WCTF

EU developments in Health and Safety

Cerame-Unie The European Ceramic Industry Association

Carcinogens and mutagens directive – respirable crystalline silica

1st batch – Finalized - 2 years for implementation (by 17 January 2020)

- Annex I: Work involving exposure to respirable crystalline silica dust generated by a work process
- Annex III: Binding Limit values: Respirable crystalline silica dust: 0.1 mg/m³

2nd batch – Finalized - 2 years for implementation (by 20 February 2021)

- The Article 13a is inserted:
  - **Social partners' agreements:** Social Partners' agreements possibly concluded in the field of this Directive shall be listed on the website of the European Agency for Safety and Health at Work (EU-OSHA). That list shall be regularly updated.

DIRECTIVE 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

Carcinogens and mutagens directive – implementation at national level

0.05 mg/m³ in Estonia and Germany (= Assessment criterion / reference value)

0.1 mg/m³ in Poland, Sweden – ongoing discussions in Belgium

Spain:

- The draft Royal Decree on carcinogens has passed the process of the National Commission for Safety and Health at Work without modifications to the claims submitted by the industry to match the limit levels to the European standard, that is 0.1 mg / m3 instead of 0.05 as it was being applied since 2015.
- This Royal Decree is on its way, although it must still be approved by the Economic and Social Council and subsequently passed to the Council of Ministers before its publication in the BOE. Once it is published it will be binding on the law that will take effect on January 17, 2020.
- Thus, if nothing changes it is very likely that finally the limit levels of application in the law will be 0.1mg / m3.

Carcinogens and Mutagens Directive – Which measures does it impose at the workplace?

According to Articles 3 to 6 of Directive 2004/37/EC, the **employers have the duty to determine and assess the risks for activities in which workers are or are likely to be exposed** to carcinogens or mutagens as a result of their work. They have to supply the responsible authorities at their request with the results of the risk assessment and the measures taken, including the reasons for which carcinogens / mutagens are used.

In so far as technically possible, **employers must reduce the use of a carcinogen** / mutagen by replacing it with substances / mixtures / processes which are not or are less dangerous and they have to submit the findings of their investigations to the competent authorities at their request. If substitution (or work in closed system) is not technically possible, the next measure(s) according to the hierarchy of preventive measures (Article 5) have to be taken.

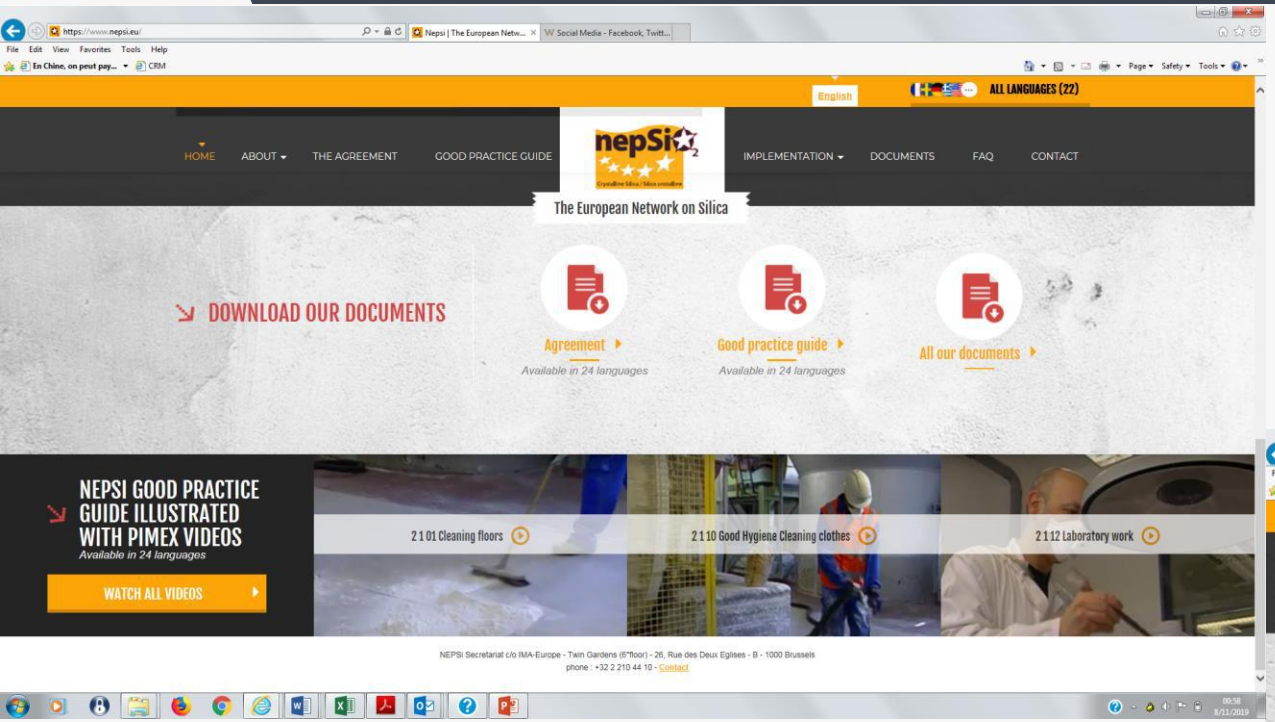
How these obligations will be implemented in Europe will largely depend on how the CMD wording is interpreted and enforced at member state level. Regarding RCS, it is important to note that the entry in Annex I refers to work processes generating such respirable dust.

