6 Comparison of impacts for carcinogenicity classifications of category 1B and 2

6.1 Comparison of regulatory provisions

6.1.1 Introduction

This section compares the impacts that would arise if TiO_2 was classified as Carc Cat 2 against those arising from a Carc Cat 1B classification. It is important to note that key legislation driving the impacts described in Section 4 would not apply, e.g. the automatic REACH Annex XVII restriction on consumer uses of formulations containing CMR category 1B substances, and the requirements for minimisation of exposure of workers under the Carcinogens and Mutagens Directive. This, however, would not mean that there would be no significant impacts, as is elaborated below.

6.1.2 Provisions of EEA-wide regulatory framework

A comparison between the provisions of relevant EEA-wide legislation that makes provisions for the marketing and use of CMR substances has been undertaken and is summarised in **Table 6-1** below.

Generally, in only a few cases the provisions for Carc Cat 2 substances are the same as for Carc Cat 1B ones. We may group the differences noted across the different regulations in five groups, as shown in **Figure 6–1** with further explanation provided overleaf:

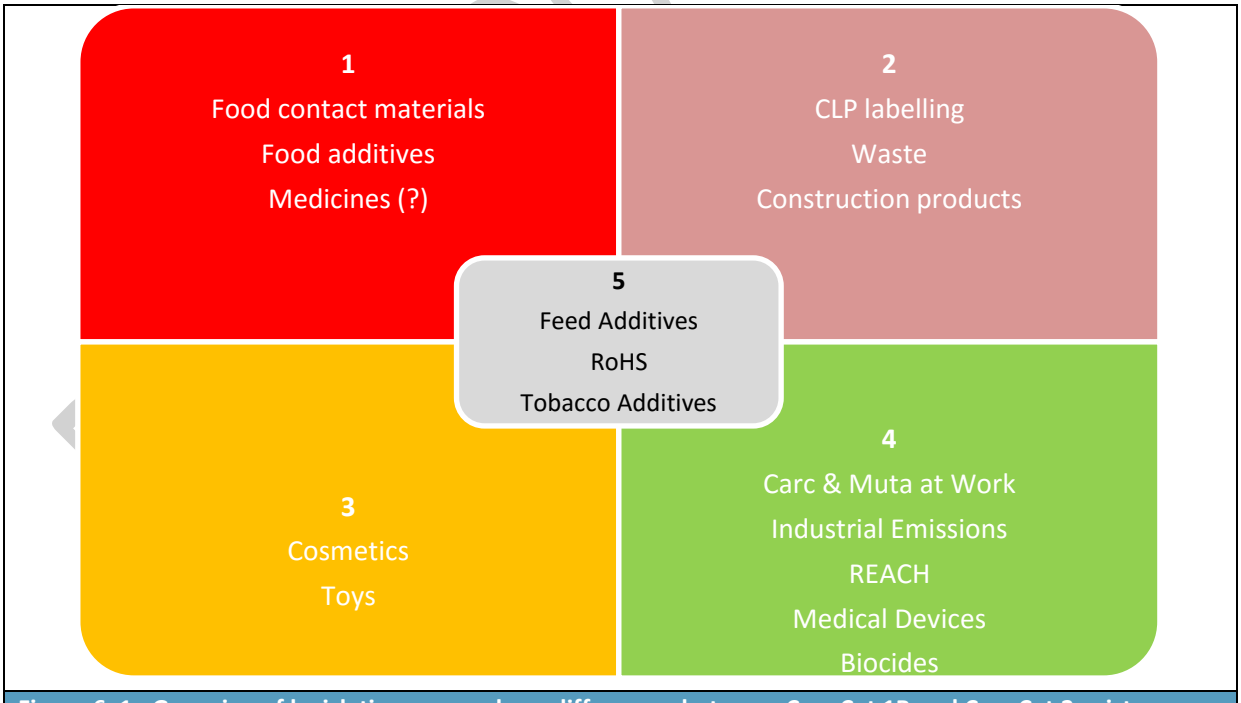

Figure 6–1: Grouping of legislation areas where differences between Carc Cat 1B and Carc Cat 2 exist

- **Group 1 – no change in provisions**: here, Carc Cat 2 substances are treated the same as Carc Cat 1B substances. This group includes regulations on food contact materials (e.g. plastics and others), food additives and medicinal products. Notably, there is some uncertainty in relation to medicinal products where the regulations do not appear to make a distinction between carcinogenicity categories, however, the classification category might be taken into consideration in the carcinogenic-potential testing and when authorising the use of the substance;

- **Group 2 – theoretically less onerous but, in practice, potentially similar provisions**: here, Carc Cat 2 substances are treated less stringently than Carc Cat 1B ones but in practical (and economic) terms manufacturers and downstream users would be facing essentially very similar requirements. This group includes the labelling provisions of the CLP Regulation, waste management and the Construction Products Regulation. By way of example, classification of TiO_2-containing waste as hazardous would occur at a higher concentration (1% by weight vs. 0.1% for Carc Cat 1B substances), but as the concentration of TiO_2 typically exceeds 1% in the vast majority of its formulations or articles, hazard classification of the waste would still be warranted;

