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CASE NOTES

Science in the Courtroom EU Courts Wisely Steer Clear of Judicial Passivism Joined Cases C-71/23 P and C-82/23 P, France and Commission/CWS Powder Coatings and Others [2025] ECLI:EU:C:2025:601

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Abstract

In a ruling delivered on 1 August 2025, the Court of Justice upheld a General Court judgment annulling the classification as a suspected carcinogen of titanium dioxide in powder form containing at least 1% of particles of a diameter equal to or below 10 µm. Both EU Courts criticise the scientific assessment underlying that classification, but the Court of Justice relies on conceptual distinctions that reveal its reluctance to perform a genuine "manifest error of assessment" review. While these issues are not addressed by the Court of Justice, the case also raises thorny questions regarding the meaning of "intrinsic properties" of a substance.

Keywords: CLP regulation; complex scientific assessment; intrinsic properties; judicial review; substance

I. Legislation

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).

II. Facts

Titanium dioxide ("TD") is a chemical substance that can be found in nature or produced industrially. It is used for its colourant (i.e., whitening) and covering properties in products such as paints, plastics, paper, cosmetics and toys. In 2016, the French National Agency for Food, Environmental and Occupational Health and Safety (ANSES) submitted a dossier under Regulation (EC) No 1272/2008 ("the CLP Regulation") proposing the harmonised classification and labelling of TD powder as a presumed carcinogen[1] by inhalation. After examining the dossier submitted by ANSES as well as the results of the stakeholders' consultation, the European Chemical Agency's Risk Assessment Committee ("the RAC") proposed to classify TD powder containing at least 1% of particles with aerodynamic

[1] "Presumed carcinogen" corresponds to category 1B under the CLP Regulation.

diameter ≤ 10 µm ("PM_{10}") as a suspected carcinogen[2] by inhalation. In 2020, the Commission endorsed such a classification through Delegated Regulation 2020/417[3] ("the contested Regulation").

In 2020, a number of manufacturers, importers, downstream users and suppliers of titanium dioxide sought the annulment of the contested Regulation before the General Court (the "GC"). In a judgment delivered on 23 November 2022, the GC upheld the applicants' view.[4] It annulled the contested Regulation on the ground that it was vitiated by several manifest errors of assessments. First, it considered that the classification of TD powder was decisively based on one study (the "Heinrich study") that was not sufficiently reliable and adequate. To make a long story short, the applicants claimed that the lung tumours observed in that study may have been due to an excessive "lung overload," i.e. an excessive level of TD in the lungs, which invalidated that study's findings. According to the applicants, the method used by the RAC to calculate this lung overload in the Heinrich study was erroneous. The RAC had considered that the lung overload in that experiment was not excessive (and therefore that its results were reliable) based on the standard density of individual particles of TD, thereby failing to take into account the fact that nanoparticles of TD tend to agglomerate and, therefore, take more space in the lung than individual particles. The GC fully endorsed that line of reasoning.

The GC found a second manifest error of assessment in the fact that the classification of TD powder was not based on an "intrinsic property" of that substance but on the accumulation of very small particles of that substance in the lung in sufficient quantities to bring about a significant impairment of particle clearance mechanisms. As the GC puts it, "*it is the quantity of inhaled particles, which must be sufficient to bring about a significant impairment of particle clearance mechanisms, and it is that impairment which is essential to the development of chronic inflammation, which, in turn, results in the carcinogenic effects observed.*"[5] According to the GC, the fact that carcinogenicity is only triggered by TD when certain conditions are met (in terms of format, quantity and route of exposure) prevents the conclusion that this substance is intrinsically carcinogenic and does not support its classification as a category 2 carcinogen.

III. Judgment

Both the Commission and the French Republic (which intervened in support of the Commission in the first instance) lodged an appeal against the GC's ruling. Through their first ground of appeal, they challenged the alleged "*decisiveness*" of the Heinrich study and of the method used to determine the lung overload. The Court of Justice (the "CJ") rejected that first plea and upheld the GC's analysis of the RAC opinion. It found, *inter alia*, that giving a specific study a decisive weight is not incompatible with the "weight of evidence" approach that is supposed to guide the assessment of a substance and that requires to take into account all the available evidence.

Through their second ground of appeal, the Commission and France argued that, by substituting its own assessment to that of the RAC and of the Commission in determining

[2] "Suspected carcinogen" corresponds to category 2 under the CLP Regulation.

[3] 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).

[4] Joined cases T-279/20 and T-288/20 and case T-283/20, CWS Powder Coatings GmbH e.a./Commission [2022] ECLI:EU:T:2022:725.

