



11 September 2019

## **Position paper on the proposal for a classification of titanium dioxide as hazardous substance**

The European Commission proposes a classification of titanium dioxide in Annex VI of the CLP Regulation as a "*substance with a suspected carcinogenic effect in humans*" through inhalation (Category 2, labelling with GHS08 and H351). We, the German paint, coatings and printing ink industry, are not convinced that a classification is scientifically justified, legally correct and politically the right approach. With this position paper we are taking the opportunity to participate in the ongoing discussion.

### **Executive Summary**

With a share of 57%, the **paint, coatings and printing ink industry is the main customer** of titanium dioxide. Due to the high light scattering power of its crystals, titanium dioxide has the highest covering capacity of all white pigments. It is indispensable in the production of white wall paint, coloured shades and printed packaging. There are no equivalent alternatives.

Titanium dioxide is added to paints as a pigment and is then permanently **bound in the binder matrix**. Titanium dioxide poses **no risk to humans**, either at the workplace or in the use phase of products containing titanium dioxide.

ECHA's Risk Assessment Committee (RAC) has made clear that the discussed **issue is wider than titanium dioxide**: The hazard described for titanium dioxide ("*general particle effects*") is not specific to the substance itself, but applies to more than 300 substances in powder form known as "Poorly Soluble particles with Low Toxicity" (PSLTs). Therefore, any decision taken on titanium dioxide sets a **precedent** for this entire group of substances.

Germany has made the alternative proposal to **harmonise the different occupational dust limits** which are currently applied in Europe. This approach addresses effectively and proportionately the potential effects of PSLT substances like titanium dioxide. In addition, such harmonisation would be a great step for European workers health and safety standards.

In contrast, the proposed classification of titanium dioxide under CLP would have **no direct beneficial effect on the health and safety of workers**. In addition, it is highly questionable if the CLP regulation legally allows a classification based on non-substance specific effects.

Also, a classification of titanium dioxide would have far-reaching and significant unwanted consequences: Automatic legal consequences of a CLP classification in other EU legislation (e.g. for waste, toys, food contact materials and cosmetics) would lead to **unwanted and unreasonable results with significant negative effects** on the economy and consumer trust.

From a health policy point of view, too, the proposed classification brings only disadvantages, since in future many more products would be marked as potentially carcinogenic. Here, there is a **danger of over-labelling** which would jeopardize the entire hazard labelling system.

## **Conclusion**

We oppose the suggested classification of titanium dioxide in Annex VI of the CLP regulation as unjustified and not proportionate. The alternative proposal to harmonise the different occupational dust exposure limits (OELs) currently applied in Europe gives the right answer to the issue at stake and would be a big step for European occupational safety standards. The proposed warning label for liquid mixtures (in Annex II CLP regulation) has no legal basis, is disproportionate and misleading.

We call on the Commission to **exercise its discretion** according to Art. 37 (5) CLP regulation and decide whether a classification and labelling in this specific case is the right tool or not. To ensure that the proposal has a legal standing, we encourage the Commission to obtain an **opinion by the Legal Service** to clarify whether the CLP regulation allows a classification based on general particle effects and whether a classification in this case would be proportionate. In addition, we propose to **assess the impacts** of a classification beforehand - in accordance with the "Better Regulation" approach and the recommendations of the REFIT report.

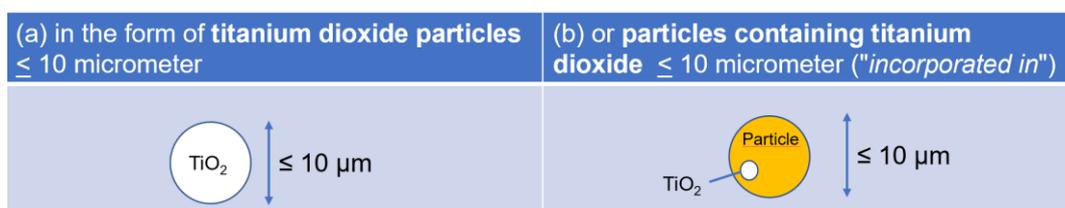
## A. Background and current classification proposal

The background to the classification proposal is explained in a Commission document ([Doc. CA/90/2017](#)): According to this, the proposal by the French authority ANSES was preceded by a dispute between France and the European Chemicals Agency (ECHA), on the one hand, and the titanium dioxide producers, on the other hand, regarding the scope of information in the REACH dossier on titanium dioxide. Reviewing the registration dossier for titanium dioxide in 2014, ECHA demanded additional information from the manufacturers, including titanium dioxide **nanomaterials**. The lead registrant objected to this. In 2017, ECHA's *Board of Appeal* ruled in favour of the manufacturer, concluding that ECHA's demand for information regarding nanomaterials was not covered by the REACH regulation and was therefore unjustified ([link](#)).