- **Group 3 – less onerous provisions**: here, Carc Cat 2 substances are treated less stringently than Carc Cat 1B ones. This group includes cosmetics and toys where both Carc Cat 1B and Carc Cat 2 substances are prohibited from use but derogations for Carc Cat 2 substances are easier to obtain;

- **Group 4 – no provisions**: here, Carc Cat 2 substances fall outside the scope of the relevant legislation. This group includes the Carcinogens and Mutagens at Work Directive, the Industrial Emissions Directive, the REACH Regulation (restrictions on consumer use of substances and formulations, and potential Authorisations), the upcoming Medical Devices Regulation and the Biocidal Products Regulation; and

- **Group 5 – differences are uncertain**: here, it is unclear how the carcinogenicity category of a substance is taken into account. This group include feed additives regulations, the RoHS Directive and the tobacco additives legislation. It can be envisaged that requirements on Carc Cat 2 substances might be less onerous than Carc Cat 1B.

In conclusion, impacts that would arise for the manufacture and use of TiO_2 in the EEA as a result of the requirements of EEA-wide legislation would overall be lower if the substance was classified as Carc Cat 2 in comparison to Carc Cat 1B. This, however, would not mean that there would be no significant impacts, as discussed below.

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
Key: red – same provisions; orange – similar but lower impact; green – no provision/impact; grey – unclear				
CLP	Regulation	1272/2008/EC	Labelling provision: • Signal word = Danger • Hazard statement and code = H350 may cause cancer (state exposure route if it has been conclusively proven that no other routes of exposure cause the hazard) • Precautionary statement: prevention P201, P202, P281; response P308, P313; storage P405; disposal P501. Generic concentration limit for mixture classification as carcinogenic ≥0.1%	Labelling provision: • Signal word = Warning • Hazard statement and code = H351 suspected of causing cancer (state exposure route if it has been conclusively proven that no other routes of exposure cause the hazard) • Precautionary statements are the same as for category 1B. Generic concentration limit for mixture classification as carcinogenic ≥1.0%. If at greater concentration, then SDS should be made available. Additional labelling would be mixtures not intended for the general public. Tactile warning
Carcinogens and Mutagens at Work	Directive	2004/37/EC	Employers should consider the use of alternative substances. If the substance cannot be replaced, closed systems should be used. Where this is not possible, exposure should be reduced. Employers have to make certain information available to the competent authority if requested (activities, quantities, exposures, number of exposed workers, preventive measures)	Not applicable to Category 2
Waste Framework	Directive	2008/98/EC	Waste is rendered hazardous (HP7) if it contains substances which are carcinogenic. For TiO_2, if it classified as a Cat 1B carcinogen, a concentration of 0.1% would render the waste hazardous. If a Member State has evidence that the waste that appears on the list of hazardous waste does not display any of the properties in Annex III, it may consider that waste as non-hazardous. The Commission shall be notified in such cases and be provided with the necessary evidence. In light of this evidence, the list shall be reviewed	Same provisions apply, except that the concentration at which the waste is considered hazardous is 1%

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
	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	Same provisions apply as above
Industrial Emissions	Directive	2010/75/EC	Substances classified as a Carc Cat 1A or 1B should be replaced, as far as possible by less harmful substances or mixtures is the shortest possible time. Carcinogens are listed in Annex II "*list of polluting substances*", under air and water. Member States shall ensure that the permit includes all measures necessary for compliance with the requirements of Articles 11 and 18	No substitution requirement. Unclear if Annex II applies to all classification categories for carcinogens as the hazard statement code is not given
REACH	Regulation Annex XVII	1907/2006/EC	Substances which appear in Part 3 of Annex VI to the CLP Regulation as Carc Cat 1B shall not be placed on the market or used as a substance, constituent of other substances, or mixture for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than the specific concentration limit outlined in Part 3 of Annex Vi to CLP, or the generic concentration limit specified in Part 3 of Annex I to CLP. Such substances or mixtures should be labelled as "*restricted to professional users*". There is also a so-called 'fast-track' restriction procedure under Article 68(2)	No restriction
	Regulation Annex XIV	1907/2006/EC	Authorisation may be required if substance is placed on Annex XIV	No Authorisation required

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
Cosmetics	Regulation	1223/2009/EC	Carc Cat 1B substances are prohibited for use in cosmetic products. A derogation may be granted where all of the conditions are fulfilled: • They comply with the food safety requirements as defined in Regulation 1748/2002; • There are no suitable alternatives, as documented in an analysis of alternatives; • The application is made for a particular use of the product category with a known exposure; and • They have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, particularly for vulnerable populations	Carc Cat 2 substances are prohibited for use in cosmetic products. A derogation may be granted and is based on an opinion on safe use from the SCCS only
	Regulation	(EU) 2016/1143	TiO_2 may be used in its nano-form as a UV-filter in cosmetic products at a maximum concentration of 25%w/w except where exposure via inhalation may occur (this may be reviewed after a CLH is adopted)	Perhaps less likely to be reviewed after a harmonised classification is adopted