Through the **NEPSI Social Dialogue Agreement (SDA), the signatory industries have developed a comprehensive set of guidance and assessment techniques that address the minimization measures**, taking into account the wide diversity of industrial circumstances and the best ways to address them with specific sectoral expertise.

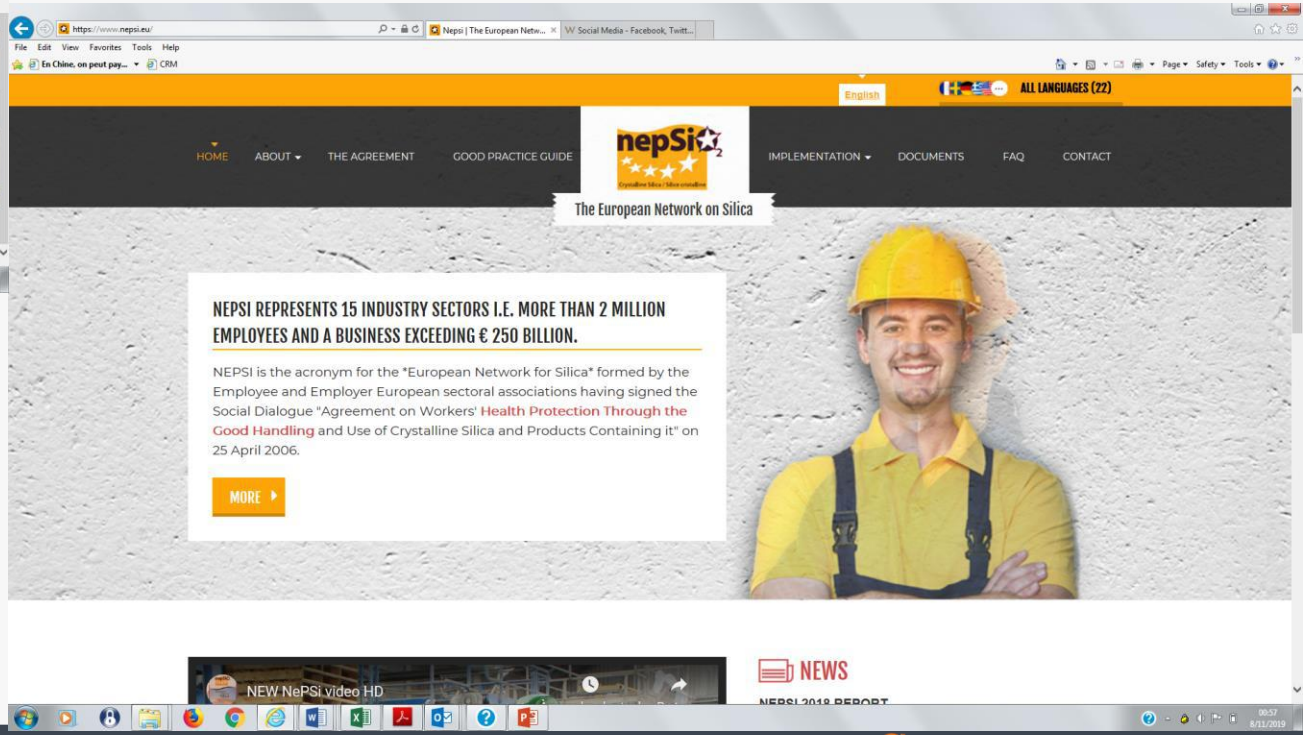
It can be seen that the **SDA is complementary to the general requirements of the Directive** and, by following the NEPSI Guidance, the signatories implement these requirements in an informed and tailored way. This means, that if NEPSI employers' industries can demonstrate after their risk assessment to the competent authorities that substitution of the processes generating respirable crystalline silica dust is not possible, then they can go to the next step of the hierarchy of obligations of the CMD.