Earlier, however, in May 2016, on the instruction of the French Ministry of Labour, the French authority ANSES submitted a proposal for a harmonised classification of titanium dioxide as "*May cause cancer*" (category 1B) ([link](#)). On 8 June 2017, based on a hazard assessment, ECHA's Risk Assessment Committee (RAC) recommended that titanium dioxide should be classified as a "*suspected carcinogen in humans*" by inhalation (Category 2) ([link](#)).

According to the latest Commission's proposal (from 26 August 2019), the **classification** of titanium dioxide as a "*substance with a suspected carcinogenic effect in humans*" through inhalation (Category 2, labelling with GHS08 and H351) in Annex VI CLP regulation would apply to

- (1.) **titanium dioxide in powder form** containing 1% or more of particles with aerodynamic diameter  $\leq 10 \mu\text{m}$   
and
- (2.) **mixtures in powder form** containing 1% or more of titanium dioxide which is in the form of [(a)] or incorporated in [(b)] particles with aerodynamic diameter  $\leq 10 \mu\text{m}$  (ccf. Note 10).



*Two different sorts of "mixtures in powder form" shall be classified.*

In addition, the Commission proposes for Annex II CLP regulation the following **warning label on the packaging of “liquid mixtures”** containing 1 % or more of titanium dioxide particles with aerodynamic diameter equal to or below 10 µm:

*“EUH211: 'Warning! **Hazardous respirable droplets** may be formed when sprayed. Do not breathe spray or mist.’”*

A warning should also apply to “solid mixtures” containing 1% or more titanium dioxide:

*“EUH212: 'Warning! **Hazardous respirable dust** may be formed when used. Do not breathe dust.’”*

The Commission formally introduced this proposal into the notification procedure of the WTO Technical Barriers to Trade committee and has received very critical comments by trading partners like the USA, Canada and others ([link](#)).

## **B. Scientific basis of the proposal**

Titanium dioxide is **one of the best studied substances** in the world. It has long been used as a reference substance for, among other, inhalation studies. The substance has **no toxic effect**, is not mutagenic and not genotoxic. It is (bio-) chemically inert and, due to its very low solubility in biological fluids, not bioavailable.

Provided it is present as a solid in respirable, alveolar form, titanium dioxide belongs to the group of so called “Poorly Soluble particles with Low Toxicity” (**PSLTs**). Chronic inhalation exposure to PSLTs can lead to inflammatory reactions in the lungs as a result of overloaded natural lung cleansing processes (so called “lung overload”). For this reason, in Germany as well as in many other EU Member States, there are defined binding limits in place for the exposure of particles/dust in the workplace (Occupational Exposure Limits (OELs)).

### **1. RAC recommendation is based on a single, controversial animal study**

The decision of the RAC is essentially **based on a single, nearly 25-year-old animal study** by *Prof Uwe Heinrich* on rats, which - measured against today's standards - is not valid: Specifically, there are considerable **methodological doubts** about the usability of the research by *Heinrich* in 1995 for the classification proposal: For example, only female rats were tested, which are particularly vulnerable to lung tumours. Instead of the scientifically recommended 6-8 hours, the rats were exposed to titanium dioxide in powder form for **18 hours a day**. Due to these methodological weaknesses, the French authority ANSES in its proposal had classified the *Heinrich* study as **“not reliable”**. This view is confirmed by the joint statement of German

authorities BfR and UBA of 2011 ([No. 005/2011](#)), which, having noted this study, stated: "... the data currently available are **not sufficient** to support these materials [including titanium dioxide] as "potentially carcinogenic to humans" with reasonable certainty". In our view, neither the RAC nor the Commission did take sufficient account of the methodological weaknesses of the *Heinrich* study.

In addition, as is known today, due to physiological differences the **results from "lung overload" studies are not transferable from rats to humans**. The relevant guidelines of the [ECHA, OECD](#) and ECETOC make this clear (OECD Guidelines for the Testing of Chemicals (No 403.433), ECETOC Technical Report No 122).

## 2. Epidemiological studies show no risk for humans

General particle effects pose a **potential risk only in the workplace**. For consumers titanium dioxide does not present a relevant risk. This is confirmed by a Commission statement: "*The **risk for consumers is negligible** given the very high levels of exposure that would be required, which are unrealistic under normal and foreseeable conditions.*" (Minutes of the CARACAL Sub-Group meeting on 23 April 2018, accessible via [CIRCAB](#)).

