Risk Management Options Analysis for Titanium Dioxide (TiO_2)

Final Report

prepared for

Titanium Dioxide Industry Consortium

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RPA
Risk & Policy Analysts

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The views and propositions expressed herein are, unless otherwise stated, those of Risk & Policy Analysts and do not necessarily represent any official view of the TDIC or any other organisation mentioned in this report.

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Executive Summary

In May 2016 the French authorities proposed a classification for titanium dioxide (TiO_2) as a carcinogen category 1B. The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) has concluded that the proposed classification cannot be scientifically justified. In its opinion of 14 September 2017, the RAC stated that TiO_2 meets the criteria for classification as a carcinogen category 2 (suspected of causing cancer), specifically through the inhalation route (linked to respirable dust). In response to this proposed classification, RPA has been contracted by TDIC to prepare an expanded Risk Management Option Analysis (RMOA) for TiO_2 which can be used in discussions with the European Commission and ECHA.

This assessment has:

- Drawn on work carried out by EBRC to assess the risks associated with different TiO_2 exposure pathways (manufacturing, industrial use and some professional/consumer uses);
- Identified the activities, processes or products responsible for the risks that where identified in the exposure assessment;
- Identified potential risk management options for several of these activities, processes or products, which include substitution and measures to reduce worker exposure to an appropriate level; identified other measures which would be triggered automatically by the proposed harmonised classification under CLP; and
- Examined the costs and the benefits of the different risk management option(s) for reducing the risks associated with the inhalation of TiO_2.

The analysis has been carried out in a manner consistent with Eurometaux Guidelines[1] and with the template developed by ECHA for MS reporting on RMOAs; although, the aim has also been to provide a more detailed level of analysis, and in particular on the costs and benefits of the different RMOs and/or automatically triggered measures.

Proposed threshold for effect

EBRC has established a DNEL of 1.3mg/m^3 for the respirable fraction for TiO_2 with respect to lung inflammation. At this limit, workers and consumers should be protected against inflammation and carcinogenic effects. As such, 1.3 mg/m^3 has been assumed in the analysis as also the level at which an Occupational Exposure Limit Value (OELV) would be set, with this also reflecting a level consistent with the findings of SCOEL and RAC.

Availability of alternatives

Titanium dioxide is the universal choice for white pigments. Its technical functions (high opacity, refractive index and light fastness) and availability mean that it is suitable for almost every application, whereas each of the possible alternatives has disadvantages. Mineral filters such as zinc oxide, lithopone, kaolin and talc find use in a number of applications as extender pigments, but they are not able to fully replace TiO_2. Titanium dioxide has the highest refractive index of all known white pigments, meaning it has the greatest opacity. As a result, pigmented materials that use substances such as zinc oxide, aluminium oxide or barium sulphate would require much larger

1 Eurometaux (2017): Guidelines for an Industry Risk Management Options Analysis, Version 3, May.

quantities of pigment; this can cause "crowding", reducing the light scattering properties, and the physical performance of the product. Very few pigments are available in similar quantities to TiO_2, indicating that it is not currently possible to physically replace it in all applications, even where the technical functions of alternatives are suitable. As a result, there is currently no alternative pigment available on the market in sufficient quantities and which can match the opacity, hiding power, cost-efficiency, inertness or weatherability of TiO_2.

Furthermore, as the carcinogenic effect observed in animal testing discussed in the French CLH proposal is not substance-specific but characteristic of respirable poorly soluble dusts, such effects could be expected to be associated with most, if not all, potential alternative substances. Therefore, all poorly soluble powders that could replace TiO_2 (including minerals such as chalk, talc, etc.) could be considered to exert carcinogenicity in a similar manner.

Risk Management Options

The eight potential risk management options and automatically triggered "measures" have been examined in detail. These are:

1) EU-wide IOELV or Social Partnership Agreement
2) Labelling and packaging of mixtures, and in particular consumer mixtures;
3) Awareness raising and training for professionals;
4) REACH restriction requiring provision of masks with paint sprayers;
5) REACH restriction requiring provision of masks with aerosol paints;
6) Removal of approval for use as an additive in food;
7) Removal of approval in the Union list for food contact; and
8) Risk management under waste legislation.

Figure 1 below provides a graphical summary of the assessment conclusions based on a scoring system ranging from 1 to 5, where 1 reflects very poor performance and 5 reflects very good performance. Further details on how these scores were assigned are provided in Section 7 of this report.

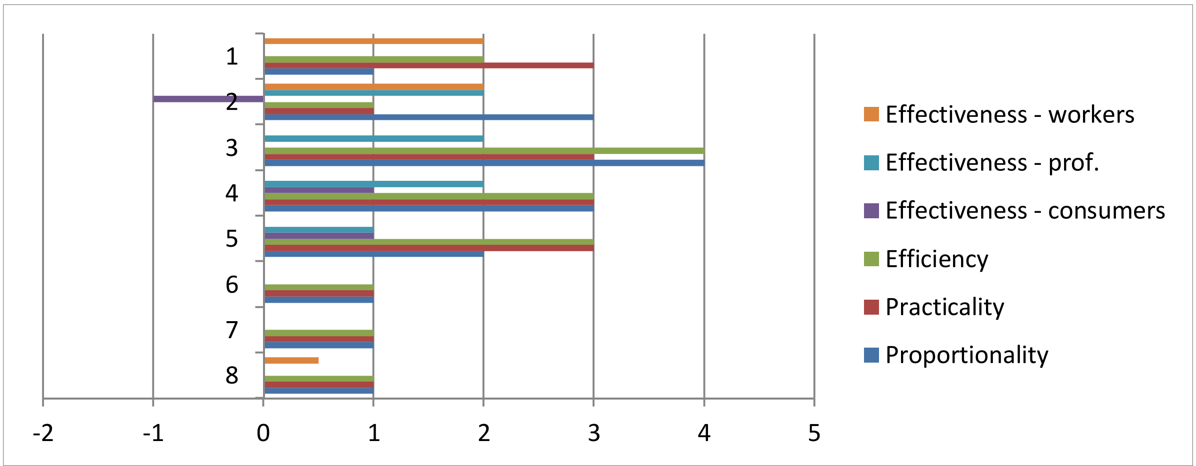

Figure 1: Scoring based assessment of RMOs
Notes: Scoring from 0 to 5, by option; see also Section 7

Overall, the most effective and proportionate measures are assessed to be:

1) An industry-wide commitment via a Social Partnership agreement to voluntarily reducing worker exposures during manufacturing activities to TiO_2 dust levels are below 1.3 mg/m^3; this is likely to be more proportionate than an IOELV introduced under the Chemical Agents Directive as implementation of the latter at the national level can require facilities to meet much lower exposure levels in order demonstrate compliance for, say, the 90 percentile of exposures;

2) Classification and labelling of mixtures where the target audience is industrial and professional users and the mixtures are supplied with an accompanying safety data sheet; although compliance with CLP is mandatory for placing mixtures on the EU market, the assessment finds that the full application of CLP is highly unlikely to be effective and hence proportional in relation to consumer mixtures and poison centre reporting obligations, given that the large majority of mixtures will be in liquid form and hence TiO_2 will not be available in a respirable form;

3) Industry sponsored training and awareness raising focused on ensuring that workers and the self-employed in sectors such as construction, building repair and building maintenance adopt appropriate practices to minimise exposures to TiO_2 containing dusts. In particular, this would be aimed at those involved in spray painting, sanding and mixing of dry powders.

In addition, the classification of TiO2 could result in large volumes of waste also becoming classified as hazardous. Under Directive 2008/98/EC, a Carc Cat 2 classification for TiO_2 would mean any waste that contains it at a concentration exceeding 1.0% would be classified as hazardous according to Annex III of the Directive. This would be counterproductive to the European Union's wider policy goal of promoting the Circular Economy, and would, in effect, make TiO_2 a *legacy substance*, one whose presence in already manufactured goods (i.e. paint, PVC and paper) would serve to make these goods *hazardous*, and thus, unrecyclable. Examples of the types of waste streams that might be affected (due to there being mirror entries for hazardous wastes) include:

- Municipal / Household wastes: paints, inks, adhesives and resins; wood coated with paint
- Paint wastes: waste paint and varnishes
- Construction wastes: glass, plastic and wood

FEAD estimates that the classification of plastics containing TiO_2 at >1% as hazardous could affect around 1.25 million tonnes per annum. They further note that the recycling of these plastics prevents the release of an estimated 1.8 to 2.4 million tonnes of CO_2 equivalents per year in comparison to the use of virgin resins. Even assuming a relatively low value for carbon, based on carbon credits traded under the EU ETS, at €5 per tonne CO_2 equivalent, this equates to social damage costs of around €9 to €12 million per annum. Given that the estimated volume of plastic assumed to be impacted by FEAD is much smaller than that implied by the figures presented above on the volumes of plastic currently being recycled, the social damage costs associated with increased CO_2 emissions alone due to the loss of recycling due to wastes containing TiO_2 at >1% could be much more significant.

These social costs would be in addition to the increased costs of sorting, shipment and final disposal of such wastes, to both the private and public sector.

1 Introduction

1.1 Background

Titanium dioxide (TiO_2) is by far the highest volume and most versatile globally-used white pigment, and is also widely used as a brightener for colours other than white. No other pigment comes close to matching its exceptionally high opacity (a result of TiO_2 having the highest refractive index among all known white pigments), bright whiteness and UV absorbing, protective properties. It is manufactured in 18 plants in the European Economic Area (EEA) with an annual production volume of ca. 1,100 ktonnes and an estimated market value of ca. €3 billion.

Most TiO_2 is used in paints and coatings (architectural: 36%; industrial: 17%; inks: 4%), followed by plastics (25%), paper (12%) and specialty applications (6%) (based on Cefic data for 2013). Approximately 1–2% of all TiO_2 is made in non-pigmentary forms for use in many high-value-added applications including cosmetic sunscreens and clean air environmental technologies.

The French authorities proposed the classification of TiO_2 as a Carcinogen Category (Carc Cat) 1B substance in May 2016. Whilst ECHA's Risk Assessment Committee (RAC) has concluded that a Carc Cat 1B classification cannot be scientifically justified, it has also asserted in its opinion dated 14 September 2017 that TiO_2 meets the criteria to be classified as suspected of causing cancer (Carc Cat 2) specifically through the inhalation route. Although, a Carc Cat 2 harmonised classification is less severe than that proposed by the French authorities, this classification would still have severe adverse consequences as a result of:

- The absence of technically feasible alternatives for TiO_2;
- The triggering of a series of changes in how the marketing and use of TiO_2 is treated under a variety of chemical safety regimes in the EEA; and
- the negative perceptions that would develop among users and consumers over the safety of the substance.

These impacts would arise despite the fact that risks related to TiO_2 exposure stem from inhalation; as specified by RAC in their opinion, there can be no or extremely low levels of human exposure by inhalation from the presence of TiO_2 in a mixture or matrix of any form.

1.2 Aims of this report

In order to respond to the proposed classification, the Titanium Dioxide Industry Consortium (TDIC) has contracted Risk & Policy Analysts Ltd (RPA) to carry out an analysis of appropriate risk management options for TiO_2. This analysis is carried out in line with past approaches on undertaking assessments of the advantages and drawbacks of different risk reduction measures, Eurometaux Guidelines[2] on the preparation of industry RMOAs and the template developed by ECHA for Member State reporting on RMOAs.

[2] Eurometaux (2017): Guidelines for an Industry Risk Management Options Analysis, Version 3, May.

More generally:

1) The assessment starts from consideration of the different uses of TiO_2, and then identifies the EU legislation relevant to these uses and the extent to which a harmonised classification under CLP would trigger risk management measures under the different legislation;

2) It draws on exposure assessment work carried out by EBRC to assess the risks associated with TiO_2 exposure, covering manufacturing/industrial use, and a sub-set of professional and consumer uses;

3) For the different activities, processes or products which could lead to exposures of concern, potential risk management options (RMOs) have been identified and screened to allow the assessment to focus on a subset of the most suitable and proportionate measures.

4) It then assesses the different RMOs in terms of effectiveness, economic implications, practicality, and proportionality.

Note that this study also draws on the findings of work carried out for TDIC involving an assessment of the socio-economic impacts from the Carc Cat 2 classification for TiO_2[3].

1.3 Structure of this report

This report sets out the types of information to be included in a RMOA based on the template structure developed by ECHA for reporting on the outcomes of RMOA work. It goes beyond this by providing a quantitative assessment of potential RMOs.

The contents have been organised in a different order from that proposed in the template, as follows:

- Section 2 provides a summary of the tonnage of TiO_2 placed on the market and the known uses of TiO_2;
- Section 3 summarises the basis for RAC's proposed Harmonised Classification for TiO_2, and provides a discussion on the findings of exposure assessment work in terms of the need for further risk management;
- Section 4 sets out an overview of relevant EU legislation governing the current and potentially the future use of TiO_2, and which provides the basis for risk management;
- Section 5 discusses the availability of alternatives to TiO_2;
- Section 6 identifies potential RMOs and assesses the potential costs and benefits of these;
- Section 7 presents the conclusions of this assessment on the most appropriate RMOs.

[3] RPA (2017): Assessment of the socio-economic impacts from Carc Cat 2 CLH for TiO_2, Updated Final Report, prepared for the Titanium Dioxide Industry Consortium, November 2017.

2 Information on (Aggregated) Tonnage and Uses

2.1 Tonnage and registration status

According to ECHA there are 178 active registrations under REACH, with these all involved in one joint submission (there are no individual submissions). A full registration dossier for TiO_2 exists, with the substance registered at between 1–10 million tonnes per annum.

2.2 Manufacture

There are two main manufacturing pathways for TiO_2 production, as can be seen in the figure below. The PROC descriptors for the manufacturing process stages where exposures could present are detailed in Annex 1.

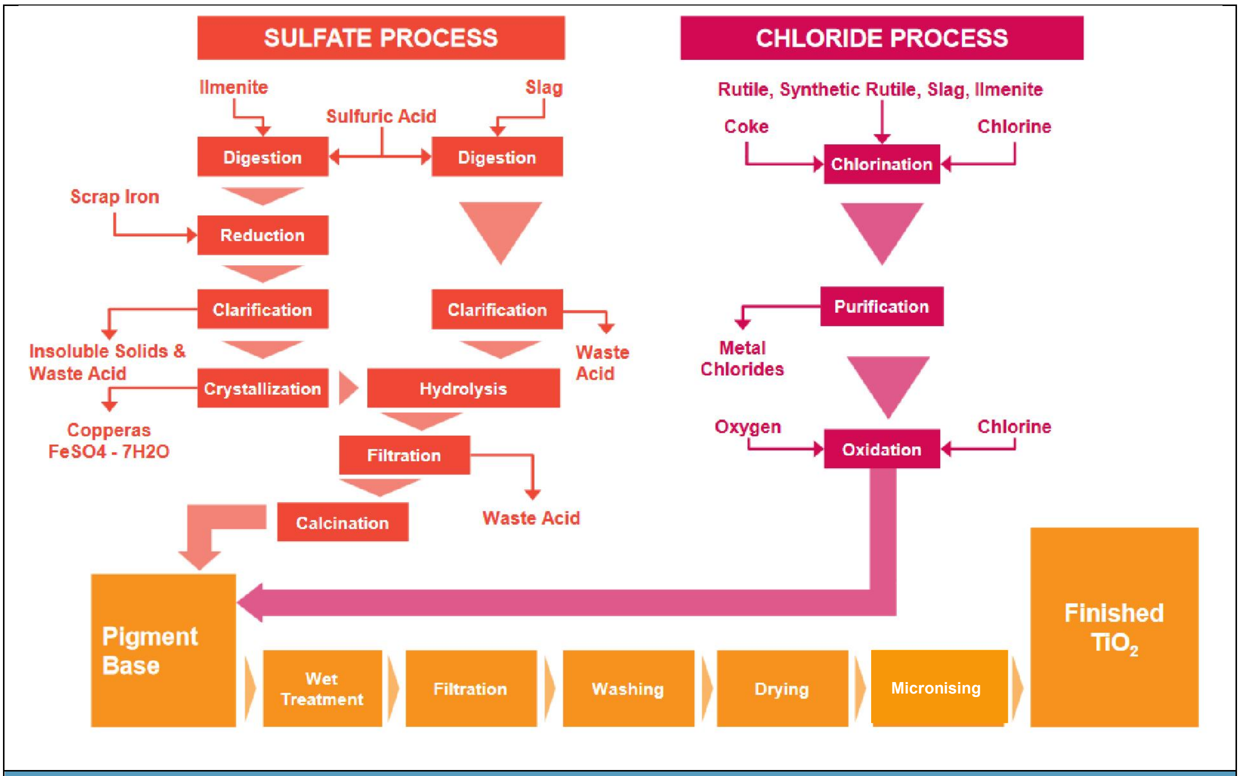

Figure 2–1: Chloride and sulphate TiO_2 production processes
Source: Chemours (2015)

2.3 Overview of uses

TiO_2 is by far the most prominent raw material for the manufacture of pigments and pigment preparations. Pigments and pigment preparations containing TiO_2 are primarily used in industrial (e.g. high quality coatings, paintings, printing inks, plastics, paper, ceramics) and professional (dispersion paints and varnishes) applications and, secondly, in the field of private consumer applications (e.g. cosmetics, pharmaceuticals, ceramics and glass) (Eurocolour, 2016).

Table 2-1 contains a summary of publicly available information on the breakdown of the global consumption of TiO_2 pigments for the year 2013. Other sources are available with somewhat variable percentages for specific market segments.

Table 2–1: Global TiO_2 pigments consumption breakdown by end-use sector	
End-use sector	**Year: 2013**
Paint	53% (assumed architectural 36% and industrial 17%)
Plastic	25%
Paper	Laminates: 10%; Paper: 2%
Inks	4%
Specialty	Food, Pharma, etc.: 1%; Catalysts: 1%; Other (e.g. cosmetics): 4%
Source: Cefic, aggregates of TDIC members' data	

The table identifies four key market segments: paints (incorporating functional coatings), plastics, paper and inks. These typically account for over 90% of total TiO_2 pigment consumption in the world. These are described as "mass applications" of TiO_2 with the remainder grouped as "specialty applications". Figure 2-2 provides a summary of the full range of applications.

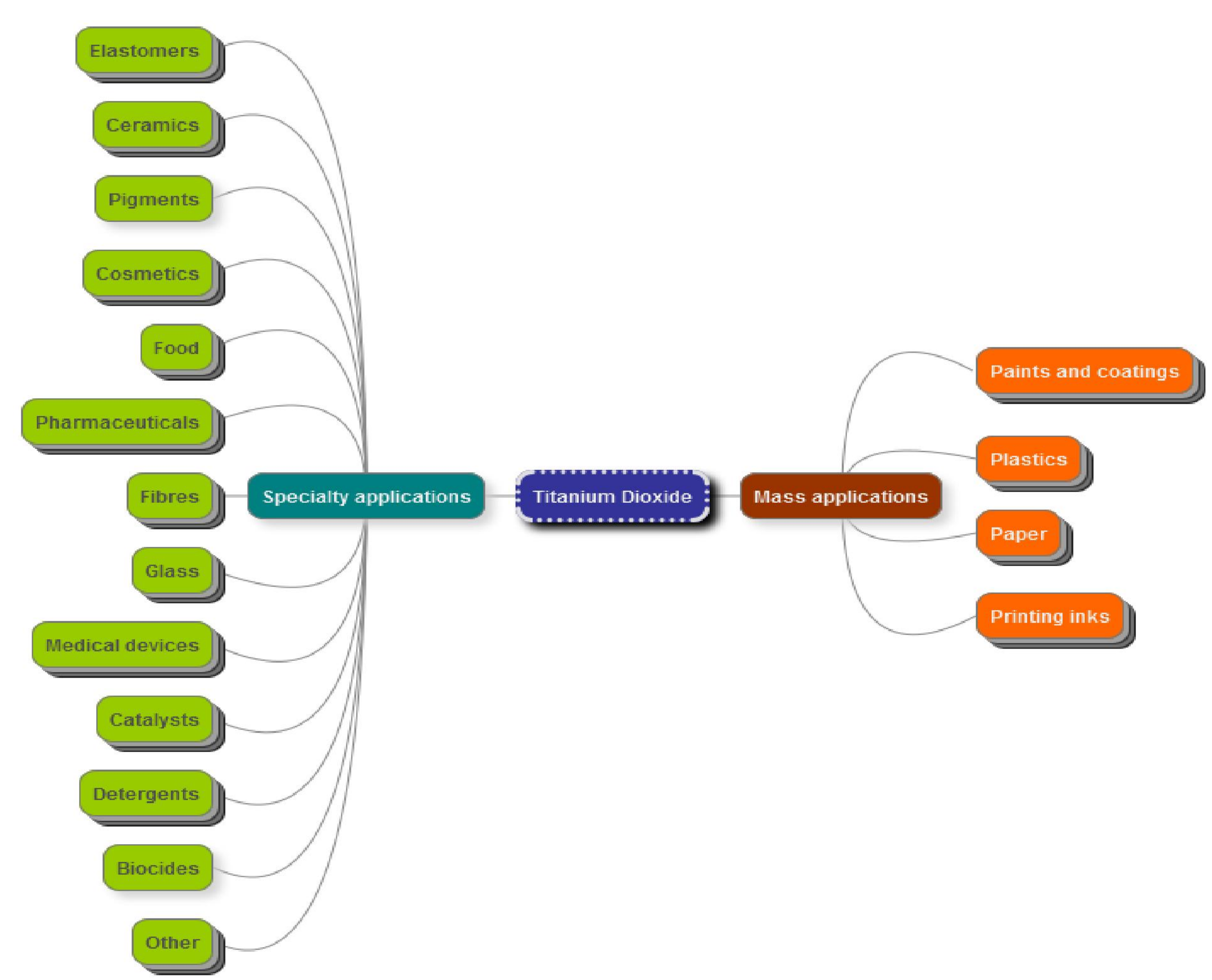

Figure 2–2: Overview of applications of TiO_2 pigments

A market overview for the different mass applications is provided in Table 2-2 below, with this information drawn from the more detailed Socio-Economic Analysis (SEA) report (RPA, 2017).

Further details on the mass and speciality uses, together with their economic importance can be found in the SEA report. Short summaries are provided below for completeness.

Table 2-2: Market overview				
Sector	**Consumption breakdown**	**GVA**	**Number of companies**	**No. Employees**
Paint and coatings	53% (assumed architectural 36% and industrial 17%)	€5 billion	800	110,000 (15-20% regular contact with TiO_2)
Plastic	25%	€118.4 billion	55,000	1.5 million
Paper	Laminates: 10%; Paper: 2%	>€0.34 billion		208,000
Inks	4%	*See paints and coatings*	>150	*See paints*
Speciality	Food, Pharma, etc.: 1%; Catalysts: 1%; Other (e.g. cosmetics): 4%	*Man-made fibre* – NA *Cosmetics* - €8 billion *Pigments* – No data *Ceramics* – No data *Glass* – No data	42 *Ingredients:* 100 *Cosmetic products:* 5,000 *Distribution:* 120,800 100 >200 70	20,000 152,000 23,000 >50,000 185,000
Source: RPA (2017): Analysis of the socio-economic impacts of a harmonised classification of Carc Cat2 for TiO_2				

2.3.1 Mass applications

Paints

As a white pigment, TiO_2 is by far the most important raw material for paints and coatings. Paint and coating applications for TiO_2 are numerous and diverse and can generally be distinguished between architectural (interior coatings ("wall paints"), façade coatings and wood and "trim" coatings) and industrial (automotive and aerospace, coil coatings, can coatings, UV-resistant coatings etc.). TiO_2 is utilised in either slurry or powder form, in series of unit operations using batch processes. There are few chemical reactions taking place; with the operations being mostly mechanical.

Typical concentrations of TiO_2 in paints are given in Table 2-3.

Table 2–3: Concentration of TiO_2 in paints and industrial coatings	
Application	**Typical TiO_2 concentration (by weight)**
Professional and DIY paints	From 0.1% (varnishes) to 50% (and up to 70% for filling compounds)
General industrial coatings	up to 30%
Anti-corrosion coatings	up to 20%
Automotive refinishing coatings	25%
Eco-friendly natural paints	up to 40%
Wood paints	up to 20%
Road markings	0.2-15%
Source: data from consultation for RPA (2017) and VCI (2016)	

Plastics

According to the European Plastics Converters (EuPC), TiO_2 finds wide use in the plastic conversion industry. The plastics converting area covers a variety of sectors where TiO_2 may be used such as packaging, building and construction, automotive, electric and electronic equipment, medical, household, leisure, footwear, clothes, toys and advertising. TiO_2 can be both mixed with dry resin powder and the liquid containing the plasticiser.

A significant proportion of the TiO_2 used in this sector will not be added directly as a powder but through the inclusion of masterbatches or compounds by the converters. In masterbatch, the TiO_2 is dispersed at high concentrations into a plastic resin, which is then used by plastics converters in film applications, as well as in the manufacture of articles by injection moulding and sheets (plastic containers, bottles, packaging and agricultural films (Kronos Worldwide, 2016)).

The types of polymers that may contain TiO_2 include (RPA, 2017):

- Polyolefin (polyethylene and polypropylene) for blow moulding, blown film, cast film, extrusion coating, high temperature cast film, injection moulding, liquid colourant;
- PVC, mainly for construction applications (interior grid, exterior rigid, flexible, plastisol);
- Engineering plastics for automotive and consumer goods (acrylonitrile butadiene styrene (ABS), polystyrene (PS) and High Impact Polystyrene (HIPS), polycarbonate (PC) and PC blends, polyamide (PA), polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polyphenylene ether (PPE), polyphenylene sulphide (PPS), polysulphone (PES), acrylics (PMA and PMMA), etc,); and
- Composites (EP and UP resin-based materials).

Consultation for the RPA (2017) report indicated the concentrations of TiO_2 reported in Table 2-4.

Table 2-4: Concentration of TiO_2 in plastic applications

Application	Typical TiO_2 concentration (by weight)
Masterbatches	Up to 80%
Plastics (engineering and decorative)	1-10%
uPVC windows	2-4%
PVC plastisol	5%
Packaging films and containers	1-20%

Paper

TiO_2 is mostly used as an opacifier and less frequently for its whitening, brightness and surface finishing properties in:

- Décor paper for laminate flooring and furniture;
- Packaging, including board;
- Printing and writing;
- Wallpapers; and
- Paper filling.

Typical concentrations of TiO_2 in paper applications are shown in Table 2-5.

Table 2-5: Concentration of TiO_2 in paper applications	
Application	**Typical TiO_2 concentration (by weight)**
Décor paper	20-40%
Wallpapers	1-10%
Source: data from consultation for RPA (2017) report.	

Printing Inks

TiO_2 has been used for several decades in toners, inks, backings for inkjet printing substrates, coated layers on specialty foils, and incorporated into PET for some applications (I&P Europe, 2016). Applications of note include (Huntsman, 2016):

- Inks for packaging: white is usually printed as a full layer, either as a first ink layer (surface print) or as a last layer (reverse and lamination) on flexible packaging (plastic or aluminium films). This produces maximum opacity in order to hide the packaged good. The excellent hiding power of TiO_2 is also crucial for barcode scanning, which requires a perfect contrast. Titanium dioxide pigments perform well in flexo, gravure and screen printing with gravure inks, pad printing, inkjet or sheet fed offset applications and are suitable for flexible, paper and card or metal packaging;
- Labels: UV curable printing inks for the narrow to mid–web may contain TiO_2 and are used in self-adhesive labels, wrap around labels, lidding, shrink sleeve, in-mould labelling, etc. Titanium dioxide is used in these applications to produce high opacity white printing inks that allow the conversion of clear/metallic materials;
- Toner: TiO_2 pigments offer free flow and charge control;
- Writing materials and children's modelling materials: including coloured pencils, crayons, finger paints, school tempera paints, lacquers and modelling clays; and
- Inks for textiles and leather: TiO_2 pigments can support the delivery of a strong opaque colour which helps printed textiles stand out.

Typical concentrations of TiO_2 in these applications are provided in Table 2-6.

Table 2–6: Concentration of TiO_2 in inks and related products	
Application	**Typical TiO_2 concentration**
White printing inks	Up to 50-60%, even 70% in dispersions
Printing pastes	White concentrate: 80% Ready-to-use compound: 20-30%
Shaded inks	5-10%
Pencils and similar products	3-35%
Correction fluids	Up to 50%
Artists' and recreation colours	0.1-100%
Toner	1-5%
Erasers	ca. 1%
Source: data from consultation for RPA (2017) report.	

2.3.2 Selected specialty applications

Ceramics

The term "ceramics" is broad and covers a wide range of applications and is interconnected with many other applications, namely pigment manufacture and glass manufacture. In ceramics, the focus is not solely on optical performance, but also chemical purity, reactivity and sintering properties.

Uses may include:

- Pigments: TiO_2 is a key raw material in the manufacture of Complex Inorganic Pigments that find applications in ceramics. These pigments are largely used for yellow and brown colours in the ceramic tile industry;
- Frits, glazes and enamels: a frit is a ceramic composition that has been fused in a special fusing oven, quenched to form glass and granulated. The purpose of this is to render any soluble and/or toxic components insoluble by causing them to combine with silica and other added oxides (a reaction between metal oxides and TiO_2). Titanium dioxide is mainly used as an opacifier in order to obtain the very white opaque frits for the production of porcelain enamels at low temperature. It is also required for: white and pastel flatware, cookware, hollowware; sanitaryware; hot water tanks; silos; ovens and cooker tops; architecture; roof tiles;
- Electroceramics: high purity pigment grades are used in the production of ceramic materials for electronic components, as well as high-quality electroceramics (e.g. capacitors, PTC resistors and piezoceramic elements). TiO_2 may also be used in vitreous enamels for electrodes; and
- Technical ceramics: e.g. medical components (hip or knee replacement) and protection against abrasion (components for textile industry, automotive applications).

Table 2-7: Concentration of TiO_2 in ceramics applications

Application	Concentration of TiO_2
Frits	3-20% (ANFFECC, 2016)
Porcelain enamels	5-25%
Ceramic pigments	5-60% (VCI, 2016; VdMI, 2016; VdMI, 2016b)
Complex Inorganic Pigments	No TiO_2 present

Cosmetics

TiO_2 is currently listed in Annex IV of the Cosmetics Regulation EC 1223/2009 (list of colorants allowed in cosmetic products); and Annex VI (list of UV filters allowed in cosmetic products), as shown in Table 2-8.

Table 2–8: Cosmetics Regulation entries for TiO_2

Annex		Entry No.	Notes
IV	List of colorants allowed in cosmetic products	143	The use if TiO_2 (CI 77891) is allowed in all cosmetic products. Purity criteria as set out in Commission Directive 95/45/EC (E 171) and its amendments

Table 2–8: Cosmetics Regulation entries for TiO_2			
Annex		Entry No.	Notes
VI	List of UV filters allowed in cosmetic products	27	Maximum concentration in ready for use preparation: 25%[4]
VI	List of UV filters allowed in cosmetic products	27a	Titanium Dioxide (nano): Maximum concentration in ready for use preparation: 25%[5]

Specific applications of TiO_2 in cosmetics include:

- Sunscreens: TiO_2 is used as a UV filter in sunscreens and is recognised as safe by the Scientific Committee on Consumer Safety (SCCS) up to a maximum concentration of 25% when applied on healthy, intact or sunburnt skin. Only two mineral UV filters are allowed in cosmetics, TiO_2 and ZnO.
- Colour cosmetics (make up) and skin care products: TiO_2 can confer satiny effects, lustre effects and interference colours when used as a colourant in cosmetics. It is found in products such as foundation and face powder, lipstick, eye shadow and blushers.
- Soaps (liquid and solid), shampoos, shower gels and depilatory products: TiO_2 acts as a pearlescent colourant and exhibits opacifier effects due to its high refractive index.
- Toothpaste: TiO_2 can be used as a white pigment and as an abrasive.
- Hair colour formulation: used as an opacifier.
- Nail polishes: TiO_2 is used as a colourant and opacifier in UV-curing nail polishes and gels. It may also be present in (anaerobic) nail adhesives.

Glass

Titanium dioxide has a wide range of applications in glass, which include:

- Glass with enhanced hardness and higher resistance to abrasion;
- Glass with sun protection properties, good light, anti-reflection and energy performance for window glass in buildings and in cars (TiO_2 is used as a coating, it is not used as a raw material to produce the glass sheet);
- Glass with self-cleaning properties in buildings (TiO_2 is used as a coating, it is not used as a raw material to produce the glass sheet; see photocatalysts, above);
- Radiation protection in the UV range for the pharmaceuticals industry (containers etc.);
- Glass for ophthalmic and optic applications;
- Glass-to-metal-seals for lithium batteries used in medical implantable devices such as pacemakers, heart defibrillators, and neuro-stimulators; and
- Paints and decorating inks used to produce white-colour glass.

The applications are required for medical/public health protection, drug safety (inertness of medical drug containers), eye protection and visual correction, high-end medical applications.

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4 It is understood that in other jurisdictions (e.g. Japan) no upper limit has been established.

5 Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials meeting the characteristics set out in the Regulation are allowed. In case of combined use of Titanium Dioxide and Titanium Dioxide (nano), the sum shall not exceed 25%.