The NEPSI Good Practice Guide contains a tailor-made approach for industrial processes to substitute RCS generating processes by less dangerous ones or at least to minimize exposure as low as technically possible.

Good practices available on the NEPSI website



https://www.nepsi.eu/



30 May 2018: France withdraws its intention to submit a harmonized classification of crystalline silica

European Chemical Agency website:

As “work involving exposure to respirable crystalline silica dust” is now included in the Directive 2017/2398/CE, French authorities consider that the need to propose a classification as carcinogen for crystalline silica has an added-value for human health protection mostly if consumer uses is identified. **However, no consumer use leading to a significant exposure to crystalline silica by inhalation has been identified.** Therefore, French authority has decided to withdraw the intention to submit a CLH report for this substance.

This is a very important precedent and confirms that industry and the European Commission adopted the right approach by managing the RCS dust emissions at the workplace

NEPSI 5-year Roadmap

In the next 5 years NEPSI will support the implementation on the ground of the CMD and will prepare for the evaluation of the BOEL (binding occupational exposure limit)

The roadmap subject of an EC Grant Request

- **Update of the NEPSI Good Practice Guide** and new design/format
- Development of **guidance documents and tools for SMEs** (incl. micro enterprises)
- Development of **training programme for the new workers**, especially the young generation
- Renewal of the NEPSI Reporting system software.
- Development of a **standardised respirable crystalline silica measurement methodology**.
- Translation of the different new materials into all EU languages.
- Closing Conference

Dates: February 2019 – January 2021

NEPSi Reporting exercise 2020

Cerame-Unie has decided to remain a NEPSi signatory at least until the next data collection in 2020. By 2020, the carcinogens and mutagens directive requirements will have had to be implemented, and by then we wish to assess the role NEPSi has played in the implementation and with the authorities.

A new NEPSI platform will be used to gather the KPIs

Email with details will be sent beginning of 2020

Reporting expected to start in February 2020

NEPSI reporting 2018 – CET Specific Data

General Site Information	2008	2010	2012	2014	2016	2018
Number of Sites:	154	190	187	202	192	165
Number of Reported Sites:	143	99	158	170	130	122
% of Reported Sites:	92,86%	52,11%	84,49%	84,16%	67,71%	73.94%
Number of Reported Employees:	19812	14507	20043	22903	19446	20838

NEPSI reporting 2018 – CET Specific KPIs

Key Performance Indicators	2008	2010	2012	2014	2016	2018
% of Employees potentially exposed to respirable crystalline silica:	53,05%	38,08%	42,40%	48,01%	45,36%	46.27%
% covered by risk assessment:	86,04%	98,70%	95,88%	98,37%	98,81%	95.44%
% covered by exposure monitoring:	55,95%	51,83%	42,26%	59,90%	57,66%	62.36%
% with risk assessment requiring Health Surveillance Protocol for Silicosis:	38,15%	44,28%	49,52%	38,21%	48,05%	46.41%
% covered by generic health surveillance:	95,04%	95,75%	96,54%	97,74%	92,13%	88.87%
% covered by Health Surveillance Protocol for Silicosis:	34,75%	44,06%	46,69%	36,70%	44,92%	43.36%
% covered by information, instruction and training on General Principle:	28,67%	55,94%	65,89%	75,35%	70,16%	77.33%
% covered by information, instruction and training on Task Sheets:	19,80%	30,67%	28,82%	32,92%	36,22%	41.37%
% of Reported Sites with technical measures to reduce generation/dispersion of fine particles at source:	95,80%	97,98%	96,84%	94,12%	96,15%	99.18%
% of Reported Sites with Organizational measures:	35,66%	57,58%	46,84%	57,06%	58,46%	77.87%
% of Reported Sites with Distribution and use of Personal Protective Equipment:	95,10%	97,98%	97,47%	96,47%	94,62%	99.18%

