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Position paper on the proposal for a substance classification for titanium dioxide

On the recommendation of the Risk Assessment Committee (RAC) of the ECHA, the European Commission and the Member States are currently consulting on the 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 believe that such a classification would be wrong and comment on the ongoing discussion in this position paper.

Executive Summary

With a share of 57%, the paint and printing ink industry is the largest buyer of titanium dioxide. Due to the high light scattering power of its crystals, titanium dioxide has the highest covering capacity of all white pigments and is indispensable in the production of white wall paint and coloured shades. 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 of products containing titanium dioxide. For example, the German employers' liability insurance associations have not recorded a single recognised case of occupational disease due to titanium dioxide.

Classification of titanium dioxide as suspected carcinogenic Category 2 would have far-reaching consequences: Paints would have to be labelled with the hazard symbol GHS08 and the words "Suspected of causing cancer", which would cause considerable uncertainty, especially among consumers. Paint residues and other wastes with a titanium dioxide content of 1% or more would in principle have to be treated as "hazardous waste", which would drastically increase disposal costs. This would apply to a variety of waste streams, such as plastic waste, construction waste such as old window frames, wallpaper and paint residues, high quality papers, furniture, ceramics, medicines and cosmetics.

From a health policy point of view, too, the proposed classification brings only disadvantages, since in future many more consumer products would be marked as potentially carcinogenic. Here, there is a danger of over-labelling and, as a result, a blunting of the impact on consumers, which would jeopardise the entire hazard labelling system.

Conclusion

Classification of titanium dioxide is not justified, neither scientifically nor politically. It would have incalculable negative effects for consumers and the economy.

A. Background to the 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: the registration dossier for titanium dioxide was reviewed in 2014. Due to the broadly defined substance identity, the ECHA demanded additional information from the manufacturers, including on the nanoform. The lead registrant objected to this and appealed to the *Board of Appeal* of the ECHA. This ruled in favour of the manufacturer in 2017, concluding that the demand of the ECHA for information regarding nanomaterials was not covered by the REACH regulation and was therefore unjustified.

Earlier, however, in May 2016, on the instruction of the French Ministry of Labour, the French authority ANSES had submitted a proposal for a harmonised classification of titanium dioxide as " May cause cancer" (category 1B). 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).

B. Scientific basis of the proposal

Titanium dioxide is one of the best studied substances ever. It has long been used as a reference substance for, among other things, 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
poorly soluble particles with low toxicity (PSLT). Chronic inhalation exposure to PSLTs can lead to inflammatory reactions in the lungs as a result of overloaded natural lung cleansing processes (lung overload). For this reason, in Germany as well as in many other EU Member States, there are defined limits in place for dust exposure in the workplace.

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

The decision of the RAC is essentially based on a single, **more than 20-year-old animal study** by *Prof Uwe Heinrich* on rats, which - measured against today's standards - is not valid:

Specifically, considerable methodological doubts exist as to the usability for the classification procedure of the results of the research by *Heinrich* in 1995. 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 powdery 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, pronounced: *"... 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, the RAC did not take sufficient account of these methodological weaknesses of the *Heinrich* study.

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

2. Epidemiological studies show no danger to humans

In the RAC recommendation, the epidemiological studies on approximately **24,000 workers** in 18 titanium dioxide factories, including in Germany, were considered insufficient. Here, over several decades, no adverse effects of titanium dioxide on health could be detected. 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, 14.6.2017).

This is confirmed by statements of the competent German employers' liability insurance associations (BG Bau & BG RCI), according to which there is **no recognised case of occupational disease** in Germany due to titanium dioxide.

In the coatings industry, in addition to manufacturing practice and the associated handling of dust and nanoparticles, the product life cycle must also be considered. Dust containing titanium dioxide may form when sanding coated surfaces. Therefore, respiratory protection must be worn when performing work of this nature. Extensive investigations by the TU Dresden have confirmed that the **nanoparticles** contained in paint or varnish **are permanently bound in the matrix of the abrasion particles**. Therefore, they cannot be released and, consequently, cannot be inhaled. (see 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)

C. Socio-economic impact of a classification

A classification of titanium dioxide as suspected carcinogenic would have grave consequences for consumers and the economy without raising the level of health protection. The consulting firm RPA has compiled a comprehensive overview of the impact on the coatings and printing inks industry as well as other affected industries under the title "Analysis of the socio-economic impacts of a harmonized classification of carcinogen Category 2 for titanium dioxide (TiO2)" (November 2017).

