



**Titanium Dioxide Carcinogen Classification Case - the EU Court of  
Justice annulled Titanium Dioxide Classification on August 1, 2025**

**Scientific Evidence and Future Implications**

*Detailed ERIF Report – 3 September 2025*

*The titanium Dioxide case underscores the necessity for hazard classifications to be rooted in robust science and intrinsic properties. It highlights the importance of rigorous, transparent science in regulatory decisions and sets a precedent for future classifications. The outcome should encourage regulatory efforts to be directed towards substances with true intrinsic dangers, maintaining both safety and scientific integrity.*

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## Executive Summary

This report provides a comprehensive analysis of the legal and scientific journey surrounding the classification of titanium dioxide (TiO<sub>2</sub>) as a carcinogen by the European Union. It covers the background to the TiO<sub>2</sub> issue, the contested classification, the court judgment, and its implications for future regulatory decisions.

**Background and Contested Classification** Titanium dioxide, a widely used white pigment, was classified by the European Union in 2019 as a suspected carcinogen (Category 2) by inhalation, based on studies where rats exposed to high concentrations of TiO<sub>2</sub> dust developed lung tumors. This classification was highly controversial and led to immediate legal challenges from the titanium industry and product users.

**Court Judgment and Key Findings** In November 2022, the EU General Court annulled the classification, citing significant scientific assessment errors. The court found that the scientific evidence was not reliably assessed, particularly the chronic inhalation study in rats, which was based on flawed assumptions. The court also held that the classification violated the requirement that a harmonized classification must be based on a hazard intrinsic to the substance. The EU Court of Justice upheld this annulment in August 2025, effectively removing TiO<sub>2</sub>'s carcinogenic classification.

**Scientific Evidence and Credibility** The primary evidence for TiO<sub>2</sub>'s classification was a set of chronic inhalation studies in rodents, particularly a 1995 study by Heinrich et al.<sup>1</sup> However, the court found that the conditions of these studies, such as the extremely high dust concentrations, were not relevant to typical human exposure. The court also noted that the evidence from human studies did not provide a clear link between TiO<sub>2</sub> exposure and cancer.

**Impact on Future Harmonized Classifications** The judgment has significant implications for the EU's approach to classifying chemicals. In order to avoid legal challenges, regulators will need to be more cautious and rigorous in their scientific assessments, ensuring that any classification is based on solid, reliable studies and intrinsic hazards. This may result in slower but more robust decision-making and could influence how borderline substances are handled in the future.

**Regulatory and Policy Response** The European Commission and ECHA may respond by clarifying guidelines, providing training and awareness, and possibly introducing new hazard categories. The precautionary principle will still be applied, but more carefully within the bounds of intrinsic hazard.

**Conclusion** The TiO<sub>2</sub> case underscores the necessity for hazard classifications to be rooted in robust science and intrinsic properties. It highlights the importance of rigorous, transparent science in regulatory decisions and sets a precedent for future classifications. The outcome should encourage regulatory efforts to be directed towards substances with true intrinsic dangers, maintaining both safety and scientific integrity.

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<sup>1</sup> <https://www.tandfonline.com/doi/abs/10.3109/08958379509015211>

## Timeline



## 1. Introduction

**Titanium dioxide (TiO<sub>2</sub>)** is a widely used white pigment found in paints, plastics, paper, cosmetics, and food. It is valued for its brightness, opacity, and inertness. In 2019, the European Union classified certain respirable powdered forms of TiO<sub>2</sub> as a suspected carcinogen (Category 2, by inhalation) based on studies where rats exposed to high concentrations of TiO<sub>2</sub> dust developed lung tumors<sup>2</sup>. This **unprecedented classification** – essentially labeling an inert dust as a cancer hazard – was highly controversial and triggered immediate legal challenges from industry. In **November 2022**, the EU General Court **annulled** the classification, finding that regulators had made significant scientific assessment errors<sup>3</sup>. Subsequently, in **August 2025**, the EU Court of Justice (the highest EU court) upheld the annulment, definitively removing TiO<sub>2</sub>'s carcinogenic classification<sup>4</sup>.

This report analyzes the **court judgment on TiO<sub>2</sub>**, focusing on the **scientific evidence** presented and the **implications for future harmonised classifications**. First, the key points of the ruling are summarized. Next, the report reviews and assesses the scientific evidence at the heart of the case. This is followed by an assessment of how the judgment may influence future classification decisions for TiO<sub>2</sub> and similar substances. Finally, recommendations are offered for stakeholders – including regulators and businesses – in the light of the case outcome. The aim is to objectively distinguish the facts and findings of the case and to identify prudent steps going forward.

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## 2. Background: TiO<sub>2</sub> and the Contested Classification

Titanium dioxide has been produced and used for decades and was generally regarded as a substance of **low toxicity** under normal usage conditions. It is chemically inert and not bioactive in the way many hazardous chemicals are. However, **inhalation of fine TiO<sub>2</sub> dust** raised concerns in the scientific community after animal studies indicated potential risks. In 2006, the International Agency for Research on Cancer (**IARC**) classified TiO<sub>2</sub> as “possibly carcinogenic to humans” (Group 2B) based on **sufficient evidence** that high concentrations of TiO<sub>2</sub> dust caused lung cancer in rats, although there was **inadequate evidence** of carcinogenicity in humans<sup>5</sup>. Essentially, rats in some studies developed lung tumors when exposed to extremely heavy TiO<sub>2</sub> dust concentrations, but epidemiological studies of TiO<sub>2</sub> workers did not show a clear increase in lung cancer.