Table 2-9: Concentration of TiO_2 in glass applications	
Application	**Concentration of TiO_2**
Ceramic glass colours	4-20%
Special glass	1-30%

Fibres

Titanium dioxide is used for a number of reasons in fibre applications. Anatase grades may be used for delustering man-made fibres. This is key to the complex production of man-made fibres such as polyester, polyamide, acrylic, viscose, rayon and cellulose acetate fibres. Fibres of variable dullness (which is dependent on the amount of TiO_2 used) may be used in consumer textiles, including high-class, high-fashion textile products of well known fashion brands where dull lustre and handfeel is sought after.

When used as a white pigment, TiO_2 may act as (VCI, 2016):

- A component coating applied to commercial textiles such as those for sun protection (black-out, dim-out)/roller and vertical blinds/decorative textile ceilings;
- A component of printing inks (inkjet, digital printing) and in printing pastes for pigment print;
- A carrier material for biocides;
- A component for the pigmentation of leather (i.e. pigment dispersions in polymer matrices that are sprayed onto leather to produce pigmented leathers).

TiO_2 is used in delustering within the range of 0.1-1.5% with the level depending on the lustre required by end users (CIRFS, 2016).

2.4 Conclusion

Titanium dioxide has a wide range of applications due to its technical specifications. It is widely used in consumer and professional products, with those which consume the greatest amount of TiO_2 being paints and coatings, printing inks, plastics and paper. The key technical performance characteristics for TiO2 applications is outlined in Table 2-10.

Table 2–10: Overview of key technical performance characteristics and advantages of TiO_2 use in its different applications																	
Properties	**Paints and coatings**	**Plastics**	**Paper**	**Inks**	**Construction products**	**Fibres**	**Catalysts**	**Food**	**Pharmaceuticals**	**Cosmetics**	**Elastomers**	**Pigments**	**Ceramics**	**Glass**	**Medical devices**	**Detergents**	**Biocides**
Good hiding power/opacity	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓		
Ability to lighten coloured media	✓	✓		✓	✓			✓				✓					
Base for colour development	✓	✓		✓				✓	✓			✓		✓			
Whiteness and brightness	✓	✓	✓	✓	✓			✓	✓	✓	✓		✓		✓	✓	
Stability to heat, light and weathering	✓	✓	✓	✓	✓	✓		✓			✓	✓					✓
Thermal stability and flame retardancy	✓	✓			✓												
Light reflection	✓	✓								✓							
UV absorbance	✓	✓		✓	✓	✓		✓	✓	✓				✓			
Offers support for catalysts							✓										
Photocatalytic activity	✓													✓			
Approved for use in specific areas		✓						✓	✓	✓							
High efficiency	✓	✓	✓	✓	✓			✓	✓				✓		✓	✓	
Easy dispersion and particle distribution and processability	✓	✓	✓	✓	✓	✓				✓	✓	✓	✓				
Inertness in the presence of other components	✓	✓			✓	✓		✓		✓	✓						
Purity	✓			✓	✓		✓	✓	✓	✓							
Other	✓	✓			✓	✓				✓			✓	✓		✓	✓
Source: RPA (2017)																	

3 Information on Hazard and Risk

3.1 Proposed Harmonised Classification

At present, there is no classification or labelling for TiO_2 included in the current joint REACH registration dossier for TiO_2. Where hazards have been notified to the Classification and Labelling Inventory, these have been notified by non-REACH registrants; in addition, from ECHA's brief profile, it would appear that some of these may relate to "an impurity or an additive present in the substance", with this impacting on the notified classification.

As noted in the Introduction to this RMOA, the French authorities proposed the classification of TiO_2 as a Carc Cat1B substance in May 2016. ECHA's RAC concluded, however, that a Carc Cat 1B classification cannot be scientifically justified, and proposed in its opinion dated 14 September 2017 that TiO_2 be classified as Carc Cat 2 (suspected of causing cancer) specifically through the inhalation route. This classification is linked in particular to respirable particles of TiO_2.

Table 3–1: Table of CLP notifications

	Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
					Hazard Class & Category Code(s)	Hazard Statement code(s)		
Resulting Annex VI entry if agreed by COM	TBD	Titanium dioxide	236-675-5	13463-67-7	Carc. 2	H351 (inhalation)	None	None

3.2 Collection of monitoring data

In 2017, the TDIC asked EBRC to undertake an exposure assessment for TiO_2 in order to update its REACH Chemical Safety Assessment. This work included a survey of both TiO_2 manufacturers, as well as the key downstream user sectors in order to identify exposure hotspots and areas of concern.

In total 94 companies provided data to feed into this process. 280 individual sets of personal exposure monitoring data were provided for workplace and more specific hotspots (e.g. hand-mixing, powder handling, etc.). 842 out of the total 853 data points were considered by EBRC to meet data quality requirements, with these including 722 personal and 120 static monitoring values. 475 of the data points were specific to TiO_2, with 367 being more general to dust exposure. Most of the measurement data are based on inhalable TiO_2 or dust, with roughly one third based on respirable TiO_2 or dust.

Table 3-2 below sets out the workplaces and tasks that are covered by these data.

Table 3–2: Workplaces and tasks reflected in TiO_2 manufacturing and downstream monitoring data

Workplace		Tasks	
Raw material handling	Milling/screening	Powder handling	Hand-mixing
Filtration	Packaging	Spraying application	Cleaning and maintenance
Furnace operation	Cleaning and maintenance	Abrasive tasks	Other
Chloride process	Supervision	Powder processing	Multiple workplaces/tasks
Surface treatment	Other		
Drying			

In addition to the use of the measurement data collected from manufacturers and downstream users, a literature review was also undertaken to gather information on exposure levels and particle/droplet size information for professional uses, in particular in relation to spraying and sanding operations. Over 300 potential titles were identified and screened, with 28 of these retrieved and acting as the starting point for the exposure assessment of such activities.

3.3 Summary of exposure assessment conclusions

In order to carry out the exposure assessment, EBRC established an interim DNEL at 1.3 mg/m^3. This DNEL is considered to represent the threshold for effects, albeit for lung inflammation rather than potential cancer effects (which would occur at a higher level of exposure). However, EBRC also noted that it is likely that if Scientific Committee on Occupational Exposure Limits (SCOEL) or RAC were to recommend an EU-wide limit value they would also identify a threshold value in this range as the most appropriate level for ensuring worker protection.

At this point in time, the exposure assessment has not been finalised. A preliminary assessment was carried out for the purposes of providing input to this RMOA. In undertaking the preliminary exposure assessment, EBRC deliberately did not take account of the use of respiratory protective equipment (RPE; as a result, all of the exposure estimates are likely to be refined when the exposure scenarios are finalised, given the need to demonstrate safe use).

From this work, EBRC identified the following contributing exposure scenarios as being those for which exposure above 1.3 mg/m^3 (respirable fraction) cannot be excluded in a reasonable worst case (RWC) situation for workers in industrial settings:

- Packing of powders (could be assigned to PROC 26) at manufacturing sites: the assessment is based on the 90 percentile (P90) of monitoring data (n=76). The Reasonable Worst Case (RWC) estimate of 1.53 mg/m^3 for the respirable fraction is slightly above the interim DNEL of 1.3 mg/m^3 with a resulting RCR of 1.17;

- Cleaning (could be assigned to PROC 28) at manufacturing sites: the assessment is based on the P90 of monitoring data (n=16). The RWC estimate of 1.91 mg/m^3 for the respirable fraction is slightly above the interim DNEL of 1.3 mg/m^3 with a resulting RCR of 1.47. Wearing of RPE is generally accepted for cleaning activities;

- Milling of powders (could be assigned to PROCs 4, 24, 26) at manufacturing sites: the assessment is based on the P90 of monitoring data (n=16). The RWC estimate of 1.34 mg/m^3 for the respirable fraction is slightly above the interim DNEL of 1.3 mg/m^3 with a resulting RCR of 1.03.

In addition, EBRC found the following for professional exposures (i.e. not in industrial settings):

- Paint spraying professionals (could be assigned to PROC 11): the assessment is currently based on MEASE modelling. It assumes no LEV present, limited exposure duration of 240 minutes, and more than 25% of TiO_2 in spraying suspension. The RWC exposure level was estimated at 12 mg/m^3 resulting in an RCR of 9.23. It needs to be noted that the MEASE estimate is for the inhalable fraction. It should be noted that during the paint manufacturing process TiO_2 is permanently bound into the binder matrix and, depending on the droplet/particle size distribution (PSD), the content of respirable particles in inhalable dust may vary between 2–10 mg/m^3. The RCR would proportionally decrease with an increasing transformation factor. In addition, RPE is generally accepted during paint spraying in professional settings so that the exposure estimate could be lowered in a refined assessment considering RPE.

- Sanding in professional settings (i.e. not in industrial settings – could be assigned to PROC 24): the assessment is currently based on MEASE modelling. No LEV is assumed to be in use and there is more than 25% of TiO_2 in abraded coating. The RWC exposure level was estimated at 3.3 mg/m³ resulting in an RCR of 2.54. It needs to be noted that the MEASE estimate is for the inhalable fraction and that, as previously mentioned, TiO_2 is bound into a matrix during the manufacturing process. Depending on the PSD, the content of respirable particles in inhalable dust may vary between 2–10 mg/m³. The RCR would proportionally decrease with an increasing transformation factor. In addition, RPE is generally accepted during sanding in professional settings so that the exposure estimate could be lowered in a refined assessment considering RPE.

- Hand-mixing (mixing with hand-held tools) of powder in professional settings (i.e. not in industrial settings – could be assigned to PROC 19): the assessment is currently based on MEASE modelling. No LEV is assumed to be present, limited exposure duration of 15 minutes, more than 25% of TiO_2 in powder to be mixed. The RWC exposure level was estimated at 5 mg/m³ resulting in an RCR of 3.85. It needs to be noted that the MEASE estimate is for the inhalable fraction. Depending on the PSD, the content of respirable particles in inhalable dust may vary between 2–10 mg/m³. The RCR would proportionally decrease with an increasing transformation factor. In addition, RPE is generally accepted during paint spraying in professional settings so that the exposure estimate could be lowered in a refined assessment considering RPE.

In providing these preliminary results for use in this RMOA, EBRC note that where the assessment was based on monitoring data (as indicated above), these are reflective of any RMMs that were actually present during monitoring. Thus, assumptions on RMMs are not required for exposure estimation. Although it should also be noted that estimates based on monitoring data are not reflective of any RPE worn, so that such equipment could still be considered in a refined exposure assessment. Only where no monitoring data were available (i.e. in relation to professional exposures), was the MEASE 1 model used to estimate exposure.

4 Relevant EU Legislation

4.1 Introduction

EU legislation regulating the use of and exposure to carcinogens generally does not distinguish between routes of exposure. Therefore, although the French proposal for the classification of TiO_2 specifically indicates that the substance be classified as a carcinogen by inhalation of its powder form and RAC's opinion also recommends a Carc Cat 2 harmonised classification through the inhalation route, the existing regulatory framework does not generally distinguish classification by routes of exposure. As a result, the proposed classification, if implemented, by 'consequent' legislative requirements might not give due regard to the critical route of exposure. Uses of the substance which do not pose any inhalation risk could therefore fall within the scope of the risk management requirements that would arise under downstream legislation within linkages to the CLP Regulation.

It should be clear that, in the vast majority of cases, TiO_2 is used by the end user within a matrix, typically as a pigment in paints, plastics, inks, paper, rubber, construction products, ceramics, dermally applied cosmetics, etc., from which exposure to TiO_2 via inhalation is either impossible or highly improbable. Exposure to TiO_2 powder by inhalation could only reasonably be envisaged when the substance is handled (in its powder form) by manufacturers, industrial users or professional users as a raw material, or potentially via aerosols. Some waste materials that contain TiO_2 might be in a granular or powder form but the substance should not be considered biologically available within such matrices.

An overview of the legal obligations that would be triggered by the proposed harmonised classification of TiO_2 as Carc Cat 2 and its entry onto Annex VI of the CLP Regulation is provided below, with Table 4-1 providing a summary.

Table 4-1: Legislation that links to a Harmonised Classification for Carc Cat 2 under CLP

Relevant legislation	Sector affected
Carcinogens and Mutagens Directive and the Chemical Agents Directive	Multiple
REACH Regulation	Multiple
Waste Framework Directive 2008/98/EC and Regulation 1357/2014 (repealing Annex III of Waste Framework Directive)	Multiple (including manufacturing)
Cosmetic Products Regulation 1223/2009/EC	Cosmetics
Toy Safety Directive 2009/48/EC	Toys
Framework Regulation (EC) No 1935/2004 – Food Contact materials - Plastics in Materials and Articles Regulation EU/10/2011 - - Recycled Plastic Materials and Articles Regulation 282/2008/EC - Active and Intelligent Materials Regulation 450/2009/EC	Plastics, Printing inks Adhesives, Silicones Ceramics, Textiles Rubbers, Varnishes and coatings Glass, Paper and board
Food Additives Regulation 1333/2008/EC Specifications for food additives Regulation 231/2012/EU	Food manufacture; indirect links to cosmetics and pharmaceuticals
Community code for medicinal products for human use Directive 2001/83/EC Medicinal Products for Paediatric Use Regulation 1901/2006/EC Colouring matters in medicinal products Directive 2009/35/EC	Medicinal products
Construction Products Regulation 305/2011/EU	Construction products
Tobacco Products Directive 2014/40/EU Decision (EU) 2016/787	Tobacco Products

4.2 CLP Regulation

Under the CLP Regulation, manufacturers of substances and of mixtures have classification, labelling and packaging obligations which must be fulfilled before placing a substance or mixture on the EU market. These obligations will vary depending on the classification of the substance or mixture being placed on the market.

As TiO_2 is currently unclassified, manufacturers and formulators using TiO_2 currently have no legal obligations in relation to its hazard properties. The proposed harmonised classification would trigger new obligations for its placing on the market as a substance and for all mixtures containing TiO_2 at concentrations above the generic concentration limit for classification purposes. These include:

- Labelling requirements under CLP, which could have significant impacts on consumer perceptions of mixtures and articles containing TiO2, as well as lead to significant costs for mixture manufacturers;
- Packaging requirements under CLP, as the proposed Carc Cat 2 classification would trigger the need for tactile warnings of hazard to be attached to the packaging of consumer mixtures containing TiO_2, with this leading to mixture manufacturers having to change their current packaging; and
- Requirements under CLP to notify information to national Poison Centres where TiO_2 concentrations in mixtures exceed 1.% by weight;

Within the main sectors of use, it is likely that up to 2 million different mixtures might be affected. Based on cost-benefit analysis for the harmonisation of information submitted to poison centres[6], roughly 1.65 million paint and coating mixtures alone could be affected, assuming that a realistic 75% contained TiO_2. For these mixtures, it is highly likely that the labelling and packaging would have to be modified, with this entailing costs not only of new artwork and changes to the packaging, but also the disposal of redundant artwork and packaging (i.e. packaging that does not currently have a tactile warning).

Although there is usually an 18 to 24 month transition period under CLP for manufacturers to make such changes, this may not be possible logistically, given the number of different volumes at which a mixture (e.g. a paint) may be sold, as well as the sheer number of mixtures that have to be addressed.

Although not directly related to CLP, additional measures may be triggered in relation to consumers and to the sale of mixtures classified as CMR. For example, under French national legislation, a CMR 2 classified mixture has to be stored under lock (this provision should shortly be amended to storage in a place not accessible to the public); as a result, such mixtures would be stigmatised as potentially being unsafe.

More generally, there is a concern that widespread labelling of mixtures containing TiO_2 would impact on the effectiveness of CLP labelling requirements due to the large number of products that would be labelled. It may also lead to a stigma being placed on mixtures that pose no risks due to TiO_2 not being available or used in powdered form. This issue is addressed further in Section 6.

[6] http://ec.europa.eu/DocsRoom/documents/14006/attachments/1/translations

4.3 OSH legislation

Occupational Exposure Limits (OELS) for TiO_2 currently exist in several EEA Member States, with examples provided in Table 4-1 below. Even so, the proposed CLH for TiO_2 as a Carc Cat 2 substance may trigger new obligations at the national level. For example, the new classification might result in a tightening of national OELs. It has been suggested that the current OEL in the UK, which is set at 10 mg/m^3, could be reviewed following classification of the substance as a carcinogen, resulting in a lower exposure limit. This could have an impact on the use of dry TiO_2 pigment in downstream facilities in terms of LEV and PPE provision, and in terms of monitoring worker exposure. The same would be true in other Member States if they revised their national OELs downwards.

Table 4–2: Example national OELs for TiO_2 in Europe		
Country	**OEL in mg/m^3**	**Notes**
Belgium	10	
Denmark	6	Total dust
France	11	Inhalable aerosol
Germany	1.25	Respirable fraction
Ireland	10	Inhalable : 4 mg/m^3 for respirable
Latvia	10	
Poland	10	
Portugal	10	
Spain	10	Inhalable aerosol
Sweden	5	Inhalable aerosol
Switzerland	3	Respirable aerosol
United Kingdom	10	Inhalable fraction Limit is 4 mg/m^3 for respirable fraction
Source: GESTIS (available at http://limitvalue.ifa.dguv.de/, accessed on 18 September 2017)		

With respect to regulation under EU legislation, SCOEL has considered an OELV for TiO_2 and reached a preliminary opinion that a value of 1–2 mg/m^3 would be warranted[7] (with this being lower than all of the national OELs listed in Table 4-1). This could provide the basis for the introduction of a Indicative OELV under the Chemical Agents Directive. Although this could be linked to the harmonised classification for the substance, it should not be assumed that it would be a direct consequence of a harmonised classification (i.e. an OELV under the CAD would not be automatically triggered).

In addition, the harmonised classification would trigger obligations under the Carcinogens and Mutagens Directive (CMD - 2004/37/EC) for employers to conduct risk assessments and to adopt appropriate worker health protection measures, following the hierarchy of measures set out in the CMD.

7 Based on the minutes of the 86th SCOEL meeting.

4.4 Cosmetic Products Regulation

TiO_2 is included in three 'positive lists' of the Cosmetics Regulation:

- Annex IV (List of colourants allowed in cosmetic products), entry 143; and
- Annex VI (List of UV filters allowed in cosmetic products) entries 27 and 27a with a concentration limit of 25%.

As a Carc Cat 2, TiO_2 would be banned in cosmetic products unless they have been evaluated and found safe by the Scientific Committee on Consumer Safety (SCCS) for use in cosmetic products. This must take into account exposure to these products, overall exposure from other sources and vulnerable population groups. Note that the Scientific Committee on Cosmetic Products and Non-Food Products (SCCNFP) is of the opinion (SCCNFP Opinion 0005/98) that TiO_2 is safe for use in cosmetic products at a maximum concentration of 25% in order to protect the skin from certain harmful effects of UV radiation. This opinion concerns crystalline (anatase and/or rutile) TiO_2, whether or not subjected to various treatments (coating, doping, etc.), irrespective of particle size, provided only that such treatments do not compromise the safety of the product. The SCCNFP proposes no further restrictions or conditions for its use in cosmetic products.

In addition, in April 2014, the SCCS concluded Opinion 1516/13 that the use of nano-scale TiO_2 with the characteristics as indicated below, at a concentration up to 25% as a UV-filter in sunscreens, can be considered to not pose any risk of adverse effects in humans after application on healthy, intact or sunburnt skin.

This, however, does not apply to applications that might lead to inhalation exposure to TiO_2 nanoparticles (such as powders or sprayable products) (Scientific Committee on Consumer Safety, 2014). As of November 2016, two further TiO_2-related opinions are pending, with one of these on coatings for nano-scale TiO_2 used as a UV filter in dermally applied cosmetic products (SCCS positive draft opinion published and submitted to public consultation – the SCCS considers that the use of the three TiO_2 nanomaterials coated with either cetyl phosphate, manganese dioxide or triethoxycaprylylsilane, can be considered safe for use in cosmetic products intended for application on healthy, intact or sunburnt skin).

4.5 Toy Safety Directive

Under the Toy Safety Directive (2009/48/EC), there would be a prohibition of the use of TiO_2 in toys, in components of toys or in micro-structurally distinct parts of toys, unless derogated by the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) due to demonstrable evidence that exposure of children will be sufficiently low/zero. Exceptions can be made when the substances or mixtures are inaccessible to children in any form, including inhalation, when the toy is used as intended, or a decision has been taken to "permit" the use of the substance and/or mixtures; in addition, the substance or mixture should not be prohibited for use in consumer articles under the REACH Regulation.

SCHEER must provide their opinion on the use of CMR in toys following the same rules of procedure as the SCCS (in relation to cosmetics). Under Article 46(3) the formal decision on the authorisation of CMRs in toys is taken by the Commission after they have been evaluated by SCHEER (the relevant scientific committee). The resulting measures are adopted in accordance with the regulatory procedure with scrutiny, with the timeframe for SCHEER opinion decided upon by the Chairman of the Committee. As a result, any revisions to the EN Standard EN71, which sets out the requirements that toys must meet in order to be sold in the EU, may take some time before potentially including TiO_2.

4.6 Food and Feed Additives

4.6.1 Food additives

In the EU, TiO_2 (E171) is listed in Annex I of Directive 94/36/EEC as a permitted colour in foodstuff and it is presumed safe. E171 is accompanied by specific purity criteria (Commission Regulation (EU) No 231/2012) and its use is authorised by Regulation (EC) No 1333/2008 on food additives. A recent EFSA opinion on the re-evaluation of its safety for use as a food additive, published on 14 September 2016 concluded that available data on TiO_2 in food, do not indicate health concerns to consumers (EFSA, 2016).

EU legislation regulating the use of and exposure to carcinogens generally does not distinguish between routes of exposure. Therefore, although RAC's opinion recommends a Carc Cat 2 harmonised classification through the inhalation route, the existing regulatory framework will not distinguish classification by routes of exposure. As a result, the proposed classification, if implemented, by 'consequent' legislative requirements might not give due regard to the critical route of exposure.

The proposed CLH as Carc Cat 2 would trigger the following new legal obligations:

- Labelling and packaging requirements under CLP, which could have significant impacts on consumer perceptions of mixtures and articles containing TiO_2;
- Requirements under CLP to notify information to national Poison Centres where TiO_2 concentrations exceed 1.% by weight;
- Obligations under the Carcinogens and Mutagens Directive (2004/37/EC) for employers to conduct risk assessments and to adopt appropriate worker health protection measures;
- Removal from the list of permitted colours in food stuffs.

Table 4-3: Summary of EU/EC regulations relating to food	
Regulation (EC) No 1333/2008	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF
Regulation (EU) No 231/2012	laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0231&from=EN
Regulation (EC) No 1272/2008	classification, labelling and packaging of substances and mixtures http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF
Regulation (EC) No 178/2002	
Regulation (EU) No 257/2010	EU food additive re-evaluation programme
Directive 94/36/EC	Colours for use in foodstuffs

Label elements for carcinogenicity

Classification	Category 1A or Category 1B	Category 2
GHS Pictograms		
Signal Word	Danger	Warning
Hazard Statement	H350: May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	H351: Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
Precautionary Statement Prevention	P201 P202 P281	P201 P202 P281
Precautionary Statement Response	P308 + P313	P308 + P313
Precautionary Statement Storage	P405	P405
Precautionary Statement Disposal	P501	P501

4.6.2 Animal feeds

With respect to animal feeds, no feed additive can be placed on the market, processed or used if it is not authorised in accordance with Regulation 1831/2003 and the conditions for use and labelling are met. TiO_2 is currently listed in Annex I under Category 2 (colourants), Functional Group a with the entry: "*Titanium dioxide (anatase & rutile structure) as colouring agents authorised for colouring foodstuffs by Community rules [Dogs; Cats]*".

4.7 Food contact legislation

The continued use of TiO_2 in food contact materials would depend on actions taken under the relevant legislation: Regulation (EC) No 1935/2004; Regulation (EC) No 2023/2006; Regulation EU/10/2011; Regulation 282/2008/EC; and Regulation (EC) No 450/2009. This may include a ban on use, for example, because substances classified as carcinogenic should not be used in food contact materials and cannot be listed in the Union List.

At present TiO_2 appears in List 1 of approved additives under Council of Europe (CoE) Resolution ResAP(2004)1 on coatings intended to come into contact with foodstuffs. It is understood however that a Draft CoE/EDQM General Resolution is in preparation which will (once approved) be overarching across all existing Coe/EDQM Resolutions and guides; it is expected that this General Resolution would require that all CMR additives demonstrate zero transfer into foodstuff. It would therefore appear that a harmonised Carc Cat 2 classification might generate the need to demonstrate zero migration from coatings so that the use of TiO_2 in food contact material coatings could be approved under national legislation implementing the CoE Resolution. This could ultimately result in the listing (approval) of TiO_2 in food packaging materials, being reviewed.

It is also worth noting that coated and printed plastic food contact materials and articles are covered by the scope of European Regulation (EU) 10/2011. Plastics held together by adhesives are also covered by its scope. However, substances used only in printing inks, adhesives and coatings are not included in the Union list because these layers are not subject to the compositional requirements of the Plastics Regulation. The only exceptions are substances used in coatings which form gaskets in closures and in caps. The requirements for printing inks, adhesives and coatings are intended to be set out in separate specific Union measures. Until such measures are adopted, they are covered by national law. If a substance used in a coating, a printing ink or an adhesive is listed in the EU list, the final material or article has to comply with the migration limit of this substance, even if the substance is used in the coating, printing ink or adhesive only. Even though colourants fall under the definition of additives, they are not covered by the Union list of substances. Colourants used in plastics are covered by national measures and are subject to risk assessment in line with Article 19 of the EU List Regulation (RPA, 2017).

Pending the adoption of more specific EU measures, food contact materials must comply with any relevant national legislation in different EU Member States. Literature suggests that specific pieces of national legislation on different types of materials are currently in place in 19 EU Member States (Baughan, 2015). Member States such as Finland and the Netherlands, for example, maintain national requirements for paper and board, while Germany has established Recommendations concerning paper and board for different end-uses (e.g. baking and filter papers). On 25 September 2016, the Belgian Federal Public Service (FPS) Public Health and Safety of the Food Chain and Environment released a Royal Decree on varnishes and coatings intended to come into contact with foodstuffs, which was planned to come into force on 1 January 2017. According to the decree, the following substances can be used intentionally to make coatings intended for food contact: those substances listed in Annex I to Regulation (EU) No 10/2011 on plastics, those approved by a Member State, those approved by the European Food Safety Authority, those that do not migrate to a detectable amount in the food, and those that are not classified as CMR, and are not in nano-form (Food Packaging Forum, 2016).

More generally, national regulations with respect to food contact materials may include positive lists for substances, impurity specifications, and sanctioned test methods. For Member States without specific requirements for paper and board (e.g., the United Kingdom, Denmark, and Sweden), such materials are required to be safe, which can be established through references to national positive listings, EU Directives, evaluations by the EU Scientific Committee on Food (now the European Food Safety Agency), clearances in other jurisdictions (e.g., clearances under the U.S. Food and Drug Administration's food additive regulations), and CoE Resolutions (Misko, 2004).

TiO_2 is also present in Annex III (Incomplete List of Additives) of the "CEPE Code of Practice for Printed Articles Where the Food Contact Layer is a Coating" without any limitation on migration or other use condition; the harmonised classification of TiO_2 would not have any immediate impact under the CEPE Code of Practice, unless EFSA took the decision to review/revoke the authorisation of the substance. Such a development would then be mirrored under the CEPE Code of Practice (RPA, 2017).

Whilst Carc Cat 2 substances fall outside the scope of the EuPIA Exclusion Policy on printing inks, a specific CoE Resolution (Resolution ResAP (2005)2 on "Packaging Inks Applied to the Non-Food Contact Surface of Food Packaging" makes specific reference to CMR 1A/1B/2 classifications falling within the exclusion criteria listed in the accompanying Technical Document 1. As such, implementation of the Resolution would mean that inks classified as Carc Cat 2 could no longer be used for non-food contact on food packaging. While CoE Resolutions are not legally binding, they are considered as statements of policy for national policy makers of the Partial Agreement Member States. (RPA, 2017).

4.8 Colouring Matters for Medicinal Products

Regulation 1901/2006 on medicinal products for paediatric use includes a Commission Statement requesting the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) to draw up an opinion on the use of CMR substances as excipients of medicinal products for human use, on the basis of Articles 5(3) and 57(1)(p) of Regulation (EC) No 726/2004.

The CHMP has stated that: "*In the event that CMR toxicity has been identified for an excipient, the rule is to avoid and replace this excipient. In the rare cases where this would not be possible, the use of such CMR excipients in a medicinal product would only be considered after careful evaluation of the benefits of the medicinal product in the target patient population versus the potential risks (…) any risk identified for an excipient and in particular a CMR substance, would be acceptable only on condition that this excipient cannot be substituted with a safer available alternative, or that the toxicological effects in animal models are considered not relevant for humans (e.g. species specific, very large safety ratio), or where the overall benefit/risk balance for the product outweighs the safety concern with the product. Overall, the use of any excipient with a known potential toxicity, and which could not be avoided or replaced, would only be authorised if the safety profile was considered to be clinically acceptable in the conditions of use, taking into account the duration of treatment, the sensitivity of the target population and the benefit-risk ratio for the particular therapeutic indication*" (Cosmetics Europe, 2016)[8].

In addition, Directive 2009/35/EC requires that colouring matters used to colour medicinal products for human and veterinary use must abide by the rules on colouring matters in Annex II to Regulation (EC) No. 1333/2008 and Regulation 231/2012 (that has repealed Directive 95/45/EC) laying down the specific purity criteria concerning colours for use in foodstuffs apply to medicinal products. A Carc Cat 2 classification could result in the review and potential de-authorisation of TiO_2.

4.9 Construction Products

Under the Construction Products Regulation (EU) 305/2011, the manufacturer must draw up a Declaration of Performance (DoP) when placing on the market a construction product which is covered by a harmonised standard, or for which a European Technical Assessment has been issued. A copy of the DoP must be further supplied with every product which is made available on the market. The Regulation also provides in Article 6(5) that the information referred to in Article 31 (requirements for safety data sheets), or Article 33 (duty to communicate information on substances in articles), of REACH shall be provided together with the DoP. This information therefore accompanies the construction product in all steps of the supply chain up to the final end user (contractor, worker and consumer). If a Category 2 Carcinogen is present in a mixture at a concentration ≥0.1%, then a SDS must be available upon request (as per Note 1 under Table 3.6.2 of the CLP Regulation).

8 Interestingly, the opinion also states, "*For non-genotoxic rodent carcinogens (which are known to be around 50% of molecules tested in life span rodent carcinogenicity studies) only those for which the mechanism of tumorigenesis (including the route of administration) has been identified as relevant for man, should be carefully considered before a decision is taken to include them in a pharmaceutical product. It is important to highlight that many of the substances positive in the carcinogenicity studies are specific rodent carcinogens with no relevance to humans. In addition, the 'safety ratios' (e.g. the relation between the exposures that were tumorigenic in rodents and those to be reached in patients) should be taken into consideration*" (European Medicines Agency, 2007).

4.10 Tobacco Products

Directive 2014/40/EU sets out additional enhanced reporting obligations for additives included in a priority list in order to assess, inter alia their toxicity, addictiveness and CMR properties, including in combusted form. Manufacturers or importers need to prepare reports on the available scientific literature on the effects of each listed additive. This is then used by the Commission and Member States when taking decisions pursuant to Article 7, including a prohibition on the marketing of tobacco products containing additives that have CMR properties in unburnt form or increase the CMR properties of a tobacco product at the stage of consumption to a significant or measurable degree. Decision (EU) 2016/787 sets out the priority list of additives and adds TiO_2 into the list. The Decision applies from 1 January 2017 and manufacturers and importers will be required to submit enhanced reports in respect of the first set of identified additives by 1 July 2018.

4.11 Waste

The proposed CLH as Carc Cat 2 would trigger new legal obligations under Directive 2008/98/EC, Regulation 1357/2014, and Decision 2000/352/EC (as amended by Decision 2014/955/EU) regarding the classification of waste as hazardous for both manufacturers and downstream users of TiO_2. The most significant of these is by far Directive 2008/98/EC – the Waste Framework Directive, which is the primary legislative instrument in the European Union on waste. See also Table 4-4 below.

Under Directive 2008/98/EC, when a waste contains a substance classified as a carcinogen under CLP and exceeds or equals one of the concentration limits shown in Table 6 of the Annex, the waste will be classified as hazardous by HP 7. The criteria of Annex III of the Directive would apply only to 'mirror' entries in the List of Waste established by Decision 2000/352/EC, not the entries classified as 'absolute non-hazardous' or 'absolute hazardous'. A Carc Cat 2 classification for titanium dioxide would mean any concentration that exceeds 1.0% would render any TiO_2-containing waste hazardous.

However, under Article 7(3) of Directive 2008/98/EC, where a Member State has evidence to show that specific waste that appears on the list as hazardous waste does not display any of the properties listed in Annex III, it may consider that waste as non-hazardous waste. The Member State shall notify the Commission of any such cases without delay and shall provide the Commission with the necessary evidence. In the light of notifications received, the list shall be reviewed in order to decide on its adaptation. Under the WFD, there is an obligation to provide evidence for the tracking of the waste according to the system of the relevant Member State (Article 17).

Table 4-4: Relevant European waste legislation

Law	Description
Relevant legislation	Directive 2008/98/EC (Waste Framework Directive) Regulation 1357/2014 Decision 2000/352/EC (as amended by Decision 2014/955/EU Basel Convention
Directive 2008/98/EC (Waste Framework Directive)	This directive sets out the properties that render wastes hazardous in Annex III. When a waste contains a substance classified as a carcinogen under CLP and exceeds or equals one of the concentration limits shown in Table 6 of the Annex, the waste will be classified as hazardous by HP 7. The criteria of Annex III of the Directive would apply only to 'mirror' entries in the List of Waste established by Decision 2000/352/EC, not the entries classified as 'absolute non-hazardous' or 'absolute hazardous'.

