



Harmonized Classification of Titanium Dioxide

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Overview

- Use and significance of titanium dioxide
- Classification proposal
- Toxicological and epidemiological informationen
- General dust limit
- Implications and consequences of classification
- Summary

What is Titanium Dioxide?

Characteristics of titanium dioxide:

- highest opacity of all white pigments
- excellent tinting strength
- Light-resistant
- thermally stable
- chemically and biologically inert
- non-flammable
- nearly insoluble in water, diluted acids and organic solvents

Functions of titanium dioxide:

- white pigment
- opacifier
- hiding power
- brightener for other colours
- increased stability

Special applications:

- UV-blocker (e.g. protection in sunscreen, pharmaceuticals)
- photocatalyst (NO_x degradation)

Applications of Titanium Dioxide



Paints & Varnishes



Construction products



Plastics



Papers



Automotive products



Printing inks



Ceramics



Cosmetics



Fibers & Textiles



Toys



Catalytic systems



Pharma



Food

Application of Titanium Dioxide by Industries

Technically manufactured titanium dioxide has been used for 100 years in various industrial applications and consumer goods.



Titanium dioxide is found as a passivating oxide layer on the surface of titanium metal also in less obvious areas, such as traffic technology, jewelry and medical implants.

Classification Proposal

RAC recommendation for harmonized CLP classification

Carc. 2 – H351 (Inhalation)



Warning

Suspected of causing cancer

Toxicological and Epidemiological Information: Single Substance vs. PSLT Group

- ▶ TiO_2 has no substance-specific toxicity beyond general particle effects.
- ▶ TiO_2 is not mutagenic and not genotoxic
- ▶ TiO_2 is (bio)chemically inert and not systemically bioavailable due to its very low solubility in biological fluids.
- ▶ TiO_2 in solid, respirable form is a representative of the group of granular biopersistent dusts without known significant specific toxicity, also described as poorly soluble particles with low toxicity (PSLTs).
- ▶ Relevant mode of action of the substance group PSLT by chronic inhalation are particle-induced inflammatory reactions in the lung as a result of overburdened natural cleaning processes (“lung overload”).
- ▶ Threshold (limit) values can be derived for PSLT-induced inflammatory reactions below which no effects occur (general dust limit value in Germany)
- ▶ A general dust limit value has been set for the PSLT group, but no classification/labelling as CMR

Toxicological and Epidemiological Information

- Proposed classification does not sufficiently respect basic scientific principles
 - Evidence of carcinogenicity is based on a very limited database (in fact, on one study only)
 - Deficiencies of the study by Heinrich, questioning the validity and scientific plausibility, respectively (artificially pushes findings):
 - no OECD guideline study, no information on GLP
 - only female animals exposed
 - only one (variegating) test concentration (no prediction of dose-response relationship possible)
 - Exposure 18 h/day (Guideline 6 – 8 h/day)
 - Ambiguities and contradictions in findings: lung exposure and lung clearance reach a maximum (steady state) after 12 months despite continued exposure
 - Lung tumours in rats as an “artificial” (pushed) high dose effect
 - Lung tumours caused by particle inhalation not generally valid even in rats as the most sensitive species (“Lege artis study”)

Toxicological and Epidemiological Information

► Epidemiology of titanium dioxide

- Epidemiological studies / experiences on titanium dioxide are available for more than four decades
- Independent case-control and cohort studies of more than 30,000 workers exposed to titanium dioxide at 18 different production sites in various countries, with – in part - decades of follow-up, show no correlation between titanium dioxide exposure and lung tumours.

► Epidemiology of PSLT and dusts in general

- No evidence of PSLT-induced lung tumors in humans
- Epidemiological studies of more than 33,000 workers exposed to toner did not show increased lung tumour incidence.
- Independent epidemiological studies over more than 30 years of the highest exposed collective (mine workers in coal mining) show no clear or statistically verifiable link between exposure to coal dust and lung cancer.

Classification of Titanium Dioxide would have a “Domino Effect“ for Alternative Pigments and other Dusty Substances*

Titanium dioxide



Carbon Black

Inorganic coloured pigments

Iron oxides

Cerium oxide

Aluminium oxide

Magnesium oxide

Plastic dusts

...

