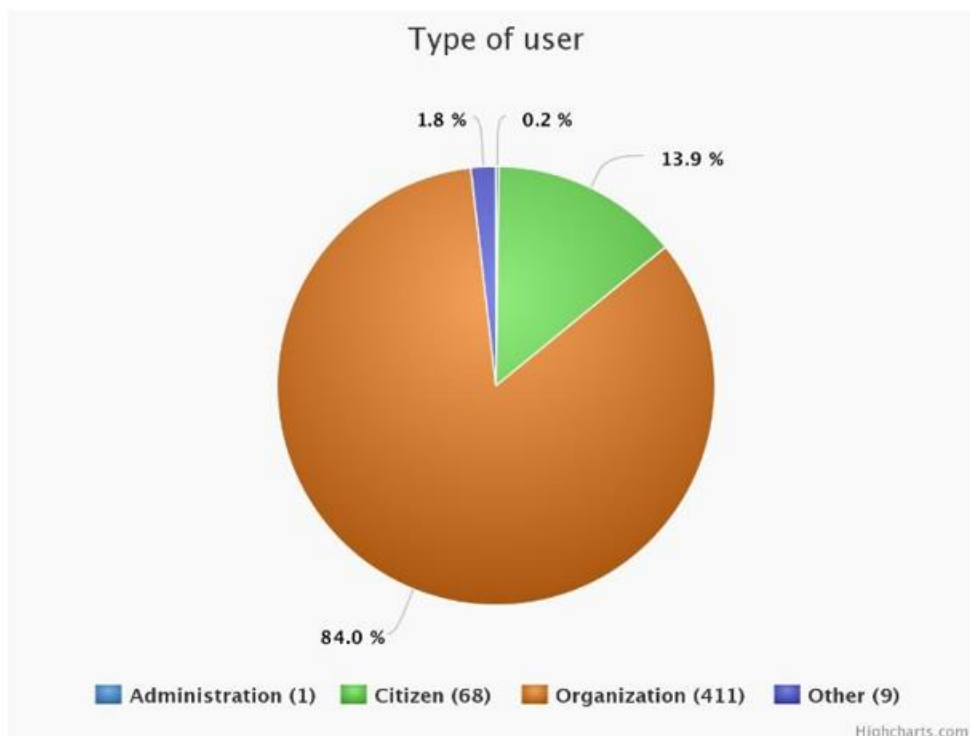
<sup>1</sup> Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (OJ L 198, 25.7.2019, p. 241).

Pursuant to Article 53a(4) of Regulation (EC) No 1272/2008 (which was inserted in accordance with Regulation (EU) 2019/1243), experts designated by each Member State were consulted in the relevant expert group CARACAL (Competent authorities for REACH and CLP), in line with point 4 of the Annex to the Interinstitutional Agreement on Better Law-Making of 13 April 2016<sup>2</sup>. Furthermore, in accordance with point 10 of the Annex to that Agreement, the European Parliament and the Council have been invited to participate in the CARACAL expert group.

Below is a summary of the above-mentioned public feedback, received from 11 January to 8 February 2019, on the “Hazardous chemicals — new rules on classification, labelling and packaging” proposal (Hazardous chemicals proposal). The Commission received feedback from a number of individuals and organisations, mostly associated with chemical industry, from both Europe and elsewhere (hyperlink to the consultation: [https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-141469/feedback\\_en?p\\_id=352721](https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-141469/feedback_en?p_id=352721)). This feedback referred to only 3 out of the 28 substances subject to amendment in the draft Commission Regulation: titanium dioxide, cobalt and DTPA.

More specifically, 489 comments were received, 411 of which came from various organisations: businesses, business associations and consortia from various sectors. The other comments were submitted by individuals, either in their own name or anonymously or as representatives of companies, often sharing the views of the business organisations. Moreover, around the time of the public consultation, 27 NGOs reacted outside the framework of the public feedback mechanism. They did not share the views of the industry.

The following summarises the feedback received on the Hazardous chemicals proposal.



<sup>2</sup> Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

## **A. Titanium dioxide (TiO<sub>2</sub>)**

### **a. Scientific arguments**

The overwhelming majority of the comments focuses on the classification of titanium dioxide (TiO<sub>2</sub>). According to these comments, the measure is disproportionate and inefficient, in particular for TiO<sub>2</sub> used as a pigment in the pulp and paper industry, in the ceramics, paint, aluminium, printing ink, coating, and wood-based materials industry, and especially for SMEs. It would lead to reduced sales and uncertainty for consumers.

