

Cefic Members BRIEFING PAPER

November 2022

EU Court ruling – Titanium Dioxide classification and labelling Ruling of 23 November 2022, Joined cases T-279/20, T-288/20 and T-283/20

INTRODUCTION

On 23 November 2022, the EU General Court **annulled** the Commission 2019 CLP Delegated Actⁱ insofar as it concerns the **harmonised classification and labelling of titanium dioxide (TiO2)**.

The decision was delivered in the case brought by Titanium Dioxide producers in May 2020, and in which **Cefic formally intervened** (case <u>T-283/20</u>), along with two other cases.

The Court decision is based on two main grounds:

- 1. The requirement to base the classification of a carcinogenic substance **on reliable and acceptable studies** was <u>not</u> satisfied.
- 2. The classification of a substance as carcinogenic can apply <u>only</u> to a substance that has the **intrinsic property** to cause cancer.

The Court ruling is **not yet final**: the decision can be appealed before the EU Court of Justice (CJEU) within two months and ten days.

EU COURT FINDINGS

Requirement of reliable and acceptable studies

The Court found that the ECHA Risk Assessment Committee (RAC) committed a manifest error of assessment, rendering implausible the finding that the results of a decisive study were sufficiently reliable (application of wrong density value to assess lung overload).

The Commission committed the same manifest error of assessment by relying on the RAC Opinion to decide the classification and labelling of TiO2.

The classification and labelling do not relate to a substance that has the intrinsic property to cause cancer

In absence of a definition in the CLP Regulation, the Court interprets the concept of 'intrinsic properties' in its literal sense as referring to the 'properties which a substance has in and of itself'.

An accumulation of particles in the lung in sufficient quantities to bring about a significant impairment of particle clearance mechanisms, which can be verified only when certain quantities of particles are inhaled cannot be regarded as forming part of the intrinsic properties of the particles at issue.

The Commission committed a manifest error of assessment when applying the criterion for classifying a substance as carcinogen laid down in CLP.





CEFIC INTERVENTION

When the ExCom agreed that Cefic should formally intervene in the TiO2 court case, this was with a specific and focused mandate: to question the Commission's reading of 'intrinsic property'.

The point which lead to Cefic's intervention (on the requirement for the inherent/intrinsic properties) is one of the points explicitly referenced in the Court ruling as leading to the annulment.

In our written statement in 2021 and in the hearing in May 2022, Cefic highlighted that a 'particle effect' is not an inherent property of a substance under the CLP Regulation.

ASSESSMENT / NEXT STEPS

The outcome of the ruling is positive, both for TDMA companies and for Cefic members.

Further assessment and implications for other Cefic Sector Groups will be assessed and clarified, in collaboration with outside counsel.

It will also be important to monitor how the Commission will respond, e.g. via an appeal before the CJEU or other legislative or regulatory options.

CONTACT

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¹ Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 amending, for the purposes of its adaptation to technical progress, Regulation (EC) No 1272/2008 (CLP).