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
Toy Safety	Directive	2009/48/EC	Prohibited in toys, in components of toys or in micro-structurally distinct parts of toys. Derogation is possible (one of the following conditions met): a) These substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances; b) These substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2); c) A decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A. That decision may be taken if the following conditions are met: i. The use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure; ii. There are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and iii. The substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006. The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every 5 years	Prohibited in toys, in components of toys or in micro-structurally distinct parts of toys. Derogation conditions are the same, except for the requirement to demonstrate in an analysis of alternatives that there are no suitable alternative substances or mixtures available, as documented

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
Food Contact Materials	Regulation	1935/2004	Under Article 3, materials and articles (including active and intelligent materials and articles) shall be manufactured in compliance with good manufacturing practice so that they do not transfer their constituents to food in quantities which could: • Endanger human health; • Bring about an unacceptable change in the composition of the food; or • Bring about a deterioration in the organoleptic characteristics	Any difference between classification categories are not noted in this Regulation and can be found in the material specific Regulations
	Regulation Plastics in Materials and Articles	EU/10/2011	Substances that are classified as carcinogenic should not be used in food contact materials without previous authorisation and should therefore not be covered by the functional barrier concept. ***Plastic multi-layer materials and articles***: substances not listed in the Union list or provisional list may not be classified as a carcinogen in accordance with the criteria in sections 3.6 of Annex I of the CLP Regulation. ***Multi-material multi-layer materials and articles:*** substances not listed in the Union list or provisional list may not be classified as a carcinogen in accordance with the criteria in sections 3.6 of Annex I of the CLP Regulation	Same provisions apply
	Regulation Recycled Plastic Materials and Articles	282/2008/EC	Only monomers and additives authorised under Reg. (EU) 10/2011 should be added to the recycled plastics and their migration limits should be respected. Use of TiO_2 would be dependent on it remaining in the Union list	Same provisions apply as they are in reference to Reg. (EU) 10/2011
Food Contact Materials	Regulation	(EC) No 450/2009	Substances classified as a carcinogen under section 3.6 of Annex I of CLP cannot be present in active or intelligent components even if they are not in direct contact with food or the environment surrounding food and are separated by a functional barrier	Same provisions apply

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
Food Additives	Regulation	1333/2008/EC	Only food additives included in the Community list in Annex II may be placed on the market and used in foods under the conditions of use specified therein. Only food additives included in the Community list in Annex III may be used in food additives, in food enzymes and in food flavourings under the conditions of use specified therein. Food additives must comply with the specifications outlined in Article 14. A food additive may be added to the Community list where it meets the following conditions: • It does not, on the basis of available scientific evidence, pose a safety concern to the health of the consumer at the level of use; • There is reasonable technological need that cannot be achieved by other economically and technologically practicable means; • It does not mislead the consumer. Only food colours listed in Annex II may be used for the purpose of health marking, or for the decorative colouring or stamping of eggshells	Same provisions apply
	Regulation	231/2012	Lays out the purity specifications for TiO_2.	At present, the same applies

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
	Regulation	1831/2003/EC	No feed additive can be placed on the market, processed or used if it is not authorised in accordance with this Regulation and the conditions for use and labelling are met. Conditions for authorisation are that the feed additive must not: • Have an adverse effect on animal health, human health or the environment; • Be presented in a manner which may mislead the user; or • Harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products. 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]*" An authorisation may be revoked if the Commission decide, on the basis of an opinion by the Authority, that it no longer meets the criteria for authorisation	*The hazard classification of a substance is not given as a condition for authorisation within the legal text. It is not apparent whether or not it is taken into account in the EFSA authorisation*

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
Medicinal Products	Directive	2001/83/EC	All colourants must satisfy the requirements of Directive 2009/35/EC. Carcinogenic potential included in toxicological and pharmacological tests. Testing required: • In respect of substances having a close chemical analogy with a known carcinogenic or carcinogenic compounds; • In respect of substances which have given rise to suspicious changes during long-term toxicological tests; and • In respect of substances which have given rise to suspicious results in the mutagenic-potential tests or in other short-term carcinogenicity tests	*No differentiation between carcinogenic category in the legal text but this may be taken into account in the carcinogenic-potential testing*
	Regulation	1901/2006	The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency drew up an opinion on the use of these categories of 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. It was determined that "*any risk identified for an excipient and in particular a CMR substance, would be acceptable only on condition that this excipient cannot be submitted with a safer available alternative, or that the toxicological effects in animal models are considered not relevant for humans, or where the overall benefit/ risk balance for the product outweighs the safety concern with the product*.[1]"	*There may be a possibility that it could be easier to obtain an authorisation with a category 2 carcinogen as the evidence for classification as carcinogenic category 2 is considered to "limited". This is not a guarantee*

[1] European Medicines Agency – Committee for Human Medicinal Products (2007) CHMP Scientific Article 5(3) opinion on the potential risks of carcinogens, mutagens and substances to reproduction when these substances are used as excipients of medicinal products for human use. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004013.pdf .

