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Judgment of the General Court in Joined Cases T-279/20, T-288/20 and T-283/20 | CWS Powder Coatings and Others v Commission

The General Court annuls the Commission Delegated Regulation of 2019 in so far as it concerns the harmonised classification and labelling of titanium dioxide as a carcinogenic substance by inhalation in certain powder forms

First, the Commission made a manifest error in its assessment of the reliability and acceptability of the study on which the classification was based and, second, it infringed the criterion according to which that classification can relate only to a substance that has the intrinsic property to cause cancer

Titanium dioxide is an inorganic chemical substance used, in particular in the form of a white pigment, for its colourant and covering properties in various products, ranging from paints to medicinal products and toys. In 2016, the competent French authority submitted to the European Chemicals Agency (ECHA) a proposal to classify titanium dioxide as a carcinogenic substance. ¹ The following year, ECHA's Committee for Risk Assessment ('the RAC') adopted an opinion classifying titanium dioxide as a category 2 carcinogen, including the hazard statement 'H 351 (inhalation)'.

On the basis of the RAC Opinion, the European Commission adopted Regulation 2020/217, ² by which it proceeded with the harmonised classification and labelling of titanium dioxide, recognising that that substance was suspected of being carcinogenic to humans, by inhalation, in powder form containing 1% or more of particles of a diameter equal to or below 10 µm.

The applicants, in their capacity as manufacturers, importers, downstream users or suppliers of titanium dioxide, brought actions before the General Court for the partial annulment of Regulation 2020/217.

By its judgment, delivered in a chamber sitting in extended composition in three joined cases, ³ the General Court annuls the contested regulation in so far as it concerns the harmonised classification and labelling of titanium dioxide. On that occasion, it rules on novel questions alleging manifest errors of assessment and infringement of the criteria established for harmonised classification and labelling under Regulation No 1272/2008 as regards, first, the reliability and acceptability of the scientific study on which the classification was based and, second, compliance

¹ Proposal for harmonised classification and labelling pursuant to Article 37(1) of 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 (OJ 2008 L 353, p. 1).

² Commission Delegated Regulation (EU) 2020/217 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 (OJ 2020 L 44, p. 1, 'the contested regulation').

³ T-279/20, T-283/20 and T-288/20.

with the classification criterion laid down by that regulation, according to which the substance must have the intrinsic property to cause cancer.⁴

Findings of the Court

In the first place, the General Court holds that, in the present case, **the requirement to base the classification of a carcinogenic substance on reliable and acceptable studies was not satisfied.**

In recognising that the results of a scientific study on which it based its opinion on the classification and labelling of titanium dioxide were sufficiently reliable, relevant and adequate for assessing the carcinogenic potential of that substance, the RAC committed a manifest error of assessment. Specifically, in order to verify the degree of lung overload of titanium dioxide particles in that scientific study in order to assess carcinogenicity, the RAC used a density value corresponding to the density of unagglomerated primary particles of titanium dioxide, which is always higher than the density of the agglomerates of nano-sized particles of that substance. However, in so doing, it did not take into account all the relevant factors in order to calculate the lung overload during the scientific study at issue, namely the characteristics of the particles tested in that scientific study, the fact that those particles tend to agglomerate and the fact that the density of the agglomerates of particles was lower than the particle density and that, for that reason, those agglomerates occupied more volume in the lungs. Thus, the RAC's findings that the lung overload in the scientific study at issue was acceptable were implausible.

Consequently, in so far as, for the purposes of the harmonised classification and labelling of titanium dioxide, the Commission based the contested regulation on the RAC Opinion and thus followed the RAC's conclusion as to the reliability and acceptability of the results of the scientific study at issue, which constituted a decisive study for the classification proposal for titanium dioxide, it made the same manifest error of assessment as the RAC.

In the second place, the General Court finds that **the contested classification and labelling infringed the criterion according to which the classification of a substance as carcinogenic can apply only to a substance that has the intrinsic property to cause cancer.**

In that context, in view of the fact that, under Regulation No 1272/2008, harmonised classification and labelling of a substance as carcinogenic may be based only on the intrinsic properties of the substance which determine its intrinsic capacity to cause cancer, the General Court goes on to interpret the concept of 'intrinsic properties'. In that regard, it states that, although that concept does not appear in Regulation No 1272/2008, it must be interpreted in its literal sense as referring to the 'properties which a substance has in and of itself', which is consistent, *inter alia*, with the objectives and purpose of harmonised classification and labelling under that regulation.

In addition, it notes that **the contested classification and labelling are intended to identify and notify a carcinogenic hazard of titanium dioxide which, in the RAC Opinion, was classified as 'non-intrinsic in a classical sense'.** The General Court states that that 'non-intrinsic in the classical sense' nature stems from several factors, referred to both in that opinion and in the contested regulation. **The carcinogenicity hazard is linked solely to certain respirable titanium dioxide particles, when they are present in a certain form, physical state, size and quantity, it occurs only in lung overload conditions and corresponds to particle toxicity.**

The General Court therefore concludes that, by upholding the conclusion contained in the RAC Opinion that the mode of action of carcinogenicity on which that committee relied could not be regarded as intrinsic toxicity in the classical sense, but which had to be taken into consideration in the context of harmonised classification and labelling under Regulation No 1272/2008, the Commission committed a manifest error of assessment.

The General Court states that the examples of classification and labelling of other substances, relied on in order to compare them with the classification and labelling of titanium dioxide, illustrate only cases in which, even though the form and size of the particles were taken into account, certain properties specific to the substances were

⁴ Criteria referred to in Section 3.6.2.2.1 of Annex I to Regulation No 1272/2008.

nevertheless decisive for their classification, which does not correspond to the case here.

NOTE: An action for annulment seeks the annulment of acts of the institutions of the European Union that are contrary to EU law. The Member States, the European institutions and individuals may, under certain conditions, bring an action for annulment before the Court of Justice or the General Court. If the action is well founded, the act is annulled. The institution concerned must fill any legal vacuum created by the annulment of the act.

NOTE: An appeal, limited to points of law only, may be brought before the Court of Justice against the decision of the General Court within two months and ten days of notification of the decision.

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The [full text](#) of the judgment is published on the CURIA website on the day of delivery.

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