Table 4-4: Relevant European waste legislation	
Law	**Description**
	A Carc Cat 2 classification for titanium dioxide would mean any concentration that exceeds 1.0% would render any TiO_2-containing waste hazardous. However, under Article 7(3) of Directive 2008/98/EC, where a Member State has evidence to show that specific waste that appears on the list as hazardous waste does not display any of the properties listed in Annex III, it may consider that waste as non-hazardous waste. The Member State shall notify the Commission of any such cases without delay and shall provide the Commission with the necessary evidence. In the light of notifications received, the list shall be reviewed in order to decide on its adaptation. Under the WFD, there is an obligation to provide evidence for the tracking of the waste according to the system of the relevant Member State (Article 17).
Regulation 1357/2014	Concentrations for the definition of waste as hazardous are as above. This regulation outlines the update from DSD and DPD to CLP.

5 Alternatives

5.1 Introduction

TiO_2 is the universal choice for white pigments, known as Pigment White 6 (PW 6). As a pigment, it is used primarily to scatter light as it absorbs almost no incident light in the visible region of the spectrum.

As a result of its technical performance and availability, TiO_2 is suitable for almost every application, while all of the possible alternatives have disadvantages. Zinc compounds, such as zinc oxide and zinc sulphide (lithopone), carbonates and other mineral compounds, such as kaolin and talc, find extensive use in the same applications as TiO_2. Many of these pigments are mineral fillers that may be suitable as extender pigments, however, they may not be able to fully replace TiO_2 in an application.

In addition, TiO_2 holds approvals which other pigments do not. For instance, TiO_2 is the only white pigment which is allowed for use as a colouring agent in pharmaceuticals. Whilst for foodstuffs, calcium carbonate (E170) is also an approved colourant (the only other approved white colourant), it is used in different applications to TiO_2. Any potential alternative pigment, if there is one to be found, would have to go through the long authorisation process for food additives.

If TiO_2 is classified as a Carc Cat 2 then there will be a need to substitute it in a number of applications. It may be technically possible to replace TiO_2 on a case-by-case basis, particularly if the technical requirements of an application are not stringent, but there is concern in relation to the level of opacity and hiding power required. If an alternative is used, then it may be the case that increased loadings will be required, which would reduce the cost-efficiency of an alternative in comparison with TiO_2. When considering an alternative for TiO_2, it is important to consider the technical function (opacity, hiding power, refractive index), availability and hazard profile.

The remainder of this section draws extensively on information and analysis reported in the more detailed study undertaken by RPA for the TDIC[9], with this drawing together information for consultation and a range of published sources. For the sake of brevity, these other sources are not repeated here. Other references used for the purposes of this RMOA are indicated in the discussion that follows.

5.2 Technical feasibility

Technical feasibility is one of the key factors determining whether or not a potential alternative is suitable for replacing TiO_2 in an application.

Of most importance in assessing technical feasibility is consideration of the refractive index of alternative pigments, as this is one of TiO_2's most important technical functions, and is the function central to its mass applications. There are three mechanisms for scattering light: reflection from the surface of the crystal; refraction within a crystal; and diffraction. It is possible to maximise refraction

9 RPA (2017): Analysis of the socio-economic impacts of a harmonised classification of carcinogen category 2 for titanium dioxide (TiO_2)

and reflection by increasing the refractive index of the pigment and that of the polymer matrix or other material in which it is dispersed[10].

For white pigments, the higher the refractive index the greater the opacity of the white coating due to high light scattering properties. TiO_2 has the highest refractive index of all known white pigments, as illustrated in Figure 5-1. Rutile TiO_2 has a refractive index exceeding 2.7. This is considerably higher than other pigments available on the market: Zinc oxide (ca. 2); lithopone, kaolin, chalk and talc (<2). Extender pigments have a relatively low refractive index of ca. 1.5 and so cannot meet the requirements for TiO_2 applications on their own. The surrounding medium has a large impact on the light scattering effect and consequent opacity. If the surrounding medium is air with a refractive index of 1.0, the difference in the two index values produces substantial light scattering, so that extender pigments appear white. However, when such alternative pigments are dispersed in other media, e.g. a paint binder which itself has a refractive index of ca. 1.5, they scatter light very poorly and appear much more transparent.

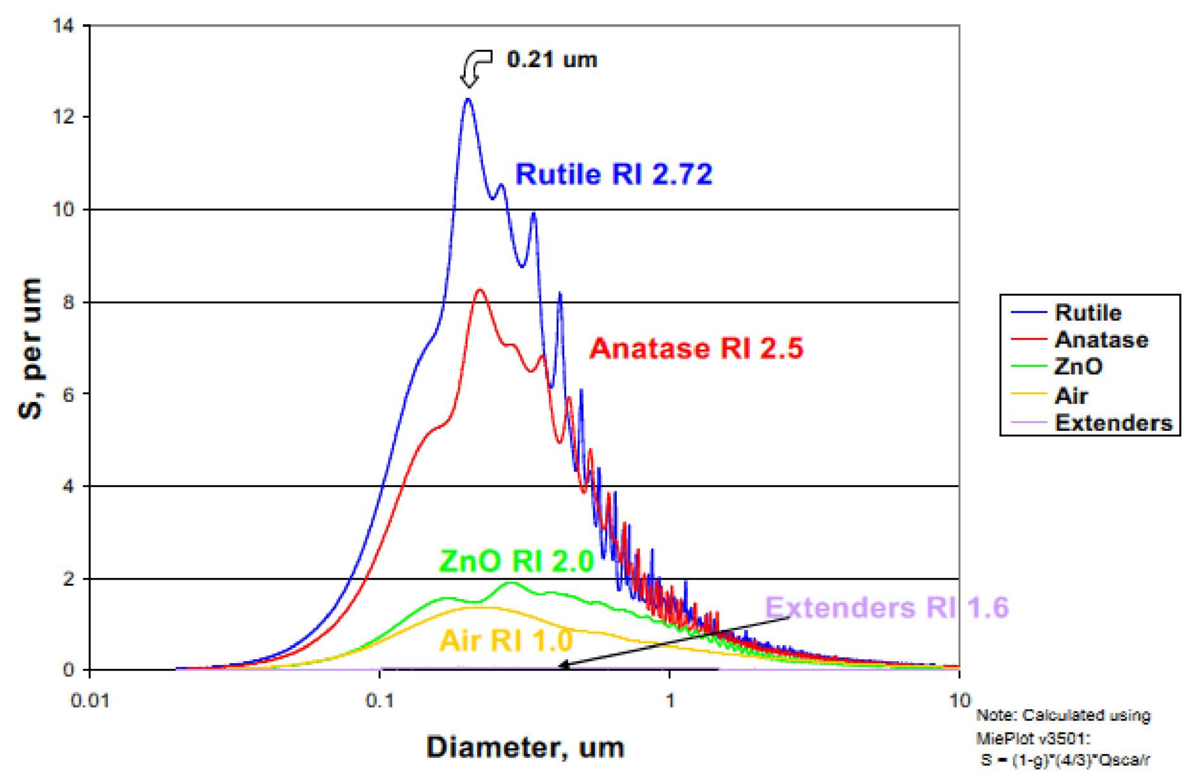

Figure 5–1: Pigment scattering coefficients of TiO_2 and selected alternatives
Source: (Crowther & Johnson, undated)

It has been observed that "*to obtain the same effect in pigmented materials with alternative substances such as zinc oxide, aluminium oxide or barium sulphate, 4 to 6 times as much pigment (ZnO) or 10 to 14 times as much pigment (Al_2O_3 and $BaSO_4$) would need to be added, amounts which are so high that the high pigment concentration results at one hand in a loss again in scattering properties because of 'crowding' at the percolation point and at the other in a loss in physical*

[10] Gázquez, M. J., Bolívar, J. P., Garcia-Tenorio, R. & Vaca, F., (2014): A Review of the Production Cycle of Titanium Dioxide Pigment. Materials Sciences and Applications, Volume 5, pp. 441-458.

performance of the product (due to loss in mechanical strength of the pigmented matrix or viscosity increased or solidification of liquid products)"[11].

A simple test can be used to ascertain a pigment's potential hiding power, whereby the pigment is tinted with a standard black pigment and assessed using an arbitrary scale. The tinting strength for rutile TiO_2 pigments range between 1,550 and 1,850, whilst anatase TiO_2 pigments range between 1,150 and 1,350. As can be seen from Table 5-1, the closest alterative pigment is zinc sulphide, although this has only half the hiding power of rutile[12]. The lower hiding power of TiO_2 alternatives could be combatted by deposition of thicker layers. This method does have its drawbacks as thicker layers can be more difficult to dry/cure and the functionality may be compromised. This would have an impact on all coating operations but is of particular concern for printing processes.

TiO_2 not only has good hiding power and opacity, it also has excellent resistance to chemical attack, good thermal stability and resistance to ultraviolet (UV) degradation. For paints, plastics and inks, particularly those exposed to outdoor conditions, rutile pigment is the preferred option as it is more resistant to UVB light than anatase. In comparison, anatase is less abrasive and is mainly used for indoor paints and paper, ceramics, rubber and fibre manufacture.

As illustrated by the data set out in Table 5-1, there is currently no alternative pigment to TiO_2 that can match its opacity, hiding power, cost-efficiency, inertness or weatherability. Extender pigments may also have an adverse effect on the physical properties of matrices such as paints, such as the consistency, gloss[13], stability and scrub resistance[14].

Food and feed

The technical characteristics of TiO_2, that lend it to use in foodstuffs are (RPA, 2017):

- **High opacity**: alternatives are needed in much higher quantities;
- **Whiteness and brightness;**
- **Base for other colours**: can be used to separate layers of colour;
- **Lustre and glitter**: In conjunction with E555, TiO_2 is used to produce 'glitter' powders which are used as decorations for baked goods;
- **Stability to heat, light and weathering**: reducing risk of food spoiling;
- **Inert in the presence of other foods**: TiO_2 does not react with other substances present in foods (e.g. food acids) and will withstand cooking and baking unchanged; and
- **Purity.**

There is no other white colourant approved under Regulation 1333/2008 that meets the performance of TiO_2 and so reformulation is not feasible. Calcium carbonate (E170) is the only other white additive, but it does not have the opacity of TiO_2 and has severe technical limitations (RPA, 2017):

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[11] I&P Europe (2016) Comments made to the public consultation of the TiO_2 CLH dossier. Available at: https://echa.europa.eu/documents/10162/48252319-d727-42aa-8b3e-bb97cb218f0e

[12] Gázquez, M. J., Bolívar, J. P., Garcia-Tenorio, R. & Vaca, F. (2014) A Review of the Production Cycle of Titanium Dioxide Pigment. Materials Sciences and Applications, Volume 5, pp. 441-458.

[13] Zorll, U. (2000) European Coatings Handbook, Hannover: Curt R. Vincenzt Verlag.

[14] Karakaş, F., Hassas, B. V. & Çelik, M. S. (2015) Effect of precipitated calcium carbonate additions on waterborne paints at different pigment volume concentrations. Progress in Organic Coatings, Volume 83, pp. 64-70.

- It is a much less effective white colour than TiO_2. There are applications where the layer thickness of a print on a foodstuff (for instance, prints on dark and milk chocolate) is too thin to enable any other product to be opaque enough (and white/neutral in colour) in order to have a clear visual effect;
- It will readily react with any acids present in foods to generate carbon dioxide and a (possibly soluble) calcium salt with no white colouring properties;
- It could not be used as a colour in any foods with low pH as it would neutralise the acid present, adversely affecting the product flavour, quality and possibly shelf life;
- It could not be used as a white colour in cake batters, scone doughs, etc. since it would interfere with the raising agent system;
- It could not be used as a replacement to produce white glitter powders since E555 (Potassium aluminium silicate - mica) is only authorised for use as a carrier for TiO_2 (and E172 iron oxides which produce red/brown colour glitter powders).

5.3 Availability of alternatives

One way to determine the availability of alternatives in comparison with TiO_2 is to compare the registration tonnages. As can be seen from Table 5-3, very few pigments are available in similar quantities to TiO_2, meaning that it may not be physically possible to replace TiO_2 in all applications whether or not the technical functions are suitable. Pigments such as zinc oxide and lithopone may be suitable for replacing TiO_2 in some cases but the global market for these substances is ca. 15–23 times smaller than TiO_2[15]. The only substances that are within the same registration tonnage band are: chalk; precipitated chalk; alumina blanc fixe; aluminium hydroxide; and gibbsite.

With respect to food, any alternative would have to go through the long authorisation process for food additives, involving a Scientific Opinion on its safety from EFSA, authorisation by the European Commission and an implementing Regulation to amend Regulation EC No 1333/2008. This process would take years.

[15] RPA (2017): Analysis of the socio-economic impacts of a harmonised classification of carcinogen category 2 for titanium dioxide (TiO_2), Final report prepared for the TDMA.

Table 5-1: Technical feasibility							
Colour Index generic name	C.I. Common or Historical Name	Chemical composition	Density	Refractive Index	Opacity 1 = opaque 4 = trans	Light fastness I = excellent IV= fugitive	REACH registration tonnage (t/y)
PW1	Lead white	Basic lead carbonate CAS No: 1319-46-6	6.70-6.86	1.94 - 2.09	1-2	I	10-100
PW2	Lead sulphate white	Basic lead sulphate CAS No: 12397-06-7			2	I	Not registered
PW3	Basic lead sulphate white	Lead sulphate CAS No: 7446-14-2	6.12-6.39	1.878; 1.883; 1.895	2	I	Intermediate only
PW4	Zinc oxide white	Zinc oxide CAS No: 1314-13-2 CAS No: 91315-44-5	5.47-5.65	2.00 - 2.02	2	I	100,000 – 1,000,000 Not registered
PW5	Lithopone	Barium sulphate (28 - 30%) and zinc sulphide (68 - 70%) with trace amounts of zinc oxide CAS No: 7727-43-7 CAS No: 1314-98-3	4.3	2.3 (ZnS); 1.64 ($BaSO_4$)	1-2	I	10,000 – 100,000 100,000 – 1,000,000
PW6	Titanium white (Rutile)	Titanium dioxide: CAS No: 13463-67-7	3.75-4.3	2.71 - 2.72	1	I	1,000,000 – 10,000,000
PW6	Titanium white (Anatase)	Titanium dioxide: CAS No: 13463-67-7	3.9	2.54 - 2.55			
PW7	Zinc sulphide white	Zinc sulphide CAS No: 1314-98-3			1-2	I	100,000 – 1,000,000
PW8	Strontium sulphide	Strontium sulphide CAS No: 1314-96-1			-	-	10,000 – 100,000
PW10	Barium carbonate	Barium carbonate CAS No: 513-77-9	4.3	1.529; 1.676; 1.677	3	-	100,000 – 1,000,000
PW11	Antimony white	Diantimony trioxide CAS No: 1309-64-4	5.67-5.75	2.18 - 2.35	1	I	10,000+
PW12	Zirconium oxide	Zirconium oxide CAS No: 1314-23-4	2.40	2.16	-	-	10,000 – 100,000
PW13	Barium tungstate	Barium wolframate CAS No: 7787-42-0			-	I	Not registered

Table 5-1: Technical feasibility							
Colour Index generic name	C.I. Common or Historical Name	Chemical composition	Density	Refractive Index	Opacity 1 = opaque 4 = trans	Light fastness I = excellent IV= fugitive	REACH registration tonnage (t/y)
PW14	Bismuth oxychloride	Bismuth chloride oxide CAS No: 7787-59-9			-	-	Not registered
PW15	Tin oxide	Tin dioxide CAS No: 18282-10-5			1	I	1,000 – 10,000
PW16	Lead silicate	Lead monosilicate CAS No: 10099-76-0			1	-	Not registered
PW17	Bismuth subnitrate	Basic bismuth nitrate CAS No: 1304-85-4			1	II	100 – 1,000
PW18	Chalk	Natural calcium carbonate with magnesium carbonate as an impurity CAS No: 471-34-1 CAS No: 546-93-0	2.7-2.95	1.486 (1.510); 1.645	1-4	I	1,000,000 – 10,000,000 1,000+
PW18	Precipitated chalk	Pure calcium carbonate CAS No: 471-34-1			1-4	I	1,000,000 – 10,000,000
PW18:1	Dolomite	Calcium magnesium carbonate CAS No: 83897-84-1			1-4	I	100,000 – 1,000,000
PW19	Kaolin	White clay rock, mostly natural hydrated aluminium silicate with impurities of magnesium, iron carbonates, ferric hydroxide, mica, quartz-sand, etc. CAS No: 1332-58-7	2.16-2.63	1.558; 1.565; 1.564	1-4	I	100,000 – 1,000,000
PW20	Mica	Hydrous aluminium potassium silicate	1.58-1.61	1.56 - 1.60/61	4	I	Annex V exemption

Table 5-1: Technical feasibility							
Colour Index generic name	**C.I. Common or Historical Name**	**Chemical composition**	**Density**	**Refractive Index**	**Opacity 1 = opaque 4 = trans**	**Light fastness I = excellent IV= fugitive**	**REACH registration tonnage (t/y)**
		CAS No: 12001-26-2					
PW21	Barium sulphate (synthetic)	Synthetic barium sulphate CAS No: 7727-43-7	4.3-4.6	1.636; 1.637; 1.648	2-3	I	10,000 – 100,000
PW22	Barytes (natural barium sulphate)	Natural barium sulphate CAS No: 7727-43-7			2-3	I	10,000 – 100,000
PW23	Alumina blanc fixe	Aluminium hydrate, barium sulphate; coprecipitate of ca. 25% aluminium hydroxide and 75% barium sulphate CAS No: 21645-51-2 CAS No: 7727-43-7			-	I	1,000,000 – 10,000,000 10,000 – 100,000
PW24	Aluminium hydroxide	Aluminium hydroxide CAS No: 21645-51-2	2.42-2.45	1.568 - 1.587	3-4	I	1,000,000 – 10,000,000
PW24	Gibbsite (natural form of aluminium hydroxide)	Natural aluminium hydroxide with varying amounts of basic aluminium sulphate CAS No: 21645-51-2			4	I	1,000,000 – 10,000,000
PW25	Gypsum	Hydrated calcium sulphate CAS No: 91315-45-6 CAS No: 10101-14-4	2.32-2.36	1.520; 1.523; 1.530	1-3	I	Annex V exemption
PW26	Talc	Mixed hydrated silicate of magnesium with varying impurities of calcium, iron and other compounds	2.5-2.8	1.539; 1.589; 1.589	1-3	I	Annex V exemption

Table 5-1: Technical feasibility							
Colour Index generic name	C.I. Common or Historical Name	Chemical composition	Density	Refractive Index	Opacity 1 = opaque 4 = trans	Light fastness I = excellent IV= fugitive	REACH registration tonnage (t/y)
		CAS No: 14807-96-6 CAS No: 8005-37-6					
PW27	Silica	Two types: Hydrous = diatomaceous earth; Anhydrous = silica Silicon dioxide CAS No: 7631-86-9	2.2-2.65	1.40 - 1.55	1-4	I	Annex V exemption
PW28	Calcium silicate	Calcium metasilicate; Calcium silicate; CAS No: 10101-39-0 CAS No: 10101-41-4 CAS No: 13397-24-5 CAS No: 26499-65-0			2-3	I	Annex V exemption
PW28	Hydrated calcium silicate	Hydrated calcium silicate			4	I	Annex V exemption
PW 30	Lead phosphate	Trilead bis(orthophosphate) CAS No: 7446-27-7			-	-	Not registered
PW32	Zinc phosphate	Trizinc bis(orthophosphate) CAS No: 7779-90-0			1	I	10,000 – 100,000
PW33	Calcium sulphoaluminate	Calcium sulphoaluminate			-	-	No data

Sources: http://cameo.mfa.org/images/c/cd/Download_file_536.pdf; https://refractiveindex.info/?shelf=main&book=ZrO2&page=Wood; https://www.emsdiasum.com/microscopy/products/preparation/mica.aspx; https://echa.europa.eu/information-on-chemicals/registered-substances

Table 5–2: Registration tonnages for alternative white pigments	
Application C.I. Common or Historical Name	Technical feasibility
Paint	- ZnO has a worse refractive index and durability meaning that a higher amount would be needed to achieve the desired hiding power and opacity (opacity is 5 times lower). This means that one paint layer containing TiO_2 would most likely need to be replaced by 4 layers of a ZnO-containing formulation. Zinc oxide can also cause thickening when used in water-based paints affecting the performance. - $BaSO_4$ has a very high specific gravity which causes a tendency to form a hard settlement in paint cans. - Lithopone offers only 2/3 of the opacity/hiding power of TiO_2 and does not have the same level of whiteness. - ZrO_2 would require a fourfold increase in film thickness. - Bismuth chloride oxide is only suitable for niche applications such as hobby colours and artistic use and so cannot be used for all TiO_2 paint applications. - Opaque Polymer Systems are widely marketed as extender pigments for TiO_2 under various trade names as they are easy to handle, relatively cost effective, and have little impact on application properties. This being said, they are not capable of delivering an opaque paint system in isolation or in combination with any other pigment.
Plastics	- ZnO has poor weatherability and stability against yellowing due to a lack of UV stability compared with TiO_2. - ZnS is unstable upon exposure to UV light and decomposes, leading to a darkening of the pigment called "zinc burn" in plastics.
Cosmetics	- ZnO is permitted in sun-care products in the EU and some other regions in the world. It is not easy to formulate and fewer grades are available than TiO_2. Zinc Oxide contributes mainly to UVA protection, whilst TiO_2 contributes to the SPF, and has weaker performance against UVB radiation. Sunscreens would require increased concentrations to cover a similar spectrum making it cost more and be undesirably whiter on the skin. - In other cosmetics ZnO is not as good at skin coverage and cannot produce pearl effect pigments. The only pigment suitable for this is TiO_2. - Organic filters (avobenzone, EHT, Tinosorb® S and others) can be unstable in light and can complex leading to a reduction of UV protection.
Paper	- Optical brighteners have been used by the paper industry in order to reduce, but not eliminate, the consumption of TiO_2. They are not considered to be feasible alternatives if opacity is the desired function. Optical brighteners are also limited in food contact material applications in several jurisdictions. For example, the German Federal Institute for Risk Assessment (BfR) imposes limitations, whilst the US FDA restricts the use by imposing conditions of use by food type, and China prohibits their use.
Inks	- ZnS cannot match TiO_2's whiteness or opacity properties and is not suitable for thin film applications such as 1–3 µm in printing inks. It also has poor application properties, low gloss and poor wet and dry hiding characteristics.
Food additives	- Calcium carbonate (E170) is authorised under the EU Additives Regulation (EC) No 1333/2008 for a Group II food colour. Its value as a food colour is limited as it has poor or no functionality in many food applications and readily reacts with acids to generate carbon dioxide and calcium salt. Examples of where it cannot be used in foods are: those with a low pH as it would neutralise the acid, affecting flavour, quality and possibly shelf life; as a white colouring in cake batters as it would interfere with raising agents; it cannot be used as a replacement to produce white glitter powders as it is not authorised for that use.

5.4 Economic considerations

The economic feasibility of alternatives also has an impact on the suitability of alternatives. Cost estimates are not available for all TiO_2 alternatives. Zinc oxide is lower in cost than TiO_2 but is less efficient. This makes it less cost effective as greater quantities are required. The price of ZnO also depends on the price of zinc, which is known to be volatile. Zinc sulphide is not considered an alternative for TiO_2 in the majority of applications for a number of reasons. At present there is only one producer of ZnS in the world and the price is several times higher than that of TiO_2. It also has lower whiteness and opacity meaning that greater amounts would be required if it was to act as a full replacement. It has been suggested that the price of ZnS would rise further if TiO_2 became unavailable.

Barium sulphate is less costly than TiO_2 but as it has less effective hiding power, a higher dosage is required. This means that there will be higher costs associated with its use (a ten-times higher loading is required to obtain a nearly comparable result negating the lower cost)[16]. Extender pigments can be (and in some cases have been) used to partly replace TiO_2 in formulations, primarily for cost reasons, but as explained in previous sections they cannot be used to replace to TiO_2 entirely.

As well as these direct economic impacts, the larger volumes of substitutes required to meet demand are likely to be beyond the industries' production capacity and would generate equally large volumes of waste, all of which has further economic impacts in terms of reduced efficiency.

5.5 Risk reduction capacity (human health)

An alternative to TiO_2 should be less harmful to human health and the environment. A simplified way to determine this is to compare the hazard classifications that have been assigned to both TiO_2 and the alternatives. As the carcinogenic effect observed in animal testing discussed in the French CLH proposal is not substance-specific but characteristic of respirable poorly soluble dusts, this can be expected to occur with most, if not all, potential alternative substances. Therefore, if it were accepted that TiO_2 is a carcinogen, all poorly soluble powders that could replace it (including minerals such as kaolin, chalk, talc, etc.) could be considered to exert carcinogenicity in a similar manner. This is especially a concern where a substance has not been as widely used as TiO_2 and so there is less experience with its use.

Aside from this concern regarding other respirable poorly soluble dusts, some potential alternatives may pose significant hazards. Lead-based pigments in particular are far more hazardous than TiO_2 with a concern over neurotoxicity and reprotoxicity. As a result, they currently find very little use, if any, and have been replaced by TiO_2. Many of the other alternatives show specific target organ toxicity related to the lungs or respiratory system, which may be related to their being respirable poorly soluble dusts. See Table 5-3 for a summary of hazard classifications of some of the alternatives.

Of the possible alternatives that hold harmonised classifications, zinc oxide and zinc phosphate only have environmental classifications. Diantimony trioxide has a carcinogen cat. 2 classification which would make it unsuitable for those applications that prohibit the use of carcinogenic substances.

[16] RPA (2017): Analysis of the socio-economic impacts of a harmonised classification of carcinogen category 2 for titanium dioxide (TiO_2), Final report prepared for the TDIC.

Table 5-3: Hazard classifications of potential alternatives to TiO_2				
Colour Index generic name	**C.I. Common or Historical Name**	**Chemical Composition**	**CAS No.**	**Hazard classification**
PW1	Lead white	Basic lead carbonate	1319-46-6	**Not harmonised** Acute Tox. 4 (H302) Acute Tox. 4 (H332) Repr. 1A (H360) STOT RE 2 (H373) Aquatic Chronic 1 (H410)
PW2	Lead sulphate white	Basic lead sulphate	12397-06-7	**Not classified** (but likely to have a profile similar to other lead pigments)
PW3	Basic lead sulphate white	Lead sulphate	7446-14-2	**Not harmonised** Acute Tox. 4 (H302) Acute Tox. 4 (H332) Repr. 1A (H360) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
PW4	Zinc oxide white	Zinc oxide	1314-13-2 91315-44-5	**Harmonised** Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
PW5	Lithopone	Barium sulphate (28 - 30%) and zinc sulphide (68 - 70%) with trace amounts of zinc oxide	7727-43-7 1314-98-3	7727-43-7: **Not harmonised** Acute Tox 4 (H302) Eye Irrit 2 (H319) STOT RE 2 (H373 lungs) 1314-98-3: **Not harmonised** Aquatic acute 1 (H400)
PW7	Zinc sulphide white	Zinc sulphide	1314-98-3	**Not harmonised** Aquatic acute 1 (H400)
PW8	Strontium sulphide	Strontium sulphide	1314-96-1	**Not harmonised** Met. Corr. 1 (H290) Acute Tox. 3 (H301) Skin Corr. 1A (H314) Eye Dam. 1 (H318) Aquatic Acute 1 (H400)
PW10	Barium carbonate	Barium carbonate	513-77-9	**Harmonised** Acute Tox. 4 (H302)
PW11	Antimony white	Diantimony trioxide	1309-64-4	**Harmonised** Carc. 2 (H351)
PW12	Zirconium oxide	Zirconium oxide	1314-23-4	**Not harmonised** STOT SE 3 (H335) Skin Irrit 2 (H315) Eye Irrit 2 (H319)
PW13	Barium tungstate	Barium wolframate	7787-42-0	**Not harmonised** Acute Tox. 4 (H302) Acute Tox. 4 (H332)
PW14	Bismuth oxychloride	Bismuth chloride oxide	7787-59-9	**Not harmonised** STOT SE 3 (H335) Skin Irrit 2 (H315) Eye Irrit 2 (H319)

Table 5-3: Hazard classifications of potential alternatives to TiO_2				
Colour Index generic name	**C.I. Common or Historical Name**	**Chemical Composition**	**CAS No.**	**Hazard classification**
PW15	Tin oxide	Tin dioxide	18282-10-5	**Not harmonised** STOT SE 3 (H335)
PW16	Lead silicate	Lead monosilicate	10099-76-0	**Not classified** (but likely to have a profile similar to other lead pigments)
PW17	Bismuth subnitrate	Basic bismuth nitrate	1304-85-4	**Not harmonised** STOT SE 3 (H335) Skin Irrit 2 (H315) Eye Irrit 2 (H319)
PW18	Chalk	Natural calcium carbonate with magnesium carbonate as an impurity	471-34-1 546-93-0	471-34-1: **Not harmonised** STOT SE 3 (H335) Skin Irrit 2 (H315) Eye Irrit 2 (H319) Eye Dam 1 (H318) 546-93-0: **Not harmonised** Eye Irrit 2 (H319)
PW18	Precipitated chalk	Pure calcium carbonate	471-34-1	**Not harmonised** STOT SE 3 (H335) Skin Irrit 2 (H315) Eye Irrit 2 (H319) Eye Dam 1 (H318)
PW18:1	Dolomite	Calcium magnesium carbonate	83897-84-1	**Not harmonised** Skin Irrit. 2 (H315) Eye Dam. 1 (H318) STOT SE 3 (H335)
PW19	Kaolin	White clay rock, mostly natural hydrated aluminium silicate with impurities of magnesium, iron carbonates, ferric hydroxide, mica, quartz, etc.	1332-58-7	**Not harmonised** STOT RE 2 (H373 lungs) Eye Irrit 2 (H319)
PW20	Mica	Hydrous aluminium potassium silicate	12001-26-2	**Not harmonised** Eye Irrit 2 (H319)
PW21	Barium sulphate (synthetic)	Synthetic barium sulphate	7727-43-7	**Not harmonised** Acute Tox 4 (H332) (H302)
PW22	Barytes (natural barium sulphate)	Natural barium sulphate	7727-43-7	**As above**
PW23	Alumina blanc fixe	Aluminium hydrate, barium sulphate; coprecipitate of ca. 25% aluminium hydroxide and 75% barium sulphate	21645-51-2 7727-43-7	21645-51-2: **Not harmonised** Eye Irrit 2 (H319) 7727-43-7: **Not harmonised** Acute Tox 4 (H332) (H302)
PW24	Aluminium hydroxide	Aluminium hydroxide	21645-51-2	**Not harmonised** Eye Irrit 2 (H319)
PW24	Gibbsite (natural form of aluminium hydroxide)	Natural aluminium hydroxide with varying amounts of basic aluminium sulphate	21645-51-2	**Not harmonised** Eye Irrit 2 (H319)
PW25	Gypsum	Hydrated calcium sulphate	91315-45-6	**Not classified**

Table 5-3: Hazard classifications of potential alternatives to TiO_2				
Colour Index generic name	C.I. Common or Historical Name	Chemical Composition	CAS No.	Hazard classification
			10101-14-4	(calcium sulphate, CAS No: 7778-18-9 is also not classified)
PW26	Talc	Mixed hydrated silicate of magnesium with varying impurities of calcium, iron and other compounds	14807-96-6 8005-37-6	14807-96-6: **Not harmonised** Acute Tox 4 (H332)
PW27	Silica	Hydrous = diatomaceous earth; Anhydrous = silica Silicon dioxide	7631-86-9	**Not harmonised** STOT SE 3 (H335) Eye Irrit 2 (H319) Skin Irrit 2 (H315)
PW28	Calcium silicate	Calcium metasilicate; Calcium silicate;	10101-39-0 10101-41-4 13397-24-5 26499-65-0	10101-39-0: **Not harmonised** STOT SE 3 (H335)
PW28	Hydrated calcium silicate	Hydrated calcium silicate		
PW 30	Lead phosphate	Trilead bis(orthophosphate)	7446-27-7	**Harmonised** Repr. 1A (H360Df) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
PW32	Zinc phosphate	Trizinc bis(orthophosphate)	7779-90-0	**Harmonised** Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
PW33	Calcium sulpho-aluminate	Calcium sulphoaluminate		**Not classified**
Source: http://www.artiscreation.com/white.html#ci_pigment_white; ECHA C&L Inventory, https://echa.europa.eu/information-on-chemicals/cl-inventory-database				

5.6 Summary

TiO_2 has excellent light scattering properties as it absorbs almost no incident light from the visible spectrum. Due to its high opacity, refractive index and subsequent light fastness, as well as availability, TiO_2 is suitable for the majority of applications that require a white pigment or pearlescent effect. Although mineral fillers such as zinc oxide, lithopone, kaolin and talc find use in a number of applications as extender pigments, they are not able to fully replace TiO_2. At present there is no alternative that can match the technical function of TiO_2 or is available in large enough quantities to cover all applications. There is also concern that other respirable poorly soluble dusts may be similarly classified as carcinogenic category 2, which would reduce the number of available alternatives even further.

