

Legal Analysis
on
the proposed classification of titanium dioxide under the CLP Regulation

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1. Introduction

We have been asked by the *Verband der deutschen Lack- und Druckfarbenindustrie e.V.* to assess the legal aspects of the proposed classification of titanium dioxide as a carcinogenic substance category 2, through the inhalation route. The proposal was originally submitted by France (*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail* (ANSES)) under Article 37 of the CLP Regulation which deals with the harmonised classification and labelling of substances. While France, in its CLH-Report, proposed a classification in the carcinogenicity category 1B (presumed to cause cancer), ECHA's Committee for Risk Assessment (RAC) concluded in its Opinion (adopted on 14 September 2017) that there is not sufficient evidence for such classification. Yet, the RAC concluded that there is sufficient scientific data to classify titanium dioxide as a substance suspected of causing cancer by inhalation (category 2). Basically, the classification proposal of RAC is derived from the argument that workers may develop lung cancer when exposed to titanium dioxide dust in industrial production and processing. The following analysis will deal with the legal issues connected with the (potential) classification of titanium dioxide under the CLP Regulation.

2. The scope of hazard classification under CLP

As stipulated by Articles 36 to 38 of the CLP Regulation, it is the idea of a harmonised hazard classification to enable a uniform classification of hazardous substances at EU level. It is embodied in this regulatory approach that the hazard classification is always focused on the substance itself and its properties. Thus, as the RAC states in its Opinion (page 41), the classification is based solely on the hazardous properties of a substance, and not the likelihood of exposure to a substance. The scope of hazard classification is further explained in ECHA's Guidance on the Application of the CLP Criteria (ECHA-17-G-21-EN, Version 5.0, July 2017): "*The objective of hazard classification is to identify the intrinsic physical, health and environmental hazards of substances and mixtures taking into account all uses that can be reasonable expected*" (subsection 1.2.1.).

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First, this demonstrates the holistic approach of hazard classification under the CLP Regulation by taking all uses of a substance into account. As a consequence, CLP foresees a uniform hazard classification, independent of the specific uses of this substance. Yet, the scope of hazard classification must be always related “*to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used*” (cf. Articles 5(1), 6(1), 8(6) and 9(5) of the CLP Regulation).

Second, ECHA’s Guidance on the Application of the CLP Criteria (subsection 1.2.1) explains that only the intrinsic properties of a substance are relevant for a classification, also by referring to UN’s Globally Harmonized System of Classification and Labelling of Chemicals (GHS) of 2011: “*The GHS (subsection 1.3.2.2.1) uses the term ‘hazard classification’ to indicate that only the **intrinsic hazardous properties** of substances or mixtures are considered*” (see also subsection 1.1.3.1.1 of GHS: “*The goal of GHS states is to identify the intrinsic hazards found in substances and mixtures ...*”).

This regulatory concept of hazard classification under CLP is, inter alia, repeated in Annex I, section 3.6 of the CLP Regulation which deals with classifying substances as carcinogens. In this context, paragraph 3.6.2.2.1 stipulates: “*Classification as a carcinogen is made on the basis of evidence from reliable and acceptable studies and is intended to be used for substances which have an intrinsic property to cause cancer.*” According to this approach, the question is whether titanium dioxide has an intrinsic property to cause cancer or not.

3. **Intrinsic properties (of titanium dioxide)**

The term „intrinsic properties“ is neither defined in the CLP Regulation nor in the REACH Regulation. GHS (subsection 1.1.2.6.2.1) refers to the “*degree of its capacity to harm*” for explaining the specifics of intrinsic properties of a substance. Further, subsection 1.1.2.6.2.1 of GHS states that intrinsic properties must be distinguished from the concept of risk (i.e. the likelihood of harm). ECHA’s Guidance on the Application of the CLP Criteria (subsection 1.1.3) defines intrinsic properties as “*the basic properties of a substance or mixture as determined in standard tests or by other means designed to identify hazards*”.

Since intrinsic properties of a substance are properties which are inherent to the substance itself, intrinsic properties are always attributed specifically to a substance as such, but not the properties which result solely from its form, physical state or size. Thus, the particular hazardous properties must always be substance-specific to consider them as intrinsic. Forms, physical states or sizes of a substance are not a specific property of the substance.

As described above (under 1.), the proposed classification of titanium dioxide as a carcinogen is based on the inhalation of titanium dioxide dusts, mainly by workers. Consequently, the carcinogenic effects can only be attributed to the intrinsic hazardous properties of titanium dioxide if those effects result from the specific characteristics of titanium dioxide and

not only from the form and particle size (dust). While a hazard classification under CLP is possible if the specific hazardous effects of a substance only occur if the substance has a certain form, physical state or size, such classification is not feasible under CLP, if the decisive trigger for the hazard is purely the particle size.