Under the EU's **CLP Regulation** (Classification, Labelling and Packaging of substances), regulators can assign a harmonised hazard classification to a substance if the scientific criteria for that hazard are met. In **2016**, prompted by the rat data and IARC's evaluation, France's agency **ANSES** submitted a dossier proposing to classify TiO<sub>2</sub> as a carcinogen. After reviewing the evidence, the European Chemicals Agency's **Risk Assessment**

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<sup>2</sup> <https://curia.europa.eu/jcms/upload/docs/application/pdf/2025-08/cp250099en.pdf>

<sup>3</sup> <https://curia.europa.eu/jcms/upload/docs/application/pdf/2022-11/cp220190en.pdf>

<sup>4</sup> <https://curia.europa.eu/jcms/upload/docs/application/pdf/2025-08/cp250099en.pdf>

<sup>5</sup> [IARC Monograph 93](#)

**Committee (RAC)** concluded in 2017 that TiO<sub>2</sub> should be classified as a **Category 2 carcinogen (suspected human carcinogen)** by inhalation. The classification was limited to inhalation exposure because that was the only route of concern – oral or dermal exposure showed no such issues.

In **February 2019**, the RAC's opinion was made public, stirring much debate. Many experts noted that TiO<sub>2</sub> did not behave like a typical chemical carcinogen (it's not genotoxic or chemically reactive) and that the observed rat cancers were likely due to the physical overload of dust in the lungs, a phenomenon not expected to occur at occupational exposure levels with proper controls. Nevertheless, applying a precautionary approach, the European Commission moved forward and in **October 2019** adopted a delegated regulation (EU) 2020/217 (the 14th **Adaptation to Technical Progress** for CLP) to add TiO<sub>2</sub> to the EU's list of classified carcinogens. The entry, as finally adopted in early 2020, was quite specific: it classified **powdered TiO<sub>2</sub>** as *Carc. 2* with the hazard statement *H351 (inhalation)*, and this applied only to mixtures in powder form containing **≥1% TiO<sub>2</sub> particles with aerodynamic diameter ≤10 µm**. In other words, only respirable powdered forms of TiO<sub>2</sub> were covered. The classification also mandated accompanying warnings on product labels, such as advising not to breathe dust from TiO<sub>2</sub>-containing mixtures.

This marked the first time a substance was classified as a carcinogen in the EU essentially **due to dust effects** rather than intrinsic chemical toxicity. The decision had wide-ranging implications. TiO<sub>2</sub> is used in thousands of products, so manufacturers and downstream users (paints, coatings, plastics, cosmetics industries, etc.) faced the prospect of labeling products as containing a potential carcinogen, handling TiO<sub>2</sub> waste as hazardous, and perhaps reformulating products to avoid regulatory and reputational issues. Many in industry argued that this classification would **mislead the public** (by equating TiO<sub>2</sub> dust with cancer-causing agents like asbestos or silica, whereas they believed the risk was only under extreme conditions) and could result in unnecessary panic and costs.

Thus, in mid-2020, a coalition of TiO<sub>2</sub> producers and users – including major chemical companies and industry associations – filed lawsuits at the **General Court of the EU** seeking to annul the classification. They contended that the Commission had overstepped its legal powers and that the scientific evidence did not meet the legal criteria for classification. Several EU Member States (notably **France**, which championed the classification, and others concerned with health) intervened in support of the Commission, while industry groups and even some non-EU countries' industries (e.g., from the US and Canada) submitted observations supporting the annulment. This set up a clash between reliance on a **precautionary regulatory approach** and a defense of **scientific rigor and proper legal procedure**.

In the interim, while the court case was pending, the TiO<sub>2</sub> classification officially took effect in September 2021. Companies started to implement compliance measures but also held out hope that the court might overturn the requirement. This was against the backdrop of broader questions: Would this classification open the door to labeling other low-toxicity dusts as carcinogens? Was the EU taking precaution too far from scientific rigour and hurting its own industries, while not correctly describing and prioritising health risks?

### 3. Court Judgment Summary: Key Findings

In **November 2022**, the EU General Court delivered its judgment (Joined Cases T-279/20 and others) and **annulled TiO<sub>2</sub>'s classification**. This was a remarkable decision – it is rare for courts to overturn scientific regulatory decisions. The Court identified **two main faults** in the TiO<sub>2</sub> classification:

#### Reliability of Key Study in Question

The pivotal rat inhalation study underlying the TiO<sub>2</sub> classification was not properly interpreted. Regulators **miscalculated the lung "dust overload"** in that study by using the density of primary TiO<sub>2</sub> particles (~4 g/cm<sup>3</sup>) instead of the lower effective density of the fluffy particle agglomerates, thus **underestimating the volume of dust in the rats' lungs**. When corrected, it's clear the rats' lungs were overloaded with particles, making the tumor findings questionable as evidence of intrinsic toxicity.