The majority of contributors focuses on the alleged lack of data demonstrating adverse health effects of TiO<sub>2</sub>. It is argued that the results of the toxicity study on TiO<sub>2</sub>, which was carried out in 1995 on rats and was used in RAC's Opinion, cannot be extrapolated as such to humans. Some stakeholders additionally refer to the epidemiological studies on 24,000 employees in TiO<sub>2</sub> factories, which did not show negative health effects for humans.

Moreover, according to the contributors, the human impact is arguably not based on the intrinsic nature of TiO<sub>2</sub>, but only on its physical form, since the lung overload effect observed in the above-mentioned toxicity study resulted from the physical characteristics of a broad range of poorly soluble low toxicity (PSLT) respirable dusts. In the same framework, it is argued that, although the specific study was strictly limited to the assessment of TiO<sub>2</sub> in its particulate form, the proposed classification would extend to TiO<sub>2</sub> that is embedded in a solid or liquid matrix. The relevant IARC (International Agency for Research on Cancer) Monograph<sup>3</sup> is also invoked as stating that where TiO<sub>2</sub> particles are encapsulated within a matrix, such as paint, human exposure is not significant. Thus, if TiO<sub>2</sub> were classified on the basis of particle toxicity only, a precedent might be set for other poorly soluble, low toxicity substances, with potential hazards resulting from particle toxicity.

Furthermore, a few contributors refer to the scientific evaluation of TiO<sub>2</sub> carried out by the European Food Safety Agency (EFSA) in 2018, which confirmed its safety as a food additive (E 171).

In addition, some contributors argue that TiO<sub>2</sub> is also a substance under evaluation in the framework of the REACH Regulation, under the Community Rolling Action Plan (CoRAP). Thus, more test results are expected on carcinogenicity via inhalation, which would increase the reliability of the final decision.

### **b. Downstream legal consequences**

Further arguments are put forward by a number of contributors, regarding the downstream legal consequences triggered by a classification of TiO<sub>2</sub> as a carcinogen Category 2. In particular, it is suggested that the EU's circular economy strategy would be seriously impacted. The proposed classification would allegedly lead to additional waste management obligations to deal with waste containing 1% or more TiO<sub>2</sub>, such as plastics, wallpaper and paint residues, porcelain or furniture, since this would be classified as hazardous waste, even if there were no potential for inhalation. In addition to the economic repercussions for industry, the recycling of these materials would be hindered, according to this argument.

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<sup>3</sup> *Carbon Black, Titanium Dioxide, and Talc*, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 93, Lyon 2010

Furthermore, it is suggested that any products containing TiO<sub>2</sub> as white pigment would not be able to get an eco-label.

Claims of impact were also made with regard to: the PET (packaging resin) industry (as their EU-based recovery targets would be threatened, since they claim that certain waste would be classified as hazardous); food security, since TiO<sub>2</sub> is used in plastic packaging of food to keep it from spoiling; energy efficiency and climate change; international trade, as the EU would be advancing an unfounded interpretation of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

### **c. Suggestions**

A counter-suggestion made by a number of Member States' competent authorities, which was supported by many contributors, focuses on dealing with the dust hazard. As argued, the hazard of TiO<sub>2</sub> is not due to its chemical composition, according to these comments, but rather to the inhalation of dust particles as such. Thus, a harmonised occupational exposure limit (OEL) for the EU, within the framework of the occupational health legislation, should be considered as an alternative solution.

In more general terms, better enforcement of existing legislation is recommended as a more appropriate measure. As a minimum next step, a full impact assessment is proposed by some contributors.

In case the classification proposal proceeds as intended, some contributors also suggest rephrasing Note 10 of Annex VI into: 'The classification as a carcinogen by inhalation applies only to mixtures placed on the market in powder form containing 1% or more of titanium dioxide particles with diameter  $\leq 10 \mu\text{m}$  not bound within a matrix'.