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
	Directive	2009/35/EC	Colouring matters must abide by the rules on colouring matters in Regulation (EC) No. 1333/2008 and the Annex to Directive 95/45/EC laying down the specific purity criteria concerning colours for use in foodstuffs apply to medicinal products	The same rules should apply for Category 2 Carcinogens as this Regulation is based on Reg. 1333/2008 and Directive 95/45/EC
Medical devices	Directive	93/42/EEC (amendment agreed in June 2016)	Carc Cat 1B substances shall not exceed the concentration limit of 0.1% w/w in devices, or those parts thereof or those materials used therein: • That are invasive and come into direct contact with the human body; or • That (re)administer medicines, body liquids or other substances, including gases, to/ from the body; or • That transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body. Information on use must explain the precautions related to materials incorporated into the device that are carcinogenic	There are no concentration limit provisions for Carc Cat 2 substances. *It is not clear if this covers all categories of carcinogens*

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
Construction Products	Regulation	305/2011	Where applicable, the declaration of performance should be accompanied by information on the content of hazardous substances in the construction product, this is limited to those substances referred to in Articles 31 and 33 of REACH but more should be further investigated in line with CLP, Regulation 528/2012, Directive 2000/60/EC and Directive 2008/98/EC. Article 4 requires manufacturers to draw up a declaration of performance for products which are covered by a harmonised standard or conforms to a European Technical Assessment. Article 3(3) allows the Commission to decide those essential characteristics for which the manufacturer should declare the performance of the product when it is placed on the market. An SDS is required for any product containing TiO_2 in a concentration ≥0.1% if it has a CLH for carcinogenicity category 1B	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)

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
Biocides	Regulation	EU/528/2012	Substances classified as a Carc Cat 1B are exclusion criteria and so prevent active substance approval. Derogation is available if at least one of the following conditions is met: • The risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment; • It is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or • Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance. The availability of suitable and sufficient alternatives should be taken into account when granting a derogation. Biocidal products shall not be authorised for making available on the market for use by the general public if it has been classified as a Carc Cat 1B. Substances that are classified as a Carc Cat 1B are considered to be candidates for substitution	Category 2 Carcinogens are not within the scope of the Regulation

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
Restriction of hazardous substances in electrical & electronic equipment	Directive	2011/65/EU	Where scientific information has become available, taking into account the precautionary principle, the restriction of hazardous substances, including nanomaterials which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined. Review and amendment of Annex II should be coherent and maximise synergies with work carried out under other Union legislation, in particular REACH. Following the classification of TiO_2 as a carcinogen, a Member State may submit a proposal for it to be added to Annex II of the RoHS Directive	*It is unclear whether or not a Carc Cat 2 would be subject to the same provisions as there is no definition of "hazardous" or differentiation between hazard class categories. It is noted that the aim of the Directive is to protect the environment and human health via the environmental release of hazardous substances. It would be at the discretion of Member States if any action were to be taken*
	Directive	2012/19/EU	Minimum recovery targets are set in Annex V for the categories of EEE in Annex I	*As above*
Tobacco additives	Directive	2014/40/EU	Additional enhanced reporting obligations are required for additives within the priority list which are carcinogenic. The use of additives that are necessary for the manufacture of tobacco products are allowed as long as they do not increase carcinogenic properties. Additives that have carcinogenic properties in unburnt form should be prohibited. On the basis of scientific evidence, tobacco products that contain additives that increase carcinogenic properties at the stage of consumption to a significant or measureable degree are prohibited from being placed on the market	*There is no distinction between hazard class categories and so it is unclear whether there may be different obligations. It appears that it is based on a carcinogenic classification and so the provisions may apply to category 2 carcinogens as well*

Table 6-1: Comparison of provisions of EEA-wide legislation for Carc Cat 1B and Carc Cat 2 classified substances				
Regulation	**Type**	**Number**	**Provisions for Carc Cat 1B substances**	**Provisions for Carc Cat 2 substances**
	Decision	(EU) 2016/787	Establishes a priority list of additives that are subject to enhanced reporting obligations. TiO_2 is listed. The enhanced reports will be required as of 1 July 2018.	*Same provisions may apply to category 2 carcinogens as no distinction is made between hazard class categories*

6.1.3 Other provisions

A range of other provisions are discussed in Section 4 and Annex 1 (Section 8.2) of this document. The differences between Carc Cat 2 and Carc Cat 1B substances under those provisions can be summarised as follows:

- **National Health and Safety at Work Legislation**: assessing impacts under national legislation has been outside the scope of this project. As such it cannot be certain what differences would arise on the national level but it is reasonable to assume that some requirements and controls would apply to a Carc Cat 2 substance;

- **CoE Resolutions and national rules on food contact materials**: Section 8.2.1 of Annex 1 discusses the Council of Europe (CoE) Resolutions on coatings, paper and board, and printing inks and existing national rules on a variety of food contact materials and articles. Pending the adoption of more specific EU measures, food contact materials need to comply with these measures. As the details of national legislation are not known, it cannot be certain how the provisions for different carcinogenicity classification categories would vary. As far as CoE Resolutions are concerned, the one for printing inks makes specific reference to CMR 1A/1B substances and in that sense a classification of Cat 2 would not affect the use of TiO_2 in printing inks (also see discussion on the EuPIA Exclusion Policy below). On the other hand, no specific reference to hazard categories is made in the CoE Resolutions on coatings and paper/board and as such, a Carc Cat 2 classification, similarly to a Carc Cat 1B one could lead to the listings (approvals) of TiO_2 being reviewed;