#### "Intrinsic Property" Criterion

The identified hazard was **not due to TiO<sub>2</sub>'s intrinsic properties** but a consequence of particle exposure under extreme conditions. The Court noted that EU classification is reserved for intrinsic hazards – a substance that is inherently carcinogenic. Since TiO<sub>2</sub> caused tumors only when inhaled in extreme overload conditions (a "particle effect"), treating it as an intrinsic carcinogen was a legal error.

**First**, the General Court found that the **scientific evidence was not reliably assessed** by ECHA's RAC and the Commission. The classification rested heavily on a chronic inhalation study in rats, but the court determined that the regulators had made a **manifest error** in interpreting this study. In particular, the RAC had concluded that the lung particle exposure in the study did not exceed levels of overload that would invalidate the results. However, the Court pointed out that this conclusion was based on flawed assumptions: RAC **failed to account for the actual behavior of TiO<sub>2</sub> particles in the lung**. TiO<sub>2</sub> particles tend to aggregate into lighter, bulkier clumps inside lungs. By mistakenly using the density of individual TiO<sub>2</sub> particles (which are very heavy) instead of these agglomerates, RAC grossly **underestimated the particle volume** in the rats' lungs. When the correct perspective is applied, the evidence indicated the rats likely experienced **severe pulmonary overload**,

meaning their lung clearance mechanisms were overwhelmed. Under such conditions, even biologically inert particles can cause chronic inflammation and cancer in rats. The General Court judged that ignoring this key fact – essentially treating an overloaded exposure as if it were a normal exposure – was a **clear scientific error**. As a result, the study could not be deemed “reliable and acceptable” evidence of TiO<sub>2</sub>’s carcinogenicity under normal conditions, as required by law. In legal terms, the Commission had made a “**manifest error of assessment**” in relying on that study without proper qualification.

**Second**, the Court held that the classification violated the requirement that a harmonised classification must be based on a hazard **intrinsic to the substance**. The EU’s CLP regulation doesn’t explicitly define “intrinsic property,” but the court interpreted it in line with the regulation’s purpose: a substance should be classified as a carcinogen only if the substance *as such* is capable of causing cancer. In this case, the RAC and Commission themselves had noted that TiO<sub>2</sub>’s carcinogenic effect was “**not intrinsic in a classic sense**” – it manifested only in specific physical forms (respirable fine powder) and under extreme exposure (lung overload). TiO<sub>2</sub> did not cause genetic damage or tumors through any inherent chemical action; the effect was a generic dust phenomenon. The Court found it **unreasonable to label the substance itself as carcinogenic** when the harm was entirely conditional on external factors (particle size and high concentration). By doing so, the Commission had overreached the legal definition of a carcinogen under CLP, which was another **manifest error**. The judges drew a line, saying in essence: *if a hazard is not a built-in characteristic of the substance, but rather arises from how it’s used or encountered, then the harmonised hazard label is not the appropriate regulatory tool.*

Consequently, the General Court annulled the TiO<sub>2</sub> entry in the 2019 regulation. The effect was retroactive – as if TiO<sub>2</sub> had never been officially classified. The Commission was ordered to pay costs, and the judgment received considerable attention through regulatory circles and industry. The Commission, backed by France (and supported by some other Member States), **appealed** this decision, taking the case to the **European Court of Justice (CJEU)**. They argued, among other things, that the General Court had overstepped by second-guessing complex scientific analysis (since courts generally should defer to scientific experts), and that it wrongly imposed an “intrinsic property” test that isn’t explicitly spelled out in the legislation.

In **July 2023**, Advocate General Ćapeta (an advisor to the CJEU) issued an opinion largely siding with the Commission’s view that the General Court went too far in reassessing scientific evidence. She famously cautioned that “*the Courts are not scientists and cannot become scientists*”, warning against judges supplanting expert risk assessors. However, in the final ruling on **1 August 2025**, the Court of Justice **dismissed the appeals**, effectively upholding the annulment. The CJEU’s judgment was somewhat nuanced: it agreed that courts must be careful, but concluded that in this case the General Court did **not** overstep because the error identified (the particle density miscalculation) was sufficiently clear-cut. The CJEU did not explicitly rule on the “intrinsic property” debate, deeming it unnecessary once the scientific assessment error was confirmed, but it did not contradict the General Court’s reasoning on that point. Thus, the annulment stood.

In sum, the courts found that **TiO<sub>2</sub> should never have been classified as a carcinogen**, because the decision was based on an improperly interpreted study and stretched the definition of a carcinogenic hazard beyond its intent. This outcome sets an important precedent: it reinforces that **EU hazard classifications must be grounded in robust science and truly intrinsic hazards**. As a direct result, titanium dioxide was **removed from the EU list of carcinogens** (no H351 inhalation label required), restoring its regulatory status to what it was prior to 2019.

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#### 4. Scientific Evidence in the Case

The TiO<sub>2</sub> case hinged on how the scientific evidence was interpreted. This section examines the key studies and data involved, the credibility and relevance of that evidence, and how the court evaluated the science.