* See also TRGS 900 – List of examples of substances falling within the scope of the German general dust limit values.

General Dust Limit Value and Exposure Data for Titanium Dioxide

General dust limit (Germany)

- ▶ Aim: To prevent impairment of respiratory function due to a general dust effect.
 - ▶ **Respirable dust fraction („A-dust“): 1,25 mg/m³** based on an average density of 2,5 g/cm³
 - ▶ **Inhalable dust fraction „E-dust“): 10 mg/m³**
- ▶ The derivation is based on the **endpoint of chronic inflammation**. This also prevents associated pathological changes, such as the development of lung tumours observed in rats in animal experiments (“threshold mode of action“)

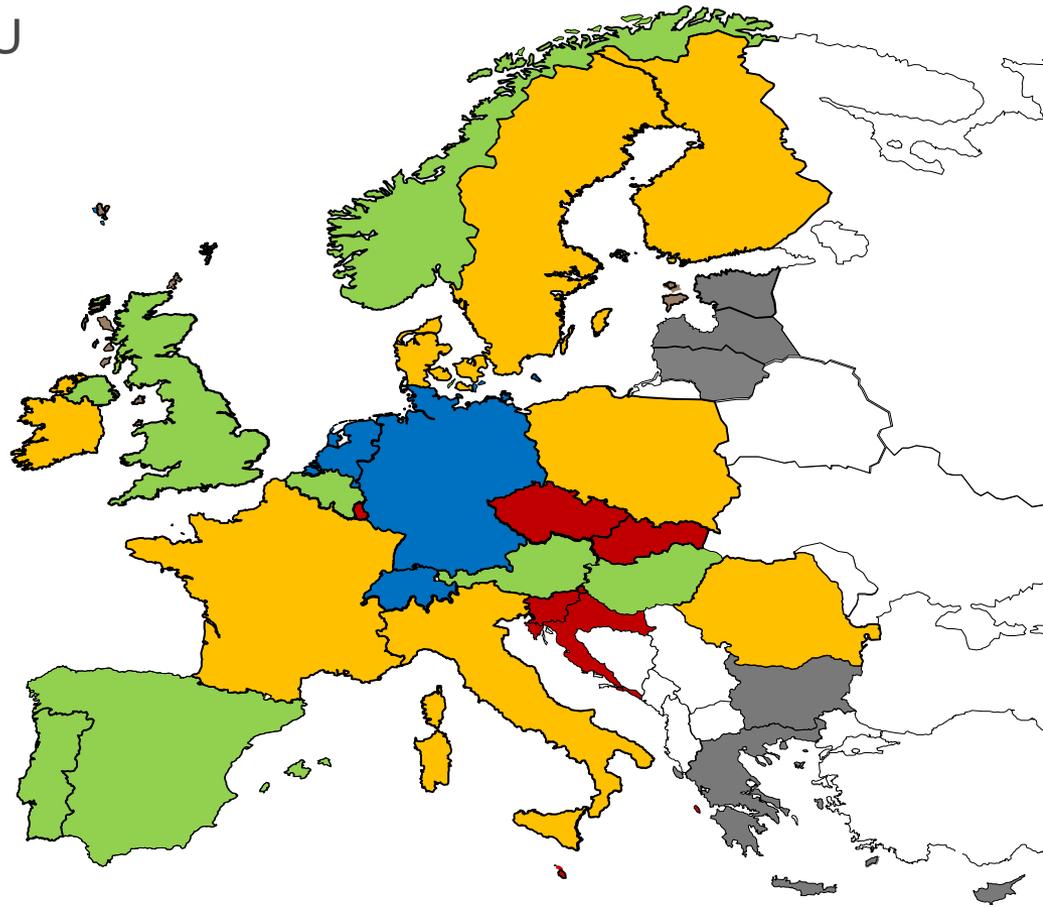
Explanatory statement general dust limit, TRGS 900

Other countries have similar limit values for dusts.