- **EuPIA (European Printing Ink Association) Exclusion Policy**: this Policy is an important driving force behind the exclusion of hazardous substances from ink formulations in Europe. A classification as Carc Cat 1B would require ink manufacturers to cease the use of TiO_2, unless an exemption were provided (the substance would fall under the Group A exclusion criteria - see Section 8.2.2). However, a classification of Carc Cat 2 would mean that the substance would fall outside the scope of the exclusion criteria, thus its use would not be prohibited;

- **Global Automotive Declarable Substance List (GADSL)**: classification of TiO_2 as Carc Cat 2 would render the substance a "Declarable" one but it would be unlikely to make it a candidate for a "Prohibited" substance classification;

- **CE marking**: Section 8.2.3 refers to relevant CE marking provisions for toys and energy related products. For toys, provisions for a Carc Cat 2 substance would appear to be same as Carc Cat 1B, except that there is a slight difference in derogation criteria which means that the use of a Carc Cat 2 substance might be granted a derogation where Carc Cat 1B would not and the generic concentration limit is 1% up from 0.1%. For ecodesign of energy related products, CE marking provisions would appear to be the same for both hazard classification categories;

- **Ecolabel**: there appears to be no difference between Carc Cat 1B and Carc Cat 2, as provisions on carcinogens are based on a carcinogenicity classification in general (H350 or H351); and

- **Oeko-Tex® certification**: there appears to be no difference between Carc Cat 1B and Carc Cat 2. There is at least one Carc Cat 2 substance already listed under colourants.

6.2 Impacts of a Carcinogenicity Category 2 classification of the manufacture and use of titanium dioxide

Table 8-19 in Annex 1 shows the impacts of different regulatory regimes on the manufacture and applications of TiO_2. A revised version, presented overleaf as **Table 6–2**, reflects the impacts from a potential Carc Cat 2 harmonised classification and confirms that the overall impact would be lower than in the case of a Carc Cat 1B classification. Still, whilst differences between a Carc Cat 1B and a Carc Cat 2 classification would vary by application, labelling requirements and socio-economic impacts would be far from negligible. Moreover, as regulatory-driven impacts would become less severe, the role of user and (particularly) consumer, media and NGO perceptions about a classified carcinogen and concerns prompted by labelling could become more critical for the magnitude of overall impacts. A further table, **Table 6-3**, assesses the magnitude of changes in adverse impacts when a Carc Cat 2 hazard classification is adopted as opposed to a Carc Cat 1B one.

Table 6-3 suggests that impacts would overall be significantly lower than under a Carc Cat 1B classification, but adverse impacts would still arise. In general terms, we may distinguish three groups of applications/supply chain areas: (a) those where a lower carcinogenicity category would have a limited impact, (b) those where a lower carcinogenicity hazard category would have an impact notably lower than Carc Cat 1B, and (c) those where impacts would generally be very low. Errore. L'origine riferimento non è stata trovata. summarises these three groups. The manufacture of TiO_2 and its mass applications generally fall under the second group, i.e. impacts on them would be lower than under a Carc Cat 1B classification but adverse impacts would still arise. The applications in the first group, where differences between Carc Cat 2 and Carc Cat 1B would be small, generally account for a modest percentage of TiO_2 consumption (ca. 1% according to Cefic data for the year 2013).

It is important to note that quantification of the impacts from a classification of Carc Cat 2 is fraught by uncertainty even larger than for a Carc Cat 1B classification. This is particularly true because the scale of impacts on the mass applications of TiO_2 (paints, coatings, inks, plastics, paper) is not possible to accurately scope, as they as they are invariably more likely to result from NGO, media and stakeholder pressure than from regulatory requirements.