### **B. Cobalt (32 comments)**

All but one comment challenges the classification of cobalt as a carcinogen for all routes of exposure and as a mutagen. The classification as a carcinogen by inhalation Category 1B and the use of the generic concentration limit of 0,1%, instead of a specific one of 0,01%, are supported. The postponement of the decision related to the cobalt classification is requested, until the following ongoing initiatives are completed or clarified: the review of the T25 methodology used to derive the concentration limit as well as the assessment of the approach for classifying alloys using the bioelution methodology. It is also requested to review epidemiological studies and to rediscuss the classification on mutagenicity.

One comment provides reference to scientific publications on cancer mortality and morbidity in a cohort of Swedish hard-metal workers.

### **C. DTPA (13 comments)**

All comments express the request to the European Commission and the Member States to postpone the final decision on DTPA classification on reproductive toxicity, until RAC has had a chance to review the new scientific information provided by the dossier submitters.

### **Conclusion**

The comments submitted in the framework of the public consultation on the draft Commission Regulation have been taken into account. The Commission concluded that the comments regarding the substances TiO<sub>2</sub> and cobalt did not justify amending the draft Commission Regulation, since no new substantial information that would challenge RAC's scientific opinion was put forward. As to the comments regarding the substance DTPA, the Commission concluded that they warranted amending the draft Commission Regulation regarding that substance, in particular its classification as toxic for reproduction Category 1B,

which has been deleted for the time being, in view of the new scientific information that was provided.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The legal act amends Regulation (EC) No 1272/2008. The legal bases of this delegated act are Articles 37(5) and 53(1) of Regulation (EC) No 1272/2008. It also corrects an error made due to an oversight in Commission Regulation (EU) 2018/669, which had previously amended Regulation (EC) No 1272/2008.

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(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 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 1907/2006<sup>4</sup>, and in particular Articles 37(5) and 53(1) thereof,

Whereas:

- (1) Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 contains the list of harmonised classification and labelling of hazardous substances based on the criteria set out in Parts 2 to 5 of Annex I to that Regulation.
- (2) Proposals to introduce harmonised classification and labelling of certain substances and to update or delete the harmonised classification and labelling of certain other substances have been submitted to the European Chemicals Agency ('Agency') pursuant to Article 37 of Regulation (EC) No 1272/2008. Based on the opinions on those proposals issued by the Committee for Risk Assessment of the Agency (RAC), as well as on the comments received from the parties concerned, it is appropriate to introduce, update or delete harmonised classification and labelling of certain substances. Those RAC opinions<sup>5</sup> are:
  - Opinion of 9 June 2017 concerning 4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH<sub>4</sub>Cl), pentachlorophosphorane and phenol
  - Opinion of 22 September 2017 concerning disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene-2,7-disulfonate
  - Opinion of 9 June 2017 concerning Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide;
  - Opinion of 22 September 2017 concerning cobalt;

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<sup>4</sup> OJ L 353, 31.12.2008, p.1.

<sup>5</sup> [https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/name/-/ecNumber/-/casNumber/-/dte\\_receiptFrom/-/dte\\_receiptTo/-/prc\\_public\\_status/Opinion+Adopted/dte\\_withdrawnFrom/-/dte\\_withdrawnTo/-/sbm\\_expected\\_submissionFrom/-/sbm\\_expected\\_submissionTo/-/dte\\_finalise\\_deadlineFrom/-/dte\\_finalise\\_deadlineTo/-/haz\\_additional\\_hazard/-/lec\\_submitter/-/dte\\_assessmentFrom/-/dte\\_assessmentTo/-/prc\\_regulatory\\_programme/-](https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/name/-/ecNumber/-/casNumber/-/dte_receiptFrom/-/dte_receiptTo/-/prc_public_status/Opinion+Adopted/dte_withdrawnFrom/-/dte_withdrawnTo/-/sbm_expected_submissionFrom/-/sbm_expected_submissionTo/-/dte_finalise_deadlineFrom/-/dte_finalise_deadlineTo/-/haz_additional_hazard/-/lec_submitter/-/dte_assessmentFrom/-/dte_assessmentTo/-/prc_regulatory_programme/-)