Member States with Dust Limits in Place

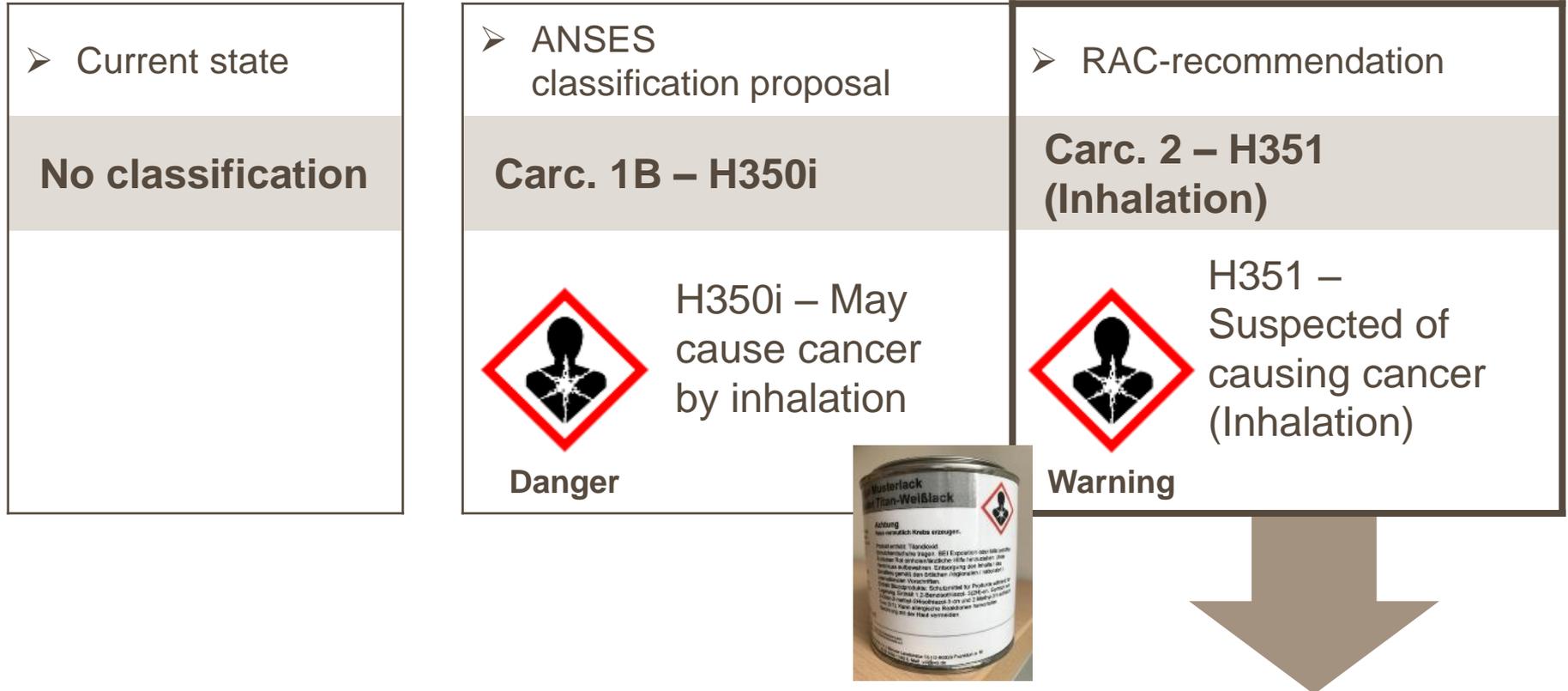
Dust limits at the workplace in the EU (+ Switzerland and Norway):

-  No limit value
-  10 mg/m³ (inhalable fraction)
-  4-6 mg/m³ (respirable fraction)
-  ≤ 3 mg/m³ (respirable fraction)
-  No information