6 Assessment of Risk Management Options

6.1 Identification of potential risk management options

6.1.1 Potential risks of concern

RMOs may be required in order to eliminate, control or minimise the exposure of workers and consumers to respirable TiO_2 dusts via inhalation. The type of RMO that is most relevant will depend on:

- The potential routes of exposure;
- The population exposed and whether it is a worker population or a consumer population;
- The nature of the exposure, in terms of frequency, duration and level of exposure; and
- The potential measures available for implementing an option.

The exposure assessment undertaken by EBRD concluded that there were potential risks of concern related to the following activities at TiO_2 manufacturing sites and downstream industrial users:

- Packing of powders at manufacturing sites;
- Cleaning at manufacturing sites;
- Milling of powders at manufacturing sites.

In addition, risks of concern (RCR>1) were identified for professionals involved in paint spraying, sanding and hand mixing operations. The use of aerosols by consumers was also identified as posing potential risks of concern.

In addition to the above, there may be other potential sources of exposure for uses and/or activities falling outside the scope of EBRC's exposure assessment remit. These include professional and downstream uses in sectors such as cosmetics, toys, pharmaceuticals, food packaging, animal feed and as a food additive. As noted in Section 4, only exposures to inhalable/respirable TiO_2 in these sectors would pose a risk of concern, even though under the current legislation risk management may be triggered by the harmonised classification alone. In addition, as noted in Section 4, the Carc Cat 2 hazard classification would also trigger RMMs under waste legislation.

6.1.2 Potential RMM

In response to the above findings, a long list of potential RMM has been identified. We have distinguished between RMOs aimed at addressing risks to different types of exposed population: workers (as defined by EU OSH legislation), professional users and consumers. For each population, potential RMOs have been identified based on the range of possibilities given the associated legal framework. Table 6-1 provides a summary and initial screening of the potential RMOs identified on the basis of exposed population, and the type of exposure that each would address.

As can be seen from Table 6-1, many of these potential RMOs can be screened out on the basis of their suitability, necessity and proportionality, which is based on an EU jurisprudence approach:

- Suitability: Is the risk management measure appropriate to achieve the objective that is pursued?

- Necessity: Is there no other risk management option considered suitable to achieve the objective that is less cumbersome, costly or restrictive whilst equally effective in achieving the objective?
- Proportionality: Is this risk management option considered suitable and necessary, while not too excessive? This is where the balance between the different interests at stake (e.g. industry and society) are considered.

However, in some cases, RMOs cannot simply be screened out on this basis, as action would automatically be triggered under the legislation by the proposed harmonised classification for Carc Cat 2. This is the case, for example, for RMMs triggered under food safety, food packaging and waste legislation.

Table 6-1: Potential RMOs by Exposed Population					
Exposed Population	**Potential RMM**	**Relevant exposure**	**Suitability**	**Necessity**	**Proportionality**
Workers (as defined under OSH legislation)					
- TiO_2 manufacture	CLP classification and labelling of TiO_2 powders	Worker exposures to raw materials containing TiO_2 (substance and mixtures)	Would ensures DUs have data on hazard classification and safe use	Only necessary for substance when sold in powder form	Proportional. Not considered further as part of legal minimum for placing on the market in the EU.
	Chemical Agents Directive - IOELV Voluntary adherence to an OEL - agreed with Social Partners	Worker exposures to TiO_2 dusts during processing activities	Would ensure workers are not exposed to levels above the DNEL	Not all operations are linked to a RCR >1, so an OEL would not have an impact across all activities/operations; some national OELs would appear to be close to the DNEL for respirable particles, or be below it already (Germany). Data on prevalence of lung inflammation-like effects in workforce does not support the general necessity for such a measure across the board, although there may be a need in relation to certain operations	Does not appear proportional based on prevalence of effects compared to the costs of investing in equipment. This may particularly be the case given additional reductions below OEL that would be required to demonstrate compliance in many MS
- Downstream industrial sectors*	CLP classification and labelling of mixtures	Worker exposures to TiO_2 and to mixtures containing TiO_2	Would ensures industrial DUs have data on hazard classification and safe use	Only necessary for substance/mixtures in powder form	Proportional. Not considered further as part of legal minimum for placing on the market in the EU.
	Chemical Agents Directive - IOELV Voluntary adherence to an OEL - agreed with Social Partners	Worker exposures to TiO_2 dusts during processing activities	Would ensure workers are not exposed to levels above the DNEL	Not all operations are linked to a RCR>1, so an OEL would not have an impact across all activities/ operations; some national OELs would appear to be close to the DNEL for respirable particles, or be below it already (Germany).	Does not appear proportional based on prevalence of effects compared to the costs of investing in equipment. This may particularly be the case given additional reductions below OEL that

Table 6-1: Potential RMOs by Exposed Population					
Exposed Population	**Potential RMM**	**Relevant exposure**	**Suitability**	**Necessity**	**Proportionality**
				Data on prevalence of lung inflammation-like effects in workforce does not support the general necessity for such a measure across the board, although there may be a need in relation to certain operations	would be required to demonstrate compliance in many MS
- Downstream sectors*	REACH Restriction on the form of supply - substitution of powder form with a slurry (industry initiative)	Worker exposures to TiO_2 dusts during processing activities	Some TiO_2 supply is already in slurry form. Not appropriate for all downstream use sectors where needed in powder form.	Not all activities which use TiO_2 in powder form will be giving rise to exposures of concern. Other measures can be taken at the site level to reduce worker exposures to below the assumed threshold for effects.	Does not appear proportional based on prevalence of effects compared to the costs of investing in equipment. In addition, as substitution would be with another "dusty" substance, would not necessarily address the main issue regarding poorly soluble respirable particles
Professional users (not covered by OSH)					
- Painters and decorators - Plasterers - Flooring and tiling - Builders - Demolition	CLP classification, labelling and packaging of mixtures	Professional exposures to mixtures containing TiO_2	Could cause confusion for liquid mixtures; may be more suitable for powder mixtures. Does not address with dust generated from legacy applications	Most relevant to mixtures sold in powder form, where mixing is carried out by the professional user; may also be relevant to some aerosols, as there is the potential for exposure to respirable particles	As adherence to CLP is required for market access, proportionality is less relevant. May have particular benefits where there is the potential for significant exposures, e.g. mixing plaster
	Substitution	Exposures to mixtures, aerosols or dusts containing TiO_2	No technically feasible alternative available in sufficient quantities and would	Substitution not necessary as other measures can be taken to reduce professional exposures to dusts or TiO_2 in	Does not appear proportional based on low prevalence of effects, and given the lack of available

Table 6-1: Potential RMOs by Exposed Population						
Exposed Population		Potential RMM	Relevant exposure	Suitability	Necessity	Proportionality
				not reduce exposure to respirable particles from dusty powders given nature of alternatives	aerosols; substitution could also just shift the issue to the potential for exposure to respirable particles of another PSLT	alternatives. In addition, as substitution would be with another "dusty" substance, would not necessarily address the main issue regarding respirable particles from PSLT
		Awareness raising and training rolled out across the EU	Exposures to mixtures, aerosols or dusts containing TiO_2	Would help ensure that professionals are aware of the dangers of respirable particles more generally from both dusty activities as well as those that generate / involve fine aerosol sprays. Risk that it may not reach all relevant professionals	Exposure assessment found RCRs >1 for some professional uses / activities, including those associated with legacy uses of TiO_2 (e.g. sanding) so measures are necessary. This RMM would help deal with both new and legacy exposures.	Measure is likely to be proportionate, given that a coordinated approach could be rolled out across the EU, with this helping to ensure effectiveness and efficiency. As a result, costs are more likely to be proportionate to the number of cases of lung inflammation that could be avoided across the range of activities.
		REACH Restriction – requirement for provision of respiratory masks with power sprayers	Exposures to aerosols containing TiO_2	Would reduce the potential for professionals using powered paint sprayers and hence the potential for exposure to respirable particles. Would require authorities to monitor compliance	Exposure assessment found an RCR >1 associated with powered paint sprayers, although most professionals should already wear masks.	Uncertain. Paint spraying has a high prevalence of respiratory illnesses, related to other components of the paint system and more likely to be linked with industrial paint spraying. Costs of masks in addition to the cost of sprayer may be proportionate, but does not guarantee continued replacement and use
	- Cosmetics workers	Substitution	Exposures to dusts /	Would ensure that	Only necessary for cosmetic	Does not appear

Table 6-1: Potential RMOs by Exposed Population					
Exposed Population	**Potential RMM**	**Relevant exposure**	**Suitability**	**Necessity**	**Proportionality**
		aerosols containing TiO_2	workers are not exposed to TiO_2	products which are aerosols/powders or release a powder when used (e.g. acrylic nails)	proportional as it is unlikely exposure would be long enough or frequent enough
	Awareness raising	Exposures to dusts / aerosols containing TiO_2	Would increase awareness but may not increase safe use of products containing TiO_2	Only relevant to professional users who are working with TiO_2 containing powder /aerosol products or applications that release dusts on a regular, day-to-day basis.	Does not appear proportional as it is unlikely exposure would be long enough or frequent enough
	REACH Restriction	Exposures to dusts / aerosols containing TiO_2	Would ensure that workers are not exposed to TiO_2	Only necessary for cosmetic products which are aerosols/powders or release a powder when used (e.g. acrylic nails)	Not proportional as it is unlikely exposure would be long enough or frequent enough
- Agricultural users of feed	Animal feed additives (removal from *authorisation* list)	Exposures to dusts from animal feed	Would prevent humans being exposed to TiO_2 as a result of using animal feeds	Only foreseeably needed where workers are dealing with large quantities of dried feed in an enclosed space and for long durations	Does not appear proportional as it is unlikely exposure would be long enough
	Animal feed additives (removal from *authorisation* list)	Exposures to dusts from animal feed	Would prevent humans being exposed to TiO_2 as a result of using animal feeds	Only foreseeably needed where workers are dealing with large quantities of dried feed in an enclosed space and for long durations	Does not appear proportional as it is unlikely exposure would be long enough
- Bakers, etc.	Food Additives (removal from list of *permitted additives*)	Exposures to dusts / aerosols containing TiO_2	Would prevent humans being exposed to TiO_2 as a result of using it as a food additive	Only foreseeably needed where professionals are dealing with large quantities of dried foods in an enclosed space; such workers are likely to already be covered by OSH legislation	Automatically triggered but does not appear proportional as it is unlikely that consumers would face a significant risk from exposures through food products
Consumers (including DIY and end-product consumers)					

Table 6-1: Potential RMOs by Exposed Population					
Exposed Population	**Potential RMM**	**Relevant exposure**	**Suitability**	**Necessity**	**Proportionality**
- Paints/aerosols - Cements, plaster, mortars, etc.	CLP classification, labelling and packaging of mixtures	Exposures to dusts / aerosols containing TiO2	Would only effectively reduce exposures associated with use of powdered mixtures and aerosols, which will not form the bulk of uses; would not address exposures associated with refurbishment/ demolition	Only potentially necessary for powder-based mixtures and aerosols (although many of the latter will already hold multiple hazard warning due to other ingredients). Most consumer users will not be regular users so will not be exposed for significant periods of time, and they will already use respiratory protection (masks) when using such mixtures or undertaking relevant activities (sanding)	As adherence to CLP is required for market access, proportionality is not strictly relevant. May be more proportional where there is the potential for significant exposures, e.g. mixing powder-based plasters or using some aerosols
	Substitution	Exposures to mixtures, aerosols or dusts containing TiO_2	No technically feasible alternative available in sufficient quantities and would not reduce exposure to respirable particles from dusty powders given nature of alternatives	Substitution not necessary as consumer exposures to dusts or TiO_2 in aerosols is unlikely to be of significant durations; substitution could also just shift the issue to the potential for exposure to respirable particles of another PSLT	Does not appear proportional based on low prevalence of effects, and given the lack of available alternatives. In addition, as substitution would be with another "dusty" substance, would not necessarily address the main issue regarding respirable particles from PSLT
	Awareness raising and training rolled out across the EU	Exposures to mixtures, aerosols or dusts containing TiO_2	Would help ensure that professionals are aware of the dangers of respirable particles more generally from both dusty activities as well as those that generate / involve	Exposure assessment found RCRs >1 for some professional uses / activities, including those associated with legacy uses of TiO_2 (e.g. sanding) so measures are necessary. This RMM would help deal with both new and legacy	Measure is likely to be proportionate, given that a coordinated approach could be rolled out across the EU, with this helping to ensure effectiveness and efficiency. As a result, costs are more likely to be proportionate to

Table 6-1: Potential RMOs by Exposed Population						
Exposed Population		**Potential RMM**	**Relevant exposure**	**Suitability**	**Necessity**	**Proportionality**
				fine aerosol sprays. Risk that it may not reach all relevant professionals	exposures.	the number of cases of lung inflammation that could be avoided across the range of activities.
		REACH Restriction – requirement for provision of respiratory masks with power sprayers	Exposures to aerosols containing TiO_2	Would reduce the potential for professionals using powered paint sprayers and hence the potential for exposure to respirable particles. Would require authorities to monitor compliance	Exposure assessment found an RCR >1 associated with powered paint sprayers, although most professionals should already wear masks.	Uncertain. Paint spraying has a high prevalence of respiratory illnesses, related to other components of the paint system and more likely to be linked with industrial paint spraying. Costs of masks in addition to the cost of sprayer may be proportionate, but does not guarantee continued replacement and use
	- Food products, e.g. baking products	Food Additives (*removal from list of permitted additives)*	Exposures to dusts / aerosols containing TiO_2	Would ensure that consumers are not exposed to TiO_2 from baking products	Only a limited number of products would appear to contain TiO_2 in powdered form and these are unlikely to be used for sufficiently long periods of time	Not considered proportional as it is unlikely exposure would be frequent enough
	- Food packaging	Food Packaging legislation (*removal from list)*	None	No benefits to consumers identified	None	Not considered proportional
End-of-life						
	- Manufacturers - Waste collectors/handlers - Recyclers	Hazardous waste classification	Exposures to dusts and mixtures containing TiO_2	Is not the most appropriate means of minimising exposures to dust	Not considered necessary; potential concerns in recycling can be addressed through other means	Not considered proportionate, and would result in national requests for exemptions.
*	Downstream sectors include the following manufacturing activities: paints and coatings, paper and card, plastics, glass and ceramics, cosmetics, food, animal feed, medicinal products, pharmaceuticals manufacture, tobacco products, etc.					

As a result, the screening of measures has been based on a combined consideration of the degree to which measures would be proportional and whether risk management under downstream legislation is based on "generic risk considerations" (i.e. the Carc Cat 2 hazard classification under CLP) or there is the potential for derogation/exemption under downstream legislation based on risk considerations (e.g. as under the Cosmetics Regulation, where the classification triggers a second step involving risk assessment by the SCCS for those cases where industry requests a derogation from a ban on use).

The results of this process refines the list of RMOs taken forward for further, more detailed analysis, with these being those shaded in light blue within Table 6-1. These are:

- Introduction of an EU-wide OEL, either via CAD or via a voluntary initiative;
- Labelling and packaging of mixtures under CLP with a focus on professional users and consumers, even though this is not strictly an RMO given that CLP is market access legislation;
- REACH Restriction on:
  - the form that TiO_2 is supplied in to industrial users,
  - the need to provide protective equipment as part of the sale of powered paint sprayer equipment to professional users and consumers, and
  - the need to provide protective equipment as part of the sale of aerosols to professional users and consumers,
  - recycling of waste plastic and paper due to concerns over hazardous materials within recycled products;
- Industry sponsored awareness raising and training programmes, focused on professional users (and potentially extended to consumer users);
- Withdrawal of approval for use in food and food packaging; and
- Waste classification of TiO_2 as hazardous.

Each of these is addressed in turn below, with the assessment examining the potential effectiveness and efficiency of the RMO together with its practicality and overall proportionality.

6.2 Worker exposures and introduction of an EU-wide OEL

6.2.1 The RMO and relevant exposures

One potential measure for reducing worker exposures would be the introduction of an EU-wide OEL value. Adoption of an EU-wide OEL would help ensure that all workers across the EU were protected from inhalation of respirable TiO_2 at levels above the DNEL, with this creating an equivalent level of protection across Member States and also delivering a level playing field for industry. Both of these would be of benefit given the variations in OELs that exist at the national level.

An EU-wide OEL could be adopted voluntarily by TiO_2 manufacturers, as well as by the main downstream using sectors listed in Section 3 of this report. In this respect, it is of note that other sectors have established Voluntary Agreements with the European Trade Unions Congress (ETUC), for example in relation to formaldehyde, with the aim of demonstrating their willingness to take action without the need for additional regulatory measures.

Alternatively, an OELV could be introduced under the Chemical Agents Directive (CAD), with this being more relevant than the Carcinogens and Mutagens Directive for a substance classified as Carc. Cat 2 and having a threshold for effects.

For the purposes of this assessment, it has been assumed that an OELV would be set at 1.3 mg/m^3 even though the TDIC is still investigating what would be the appropriate threshold for effects with respect to lung inflammation (which occurs at a lower exposure level than the potential cancer effects). As discussed in Section 2, this limit value is based on an interim DNEL developed by EBRC, but is also considered to reflect the preliminary SCOEL opinion, has been selected as also reflecting a level that SCOEL or RAC may recommend for an EU-wide limit, as it would protect against both inflammation and cancer effects.

The exposure assessment work carried out by EBRC found that there were risks of concern for certain TiO_2 manufacturing and industrial use exposure scenarios (although further consideration of RMMs in place may modify these conclusions). The findings are summarised in Table 6-2 (and reported on in Section 2.

Table 6-2: Industrial and Professional exposure scenarios giving rise to risks of concern

Exposure scenario	P90 of monitoring data	RMM assumed	Additional RMM required
Packing of powders at manufacturing sites	1.53 mg/m^3	Not stated	Assume RPE needed or some form of LEV
Cleaning at manufacturing sites *and downstream users*	1.91 mg/m^3	RPE generally worn	Assume additional RPE needed by some proportion
Milling of powders at manufacturing *and downstream users*	1.34 mg/m^3	Not stated	Assume RPE needed by some proportion, or some form of LEV
Paint spraying by professionals	12 mg/m^3 (inhalable) (4 hour duration)	RPE generally worn but not taken into account in calculation	Assume that RPE is needed for some proportion of professionals
Sanding in professional settings	3.3 mg/m^3 (inhalable)	RPE generally worn but not taken into account in calculation	Assume that RPE is needed for some proportion of professionals
Hand mixing	5 mg/m^3 (inhalable)	RPE generally worn but not taken into account in calculation	Assume that RPE is needed for some proportion of professionals

It is of note that there is considerable uncertainty as to whether or not exposures for the last three exposure scenarios could include exposures to respirable TiO_2, given that the TiO_2 will be bound in matrices and may not therefore be either bioavailable or respirable. These scenarios have been completed to err on the side of conservatism for the purposes of this assessment.

Consultation with TiO_2 manufacturers suggests that measures can be adopted at their sites to ensure that worker exposures are below the level of 1.3 mg/m^3 without disproportionate cost or technical difficulty. It is therefore assumed that this RMO would be efficient, practicable and proportionate for most EU TiO_2 manufacturers.

As a result, the remainder of the analysis carried out here for this RMO focuses on the implications for the key downstream sectors: paints, plastics, and paper and board. Together these account for 90% of the use of TiO_2 by volume.

6.2.2 Estimation of costs

Information was collected from industry associations and individual companies for the exposure assessment to identify the types of activities that are most likely to give rise to dust emissions and hence to worker exposures above the threshold. These include activities involving the following processes, with these being a slight modification and expansion of those exposure scenarios identified by EBRC to take into account the differences in activities across the downstream sectors and the need to ensure that the assessment reflects those activities most likely to give rise to worker exposures:

- Handling and storage;
- Milling/sieving;
- Mixing/blending;
- Cleaning and maintenance.

Information was also collected on the types of risk management measures that companies believed they may have to introduce in order to reduce worker exposures. This included the introduction of local exhaust ventilation, greater use of respiratory equipment, improved housekeeping, increased monitoring, etc. Cost estimates for the different potential risk management measures were collected from consultees across the different sectors of use, and supplemented with published data and by consideration of data collected by RPA as part of other studies. The annualised cost of these measures were derived by calculating the present value of the capital and operating costs for a given measure over its expected lifetime. Lifetimes are specific to each measure and may vary from a single use (with costs then recurring continually over a single year), to an initial capital investment which may last up to 20 years (including any maintenance costs).

Table 6-3: Costs of risk management measures (RMMs)

	Risk management measure (RMM)	Capital cost	Annualised cost
Small enterprise	Full enclosure	€ 108,600	€ 5,430
	Partial enclosure	€ 74,815	€ 3,740
	Open hood	€ 16,890	€ 845
	Pressurised or sealed	€ 74,820	€ 3,740
	Simple enclosure	€ 9,970	€ 500
	Breathing apparatus	€ 53,600	€ 26,800
	HEPA filter	€ 450	€ 450
	Simple mask	€ 520	€ 520
	General dilution ventilation	€ 31,440	€ 1,570
Medium to large enterprise	Full enclosure	€ 1,061,890	€ 53,090
	Partial enclosure	€ 579,215	€ 28,960
	Open hood	€ 226,860	€ 11,340
	Pressurised or sealed	€ 579,220	€ 28,960
	Simple enclosure	€ 133,860	€ 6,690
	Breathing apparatus	€ 723,600	€ 361,800
	HEPA filter	€ 6,075	€ 6,075
	Simple mask	€ 7,020	€ 7,020
	General dilution ventilation	€ 209,600	€ 10,480

The assumptions made for each sector are set out in detail below for the three largest sectors of use. These assumptions include:

- Estimates of the number of companies by size (in terms of the number of employees) based on Eurostat data;
- The "high risk" activities for each sector where employees may be exposed to respirable levels of TiO_2 above the proposed OEL of 1.3 mg/m^3, and the number of employees that may be exposed during such activities for a "typical" small, medium or large enterprise;
- Estimates of the percentage of companies by size that are assumed to already have appropriate risk management measures in place; and
- The assumed annualised cost of implementing a given RMM that would be sufficient to meet the proposed OEL.

Consultees from the various sectors were asked to provide an indication of the risk management measures currently in place, the measures that would need to be adopted to meet the proposed OELV and the likely efficiency of the different types of actions for their sector; industry associations were asked to provide information on the likely percentage of companies – small, medium and large separately – that were likely to already have implemented the different forms of risk management as part of current activities (although few associations provided a response). In addition, desk research was carried out to identify what types of RMMs are standard within the different sectors to protect workers against dust and other emissions. Taken together, the information has enabled assumptions to be made on the additional measures that would be required by a "typical" small, medium and large operator in each sector. In some cases and for some activities, no additional measures would be required, as the RMMs currently in place should already enable the OELV to be met. For example, this may be the case where measures are already taken to protect workers against dust emissions or where other more hazardous substances are in use and have already resulted in the investment of RMMs.

Further details are provided below on some of the key assumptions.

Paints and coatings sector

Eurostat (2016) data was used to provide the number of enterprises in the paints and coatings sector, by size. Germany was excluded from the analysis, because with an OEL of 1.25 mg/ml^3 respirable fraction, it is assumed that all companies in Germany will already be achieving levels below the proposed OEL of 1.3 mg/m^3 (See Section 3).

At the majority of manufacturing sites, TiO_2 pigment is delivered as powder in bags or as bulk truckload quantities. It is also available in some regions as an aqueous slurry.[17] The analysis assumes that 90% of companies will receive TiO_2 as powder pigment and the number of enterprises that would be affected by this is indicated in Table 6-4.

Table 6-4: Paints and coatings sector: enterprise size

	Enterprise size		
	Small (0–49)	Medium (50–249)	Large (250+)
No. of enterprises (excluding Germany)*	3,109	343	61
Proportion (%) enterprises handling powdered TiO_2	90%	90%	90%

17 https://www.chemours.com/Titanium_Technologies/es_US/tech_info/literature/Coatings/CO_B_H_65969_Coatings_Brochure.pdf

The manufacturing of paints varies to some degree between manufacturing facilities, but broadly involves the following steps:[18,19]

1. **Handling and storage**: raw material is received, stored and weighed;
2. **Mixing (pre-mixing)**: pigment (Including TiO_2), resin (a wetting agent), one or more solvents and additives are mixed to produce an even mill base. This moistens the pigment to form a paste;
3. **(a) Milling**: the mill base is sent to the disperser to finely disperse pigment particles. This involves a large cylinder that agitates tiny particles of sand or silica to grind the pigment particles, making them smaller and dispersing them throughout the mixture;
3. **(b) High-speed dispersion**: an alternative to milling is used in up to 90% of commercially available water-based latex paints; premixed paste is subjected to high-speed agitation in a dispersion tank;
4. **Blending**: The paste must be thinned, using solvent, to produce the final product. Colour may be adjusted at this stage;
5. **Filtering/sieving**: blended and toned paint is filtered to remove sand/silica from the milling process. This may also take place after blending;
6. **Packing**: filtered paint is packed into containers, stored and shipped, and;
7. **Cleaning and maintenance**.

Given that, after the mixing step, a paste is produced and TiO_2 is permanently bound into the binder matrix, the activities most likely to produce dust and, therefore, be high risk, are:

- Handling and storage;
- Mixing (pre-mixing); and
- Cleaning and maintenance.

Relevant assumptions are given in Table 6-5 and described below.

Table 6-5: Paints and coatings sector: high risk activities and proportions of companies that are assumed to already have appropriate RMMs in place

	Small (0–49)	Medium (50–249)	Large (250+)
High risk activity:* handling and storing			
Total number of handling workers	2	15	30
Proportion (%) enterprises with partial LEV	70%	70%	90%
Proportion (%) enterprises with HEPA masks	50%	50%	70%
Proportion (%) enterprises with specialised storage	100%	100%	100%
High risk activity:* mixing (to make paste)			
Total number of handling workers	2	15	30
Proportion (%) enterprises with full LEV	100%	100%	70%
Proportion (%) enterprises with partial LEV	40%	40%	100%
Proportion (%) enterprises with HEPA masks	70%	70%	70%
Proportion (%) enterprises with sealed vessel	50%	70%	90%
High risk activity:* cleaning and maintenance			
Total number of handling workers	2	4	10
Proportion (%) enterprises with HEPA masks	70%	80%	90%

18 http://www.cmp.co.jp/library/pdf/english/eco/en_2012/social_environmental_2012_en_09.pdf

19 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)24&doclanguage=en

Handling and storage

The number of workers involved in handling and storage of TiO_2 was estimated at 2, 15 and 30, for small, medium and large enterprises respectively (see Table 6-5).

From the exposure assessment, and for the packing of powders (PROC 26) at manufacturing sites, a reasonable worst case (RWC) estimate is 1.53 mg/m^3 for the respirable fraction, which is slightly above the interim DNEL of 1.3 mg/m^3, with a resulting RCR of 1.17. This is based on the P90 of monitoring data (n=76) and does not take into account the use of respiratory protective equipment (RPE). A reasonable assumption is therefore that the majority of enterprises have appropriate RMMs in place, particularly larger enterprises. Where additional RMMs are required, these are likely to be in the form of partial LEV or as simple masks (RPE). Large enterprises are assumed to already have specialised storage equipment in place and installation of additional storage equipment in SMEs is assumed unnecessary. See Table 6-4 for the estimated proportion of enterprises assumed to already have appropriate RMMs in place to meet the proposed OEL of 1.3 mg/m^3, based on these assumptions.

Mixing (to make paste)

The number of workers involved in mixing was estimated at 2, 15 and 30, for small, medium and large enterprises respectively (see Table 6-5).

When small amounts of powder are required for a batch, they are often weighed out on scales in a specific area, and then transferred on pallets by forklift truck to the manufacturing area. The most widely used option is to decant the required amount out of a drum in the presence of local exhaust ventilation (LEV).[20] In larger facilities, automated systems may be used. The vessel is usually sealed, whilst mixing takes place, although some open vessels may be used in smaller facilities. It is assumed that LEV would therefore only be required while adding raw material or if an unsealed vessel is being used. Some closed vessels have extraction systems attached to them to remove the airborne dusts and vapours.

The exposure assessment carried out by EBRC does not give data for mixing specifically, but it is assumed that this is similar to the milling of powders (PROCs 4, 24, 26); EBRC indicate that for manufacturing sites, a RWC estimate is 1.34 mg/m^3 for the respirable fraction, with a resulting RCR of 1.03. This is based on the P90 of monitoring data (n=16) and does not take into account the use of RPE. A reasonable assumption is therefore that the majority of enterprises have appropriate RMMs in place. Smaller enterprises are more likely to need to convert to a sealed vessel, larger enterprises may need to employ full LEV, where currently there is only partial LEV, while smaller enterprises may need to convert from no LEV to partial LEV. Simple or HEPA masks may be necessary in all enterprises. See Table 6-4 for the estimated proportion of enterprises assumed to already have appropriate RMMs in place to meet the proposed OEL of 1.3 mg/m^3, based on these assumptions.

Cleaning and maintenance

The number of workers involved in cleaning and maintenance was estimated at 2, 4 and 10, for small, medium and large enterprises respectively (see Table 6-4). It is assumed that cleaning of

20 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)24&doclanguage=en

equipment is carried out by trained professionals and the wearing of RPE is generally accepted and adopted in most facilities.

From the exposure assessment, EBRC found for cleaning (PROC 28) at manufacturing sites a RWC estimate of 1.91 mg/m^3 for the respirable fraction, with a resulting RCR of 1.47. This is based on the P90 of monitoring data (n=16) and does not take into account the use of RPE. It is likely that additional implementation of the wearing of RPE, in the form of HEPA filter-based masks will be sufficient to meet requirements; the estimated proportion of companies that already have this in place are outlined in Table 6-4.

Estimated costs

Combining the above assumptions results in the estimated costs set out in Table 6-6 below, together with the total number of workers assumed to be exposed at levels above the DNEL within companies in each size band.

Note that on first consideration the figures given in the table may not appear intuitive. It is important to recognise that it is assumed that most large enterprises are assumed to already have RMMs in place to protect most workers for exposures. As a result, the level of new investment required is assumed to be significantly lower. In addition, the costs are influenced by the number of additional workers that will require worker specific measures, leading to the differences between small and medium enterprises for example.

Table 6-6: Paints and coatings sector: predicted annualised costs and number of workers

	Small (0–49)	Medium (50–249)	Large (250+)
High risk activity:* handling and storing			
Total No. of handling workers	5,596	4,631	1,647
Cost to enterprises to install further partial LEV	€ 3,489,007	€ 2,980,059	€ 176,660
Cost to enterprises to supply further breathing (HEPA) masks	€ 699,525	€ 1,041,862	€ 111,172
Cost to enterprises to install specialised storage	€ 0	€ 0	€ 0
Total costs across all enterprises to install RMMs	€ 4,188,532	€ 4,021,921	€ 287,833
Total annualised cost per handling worker	€ 748	€ 869	€ 175
High risk activity:* mixing (to make paste)			
Total no. of handling workers	5,596	4,631	1,647
Cost to enterprise to install further full LEV	€ 0	€ 0	€ 971,632
Cost to enterprises to install further partial LEV	€ 6,978,015	€ 5,960,118	€ 0
Cost to enterprises to supply further breathing (HEPA) masks	€ 3,489,007	€ 2,980,059	€ 529,981
Total costs across all enterprises to install RMMs	€ 10,467,022	€ 8,940,177	€ 1,501,614
Total annualised cost per handling worker	€ 1,870	€ 1,931	€ 912
High risk activity:* cleaning and maintenance			
Total number of handling workers	5,596	1,080	549
Cost to enterprises to supply further breathing (HEPA) masks	€ 419,715	€ 416,745	€ 37,057
Total costs across all enterprises to install RMMs	€ 419,715	€ 416,745	€ 37,057
Total annualised cost per handling worker	€ 75	€ 386	€ 67

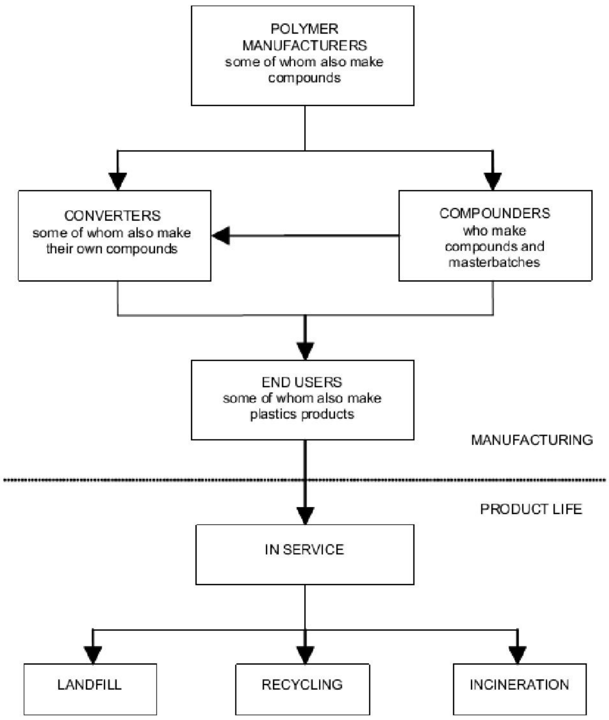
The plastics sector

Eurostat (2016) data was used to derive the number of enterprises in the plastics sector and by size. As above, companies in Germany are excluded from the analysis due to the national OEL of 1.25 mg/m^3 respirable fraction.

