

The CJEU's Judgment on Classification of Titanium Dioxide, Implications & Developments on 'Essential Uses'

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- ◆ Ales has broad experience in EU product regulatory law, including REACH, CLP, POPs, biocidal legislation, food law, medical devices, electronic products, and product and food safety. He advises on regulatory compliance of a broad range of products marketed in the EU and represents clients before EU and national competent authorities on compliance and enforcement issues. Ales also advises on product recalls and withdrawals.
- ◆ Ales primarily focuses on EU regulation of chemicals and food, including representing clients in various procedures before the European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA).



Marie Escorneboueu

- ◆ Marie Escorneboueu counsels clients on regulatory and compliance matters related to food and drug law, with an emphasis on food and drug packaging, cosmetics, chemical control, and environmental issues.
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I. The CJEU's Judgment on the Classification of Titanium Dioxide, Implications

Context of the Case: The Classification of TiO₂ as Carc. 2

- ◆ Titanium dioxide (TiO₂):
 - ◇ Classified by the COM under the CLP as Carcinogenic 2, by inhalation; based of the RAC Opinion
- ◆ Joined Cases T-279/20, T-288/20 and T-283/20
 - ◇ Action filed against the COM decision
- ◆ The pleas: manifest error of assessment in...
 - ◇ The choice of evidence in the RAC opinion; and
 - ◇ The classification does not relate to a substance that has the intrinsic property to cause cancer

Manifest Error of Assessment in General

- ◆ The concept of ‘manifest error of assessment’
 - ◇ The EU Courts generally accept that the EU Institutions have a broad margin of discretion
 - ◇ But: the Courts must verify whether the Institutions have carefully examined all relevant facts of the individual case, thereby assessing whether:
 - The institution has taken into account all relevant facts; and
 - Such facts were correctly assessed
 - ◇ First successfully invoked in Case Bilbaína de Alquitrane and others (T-689/13) regarding classification of coal tar as Aquatic Acute based on constituents summation approach
 - ◇ But: bar for the ‘manifest error’ test usually very high, especially in decisions involving scientific and technical assessment

Manifest Error of Assessment in the TiO₂ Case I: Choice of Evidence

The Court held:

- ◇ Volume of lung overload in the key study was much higher than that calculated by the RAC ('acceptable' v 'excessive' overload)
- ◇ Therefore, study under excessive lung overload conditions
- ◇ As a consequence, requirement to base the classification on reliable and acceptable studies was not satisfied

Manifest Error of Assessment in the TiO₂ Case

II: Intrinsic Property to Cause Cancer (1)

- ◆ CLP mentions ‘intrinsic properties’ but does not define it
 - ◇ Here, RAC mentioned that the toxicity was not intrinsic « in a classical sense »
- ◆ The Court defines: “properties which a substance has in and of itself”, i.e., only the properties specific to a substance must lead to its classification

Manifest Error of Assessment in the TiO₂ Case

II: Intrinsic Property to Cause Cancer (2)

- ◇ TiO₂ has low solubility and can be inhaled when present in airborne particles
- ◇ Classification of Carc. 2 was linked solely to TiO₂ particles which are respirable
- ◇ = classification concerned a hazard solely occurring as a consequence of lung overload conditions
- ◇ Therefore, not pointing to an intrinsic property of titanium dioxide to cause cancer, but a situational hazard: any respirable substance may be hazardous

Impact of the Case

◆ Short-term consequences:

- ◆ TiO₂ classification has been annulled: no legal effects any longer
 - Appeal would not have suspensive effect; however, coal tar precedent shows that COM awaited the appeal judgment to withdraw the CLP entry
 - = possible action for failure to act in case of non-execution
- ◆ Question mark: the Court annulled C&L of TiO₂ where 1%/10 μm; how about supplemental statements for mixtures?