Proposed classification of TiO2

- The Commission proposes to classify TiO_2 as a suspected carcinogen by inhalation with derogations
  - Note 10 limits the classification to mixtures placed on the market in powder form containing 1% or more of TiO_2 particles with diameter ≤ 10 µm
  - Note W specifies that the classification is limited to 'lung overload'
  - Liquid mixtures would not be classified, but a specific hazard statement needs to be applied
- The Commission's proposal leaves fundamental issues unresolved
  - Particle toxicity is not an intrinsic property as required by CLP
  - The proposal does not resolve the potential downstream regulatory issues
  - Precedent for 300+ other poorly soluble low toxicity substances

EUROPEAN COMMISSION

Brussels, XXX
[…](2018) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending, for the purposes of its adaptation t
Regulation (EC) No 1272/2008 of the European
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Commission Regulation (

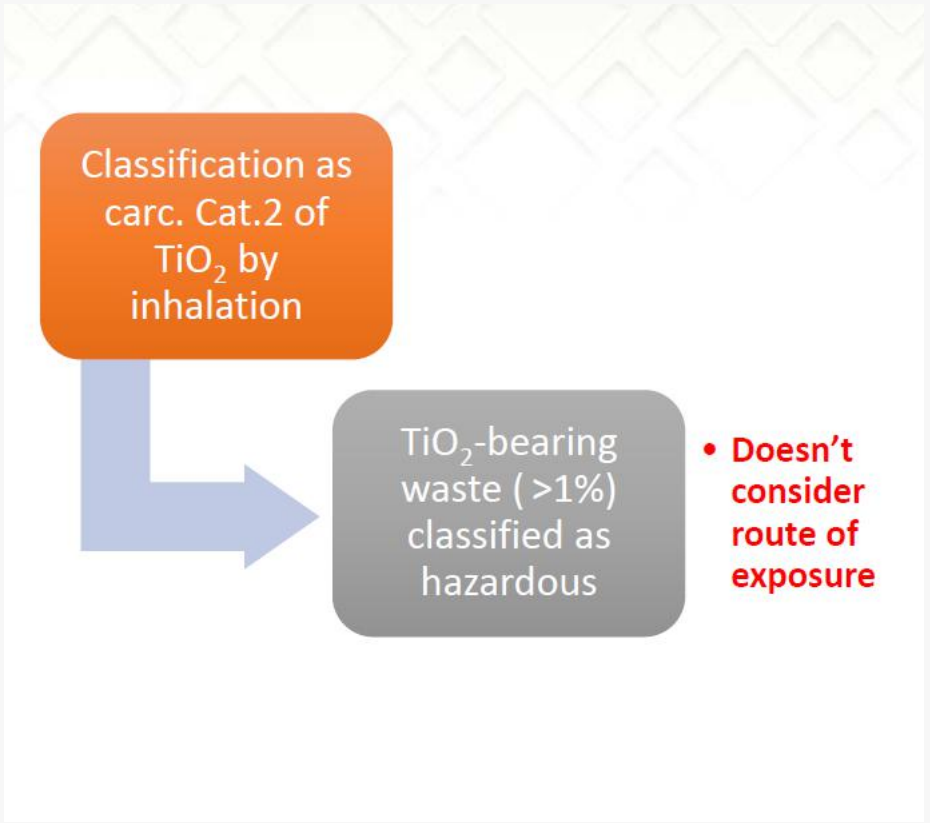
(Text with EEA rel

Downstream impacts

The Commission acknowledges the unintended downstream impacts as confirmed by the proposal to update waste guidance

- Update to waste classification guidance is not a sufficient solution.
- Changes to EU waste law would be required (but unlikely before2022)
  - Patchwork in waste management across the EU
  - Fundamental legal uncertainty regarding status of waste
  - Significant burdens in implementation for waste classifiers

- The Commission has not made any efforts to address other unwarranted downstream impacts (cosmetics, toys etc.)