Plastics manufacturing is complex, with different manufacturers undertaking different activities. These are summarised in Figure 6-1. The manufacturers that are likely to use TiO_2 are (OECD, 2009):[21]

- Compounders (52%): blend into the polymers various additives, including pigments such as TiO2, to meet the requirements of specific applications of plastic materials. These are called masterbatches (high concentration of additive for later dilution) and compounds (concentration of additive is the same as in the final article). There are companies that specialise in this, but many polymer manufacturers (and some converters) also compound;
- Converters (46%): convert compounds into finished articles using a variety of different processes. Within the EU there are roughly 50,000 plastics converters according to EuPC data; and
- "In house" manufacturers: undertaken in some sectors where companies wish to manufacture their own plastics and have the required facilities for conversion, and in a small number of cases, compounding.

Figure 6-1: Manufacturing stages of the plastics industry (OECD, 2009)



21 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)24&doclanguage=en

EuPC data indicate that there are around 2,000 plastics manufacturers in the EU, with this also assumed to include compounders.

TiO_2 is used as a pigment additive and is therefore added during compounding which, as indicated above, may be carried out by specialist compounders or in parallel with the conversion process. The former is most common. A survey by Mytenka *et al.* (2017)[22] found all masterbatchers and compounders use TiO_2 powder and 67% of converters also use it. Overall, 83% of all plastics companies in the EU are considered to use TiO_2 powder, with this then acting as the core assumption for this analysis (see Table 6-7).

Table 6–7: Plastics sector: enterprise size

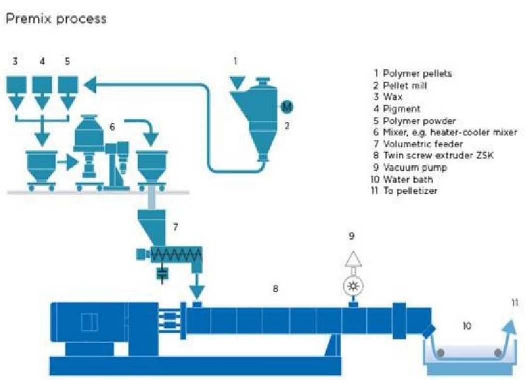
	Enterprise size		
	Small (0–49)	Medium (50–249)	Large (250+)
No. of enterprises (excluding Germany)*	43,797	3,646	548
Proportion (%) enterprises handling powdered TiO2	83%	83%	83%

The masterbatch manufacturing process is summarised in Figure 6-2, and involves:

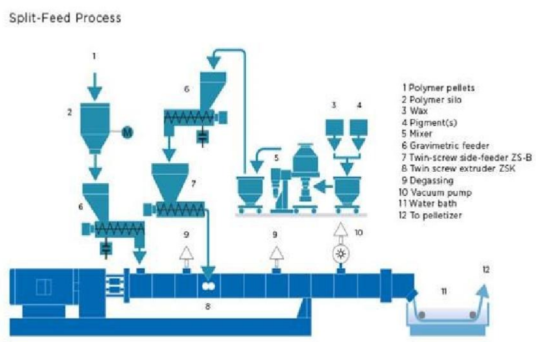
1. **Handling and storage**: raw material is received, stored and weighed;
2. **Mixing**: polymer (pellets are milled to a powder), pigment (Including TiO_2) and a carrier material (e.g. wax) are added to a mixer. This process binds the TiO_2 into a resin;
3. **Extrusion**: the resin is extruded and the "spaghetti-like" resin fed into a waterbath for cooling;
4. **Pelletisation**: The resin is then pelletised;
5. **Packing**: pelletised masterbatch is bagged and shipped to converters; and
6. **Cleaning and maintenance**.

Figure 6-2: Masterbatch manufacturing process[23]

Pre-mix process



Split-feed process



22 Mytenka, A., de Kort, P. & and Tillieux, G., 2017. *TiO_2 Risk Assessment. Internal Report of the Plastics Industry,* s.l.: EuPC

23 https://www.coperion.com/en/industries/plastics/masterbatch/

Given that after the mixing step, a resin is produced into which TiO_2 is bound, the activities most likely to produce dust and, therefore, be high risk, are as follows:

- Handling and storage;
- Mixing; and
- Cleaning and maintenance.

Relevant assumptions are given in Table 6-8 and described below.

Table 6–8: Plastics sector: high risk activities and proportions of companies that are assumed to already have appropriate RMMs in place

	Small (0–49)	Medium (50–249)	Large (250+)
High risk activity:* handling, including packaging			
Total number of handling workers	2	15	30
Proportion (%) enterprises with partial LEV	70%	70%	90%
Proportion (%) enterprises with HEPA masks	90%	90%	100%
Proportion (%) enterprises with specialised storage	100%	100%	100%
High risk activity:* mixing and blending (masterbatch formation through addition to resin)			
Total number of handling workers	2	15	30
Proportion (%) enterprises with full LEV	90%	90%	90%
Proportion (%) enterprises with partial LEV	60%	60%	70%
Proportion (%) enterprises with HEPA masks	90%	90%	100%
Proportion (%) enterprises with sealed vessel	50%	70%	90%
High risk activity:* mixing and blending (dry pigment mixing into polymer)			
Total number of handling workers	2	15	30
Proportion (%) enterprises with full LEV	90%	90%	90%
Proportion (%) enterprises with partial LEV	60%	60%	70%
Proportion (%) enterprises with HEPA masks	90%	90%	100%
Proportion (%) enterprises with sealed vessel	50%	70%	90%
High risk activity:* cleaning and maintenance			
Total number of handling workers	2	4	10
Proportion (%) enterprises with HEPA masks	90%	90%	100%

Handling and storage

The number of workers involved in handling and storage of TiO_2 was estimated at 2, 15 and 30, for small, medium and large enterprises respectively (see Table 6-8).

Research by the EuPC[24] showed that, of plastics manufacturing companies surveyed, 57% reported respirable dust concentrations of 0–0.3 mg/m^3, 14% reported 0.3–1.0 mg/m^3 and 29% reported 1.0–2.4 mg/m^3. Those using small/big bags to receive TiO_2 are more likely to be using an open system, while those using silos or big bags are likely using a closed system. The survey also found that 48% bought TiO_2 in small bags only and were indeed more likely to have an air concentration of >2.4 mg/m^3. Taken together, a reasonable assumption is, therefore, that the majority of enterprises have appropriate RMMs in place. Some smaller enterprises, receiving smaller bags of TiO_2 are, however, likely to need to install partial LEV to meet the proposed OEL of 1.3 mg/m^3. Additional RPE (e.g.

24 Mytenka, A., de Kort, P. & and Tillieux, G., 2017. *TiO_2 Risk Assessment. Internal Report of the Plastics Industry,* s.l.: EuPC

HEPA masks) may be required in a minority of cases, although the EuPC survey found that 87% of workers already use masks when handling TiO_2. See Table 6-8 for the estimated proportion of enterprises assumed to already have appropriate RMMs in place to meet the proposed OEL of 1.3 mg/m^3, based on these assumptions.

Mixing

The number of workers involved in mixing was estimated at 2, 15 and 30, for small, medium and large enterprises respectively (see Table 6-8).

Firstly, we assume similar processes are followed for masterbatch formation and compounding. There are several processes for the incorporation of additives, including TiO_2 into the end polymers. These may be classed as closed or partially-open processes, but all produce volatile and particulate emissions.[25] Additional LEV would therefore only be required while adding raw material or if a partially open system is being used.

The exposure assessment carried out by EBRC does not give data for mixing specifically, but we assume that it is similar to the milling of powders. In this case (PROCs 4, 24, 26), a RWC estimate of 1.34 mg/m^3 was found for the respirable fraction, which is very slightly above the interim DNEL of 1.3 mg/m^3, with a resulting RCR of 1.03. This is based on the P90 of monitoring data and does not take into account the use of RPE. Combined with the previously outlined data from the EuPC survey, a reasonable assumption is therefore that the majority of enterprises have appropriate RMMs in place. Smaller enterprises are more likely to need to convert to a more closed process, while larger enterprises may need to employ full LEV where currently there is only partial LEV. Additional RPE (e.g. HEPA masks) may be required in a minority of cases although, as indicated above, the EuPC survey found that 87% of workers use masks when handling TiO_2. Table 6-8 provides a summary of the estimated proportion of enterprises who already have appropriate RMMs in place to meet the proposed OEL of 1.3 mg/m^3, based on these assumptions.

Cleaning and maintenance

The number of workers involved in cleaning and maintenance was estimated at 2, 4 and 10, for small, medium and large enterprises respectively (see Table 6-8). It is assumed that cleaning of equipment is carried out by trained professionals and the wearing of RPE is generally accepted and adopted in most facilities.

The exposure assessment found a RWC estimate is 1.91 mg/m^3 for the respirable fraction, with a resulting RCR of 1.47. As noted above, the EuPC survey found that 87% of workers use masks when handling TiO_2, and it is assumed there is a similarly high compliance rate amongst cleaners. It is likely that additional implementation of the wearing of RPE, in the form of masks in the minority of cases, will be sufficient to meet requirements. The estimated proportion of enterprises assumed to already have appropriate RPE in place is given in Table 6-8 above.

Cost estimates

Combining the above assumptions results in the estimated costs set out in Table 6-9 below, together with the total number of workers assumed to be exposed at levels above the DNEL within companies in each size band.

[25] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2004)8/rev1&doclanguage=en

Table 6-9: Plastics sector: estimated costs and number of workers			
	Small (0–49)	Medium (50–249)	Large (250+)
High risk activity:* handling and storing			
Total No. of handling workers	72,703	45,393	13,645
Cost to enterprises to install further partial LEV	€ 49,150,228	€ 31,677,243	€ 1,587,048
Cost to enterprises to supply further breathing (HEPA) masks	€ 1,970,865	€ 2,214,945	€ 0
Cost to enterprises to install specialised storage	€ 0	€ 0	€ 0
Total cost for enterprises to install RMMs	€ 51,121,092	€ 33,892,188	€ 1,587,048
Total annualised cost per handling worker	€ 703	€ 747	€ 116
High risk activity:* mixing and blending (masterbatch formation through addition to resin)			
Total no. of handling workers	72,703	45,393	13,645
Cost to enterprise to install further full LEV	€ 23,782,368	€ 19,358,317	€ 2,909,588
Cost to enterprises to install further partial LEV	€ 65,533,637	€ 42,236,325	€ 4,761,144
Cost to enterprises to supply further breathing (HEPA) masks	€ 16,383,409	€ 10,559,081	€ 0
Total cost for enterprises to install RMMs	€ 105,699,414	€ 72,153,723	€ 7,670,731
Total annualised cost per handling worker	€ 1,454	€ 1,590	€ 562
High risk activity:* mixing and blending (compounding)			
Total no. of handling workers	72,703	45,393	13,645
Cost to enterprise to install further full LEV	€ 23,782,368	€ 19,358,317	€ 2,909,588
Cost to enterprises to install further partial LEV	€ 65,533,637	€ 42,236,325	€ 4,761,144
Cost to enterprises to supply further breathing (HEPA) masks	€ 16,383,409	€ 10,559,081	€ 0
Total cost for enterprises to install RMMs	€ 105,699,414	€ 72,153,723	€ 7,670,731
Total annualised cost per handling worker	€ 1,454	€ 1,590	€ 562
High risk activity:* cleaning and maintenance			
Total number of handling workers	72,703	10,592	4,548
Cost to enterprises to supply further breathing (HEPA) masks	€ 1,970,865	€ 2,214,945	€ 0
Total cost for enterprises to install RMMs	€ 1,970,865	€ 2,214,945	€ 0
Total annualised cost per handling worker	€ 27	€ 209	€ 0

As noted earlier, it is important to recognise that it is assumed that most large enterprises are assumed to already have RMMs in place to protect most workers for exposures. In this case, it is assumed that HEPA masks are used by all workers in large enterprises. The extent to which such masks are used in small and medium enterprises is assumed to far lower, as is the extent to which such facilities have LEV in place.

Paper

Eurostat (2016) data was used to provide the number of enterprises in the paper sector, by size (see Table 6-10). As for the other sectors, German companies were removed from the calculations due to the existing national OEL.

Table 6-10: Paper sector: enterprise size			
	Enterprise size		
	Small (0–49)	Medium (50–249)	Large (250+)
No. of enterprises (excluding Germany)*	15,750	1,548	342
Proportion (%) enterprises handling powdered TiO2	89%	89%	89%

While there is considerable variation in the products made and the processes used, most paper-making processes involve the following steps, as also detailed in Figure 6-3 overleaf:[26]

1. **Handling and storage**: raw material is received, stored and weighed;
2. **Stock preparation**: virgin fibre (usually as imported dried pulp), recovered paper (usually as bales of waste paper) or a suspension of fibres (for integrated mills) are pulped and cleaned to remove contaminants. Dyes, pigments and optical brighteners (e.g. TiO_2) may be added at this stage.
3. **Paper machining**:
    - Headbox: introduces the suspension of fibres to the wire
    - Wire section: drains paper so that it contains 12–20% solids
    - Press section: removes more water from the web and increases solids content to 50%
    - Drying section: removes the rest of the water by heating the web with drying cylinders
    - Reeler: reels the paper web into a roll

4. **Optional finishing processes**, including:
    - Coating: paper grades such as art paper, machine coated papers, lightweight coated papers (e.g. for magazines) and folding boxboard, are typically coated with water-based emulsions of white pigments (e.g. TiO_2), binder and various additives.
    - Dyeing: if not added at the pulping stage, dyes, pigments and optical brighteners (e.g. TiO_2) may be added to the surface of the paper.

5. **Packing**
6. **Cleaning and maintenance**.

As described, TiO_2 may be added at the stock preparation stage or as part of a finishing process.

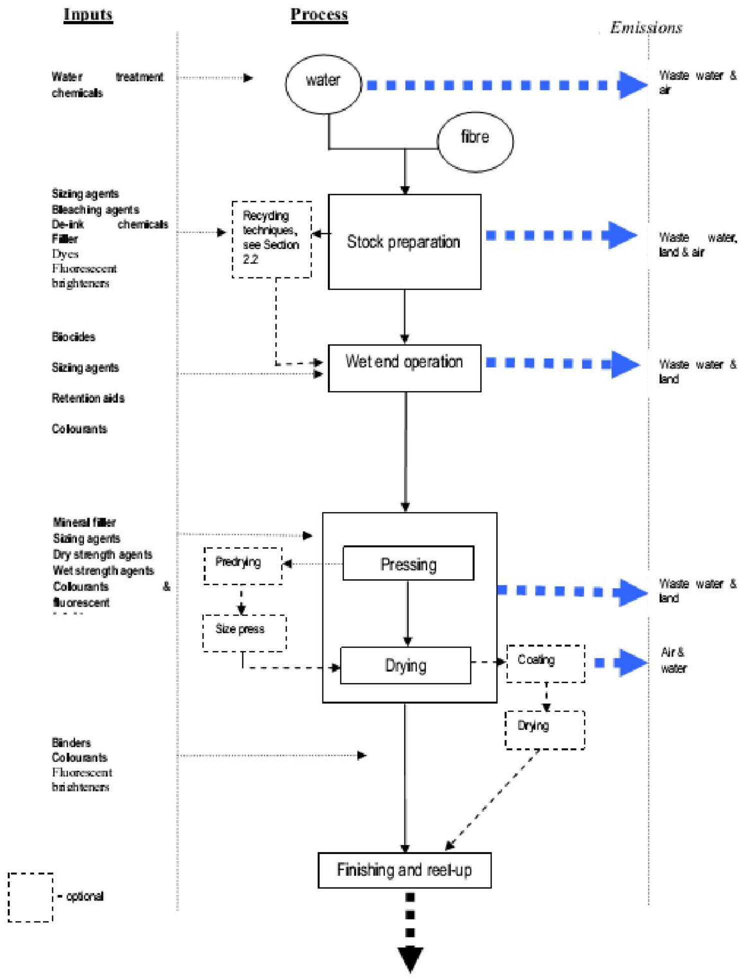
Due to its relatively high price, TiO_2 is not used in all paper production. Other additives such as kaolin, chalk, talc or calcium carbonate are used in its place, but have lower hiding power and whiteness. For some grades of paper, such as decorative papers, used for the production of furniture, flooring and wallpaper, TiO_2 is essential.

CEPI statistics indicate the production of 34 million tonnes of graphic papers, 7 million tonnes of sanitary and household papers, 46 million tonnes of packaging papers and 4 million tonnes of other paper and board in Europe (2016).[27] If, as an estimate, we assume that TiO_2 is used in all enterprises producing graphic and packaging papers, at the exclusion of others, approximately 89% of enterprises will be handling powdered TiO_2. This is a core assumption used in the analysis (see Table 6-10).

26 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)25&doclanguage=en

27 http://www.cepi.org/system/files/public/documents/publications/statistics/2017/KeyStatistics2016_Final.pdf

Figure 6-3: Key processes, chemical and releases in paper-making



Source: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)25&doclanguage=en

Given the manufacturing process described above, the activities most likely to produce TiO_2 dust and, therefore, be high risk, are as follows:

- Handling and storage;
- Stock preparation;
- Finishing processes (coating/dying); and
- Cleaning and maintenance.

Relevant assumptions are described below.

Handling and storage

The number of workers involved in handling and storage of TiO_2 was estimated at 2, 15 and 30, for small, medium and large enterprises respectively (see Table 6-10).

As for the other sectors, a RWC for handling of powders of 1.53 mg/m^3 for the respirable fraction is assumed, resulting in a RCR of 1.17. Papermills in particular are sensitive to controlling dust emissions due to the potential threat to workers from wood, paper and tissue dust. A reasonable assumption is therefore that the majority of enterprises have appropriate RMMs in place, particularly those that are larger. Where additional RMMs are required, these are likely to be in the form of partial LEV or a simple mask (RPE) during shorter duration handling activities, and in some enterprises only. Large enterprises are assumed to already have specialised storage and handling equipment in place and installation of additional storage equipment in SMEs is assumed unnecessary. See Table 6-11 for the estimated proportion of enterprises that already have appropriate RMMs in place to meet the proposed OEL of 1.3 mg/m^3, based on these assumptions.

Table 6-11: Paper sector: high risk activities and proportions of companies that are assumed to already have appropriate RMMs in place

	Small (0–49)	Medium (50–249)	Large (250+)
High risk activity:* handling and storage			
Total number of handling workers	2	15	30
Proportion (%) enterprises with partial LEV	70%	70%	90%
Proportion (%) enterprises with HEPA masks	50%	50%	70%
Proportion (%) enterprises with specialised storage	100%	100%	100%
High risk activity:* stock preparation			
Total number of handling workers	2	15	30
Proportion (%) enterprises with full LEV	90%	90%	90%
Proportion (%) enterprises with partial LEV	60%	60%	70%
Proportion (%) enterprises with HEPA masks	50%	70%	80%
Proportion (%) enterprises with sealed vessel	50%	70%	90%
High risk activity:* finishing processes			
Total number of handling workers	2	15	30
Proportion (%) enterprises with full LEV	90%	90%	90%
Proportion (%) enterprises with partial LEV	60%	60%	70%
Proportion (%) enterprises with HEPA masks	50%	70%	80%
Proportion (%) enterprises with sealed process	50%	70%	90%
High risk activity:* cleaning and maintenance			
Total number of handling workers	2	4	10
Proportion (%) enterprises with HEPA masks	70%	80%	90%

Stock preparation and finishing processes

The number of workers involved in mixing was estimated at 2, 15 and 30, for small, medium and large enterprises respectively (see Table 6-10).

Firstly, we assume that exposures are similar for the addition of TiO_2 during stock preparation and as part of the finishing process. A conservative estimate could be that the exposure levels are similar to those reported by EBRC for the milling of powders. In this case (PROCs 4, 24, 26), they state that at manufacturing sites, a RWC estimate is 1.34 mg/m^3 for the respirable fraction, with a resulting RCR of 1.03. As indicated above, it is a reasonable assumption that the majority of enterprises have appropriate RMMs in place for the control of wood and other dusts. Smaller enterprises are more likely to need to convert to a sealed vessel, while larger enterprises may need to employ full LEV, where currently there is only partial LEV. See Table 6-11 for the estimated proportion of enterprises that already have appropriate RMMs in place to meet the proposed OEL of 1.3 mg/m^3, based on these assumptions.

Cleaning and maintenance

The number of workers involved in cleaning and maintenance was estimated at 2, 4 and 10, for small, medium and large enterprises respectively (see Table 6-10). It is assumed that cleaning of equipment is carried out by trained professionals and the wearing of RPE is generally accepted and adopted in most facilities.

It is likely that additional implementation of the wearing of RPE, in the form of HEPA masks will be sufficient to meet requirements and the estimated proportion of enterprises that already have this in place is outlined in Table 6-11.

Cost estimates

Combining the above assumptions results in the estimated costs set out in Table 6-12 below, together with the total number of workers assumed to be exposed at levels above the DNEL within companies in each size band. The comments made with regard to variations in the estimates by company size for the previous sectors also hold here, with the figures varying depending on the number of facilities and workers assumed to be impacted.

Table 6-12: Paper sector: estimated costs and number of workers

	Small (0–49)	Medium (50–249)	Large (250+)
High risk activity:* handling and storing			
Total No. of handling workers	28,035	20,666	9,131
Cost to enterprises to install further partial LEV	€ 17,675,094	€ 13,449,362	€ 990,457
Cost to enterprises to supply further breathing (HEPA) masks	€ 3,543,750	€ 4,702,049	€ 623,295
Cost to enterprises to install specialised storage	€ 0	€ 0	€ 0
Total cost for enterprises to install RMMs	€ 21,218,843	€ 18,151,411	€ 1,613,752
Total annualised cost per handling worker	€ 757	€ 878	€ 177
High risk activity:* stock preparation (raw material)			
Total no. of handling workers	28,035	20,666	9,131
Cost to enterprise to install further full LEV	€ 8,552,465	€ 8,219,055	€ 1,815,838
Cost to enterprises to install further partial LEV	€ 23,566,792	€ 17,932,482	€ 2,971,371
Cost to enterprises to supply further breathing (HEPA) masks	€ 29,458,490	€ 13,449,362	€ 1,980,914
Total cost for enterprises to install RMMs	€ 61,577,746	€ 39,600,899	€ 6,768,122
Total annualised cost per handling worker	€ 2,196	€ 1,916	€ 741
High risk activity:* finishing processes (coating/dying)			
Total no. of handling workers	28,035	20,666	9,131
Cost to enterprise to install further full LEV	€ 8,552,465	€ 8,219,055	€ 1,815,838
Cost to enterprises to install further partial LEV	€ 23,566,792	€ 17,932,482	€ 2,971,371
Cost to enterprises to supply further breathing (HEPA) masks	€ 29,458,490	€ 13,449,362	€ 1,980,914
Total cost for enterprises to install RMMs	€ 61,577,746	€ 39,600,899	€ 6,768,122
Total annualised cost per handling worker	€ 2,196	€ 1,916	€ 741
High risk activity:* cleaning and maintenance			
Total number of handling workers	28,035	4,822	3,044
Cost to enterprises to supply further breathing (HEPA) masks	€ 2,126,250	€ 1,880,820	€ 207,765
Total cost for enterprises to install RMMs	€ 2,126,250	€ 1,880,820	€ 207,765
Total annualised cost per handling worker	€ 76	€ 390	€ 68

6.2.3 Estimation of benefits

There is a lack of data on the actual number of workers currently exposed to TiO_2 dust emissions at levels above the proposed OEL, making it impossible to calculate the benefits of a newly introduced OEL in terms of the number of cases of lung inflammation that would be avoided in the future. As a result, we have instead imputed the number of cases that would have to be avoided in order for the costs that could be incurred by industry in implementing further RMM to equate to the benefits of those avoided cases; in other words, we have calculated the "breakeven" number of cases avoided.

In undertaking these calculations, we have assumed the following:

- Current exposures are not leading to mortalities within the worker population but they may be leading to morbidity effects associated with lung inflammation[28];
- Lung inflammation at current exposures could vary from asthma-like effects to mild/moderate chronic obstructive pulmonary disease (COPD);
- Relevant benefits include reductions in medical costs, reductions in lost working days and workers' willingness to pay (WTP) to avoid a case of disease.

A study contracted by the European Chemical Agency looked at the WTP for avoiding respiratory sensitisation episodes (Máca, 2014[29]). The description of respiratory sensitisation used a profile of an acute hypersensitivity pneumonitis episode. Hypersensitivity pneumonitis (also called extrinsic allergic alveolitis) is an inflammation of the lungs due to breathing in a foreign substance, often organic dusts, moulds, fungus, and chemicals such as isocyanates or acid anhydrites. The description used in the survey is summarised below.

- Symptoms: fever, chills, cough, chest tightness, headaches and fatigue lasting for 1 day;
- Frequency: all day long;
- Duration: for one day;
- Consequences: normal quality of life;
- Outlook: return to normal health.

The estimated willingness to pay across the three countries where individuals were surveyed was around €16 per episode as the best estimate, with an upper bound figure of €50.

These figures look low, however, when compared to those used by the UK HSE[30] in quantifying the human health costs associated with a case of occupational lung inflammation. These are as follows based on UK figures for up to 6 days absence per annum for willingness to pay, as well as lost productivity and health care costs:

- Non-financial human costs (willingness to pay): €2500 to €4000 per annum
- Lost productivity: €1000 to €2,500 per annum
- Health care costs: €200 to €500 per annum

[28] Based on information provided by TDMA and its analysis of supporting epidemiological data.

[29] Máca V. (2014) Appendix: Willingness to pay for avoiding respiratory sensitisation outcomes. https://echa.europa.eu/documents/10162/13630/appendix_study_economic_benefits_avoiding_adverse_health_outcomes_1_en.pdf

[30] http://www.hse.gov.uk/economics/eauappraisal.htm

An alternative approach to using willingness to pay estimates is to draw on estimates of the disability adjusted life years (DALYs) associated with a case if respiratory illness. Based on DALYs given in the European Burden of Disease study, the avoided impacts could range from either:

- Avoidance of mild COPD and other chronic respiratory problems: 0.025
- Avoidance of asthma, partially controlled: 0.045
- Avoidance of moderate COPD and other chronic respiratory problems: 0.284

If it is assumed that a DALY equates to €100,000 per individual, then on a per annum per case basis, the above figures translate to an avoided health impact valued at between €2500 to €4500 to €28,400 for a much more severe case. These estimates therefore show a good degree of correlation with the figures assumed by the UK HSE for the milder forms of respiratory illness.

With respect to the economic costs of a case of ill health, asthma-related reference costs for the year 2015–2016 are available for the UK National Health Service. A single case of severe asthma, with interventions costs the healthcare system around £2,800 on average, with asthma related costs decreasing from this for less severe cases to around £660. This gives a range of around €3000 to €700 per case. Note that these figures are significantly higher than the health care costs assumed by the UK HSE. They also reflect costs within the UK, and these costs would vary in other EU Member States due to variations in health care provision.

Given the above, we use here the UK figures for up to 6 days absence per year due to respiratory illness, as the analysis also draws on UK prevalence data in the next step; the assumed total costs of a case of illness (or conversely the benefits of an avoided care) are:

- Non-financial human costs (willingness to pay): €2500 to €4000 per annum
- Lost productivity: €1000 to €2,500 per annum
- Health care costs: €200 to €700 per annum

If the annualised costs to industry of complying with the proposed OEL of 1.3 mg/m^3 are divided by the total costs of a case of illness, then the result is the estimated number of cases of respiratory illness that would have to be avoided for the benefits to equate to costs. The resulting figures are set out in Table 6-13.

The figures presented in Tables 6-13 based on the lower bound health costs (€3,700) suggest that, for most of the activities, an unrealistic percentage of the estimated number of exposed workers would have to experiencing respiratory effects for a period of 6 days for the health benefits of an OEL to equate to the costs of compliance. The key activity where it is clear that additional RMMs in the form of ensuring that workers wear appropriate masks relates to cleaning and maintenance activities. In some cases, there may also be merit in improving RMMs in relation to handling and storing activities.

If the upper bound costs are used (€7000 per annum – Table 6-14), then the arguments for ensuring appropriate respiratory protection for cleaning and maintenance activities become more clear as only a small percentage of workers need to experience effects for breakeven. The figures again become more unrealistic for the other activities, with the potential exception of handling and storing activities in some companies.

More generally though, the number of cases for breakeven should be considered within the context of the prevalence of occupational exposure related respiratory effects. One of the better sources of such data within the EU, and used in a number of EU studies as a result[31], are statistics produced by the UK Health & Safety Executive (HSE). This includes both data on physician reported and self-reported cases.

Table 6-13: Breakeven number of cases for high risk activities, by sector (lower-bound)								
Lower-bound Health costs: €3,700	Number of cases for breakeven				Percentage of all handling workers			
	Small (0–49)	Med (50–249)	Large (250+)	Total	Small (0–49)	Med (50–249)	Large (250+)	Total
Paints and coatings								
Handling and storing	1,132	1,087	78	**2,297**	20.23%	23.47%	4.72%	**19.34%**
Mixing (to make paste)	4,401	3,222	454	**8,076**	78.64%	69.58%	27.54%	**68.01%**
Cleaning and maintenance	113	113	10	**236**	2.03%	10.42%	1.82%	**3.27%**
Plastics								
Handling and storing	13,817	9,160	429	**23,405**	19.00%	20.18%	3.14%	**17.77%**
Mixing (masterbatch formation)	50,708	28,062	2,502	**81,272**	69.75%	61.82%	18.34%	**61.69%**
Mixing (compounding)	50,708	28,062	2,502	**81,272**	69.75%	61.82%	18.34%	**61.69%**
Cleaning and maintenance	533	599	0	**1,131**	0.73%	5.65%	0.00%	**1.29%**
Paper								
Handling and storing	5,735	4,906	436	**11,077**	20.46%	23.74%	4.78%	**19.15%**
Stock preparation (raw material)	24,605	14,338	2,097	**41,039**	87.76%	69.38%	22.96%	**70.96%**
Finishing process (coating/dying)	24,605	14,338	2,097	**41,039**	87.76%	69.38%	22.96%	**70.96%**
Cleaning and maintenance	575	508	56	**1,139**	2.05%	10.54%	1.84%	**3.17%**

Table 6-14: Breakeven number of cases for high risk activities, by sector (upper-bound)								
Upper-bound Health costs: €7,000	Number of cases for break-even				Percentage of all handling workers			
	Small (0–49)	Med (50–249)	Large (250+)	Total	Small (0–49)	Med (50–249)	Large (250+)	Total
Paints and coatings								
Handling and storing	598	575	41	**1,214**	10.69%	12.41%	2.50%	**10.22%**
Mixing (to make paste)	2,326	1,703	240	**4,269**	41.56%	36.78%	14.56%	**35.95%**
Cleaning and maintenance	60	60	5	**125**	1.07%	5.51%	0.96%	**1.73%**
Plastics								
Handling and storing	7,303	4,842	227	**12,371**	10.04%	10.67%	1.66%	**9.39%**
Mixing (masterbatch formation)	26,803	14,833	1,323	**42,958**	36.87%	32.68%	9.69%	**32.61%**
Mixing (compounding)	26,803	14,833	1,323	**42,958**	36.87%	32.68%	9.69%	**32.61%**
Cleaning and maintenance	282	316	0	**598**	0.39%	2.99%	0.00%	**0.68%**
Paper								
Handling and storing	3,031	2,593	231	**5,855**	10.81%	12.55%	2.52%	**10.12%**
Stock preparation (raw material)	13,005	7,579	1,108	**21,692**	46.39%	36.67%	12.14%	**37.51%**
Finishing process (coating/dying)	13,005	7,579	1,108	**21,692**	46.39%	36.67%	12.14%	**37.51%**
Cleaning and maintenance	304	269	30	**602**	1.08%	5.57%	0.98%	**1.68%**

31 See for example: http://ec.europa.eu/environment/chemicals/reach/pdf/study_final_report.pdf

The UK HSE has collected self-reported data (via survey) on work-related breathing or lung problems since 2001, and uses this to calculate the annual prevalence (and incidence) rates for the UK worker population. The rate reduced from around 200 cases per 100,000 workers in the early 2000s but has remained broadly constant over the last 10 years; there are currently an estimated 130 cases per 100,000 workers based on the latest three Labour Force Surveys, equivalent to 41,000 prevalent cases (95% Confidence Interval: 34,000 to 48,000).[32] This suggests an across all workers/sectors prevalence rate of 0.0013 cases per worker. In terms of the specific sectors relevant to the use of TiO_2, around 13% of self-reported cases are attributed to "airborne materials from spray painting or manufacturing foam products" (although these are most likely attributed to exposures to other substances such as isocyanates).

More specific data are also available for certain occupations, based on data reported by doctors participating in a national reporting scheme (SWORD). The relevant industry divisions with the highest rates of occupational asthma as seen by chest physicians are:

- Manufacture of chemicals: 10.4 cases per 100,000
- Other manufacturing: 7.3 cases per 100,000
- Manufacture of food products: 5.1 cases per 100,000

Rates for the manufacture of food products will be mainly driven by exposures to flour/grain and enzymes. As expected given the difference between these rates and the self-reporting rates, the UK HSE report[33] notes that these rates should be seen as minimal estimates.

Comparing these prevalence rates to the breakeven number of cases and the ratio of these to the number of workers indicates that an unrealistically high number of workers would need to be suffering from inflammation due to current exposures for the benefits of introducing a formal IOELV under CAD to equate to the costs on a strict costs versus benefits basis.