##### Key Studies and Data Considered

The primary evidence for TiO<sub>2</sub>'s classification was a set of **chronic inhalation studies in rodents**, especially the **1995 study by Heinrich et al.** in rats (conducted in the 1980s-90s). In that study, groups of rats were exposed to different concentrations of TiO<sub>2</sub> dust over about two years. The highest exposure group (250 mg/m<sup>3</sup> of fine TiO<sub>2</sub>) showed a significant increase in lung tumors (approximately 20% of rats developed lung cancer, mainly lung adenocarcinomas)<sup>6</sup>. These results were a driving force behind classifying TiO<sub>2</sub> as a Category 2 carcinogen: regulators argued that if high exposures caused tumors in rats, there could be a risk for humans who inhale TiO<sub>2</sub>, warranting a “suspected carcinogen” label.

However, several contextual points about this and similar studies are crucial:

- **“Particle Overload” Phenomenon:** The dust concentrations used in the rat studies were extremely high – for instance, 250 mg/m<sup>3</sup> is huge (by comparison, most workplace dust limits are under 10 mg/m<sup>3</sup>). At such high levels, the rats’ lung clearance mechanism was impaired. **Lung overload** means particles accumulate faster than they can be cleared, leading to persistent inflammation. This condition is known to cause tumors in rats even with inert materials. In the TiO<sub>2</sub> study, lower concentrations (e.g., 50 mg/m<sup>3</sup>) did not cause a statistically significant increase in tumors. This suggests that there might be a **threshold effect** – below a certain dust burden, no tumors occur. The classification dossier, however, took a conservative view that any indication of carcinogenicity, even if only at high doses, was cause for concern.
- **Other Animal Studies:** Mice and hamster studies with TiO<sub>2</sub> have generally **not shown carcinogenic effects** or have been inconclusive. Rats seem uniquely prone to developing lung tumors under particle overload conditions; mice have more robust lung clearance in some respects. This species difference raised questions: Are rats acting as a sensitive indicator of a hazard that humans might also face, or are they

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<sup>6</sup> <https://www.sciencedirect.com/science/article/pii/S0300483X1630292X>

an outlier that isn't predictive for humans? Regulators tend to err on the side of caution, but the species specificity made the evidence less clear-cut.

- **Epidemiological (Human) Evidence:** The evidence from humans was, and remains, **limited and largely negative**. TiO<sub>2</sub> has been produced since the early 20th century, and workforce studies have not found strong links to cancer. A cohort study of TiO<sub>2</sub> factory workers (published in 2010) did not find a statistically significant increase in lung cancer overall; one sub-group showed a slight, non-significant uptick, but it was not conclusive. Another study (case-control in workers) saw no association. Overall, the **epidemiological studies did not provide evidence** of a carcinogenic effect in occupational settings, albeit with some data limitations (relatively small cohorts and difficulty assessing past exposure levels). In the absence of clear human harm signals, the case for classification rested entirely on the animal data and related mechanistic reasoning.
- **Mechanistic Understanding:** Research has indicated that TiO<sub>2</sub> is **not genotoxic** (it doesn't directly damage DNA) and doesn't initiate cancer through chemical interaction. Instead, the mechanism for the rat tumors is thought to be **secondary chronic inflammation**: overloaded macrophages in the lung release reactive oxygen species and cytokines, leading to tissue damage and eventually tumor formation after prolonged exposure. This mechanism is a general "dust effect" rather than something unique to TiO<sub>2</sub>. Other poorly soluble, low-toxicity dusts (sometimes called **PSLTs**, e.g. carbon black, toner, diesel soot) cause the same phenomenon in rat lungs when inhaled at high concentrations. This was acknowledged by the RAC – they noted the mode of action for TiO<sub>2</sub> was a "**non-intrinsic, particle effect**". Nonetheless, RAC and the Commission felt that because the end result was cancer in an animal model, TiO<sub>2</sub> should be classified (Category 2 allows for suspected hazards with limited evidence).
- **Other Expert Assessments:** As noted previously, the IARC classified TiO<sub>2</sub> as Group 2B (possibly carcinogenic) in 2006. The wording "possibly" means the evidence is not strong – it's two notches below "carcinogenic to humans". After the EU's 2019 classification, some agencies outside the EU reviewed their positions. For instance, Canada did not add a carcinogen classification but recommended treating TiO<sub>2</sub> dust as a nuisance dust requiring controlled exposure. The U.S. OSHA did not classify TiO<sub>2</sub> as a carcinogen, but NIOSH (an advisory body) had earlier recommended exposure limits and cautioned that ultrafine TiO<sub>2</sub> particles might be more potent in causing lung inflammation. These perspectives show that globally there was concern about dust effects but no consensus on labeling TiO<sub>2</sub> a carcinogen.

In the court case, the **Commission and supporting parties** leaned on the argument that the **animal evidence, though not perfect, warranted precaution**. It would be ethically unacceptable to expose humans to high levels to "prove" harm, so regulators must decide based on animal data and mechanistic plausibility, even if the data arises from just one species, if the exposure conditions might be met in real-world worst cases (e.g., a worker without proper protection in a dusty environment). The **industry and opposing experts** emphasized the nuances: that the rat study's conditions were extreme and not relevant to

typical human exposure, and that the totality of evidence (especially human data) did not indicate a real carcinogenic risk from TiO<sub>2</sub>.

### Credibility and Relevance of the Evidence

One of the central questions was whether the rat inhalation study (and related data) constituted “**reliable and acceptable**” evidence for classification under the CLP regulation’s criteria. The General Court’s analysis homed in on this reliability issue. By dissecting the technical details (like particle density and overload), the Court effectively questioned the **validity of the rat study as evidence of hazard** in normal use. The fact that a judicial body engaged itself deeply into these scientific details was unusual but pivotal.