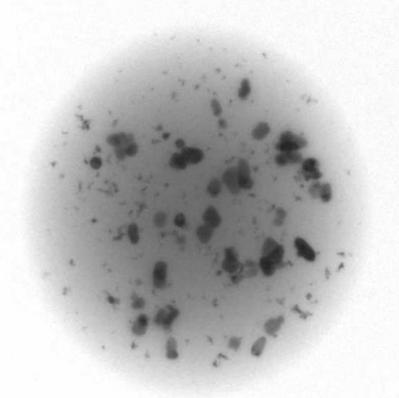
Epidemiological studies on approximately **24,000 workers** in 18 titanium dioxide factories, inter alia in Germany, over several decades showed **no adverse effects** of titanium dioxide on health. Regarding these studies, *Prof Harald Krug* (University of Bern) confirmed that "*reliable studies known to me ... [have] not produced any alarming results for humans under real conditions and the **epidemiology definitively says 'not carcinogenic'***" (Source: [ScienceMediaCenter](#), 14 June 2017).

Accordingly, the competent German employers' liability insurance associations (*Berufsgenossenschaft Bau & Berufsgenossenschaft Rohstoffe und chemische Industrie*) stated that there is no recognised case of occupational disease in Germany due to titanium dioxide. During the latest public consultation, among others the German Statutory Accident Insurance confirmed that there **is not a single case of an occupational disease known** that relates to titanium dioxide ([link](#) to the statement in German language).

In the **production phase** of paints, coatings and printing inks dust containing titanium dioxide particles may occur, however strict **occupational dust exposure limits (OELs)** (for example in Germany: 1.25 mg/m<sup>3</sup>) effectively protect workers against negative inflammation effects.

Also with regard to **professional painters and varnishers** who come into contact with titanium dioxide containing mixtures on a daily basis there is no risk: Rolling out fresh paint or removing for example old wallpaper does not present any risk, as confirmed by an expert of the *German Federal Institute for Occupational Safety and Health* ([link](#) in German language).

Dust containing titanium dioxide may occur when **sanding** coated surfaces. However, when performing such work, respiratory protection must be worn. In addition, extensive investigations by the Technical University of Dresden have confirmed that nanoparticles contained in paint and coatings are permanently **bound in the matrix of the abrasion particles**. Therefore, they cannot be released and, consequently, cannot be inhaled. (cf. summary of the study results: *Prof Michael Stintz, Daniel Göhler, Aline Rommert, Dr Matthias Voetz* "Studies on the release of and exposure to nanostructured paints and coatings", download [here](#)).



TEM-image of a dried acrylate spray droplet from a propellant spray can with embedded ZnO additive particles and TiO<sub>2</sub> pigment particles.

**Spray paint applications** are almost exclusively used in the professional environment, e.g. in automotive paint shops. Also here the occupational dust limit effectively protects workers. For example, respiratory protection must be worn for every type of spray application. In addition, titanium dioxide in spray paint applications is equally as bound in the binder matrix and therefore not inhalable.

### C. Socio-economic impact of a classification

A classification of titanium dioxide as suspected carcinogenic would have significant consequences for consumers and the economy without raising the level of health protection. The assessment by the consulting firm RPA under the title "Analysis of the socio-economic impacts of a harmonized classification of carcinogen Category 2 for titanium dioxide (TiO<sub>2</sub>)" (November 2017) gives a first overview of some of the impacts. However, **a full impact assessment is necessary**.

#### 1. Use and importance of titanium dioxide for paints, coatings and printing inks

With a share of 57%, the paint and printing ink industry is the **main customer** of titanium dioxide. For our industry, this white pigment is by far the most important raw material and is contained in most paints, coatings and printing inks, for example in:

- Emulsion paints and decorative coatings
- Plasters and fillers
- Anti-corrosion coatings
- Wood stains and varnishes
- Industrial coatings
- Automotive refinish coatings
- Printing inks
- Powder coatings
- Natural paints
- UV coatings

Depending on the formulation, the average concentration of titanium dioxide, for example, in emulsion paints and decorative coatings is up to 25%, in plaster and fillers up to 10%, in automotive refinish coatings up to 25%, in automotive, anti-corrosion coatings and in industrial coatings up to 30%, in wood coatings up to 35% in natural paints up to 40%, and in printing inks up to 60%.

Due to the high light scattering power of its crystals, titanium dioxide has the highest covering capacity of all white pigments and very good tinting strength. It is **indispensable** in the production of white wall paint, coatings and chromatic colours. Of the 2,328 colours of the RAL system, **only 119 (5%) are produced without titanium dioxide**.

There are **no equivalent alternatives**: pigments such as calcium carbonate, zinc oxide, zinc sulphide and barium sulphate have inferior properties, both technically and colouristically, e.g. in terms of covering capacity and weather resistance. In addition, **alternative pigments are not available in the required quantities**: Global titanium dioxide production in 2015 was around 7.2 million tons. Worldwide availability of other white pigments is significantly lower, e.g. the global zinc oxide market is about 20 times smaller than the titanium dioxide market. Finally, all alternative pigments are also in a powder form. Any substitution of titanium dioxide would lead to the use of other pigments being PSLT substances as well, and would thus not yield any benefit regarding potential dust exposure.