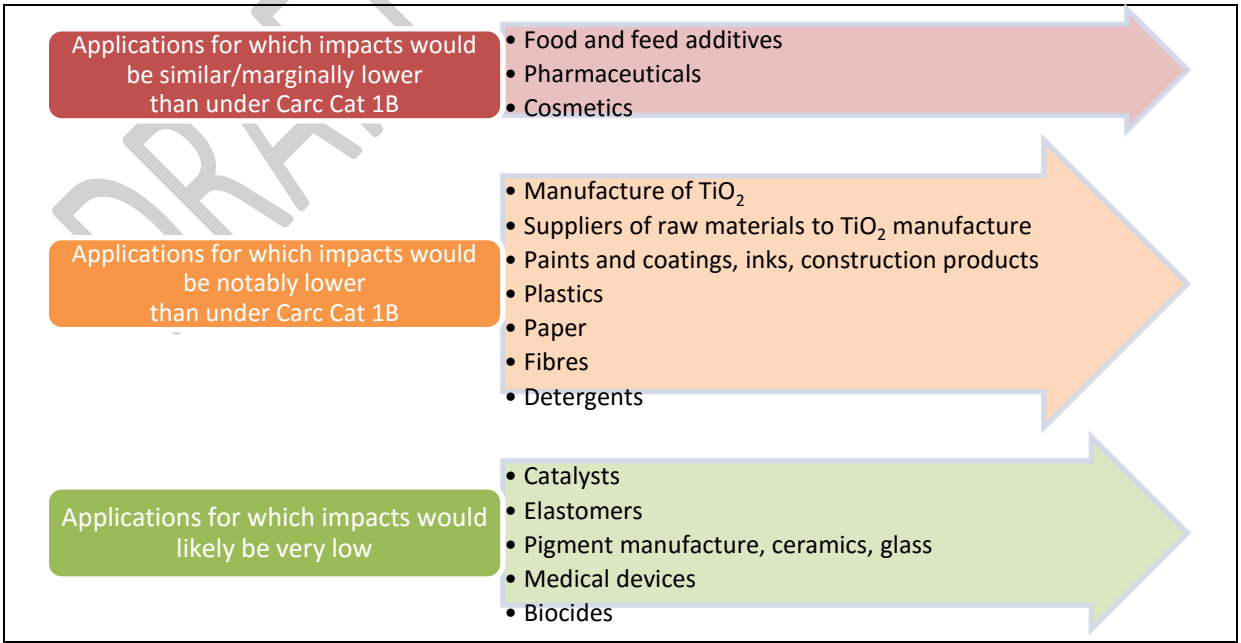

Figure 6–2: Classification of applications of TiO_2 based on envisaged impacts under a Carc Cat 2 classification

Table 6–2: Relevance of different regulatory instruments to the applications of TiO_2 following a harmonised classification of Carc Cat 2																		
Relevant legislation	**Manufacture and import of TiO_2**	**Paints**	**Plastics**	**Paper**	**Inks**	**Construction materials**	**Fibres**	**Catalysts**	**Food, feed and food contact materials**	**Pharmaceuticals**	**Cosmetics**	**Elastomers**	**Pigment manufacture**	**Ceramics**	**Glass**	**Medical devices**	**Detergents**	**Biocides**
Key: red: relevant; orange: marginally relevant/relevant under conditions; light red: relevant but less stringent than under Carc Cat 1B; light orange: relevant but less stringent than under Carc Cat 1B; grey: uncertain																		
CLP																		
Carcinogens and Mutagens at Work																		
Waste Framework																		
Industrial Emissions																		
REACH Annex XVII																		
REACH Annex XIV																		
Cosmetics																		
Toy Safety																		
Food Contact Materials																		
Food Additives																		
Medicinal Products																		
Construction Products																		
Biocides																		
Medical Devices																		
RoHS																		
Tobacco additives																		
Other		Eco-label	GADSL		Eco-label	GADSL	Oeko-Tex Eco-label		CoE									
Change in overall impact	↓↓	↓↓	↓	↓↓	↓↓	↓	↓	↓↓	↓	↓	↓	↓	↓	↓	↓	↓↓	↓↓	↓↓

Table 6-3: Analysis of changes in impacts for TiO_2 supply chain actors when comparing Carc Cat 2 to Carc Cat 1B hazard classification				
Application area	**Key impact drivers under Carc Cat 1B**	**Change in the importance of impact drivers with Carc Cat 2**	**Changes to supply chain and consumer perceptions**	**Conclusion on impacts under Carc Cat 2**
Manufacture of TiO_2	• CMD* impact on operations • WFD** impact on operations • Loss of market from restrictions on TiO_2 use downstream • Loss of ancillary product generation	• CMD no longer relevant • Fewer restrictions on downstream use of TiO_2 • Less incentive for DUs to seek substitution • But labelling requirements remain	Not relevant (see discussion on downstream applications below)	Market losses will be much lower as mass applications will be considerably less impacted and closures of production plants are less likely to occur. However, profit generation will suffer
Suppliers of raw materials to TiO_2 manufacturers	• Loss of demand due to reduced TiO_2 generation in the EEA (possible plant closures)	• Plant closures far less likely	Not relevant	Some loss of income would materialise but far lower than under Carc Cat 1B
Paints and coatings	• CMD pushing for substitution and better exposure controls • WFD • REACH Annex XVII for DIY formulations	• CMD no longer relevant • DIY formulations no longer subject to a restriction • WFD impacts would largely remain (exemption still an option) • Labelling requirements remain	Role of perceptions under Carc Cat 1B mostly relevant to industrial users. Now, under Carc Cat 2, consumer perceptions become more critical; a carcinogen in significant concentrations in formulations for use by the public would raise concerns, despite the classification being for carcinogenicity by inhalation (of powder) only	The lack of relevance of the CMD and REACH Annex XVII makes the key difference and leads to dramatically lower impacts. However, the ubiquitous presence of TiO_2 in a very large number of products, particularly consumer formulations, could lead to some attempts at substitution and might raise concern among the public. As explained elsewhere in this document, TiO_2-free paints and coatings would be near impossible to source
Plastics	• CMD pushing for substitution and better exposure controls • WFD • REACH XIV in longer term	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option) • REACH restriction/ Authorisation not relevant	Consumer concerns over the presence of a carcinogen in articles would remain to a certain extent, despite the classification being for carcinogenicity by inhalation (of powder) only. Supply chain pressures likely to be less intense	Assuming that waste disposal and recycling impacts could be avoided through an WFD Art.7 exemption, impacts on the use of TiO_2 in plastics would be much lower but not eliminated. For some applications, e.g. food contact materials, impacts could remain the same. Also, consumer perceptions might affect the marketing of TiO_2-containing plastic articles
Paper	• CMD pushing for substitution and better exposure controls • WFD • Food Contact Materials	• CMD no longer relevant • Consumer formulations no longer subject to a restriction • WFD impacts would largely remain (exemption still an option) • Food Contact Materials regulations unlikely to vary too much compared to Carc Cat 1B	Consumer concerns over the presence of a carcinogen in articles would remain to a certain extent, despite the classification being for carcinogenicity by inhalation (of powder) only. Supply chain pressures likely to be less intense	Assuming that waste disposal and recycling impacts could be avoided through an WFD Art.7 exemption, impacts on the use of TiO_2 in paper products would be much lower but not eliminated. For some applications, e.g. food contact materials, impacts could remain the same. Also, consumer perceptions might affect the marketing of TiO_2-containing paper articles