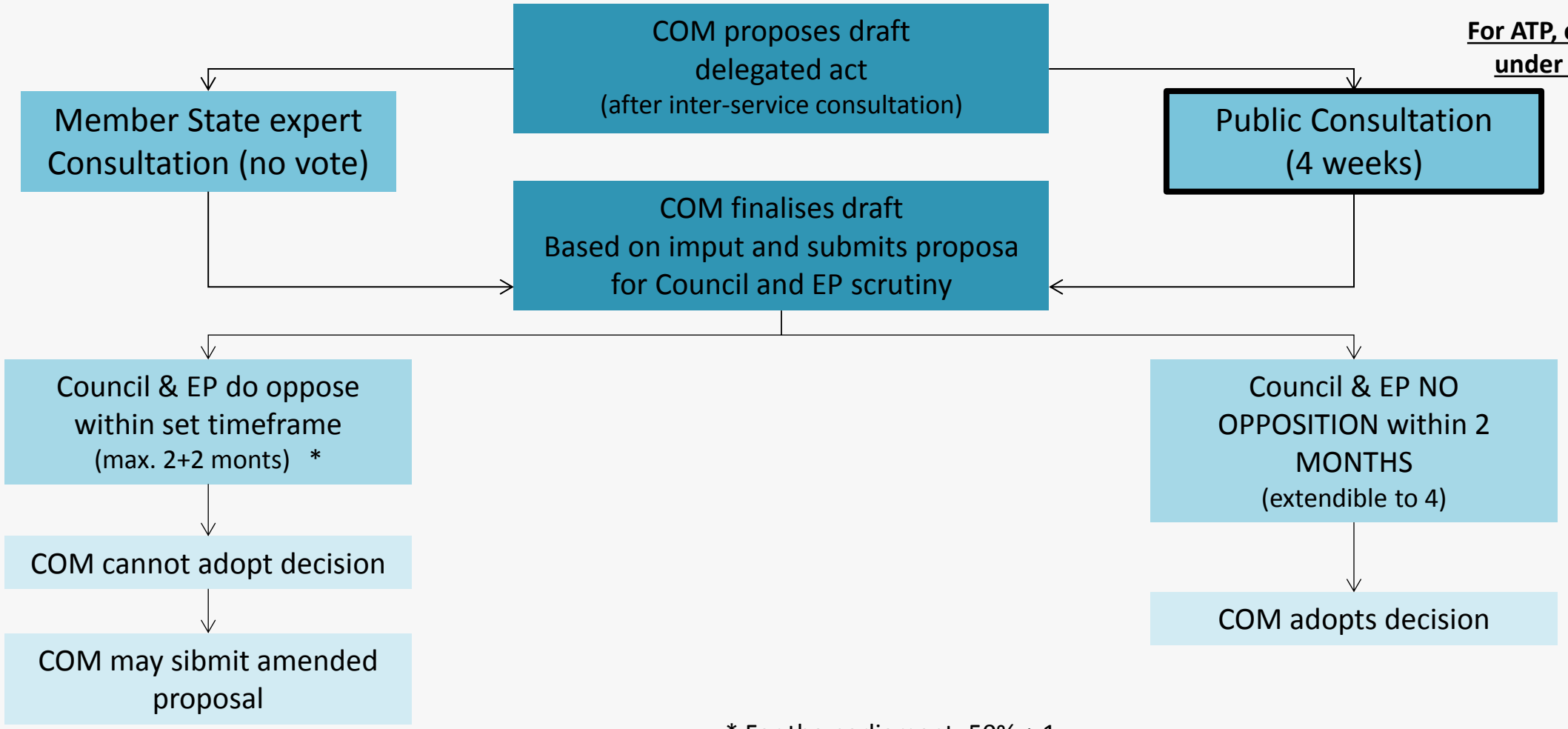


Back-up slides

From “Regulatory Procedure with Scrutiny” to “Delegated acts”