## 2. Consequences for industry, retailers, painters, consumers and the environment

Since the classification in general (see above A (1)) applies only to titanium dioxide in powder form, most paints, coatings and printing inks which are sold in liquid form are not within the scope of the classification itself. However, according to the new Note 10 (see above A (2)), **powder coatings would be covered**, because they usually contain more than 1% titanium dioxide in total and consist of particles which “incorporate” titanium dioxide and which can be below 10 micrometers.



Powder coatings were developed in the 1960s and have since been used in many different industrial applications, including the automotive, construction, mechanical engineering, furniture and household appliance industries. For all of these applications, occupational dust exposure limits (OELs) apply. Therefore, it is e.g. mandatory to

wear protective equipment when applying powder coatings.

The wide range of applications places high demands on powder coatings. For example, they must be resistant to weathering, corrosion or chemicals and have decorative and functional properties. Powder coatings are characterized in particular by the fact that no solvents are required during the manufacture of the coatings or in the coating process, and thus **no VOC emissions** are generated.

Despite of the very positive contributions of powder coatings to the environment and the lack of any risk when applied correctly, powder coatings would be classified as potentially carcinogen, would have to carry the GHS08 pictogram and the hazard sentence “*Suspected of causing cancer*”.



On top, the proposal would cause a lot of uncertainty among retailers, painters and consumers. The proposed **warning label** for the packaging of all liquid paints, coatings and printing inks (Annex II) – even if they are not used for spray applications – would lead to irritation and uncertainty among consumers, retailers and painters, with **significant adverse economic effects**.

In a survey, **87% of consumers** said they would not buy indoor wall paint which is connected to the word “cancer” (results from a representative YouGov survey of 2,032 people, end of August 2017). In theory, this would affect sales of over 530 million Euros per year in Germany. This effect would be even more significant in case the classification would apply to liquid mixtures, because then all liquid paints and coatings would have to carry a warning label saying “*May cause cancer*”.

### **3. Consequences for manufacturers of paints, coatings and printing inks and their employees**

The manufacturers of paints, coatings and printing inks are the main customers of titanium dioxide and would also be the most affected by a classification. In Germany, approximately **25,000 people are directly employed** in this sector. Many of these jobs, especially among the many small and medium-sized enterprises, would be

seriously threatened by the classification of titanium dioxide. In addition, there are considerable risks for the approximately 130,000 employees in paint stores and for the approximately 205,000 painters and varnishers (Source: German Federal Statistical Office, 2015).

In case of a classification as carcinogenic Category 2, it is very likely that retailers would put considerable pressure on manufacturers to **change paint formulations** and formulate without titanium dioxide. Overall, the companies in our industry have over 600,000 so-called "living" formulations, i.e. formulations that are used at least once a year. Approximately **570,000 formulations are based on titanium dioxide** and would have to be changed. This affects 1.89 million tons of paints, coatings and printing inks worth 4.8 billion Euros.

Such a reformulation – with an **inferior quality!** - would take **up to ten years**, and **overstrain**, in particular, the **more than 200 small and medium-sized manufacturers** in Germany. Most of them do not have their own research and development departments that could make such a comprehensive formulation change. Their survival on the market would therefore be under serious threat.

**Article 45** of the CLP Regulation requires manufacturers to disclose formulations for mixtures containing substances classified as dangerous to **poison information centres**. Consumer products are largely exempt, as they generally do not contain dangerous substances. However, this would change if titanium dioxide were to be classified as carcinogenic category 2. In case the classification proposal would apply also to liquid mixtures, this would have a significant impact on the costs and workload of the entire paint and coatings industry: For the German companies alone, one-time costs of about 2 million Euros for the first report would incur as well as at least 500,000 Euros annually for change notifications. In addition, companies that were not previously subject to reporting would face costs for software and personnel.

A classification of titanium dioxide would result in **serious disadvantages in international competition** for manufacturers of paints, coatings and printing inks within the EU. One consequence of this would be, for example, that companies relocate production to neighbouring countries outside the EU. In any case, the loss of thousands of jobs in downstream industries within the entire value chain would be inevitable.