- Opinion of 22 September 2017 concerning nickel bis(sulfamidate); nickel sulfamate;
- Opinion of 22 September 2017 concerning ethylene oxide; oxirane;
- Opinion of 22 September 2017 concerning 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane; metaldehyde;
- Opinion of 15 March 2017 concerning 2-benzyl-2-dimethylamino-4'morpholinobutyrophenone;
- Opinion of 5 December 2017 concerning pyridate (ISO); O-(6-chloro-3-phenylpyridazin-4-yl) S-octyl thiocarbonate;
- Opinion of 22 September 2017 concerning dodecyl methacrylate;
- Opinion of 5 December 2017 concerning 2-phenylhexanenitrile;
- Opinion of 15 March 2017 concerning thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole;
- Opinion of 9 June 2017 concerning N,N-diethyl-m-toluamide; deet;
- Opinion of 14 September 2017 concerning Titanium dioxide;
- Opinion of 15 March 2017 concerning Methylmercuric chloride;
- Opinion of 9 June 2017 concerning benzo[*rst*]pentaphene;
- Opinion of 9 June 2017 concerning Dibenzo[*b,def*]chrysene; Dibenzo[*a,h*]pyrene;
- Opinion of 22 September 2017 concerning Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs;
- Opinion of 5 December 2017 concerning cyflumetofen (ISO); 2-methoxyethyl (RS) -2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-( $\alpha,\alpha,\alpha$ -trifluoro-*o*-tolyl)propionate;
- Opinion of 9 June 2017 concerning Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diyl)nitri]pentaacetate;
- Opinion of 9 June 2017 concerning N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid);
- Opinion of 9 June 2017 concerning pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo) tetraacetate;
- Opinion of 9 June 2017 concerning diisohexyl phthalate;
- Opinion of 9 June 2017 concerning fludioxonil (ISO); 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile;
- Opinion of 22 September 2017 concerning halosulfuron-methyl (ISO); methyl 3-chloro-5{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1H-pyrazole-4-carboxylate;
- Opinion of 5 December 2017 concerning 2-methylimidazole;
- Opinion of 15 March 2017 concerning (RS)-2-methoxy-N-methyl-2-[ $\alpha$ -(2,5-xylyloxy)-*o*-tolyl]acetamide; mandestrobin;
- Opinion of 5 December 2017 concerning carboxin (ISO); 2-methyl-N-phenyl-5,6-dihydro-1,4-oxathiine-3-carboxamide; 5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide;
- Opinion of 5 December 2017 concerning metaflumizone (ISO); (*EZ*)-2'-[2-(4-cyanophenyl)-1-( $\alpha,\alpha,\alpha$ -trifluoro-*m*-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [*E*-isomer  $\geq$  90%, *Z*-isomer  $\leq$  10% relative content] [1] (*E*)-2'-[2-(4-cyanophenyl)-1-( $\alpha,\alpha,\alpha$ -trifluoro-*m*-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [2];
- Opinion of 5 December 2017 concerning Dibutylbis(pentane-2,4-dionato-O,O')tin.



- (3) Acute Toxicity Estimates (ATE) are mainly used to determine the classification for human health acute toxicity of mixtures containing substances classified for acute toxicity. The inclusion of harmonised ATE values in the entries listed in Annex VI to Regulation (EC) No 1272/2008 facilitates the harmonisation of the classification of mixtures and provides support for enforcement authorities. Following further scientific assessments of some substances, ATE values have been calculated for methylmercuric chloride, pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diyl)nitri]lo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid), pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA), ethylene oxide, oxirane and metaldehyde (ISO), 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane, in addition to those proposed in the RAC opinions. Those ATE values should be inserted in the penultimate column of Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008.
- (4) In its scientific opinion of 22 September 2017 on the substance cobalt, RAC proposed to classify that substance as carcinogen category 1B with a specific concentration limit of  $\geq 0,01$  %. However, the methodology used to determine a specific concentration limit required further assessment, in particular of its applicability to metal compounds. It is therefore appropriate not to introduce, for the time being, any specific concentration limit in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 for cobalt, in which case the general concentration limit of  $\geq 0,1$  % applies, in accordance with Table 3.6.2 of Annex I to that Regulation.
- (5) In its scientific opinion of 14 September 2017 on the substance titanium dioxide, RAC proposed to classify that substance as carcinogen category 2 by inhalation. As titanium dioxide-induced lung carcinogenicity is associated with inhalation of respirable titanium dioxide particles, retention and poor solubility of the particles in the lung, it is appropriate to define respirable titanium dioxide particles in the titanium dioxide entry. The deposited particles, but not solutes of titanium dioxide, are assumed to be responsible for the observed toxicity in the lung and subsequent tumour development. In order to avoid unjustified classification of non-hazardous forms of the substance, specific notes should be laid down for the classification and labelling of the substance and mixtures containing it. In addition, as some hazardous dust or droplets could be formed during the use of mixtures containing titanium dioxide, it is necessary to inform the users of the precautionary measures that need to be taken to minimise the hazard for human health.
- (6) With regard to the substances pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diyl)nitri]lo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) and pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA), the classification as acute toxicant category 4 and specific target organ toxicant - repeated exposure (category 2) recommended in the RAC opinions of 9 June 2017 should be included in Annex VI to Regulation (EC) No 1272/2008, since sufficient scientific evidence is available justifying those new classifications. With regard to the substances pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diyl)nitri]lo)pentaacetate and N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid), the classification as eye irritant category 2, recommended in the RAC opinions of 9 June 2017, should be included in Annex VI to Regulation (EC) No 1272/2008, since sufficient scientific evidence is available justifying those new classifications. However, the classification of the substances pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diyl)nitri]lo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)