Table 6-3: Analysis of changes in impacts for TiO_2 supply chain actors when comparing Carc Cat 2 to Carc Cat 1B hazard classification				
Application area	**Key impact drivers under Carc Cat 1B**	**Change in the importance of impact drivers with Carc Cat 2**	**Changes to supply chain and consumer perceptions**	**Conclusion on impacts under Carc Cat 2**
Inks	• CMD pushing for substitution and better exposure controls • WFD • REACH Annex XVII for consumer formulations • EuPIA Exclusion List	• CMD no longer relevant • Consumer formulations no longer subject to a restriction • EuPIA Exclusion List no longer applies • WFD impacts would largely remain (exemption still an option) • Labelling requirements remain	Consumer concerns over the presence of a carcinogen in consumer inks, toners, colours, etc. would remain to a certain extent, despite the classification being for carcinogenicity by inhalation (of powder) only. Supply chain pressures likely to be less intense	Similar to paints. CMD, REACH Annex XVII and EuPIA Exclusion List would not apply meaning that impacts would be much lower and would largely be limited to specific areas, such as food packaging materials. Still, consumer perceptions of the safety of numerous products could affect their marketing
Construction Products	• CMD pushing for substitution and better exposure controls • WFD • REACH Annex XVII for consumer formulations	• CMD no longer relevant • Consumer formulations no longer subject to a restriction • WFD impacts would largely remain (exemption still an option) • Construction Products Regulation would still apply but burden is limited to information provision • Labelling requirements remain	Consumer concerns over the presence of a carcinogen in consumer adhesives, sealants, etc. would remain to a certain extent, despite the classification being for carcinogenicity by inhalation (of powder) only. Supply chain pressures likely to be less intense	Similar to paints and inks. The lack of relevance of the CMD and REACH Annex XVII makes the key difference and leads to dramatically lower impacts
Fibres	• CMD pushing for substitution and better exposure controls • WFD • REACH Annex XVII for consumer products (e.g. textiles)	• CMD no longer relevant • Consumer products no longer subject to a restriction • WFD impacts would largely remain (exemption still an option) • Oeko-Tex® and Ecolabel provisions remain • Some impacts under Toy Safety Directive could remain	Most man-made fibres come into contact with consumer skin in everyday life (this includes clothing, underwear, sports clothing, etc.). TiO_2 contents above 0.1% by weight would affect consumers' perceptions, even if the risk for consumer exposure by inhalation is non-existent	Whilst impacts on the manufacturing side would be lower, impacts on marketing of fibre products would be impacted by the provisions of schemes such as Oeko-Tex® and Ecolabel and the perceptions of consumers
Catalysts	• CMD pushing for substitution and better exposure controls • WFD	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option)	No consumer use. Much weaker incentive to substitute TiO_2	Impacts on the use of TiO_2 in catalysts are likely to be very low

Table 6-3: Analysis of changes in impacts for TiO_2 supply chain actors when comparing Carc Cat 2 to Carc Cat 1B hazard classification				
Application area	**Key impact drivers under Carc Cat 1B**	**Change in the importance of impact drivers with Carc Cat 2**	**Changes to supply chain and consumer perceptions**	**Conclusion on impacts under Carc Cat 2**
Food and feed additives and packaging	• CMD pushing for substitution and better exposure controls • WFD • Food Contact Materials • Food/feed additives	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option) • Food Contact Materials regulations unlikely to vary too much compared to Carc Cat 1B • Food additives provisions remain – but is assumed that even with Carc Cat 1B impacts would realistically be contained	Consumer concerns over the presence of a carcinogen in foodstuff would remain, despite the classification being for carcinogenicity by inhalation (of powder) only. Public unlikely to be able to distinguish between hazard categories	Impacts under Carc Cat 2 would not be dramatically different than under Carc Cat 1B
Pharmaceuticals	• CMD pushing for substitution and better exposure controls • WFD • Food additives	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option) • Food additives provisions remain – but is assumed that even with Carc Cat 1B impacts would realistically be contained	Consumer concerns over the presence of a carcinogen in medicines and nutraceuticals would remain, despite the classification being for carcinogenicity by inhalation (of powder) only. Public unlikely to be able to distinguish between hazard categories	Impacts under Carc Cat 2 would not be dramatically different than under Carc Cat 1B
Cosmetics	• CMD pushing for substitution and better exposure controls • WFD • Cosmetic Products Directive	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option) • Restriction on cosmetics use would remain but an exemption may be easier to obtain	Consumer concerns over the presence of a carcinogen in cosmetics applied directly on the body would remain, despite the classification being for carcinogenicity by inhalation (of powder) only	Impacts would depend on whether exemption can be secured. This should be easier with a Carc Cat 2 hazard classification
Elastomers	• CMD pushing for substitution and better exposure controls • WFD • Food Contact materials	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option) • Food Contact Materials regulations unlikely to vary too much compared to Carc Cat 1B	Consumer applications exist but it is not clear how extensive they are	Impacts under Carc Cat 2 would probably be considerably lower than under Carc Cat 1B
Pigment manufacture	• CMD pushing for substitution and better exposure controls • WFD	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option)	No consumer use. Much weaker incentive to substitute TiO_2	Impacts on the use of TiO_2 in pigment manufacture would likely be very low