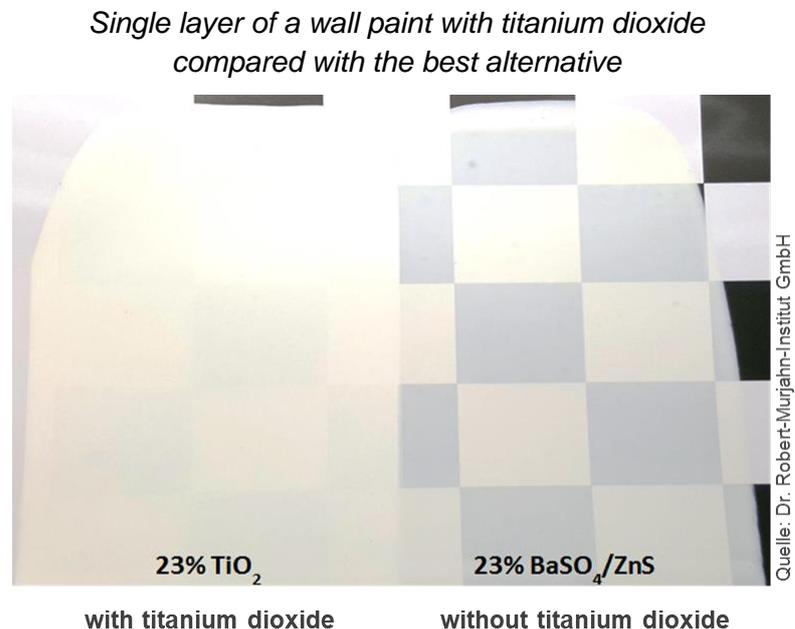
#### **4. Negative consequences for quality, safety and sustainability of paints, coatings and printing inks**

Since there are **no alternatives** to titanium dioxide that would allow the reformulation of paints, coatings and printing inks in comparable quality, paints would be of **inferior quality and less sustainable**. Possible alternative substances, such as calcium carbonate, zinc oxide, zinc sulphide and barium sulphate, have neither the same covering power nor a non-white tone, or cannot be used in paints and

coatings because, for example, they react with other ingredients or are not permitted for this purpose.

Furthermore, alternative pigments are **less well researched** or have been found to be hazardous and hence were replaced by titanium dioxide, e.g. white lead. Alternative substances are also processed in powder form. As a result of a classification of titanium dioxide, classification of these substances would also be likely.

Paints without titanium dioxide are also **less sustainable**, because their covering power is lower: whereas paint containing titanium dioxide can provide adequate coverage with one or two layers, **3 to 4 layers of titanium dioxide-free paint would be required**. The amount of paint used, the renovation time and the material and labour costs would therefore **double**.



This would negatively affect in particular low-income households and the environment.

## 5. Dealing with "hazardous waste" and negative impacts on plastics and paper recycling, thus for the Circular-Economy-Initiative

According to the EU Waste Framework Directive (WFD, 2008/98/EC, Article 3 No. 2, [Annex III, HP7](#)), waste containing 1% or more potentially carcinogenic substances (Category 2) is defined as "**hazardous waste**" and has to be disposed of separately (see Article 18 WFD, implementation in Germany through [§ 9 and 48 Recycling Management Act](#) (KrWG) in conjunction with the [Waste Catalogue Regulation](#)).

The classification as proposed would have serious negative impacts on the disposal, transport and recovery of waste containing titanium dioxide: For example, **construction and demolition waste in powder form** containing 1% or more of titanium dioxide (e.g. from paint and coating residues, removed wallpapers etc.) would have to be separated on site as "hazardous waste". In practical terms, it will be already very difficult and costly to determine on site whether the building and construction waste contains more than 1% titanium dioxide with the specific parameter of Note 10. One would have to assume that such waste containing titanium dioxide would have to be regarded as "hazardous waste" if one cannot

provide proof to the contrary (which would be difficult and very costly). The separation of such waste and its separate packaging, labelling, transportation, documentation and disposal would significantly increase the overall costs for buildings.

The same holds true for powdery waste in **waste sorting plants** and **plastic recycling plants**. Overall, a recent study by the plastics industry assumes that nearly half of the plastic produced in Germany, over 7 Million tonnes each year, contains more than 1% titanium dioxide and could become hazardous waste during the sorting and recycling process ([link](#)). Since most of the existing waste facilities do not have the appropriate emission allowances for the treatment of hazardous waste, a classification of titanium dioxide could therefore limit the overall recycling of plastic waste because. The ambitious recycling targets of the **EU's Circular Economy initiative would be at risk**.

It remains unclear how the unwanted negative consequences for waste and recycling as a result of classification could be avoided. In a previous text from 21 September 2018, the Commission proposed either a **guideline** or a future amendment of **Annex III to the Waste Framework Directive** with the following content: *“The presence of titanium dioxide referred to in entry [X] of Annex VI to Regulation (EC) No 1272/2008 renders waste carcinogenic only if the waste is in a powder form containing 1% or more of particles with diameter  $\leq 10 \mu\text{m}$  containing titanium dioxide.”*

However, this proposal is inappropriate to prevent the outlined consequences of a classification. First of all, it is **practically impossible to implement**: It is already challenging to measure whether e.g. on a construction or demolition site the dust emissions comply with the occupational dust limits. There are no measurements known how to specify whether this dust contains *“1% or more of particles with diameter  $\leq 10 \mu\text{m}$  containing titanium dioxide”*.