◆ Long-term consequences:

- ◆ Possible impact on other substances classified based on their physical characteristics, incl. nanomaterials

Important Precedent for Actions for Annulment

- ◆ In general, EU legal acts can be challenged for annulment in the EU General Court
- ◆ Applicant must show direct concern (change of legal situation)
- ◆ Deadline: 2 months (+10 days)
- ◆ Generally, uphill battle: most applications dismissed
- ◆ Current case: confirms that the Court does not shy away from scrutinizing scientific assessment by EU scientific bodies
- ◆ + the Court seems to accept technical experts in oral hearing
- ◆ = important precedent for future actions for annulment

Lack of Suspensive Effect

- ◆ But: Filing of action for annulment does not have a suspensive effect, unless granted in a separate procedure
- ◆ = the challenged act continues to apply and produces effects (after the transition period if any)
- ◆ In average, the General Court delivers its judgment in 18 months

To Compare: Board of Appeal of ECHA (BoA)



- ◆ BoA deals with appeals against ECHA decisions enumerated in Article 91(1) REACH (e.g., decisions related to registration and substance/dossier evaluation)
- ◆ The bar is lower: ‘error of assessment’ is sufficient
- ◆ Suspensive effect! (can be used to delay ECHA decision)
- ◆ Deadline: 3 months
- ◆ Roughly 50% of cases end either by ECHA’s Director rectifying the decision, or by annulling ECHA decision
- ◆ Lately, not many cases

II. Developments on ‘Essential Uses’

Background – Introduction of the Concept Within the CSS

- ◆ Introduced in the CSS:
 - ◇ Concept already used under the Montreal Protocol, beyond that its application is not accompanied by detailed criteria
 - ◇ Here COM mandated a consultant WSP (formerly Wood) to elaborate an EU definition
 - ◇ Wood presented an overview of its upcoming report on 24 November 2022
 - Only represents the consultant’s view
 - Final definition potentially to be incorporated in the REACH review
 - Final report to be published ‘soon’
- ◆ Goals:
 - ◇ Facilitating the phasing out of the ‘most harmful chemicals’ (e.g., aligned with SVHCs)
 - ◇ Minimisation of essential uses and encouragement of substitutions

The Proposed Definition (1)

◆ Functioning of the concept

- ◆ Replacing the current concept where exemptions from restrictions are granted based on a risk assessment + socio-economic analysis
- ◆ Defines what uses of the most harmful substances that are a priority for phasing out (primarily SVHCs) shall be deemed essential
- ◆ Horizontal concept
 - To be potentially integrated in REACH in the context of the review, taking it into consideration in the context of authorisations (if maintained in REACH) and derogations from restrictions
 - Potential to be included in sectoral legislation i.e. cosmetics, BPR, FCM
 - However specific uses could be defined essential or not depending on the sector, leaving the necessity for a case-by-case assessment

The Proposed Definition (2)

- ◆ The definition: the use of a substance, to be defined as ‘essential’ shall be:
 1. Necessity for health and safety, **AND/OR** critical for the functioning of society,
 2. **AND** there are no alternatives that are acceptable from the standpoint of environment and health

The Proposed Definition (3)

- ◆ Necessary for health and safety
 - For example: preventing, monitoring, or treating severe health issues; sustaining basic conditions for human life and health; managing and preventing health crises and emergencies; personal safety; public safety; danger to animal health which cannot be contained by other means
- ◆ Critical for the functioning of society
 - ◆ Idea of dependence
 - ◆ Element to be further defined by way of a horizontal guidance
 - Indications provided by the consultant include providing resources or services critical for society; managing societal risks and impacts from natural and man-made crises and emergencies; protecting and restoring the natural environment

The Proposed Definition (4)

◆ Conclusions

- ◆ Essentially health and safety driven, no place for purely financial considerations
- ◆ Environmental benefits: not a closed door
 - Some hints: ‘Sustaining basic conditions for human life and health issues’/’Protecting and restoring the natural environment’
- ◆ Criteria remain broad, importance of framing within related guidance

The Proposed Definition (5)

- ◆ Integration of a notion of time limitation
 - ◆ For all essential uses, the industry must take steps to minimise the essential use and any associated emissions of and exposure to the controlled substance
 - ◆ Derogations are time-limited
 - ◆ Industry must demonstrate appropriate efforts are made to substitute the controlled substance
 - ◆ Therefore, the goal remains phasing out

Impact Beyond REACH

- ◆ Impact beyond REACH:
 - ◆ Principle of a default ban on all the non-essential uses of the most harmful chemicals
 - ◆ Progressive reduction of the number of essential uses allowed
 - ◆ Authorisations and restrictions under REACH supersede to use the substance including where sectoral legislation exists
 - ◆ In parallel, consultant suggests an incorporation in the sectoral legislation (quoting FCM, Cosmetics, BPR, PPPR), with possible adaptations to the criteria



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Please join us at 10:00 AM Eastern U.S.
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Thank You

Any questions?

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