Against this background, the proposed classification of titanium dioxide cannot be justified only on the grounds that titanium dioxide dust – due to particle effects of the dust – may cause cancer. If the described dust effects are not inherently unique to titanium dioxide, but apply to a great number of substances in powder form, then the carcinogenic effects are triggered by the particle size and do not have their cause in the intrinsic properties of titanium dioxide. In other words: the particle size of titanium dioxide dusts as such cannot be regarded as an intrinsic property.

On pages 38-41 of the Opinion, the RAC acknowledges that the titanium dioxide inhalation toxicity has to be considered as particle toxicity (cf. page 38): Since the deposited particles, but not solutes of titanium dioxide molecules shall be assumed to be responsible for the observed toxicity, the RAC denies an intrinsic toxicity in a “classical sense” (cf. pages 38, 40). Further, the RAC acknowledges that the carcinogenicity profile described for titanium dioxide is not exclusively characteristic for titanium dioxide but applies to the whole group of chemicals referred to as “poorly soluble low toxicity particles” (PSLT particles) (cf. pages 38, 41). Yet, RAC considers this as a basic and therefore intrinsic property of titanium dioxide.

The line of argumentation of the RAC is built upon the hypothesis that the feature of a substance being “poorly soluble” constitutes an intrinsic property of this substance. By referring to the group of PSLT particles the RAC suggests that a definable group of substances exist having a specific property. Yet, a lot of substances are to be regarded being “poorly soluble”. Therefore, this feature alone cannot be considered of being specific for titanium dioxide. The characteristic “poorly soluble” as such is not an intrinsic property. The possible effects resulting from “poorly soluble” substances are a purely physical phenomenon, i.e. they are not caused by intrinsic properties.

Against this background, the situation for titanium dioxide has to be clearly distinguished from the classification of other substances, e.g. asbestos. Asbestos has been classified as cancerogenic cat. 1A as a result of the proven health hazards arising from asbestos fibers which may lead to asbestosis even if only small amounts reach the lungs. In the case of asbestos, the occurrence as fibers is a specific characteristic which has its origin in the specific structure of the substance, resulting either in forms of thin needles (amphibole asbestos) or thin layers (chrysotile asbestos). Specifically for asbestos, the physical form (fibers) is directly linked with its chemical composition, resulting in the particular carcinogenic effects. Therefore, in the case of asbestos, it is specifically the chemical composition of the substance which causes – in fibrous form – the effects. The fibrous form as such is not an intrinsic property, like the characteristic “poorly soluble”.

For the sake of completeness, it has to be noted: Even if one should reach the conclusion that the characteristic “poorly soluble” can be regarded as an intrinsic property, the question remains if sufficient scientific evidence exists to classify titanium dioxide as carcinogenic. As Annex I subsection 3.6.2.2.1 of the CLP Regulation stipulates, the “*evaluations shall be based on all existing data, peer-reviewed published studies and additional acceptable data.*” Currently, it is highly disputed between the authorities (with different opinions of ANSES and RAC), the industry and the scientific community which of the available studies on the effects of titanium dioxide shall be used for the scientific assessment and if those studies can be considered valid at all. Already this demonstrates that the scientific assessment – at the present stage – obviously does not lead to clear results and indicates that, due to a lack of a scientific consensus, there may be not sufficient scientific evidence for a classification of titanium dioxide as carcinogenic.

4. The undifferentiated approach of hazard classification under CLP

It is the consequence of the regulatory concept of hazard classification under CLP which covers all uses of a substance, that the information mechanisms relying on such classification (e.g. labelling under CLP) may not describe the hazards connected with the specific use of a substance correctly and are, therefore, misleading. This is the case for titanium dioxide: For justifying the proposed classification of titanium dioxide as a carcinogenic substance category 2, the RAC bases its Opinion only on the exposure by inhalation. An inhalation of titanium dioxide dusts may occur in a workplace, but is excluded if titanium dioxide is strongly bound in a polymeric product matrix (e.g. in paints and coatings). As a consequence, the use of paints and coatings by the consumer or industry does not present a hazard, if – which is regularly the case – the titanium dioxide contained in those products is not respirable. However, the RAC-Opinion proposes a classification as carcinogenic cat. 2 which would demand a respective labelling of such products, even an inhalation hazard does not exist.

Further, a carcinogenic category 2-classification of titanium dioxide would also have regulatory impacts in context with other EU legislation. Such classification would automatically trigger statutory requirements, e.g. under immissions control law or under EU waste legislation (due to the subsequent classification as hazardous waste). Insofar as other legal acts of the EU simply rely on the hazard classification under CLP without taking the actual hazards in the specific situation into account, then the hazard classification may result in erroneous regulatory measures or contradictions. E.g., based on expert risk assessments, titanium dioxide is explicitly authorized under Regulation (EC) 1223/2009 on cosmetics to be used as UV-filter or colorant. It would be contradictory if titanium dioxide would also be classified as carcinogenic under CLP.