Impact of a Classification

Classification and labelling according to CLP

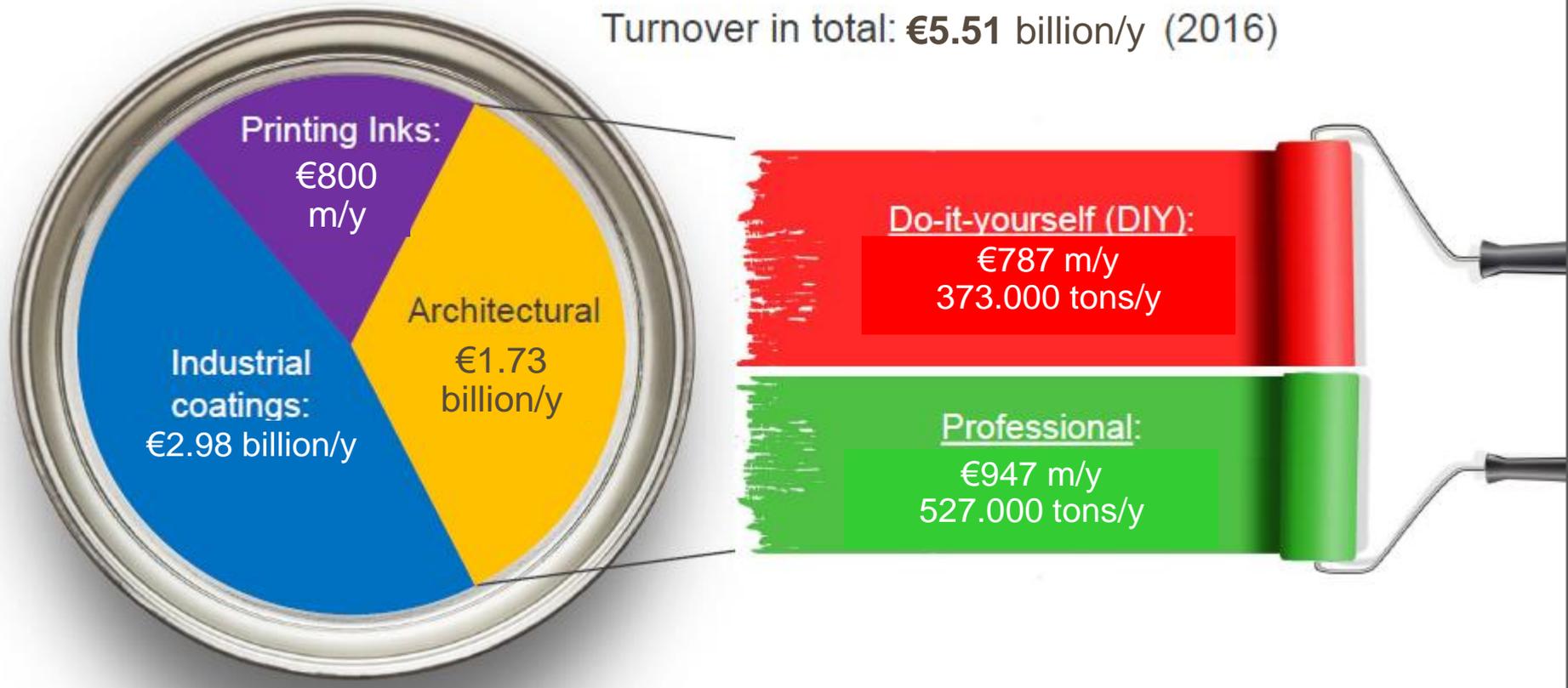


Legal consequences of downstream legislation which go beyond simple labelling.

Classification of Carc. 2 for TiO_2 would negatively affect paints, coatings and printing inks