Table 6-3: Analysis of changes in impacts for TiO_2 supply chain actors when comparing Carc Cat 2 to Carc Cat 1B hazard classification				
Application area	**Key impact drivers under Carc Cat 1B**	**Change in the importance of impact drivers with Carc Cat 2**	**Changes to supply chain and consumer perceptions**	**Conclusion on impacts under Carc Cat 2**
Ceramics	• CMD pushing for substitution and better exposure controls • WFD • Food Contact materials	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option) • Food Contact Materials regulations unlikely to vary too much compared to Carc Cat 1B	Consumer concerns over the presence of a carcinogen in ceramics used in contact with food would remain, despite the classification being for carcinogenicity by inhalation (of powder) only	Impacts under Carc Cat 2 would overall probably be considerably lower than under Carc Cat 1B
Glass	• CMD pushing for substitution and better exposure controls • WFD	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option)	Apparently limited direct consumer use. Much weaker incentive to substitute TiO_2	Impacts on the use of TiO_2 in glass manufacture would likely be very low
Medical devices	• CMD pushing for substitution and better exposure controls • WFD • Medical Devices Regulation	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option) • Medical Devices Regulation no longer relevant	Consumer concerns over the presence of a carcinogen in medical devices would remain, despite the classification being for carcinogenicity by inhalation (of powder) only	Impacts on the use of TiO_2 in medical devices would likely be very low
Detergents	• CMD pushing for substitution and better exposure controls • WFD • REACH Annex XVII for consumer formulations	• CMD no longer relevant • Consumer formulations no longer subject to a restriction • WFD impacts would largely remain (exemption still an option) • But labelling requirements remain	Consumer concerns over the presence of a carcinogen in detergents would remain to a certain extent. Supply chain pressures likely to be less intense	Similar to paints, inks and construction products. CMD and REACH Annex XVII would not apply meaning that impacts would be low
Biocides	• CMD pushing for substitution and better exposure controls • WFD • Biocidal Products Regulation	• CMD no longer relevant • WFD impacts would largely remain (exemption still an option) • Biocidal Products Regulation no longer relevant	Consumers most likely unaware of the presence of TiO_2 in biocides, so concerns are unlikely to arise	Impacts on the use of TiO_2 in biocides would likely be very low
* Carcinogens and Mutagens at Work Directive ** Waste Framework Directive				

6.3 Impacts on actors outside the titanium dioxide supply chains

Many industrial minerals contain TiO_2 as a natural impurity at concentrations of up to 4% by weight. This means that if TiO_2 were to be classified as Carc Cat 2, many (but not all) of these industrial minerals would also have to be classified as Carc Cat 2[2]. This could have adverse impacts on their use, but similar to TiO_2, such impacts would be far less pronounced than under a Carc Cat 1B classification.

In addition, the proposed classification for TiO_2, if adopted, would set a precedent for the subsequent hazard classification of other poorly soluble powders regardless of each and every substance's human health carcinogenicity data. We note once again that the classification of carcinogenic for TiO_2 is by inhalation (of a powder) only and therefore by definition not applicable to the vast majority of mixtures and, especially, articles that contain the substance. However, the limitation of related legislation (e.g. REACH Annex XVII) means that this specificity is not relevant.

6.4 Impacts on consumers

Impacts on consumers from a classification of Carc Cat 2 would be significantly lower than Carc Cat 1B, primarily because the 'automatic' restriction on the marketing and consumer use of TiO_2-based formulations would not apply. However, depending on perceptions of supply chains and the consumers themselves, some consumer products might be removed from the market or become more costly if reformulated. Cosmetics in particular might be an area where adverse effects might arise if the classification of the substance results in the cessation of its use as a UV filter in sunscreens. As noted in Section 4.6.5, replacement of TiO_2 would mostly affect children's products and formulations for people with sensitive skin as the formulators would need to use chemical UV filters which are less preferred for these consumer groups. A lower level of skin protection from the sun, especially from a young age, could have a very detrimental health effect with the development of a higher number of skin cancer cases later in life.

[2] As shown in **Table 4-22**, perlite, diatomite, vermiculite and zircon contain TiO_2 impurities at a level typically below 1% by weight, thus would not warrant a classification of Carc Cat 2.