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

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

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.

Titanium dioxide is used in many areas of paints, varnishes and printing inks, for example:

- 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 5-25%, 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%.

2. Considerable uncertainty among traders, painters and consumers

Classification as carcinogenic Category 2 and labelling of paints and coatings containing titanium dioxide would lead to considerable uncertainty among all customers and users of paints, coatings and printing inks, especially among consumers, with adverse effects on the willingness to buy, building renovation, value retention of properties and living comfort.

For example, in a survey, **87% of consumers** said they would not buy a wall paint with the indication "suspected of causing cancer" and the corresponding hazard symbol (results from a representative YouGov survey of 2,032 people, end of August 2017). In theory, this would affect sales of over 600 million euros per year.

3. Consequences for manufacturers of paints, varnishes 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, trade companies would put considerable pressure on manufacturers to **change paint formulations** and formulate without titanium dioxide. Overall, the companies in the German paints, coatings and printing inks 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 - in an inferior quality! - would take **up to ten years**, and **overstrain**, in particular, the **more than 200 small and medium-sized manufacturers** in Germany, because 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.

In addition, alternative pigments are **not available** worldwide **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 present in powder form and would therefore need to be similarly evaluated with regard to exposure to dust in the workplace. Indeed, there is reason to fear that, in the long term, these alternatives would also be classified in like manner.

Article 45 of the CLP Regulation requires manufacturers to disclose formulations for mixtures containing substances classified as dangerous to national 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, with serious consequences especially for the manufacturers of paints, coatings and printing inks: the **number of formulations to be reported would double**. This would have a significant impact on the costs and workload of the industry: one-time costs of about 2 million euros would also be incurred for the first report 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, relocating 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 also be inevitable.

4. Consequences for quality, safety and sustainability of paints, varnishes and printing inks

There are **no alternatives** to titanium dioxide that would allow the reformulation of paints, coatings and printing inks **in comparable quality**, i.e. 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 can not be used in paints and varnishes 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 coats, three to four coats of titanium dioxide-free paint would be required. The amount of paint used, the renovation time and the material and labour costs would double.

5. Higher disposal costs as "hazardous waste" and negative impact on plastics and paper recycling

According to the EU Waste Framework Directive (2008/98/EC, Annex III, HP7), waste containing 1% or more potentially carcinogenic substances (Category 2) must be classified as "hazardous waste" and disposed of separately (see implementation in Germany through § 48 Recycling Management Act in conjunction with the Waste Catalogue Regulation). This would have a serious overall impact on the disposal, transport and recovery of waste containing titanium dioxide: for example, **construction site waste** containing 1% or more of titanium dioxide, e.g. paint residues, wallpapers, etc., would in principle have to be collected, transported and disposed of separately as "hazardous waste". This would increase the cost of disposal of waste containing titanium dioxide (see in particular: Analysis of the socio-economic impacts of a harmonised classification of Carcinogen Category 2 for titanium dioxide (TiO2), RPA, November 2017).

In addition, a classification of titanium dioxide could significantly limit the overall **recycling of plastic packaging and waste**. Specifically, there is the fear that emptied plastic packaging containing titanium dioxide, e.g. paint buckets, would be classified as "hazardous waste" (mirror entry 15 01 10* Waste Catalogue Regulation). The same applies to **plastic waste on the site** (mirror entry 17 02 04*), e.g. plastic window frames, laminated foils, etc. In this case, the recycling or energy recovery of this waste would be practically impossible, because most of the existing facilities do not have the appropriate emission allowances for the treatment of hazardous waste.

In Germany, 62 million plastic paint buckets are recycled each year, most of which have a titanium dioxide content of more than 1%. The disposal of commercially used containers (e.g. of painters) alone would increase from 10 million euros today to 200

million euros. The reasons for this are more stringent obligations to provide supporting documents and higher transport and disposal costs for "hazardous waste".

The printing ink industry supports the recycling of waste paper. If the recycled material is made from printed paper and cardboard, it inevitably contains printing ink components. A classification of titanium dioxide as a carcinogen would therefore have **negative consequences for paper recycling**. Paper waste containing titanium dioxide could be considered "hazardous waste" and hence would make recycling practically impossible. In addition, the impact on the granting of eco-labels for printed products is currently difficult to assess.