The aforementioned regulatory inconsistencies, leading to a hazard communication or triggering hazard related legal mechanisms even if there is no hazard in the specific situation, are the consequence of the undifferentiated approach of hazard classification under the CLP Regulation. Furthermore, specifically for titanium dioxide, the inconsistencies are aggra-

vated by the fact that the protection of workers from dust exposure is already provided by workplace legislation.

5. Legal impacts of workplace legislation

The exposure of workers to dust is typically addressed by national workplace legislation. A legal mechanism to ensure a protection of workers is provided via so called Binding Occupational Exposure Limit Values (OELs). Inter alia, the occupational safety and health regulations of Germany contain specific thresholds for dust exposure at the workplace, stipulated by technical rules for hazardous substances, the so called TRGS (*Technische Regeln für Gefahrstoffe*). In particular, the relevant TRGS 900 contains a list of substances for which dust limit values apply, also covering titanium dioxide. Also, other Member States of the EU have implemented specific limit values for dust exposure within their national workplace legislation; the thresholds are in the range from 1,25 to 10 mg/m³.

So far, there is no equivalent regulation with specific limit values for dust on the EU level. Though, such rules could be integrated in the existing legal framework of the EU, e.g. in Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work or in Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. In particular, the provisions of Directive 2004/37/EC could be regarded as a precedent, because its Annex III already contains limit values for occupational exposure to hardwood dusts. The same approach could be applied for titanium dioxide dusts.

An EU wide harmonisation of binding limit values for dust via the workplace legislation would be the appropriate regulatory approach, because it would directly focus on the problem of worker exposure to dust, while a CLP-classification of titanium dioxide as carcinogenic would not enhance worker protection. Of course, such requirements under EU workplace legislation or a classification under CLP would be only feasible, if sufficient evidence exists that titanium dioxide is indeed a substance suspected of causing cancer.

6. The principle of proportionality

The principle of proportionality is a fundamental legal principle under EU Law. As acknowledged by the Court of Justice of the European Union, the principle of proportionality guarantees that measures restricting an economic activity must be appropriate and necessary in order to achieve the objectives legitimately pursued by the legislation in question. When there is a choice between several appropriate measures, the least onerous measure has to be taken, and the disadvantages caused must not be disproportionate to the aims pursued. The proposed classification of titanium dioxide as carcinogenic category 2 under the CLP Regulation is in conflict with the principle of proportionality, because:

- First, the proposed classification is neither necessary nor proportionate. In a situation in which titanium dioxide is firmly bound within in a product matrix and an inhalation of the substance is excluded, there is no justification for a classification as car-

cinogenic. In this case, the regulatory measure would not be appropriate. Therefore, it is not convincing (and raises a conflict with the principle of proportionality), when ECHA states in its Guidance on the Application of the CLP Criteria: “*It should further be noted that classification of substances and mixtures may be required even when placed on the market in forms that are not hazardous*” (subsection 1.1.3). Neither RAC or ANSES have provided arguments that mixtures like coatings and paints should be classified as hazardous. It is there necessary to refrain from a classification, if, like in the case of titanium dioxide, a mixture or substance is placed on the market in a form for which the particular hazardous effects can be excluded.

- Second, the proposed classification of titanium dioxide would not be necessary, because – at least in most of the Member States of the EU – a protection of workers against titanium dioxide dusts is already sufficiently accomplished via national occupational safety regulations. A classification as carcinogenic would even not be suitable to achieve the goal of protecting workers from dust exposure, because such classification wouldn’t have any effect on the current national occupational safety regulations (i.e. the dust thresholds for workplaces) which apply anyhow. The background is that classification and labelling under CLP is only a communication tool. In contrast, the requirements of workplace legislation (either via Binding OELs or Indicative OELs) is directly focused on the protection of workers and is therefore more suitable to ensure such protection. Thus, a more appropriate approach (and at the same time less onerous for industry) would be to harmonize the dust thresholds within EU workplace legislation.

7. Conclusions

In sum, there are several legal implications connected with a classification of titanium dioxide as carcinogenic category 2. First, it is not clear if there is sufficient scientific evidence for such classification. Second, there are strong arguments that the proposed classification is not in line with the regulatory approach to rely on the intrinsic properties of a substance for the hazard classification. Third, there are regulatory inconsistencies with other legal acts, especially the workplace legislation. Fourth, the proposal infringes the principle of proportionality. Therefore, based on legal grounds, the classification of titanium dioxide as carcinogenic is not justified.

Even if the European authorities should reach the conclusion that, in general, a classification of titanium dioxide as carcinogenic category 2 is justified, a differentiated approach of hazard classification would be necessary. In particular, a split entry for titanium dioxide could be implemented; like the listing of titanium dioxide in the State of California which is limited to “*titanium dioxide (airborne, unbound particles of respirable size)*”. Examples demonstrating that particle size entries into Annex VI of the CLP Regulation are feasible are the entries for zinc powder / zinc dust and nickel powder, because in both cases the substance has specific intrinsic properties only in powder form.