From a scientific standpoint, the **rat study was a valid study** for researching dust effects, but its **relevance to human risk** was debated. The defense (regulators) considered the study relevant enough to justify caution; the plaintiffs (industry) argued it was not robust evidence of a hazard at realistic exposures. The General Court clearly found the latter argument more convincing, essentially agreeing that the study’s conditions undermined its applicability to human classification.

The court heavily referenced the RAC’s own documents and internal inconsistencies in its assessment:

- RAC had noted that **particle size and surface area** might be more relevant than mass for toxic effects but the classification was based only on a mass concentration threshold (1% of particles  $\leq 10\mu\text{m}$ ).
- RAC acknowledged the tumors were observed **only with lung overload** yet proceeded to classify, implying some level of intrinsic risk. The court saw this as contradictory.
- Importantly, the applicants (industry) provided analyses showing how RAC’s calculations were incorrect. For example, primary TiO<sub>2</sub> particles have a significantly higher density (density  $\sim 4$  g/cc) than agglomerates (effective density  $\sim 1$  g/cc when fluffy). Over a two-year rat study, that difference would significantly change the estimated particle load in alveoli. The Court found the applicants line of argument compelling – the error was so basic (density misused) that it constituted a “**manifest error**” visible even to non-scientists when explained. This allowed the Court to more readily accept the applicants’ argument without feeling it was overstepping its role.

On the issue of **intrinsic property** issue, the hazard (lung cancer from dust) is acknowledged to be real under certain conditions, but the question is whether this hazard arises from a property of TiO<sub>2</sub>, or rather is an effect arising from “dustiness at high concentration”? Regulators usually classify by hazard, that is, if something *can* cause cancer under some circumstance, then action is appropriate. The Court forced an intersection of hazard and exposure by invoking intrinsicness and thereby elevated the **relevance** criterion: evidence is only relevant if it demonstrates a hazard inherent to the substance itself, not as an artifact of an experimental scenario.

In terms of **experts and organizations** involved:

- **ANSES (France)** and **RAC (ECHA)** were the main bodies that compiled and evaluated the evidence for classification. Their experts leaned on a conservative interpretation, that since rat tumors occurred, this should be treated as a red flag.
- **Industry's experts** included toxicologists and material scientists who re-analyzed data. They submitted comments during the RAC process (some of which were not fully heeded) and then provided evidence to the court. For example, Prof. Dr. Uwe Heinrich, who conducted some of the original studies, was cited by the industry side in critiques of how his data were used. The Titanium Dioxide Manufacturers Association (TDMA) is understood to have coordinated expert input.
- The **General Court** didn't call its own experts but based its findings on the record and arguments presented. The fact that the Court engaged in detailed scientific issues such as densities suggests they had received detailed written submissions from both sides.

Ultimately, the Court judged that the **evidence was not strong enough** to justify the classification. The Court did not 'throw out' science; to the contrary, it said that the science, properly understood, did not meet the legal bar. The Court did not dispute the facts of the studies but rather their relevance and interpretation in law.

### Current Status of TiO<sub>2</sub> Classification

Following the Court of Justice's final ruling in 2025, **titanium dioxide is no longer classified as a carcinogen in the EU**. The entry for TiO<sub>2</sub> has been removed from Annex VI of the CLP Regulation. In practical terms this means

- Products containing TiO<sub>2</sub> no longer require the warning "H351: Suspected of causing cancer by inhalation" on labels.
- The special advice phrase about respirable dust (EUH212 and EUH210 phrases that were introduced alongside the classification) is also not mandated.
- TiO<sub>2</sub> is now treated like any ordinary chemical without a harmonised classification. Of course, standard safety measures for nuisance dust apply, but those are covered under worker safety regulations, not hazard labels.

For companies, this greatly simplifies compliance. Many had prepared Safety Data Sheet updates, labeling changes, and even reformulation plans when TiO<sub>2</sub> was classified. They can now roll back those changes. For example, a paint manufacturer can sell a TiO<sub>2</sub>-rich paint without a carcinogen warning label (unless there's some other component triggering one).

It's interesting to note that **some EU countries' agencies** might still have TiO<sub>2</sub> on watch lists. The EU's decision was harmonised (so it overrides national decisions) but, given the controversy, national hazard communications like guidance or codes of practice may emphasize avoiding inhalation of dust. However, in legal terms, they cannot enforce a classification that has been annulled at EU level.

Outside the EU, TiO<sub>2</sub> remains generally unclassified as a carcinogen. The exception was California, which under Proposition 65 lists “airborne, unbound particles of titanium dioxide of respirable size” as a carcinogen (since 2011). That’s a somewhat analogous stance to the EU’s 2019 position, but in legal terms Prop 65 acts only as a list that triggers warnings in California, not a ban or restriction. The EU’s move in 2019 was more consequential due to its integration into other regulations.

As mentioned earlier, **this annulment was only the second time** a harmonised classification was struck down. The prior case (in 2019, finalized 2021) involved certain **lead chromate pigments**, but that was a different situation, in so far as it was about an authorization under REACH being revoked on grounds of not considering alternatives<sup>7</sup>. TiO<sub>2</sub>’s case is a more direct and high-profile statement on how evidence must support classification.