6.2.4 Effectiveness, practicality, broader effects and proportionality

Given the above findings, the assessment of this potential RMO in terms of its overall effectiveness, practicality, broader effects and proportionality is as follows:

- **Effectiveness**: it is clear that an IOELV has the potential for protecting workers against exposures above the threshold for effects. However, the it must be recognised that it is unlikely that the introduction of such an IOELV could deliver the level of reduction in respiratory illnesses calculated as required for a breakeven justification. In particular, given that some Member States require that companies reduce exposures to well below the threshold in order to demonstrate compliance (e.g. to potentially as low as 10% of the OELV), then the same level of effectiveness could probably be achieved through an industry agreement via the Social Partnership aimed at ensuring appropriate RMMs are in place to reduce exposures to below the threshold for effects (also in line with requirements for safe use under REACH). However, it must also be noted that the German employers' liability insurance associations (BG Bau and BG RCI) have confirmed to industry organisations that there have been no recognised cases of occupational disease in Germany[34] due to TiO_2

[32] http://www.hse.gov.uk/statistics/causdis/respiratory-diseases.pdf

[33] http://www.hse.gov.uk/statistics/causdis/asthma/asthma.pdf

[34] Verband der deutschen Lack- und Druckfarbenindustrie e.V., position paper, 30th January 2018.

exposures and no physician reported cases of respiratory illness from worker exposures to TiO_2; furthermore, from the data, it is clear that the majority of the self-reported cases will be linked to other occupational activities and exposures.

- **Practicality**: from a practicality perspective, introduction of an IOELV at the EU level is likely to be feasible. The three sectors covered by this more detailed analysis are not the only sectors that may be impacted. The inks, food packaging, food manufacturing, pharmaceutical, and recycling sectors may also need to take action, depending on existing exposure levels.

- **Broader effects**: introduction of an IOELV under the CAD could result in significant costs being incurred by some companies in order to demonstrate regulatory compliance, with these costs significantly greater than the economic benefits from the potential reduction in the number of cases of respiratory illnesses. Investment requirements could therefore impact on the viability or competitiveness of some actors within the main sectors, and in particular on SMEs.

- **Proportionality**: based on the above assessment, the most proportional option would appear to be voluntary action by industry to ensure that measures are taken to reduce worker exposures to TiO_2 dusts (as well as other dusts) within the workplace, where exposures are occurring above the DNEL. This may include the provision of additional guidance at the sectoral level on what measures should be implemented in order to ensure adherence to safe use requirements in line with manufacturers exposure scenarios. For example, this could take the form of increased guidance from Occupational Health and Safety Authorities on appropriate measures, or the inclusion of such information in BREF documents as part of detailing appropriate risk management measures/techniques for different sectors.

6.3 Labelling and packaging of mixtures

6.3.1 The option

The CLP Regulation is not normally considered a RMO, as it is essentially market access legislation. Its classification, labelling and packaging requirements must be complied with in order to place a substance or mixture onto the EU market.

However, the proposed classification and its translation into CLP is currently the subject of discussion within the CARACAL, given the potential implications. As noted in European Commission's summary of the Open Session of the 26th Meeting of Caracal:

> *"Comments related to the various aspects of TiO_2 classification or different levels in a CLP context, ranging from the pure scientific debate on the justification of classification over questions on notes and exemptions relating to the entry in Annex VI to political questions whether CLP is the appropriate legal framework to classify TiO_2 under."*

In particular, Member States and observers raised questions over what the added value would be of classifying TiO2 and other substances that can be characterised as poorly soluble low toxicity particles (PSLT), particularly with respect to the classification of liquid mixtures containing a PSLT substance which only causes adverse effects in its particle form via inhalation.

This RMO therefore considers the potential impacts of mandatory classification and labelling of mixtures which are intended for professional or consumer use, as well as the need for tactile warnings on packaging.

6.3.2 Cost implications

New classification and labelling obligations would arise for all mixtures containing TiO_2 at a concentration above 1.0% w/w. Such mixtures would have to be labelled with the hazard symbol GHS08 "health hazard" and the hazard statement H351 – "suspected of causing cancer" (Cat 2, on inhalation).

This would include the introduction of labelling requirements for mixtures which currently have no hazard classifications as well as an extension of labelling requirements for those mixtures already classified due to other ingredients. There are significant cost implications of this:

- There are an estimated 2.5 million or more mixtures being placed on the EU market;

- A significant proportion of these will be paint, ink and lacquer formulations, with German data indicating that only 5% of paint and coating colours are produced without TiO_2. As a result, the German VdL suggests that around 570,000 paint formulations produced by the German industry sectors alone[35] will be based on TiO_2 at concentrations above 1.0%; at the EU level, the figure could clearly be significantly higher at around 1.65 million mixtures, based on estimates form work on poison centre reporting obligations for the sector[36]. To err on the side of conservatism, it is assumed here that around 1 million paint, inks and lacquer formulations could be affected;

- Based on assumptions from the recent Fitness Check on CLP and related chemicals legislation[37], and assuming fairly low costs associated with classification, labelling and SDS requirements (around €1,000 per mixture), the obligations triggered by CLP could cost mixture manufacturers around €1000 million. These costs estimates may be high, as relabeling could be organised around other changes in label design, which are carried out for consumer mixtures on a fairly regular basis. If only the costs of re-classification are taken into account, the total falls to around €400 million. Again, to a degree, these costs may be minimised by re-classifying mixtures in line with other reformulation activities as part of product development. Even if this is possible, the costs to mixture manufacturers are likely to be significant.

- In addition to these requirements, packaging would need to be modified so as to include tactile warnings. It is not possible to estimate the magnitude of such costs, however, they are likely to include: the need for new packaging design, modifications to packaging lines to accommodate the tactile warning, and the need to dispose of obsolete packaging. Indeed,

[35] Verband der deutschen Lack- und Druckfarbenindustrie e.V., position paper, 30th January 2018

[36] http://ec.europa.eu/DocsRoom/documents/14006/attachments/1/translations

[37] The CLP Fitness Check study found costs of around €400 for classification, €475 for re-labelling and costs of around €250 for providing new SDS; costs were not provided for disposal of labels or for new packaging. See: RPA et al (2017): Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding EEACH), in particular the CLP Regulation and related legislation: Annex 2, Final Report to the Eurpean Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate D.2.

costs associated with the disposal of obsolete labels and packaging are often cited as a costly aspect of changes in classification. Again, some of these costs may be mitigated by the transition period allowed for adherence with CLP's obligations, e.g. the costs associated with the need to dispose of obsolete packaging.

In addition to the above costs, the proposed classification would give rise to new Poison Centre reporting obligations under Article 45 of the CLP Regulation. Article 45 requires manufacturers to disclose formulations for mixtures containing substances classified as dangerous to national Poison Centres. If titanium dioxide were to be classified as Carc. Cat. 2, with serious consequences especially for the manufacturers of paints, coatings and printing inks.

The cost implications are potentially significant:

- Around 47% of mixtures are already estimated to be classified as hazardous and, as a result, there will already be reporting obligations for these mixtures. New obligations would only apply to the 53% not currently classified as hazardous;

- Based on the above figure for the number of paint, ink and lacquer mixtures placed on the EU market, this implies that Poison Centre reporting obligations may newly apply to around 530,000 mixtures per annum;

- The potential costs of these obligations are currently subject to some debate, and will depend on the degree to which the mixture is placed on the market in more than one Member State. At a conservative €30 per mixture, these obligations equate to around €15.9 million in a one-off obligation for first time notification;

- In addition, companies that were not previously subject to reporting would face costs for software and personnel.

6.3.3 Potential benefits

The aim of classification and labelling is to ensure that users of (substances and) mixtures have the information that they need to ensure that they are able to use them safely. This is particularly important for professional and consumer users of mixtures, who do not also receive a SDS.

There is no straightforward way of assessing what the benefits may be from the need for re-classification, labelling and poison centre reporting under CLP. We rely here on a break-even analysis using the estimates from the study undertaken for ECHA on individuals' willingness to pay to avoid a case of respiratory sensitisation (with the description based on hypersensitivity pneumonitis - also called extrinsic allergic alveolitis - an inflammation of the lungs due to breathing in a foreign substance, often organic dusts, moulds, fungus, and chemicals such as isocyanates or acid anhydrites; see Máca, 2014[38]). As detailed above, the estimated willingness to pay across the three countries where individuals were surveyed was around €16 per episode as the best estimate, with an upper bound figure of €50.

Taking only the Poison Centre reporting obligations at an estimated €15.9 million, this would equate to an estimated 318,000 avoided cases of lung inflammation. Data from the Fitness Check indicate

[38] Máca V. (2014) Appendix: Willingness to pay for avoiding respiratory sensitisation outcomes. https://echa.europa.eu/documents/10162/13630/appendix_study_economic_benefits_avoiding_adverse_health_outcomes_1_en.pdf

that for the period from 2000 to 2016, there were around 393,500 cases of non-deliberate poisonings for the EU 28. These figures reflect an average of 45,190 per year (not taking into account the significant annual decline in incidents post 2010). Thus, breakeven may occur between the costs of such obligations and the avoidance of lung inflammation related-poisonings over a 20-25 year period, given that mixture manufacturers will also face new annual reporting obligations due to the classification.

Off-setting these potential health benefits in terms of avoided cases of illness within the general population and professional user population, is concern that applying such a classification to well-known consumer products (e.g. paints for domestic use) will lead to consumers downgrading the value of CLP labelling and hence the meaning of the different precaution and hazard phrases. Classification of TiO2 as a suspected Carc. Cat. 2 would result in paints having to be labelled with the hazard symbol GHS08 and the words "suspected of causing cancer". This is likely to cause considerable uncertainty, especially among consumers and lead to confusion over the meaning of such phrases, to the detriment of the hazard communication goals of CLP more generally. This is particularly important given the number of consumer products that would be marked as potentially carcinogenic.

In France, there is a self-service ban for products containing potentially carcinogenic substances (Cat. 2). 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.

6.3.4 Effectiveness, practicality, broader effects and proportionality

- **Effectiveness**: The potential effectiveness of CLP's classification, labelling and packaging requirements in this case is likely to vary across different types of users: for industrial users, classification and labelling, together with SDS, can be viewed as important to ensuring that workers are protected and take appropriate measures to avoid respiration of TiO2 dust particles. For professional users, labelling may either be confusing in the case of most mixtures and uses or help ensure that measures are taken to avoid inhalation of respirable particles; however, the labelling of large numbers of well-known mixtures may also reduce the extent to which these users respond as intended to the labels. For consumers, effectiveness is likely to be even more questionable given the lower levels of exposure.

- **Practicality**: The need to re-classify, re-label and shift to new packaging with tactile warnings may not be practicable if an inadequate transition period is allowed for, given the significant number of mixtures that would be affected by the CLH for Carc. Cat. 2. This includes bringing new mixtures into the scope of classification as hazardous, requiring re-design of existing labels for different package sizes, etc. Note that it could also have significant implications with respect to the systems that companies need to put in place to deal with poison centre reporting obligations.

- **Broader effects**: The classification would also affect those products in which titanium dioxide is permanently bound in a matrix and therefore cannot be inhaled, with the potential for unintended consequences. Of more concern is that the use of the hazard symbol and labelling for "suspected of causing cancer" on large numbers of consumer products could raise undue concern, even when there is no danger of inhalation. As a worst case, the potential over-labelling of mixtures could impact on the effectiveness of CLP as a whole as a hazard communication tool.

- **Proportionality**: Given the above, mandatory classification, labelling and packaging according to CLP without derogations for most downstream/consumer mixtures could be considered to result in disproportionate impacts; in addition, it would not directly result in the protection of workers from dust emissions within the workplace, which would be more achievable through other measures such as adherence to dust-based exposure limit values.

6.4 Measures related to professional activities

6.4.1 The option

For professional users of paints and coatings (as the main mixtures) containing TiO_2, three different activities have been identified as giving rise to potential exposures above the DNEL. These are:

- Paint spraying by professionals;
- Sanding in professional settings; and
- Hand mixing in professional settings.

As indicated previously, there is considerable uncertainty as to whether these workers would be exposed to respirable particles when undertaking the above activities. To err on the side of conservativism, it has been assumed that this could be the case for the purposes of this assessment. This is an issue being further investigated at the time of preparing this RMOA.

These exposure settings are related to professionals in the decorating, refurbishment and potentially building/construction sectors. The populations at risk may vary given the differences in the activities, but are also assumed to overlap. For example, a professional using paint spraying equipment is also likely to undertake sanding as part of surface preparation and may carry out hand mixing of plasters and other building materials as part of the repair of surfaces prior to paint spraying. However, other workers may also be involved in both sanding activities and especially in hand mixing in a professional setting (plasters, grouts, cements).

No reliable figures at the EU level could be found for the numbers of professionals involved in the different activities and hence that may be exposed in these settings. UK figures for the number of enterprises active in the construction sector and undertaking specific trades have been used as the basis for estimating the potential population exposed.

Table 6-15: Assumptions on the potentially exposed population across the EU

Type of trade	Thousands of workers EU*	Relevant to paint spraying?	Relevant to sanding?	Relevant to mixing?
Plastering	214,240		30%	60%
Floor and wall covering	396,575		30%	60%
Painting and glazing	634,620	20%	60%	
Other building completion and finishing	479,050	10%	30%	60%

* Worker numbers based on Eurostat data for 2015, NACE Rev. 2, F [sbs_na_con_r2] extracted 02/2018

Table 6-16: Adjustments for numbers involved in an activity		
Activity	**Number of workers exposed**	**Rationale**
Total relevant to spray painting	64,270	Assume only 20% of painters use sprayers on a regular basis
Total relevant to sanding excluding painters	321,354	Assume only a small proportion of plasters but a higher proportion of other building would also undertake power sanding - 30% may be high
Total relevant to mixing excluding sanding	385,625	Assume at least half would undertake mixing on site but exclude 0.3 of plasterers
Total	771,250	

6.4.2 Costs

Three potential risk management options have been identified as potentially feasible options for reducing the risks faced by professionals undertaking paint spraying, sanding or mixing activities which could give rise to exposures above 1.3 mg/m3. These are all viewed as possible alternatives to mandatory classification and labelling of mixtures containing TiO_2 as a Carc Cat 2, where these are not supplied in powder form. Where the mixture is supplied in powder form (e.g. dry plaster), then the options may be complementary or an alternative to classification and labelling.

- Restriction on the sale of equipment: Manufacturers must supply a dusk mask and spare filters with all paint sprayers placed on the market, which are capable of generating droplets of a respirable size, together with advice on safe use;
- Additional health and safety advice as part of technical training for those entering the construction sector and relevant trades on the need to wear appropriate respiratory protection when undertaking mixing and sanding activities; and
- Information campaigns managed by manufacturers of paints, paint sprayers, and hand-held mixing tools on the need to wear appropriate respiratory protection.

Such measures could be adopted in combination or singly. Assumptions and corresponding cost figures are given in the table below. Note that no figures for the number of paint sprayers sold on the EU market were readily available. It has therefore been assumed that roughly 10% of professional painters may purchase a paint sprayer in a given year.

Table 6-17: Costs of different risk management options			
Option	**Assumptions**	**Cost per unit**	**Total costs**
Manufacturer supply of masks with paint sprayers	60,000 paint sprayers sold per annum	Mask meeting P3 standards costs €40 - including replacement filters[39]	€2 million per annum
Additional health and safety advice as part of technical training	Addition of modules in technical training courses at relevant colleges/training centres	€500k for development of materials; 200k per MS for creation of curriculum and for integration into technical courses	€6.1 million
Industry led information campaigns	Posters / leaflets distributed to suppliers servicing the construction sector	€300,000 per MS – may be an underestimate as depends on number of stores/etc.	€8.4 million
Assumes a mask with a protection factor of 20 to 40 from particle inhalation would be required			

39 https://www.dustmasksdirect.co.uk/3m-4251-reusable-dust-mask---a1p2-filters-3314-p.asp?gclid=EAIaIQobChMI8KbQ4req2QIVBLftCh3dKgihEAQYAiABEgIRLvD_BwE

With respect to the development of technical training materials and information campaigns, searches indicate that successful programmes and campaigns can be run on fairly small budgets or may require a more extensive level of activity. The figures given in Table 6-17 are guesstimates and costs may be higher or lower, depending on the breadth and depth of what is required.

Other potential measures include making sure that paint sprayers and hand-held mixing tools can only be purchased in builders'supply shops by individuals certified as having had proper training on their safe use; or, establishing requirements for building site operators to check that self-employed professionals have had proper training on safe use (with the analogy being requirements for certificates of competence for use of chain saws or fork lift trucks).

6.4.3 Benefit estimates

In order to estimate the potential benefits of the above risk management options, we draw on the same types of assumptions as for the other measures with regard to the potential benefits from reducing exposures, in this case associated with spraying, sanding or mixing. In this case, it is also assumed that any on-going problems would lead to a professional user either changing occupation or changing work practices (e.g. adopting RPE themselves). Thus, we consider as a lower bound estimate the avoidance of an episode of ill-health with the avoidance of ill-health over a year as an upper bound.

UK data on the prevalence of work related respiratory diseases are adopted here, to be consistent also with the use of UK self-reporting data. THORR records case reports of work-related respiratory disease reported by chest physicians to SWORD (respiratory disease database). These rates are based on the reported cases through THORR and The Office for National Statistics Annual Population Survey (APS) employment estimates. THORR04 gives average annual rates per 100,000 workers over a 3-year and 10-year period (2007–2016).

Figures are given for skilled trades, however, these only cover painters and decorators and not builders more generally. The annual average rate per 100,000 over a 3 and a 10 year period are 0.3 and 0.6 workers per 100,000 respectively.

As discussed above, the UK HSE has also collected self-reported data (via its periodic Labour Force Survey) on work-related breathing or lung problems since 2001, and uses this to calculate the annual prevalence (and incidence) rates for the UK worker population. The rate reduced from around 200 cases per 100,000 workers in the early 2000s but has remained broadly constant over the last 10 years, with a central estimate of 130 cases per 100,000 based on the latest three Labour Force Surveys, equivalent to a prevalence of 42,000 cases (95% Confidence Interval: 34,000 to 48,000).[40] This suggests an across all workers/sectors prevalence rate of 0.0013 cases per worker.

In terms of specific sectors relevant to the use of TiO_2, around 13% of self-reported cases are attributed to "airborne materials from spray painting or manufacturing foam products" (although these are most likely attributed to isocyanates) and "Dusts from stone, cement, brick or concrete" account for nearly 20% of cases. The latter may apply to a significantly larger population than those considered above, and include a range of other building / construction professionals; together these more specific self-reported cases equate to 42.9 cases per annum. This figure is used as a lower bound estimate.

[40] http://www.hse.gov.uk/statistics/causdis/respiratory-diseases.pdf

Combining the UK HSE self-reporting figures with the estimated numbers of workers exposed allows calculation of the potential benefits of the above risk management options. The resulting estimates are set out in the table below. Based on the figures given in the table below, the above RMOs would appear to be justified on economic grounds.

Table 6-18: Costs of different risk management options

	Number of cases based on self-reported rate	Willingness to Pay (WTP)	Lost productivity	Health care costs	Total
Lower bound economic values and rate (0.00042 per worker)	324	809,800	323,925	64,785	1,198,520
Upper bound economic value and rate (0.0013 per worker)	1003	4,010,500	2,506,560	501,310	7,018,370

6.4.4 Effectiveness, practicality, broader effects and proportionality

- **Effectiveness**: It is not clear how effective any of the above measures would be, as all rely on self-employed workers/professional users acting upon health and safety advice and adopting measures as part of their own working practices to minimise exposures to TiO_2 dusts / particles. However, all of the measures reinforce current "best practice" advice, which should help in terms of their effectiveness. As the measures would also be focused at particular types of exposures they may also be more effective than more general guidance on "best practice".

- **Practicality**: The measures involving improved technical training and information campaigns are considered to be practical. It should be possible to develop the appropriate materials, and to make these available to technical training centres and to retailers. The mandatory inclusion of masks with all relevant equipment may be difficult to enforce, especially with respect to imported products. It may also be difficult to ensure that relevant information is also available to only those that purchase sprayer or powder mixing equipment over the internet, in addition to enforcing the inclusions of masks in the sale of such equipment. The latter is a problem more generally though in terms of ensuring the safe use of substances and mixtures.

- **Broader effects**: As the measures would result in awareness raising, they may have broader effects in terms of encouraging positive behaviour in professionals and self-employed workers with regard to wearing recommended personal protective equipment. However, the extent of any such benefit is highly uncertain. The opposite may also be the case, as workers may view the need for such measures as unnecessary based on their own working experiences over many years.

- **Proportionality**: In general, these measures are seen as proportional, even given the uncertainty surrounding both the costs and the potential benefits. Although it must be stressed that there is considerable uncertainty as to whether workers could be exposed to respirable particles of TiO_2 when undertaking the above activities.

6.5 Measures related to consumer uses

6.5.1 The option

Although paint sprayers may be sold to DIY consumers, this is likely to be a much smaller number than professional users. Furthermore, the measures proposed above in relation to self-employed professionals should also result in benefits in terms of reduced exposures for the segment of the population that undertakes DIY (spray painting, sanding, mixing plaster or adhesive powders for tiling, etc.).

The above measures would not address potential exposures through the use of aerosol paints, however. The use of aerosol paints has been identified as a possible source of exposure that, if undertaken in confined conditions and for a sufficient duration, could lead to an exposure leading to temporary effects. It is assumed here that use of pre-package aerosol paints is most likely to be undertaken by the self-employed or by members of the general public.

Data available from the European Aerosols Federation and the British Aerosol Manufacturer's association indicates that:

- 5 billion aerosol cans are sold in Europe per year on average;
- The UK is the largest aerosol filler in Europe, filling over 1.5 billion units per annum;
- 65% of UK production is exported; and
- Paints and lacquers accounted for 14 million units produced in the UK in 2014; pro rata, this suggests that around 46 million aerosol units containing paints and lacquers may be produced per annum across the EU.

Based on the above, there is the potential for 46 million consumer exposures per annum in the EU if each "use" equates to only 1 can. Any one occasion of use may equate to more than 1 can, for example, if using an aerosol as part of DIY to re-paint radiators, with this then decreasing the potential number of exposure events. For example, if each "use" equates to 1.2 cans on average, then this reduces the figure to around 39 (38.89 rounded up) million consumer exposures per annum.

6.5.2 Costs

A disposable half mask with a particle filter that meets a protection factor of 20 is assumed to be sufficient to protect DIY users of aerosols from over-exposure and subsequent health effects given the likely short duration of the exposure. These can be sourced from on-line retailers for as little as €1 per disposable mask and it is likely that manufacturers of aerosol paints would be able to undertake bulk purchasing in order to reduce the costs per mask.

Cans of aerosol paint for various uses appear to retail from around €5 per can (to significantly higher prices for the more specialist products), thus the inclusion of a mask could increase the price by as much as 10% if it is assumed that a mask costs €0.5, or by around 5% if it is assumed it costs retailers only €0.25 per mask, and they are included with each can as part of an "aerosol package".

Based on these assumptions the costs to aerosol manufacturers per unit retailed would be:

- Upper bound @ €0.5 per aerosol unit for inclusion of a mask: €23.3 million
- Lower bound @ €0.25 per aerosol unit for inclusion of a mask: €11.7 million

6.5.3 Benefit estimates

Most aerosol paint cans will include a range of hazard and precautionary statements due to contents other than the presence of TiO_2, for example, xylene, 2-butanone oxime, various N-alkanes and isoalkanes, etc. These ingredients will require hazard labelling with phrases such as " Do not breathe vapour or spray", "If Inhaled: Remove person to fresh air and keep comfortable for breathing". Some REACH SDS which also cover aerosols that are accessible to consumers include wearing a mask as part of preventative measures, while others do not. Similarly, guidance on some cans indicates that users should wear a mask.

For the purpose of this benefit assessment, it is assumed that only around 30% of consumer users currently wear a mask, given that one is not currently supplied with the product. This equates to around 11.7 million of the assumed 39 million consumer exposures per annum being carried out using a mask; the remaining 27.3 million are assumed to be carried out without any respiratory protection. This may be a significant underestimate. Surveys undertaken by the US EPA in 1992 found that most consumers use spray paints outdoors, or in garages (which will have high ventilation rates relative to other rooms), and that they wore masks or gloves if instructed to do so on the label[41]. It also found a high level of awareness regarding the need for ventilation, with 81% of respondents indicating that they would have a door or window open if using an aerosol paint indoors.

As such exposures relate to one-off events, the WTP estimates for avoiding respiratory sensitisation episodes as developed by Máca (2014[42]) for ECHA are adopted to calculate a breakeven number of cases for comparison to the figure of 27 million. We adopt a lower bound value of €16 per episode (reflecting the best estimate) and an upper bound figure of €50. This suggests the number of cases that would have to be avoided as given in Table 6-19 for a breakeven between costs and benefits to be realised.

Table 6-19: Breakeven numbers of respiratory sensitisation episodes for inclusion of masks with aerosols

	Cost per mask	WTP per episode avoided	Breakeven number of episodes avoided	% of total occasions of use
Upper bound	€0.50	€16	1,458,300	12.5%
		€50	466,700	4%
Lower bound	€0.25	€16	729,200	6.2%
		€50	233,300	2%

The percentage figures given in Table 6-19 at first sight do not look unreasonable, especially if the assumed economic value of avoiding an episode of respiratory sensitisation is €50. However, the percentages do look high when compared to inquiries over exposures to paints and paint thinners to poison centres. Data for the UK poison centre, for example, indicate that 1,382 out of 465,111 reporting sessions related to inquiries about exposures to paints or paint thinners[43]. This is about 0.3% of all sessions. Clearly, these figures are not directly comparable with those given in Table 6-18, but comparison of the number of episodes that would have to be avoided with the number of sessions suggests that the breakeven numbers of episodes are unrealistically high.

41 Driver et al (2001): Residential Exposure Assessment: A Sourcebook. Kluwer Academic/Plenum Publishers, New York.

42 Máca V. (2014) Appendix: Willingness to pay for avoiding respiratory sensitisation outcomes. https://echa.europa.eu/documents/10162/13630/appendix_study_economic_benefits_avoiding_adverse_health_outcomes_1_en.pdf

43 http://www.npis.org/NPISAnnualReport2010-11.pdf

6.5.4 Effectiveness, practicality, broader effects and proportionality

- **Effectiveness**: It is not clear how effective the above measure would be, as it relies on consumers acting upon health and safety advice; it also assumes that users currently do not take preventative measures, which appears not to be the case based on surveys carried out by the US EPA (albeit over 15 years ago). Although the provision of a mask may increase the percentage of aerosol users who do then wear the mask, there is likely to be a group of individuals accustomed to the use of aerosol sprays who do not. However, it is also unlikely that many consumer users will use spray aerosols for sufficiently long periods or frequently enough to experience significant respiratory effects.

- **Practicality**: The mandatory inclusion of masks with all consumer aerosols containing TiO_2 placed on the market may be difficult to enforce, especially with respect to imported products. This may be a particular issue with products sold over the internet, and which may also include products imported into the EU.

- **Broader effects**: As the measure would result in awareness raising, it may have broader effects in terms of encouraging positive behaviour in self-employed workers and consumers with regard to wearing recommended personal protective equipment. However, the extent of any such benefit is highly uncertain. The opposite may also be the case, as consumers may view the need for such measures as unnecessary based on their own experience, and may react by also disregarding other hazard warnings.

- **Proportionality**: In general, the measure is unlikely to be proportional, given the uncertainty surrounding the potential benefits.

6.6 Removal of approval for use in food

6.6.1 The option

TiO_2 is found in food both in its bulk form and as a nanomaterial (Weir et al. 2012) (Jovanovic, 2015), although food-grade TiO_2 is not considered a nanomaterial by the current EC Recommendations[44]. TiO_2 can be found in many foods, including:

- Dairy analogues
- Edible ices
- Confectionary, e.g. breath fresheners (as barrier between colours), chewing gum and lollipops
- Decorations, coatings and fillings
- Baked goods
- Soups and broths
- Cottage and mozzarella cheese (to increase opacity)
- Sauces, e.g. pickles, relishes, chutney, horseradish and piccalilli
- Sandwich spreads
- Flavoured drinks, e.g. chocolate milk, malt products (to increase rich texture and turbidity)

[44] Food grade TiO_2 may contain up to 3.2% nanoparticles (less than 100 nanometres in size) by weight (EFSA, 2016), which has attracted some concern regarding safety to health and the environment. The current classification being analysed here, however, relates to inhalable TiO_2 and not nano- TiO_2 specifically.

- Processed nuts, and
- Desserts.

In the majority of products, it is in a liquid or suspension. Inhalable TiO_2, i.e. in a spray or powder, is available to the consumer in the following products: edible glitter sprays for baking; icing sugar; powdered jelly (with glitter/lustre); and baby formula (very small quantities).

The Carc Cat 2 classification could result in TiO_2 being removed from the list of permitted colours in foodstuff. The downstream implications of this would be:

- **Substitution**: As noted in Section 4, this would not be possible in all products and if an alternative is to be found, this would require extensive, prolonged research and authorisation, with no guarantee that it would be better for health and the environment.

- **Removal from the market**: Where possible TiO_2 could be removed from those recipes where it's use is aesthetic and has minimal impact on quality; for other products, such as edible glitters, the impact would be the removal of the end-product itself from the market entirely.

- **MS-led derogation**: following removal from the market, there would need to be action at the national level for the re-instatement of TiO_2 onto approved lists. This could take a significant period of time, and in the meantime there would be impacts on the availability of particular food products.

6.6.2 Costs

Given the extremely low probability of exposure to TiO_2 by inhalation through food, and the lack of a feasible substitute, it is likely that continued use of TiO_2 will eventually be approved. However, the mechanism for doing this would be led by the Member States' Food Safety Authorities, will be time consuming, and is likely to cause significant concern among consumers, and consequently a drop in sales of those products containing TiO_2 (RPA, 2017).

There is no other white colourant approved under Regulation 1333/2008 that meets the performance of TiO_2 and so reformulation is not feasible. Calcium carbonate (E170) is the only other white additive, but it does not have the opacity of TiO_2 and has severe technical limitations (RPA, 2017):

- It is a much less effective white colour than TiO_2. There are applications where the layer thickness of a print on a foodstuff (for instance, prints on dark and milk chocolate) is too thin to enable any other product to be opaque enough (and white/neutral in colour) in order to have a clear visual effect;
- It will readily react with any acids present in foods to generate carbon dioxide and a (possibly soluble) calcium salt with no white colouring properties;
- It could not be used as a colour in any foods with low pH as it would neutralise the acid present, adversely affecting the product flavour, quality and possibly shelf life;
- It could not be used as a white colour in cake batters, scone doughs, etc. since it would interfere with the raising agent system;
- It could not be used as a replacement to produce white glitter powders since E555 (Potassium aluminium silicate - mica) is only authorised for use as a carrier for TiO_2 (and E172 iron oxides which produce red/brown colour glitter powders).

If any alternative could be identified, it would have to go through the long authorisation process for food additives, involving a Scientific Opinion on its safety from EFSA, authorisation by the European Commission and an implementing Regulation to amend Regulation EC No 1333/2008. This process would take years.

Thus, the impact of a ban on the use of TiO_2 in food is likely to have severe detrimental consequences to colour producers (FoodDrinkEurope, 2017), including the potential loss of business due to increased costs or due to the loss of products. For those looking to substitute or to develop substitutes, there could also be negative consequences including the following (FoodDrinkEurope, 2017):

- Costs of developing and gaining approval for a substitute;
- Potential loss of business due to lower product quality;
- Increase in complexity between EU / outside-EU productions; and
- Price increases to downstream users (food manufacturers, professional users, bakers and consumers).

Professional users, such as bakers, would also need to adapt recipes and practices to accommodate the lack of TiO_2:

- Cost of developing new recipes;
- Loss of quality in terms of restriction on decorative finishes available; and
- As a result of above, potential loss of business leading to the loss of profit or a significant increase in the costs.

The loss of TiO_2 as an allowable additive to food, is likely to have a predominantly negative impact on consumers (FoodDrinkEurope, 2017):

- A significant increase to the retail cost of some food products;
- Foods may spoil more rapidly in some cases;
- Small amounts of TiO_2 are very effective, so substitution with less effective alternatives would result in larger amounts being used, with potential health effects and taste effects (FoodDrinkEurope, 2017);
- Reduction in visual quality, particularly with regards to baked goods; and
- Complete loss of some products, e.g. pearlescent baking products.

6.6.3 The benefits

It is possible that the removal of TiO_2 from manufacturing sites could have a minor benefit on the health of workers. However, these benefits could be achieved by implementation of an OEL, either through voluntary adherence, or via the Chemical Agents Directive. Similarly, it is possible that the removal of TiO_2 from, for example, bakeries could have a minor benefit on professional users. However, limits are already in place regarding the levels of dust in such environments so any benefits will be minimal.

EFSA, at the request of the European Commission, is currently re-evaluating all food additives authorised before 20 January 2009, taking into account any new evidence. Based on EFSA's scientific advice, the European Commission and Member States then decide whether to change the conditions of use for an additive or, if needed, remove it from the EU list of authorised food additives to protect consumers (EFSA, 2016). In 2016, EFSA's experts concluded that available data on TiO_2 in food do not indicate health concerns for consumers. They have recommended that new studies be carried out to fill data gaps with regards to possible effects on the reproductive system, which could enable them to set an Acceptable Daily Intake (ADI) (EFSA, 2016).

In the food additives area, when there are insufficient data for establishing an ADI, risk assessors calculate a margin of safety to determine whether current exposure might be of potential concern. Generally, a margin of safety of 100 or more is not considered to be a concern for public health. In the most realistic scenario for food-grade TiO_2, the margin of safety for high-consuming children (the most exposed population) would be 150, but for most scenarios the margins were several times higher." (EFSA, 2016)

Based on the above, the benefits of any additional measures prior to the testing proposed by EFSA would appear to be minimal.