[5] Ibid., para. 158.

the right way of measuring the density of TD particles, the GC had exceeded the limits of its judicial review.

Before ruling on this line of argument, the CJ referred to the long-standing case-law regarding the limits of judicial review as regards decisions based on the assessment of highly complex scientific and technical facts. It reminded that the EU Courts "*cannot substitute their assessment of scientific and technical facts for that of the institutions on which alone the FEU Treaty has entrusted that task.*"[6] However, EU judges must check "*whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion.*"[7] In order to demonstrate that they have actually exercised their discretion, the competent authorities must show that "*they took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate.*"[8]

Applying that case-law to the case at hand, the CJ endorsed the appellants' submission and found fault with the GC's reasoning. It considered that, by criticising the RAC for its method to calculate the density of TD's particles, the GC unlawfully substituted its own scientific assessment for that of the RAC. In her Opinion, Advocate General Ćapeta had reached the same conclusion: "*the General Court annulled the Commission's decision not because that institution did not take into account all of the relevant (scientific) factors, but because it disagreed with how the administration had assessed those factors.*"[9]

However, contrary to its Advocate General, the CJ went on to consider that this flaw in the GC's reasoning should not result in the annulment of the judgment. The CJ found that, while the lower court's approach was unlawful, the operative part of its ruling (i.e., the annulment of the contested Regulation) was nevertheless correct. In support of this finding, the CJ pointed out that the RAC had failed to examine whether the fact that TD nanoparticles tend to agglomerate could have an impact on the calculation of the degree of lung overload in the Heinrich study. This, the Court concluded, showed that the RAC had not taken into consideration all the relevant factors in its opinion in the classification of TD powder. Consequently, the CJ rejected the second ground of appeal.

The appellants raised a third and fourth ground of appeal, alleging that the GC erred in concluding that titanium dioxide was not a "*substance that has the intrinsic property to cause cancer*" within the meaning of point 3.6.2.2.1 of Annex I to the CLP Regulation. However, the CJ rejected those pleas as ineffective as they were directed at grounds included in the GC's decision purely for the sake of completeness. In other words, even if they were well founded, these grounds of appeal would not be capable of altering the conclusion that the contested Regulation must be annulled. By contrast, AG Ćapeta examined these pleas at length in her opinion. Contrary to the narrow interpretation of the concept of "intrinsic property" adopted by the General Court, she considered that such a concept "*must also cover hazards emanating from a specific form, physical state, characteristic or use of a substance and cannot be limited to the chemical composition of that substance alone.*"[10]

IV. Comment

This case raises two important issues. The first one concerns the notion of "intrinsic property" of a substance for the purpose of the CLP Regulation (see point A below). The second issue relates to the scope of judicial oversight in cases involving complex scientific assessments (see point B below).

[6] Ibid., para. 106.
[7] Ibid., para. 106.
[8] Ibid., para. 107.
[9] Opinion delivered on 6 February 2025 in joined cases C-71/23 P and C-82/23 P, France and Commission/CWS Powder Coatings and Others, ECLI:EU:C:2025:65, para. 98.
[10] Ibid. para. 121.

A. The notion of "intrinsic property"

The GC finds fault with the classification of TD as having the intrinsic property of causing cancer on the ground that "*the reason for the toxicity observed is not the properties of the titanium dioxide particles in themselves, but the deposit and retention of those particles in the alveolar macrophages of the lungs in sufficient quantities to give rise to lung overload leading to a significant impairment of particle clearance mechanisms in the lung.*"[11]

This argument is unconvincing. As the Advocate General rightly noted, considerations regarding the route and level of exposure are irrelevant to a hazard classification.[12] This is precisely what distinguishes hazard from risk assessment.

However, the GC puts forward another, possibly more powerful, argument, namely that this carcinogenicity "*is common to other poorly soluble low-toxicity particles*."[13] If this carcinogenic effect is observable for most types of particles, it suggests that the toxicity is *exclusively* due to the size, not the nature, of the particles. That hypothesis is supported by the classification of air pollution as carcinogenic by the International Agency for Research on Cancer, including particulate matters (PM) *regardless of their nature.*[14] Assuming that the above is correct, it would mean that carcinogenicity is an intrinsic property of PM_{10}, rather than of a specific substance. In view of all this, was the Commission (manifestly) wrong to classify as possibly carcinogenic TD in powder form containing at least 1% of PM_{10}?

One may argue that such an approach does not match a literal understanding of the concepts of "substance" and/or of "intrinsic property." But one could object, as Advocate General Ćapeta did,[15] that the contested Regulation is in line with the main objective of the CLP Regulation, i.e., to ensure a high level of protection of human health and the environment. By making sure that articles and mixtures containing TD in powder containing at least 1% of PM_{10} are properly labelled and regulated, the contested Regulation fits with the spirit of the Regulation.