In summary, TiO<sub>2</sub> has returned to being an **unclassified chemical** in terms of carcinogenicity in the EU. Regulatory focus should now shift away from labeling to ensuring that workplaces with TiO<sub>2</sub> dust keep exposures low through occupational safety measures. The substance itself continues to be used widely in Europe in a multitude of applications.

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## 5. Impact on Future Harmonised Classifications

The TiO<sub>2</sub> judgment has significant implications for the EU’s approach to classifying chemicals, especially in borderline cases. It can be expected to influence how scientific evidence is evaluated and how precaution is applied. Some key impacts in terms of shaping future classifications may be as follows:

### Higher Bar for Scientific Rigor

**Regulators should be more cautious and rigorous** in their scientific assessments for classification. The consequence of having a decision annulled means ECHA’s committees (like RAC) and the European Commission should be expected to take extra care to avoid any obvious errors:

- For any given study used as key evidence, a thorough **sensitivity analysis** of assumptions could be expected. RAC is likely to explicitly discuss issues such as particle behavior, species differences and dose relevance in their opinions to preempt criticisms. There should be fuller documentation of why the RAC trusts a study’s results and how this translates to human risk.
- The TiO<sub>2</sub> case showed that even technical details can become legal pivot points, so, regulators may look to involve **more external experts or peer reviews** for contentious cases. For instance, if a classification review involves complex toxicokinetics or novel science, requesting an independent expert panel to validate the approach could strengthen the eventual decision from legal challenge.

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<sup>7</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:62016TJ0837>

- The concept of “manifest error” is now firmly established in legal practice. Every ECHA opinion and Commission decision is consequently likely to undergo an informal “**could a court find a clear mistake here?**” check. If a potential issue is spotted, this is more likely to be addressed or at least acknowledged in the rationale.

This could result in **slower but more robust decision-making**. Some Member State dossiers might face tougher scrutiny and questions from RAC. It’s possible that if a classification is not sufficiently well supported, regulators might err towards not proceeding, in order to avoid a repeat of TiO<sub>2</sub>.

### Emphasis on Intrinsic Hazard

The judgement underscores that **harmonised classification is based on intrinsic hazards**. This might influence both how regulators decide and how they explain their decisions:

- Future classification proposals will likely more clearly delineate whether and how a hazard is intrinsic. For example, if dealing with another dust or a similar physical-effect case, there might be greater reluctance to classify under carcinogenicity and/or more attention to supporting notes. The Commission could, for instance, add a note to a classification along the lines of “harm via inhalation of respirable dust – see guidance”, rather than using the generic carcinogen category, or could opt not to classify at all.
- Some have suggested creating a new hazard category for “lung overload effects” separate from carcinogenicity. The Chemicals Strategy for Sustainability included updating CLP with new classes (including endocrine disruptors) and the Commission might ask ECHA to consider something like a “**particle toxicity**” hazard class, which would capture substances that cause pathology through dust overload. If so, this would be a direct regulatory response to a gap highlighted by TiO<sub>2</sub>.
- The **precautionary principle** will still be applied, but more carefully within the bounds of intrinsic hazard. In the TiO<sub>2</sub> case the Commission argued a precautionary approach of “over-warning rather than under-protecting.” The court decision doesn’t negate precaution, but it says that legal definitions cannot be stretched in its name. Regulators might thus be more restrained, proposing a precautionary classification only if it can be argued that the substance likely has an inherent hazardous trait supported by evidence, even if the evidence is not 100% certain.

Although there may be concerns that some marginal cases could now be left unclassified unless more proof emerges, regulators must strike a balance. They are tasked to protect health without misclassifying substances not proven to be inherently dangerous. The TiO<sub>2</sub> case suggests that if evidence is weak or a hazard is conditional (like a dust effect), regulators may be more hesitant to classify. This could mean fewer substances end up in Category 2 classification unless evidence is more definitive.

The judgment also **empowers scientific scrutiny**, and signals that even complex technical decisions must hold up to review, and that courts will ensure regulatory science is not

fundamentally flawed. This pressure may improve the rigor of all future classification proposals – which will be beneficial for the credibility of the entire system.

## Regulatory and Policy Response

The European Commission and ECHA could consider responding in a number of ways:

- **Clarify Guidelines:** ECHA could update guidance on classification to emphasize that hazards must be intrinsic to justify classification. Guidance could include specific pointers on how to handle cases like inert dusts, perhaps advising that if an effect is only via lung overload, classification isn't appropriate (as per the TiO<sub>2</sub> outcome). Technical guidance, designed to support the integrity and quality of scientific evidence, could be drawn up by eminent scientists and adopted by the Commission<sup>8</sup>.
- **Training and Awareness:** ECHA could take steps to ensure that RAC members and national authorities are fully aware of the TiO<sub>2</sub> case when evaluating proposals.**Possible Legislative Change.** If policymakers feel the existing CLP framework doesn't adequately cover "dust hazards" following the TiO<sub>2</sub> ruling, they could consider a new hazard category. For example, future CLP revisions could introduce a "particle toxicity hazard" class or similar terminology. Alternatively, the existing CLP criteria could be recodified to more explicitly avoid ambiguity.
- **Precautionary Approach Recalibrated:** The Commission is still likely to use precaution approaches, as enshrined in EU law, but will need to ensure that any precautionary classification is firmly within the confines of intrinsic hazard. If the evidence is borderline, an alternative could be to opt for risk management measures (such as restrictions or OELs) instead of classification, in order to avoid legal vulnerability.
- **Monitor Litigation Landscape:** This case might embolden industry to challenge other classification decisions or could discourage interest groups from pushing weak cases. Regulators are likely to prepare more robust justifications in the expectation of greater scrutiny. The Commission has no doubt taken note that, even though the Advocate General warned against deep science review, the Court still proceeded on this course. It cannot be assumed that courts will not delve into scientific issues and regulators will need to prepare as if they might.