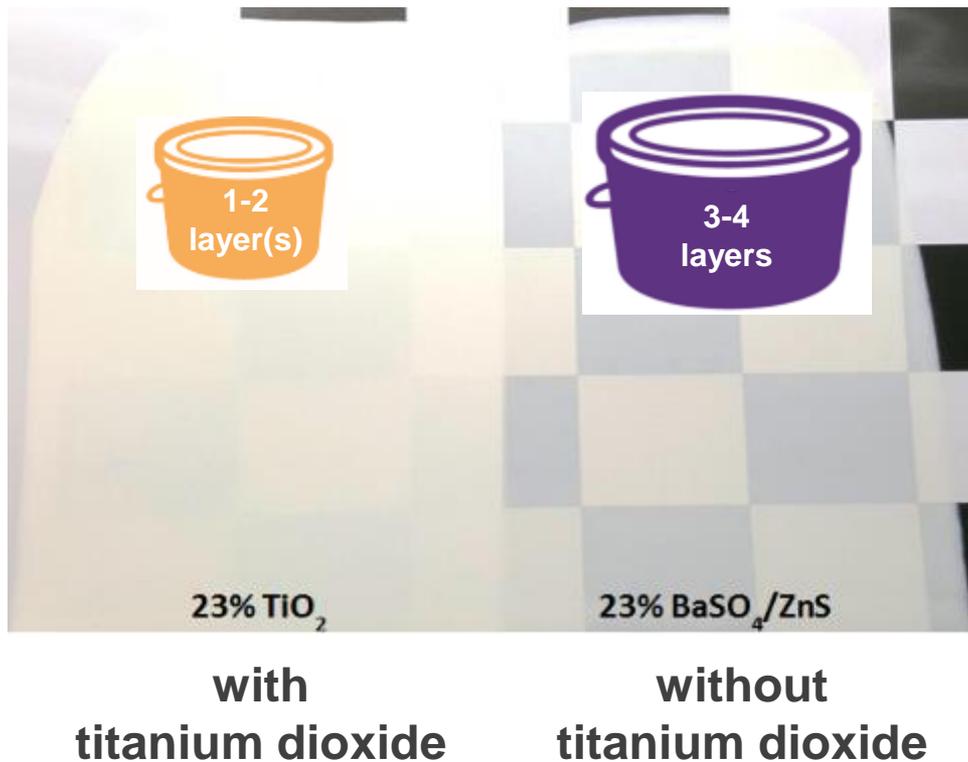


The entire German Market for Paints, Coatings and Printing Inks would be affected by a Classification of TiO_2



Practical Consequences: Without Titanium Dioxide, Paints no longer cover well and are therefore less sustainable

Single layer of a wall paint with titanium dioxide compared to the best alternative:



Poorer opacity means:

- Twice as much **paint** needed
- Twice as much **time**
- Twice as much **costs** for painters
- Twice as much **waste** due to paint buckets



Consequences in Waste Legislation

TiO₂-containing waste becomes hazardous waste

- “Hazardous waste“ from 1% content of titanium dioxide (HP7 according to annex III of the Waste Framework Directive)
- Affects a large number of waste streams such as: plastics, building rubble, wallpaper remnants, paint remnants, high-quality paper or furniture, but also industrial waste from titanium dioxide processing companies:

Sectors are substantially affected by a possible revaluation, e.g. 120.000 t of old windows/recycling material in Germany, for which a special take-back system was set up (Rewindo/plastic window recycling), with a recycling rate of >80%

- Additional immission control plant permits for hazardous waste are required (see in particular 4. BImSchV; concerns material and energy recovery)
- Waste monitoring, including “waste bureaucracy“ will become much more demanding (especially the requirements of the ordinance on the traceability of waste disposal - Verordnung über die Nachweisführung bei der Entsorgung von Abfällen)
- National law and transfer obligations apply

Legal Effects of Classification as a Carc. 2

Cosmetics

- **Ban on the use of CMR substances**
- concerns both use as a pigment in decorative cosmetics and as **UV protection in sunscreens**
- Authorisation possible following extensive testing, and assessment by SCCS

Toys

- **Ban on the use of CMR substances**
- Authorisation possible following extensive testing

Food contact materials

- **Further use debatable, e.g. for plastics in contact with foodstuff**
- Titanium dioxide is also used in packaging as UV protection for longer shelf life

Further foreseeable Consequences of a Classification

Food colourant E 171

- ▶ Possible impact on foodstuffs, unnecessary consumer unease
- ▶ EFSA assessed titanium dioxide as safe for use in foodstuffs (EFSA assessment, published in 2016)
- ▶ CLH proposal and RAC opinion limited to inhalative exposure