6.6.4 Effectiveness, practicality, broader effects and proportionality

- **Effectiveness**: As industrial food manufacturing facilities and professional users (bakeries) are likely to already have risk management measures in place to protect worker exposure to dust (e.g. flour dust), the effectiveness of removing the approval for the use of TiO_2 in food is likely to be limited. The margins of safety found by EFSA suggest that there would be no significant benefits for consumers either (subject to the findings of the recommended tests). Inhalable TiO_2 is only present in a very small number of products and there is no method of measuring whether there are any benefits to health from removing it. On the other hand the consequent removal of TiO_2 in non-inhalable form from all food products has numerous negative implications.

- **Practicality:** The practical implications of removing of TiO_2 from foodstuffs are described above, but can be summarised as follows: disruption to supply, while recipes are altered and substitutes are investigated; loss of some products with impacts on manufacturers and consumers; impacts on quality and shelf-life of some products; and negative consumer perceptions.

- **Broader effects:** There would be far reaching consequences of the removal of such a common and safe, as approved by EFSA, additive to food, with very limited apparent benefits to the health of workers, professionals and consumers. It could impact significantly on existing manufacturing methods as well as the cost of food; where TiO_2 has a preservative effect, removal of its permitted use may also result in increases in food waste. In addition, the removal of such a common ingredient and loss of products from the EU market could impact more generally on consumers' trust in food safety.

- **Overall proportionality:** EFSA consider, based on available evidence, that TiO_2 poses no health concerns to consumers (EFSA, 2016) and the availability of inhalable TiO_2 is very limited. Removal of it from the list of allowable food additives is therefore highly unlikely to have any positive effects on consumer health, while having numerous negative implications, as outlined above**.**

6.7 Removal of approval for use in food contact materials

6.7.1 The option

TiO_2 is used in food contact materials, in plastic and paper packaging as a whitener for (FoodDrinkEurope, 2017):

- Food-contact coatings;
- Food-packaging adhesives;
- Food-contact polymers;
- Paper/paperboard in contact with aqueous/fatty foods;
- Filler in food-contact rubber articles for repeated use; and
- Food-contact textiles/fibres.

It is also found in white and pastel food homewares and containers, such as ceramic articles, as a pigment in enamels applied on flatware, cookware, hollowware (decorated and non-decorated) and other white kitchenware. It is also in printing inks for food packaging (pigment white 6).

TiO_2 offers many advantages in food contact materials. It is a photo-catalytic substance and has the following applications/advantages in food packaging (Hosseini, et al., 2017): UV protecting properties; anti-bacterial and anti-microbial activity; and it is self-cleaning. In addition, TiO_2 (large and nano) has other characteristics favourable to inclusion in food contact materials. These include its low cost, its stability, its ability to be repeatedly used without substantial loss of catalytic ability, and the fact that it currently holds approvals for use (Hosseini, et al., 2017).

The proposed CLH as Carc Cat 2 could trigger new legal obligations under food contact materials legislation: Regulation (EC) No 1935/2004; Regulation (EC) No 2023/2006; Regulation EU/10/2011; Regulation 282/2008/EC; and Regulation (EC) No 450/2009. This could include a ban on use, as substances classified as carcinogenic should not be used in food contact materials and cannot be listed in the Union List; national rules may also impact on the continued use of TiO_2 in food contact materials. See Section 4 for further discussion on the relevant legislation.

It is therefore assumed that in the short-term:

- There would be a restriction on the use of TiO_2 in food contact materials and printing inks;
- This would then be followed in the medium term by a MS-led derogation, leading to re-instatement of TiO_2 onto approved lists at a national level.

It is worth noting that some industry consultees have expressed the view that a Carc Cat 2 classification by inhalation would be unlikely to result in an adverse impact on the continued use of the substance in coatings for food contact materials (RPA, 2017). However, the automatic triggers in regulation and policy change suggest that a ban and/or restrictions of TiO_2 in food contact materials and printing inks for food contact materials is likely, unless given a derogation or exemption.

6.7.2 Costs

No other pigment delivers the same performance in terms of opacity and ink film thickness as TiO_2. While it is used in large concentrations (e.g. 15–60%), alternatives, such as zinc sulphide would be required in even higher concentrations and would still not be able to provide the same opacity and performance currently required by the packaging industry. To achieve the same protective and decorative effects obtained with TiO_2, food packaging manufacturers would need to develop new designs and, in some cases, switch to different material combinations to compensate for the lack of hiding effect (RPA, 2017).

Given the negligible probability of exposure to TiO_2 by inhalation through food contact materials, and the lack of a feasible substitute, it is likely that the continued use of TiO_2 would eventually be approved through the mechanisms discussed above (and in Section 4). This will, however, be time consuming, and is likely to cause significant concern among consumers, and consequently a drop in sales of those products containing TiO_2. The impact of a ban on the use of TiO_2 in food contact materials is likely to have a severe detrimental consequences to manufacturers of food packaging.

In particular, companies in the sector would face new costs from the need to redesign packaging to compensate for the lack of hiding effect provided by TiO_2, resulting in potentially significant research and development costs. In addition, it would impact on the complexity of products and production activities within and outside the EU.

Further costs would be borne by the food producers, including marketing costs to promote the new presentation of products and the potential loss of business due to reduced consumer confidence in food products.

The loss of TiO_2 as an allowable additive to food contact materials may also have an impact on consumers and retailers. For example, the retail cost of packaged food items may increase due to the increases in costs faced by manufacturers. More importantly though, foods may spoil more rapidly, if alternatives are not as effective in terms of UV absorbancy; in addition there would be a reduction in visual quality, which may decrease consumer confidence.

In addition, the end users' perception of buying products that are packed or stored in materials that contain a suspected carcinogen could affect their buying behaviour (RPA, 2017). This extends further than plastic and cardboard containers, in which foods are bought. For example, most ceramics are manufactured using natural raw materials that have a TiO_2 content of over 1% by mass. So, classification of ceramic materials as carcinogenic would likely lead to acceptance problems among consumers, for articles such as crockery and cookware. In the case of glazed porcelains, TiO_2 is also found in glazes in order to increase opacity or to achieve a certain colour (BDI, 2018).

6.7.3 The benefits

The aim of food contact legislation is to protect consumers from harmful substances coming into contact with food. The intention therefore is not to protect workers, who should instead be protected through occupational health and safety legislation.

The benefit to consumer health of removing or reducing TiO_2 in food contact materials is impossible to quantify as it poses no risk in terms of inhalable exposure, for which the proposed Carc Cat 2 classification applies. Its removal from such materials, as an indirect consequence of the classification, is therefore ineffective in terms of reducing a health risk to consumers.

In terms of risks to health posed by ingestion of TiO_2, a recent critical review of the migration potential of nanoparticles, such as TiO_2, in food contact plastics concluded that they are completely encapsulated in the host polymer matrix, and do not have the potential to migrate into food. Thus, consumers will not be exposed, assuming the contact surface is not altered by mechanical stress (Stormer, et al., 2017). This is not, however, the risk being addressed by the Carc Cat 2 classification.

6.7.4 Effectiveness, practicality, broader effects and proportionality

- **Effectiveness: T**he linkages that exist between a harmonised classification for Carc Cat 2 and the various pieces of food contact legislation would not in this case be effective in reducing risks to consumers, the population of concern for food contact legislation. There would therefore be no benefits from any measures being triggered under this legislation.

- **Practicality:** In practical terms removing TiO_2 from food packaging materials would result in the need for a redesign of current packaging as well as research into alternatives investigated; it may also result in a reduction in the shelf-life of some products if the food preservation advantages offered by TiO_2 containing packaging cannot be replicated. It would also lead to the need for action by EU MS at the national level in order ensure that TiO_2 remain available for packaging applications.

- **Broader effects:** There could be significant consequences of the removal of TiO_2 from the list of approved food contact materials, with limited apparent benefits. It would impact significantly on existing materials and packaging, and could impact on the cost of food and the level of food waste. In addition, it could raise public concern over the safety of food packaging more generally.

- **Overall proportionality:** As inhalable TiO_2 does not pose a risk to consumers in food contact materials, and as workers can be adequately protected against any potentially negative health impacts, by adhering to appropriate OELs, removing TiO_2 from such products, as an automatic result of a Car Cat 2 classification, is not a proportional in terms of benefit to consumers. Even if its reinstatement via MS-led action were to occur, the interruption to supply and cost to those industries concerned could be significant, and result in unjustified consumer concern. Attempts to replace or redesign packaging could easily result in the use of materials with equal or greater risks to health.

6.8 Risk management under waste legislation

6.8.1 The option

As noted in Section 4, the proposed CLH as Carc Cat 2 would trigger new legal obligations under various pieces of waste legislation. Under Directive 2008/98/EC, a Carc Cat 2 classification for TiO_2 would mean any waste that contains it at a concentration exceeding 1.0% would be classified as hazardous according to Annex III of the Directive. The criteria of Annex III of the Directive would apply only to 'mirror' entries in the List of Waste established by Decision 2000/352/EC, not the entries classified as 'absolute non-hazardous' or 'absolute hazardous'.

The approach to the classification of TiO_2-containing wastes as hazardous would be based on the provisions of the Waste Framework Directive and on Decision 2000/532/EC (as revised by EU Decision 2014/955/EU) which established the European List of Wastes (LoW). The LoW is divided into 20 chapters (labelled with 2 digits) based on the key process (source) that generates the waste or specific waste types (e.g. Digit 20 for Municipal Wastes (Household waste and similar commercial, industrial and institutional wastes – Including separately collected fractions). The wastes in the LoW are labelled in three different ways depending on their hazard classification (Wahlström, et al., 2016):

- **'Absolute hazardous'** entry: the code is marked with an asterisk (*) and the waste is classified as hazardous waste (no further assessment needed). The producer of the waste does not need to consider what chemicals are in the waste to find out if it is hazardous or not (still the producer needs to establish what hazardous properties the waste displays to ensure appropriate management of it). Even if that waste has no hazardous properties, the absolute hazardous entry still applies;

- **'Mirror'** entry: the mirror entries are typically a pair of two (sometimes more) entries (6-digit codes) one hazardous and the other non-hazardous. The hazardous entry refers to the presence of hazardous substances (general or specific) while the non-hazardous entry applies where the hazardous components are absent and cross-refers to (mirrors) the hazardous entry digit code. However, there are also cases where the mirror entries are unpaired i.e. there is no cross reference from the non-hazardous entry to the hazardous entry. Both for the paired and unpaired mirror entries, the waste producer must show that the waste does not exhibit hazardous properties related to the presence of hazardous substances prior to assigning a non-hazardous waste code. For a mirror pair where the hazardous entry has a specific reference to a hazardous substance (for example, coal tar), the hazardous entry is chosen only if the waste contains the particular hazardous substance (in this case coal tar) at or above levels that make it hazardous. In short, a "mirror" entry waste is a potentially hazardous or non-hazardous waste depending on the presence of specific or generic hazardous substances and thus an assessment must be made whether any given waste is hazardous or not; and

- **'Absolute non-hazardous'** entry: the waste is classified as non-hazardous (no further assessment needed). The producer of the waste does not need to consider what chemicals are in the waste to find out if it is hazardous or not. By way of example, "*02 01 04 waste plastics (except packaging)*" under the general waste category "*WASTES FROM AGRICULTURE, HORTICULTURE, AQUACULTURE, FORESTRY, HUNTING AND FISHING, FOOD PREPARATION AND PROCESSING*" is an "absolute non-hazardous" entry and therefore waste products such as agricultural plastic films would not be classified as hazardous after the adoption of the Carc Cat 2 classification even if they do contain TiO_2 in concentrations above 1.0% by weight.

Following from the above, it may be concluded that the proposed harmonised classification would not affect the management of any 'absolute hazardous' waste that contains the substance. These wastes are currently classified as hazardous and can therefore be disregarded in this impact assessment. The classification would have an impact on the management of waste that currently falls under 'mirror non-hazardous' entries and contains more than 1% TiO_2. Such waste would need to be allocated to the respective 'mirror hazardous' entry that makes a generic reference to "hazardous substances" (for instance, *08 01 16 aqueous sludges containing paint or varnish other than those mentioned in 08 01 15* would be replaced by *08 01 15* - aqueous sludges containing paint or varnish containing organic solvents or other hazardous substances*).

Examples of types of waste streams containing TiO2 that currently fall under the 'mirror non-hazardous' entries and that could in the future be classed as hazardous include:

- Municipal / Household wastes:
    - 20.01.27* paints, inks, adhesives and resins containing hazardous substances (MH)
    - 20.01.37* wood containing hazardous substances (MH)

- Pharmaceutical wastes:

- 07.05.13* solid waste containing hazardous substances (MH)

- Paint wastes:
  - 08.01.11* waste paint and varnish containing organic solvents and other hazardous substances (MH)

- Construction wastes:
  - 17.02.04* glass, plastic and wood containing or contaminated with hazardous substances (MH)

It also might be assumed that wastes already classified as hazardous under a 'mirror hazardous' entry due to the presence of other hazardous substances would not substantially be affected by the Carc Cat 2 harmonised classification for TiO_2; however, information collected during the preparation of this report indicates that whilst the hazard classification of the waste might not change, the cost of its management might increase, as will be explained later in this document).

The management of 'absolute non-hazardous' waste might also be impacted. In principle, if a waste is allocated to an 'absolute non-hazardous' entry, in most cases it is non-hazardous without any further assessment of its composition. However, there are notable exceptions where these 'absolute non-hazardous' entries are linked to other entries in the LoW and the other entries may need to be considered to determine if they are more appropriate to the waste. A good example is empty TiO_2 packaging waste that contains over 1.0% TiO_2 residues. Paper waste of this type (i.e. empty paper bags) is currently classified as *15 01 01 paper and cardboard packaging* but once TiO_2 becomes a Carc Cat 2 substance, the appropriate entry will be *15 01 10* packaging containing residues of or contaminated by hazardous substances* (this is discussed further below).

The end result is further complicated by the fact that under Article 7(3) of Directive 2008/98/EC, where a Member State has evidence to show that specific waste that appears on the list as hazardous waste does not display any of the properties listed in Annex III, it may consider that waste as non-hazardous waste. Thus, there is the potential for national measures to be adopted to limit the automatic risk management consequences that would be triggered by the classification. Indeed, industry would be likely petition Member States to invoke Article 7(3) of the Waste Framework Directive and thus classify such waste as non-hazardous[45]. This could alleviate the impact of waste regulations on the users of TiO_2 in Europe, although empty containers of TiO_2 powders could be regarded as posing a hazard and are likely to be required to be handled as hazardous waste anyway.

Overall, the complexity and cost of compliance with existing regulation on protection of worker health and waste disposal would place a very significant burden on the EEA manufacturing base. Comments received by several stakeholders[46] suggest that the costs involved could have an impact on the economics of production leading to scaling down of operations and the loss of jobs.

Furthermore, as the implementation of the Waste Framework Directive is not uniform across the EU Member States, and the approach that Member States take to allocating waste streams to the most relevant entries in the European List of Waste (LoW) vary, the outcome under waste legislation is not clear. It is assumed here that wastes would be classed as hazardous.

[45] In addition, a mirror entry on the European Waste Catalogue could render TiO_2-containing waste non-hazardous unless the content of the pigment exceeded a certain threshold.

[46] See the separate SEA for TiO_2 prepared by RPA (2017).

As the Directive is currently being updated, this may impact on the above conclusions and the findings set out below.

6.8.2 The costs

There are a wide variety of waste streams that contain over 1.0% TiO_2 and that are generated during the use of the substance as a raw material but also at the end of the useful life of products/mixtures. Some may already be classified as hazardous due to the presence of other hazardous components (e.g. solvents) and their management might not be affected by the harmonised classification, but this will not always be the case. Others, however, may currently be handled as non-hazardous and can be disposed of in non-hazardous landfills or recycled; such waste streams would require segregation, separate storage and more specialised management after the introduction of the substance's Carc Cat 2 harmonised classification. Such requirements may vary by Member State.

Where a waste is classified as hazardous, a number of specific obligations apply under the Waste Framework Directive, e.g.

- Labelling and packaging obligations (Article 19);
- The obligation to provide evidence for the tracking of the waste according to the system put by the relevant Member State (Article 17); and
- A mixing ban (Article 18).

Hazardous waste is also required to meet the waste hierarchy prescribed in the Directive and should be minimised, reused or recycled before disposal occurs. Hazardous waste must be classified and is required to be treated before it can be disposed of, in order to prevent or reduce possible harm to human health and the environment. If hazardous waste cannot meet the upper levels of the waste hierarchy then it should either be incinerated or disposed of in a hazardous waste landfill.

There is little available data on the cost of the above requirements to either industry or authorities, but the discussion below highlights some of the cost implications. In addition to the types of costs set out below, it should be recognised that a shift in the classification of household and sme construction wastes from non-hazardous to hazardous may have other implications, such as an increase in fly-tipping, as waste producers (households, builders, etc.) try and avoid increases in the costs of waste disposal.

Impacts on industry

A few companies have provided estimates of the costs involved in establishing systems for the segregation and separate management of waste that contains more or less than 1.0% TiO_2. These range from a few thousand Euros per company to potentially millions of Euros. For example, separation of TiO_2-containing sludge at a paper mill and separate treatment would increase the cost of treating the sludge by €200 per tonne. This would translate into an additional cost of €2-3 million per year, while no additional protection to human health would be achieved (if the hazard is related to inhalation). Box 6-1 provides a summary of the compliance requirements with waste management regulations that paint manufacturers, as the greatest set of downstream users, would face following the classification. Further examples by sector are provided in Annex 2 to this document.

Box 6-1: Compliance with waste management regulations for paint manufacturers

Irrespective of the relevance of the route of exposure to the harmonised classification, the management obligations for certain types of waste would change following the classification of the substance. Consultation responses have identified the following key waste streams from the manufacture of paints:

- Empty TiO_2 packaging that contains (>1%) residues of the pigment;
- Off-spec paint that contains TiO_2 as a component;
- Paint residues left in tanks and machinery during paint production;
- Sludges and cleaning waters;
- Solid wastes arising from filtration (e.g. filters, powders) and other cleaning activities;
- Waste from quality control and lab testing.

Some of this waste is already classified as hazardous due to the presence of hazardous components, for example organic solvents used in the manufacture of solvent-based paints. However, this would not necessarily mean that the Carc Cat 2 harmonised classification would not be accompanied by adverse impacts. A French paint manufacturer has noted that manufacturing waste which may be classified as hazardous but at a 'low hazard level' (i.e. water-based paint which is non-toxic, non-corrosive, non-carcinogenic) can be disposed of as hazardous through non-specific routes such as through cement plants or other heavy industries capable of incinerating such waste. However, when the waste becomes 'high level' hazardous (e.g. it is classified as CMR, toxic to the environment, etc.), those heavy industries do not accept it anymore and specialist contractors need to be sought for specialist disposal (incineration that can accept such types of wastes). This increases the costs of waste disposal.

While some other wastes (aqueous sludges) contain less than 1.0% TiO_2 and would therefore remain classified as non-hazardous even after the classification of TiO_2 as a suspected carcinogen, several waste streams would become hazardous upon the introduction of the harmonised classification if they contain more than 1.0% TiO_2. Examples include, (a) TiO_2 packaging, (b) waste paint (off-spec and residues), (c) aqueous sludges with >1.0% TiO_2 and (d) filtering/cleaning residues. TiO_2 is in an inhalable form only within its empty packaging (to be classified as *15 01 10* Packaging containing residues of or contaminated by hazardous substances*) and in filtering/cleaning waste, if in powder form.

Process washings are often recycled and/or fully treated before leaving the site, and sub-standard product is usually reworked into production thus the volumes of hazardous paint waste would likely be small. However, the arising of hazardous waste would require segregation of wastes, collection of hazardous waste by a specialised disposal company and a significant relative increase in the cost of waste treatment.

One company has suggested that a change in hazard classification for off-spec paint and dust material from filtering operations would increase waste management costs by **30%**. Another company has estimated an overall cost of **€0.1 million** for changing the treatment of waste already classified as hazardous; this is on the basis of cost of €90-150/tonne for incineration of waste by a heavy industry installation vs. a cost of ca. €400/tonne for incineration for CMR-classified wastes by a specialist facility. A third company manufacturing thermoplastic paints has indicated a cost increase for waste sorting and segregation of **€15,000-20,000 per year**.

The presence of an impurity classified as a Carc Cat 2 would also affect the handling and disposal of process wastes generated during the **manufacture of TiO_2**:

- In sulphate plants, digester residue would be classified as a carcinogen. Some residue may already be disposed of as hazardous but for those currently treated and disposed of as non-hazardous waste, the result would be either increased costs or viability problems if a suitable disposal outlet could not be found. Similarly, where outlets for co-products could not be found due to a change in hazard classification, the resulting high volumes of hazardous waste could force plant closures due to cost or suitable lack of disposal options; and

- In chloride plants, the main wastes would be classified as hazardous. This would mean significant disposal cost increases or viability problems if no hazardous waste outlets could be identified. In some Member States the change in classification of the waste to hazardous would result in significant changes to the rate of landfill tax applied. For example, in the UK the tax rate would increase by a factor of over 30, meaning an increased annual tax cost of over five million euros for manufacturers. This would be despite detailed modelling, recognised by the UK government, showing that landfill sites used for the solid mineral waste can be recovered for agricultural use following a post-use aftercare period of just 5 years compared to normally many decades.

In **ink manufacture**, depending on the formulations generated, waste may already be treated as hazardous; hence there would be no impact from the proposed classification for TiO_2. However, this does not apply to all manufacturers (for example, those producing recreation/school products which are non-toxic) and one such manufacturer provided an indicative additional cost of €0.1 million per year for the treatment of waste.

In the manufacture of **construction products** (adhesives, sealants, etc.) several consultees have suggested that waste that contains TiO_2 is already classified as hazardous so the proposed classification would not have a discernible impact. For some companies where the classification of waste would change, the additional annual cost would be less than €0.1 million per manufacturing site per year for waste segregation and treatment.

The cost of disposal for manufacturers of **glass products**, requiring the identification of new disposal (recycling) outlets, as well as the adaptation of existing waste storage areas. Elsewhere, a company involved in the production of **food for human consumption** estimated that segregation of solid and water waste plus installation of a water purification station would cost an estimated €0.3 million.

On the other hand, some products that may contain TiO_2 would not be affected by the requirements of the waste regulations. For example, **rubber** is only referred to under code 19 12 04 of the EWC as an absolute non-hazardous waste and as such rubber waste would not be classified as hazardous even if TiO_2 was contained in it. Thus, although the implications of the Waste Framework Directive would clearly be far-reaching, impacts on waste disposal would need to be assessed on a case by case basis.

Handling of waste packaging that contained TiO_2 or TiO_2-containing mixtures would also be affected by the harmonised classification of the substance. This packaging may now become classified as hazardous and would need to be treated accordingly, depending on the level of residue / waste retained in the packaging. Chapter 15 of the LoW contains the following codes for waste packaging classified as non-hazardous under *15 01 Packaging (including separately collected municipal packaging waste)* (NB. all are 'absolute non-hazardous entries'), with this including: paper and cardboard packaging; plastic packaging; composite packaging; mixed packaging; and textile packaging. Chapter 15 of the LoW also contains the following code for waste packaging classified as hazardous: 15 01 10* packaging containing residues of or contaminated by hazardous substances.

Whilst Cefic has estimated that the price for treatment of waste classified as hazardous can be 2 to 3 times the price for the same material classified as non-hazardous, information from consultation would suggest a much higher price differential of 10-30 times. For instance, EUWID Recycling and Waste Management, a publication-source of information for the international waste management and secondary raw materials sector, suggests such price differences for the management of hazardous and non-hazardous waste[47].

Perhaps, however, the greatest threat from the classification of waste as hazardous would be the potential impacts on reuse and recycling of waste. Any impacts on the recycling of postconsumer plastic waste would have a very damaging effect on the circular economy (see below) while impacts on the ability of companies to recycle scrap that contains TiO_2 would have a very detrimental effect on production economics. For example, the manufacture of polyamide yarns would be severely impacted if fibre manufacturers could not sell their TiO_2-containing waste (amounting to 10% waste for each kg of yarn produced[48]) as an input material for engineering plastics. At present, even if in the EU these pre-consumers scraps are classified as waste, they can be considered as a very homogeneous waste (chemically it is a polyamide polymer in a physical status of fibre instead of granule), containing a minor amount of additives, such as stabilisers and pigments, including TiO_2. For this reason, the generator of the waste is paid for supplying the waste material, instead of paying for its disposal. The classification of TiO_2 as Carc Cat 2 could change the classification of this waste to hazardous (HP7) and make its direct use 'as is' as raw material for engineering plastics manufacture impossible.

A quick estimate of the increase in waste treatment costs from the proposed classification of TiO_2 on fibre manufacturers can be provided here for **polyamide fibres**, considering an average waste equivalent of 10% for each kg of yarn production, the economic loss can be evaluated as follows[49]:

- Loss of income from the sale of waste: 10% × €1 = €0.1/kg yarn produced (where €1 is the unit minimum price for the sale of 1 Kg of PA6 waste);
- Cost of disposal of the – now – hazardous waste: 0.1 × €0.15 = €0.015/kg of yarn produced (where €0.15 is the average cost of the "waste to energy" (incineration) disposal of 1 Kg of PA6 waste); and

[47] It was suggested in consultation that this significant difference in waste management costs was demonstrated in the recent case of Hexabromocyclododecane (HBCDD)-containing insulation waste in Germany. The German Federal Government revised the German Waste Catalogue Ordinance in March 2016 (the German List of Waste). This ordinance classifies non-hazardous and hazardous wastes. Following the revision, insulation waste, typically expanded polystyrene waste which contains HBCDD above the threshold of 0.1% by weight, had to be classified as hazardous from October 2016. According to waste operators, both utilising energy-from-waste as well as recyclers, this resulted to a state of emergency in Germany. The change in legislation largely brought a hitherto smoothly running and safe disposal route to a standstill. The classification increased the requirements for site logistics and disposal with transport, storage and plant permits becoming necessary. The ban on mixing hazardous waste did not only increase the disposal costs, especially for so-called monocharges, but also led to capacity problems in the waste treatment plants and thus to the unintended waste disposal bottleneck for polystyrene insulation boards in Germany (see details here: http://www.agehda.de/cms/wp-content/uploads/2017/04/Positionspapier_AGEHDA-final.pdf, accessed on 13 November 2017). As a consequence, the German Government issued a memorandum of exemption in December 2016 and in collaboration with industry eventually revised the German Waste Catalogue Ordinance again, which is now effective from August 2017.

[48] From previous RPA study q'naire: *Analysis of the socio-economic impacts of a harmonised classification of Carcinogen Category 2 for titanium dioxide (TiO_2),* RPA, 2017, p. 225

[49] According to EU regulations, it is forbidden to go below the established limits by diluting hazardous waste with other not hazardous or pure product, thus it would be legally almost impossible to recycle the waste generated by fibre spinning operations.

- Total minimum loss estimate would therefore be €0.115/kg yarn produced; in view of the often very limited contribution margin generated by nylon yarn, this loss might offset most if not all of the profit.

Impacts on recycling

The EU's current recycling targets are, by their own admittance, ambitious:

- 65% of municipal waste to be recycled by 2030;
- 75% of packaging waste to be recycled by 2030;
- Reduce landfill to a maximum of 10% of municipal waste by 2030; and
- A ban on landfilling of separately collected waste.

Two of the main objectives of the Circular Economy programme are: to encourage recovery from articles/products already in use via, for example, recycling and reusing, and to reduce the use of the Earth's natural resources. These objectives aim to significantly reduce the amount of waste that reaches landfill and incineration. However, implementing a Cat 2 classification for TiO_2 would be counterproductive to the European Union's wider policy goal of promoting the Circular Economy, and would, in effect, make TiO_2 a *legacy substance*, one whose presence in already manufactured goods (i.e. paint, PVC and paper) would serve to make these goods *hazardous*, and thus, unrecyclable.

In order to meet the 10% of waste to landfill target, it is highly likely that a significant amount of TiO_2 containing/tainted waste (if labelled Carc Cat 2) would have to either be derogated/exempted or be exported from the EU. Neither of these outcomes are particularly advantageous, or practical – Member States and industry have both recently set out reasons why a derogation for waste would not work[50]; in addition, Europe's excess waste has historically been sent to China, but the country has now introduced a ban on imports of certain plastics and twenty-three other kinds of waste (in effect as of the 1st of March 2018). At the European level, 37% of the EU28 + NO/CH's plastic waste is already exported.

For example, the Paint industry sold over 7,000,000,000 kilograms of paint to consumers in 2016 (according to Eurostat/PRODCOM data[51]). Germany alone currently recycles 62 million paint buckets with a titanium dioxide content of more than 1%, and the cost of disposing just this number would increase from 10 million euros (for recyclable buckets) to 200 million euros (for hazardous buckets under the proposed legislation); this is because of more "stringent obligations to provide supporting documents, and higher costs for specialised transport and disposal of 'hazardous' waste"[52].

The paper sector accounts for approximately 12% of TiO_2 consumption, which is around ca. 130 kilotonnes annually. Based on Cefic data (for the year 2013), laminates are the most prominent area of use and account for ca. 80% of total consumption in this sector. The European Paper Recycling Council provides the following figures for the total amount of paper recycled within the European Union.

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[50] Minutes from the *26th Meeting of Competent Authorities for REACH and CLP (CARACAL), 02/03/2018*

[51] http://ec.europa.eu/eurostat/web/prodcom/data/database/

[52] VDL Position Paper pg. 7

Table 6-20: Paper Recycling within the EU		
Statistic	**Year**	**Amount**
Amount of paper recycled within the EU*	2016	59.5 million tonnes
% of paper recycled within the EU*	2016	72.5%
Number of times paper recycled per annum (mean)*	2016	3.5
Source: *European Paper Recycling Council Monitoring Report 2016 – available at http://digibook.digi-work.com/Digibooks.aspx/Get/cepi/1669/FINAL_Monitoring_Report_2016pdf		

Paper is nearly fully-recycled within the EU at present, although 22% of print and paper products are non-recoverable; i.e. tissue, wallpaper, etc. An estimated 50% of the raw material used in the paper industry is paper sent for recycling. However, a Carc Cat 2 classification could push the recycling rate down even though this recycling waste stream of waste does not encompass the route of suspected carcinogenicity (inhalation).

Another key waste stream that would be affected is plastics waste. In 2016, 27.1 million tonnes of plastic were collected through official schemes in the EU28 + NO/CH in order to be treated; the breakdown for 2016 was as follows[53].

- 11,273,600 tonnes of plastic were sent for energy recovery;
- 8,428,100 tonnes of plastic were recycled; and
- 7,398,300 tonnes of plastic were sent to landfill.

As shown in the chart given below, for the first time in 2016, more plastic was recycled than sent to landfill. This is a significant achievement, yet the potential Carc Cat 2 classification of TiO_2 risks posing a detrimental effect to this, as a significant amount of plastic currently recycled would likely be classified as hazardous under the Waste hierarchy, with a resultant change of status on the list of waste.

Figure 6-4: Plastics waste management in the EU

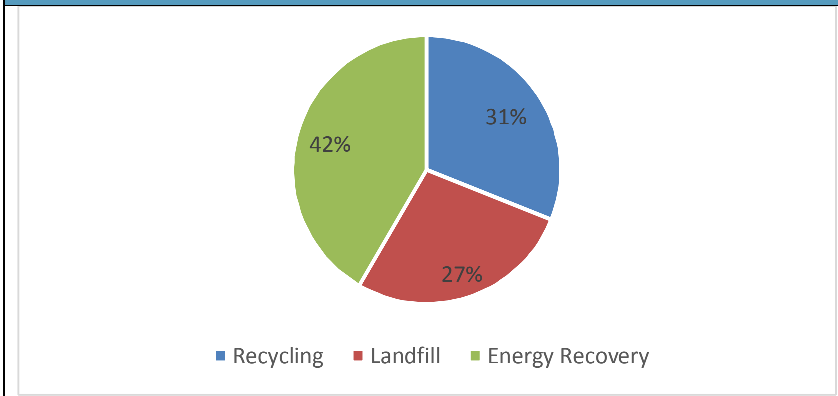

Table 6-21 shows the scale of plastic production in the EU which is dependent upon TiO_2 as an integral ingredient, with this equating to almost 37 million tonnes per year.

53 http://www.plasticseurope.org/application/files/2415/1689/2630/2017plastics_the_facts.pdf

Table 6-21: Estimated tonnage of products whose functionality depends on TiO_2	
Application	**EU production**
Plastic packaging (food, pharmaceuticals, other)	15.1 million t/y
Plastics in construction	8.2 million t/y
Plastics in automotive	2.9 million t/y
Plastics in E&E	1.4 million t/y
Plastics in agriculture	0.7 million t/y
Plastics for consumer, household, furniture, clothing, footwear	8.2 million t/y
Total converted plastics	**36.9 million t/y**
Source: EUPC	

These figures are based on an analysis carried out by EuPC. When EuPC undertook its market analysis, it considered products as functional units, i.e. products that have a certain function; if the absence of TiO_2 would have prevented those products from performing their function, then those products were assumed to be potentially impacted by a harmonised classification. This applies specifically to plastic packaging for which the high volume shown in the table not only includes products that contain TiO_2 in the plastic but also all those that are labelled with TiO_2-containing labels even if they are transparent and thus the plastic does not contain TiO_2 (e.g. a PET bottle). As a result, these figures may overestimate the impacts, as TiO_2 would need to be present at greater than 1%.