Given the legal uncertainty and practical importance of this issue, it is unfortunate that the CJ failed to address it in its judgment on appeal.

B. Judicial review of acts based on complex scientific assessments

The second issue concerns the scope of judicial oversight in cases involving complex scientific assessments. This has been a vexed and long-standing problem, recurring throughout the GC's and the CJ's case-law in areas as diverse as competition law and pesticide regulation. As this case illustrates, it is also a question that can never be definitively settled, no matter how clear or firmly established the governing jurisprudential principles may be.

On the face of it, these principles are sound and unambiguous. On the one hand, they forbid judges from acting like would-be scientists by scrutinising the merits of technical assessments made by experts. Epistemic humility and the institutional balance principle command such a judicial self-restraint. On the other hand, these judge-made guidelines aim to ensure that EU scientific agencies and the Commission are not given a free pass under the guise of complex assessments. The rule of law does not cater for blanket immunity.

[11] Joined cases T-279/20 and T-288/20 and case T-283/20, *supra* note 4, para. 156.

[12] The CJ's case-law is unambiguous: "*an assessment of the hazards linked to the substances' intrinsic properties must not be limited in light of specific circumstances of use, as in the case of a risk assessment, and may be properly carried out regardless of the place where the substance is used (in a laboratory or elsewhere), the route by which contact with the substance might arise and the possible levels of exposure to the substance*" (C-14/10 *Nickel Institute*, judgment of 21 July 2011, ECLI:EU:C:2011:503, para. 82).

[13] Joined cases T-279/20 and T-288/20 and case T-283/20, *supra* note 4, para. 153.

[14] IARC Monograph, *Outdoor air pollution*, volume 109, 2016, https://publications.iarc.who.int/538.

[15] Opinion delivered on 6 February 2025 in joined cases C-71/23 P and C-82/23 P, *supra* note 9, paras. 119-125.

Bearing these two guiding principles in mind, it appears from the case-law that the EU judiciary has the power, and indeed the duty, to review and remedy five main types of flaws.[16] The first three – misuse of powers, procedural errors and duty to state reasons – are relatively uncontroversial and not relevant to the present case. These textbook categories of EU law infringement will therefore not be discussed further.

The fourth category concerns "methodological errors" in the processing of facts and data. In exercising this type of oversight, the EU Courts engage with the scientific assessment underlying the decision, albeit in an indirect manner, through a seemingly formal approach that does not challenge head-on the conclusions of that assessment. The methodological review is rooted in the sound administration principle and the duty to act diligently, which requires a careful and impartial examination of all the relevant facts.[17] According to the CJ, this review amounts to verifying that the competent authorities have "*actually exercised their discretion*."[18] We get back to that claim below.

Finally, the EU Courts can also directly engage with the experts' evaluation and annul an act on the ground that the underlying assessment is "manifestly" erroneous. The judges consider that the scientific findings are "implausible" given that they rely on evidence that is not factually accurate, reliable and consistent or because this evidence is "*not capable of substantiating the conclusions drawn from it*."[19] With this kind of review, the judge comes very close to substituting its own assessment to that of the relevant agency or institution. However, the review remains marginal (hence the "plausibility" standard). In addition, the Courts do not replace the experts' findings with their own assessment. They will not, for instance, pronounce on the toxicity of a substance. They will limit themselves to criticising the experts' reasoning that led up to their conclusion.

This case puts into sharp relief not only the porosity between the fourth and the fifth levels of judicial scrutiny but also the reluctance of the CJ to openly engage with type-5 errors. The CJ criticises the GC for substituting its own scientific assessment for that of the RAC. According to the CJ, the GC was not entitled to "*decide the question of the appropriateness of the value of the density of titanium dioxide particles adopted by the RAC in the light of the phenomenon of agglomeration of those particles, which question required a scientific assessment to be carried out*".[20] By contrast, what the GC could have done – and what the CJ did – was to fault the RAC for not *considering* whether this tendency to agglomerate could have an impact on the density value of TD. In other words, the EU Courts could blame the risk assessor for failing to consider an element in its reasoning, i.e., for not exercising its discretion. But they could not fault it for reaching a specific conclusion, i.e., for wrongly exercising that discretion. While the latter approach implies that EU Courts engage with a substantive assessment (checking type-5 errors), the former confines them to a methodological review (scrutinising type-4 errors).