Also, any guidance would be **legally non-binding**, i.e. most likely this would result in a **patchwork** of different regulations in the EU. Any changes to Annex III of the Waste Framework Directive would have to be made **before the classification** enters into force, but usually takes several years. A **long transition phase** would be necessary to allow the waste industry to develop the necessary testing methods and invest in the millions of testing equipment.

## **6. No more Eco-labels for products containing titanium dioxide**

Most **Eco-labels** are not be awarded for products containing substances that are classified as potentially carcinogenic (Category 2). This means eco-labels such as the **Blue Angel** (which is important for many interior paints and coatings as well as for printed products) will no longer be awarded to paints and coatings or printed products containing titanium dioxide (see chapter 3.1.2 of the criteria ([link](#))). The same applies to the **EU Ecolabel** (Annex Criterion 5 ([link](#))) and the **Nordic Swan**

[\(link\)](#). Alternative pigments are not comparable with titanium dioxide in terms of wet abrasion and covering power and therefore do not meet the strict quality requirements of the eco-labels.

The Blue Angel is an important quality feature for consumers. For example, **73% of consumers** rated the Blue Angel eco-label as an important or very important purchase criterion (results of a representative YouGov survey of 2,032 people, end of August 2017). 500 low-emission interior wall paints, 951 low-emission paints and 34 interior plasters carry the Blue Angel eco-label (January 2018). 400,000 tons of interior wall paints alone, worth around 500 million Euros, would be affected.

## **7. Impacts on other products, e.g. building & construction products, toys, cosmetics and food contact materials containing titanium dioxide**

Due to the new text of the “**Note 10**”, the scope of the classification now also includes ‘mixtures in powder form’ containing 1% or more titanium dioxide “*which is incorporated in particles with aerodynamic diameter  $\leq 10$  micrometres*”). In our estimation, this considerably **expands the regulatory scope** of the classification: In the industrial, commercial and private sectors, for example, there are many mixtures in powder form that contain titanium dioxide with a corresponding proportion and whose particles are alveolar. This applies, for example, not only to industrial applications like powder coatings (see above) but also to professional applications like **plasters, dry mortars, grouts and fillers** etc. These products would be significantly affected by the hazard pictogram GHS08 and the warning "Suspected of causing cancer by inhalation".

**Toys** would also be affected because substances classified as potentially carcinogenic are generally banned in toys and their marketing is restricted in accordance with the provisions of the EU’s Toys-Safety-Directive ([2009/48/EC](#), Annex II, point III, 3). Therefore, for example **paint boxes** and other powdery mixtures for toys would no longer be allowed in Europe. Also, the EU **Cosmetics** Regulation ([1223/2009](#), Article 15) prohibits in general the use of potential carcinogenic substances in cosmetics, e.g. in **make-up, powder and eye shadow**.

A classification of titanium dioxide as a carcinogenic category 2 could also have an adverse effect on printing inks used on food contact materials such as food packaging. Although there is no specific European regulation for printing inks for food contact materials, it is an established concept in European and national regulations as well as in industry codes that substances classified as carcinogenic shall not be used in the production of food contact materials without prior authorisation and listing in the corresponding positive lists.

These cases illustrate that the rigid, **automatic legal consequences of a CLP classification may lead to unreasonable results**. The legislator must provide for exceptions in the future. The [REFIT Report](#) on the REACH regulation as well suggests allowing **exemptions from classification** in the future, either because of a "specific risk assessment" or because of serious socio-economic impacts.

## 8. Consequences for export

A classification of titanium dioxide would also negatively affect trade in Europe. In **France**, for example, there is a **self-service ban** for products containing potentially carcinogenic substances (Category 2) ([link](#)). This means that, for example, paints and coatings for Do-it-yourselfers might no longer be offered freely available in hardware stores but **must be kept under lock and key**. When selling, there is a duty on the seller to inspect and record the name and address of the buyer and the intended use.

In total, 50,000 tons of paints and coatings are exported from Germany to France each year. Of these, 8,000 tons of emulsion paints alone go to Do-it-yourselfers, e.g. in hardware stores. Assuming that a ban on self-service would reduce the market by 80%, this would mean annual **losses of approximately 8 million Euros** for German paint and coatings manufacturers each year.

## 9. Impact assessment missing

Despite the significant known impacts of a classification of titanium dioxide, the Commission so far has not undertaken any steps towards an impact assessment. In our view, this is not in line with the Commission's self-commitment in the Better-Law-Making approach: According to the "*Interinstitutional Agreement*" of 13 April 2016 on **Better Law-Making** (No 13) the Commission committed to:

*"carry out impact assessments of its legislative and non-legislative initiatives, **delegated acts** and implementing measures which are expected to have significant economic, environmental or social impacts."*

Given the large number of over 400 comments received in the last public consultation (see [here](#)), it is impossible for the Commission to deny such impact. In our view, the Commission's conclusion – as given in the "*Explanatory Memorandum*" – is completely inadequate, also with regard to its own guidelines in the Better Regulation Toolbox (e.g. in #5 and #9). We therefore call on the Commission to properly assess the economic, environmental and social impacts of a classification before making continuing with the proposal.