6. Elimination of important quality features for consumers

According to the award criteria (chapter 3.1.2 (link)), eco-labels such as the **Blue Angel** for many interior paints and coatings as well as for printed products shall not be awarded for products containing substances that are classified as potentially carcinogenic (Category 2). This means that if titanium dioxide is classified, the eco-label will no longer be awarded for paints and coatings or printed products containing titanium dioxide. The same applies to the **EU Ecolabel** (Annex Criterion 5 (link)) and the **Nordic Swan** (Chapter 1.02, Table 1 (link)). Alternative pigments are not comparable with titanium dioxide in terms of wet abrasion, covering power and spreading rate of paints and coatings and therefore do not meet the strict quality requirements of the eco-labels.

The Blue Angel, however, 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. Consequences for export

In France, 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 can no longer be freely available to the public in the hardware store 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.

8. No food contact materials or toys containing titanium dioxide

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 industry codes (e.g. EuPIA exclusion policy) 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.

Toys would also be affected, because substances classified as carcinogenic Category 2 are banned in toys and their marketing is restricted in accordance with the provisions of the Toys Safety Directive (Annex III 3.). For example, coated wooden toys, printed plastic toys or paint boxes with titanium dioxide components would no longer be allowed.

D. Legal requirements and consequences for policy

The classification proposal, in our view, attempts to set a **precedent** for the classification of all "low solubility" substances in powder form based on general particle effects. As a result, all 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 justification) and instead based its recommendation on **general particle effects**. In our view, this justification is incomprehensible because such particle effects are characteristic of the entire group of "low solubility" substances in powder form and therefore not a specific property of titanium dioxide. As long as it is not legally clear whether particle-related, non-specific effects fall within the scope of the CLP Regulation, there shall be no decision on the classification of titanium dioxide.

In addition, titanium dioxide in paints, coatings and printing inks is permanently bound in the binder matrix and therefore **can not be inhaled at all**. This is also confirmed by the IARC (chapter 1.3.2 c), link). Consequently, the labelling regulation in California (USA) excludes such products (*"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, if it should happen, a classification of titanium dioxide shall not apply to mixtures such as paints, coatings and printing inks, as according to the **"form"** there is no hazard (cf. **Articles 5 and 6 of the CLP Regulation** and CLP guidance 1.2.3.1).

2. Protection against particle effects is ensured by national occupational safety regulations

Inhalative exposure to titanium dioxide dusts, which could at least theoretically reach the critical dose range, can only be expected in workplaces. Most EU Member States have introduced **workplace dust limits** (between 1.25 and 10 mg/m^3). Germany is one of the forerunners with a limit of 1.25 mg/m³.

Dust limits for the workplace effectively protect people from general particle effects. Instead of the proposed classification of titanium dioxide, consideration should therefore rather be given to harmonising the different dust limits in Europe.

3. Breach of the principle of proportionality

A classification of titanium dioxide would violate the principle of proportionality enshrined in European law (Article 5 paragraph 4 TEU): for example, a classification as potentially carcinogenic (Category 2) would have no direct legal consequences for the occupational safety and therefore would **not be suitable** for improving it. Due to the existing national occupational dust exposure limits, such a classification would also **not be necessary**. Finally, the classification would also be **inappropriate**, because its consequences would also affect those products in which titanium dioxide is permanently bound in a matrix and therefore can not be inhaled at all. 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” (download here).

4. Classification would weaken health protection

With regard to health policy, the proposal also brings only disadvantages, because in the future the hazard symbol and the indication "suspected of causing cancer" would be printed on consumer products such as paints and coatings, although there is no danger of inhalation. The labelling of all products containing titanium dioxide, however, invalidates the entire hazard labelling system. There is a **risk of over-labelling** and, as a result, a blunting of the impact on consumers, which would **jeopardise the entire CLP/GHS system**.

The case illustrates that, in this instance, the rigid, automatic legal consequences of a CLP classification lead to unreasonable results. The legislator must provide for exceptions in the future. The REFIT Report on the REACH Regulation also criticises the automatic legal consequences of a harmonised classification and suggests allowing exemptions from classification in the future, either because of a "specific risk assessment" or because of serious socio-economic impacts.

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

Based on a classification of titanium dioxide, it would then be possible to classify any powdery, low solubility 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 **up to 350 other substances**. As a result, substance classification would lose its meaning (protection of humans and the environment) and its value as a guide for consumers and become a plaything for political interests.

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