## Implications for Industry

For industry, and especially those companies operating in sectors dealing with dusts or borderline chemicals, the following points may apply:

- **Relief and Confidence:** TiO<sub>2</sub> producers and users were obviously pleased with the decision (see for example the press statement by lawyers Mayer Brown<sup>9</sup>, which noted that the judgment "avoids potentially extensive regulatory consequences" and "upholds the integrity of scientific review").

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<sup>8</sup> [https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf\\_-\\_pn\\_32\\_-\\_scientific\\_integrity\\_event\\_18.pdf](https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_-_pn_32_-_scientific_integrity_event_18.pdf)

<sup>9</sup> <https://www.mayerbrown.com/en/news/2025/08/mayer-brown-secures-landmark-appellate-victory-for-titanium-dioxide-industry-in-front-of-the-court-of-justice-of-the-european-union>

- **Vigilance for Similar Substances:** Industries handling carbon black, talc, etc., will feel more secure that these and similar substances will not quickly follow TiO<sub>2</sub> into CLP classification. However, these companies should also ensure that they can proactively provide good quality data to regulators to support non-classification (e.g., continue funding studies to demonstrate that any health effects are threshold-based and do not arise from an intrinsic property).
- **Legal Precedent:** Companies may be more willing to legally challenge future classifications that they consider questionable. However, companies should also be clear that success will require demonstration of clear errors or misapplications (TiO<sub>2</sub> had both).
- **Sustainability and Alternatives:** Some industries may still, independently of regulation, look at alternatives to TiO<sub>2</sub> in certain uses (for other reasons such as environmental micro-particle concerns or consumer perception). However, the general regulatory pressure on TiO<sub>2</sub> has eased.
- **Corporate Responsibility:** It's wise for industry not to overplay the court outcome and they should continue to support safe practices such as dust control and exposure monitoring. If complacency were to lead to health incidents, renewed regulatory and reputational pressures would quickly follow

### Similar Cases and Precedents

Parallels or implications from the TiO<sub>2</sub> case can reasonably be drawn in related areas, for example

- **Other CLP Decisions:** If a contentious classification is proposed (e.g., a substance like synthetic amorphous silica, or another widespread inert material), the TiO<sub>2</sub> case likely will be cited. Companies will be entitled to make the comparison with the TiO<sub>2</sub> case and regulators will need to differentiate or concede accordingly.
- **Future Substance Debates:** As science evolves and new types of material become available, for example nano materials, the concept of intrinsic hazard should remain front and center in shaping any case for regulatory action.
- **Global Influence:** EU classifications are closely watched globally and the TiO<sub>2</sub> judgment is likely to maintain the international status quo (TiO<sub>2</sub> not widely labeled as carcinogen).
- **Case Law on Science:** This case, as well as the lead chromates<sup>10</sup> and chromium trioxide<sup>11</sup> cases, confirm that the EU courts can examine if regulators considered all factors and didn't make obvious mistakes, even in scientific and technical matters. These may set important precedents beyond chemicals for any administrative decisions with a scientific basis.

### Ongoing Research and Future Developments

Science continues to develop and is likely to offer new challenges including:

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<sup>10</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:62016TJ0837>

<sup>11</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:62021CJ0144>

- **Continuous Research:** TiO<sub>2</sub> will still be studied. Some ongoing work, for example, includes examining whether nano-TiO<sub>2</sub> could have unique effects and/or long-term epidemiology impacts (noting some updated cohort analyses have been done and mostly show no significant risk, with the possible exception of very high exposure groups).
- **Nano vs Bulk:** If any new hazard emerges (such as a specific form of TiO<sub>2</sub> shows genotoxicity), regulators could revisit classification with a new perspective not considered before.
- **Alternative Pigments:** Innovation may produce alternatives to TiO<sub>2</sub> for certain uses (e.g., non-nano zinc oxide or organic pigments in cosmetics). If so, some industries might gradually shift away from TiO<sub>2</sub> for reasons unrelated to CLP classification
- **Follow-up by Authorities:** The Commission may ask for a review in a decade or so to assess if any new evidence has arisen (although at this point this seems unlikely)
- **Workplace Standards:** As mentioned previously, one outcome might be a push for an EU-wide occupational exposure limit for TiO<sub>2</sub> dust. In 2019, there was discussion of an EU OEL (perhaps 1-2 mg/m<sup>3</sup> for respirable). If such a measure were to be adopted, it would provide a targeted ‘safety net’ without labeling consumer products.
- **Precaution vs Science Ongoing Debate:** The TiO<sub>2</sub> case is likely to be cited in many panel discussions or articles about how to handle emerging risks, underscoring the need for robust evidence while fully addressing hazards arising from intrinsic properties. The case may also spur efforts to develop ‘next generation’ testing methods (such as improved long-term inhalation models or better in vitro to in vivo extrapolation), to support regulatory decisions.