## D. Legal requirements and regulatory consequences

The classification proposal, in our view, attempts to set a **precedent** for the classification of all PSLTs based on general particle effects. As a result, more than 300 powdery raw materials could be classified as suspected carcinogenic. Such a procedure raises considerable regulatory, legal, economic and public health concerns.

### 1. Legal requirements for CLP classification not given

The **scope of the CLP regulation** is limited to "*substances which have an **intrinsic property to cause cancer***" ([CLP Regulation, Annex I, 3.6.2.2.1](#)). Intrinsic is a property if it can be assigned specifically to a substance and does not apply, for example, to a whole group of substances. The RAC has **denied such intrinsic toxicity "in the classical sense"** (see pages 38 and 40 of the [recommendation](#)) and instead based its recommendation for a classification on **general particle effects**. In our view, this is out of scope of the CLP regulation because such particle effects are characteristic to the entire group of PSLTs and therefore are not a specific property of titanium dioxide. As long as it is legally questionable whether particle-related, non-specific effects fall within the scope of the CLP Regulation, there should be no decision to classify titanium dioxide. We call on the Commission to ask the Legal Service for a clarification.

### 2. No proper assessment of whether classification is "**appropriate**"

According to Article 37 (5) CLP regulation, the Commission has to assess whether "*the harmonisation of the classification and labelling of the substance concerned is **appropriate***". According to settled case-law, the Commission must prove in court that it has taken "*into consideration **all the relevant factors and circumstances of the situation which the act was intended to regulate***" (see Case [C-343/09 Afton Chemical](#), paragraph 34). The Commission must not confine itself to the role of arbitrator, but must examine the relevant information "*of its own motion*". If the Commission wishes to take a decision in accordance with the RAC recommendation, it must first verify that the RAC's reasoning is "**complete, coherent and valid**". In case of doubt, the Commission must return to the RAC for clarification (see most recently [T-837/16](#), para. 64 and 68).

For example, in this case the RAC had denied an "*intrinsic toxicity in a classical sense*" and based its recommendation on general particle effects (see above). Also, the RAC has disregarded the existence of effective national dust exposure limits (OELs) at the workplace. Given the lack of clarity of the RAC justification, the Commission should have asked the RAC whether other policy measures, such as the harmonisation of OELs, could be considered as alternative to the classification. Also, the Commission has discussed during several CARACAL meetings the question of whether a classification under CLP **can** be based on general particle

effects (with no clear outcome and unfortunately no assessment by the Commission's Legal Service). However, the question whether a classification under CLP **should** be made was never raised by the Commission.

The Commission has the duty to fully assess all the relevant scientific, legal and regulatory aspects of the proposed classification to make sure that its decision is well justified, meets its objectives for the protection of human health and is overall appropriate. In this case, the Commission has failed to demonstrate that it has used its discretion correctly. The very brief conclusions in the "*Explanatory Memorandum*" (published end of August 2019 together with the proposal) confirm that the Commission deliberately avoided such a discretionary decision.

The default of a proper use of discretion raises serious doubts about the overall legality of the proposal. Therefore, we call on the Commission to **exercise its discretion** accordingly and to decide whether a classification and labelling in this specific case is actually the right tool.

### 3. Classification would not be proportionate

A classification of titanium dioxide would **violate the principle of proportionality** enshrined in European law (Article 5 paragraph 4 [TEU](#)): A classification as potentially carcinogenic (Category 2) would have no practical benefits for workers protection and would provide no greater safety for consumers. Therefore, it would **not be appropriate** for improving health and safety. Due to the existing national occupational dust exposure limits (OELs) and given the fact that there is not a single case of an occupational disease known that relates to titanium dioxide (see above), such a classification would also **not be necessary**. There are also **less onerous ways** to improve workers safety regarding dust exposure, e.g. by harmonising the existing national OELs. Such harmonisation would avoid the unwanted consequences of a classification under CLP. A comprehensive legal opinion by *Prof Dr Kristian Fischer* supports these findings "Legal Analysis on the proposed classification of titanium dioxide under the CLP Regulation" ([here](#)).

We call on the Commission to ask their **Legal Service** to assess not only whether CLP allows a classification based on general particle effects but also whether such classification would be proportionate.