New rules for CLP

Delegated acts



* For the parliament: 50% + 1

* For the Council: 55% of the members representing at least 65% of the population

From RPS to Delegated Acts: major practical changes

- **No vote in REACH Committee** – The vote in the REACH Committee will no longer be required. The REACH Committee will now only work on REACH.
- **Experts consultations – CARCAL will be the expert group** to be consulted on Das on CLP.
  - Explanatory memorandum: Opinion (incl. Dissenting view) communicated to Council/Parliament together with the draft DA.
  - More meetings >> first (CARCAL-CLP) was on 18 September 2019
  - Enhance transparency: only open sessions and documents publicly available
  - CARCAL new Rules of Procedure
- **Scrutiny by Council/Parliament** – Following Commission Adoption, the DA is transferred to the Parliament and Council for a (extendible) two-months scrutiny.

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(Text with EEA relevance)

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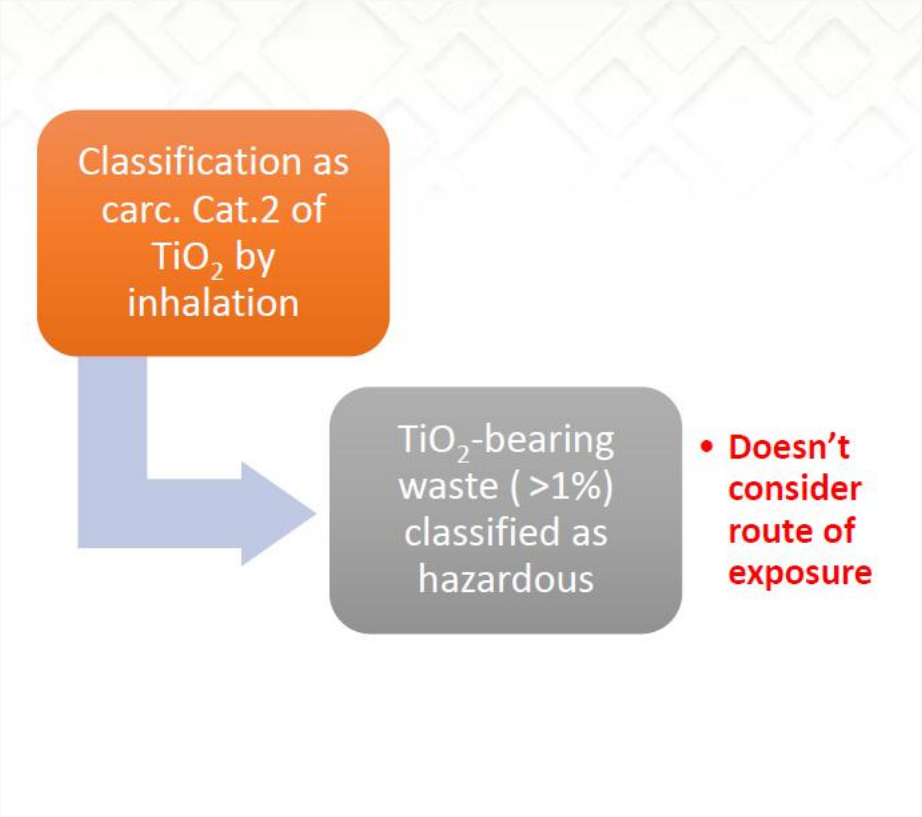

TiO2 classification proposal status

15/05/2019

- The Commission is determined to move forward with the classification
- NGO pressure is continuing for the classification of TiO2 in all its forms
- Industry asked that the 14 th ATP is allowed to proceed without TiO2 to address the suspected hazard via a more proportionate and effective measure
- TDMA has communicated to the Commission that: It would support the establishment of an appropriate EU harmonized occupational exposure limit (OEL) for TiO2 and that it supports finding a resolution within the CLP framework in line with UK/Slovenia proposal
- 2 months scrutiny period will start shortly
- If no objection is raised, the classification will be adopted by the end of the year with a 18 months implementation period
- It will be very hard to raise an objection that favours the industry position in the EP and the Council