A report prepared for the EuPC[54] also indicates that between 600 and 700 kilotonnes of plastics from long life applications (construction, automotive, electric and electronic, excluding packaging) are recycled. Over time, recycling may increase to, at least, 1,000 ktonnes/y. Some of these waste streams potentially could be affected since it is not feasible to segregate materials containing TiO_2 (the large majority) from others. Knowing that the margins of recyclers are typically low, any cost increase in the waste value chain, be it administration/certification/validation or additional treatment operation etc., will place the recyclers under pressure. As a consequence, any TiO_2-containing plastic waste management operation could come under risk, which would further impact Europe's waste treatment ability.

FEAD provides an alternative set of estimates for the levels of waste that may be affected[55]. They estimate that the classification as hazardous of plastics containing TiO_2 could be affected is around 1.25 million tonnes per annum. They further note that the recycling of these plastics prevents the release of an estimated 1.8 to 2.4 million tonnes of CO_2 equivalents per year in comparison to the use of virgin resins. Even assuming a relatively low value for carbon, based on carbon credits traded under the EU ETS, at €5 per tonne CO_2 equivalent, this equates to social damage costs of around €9 to 12 million per annum. Given that the estimated volume of plastic assumed to be impacted by FEAD is much smaller than that implied by the figures presented above on the volumes of plastic currently being recycled, the social damage costs associated with increased CO_2 emissions alone due to the loss of recycling due to wastes containing TiO_2 at >1% could be much more significant.

[54] Based on a 2012 report by Consultic.

[55] FEAD (2018): FEAD recommendations on Titanium Dioxide, April 2018.

6.8.3 The benefits

Generally, inhalation exposure to TiO_2 from end products is very unlikely, if not impossible, as the pigment is embedded in a matrix (paints, plastics, coatings, inks, etc.), and migration is nearly zero. Even if some waste management activities do generate dust (i.e. shredding of waste plastic), these are likely to be those carried out in waste recycling facilities. As a result, dust exposures will fall under EU worker protection legislation, such as the CAD, and national occupational safety and health legislation.

As a result, the additional risk management that would be triggered under the EU Waste legislation is unlikely to result in significant additional benefits for workers, professionals or consumers. This is particularly the case for those recycled waste streams that are already subject to risk management measures due to the hazard profile of other constituent substances (e.g. some waste plastics, paper).

6.8.4 Effectiveness, practicality, broader effects and proportionality

- **Effectiveness:** The linkages that exist between a harmonised classification for Carc Cat 2 and waste legislation would not result in any significant reductions in risks to workers, given that TiO_2 is not present in the end articles in an inhalable form with the exception of certain potential recycling activities. These recycling activities will include for example plastics recycling, which may involve shredding and grinding of plastics waste. Worker exposures associated with these activities are subject to national and EU worker safety legislation, and indeed as discussed in Section 6.2 above, best practice already includes measures to minimise worker exposures to dust. There are no foreseeable benefits for consumers.

- **Practicality:** In practical terms, it is likely that industry would petition individual Member States to invoke Article 7(3) of the Waste Framework Directive and to classify TiO_2 containing waste as non-hazardous[56], this would be particularly important for users of TiO_2. This would be time consuming for industry and would place the onus for ensuring that regulation remains proportionate on individual Member States. It is also not clear what level or type of evidence would be required by individual Member States.

- **Broader effects**: There could be significant consequences from the potential waste classification of TiO_2 both for the manufacturing sector as well as for the recycling and waste disposal sectors. There could also be significant impacts on the EU's ability to meet future recycling targets, as the classification may have unintended consequences on the overall chain of recycling activities, in terms of the types of waste handling permits that may be required, etc.

- **Overall proportionality:** Given the low likelihood of TiO_2 being available in an inhalable form in wastes, one must question the proportionality of the automatic waste classification that would result from the proposed harmonised classification under CLP, particularly if this were to be followed by action at the national level to de-classify such wastes.

[56] Or a mirror entry on the European Waste Catalogue could render TiO_2-containing waste non-hazardous unless the content of the pigment exceeded a certain threshold.

7 Summary

TiO_2 has an annual production volume in the EEA alone of ca. 1,100 ktonnes, with an estimated market value of ca. €3 billion. It's exceptionally high opacity (scatters almost all incident light from the visible spectrum), bright whiteness, UV absorbing properties, lack of toxicity and availability, have made it suitable for the majority of applications requiring a white opacifying or pearlescent effect, as well as non-pigmentary applications including sunscreens and clean air environmental technologies.

In September 2017, following an application by the French authorities, ECHA's RAC concluded that TiO_2 meets the criteria to be classified as suspected of causing cancer (Carc Cat 2) specifically through the inhalation route, and in particular in relation to respirable particles of TiO_2 via a physical, rather than an intrinsic chemical, effect. The consequences of this are profound, due to:

- the absence of technically feasible alternatives for TiO_2;
- the triggering of a series of changes in how the marketing and use of TiO_2 is treated under a variety of chemical risk management regimes in the EEA; and
- the negative perceptions that would be likely to develop among users and consumers over the safety of the substance.

With respect to alternatives, TiO_2 is the universal choice for white pigments. Its technical functions (high opacity, refractive index and photo-protection) and availability mean that it is suitable for almost every application, whereas each of the possible alternatives has disadvantages. Mineral fillers such as zinc oxide, lithopone, kaolin and talc find use in a number of applications as extender pigments, but they are not able to fully replace TiO_2. Titanium dioxide has the highest refractive index of all known white pigments, meaning it has the greatest opacity. As a result, pigmented materials that use substances such as zinc oxide, aluminium oxide or barium sulphate would require much larger quantities of pigment; this can cause "crowding", reducing the light scattering properties, and the physical performance of the product. Very few pigments are available in similar quantities to TiO_2, indicating that it is not currently possible to physically replace it in all applications, even where the technical functions of alternatives are suitable. As a result, there is currently no alternative pigment available on the market in sufficient quantities and which can match the opacity, hiding power, cost-efficiency, inertness or weatherability of TiO_2. Furthermore, as the carcinogenic effect observed in animal testing discussed in the French CLH proposal is not substance-specific but characteristic of respirable poorly soluble dusts, such effects could be expected to be associated with most, if not all, potential alternative substances. Therefore, if it were accepted that TiO_2 is a carcinogen, all poorly soluble powders that could replace it could be considered to exert carcinogenicity in a similar manner.

In 2017, the TDIC asked EBRC to undertake an exposure assessment for TiO_2 in order to update its REACH Chemical Safety Assessment. This work included a survey of both TiO_2 manufacturers, as well as the key downstream user sectors to identify exposure hotspots and areas of concern. In order to carry out the exposure assessment EBRC established an interim DNEL at 1.3 mg/m^3, as this represents the threshold for effects, albeit for lung inflammation rather than potential cancer effects (which would occur at a higher level of exposure). From this work, EBRC identified the following contributing exposure scenarios as being those for which exposure above 1.3 mg/m^3 (respirable fraction) cannot be excluded in a reasonable worst case (RWC) situation for workers in industrial settings: packing of powders, cleaning activities and milling of powders. EBRC also found potential risks for paint spraying professionals, sanding in a professional setting, and hand-mixing of powders in a professional setting. At the time of undertaking this RMOA there was no conclusion regarding risks for consumer users of spray paints.

The aim of this report has been to analyse the most appropriate risk management options for addressing worker, professional and potential consumer exposures above the threshold for effects taking into account the duration and frequency of such exposures. It has also considered those measures that would be triggered automatically by the harmonised classification due to the linkages in downstream legislation to harmonised classifications under the CLP Regulation. It should be noted that these measures are not directly comparable. Some are focused at worker protection, while others are focused at protecting professional users and the general public as consumers.

The analysis has been carried out in a manner consistent with Eurometaux Guidelines[57] and with the template developed by ECHA for MS reporting on RMOAs; although the aim has also been to provide a more detailed level of analysis, and in particular on the costs and benefits of different RMOs and/or automatically triggered measures.

Eight potential risk management options and automatically triggered "measures" have been examined in detail, with the outcome of the assessment presented in Table 7-1 at the end of this Section, with Figure 7-1 below providing a graphical summary based on a scoring system ranging from 1 to 5, where 1 reflects very poor performance and 5 reflects very good performance (see Table 7-1 for option numbers and for assigned scores). Note that where there would be no health effects (effectiveness) then no score has been assigned to an RMO; in the case of labelling of consumer mixtures, exceptionally, a score of -1 has been assigned to reflect the potential for consumer confusion and for the value of CLP labelling more generally to be discredited. Efficiency is generally given a low score where an option would lead to high costs (and vice versa). Scoring of practicality takes into account the ease of enforcement and monitoring but also the potential for variations at national level (a low score means not very practical). As the costs outweigh the benefits in most cases, proportionality is generally given a low score, with the exception of awareness raising and training as these may also deliver broader benefits.

It is important to note that there is no published data or other reported evidence linking lung inflammation or other respiratory effects to current exposures to TiO_2. As a result, the cost-benefit assessment carried out for this RMOA has had to rely on a "breakeven" approach, and the comparison of the number of cases of lung inflammation that would have to be avoided for the costs of different measures to equal the benefits and hence be justified. These breakeven calculations highlight the potential for disproportionate effects.

In most cases, cost estimates have been derived and the breakeven number of cases of "lung inflammation" have then been calculated for comparison with prevalence data. This has been based on the health costs associated with a case of respiratory illness, either using annual health costs (lost output, treatment costs and human costs for up to 6 days' of illness) as used by the UK HSE in their assessments or using per episode willingness to pay values as derived in surveys carried out for ECHA.[58]

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57 Eurometaux (2017): Guidelines for an Industry Risk Management Options Analysis, Version 3, May.

58 Human health costs per case of respiratory illness, covering healthcare, lost production and human costs for workers and professional users were assumed to be €3700 per annum lower bound estimate or €7000 per annum upper bound estimate. A figure of €16 per episode based on a willingness to pay study for ECHA was assumed for consumers.

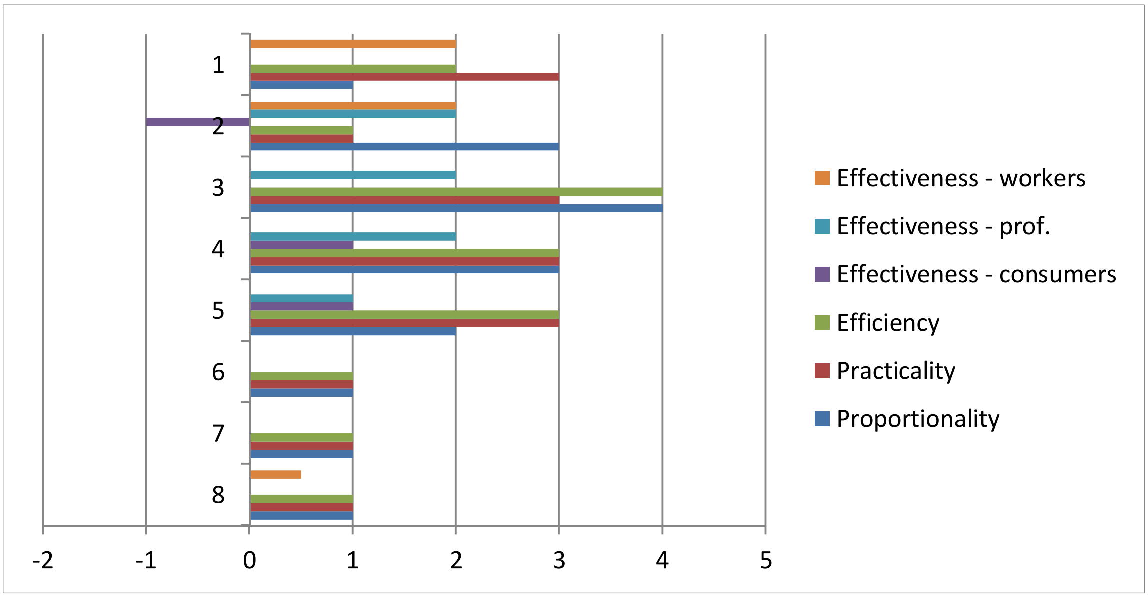

Figure 7-1: Scoring based assessment of RMOs
Notes: Scoring from 0 to 5, by option. See also Table 7-1

To err on the side of conservatism, self-reported prevalence rates for respiratory effects in the UK have been used. This is conservative as these rates will take into account exposures to a range of dusts and chemical agents, in addition to TiO_2. Furthermore, they do not reflect the assessments of occupational physicians; it has not been possible to find any physican reported cases of respiratory illness from worker exposures to TiO_2.[59]

The analysis has been carried out on a per annum basis. Where capital equipment is assumed to be required (introduction of an OELV), then capital and operating costs over the life of the equipment have been estimated and an annualised value derived to enable comparison to the annual prevalence estimates. Data on the number of workers and number of companies by size are based on Eurostat; data on protective equipment in place are based on responses to consultation and industry sector guidance on RMMs. Other data have been sourced from the CLP Fitness Check study and industry association statistics.

Overall, the most effective and proportionate measures are assessed to be:

1) An industry-wide commitment via a Social Partnership agreement to voluntarily reducing worker exposures during manufacturing activities to TiO_2 dust levels are below 1.3 mg/m^3; this is likely to be more proportionate than an IOELV introduced under the Chemical Agents Directive as implementation of the latter at the national level can require facilities to meet much lower exposure levels in order demonstrate compliance for, say, the 90 percentile of exposures;

[59] As noted previously, the German employers' liability insurance associations (BG Bau and BG RCI) have confirmed to industry organisations that there have been no recognised cases of occupational disease in Germany[59] due to TiO_2

2) Classification and labelling of mixtures where the target audience is industrial and professional users and the mixtures are supplied with an accompanying safety data sheet; although compliance with CLP is mandatory for placing mixtures on the EU market, the assessment finds that the full application of CLP is highly unlikely to be effective and hence proportional in relation to consumer mixtures and poison centre reporting obligations, given that the large majority of mixtures will be in liquid form and hence TiO_2 will not be available in a respirable form;

3) Industry sponsored training and awareness raising focused on ensuring that workers and the self-employed in sectors such as construction, building repair and building maintenance adopt appropriate practices to minimise exposures to TiO_2 containing dusts. In particular, this would be aimed at those involved in spray painting, sanding and mixing of dry powders.

Table 7-1: Overview of the RMOA findings					
Measure		**Effectiveness**	**Economic implications (broader effects)**	**Practicality and monitorability**	**Overall proportionality**
1	**EU-wide IOELV or Social Partnership Agreement** **Effectiveness: 2** **Economic implications: 2** **Practicality: 3** **Proportionality: 1**	High with respect to worker protection from exposures above threshold, but unlikely that will deliver significant benefits. Voluntary agreements should be effective if they target the main sources of exposure	Significant costs may be incurred by companies to demonstrate regulatory (statistical) compliance with a formal OELV. Such costs may be reduced under a voluntary agreement if strict statistical compliance standards as applied by some Member States would not also apply	Introduction of an IOELV under the CAD may be feasible and monitorable given the systems that already exist at the national level; voluntary action by industry to adhere to the threshold may be more difficult to agree to and to monitor, but a reporting system could be put in place as part of the Agreement	The most proportional option would be voluntary action by industry under a Social Partnership Agreement to reduce exposures to TiO_2 (and other) dusts. An EU-wide OELV under CAD may be give rise to costs that are disproportionate to the benefits in terms of reduced respiratory effects
2	**Labelling and packaging of mixtures** **Effectiveness: -1/2** **Economic implications: 1** **Practicality: 1** **Proportionality: 3**	Low to moderate depending on target group; most effective for industrial users and potentially professional users; could lead to confusion for consumer users given familiarity with affected products	Hazard symbol and labelling for "suspected of causing cancer" on large numbers of consumer products could raise undue concern, even when there is no danger of inhalation. This may raise questions over the effectiveness of CLP as a hazard communication tool	Adhering to CLP classification and labelling requirements is part of market access. However, given the large number of mixtures that would be affected, an adequate transition period will be required to ensure it is feasible to re-label and repackage	Mandatory classification, labelling and packaging without derogations for most downstream/consumer mixtures could be considered to result in disproportionate impacts; it would not directly result in the protection of workers from dust emissions within the workplace
3	**Awareness raising and training for professionals** **Effectiveness: 2** **Economic implications: 4** **Practicality: 4** **Proportionality: 4**	It is not clear how effective these measures would be, as they rely on self-employed users acting upon health and safety advice to minimise exposures to TiO_2 dusts / particles. However, this would reinforce current "best practice" advice	As the measures would result in awareness raising, they may have broader effects in terms of encouraging positive behaviour in professionals and the self-employed with regard to wearing recommended personal protective equipment	The measures involving improved technical training and information campaigns are considered to be practical. It should be possible to develop the appropriate materials, and to make these available to technical training centres and to retailers	In general, these measures are seen as proportional

Table 7-1: Overview of the RMOA findings					
Measure		Effectiveness	Economic implications (broader effects)	Practicality and monitorability	Overall proportionality
4	**REACH Restriction requiring provision of masks with paint sprayers** Effectiveness: 2 Economic implications: 3 Practicality: 3 Proportionality: 3	It is not clear how effective this measure would be, as it relies on self-employed users wearing the masks provided. Any potential reduction in self-reported health effects, is highly uncertain due the lack of data on the effects attributable to the use of paint sprayers within the construction and building repair / maintenance sectors	As the measure would result in awareness raising, it may have broader effects in terms of encouraging positive behaviour in professionals and the self-employed with regard to wearing recommended personal protective equipment. However, the extent of any such benefit is highly uncertain	The mandatory inclusion of masks with all relevant equipment may be difficult to enforce with respect to imported products and equipment sold over the internet. The latter is a problem more generally though in terms of ensuring the safe use of substances and mixtures	In general, these measures are seen as proportional, even given the uncertainty surrounding both the costs and the potential benefits
5	**REACH Restriction requiring the provision of masks with aerosol paints** Effectiveness: 1 Economic implications: 3 Practicality: 3 Proportionality: 2	It is unlikely that many consumer users will use spray aerosols for sufficiently long periods or frequently enough to experience significant respiratory effects. In addition, it is not clear how effective the above measure would be, as it relies on consumers wearing the masks provided	The measure may have broader effects by encouraging users to wear recommended personal protective equipment. The opposite may also be the case, as consumers may view the need for such measures as unnecessary and may react by also disregarding other hazard warnings	The mandatory inclusion of masks with all consumer aerosols containing TiO_2 placed on the market may be difficult to enforce, especially with respect to imported products. There may be a particular issue with products sold over the internet	In general, the measure is unlikely to be proportional, given the uncertainty surrounding the potential benefits and the potential costs to aerosol producers
6	**Removal of approval for use in food** Effectiveness: 0 Economic implications: 1 Practicality: 1 Proportionality: 1	As industrial food manufacturing facilities and professional users (bakeries) are likely to have measures in place to protect worker exposure to dust (e.g. flour dust), the effectiveness of removing the approval for the use of TiO_2 in food is likely to be limited, given there would	There would be far reaching consequences of the removal of a common and approved additive to food. It could impact significantly on existing manufacturing methods as well as the cost of food; where TiO_2 has a preservative effect, removal of its permitted use may also	There would be significant practical implications of removing TiO2 from foodstuffs: disruption to supply; loss of some products; impacts on quality and shelf-life; and negative consumer perceptions	TiO_2 is currently considered to pose no health concerns to consumers. Removal of it from the list of allowable food additives is therefore highly unlikely to have positive effects on consumer health, while having numerous negative implications for some food sectors

Table 7-1: Overview of the RMOA findings					
Measure		Effectiveness	Economic implications (broader effects)	Practicality and monitorability	Overall proportionality
		be no significant benefits for consumers	result in increases in food waste. The loss of products could impact on consumers' trust in food safety		
7	**Removal of approval from the Union list for food contact** **Effectiveness: 0** **Economic implications: 1** **Practicality: 1** **Proportionality: 1**	There are no identified risks to consumers from the use of TiO_2 in food packaging. As a result, there would be no benefits from the measures that would be triggered under the various pieces of legislation by a harmonised classification for Carc Cat 2	There could be significant consequences on existing materials and packaging, which could impact on the cost of food and the level of food waste.	Removing TiO_2 from food packaging materials would require the redesign of packaging and research into alternatives investigated. It may also trigger action at the national level in order allow TiO_2 remains available for packaging applications	As inhalable TiO_2 does not pose a risk to consumers in food contact materials, and as workers can be adequately using other measures, removing TiO_2 from the Union list is not a proportional in terms of benefit to consumers
8	**Risk management under waste legislation** **Effectiveness: 0** **Economic implications: 1** **Practicality: 1** **Proportionality: 1**	The linkages between a classification for Carc Cat 2 and waste legislation would not result in any significant reductions in risks, given that TiO_2 is not present in end articles in an inhalable form; the only potential exception is for recycling activities, but LEV and RPE would be more cost-effective. There are no foreseeable benefits for consumers	There could be significant consequences for the manufacturing sector as well as for the recycling and waste disposal sectors. There may also be significant impacts on the EU's ability to meet future recycling targets, due to changes in the need for waste handling permits, etc.	It is likely that industry would petition individual Member States to invoke Article 7(3) of the WFD to classify TiO_2 containing waste as non-hazardous[60]. This would be time consuming for industry and would place the onus for ensuring that regulation remains proportionate on individual Member States.	Given the low likelihood of TiO_2 being available in an inhalable form in wastes, it is unlikely that an automatic hazardous waste classification would be proportionate, particularly if this were to be followed by action at the national level to de-classify such wastes.

[60] Or a mirror entry on the European Waste Catalogue could render TiO_2-containing waste non-hazardous unless the content of the pigment exceeded a certain threshold.

Annex 1

Table 7-1:					
Name of Column 1	Contributing activity/technique for the environment	Contributing activity/technique for the workers	Product category	Sector of use	Technical function
Manufacture					
Manufacture of TiO_2 by sulfate process	ERC1	- Evaporation and precipitation of hydrated TiO_2 (PROC 22) - Filtration (PROC 3) - Calcination (PROC 22) - Milling (PROC 24) - Further processing (PROC 3; PROC 4) - Packaging of solid substance (PROC 26) - Cleaning and maintenance (PROC28)			
Manufacture of TiO_2 by chloride process	ERC1	- Thermal process (oxidising) (PROC 1; PROC 2; PROC 22) - Further processing (PROC 3; PROC 4) - Milling (PROC 24) - Packaging of solid substance (PROC 26) - Cleaning and maintenance (PROC28)			
Formulation					
Formulation of TiO_2 in paints, coatings, inks, dyes, lubricant, detergents, adhesives and sealants	ERC2 ERC3	- Handling of solid substance (PROC 26) - Milling (PROC 24) - Mixing and blending (PROC 5) - Handling and packaging of formulated liquid substance (PROC 8b; PROC 9)	PC 1: Adhesives, sealants; PC 9a: Coatings and paints, thinners, paint removes; PC 9c: Finger paints; PC 18: Ink and toners; PC 20: Products such as pH-regulators, flocculants,		no technical function

Table 7-1:					
Name of Column 1	Contributing activity/technique for the environment	Contributing activity/technique for the workers	Product category	Sector of use	Technical function
		- Handling and packaging final formulated solid substance (PROC 26) - Cleaning and maintenance (PROC28)	precipitants, neutralisation agents; PC 24: Lubricants, greases, release products; PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids; PC 35: Washing and cleaning products (including solvent based products)		
Formulation of TiO_2 in fillers, putties, plasters and modelling clay	ERC3	- Handling of solid substance (PROC 26) - Milling (PROC 24) - Mixing and blending (PROC 5) - Handling and packaging final formulated solid substance (PROC 26) - Cleaning and maintenance (PROC28)	PC 9b: Fillers, putties, plasters, modelling clay		no technical function
Formulation of TiO_2 in pharmaceutical and cosmetic products	ERC2 ERC3	- Handling of solid substance (PROC 26) - Milling (PROC 24) - Mixing and blending (PROC 5) - Handling and packaging of formulated liquid substance (PROC 8b; PROC 9) - Handling and packaging final formulated solid substance (PROC 26) - Tabletting (PROC 1; PROC 2; PROC 3; PROC 14) - Cleaning and maintenance (PROC28)	PC 29: Pharmaceuticals; PC 39: Cosmetics, personal care products		no technical function

Table 7-1:					
Name of Column 1	**Contributing activity/technique for the environment**	**Contributing activity/technique for the workers**	**Product category**	**Sector of use**	**Technical function**
Formulation of TiO_2 in biocidal products	ERC2	- Formulation step (PROC 5) - Handling and packaging of formulated liquid substance (PROC 8b; PROC 9) - Cleaning and maintenance (PROC28)	PC 8: Biocidal products (e.g. disinfectants, pest control)		no technical function
Use at industrial sites					
Intermediate use of TiO_2 in the manufacture of another substance	ERC6a	- Handling of solid substance (PROC 26) - Handling of liquid substance (PROC 8b; PROC 9) - Reaction step (PROC 2; PROC 3; PROC 4; PROC 5) - Cleaning and maintenance (PROC28)	SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals		intermediate (precursor)
Use of paints, coatings, inks, dyes, lubricant, detergents, adhesives and sealants	ERC5	- Chemical production where opportunity for exposure arises (PROC 1; PROC 2; PROC 3; PROC 4) - Mixing or blending in batch processes (PROC 5) - Industrial spraying (PROC 7) - Handling of liquid substance (PROC 8b; PROC 9) - Roller application or brushing (PROC 10) - Treatment of articles by dipping and pouring (PROC 13) - Cleaning and maintenance (PROC28)	PC 1: Adhesives, sealants; PC 9a: Coatings and paints, thinners, paint removes; PC 9c: Finger paints; PC 18: Ink and toners; PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents; PC 24: Lubricants, greases, release products; PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids; PC 35: Washing and cleaning products (including solvent based products)	SU 5: Manufacture of textiles, leather, fur; SU 6a: Manufacture of wood and wood products; SU 6b: Manufacture of pulp, paper and paper products; SU 11: Manufacture of rubber products; SU 12: Manufacture of plastics products, including compounding and conversion; SU 15: Manufacture of fabricated metal products, except machinery and equipment; SU 16: Manufacture of	impregnation agent; lubricating agent; opacifier; pigment; processing aid; surface modifier; UV stabiliser; Photocatalytic activity

Table 7-1:					
Name of Column 1	Contributing activity/technique for the environment	Contributing activity/technique for the workers	Product category	Sector of use	Technical function
				computer, electronic and optical products, electrical equipment; SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment; SU 18: Manufacture of furniture; SU 19: Building and construction work	
Use of fillers, putties, plasters and modelling clay	ERC5	- Chemical production where opportunity for exposure arises (PROC 1; PROC 2; PROC 3; PROC 4) - Mixing or blending in batch processes (PROC 5) - Industrial spraying (PROC 7) - Handling of liquid substance (PROC 8b; PROC 9) - Roller application or brushing (PROC 10) - Treatment of articles by dipping and pouring (PROC 13) - Cleaning and maintenance (PROC28)	PC 9b: Fillers, putties, plasters, modelling clay	SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement; SU 19: Building and construction work	opacifier; pigment; surface modifier; UV stabiliser
Use of TiO_2 as deNOx catalyst	ERC5	- Chemical production where opportunity for exposure arises (PROC 1; PROC 2; PROC 3; PROC 4) - Mixing or blending in batch processes (PROC 5)		SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	catalyst Service life of TiO_2-containing DeNOx catalysts by consumers;

Table 7-1:					
Name of Column 1	Contributing activity/technique for the environment	Contributing activity/technique for the workers	Product category	Sector of use	Technical function
		- Handling of liquid substance (PROC 8b; PROC 9) - Industrial spraying (PROC 7) - Roller application or brushing (PROC 10) - Treatment of articles by dipping and pouring (PROC 13) - Sintering (PROC 2; PROC 3; PROC 22) - Cleaning and maintenance (PROC28)			Service life of TiO_2-containing DeNOx catalysts in professional settings; Service life of TiO_2-containing DeNOx catalysts in industrial settings
Use of TiO_2-containing rubber or plastic articles in industrial setting	ERC5	- Chemical production where opportunity for exposure arises (PROC 1; PROC 2; PROC 3; PROC 4) - Calendering (PROC 6) - Handling of liquid substance (PROC 8b; PROC 9) - Industrial spraying (PROC 7) - Extrusion (PROC 14) - Roller application or brushing (PROC 10) - Treatment of articles by dipping and pouring (PROC 13) - Cleaning and maintenance (PROC28)		SU 11: Manufacture of rubber products; SU 12: Manufacture of plastics products, including compounding and conversion; SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment; SU 18: Manufacture of furniture; SU 19: Building and construction work	durability agent; filler; opacifier; pigment; surface modifier; UV stabiliser Service life of rubber articles used by consumers; Service life of plastic articles used by consumers; Handling of TiO_2-containing rubber or plastic articles in professional settings; Handling of TiO_2-containing rubber or plastic articles in industrial settings
Use of TiO_2 in the paper industry	ERC5	- Chemical production where opportunity for exposure arises (PROC 1; PROC 2; PROC 3; PROC 4) - Mixing or blending in batch	PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids	SU 6b: Manufacture of pulp, paper and paper products; SU 18: Manufacture of furniture;	opacifier; pigment Service life of paper and paperboard products used

Table 7-1:					
Name of Column 1	Contributing activity/technique for the environment	Contributing activity/technique for the workers	Product category	Sector of use	Technical function
		processes (PROC 5) - Handling of liquid substance (PROC 8b; PROC 9) - Industrial spraying (PROC 7) - Roller application or brushing (PROC 10) - Treatment of articles by dipping and pouring (PROC 13) - Cleaning and maintenance (PROC28)		SU 0: Other: Packaging, including board	by consumers; Service life of TiO_2-containing high quality paper articles used in professional settings
Use of TiO_2 in electronics, ceramics and glass	ERC5	- Chemical production where opportunity for exposure arises (PROC 1; PROC 2; PROC 3) - Mixing or blending in batch processes (PROC 5) - Handling of liquid substance (PROC 8b; PROC 9) - Industrial spraying (PROC 7) - Treatment of articles by dipping and pouring (PROC 13) - Sintering (PROC 1; PROC 2; PROC 22) - Cleaning and maintenance (PROC28)		SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement; SU 16: Manufacture of computer, electronic and optical products, electrical equipment; SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment; SU 19: Building and construction work	abrasive; opacifier; pigment; UV stabiliser; Photocatalytic activity Service life of TiO_2-containing electronics, ceramics and glass articles in industrial settings; Service life of ceramics used by consumers
Use of paints, coatings, inks, dyes, lubricant, detergents, adhesives and sealants	ERC8c ERC8f	- Chemical production where opportunity for exposure arises (PROC 1; PROC 2; PROC 3; PROC 4) - Mixing or blending in batch processes (PROC 5) - Handling of liquid substance (PROC	PC 1: Adhesives, sealants; PC 9a: Coatings and paints, thinners, paint removes; PC 9c: Finger paints; PC 18: Ink and toners; PC 20: Products such as pH-	SU 5: Manufacture of textiles, leather, fur; SU 6a: Manufacture of wood and wood products; SU 6b: Manufacture of pulp, paper and paper products;	impregnation agent; lubricating agent; opacifier; pigment; processing aid; surface modifier; UV stabiliser; Photocatalytic activity

Table 7-1:					
Name of Column 1	**Contributing activity/technique for the environment**	**Contributing activity/technique for the workers**	**Product category**	**Sector of use**	**Technical function**
		8a; PROC 8b; PROC 9) - Roller application or brushing (PROC 10) - Non industrial spraying (PROC 11) - Treatment of articles by dipping and pouring (PROC 13) - Manual activities involving hand contact (PROC 19) - Use of lubricant (PROC 24)	regulators, flocculants, precipitants, neutralisation agents; PC 24: Lubricants, greases, release products; PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids; PC 35: Washing and cleaning products (including solvent based products)	SU 11: Manufacture of rubber products; SU 12: Manufacture of plastics products, including compounding and conversion; SU 15: Manufacture of fabricated metal products, except machinery and equipment; SU 18: Manufacture of furniture; SU 19: Building and construction work	
Use of fillers, putties, plasters and modelling clay	ERC8c ERC8f	- Chemical production where opportunity for exposure arises (PROC 1; PROC 2; PROC 3; PROC 4) - Mixing or blending in batch processes (PROC 5) - Handling of liquid substance (PROC 8a; PROC 8b; PROC 9) - Roller application or brushing (PROC 10) - Non industrial spraying (PROC 11) - Treatment of articles by dipping and pouring (PROC 13) - Manual activities involving hand contact (PROC 19)	PC 9b: Fillers, putties, plasters, modelling clay	SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement; SU 19: Building and construction work	opacifier; pigment; surface modifier; UV stabiliser
Professional use of TiO_2-containing biocidal	ERC8c ERC8f	- Transfer of substance or mixture (charging and discharging) at non-	PC 8: Biocidal products (e.g. disinfectants, pest control)		UV stabiliser; vehicle (carrier)

Table 7-1:					
Name of Column 1	**Contributing activity/technique for the environment**	**Contributing activity/technique for the workers**	**Product category**	**Sector of use**	**Technical function**
products		dedicated facilities (PROC 8a) - Roller application or brushing (PROC 10) - Non industrial spraying (PROC 11) - Manual activities involving hand mixing (PROC 19)			

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