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## 6. Recommendations

In the light of the TiO<sub>2</sub> case, some recommendations may be offered for regulators and policymakers:

1. **Ensure Scientific Rigor:** Double-check that any classification proposal is built on solid, reliable studies. If key data have uncertainties, address them transparently or reconsider the proposal. Avoid proceeding with a classification if the evidence rests on a scenario not relevant to typical use (such as extreme dust overload).
2. **Clarify Criteria:** In guidance documents (and possibly legally), clarify that classifications target intrinsic properties. Provide examples (such as TiO<sub>2</sub>) so that risk assessors uniformly apply this principle. If needed, introduce new hazard categories or supporting notes such as “respirable dust hazard” outside or carcinogenic classes, to communicate those risks in an accurate way.
3. **Use Other Tools for Conditional Hazards:** If a substance only poses a risk in certain forms or uses, consider tackling the risk with targeted measures (e.g., workplace exposure limits, handling guidelines, or labeling requirements separate from CLP). For TiO<sub>2</sub>, ensure that workplaces enforce dust control. For consumer use (such as spray paints), consider advisory labels even if not classed as a carcinogen.

4. **Precaution with Robustness:** Continue to apply the precautionary principle when appropriate, but with clear acknowledgement of uncertainties and demonstrating that all relevant factors have been addressed (as RAC failed to fully do with TiO<sub>2</sub> densitometry).
  5. **Engage Stakeholders Early:** For any potentially contentious classification, engage early in the process with industry and independent scientists and gather and test all views and data, noting that the TiO<sub>2</sub> case might have turned out differently if RAC had properly considered and integrated industry's calculations on overload. Early dialogue can surface issues and potentially lead to consensus measures short of classification where appropriate.
  6. **Monitor Post-Decision:** After a classification (or de-classification), monitor relevant health outcomes. For example, though TiO<sub>2</sub> is declassified, periodically monitor relevant occupational health reports or new findings. If new human health data were to unexpectedly emerge, be ready to promptly respond and adapt.
  7. **Public Communication:** Clearly explain to the public why a classification is (or isn't) made. With TiO<sub>2</sub>, for example, it is important to communicate that "non-CLP classification means no *inherent* cancer risk under normal conditions but, as with any dust, heavy inhalation should be avoided." This nuance is important to maintain public trust and confidence.
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## 7. Conclusion

The court judgment on titanium dioxide's EU classification is a **landmark decision** in the realm of chemical regulation. It underscores the necessity that **hazard classifications are based in robust science and on the true intrinsic properties** of substances. In the titanium dioxide case, the courts concluded that a material long considered low-toxicity should not carry a carcinogen label, because the **observed cancer risk in studies was tied to extraordinary exposure conditions** (massive dust overload in rat lungs) rather than an inherent chemical property<sub>2</sub>. The judgments meticulously dissected the science and reaffirmed that regulatory decisions must consider all relevant factors and must stay within the bounds of the law's intent.

In practical terms, the outcome **removes TiO<sub>2</sub> from Europe's list of carcinogens**, averting onerous labeling and usage restrictions for countless products. This is important for producers and users and signals that substances like TiO<sub>2</sub>, which pose only a **conditional hazard**, should not be mischaracterized as universal dangers. However, it is not a signal to relax safety measures, but rather to apply them more intelligently by focusing on controlling dust exposures and monitoring health effects.

For the regulatory system, TiO<sub>2</sub>'s case is both humbling and guiding. It reminds regulators that precaution has limits and that evidence quality matters; even well-intended decisions can be overturned if not solidly founded. It guides future actions by clarifying the meaning of intrinsic hazard and by showing that rigorous, transparent science is the road to durable

regulations. The case will likely influence how similar borderline substances are handled, favoring risk management tools over classification when appropriate.

Crucially, the TiO<sub>2</sub> saga is a testament to the strength of a system that can self-correct. It shows that stakeholders – regulators, scientists, courts, industry, and public health advocates – each play a role in ensuring that measures to protect health are both effective and justified. The balance between precaution and evidence was recalibrated in this case, not to diminish safety, but to deploy safety efforts where they are relevant and needed. By avoiding an improper label on TiO<sub>2</sub>, regulators can direct attention and resources to chemicals that do have intrinsic dangers, and treat TiO<sub>2</sub> for what it is: an inert substance that is safe in normal use but demands respect as a fine dust.

In conclusion, the titanium dioxide case has **refined the practice of hazard classification**. It reinforces that protecting people and the environment is properly served by scientific accuracy and rigorous use of evidence and not weakened. When regulation is grounded in solid evidence, it withstands scrutiny and earns public trust. When it overreaches, mechanisms exist to pull it back, as happened in the case of TiO<sub>2</sub>. Moving forward, all parties can take lessons from this outcome – to continue **to improve scientific assessments, to communicate risks clearly, and to ensure that regulatory actions remain proportionate to the true hazards of substances**. In doing so, the regulatory process will uphold both safety and integrity, and serve the overall goal of safeguarding health and well-being with measures that are **justified, meaningful, and effective**.