While this distinction may be appealing in theory, it does not always hold water in practice. The problem with that distinction is that most critiques regarding methodological choices rest on a prior substantive assessment. When the CJ holds that the RAC should have considered the tendency of TD's nanoparticles to agglomerate, it presupposes that this phenomenon is relevant, which already implies a scientific assessment. There is only a difference of emphasis, not of nature, between that assessment and the review operated by the GC at first instance – which the CJ grossly mischaracterises. Contrary to what the CJ

[16] See, e.g., case C-316/24 P, PAN Europe/Commission [2025] ECLI:EU:C:2025:992, para. 96.

[17] Joined cases T-279/20 and T-288/20 and case T-283/20, *supra* note 4, para. 42 and the case-law cited.

[18] Joined cases C-71/23 P and C-82/23 P, France and Commission/CWS Powder Coatings and Others [2025] ECLI:EU:C:2025:601, para. 107; C-293/22 P, Chemours Netherlands/ECHA, [2025] ECLI:EU:C:2023:847, para. 135 and the case-law cited.

[19] Joined cases T-279/20 and T-288/20 and case T-283/20, *supra* note 4, para. 43 and the case-law cited.

[20] Joined cases C-71/23 P and C-82/23 P, *supra* note 16, para. 116.

states, the GC did not consider "*that, in any event, the value used by the RAC, corresponding to the standard density value of titanium dioxide particles, was not appropriate, given that that value was 'higher' than that of the agglomerate density*."[21] The GC simply held that the density of the particles could not be "*presumed*"[22] to be the standard density value given the agglomeration phenomenon, thereby faulting the RAC for not considering the tendency of nanoparticles to agglomerate – exactly what the CJ did on appeal – and not for reaching a specific conclusion.

The CJ's reliance on such byzantine distinctions can only be explained by its reluctance to engage with the aforementioned type-5 errors. Yet, the EU judicature should not shy away from its own case-law, which recognises its power to review *manifest* errors in *scientific* assessment. One way to operationalise such a general standard would be to treat a manifest error as a mistake that either defies *logics* or departs from *mainstream scientific opinion*. Conversely, on issues that are the subject of a genuine scientific controversy, judges should take a hands-off approach and rely on the expert judgment of the EU's regulatory agencies.

The TD dispute is a case in point. The EU judges rested their reasoning on a couple of scientifically established premises. First, given that it is a settled fact that TD nanoparticles take more space in the lung than standard particles, it stands to logic that neglecting this element resulted in underestimating the level of lung overload. Second, given that the level of lung overload is widely accepted as one of the criteria for assessing the reliability of the type of study at stake, it is common sense that overlooking that element as regards the key study in the assessment vitiates the whole reasoning. It does not take a PhD in molecular biology to hold, let alone understand, such a reasoning. However, contrary to what the CJ claims, by carrying out this kind of review, the EU Courts have done more than check whether the RAC has *exercised* its discretionary power. They have also (marginally) reviewed *the way* the RAC exercised that discretion. This is a review of type-5 errors. And it is absolutely in line with long-standing case-law.

Admittedly, not all legal scholars share this position.[23] However, in an era of growing technological governance, judicial review would become little more than a slogan if judges systematically refused to open the black box of scientific assessments. Whether citizens, NGOs or corporations, no one has in interest in seeing EU Courts lapse into *judicial passivism on these issues* – an attitude which would pose as much of a threat to the rule of law as judicial *activism* does to democracy. One should therefore commend the EU Courts for their active (while not activistic) and rigorous (albeit not vigorous) review of the RAC's opinion on TD powder. And the CJ should have the courage to call a spade a spade instead of hiding such a legitimate judicial control behind shaky conceptual distinctions.

[21] Ibid., para. 115.

[22] Joined cases T-279/20 and T-288/20 and case T-283/20, *supra* note 4, para. 102.

[23] See, e.g., the critical comment of the GC judgment by M. Weimer and M. Morvillo (Op-Ed: "Out of balance – Why the CJEU 'modern' approach to reviewing EU agency science has gone too far (CWS Powder, joined cases T-279/20, T-288/20 and T-283/20)" (2023) EU Law Live https://eulawlive.com/op-ed-out-of-balance-why-the-cjeu-modern-approach-to-reviewing-eu-agency-science-has-gone-too-far-cws-powder-joined-cases-t-279-20-t-288-20-and-t-283-20/ (accessed 21 January 2026). Of note, their criticism is partly based on "*socio-legal concerns over the CJEU inadvertently aggravating the unequal participatory dynamics of both EU regulation and litigation, which privilege economic actors*". It is submitted that, in the meantime, such concerns have been lessened by the increased access of environmental NGOs to EU Courts following the revision of the Aarhus Regulation. NGOs would therefore also benefit from a genuine judicial scrutiny of scientific assessments.

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