### 4. Warning label for all liquid paints, coatings and printing inks has no legal basis

According to Article 25(6) of the CLP Regulation a mandatory warning label on the package of a product requires that the mixture contains "*a substance classified as dangerous*". This also follows from Article 4(7) of the CLP Regulation. This requirement is not met here, as the classification in Annex VI only applies to titanium dioxide in powder form and, for example, liquid paints and coatings do not contain

titanium dioxide in powder form. Therefore, there is no legal basis for such a proposal.

Furthermore, such a warning label for all paints, coatings and printing inks would be **disproportionate**, as more than 99% of these products are not used at all for spray applications.

Finally, such a warning label would be **misleading** because even in spray applications the titanium dioxide is firmly embedded in the binder matrix and therefore cannot be inhaled as such. Spray coatings are used almost exclusively in professional environments, e.g. in car paint shops or by professional painters. The droplets formed during the spraying of paints and coatings are harmless if the relevant work safety regulations are observed. For example, respiratory protection must be worn for every type of spray application. This ensures that the applicable dust limits at the workplace are complied with.

In addition, titanium dioxide in paints, coatings and printing inks is permanently bound in the binder matrix and therefore **cannot be inhaled at all**. This is confirmed by IARC (chapter 1.3.2 c), [link](#)). Consequently, for example the regulation in California (USA) excludes such products from the labelling requirements ("*The [hazard] listing does not cover titanium dioxide when it remains bound in a product matrix.*" (OEHHA re the scope of California's "Proposition 65", [link](#))). Therefore, the classification itself should not apply to paints, coatings and printing inks, since according to the "form" of titanium dioxide in these products there is no hazard (cf. Articles 5 and 6 of CLP regulation and CLP guidance 1.2.3.1). This holds true also for powder coatings in which the titanium dioxide is firmly bound in the powder coating particles. At least, the **warning label should not apply when the titanium dioxide "remains bound in a product matrix"**.

##### **5. "Domino" effect for all raw materials in powder form**

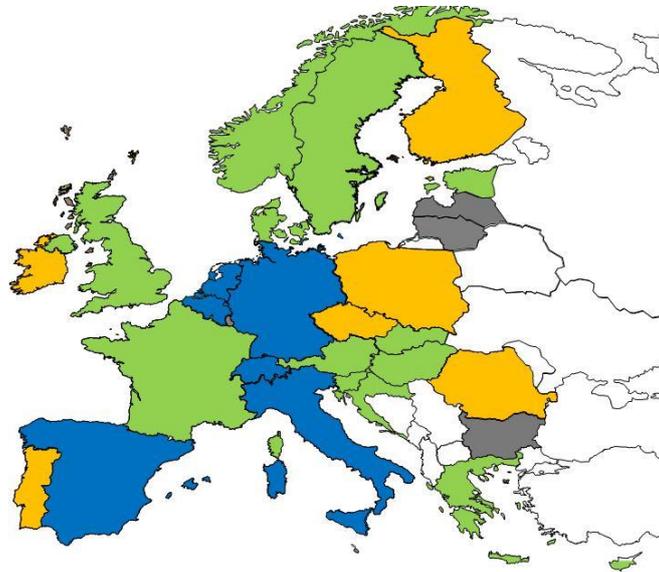
The risk of over-labelling holds in particularly true if the more than 300 PSLTs are classified in a similar way. Based on a classification of titanium dioxide, it would be possible to **classify any PSLT substance as carcinogenic**, e.g. carbon black, barium sulphate, cerium oxide, zinc oxide, iron oxides, aluminium oxide, inorganic coloured pigments etc. It is estimated that this group comprises **more than 300 other substances**. As a result, substance **classification would lose its meaning** and its value as a guide for consumers and become a pawn for political interests.

## 6. Protection against particle effects is ensured by national OELs - Harmonisation of OELs is the better approach

Exposure via inhalation to PSLTs like titanium dioxide powder, which could at least theoretically reach the critical dose range, can only be expected in workplaces. However, most EU Member States have already introduced **workplace dust limits** (between 1.25 and 10 mg/m<sup>3</sup>).

Occupational Dust Limit Values  
in the EU (+NO & CH):

-  10 mg/m<sup>3</sup> (inhalable fraction)
-  4-6 mg/m<sup>3</sup> (respirable fraction)
-  ≤ 3 mg/m<sup>3</sup> (respirable fraction)
-  Currently no information



Source: VdL, CEPE

Dust limits for the workplace effectively protect people from general particle effects. Instead of the proposed classification of titanium dioxide, we therefore support the proposal by Germany to **harmonise the different occupational dust exposure limits** (OELs) in Europe by creating a “Binding Occupational Exposure Limit Value” (BOELV) in accordance with Article 3 (4) of the **Chemical Agents Directive** (“CAD”, [Directive 98/24/EC](#) on the protection of the health and safety of workers from the risks related to chemical agents at work). Such harmonisation would be a significant step towards **higher health and safety standards for workers** in Europe.

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