Pharmaceuticals

- ▶ Use as film coatings of tablets
- ▶ Consumer unease

Further foreseeable Consequences of a Classification

Consumer unease

- ▶ Acceptance of a “suspected carcinogen“ in consumer-related applications questionable:
 - ▶ even if inhalative exposure is not possible (food, medicines, plastic matrix, varnishes...)
 - ▶ even if exemption/authorisation is possible (cosmetics, toys)

Devaluation of hazard communication

- ▶ no proportionality
- ▶ evaluation of the actual risk by the user is not possible
- ▶ long-term deadening against hazard labelling

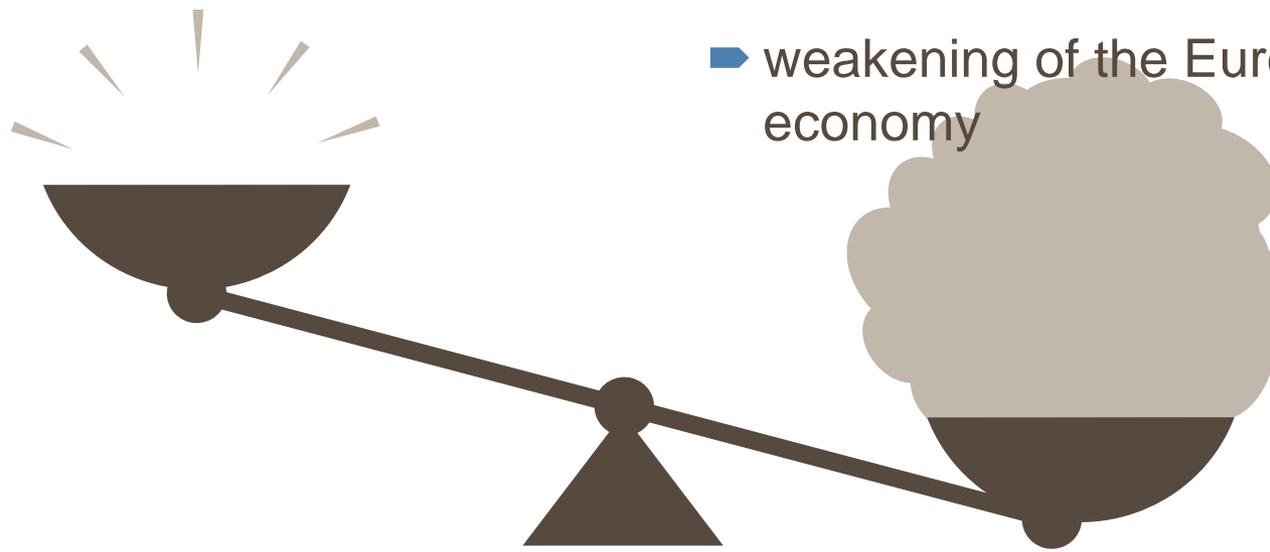
Proportionality of Regulation

- ▶ Setting of exposure limit achieves protection goal without additional disadvantages and has already been achieved by the German general dust limit (with the underlying evaluation by MAK and AGS)
- ▶ Classification & labelling is not necessary to achieve the protection objective, but it leads to disproportionate disadvantages and stigmatisation on the part of the consumer (including non-respiratory forms of TiO_2)
- ▶ The principle of proportionality should be taken into account
 - ▶ Measures should be the least burdening to achieve the goal
 - ▶ The aim is health protection at the workplace
 - ▶ PSLT (TiO_2) mode of action with threshold value, i.e. a limit concentration for exposure has been established based on the primary mechanism “inflammation”, which protects against all other effects.

What is the benefit of the classification?

No benefit, many disadvantages!

- ▶ no scientific basis for classification as carcinogenic
- ▶ particle-induced inflammatory processes are not substance-specific
- ▶ existing legislation on occupational safety and health already regulates dust exposure
- ▶ high economic consequences, even in areas without inhalative exposure
- ▶ devaluation of hazard identification
- ▶ consumer unease
- ▶ immense effects on downstream circular processes (waste, recycling)
- ▶ weakening of the European economy



Thank you for your attention!