and pentasodium (carboxylatomethyl)iminobis(ethylenitrilo)tetraacetate (DTPA), as toxic for reproduction category 1B should not be included, since it requires further assessment by RAC in view of new scientific data on toxicity for reproduction presented by the industry after the RAC opinions were forwarded to the Commission.

- (7) Regulation (EC) No 1272/2008 should therefore be amended accordingly.
- (8) Regulation (EC) No 1272/2008 contains the harmonised classification, labelling and packaging for the substance pitch, coal tar, high temp. The Commission amended the harmonised classification, labelling and packaging of that substance by Commission Regulation (EU) No 944/2013<sup>6</sup> with effect from 1 April 2016. Commission Regulation (EU) 2018/669<sup>7</sup> further amended Regulation (EC) No 1272/2008. However, due to an administrative oversight, certain amendments – the validity of which was not affected by the judgment of the General Court in Case T-689/13<sup>8</sup> as upheld by the judgment of the Court of Justice in Case C-691/15 P<sup>9</sup> – introduced by Regulation (EU) No 944/2013 were not reflected in Regulation (EU) 2018/669. That Regulation will become applicable as of 1 December 2019. Regulation (EC) No 1272/2008 should therefore be corrected, with effect from the same date.
- (9) To ensure that suppliers of substances and mixtures have time to adapt to the new classification and labelling provisions, the application of this Regulation should be deferred.
- (10) In order to be consistent with the approach underpinning Article 61(2) of Regulation (EC) No 1272/2008, suppliers should have the possibility of applying the classification, labelling and packaging provisions introduced by this Regulation on a voluntary basis before its date of application,

HAS ADOPTED THIS REGULATION:

*Article 1*  
*Amendments to Regulation (EC) No 1272/2008*

Regulation (EC) No 1272/2008 is amended as follows:

- (1) Annex II is amended as set out in Annex I to this Regulation;
- (2) Annex III is amended as set out in Annex II to this Regulation;
- (3) Annex VI is amended as set out in Annex III to this Regulation.

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<sup>6</sup> Commission Regulation (EU) No 944/2013 of 2 October 2013 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 (OJ L 261, 3.10.2013, p. 5).

<sup>7</sup> Commission Regulation (EU) 2018/669 of 16 April 2018 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 (OJ L 115, 4.5.2018, p. 1).

<sup>8</sup> Judgment of the General Court of 7 October 2015, *Bilbaína de Alquitranes and Others v Commission*, T-689/13, EU:T:2015:767.

<sup>9</sup> Judgment of the Court of 22 November 2017, *Commission v Bilbaína de Alquitranes and Others*, C-691/15 P, EU:C:2017:882.

*Article 2*  
*Correction to Regulation (EC) No 1272/2008*

Annex VI to Regulation (EC) No 1272/2008 is corrected as set out in Annex IV to this Regulation.

*Article 3*  
*Entry into force and application*

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 [*OP: please insert date to be determined as follows: Date of entry into force plus 18 months – the date should be the 1st day of the following month.*]

However, Article 2 shall apply from 1 December 2019.

Substances and mixtures may, before [*OP: please insert specific date of application determined under the second paragraph*], be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.

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

Done at Brussels, 4.10.2019

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*