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International Association of Color Manufacturers

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European Commission
DG Health and Food Safety, Unit D2-Multilateral International Relations
Rue Froissart 101
B-1049 Brussels
Via email: sps@ec.europa.eu

Re: G/SPS/N/EU/512

To whom it may concern:

The International Association of Color Manufacturers (IACM) is the trade association representing the global color industry, which comprises manufacturers and end-users of natural and synthetic coloring substances used in foods, drugs, and cosmetics. We are writing to provide information on titanium dioxide when used as a coloring agent in response to the Draft Commission Regulation amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the food additive titanium dioxide (E171).

Titanium Dioxide as a Food Color

Titanium dioxide ($TiO_2$) is a naturally occurring crystalline solid that exists in three fundamental crystal forms: rutile, anatase, and brookite. Its bright white color, high refractive index, and resistance to discoloration have historically made it versatile in many applications as a pigment. The anatase and rutile forms, resulting in white and slightly off-white powder, respectively, are permitted to produce pigment-grade material approved as a food colorant.[1] $TiO_2$ may be coated with small amounts of alumina and silica to improve technological properties, such as mixing and dispersion properties in various matrices.

For $TiO_2$ to act as a pigment, the particles must be large enough to scatter visible light. For pigment-grade $TiO_2$ to function as a color additive optimally a significant number of particles larger than 200 nm are required. Particles of this size are capable of refracting light. As the particle size decreases, the material loses its color and becomes transparent. Therefore, manufacturers produce pigment-grade $TiO_2$ to maximize the number of particles in the size range between 200 and 350 nanometers.

According to prior characterization of pigment grade $TiO_2$, the maximum refraction occurs around a particle size of 272 nm (range 180 – 300 nm). The light refraction decreases abruptly below this threshold and gradually above it. The narrower the size distribution, the better the light refractive properties of the pigment and the poorer they become as the size distribution widens or agglomeration

[1] Kuznesof and Rao. 2006. Titanium dioxide. Chemical and Technical Assessment. Accessed on March 22, 2013. http://www.fao.org/fileadmin/templates/agns/pdf/jecfa/cta/67/cta_tio2.pdf

occurs.[2,3] It is documented that optimum pigment characteristics are lost below the 100 nm threshold that generally defines nanomaterials. Thus, nanoscale $TiO_2$ has a different refractive index than pigment grade $TiO_2$ that renders it transparent.

Although useful in other applications, the loss of (white) color eliminates its utility as a color additive, and therefore it is not added directly to food for that purpose. Instead, the predominant food application for $TiO_2$ involves the use of pigment-grade material. Exposure to nanoscale $TiO_2$ through food is limited to its potential use in other limited non-colorant applications, if any, or if it is inadvertently present in small amounts in pigment-grade material used as a food colorant. It should be stressed that particles below 100 nm are not deliberately manufactured in pigmentary food-grade $TiO_2$ and are present only as part of the overall particle size distribution.

EFSA Opinion

The European Food Safety Authority's (EFSA) Expert Panel on Food Additives and Flavorings recently published an opinion regarding E171[4] stating that EFSA could not rule out concern for genotoxicity from ingestion of the material based on a perceived gap in data on this risk, which serves as the basis for the Commission's proposed action.

The 2021 opinion diverges from the previous EFSA opinions, including on the safety of E171, including its 2016 opinion,[5] that the use of $TiO_2$ as a food additive does not raise a genotoxic concern. EFSA's subsequent opinions in 2018[6] and 2019[7] appeared to reaffirm this conclusion of lack of genotoxic concern. It is worth noting that the 2021 opinion continues to confirm no general and organ toxicity, no effects on reproductive and developmental toxicity and only noted that it could not rule out genotoxicity due to insufficient data to define threshold exposures below which genotoxicity will not occur. However, the 2021 opinion is based on genotoxicity tests using $TiO_2$ nanomaterials not representative of E171 and exposure methods not representative of human exposures. The 2021 opinion showed no consideration of differences between E171 and $TiO_2$ nanomaterials and disregarded the most relevant studies, including those conducted by industry in response to EFSA's request. Therefore, the 2021 opinion reflects a hazard assessment of $TiO_2$ nanomaterials but does not reflect human exposures to E171 and is not relevant for E171 when used as a food additive.

The 2016 opinion considered that E171 contains at most 50% of particles in the range of less than 100 nm and the 2021 opinion is the first time the 2018 EFSA Scientific Committee Guidance on

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[2] Johnson, R. W., Thiele, E. S. and French, R. H. 1997. Light-scattering efficiency of white pigments: an analysis of model core–shell pigments vs. optimized rutile TiO. TAPPI Journal. 80(11):233-39.

[3] Thiele, E. S. and French, R. H. 1998. Light-Scattering Properties of Representative, Morphological Rutile Titania Particles Studied Using a Finite-Element Method. Journal of the American Ceramic Society. 81(3):469-79. https://doi.org/10.1111/j.1151-2916.1998.tb02364.x

[4] EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), 2021. Safety assessment of titanium dioxide (E171) as a food additive. EFSA Journal 2021;19(5):6585, 130 pp. https://doi.org/10.2903/j.efsa.2021.6585

[5] EFSA ANS Panel (EFSA Panel on Food Additives and Nutrients Sources added to Food), 2016. Re-evaluation of titanium dioxide (E 171) as a food additive. EFSA Journal 2016;14(9):4545, 83 pp. https://doi.org/10.2903/j.efsa.2016.4545

[6] EFSA ANS Panel (EFSA Panel on Food Additives and Nutrients Sources added to Food), 2018. Evaluation of four new studies on the potential toxicity of titanium dioxide used as a food additive (E 171). EFSA Journal 2018;16(7):5366, 27 pp. https://doi.org/10.2903/j.efsa.2018.5366

[7] EFSA FAF Panel (EFSA Panel on Food Additive and Flavourings), 2019. Scientific opinion on the proposed amendment of the EU specification for titanium dioxide (E 171) with respect to the inclusion of additional parameters related to its particle size distribution. EFSA Journal 2019;17(7):5760, 23 pp. https://doi.org/10.2903/j.efsa.2019.5760

Nanotechnology[8] has been applied to the safety assessment of a food additive. However, in its 2021 opinion, EFSA did not adhere to its own guidance for assessing nanomaterials, which indicate that tests must be performed with representative material as used in the food market and in compliance with the specifications. Additionally, EFSA did not base its opinion on all relevant data concerning the safety of E171. Previous opinions had already considered $TiO_2$ particle distribution including the fraction less than 100 nm as provided by industry via the Titanium Dioxide Manufacturers Association (TDMA). The 2021 opinion did not justify grouping $TiO_2$ nanomaterials with E171. Given that the $TiO_2$ nanomaterials subjected to genotoxicity testing on which EFSA relied in its 2021 opinion are not representative of E171 as used in foods and present in the marketplace due to the inability of the nanomaterials to provide the white color necessitating its use, EFSA did not adhere appropriately to its own guidance for assessing nanomaterials in its 2021 opinion.

The 2021 opinion also differs from EFSA's previous position that a food additive should be investigated by the dietary route of exposure in a food matrix and focuses on conditions unrealistic to dietary intake. Additionally, the 2021 opinion gave undue weight to results of *in vitro* genotoxicity studies that do not represent dietary intake of E171 and did not give appropriate weight to results of compelling *in vivo* genotoxicity studies. Considering both the application of the guidance and exclusion of specific important components of the scientific dataset for E171 that show no adverse impacts, the conclusions reached by the 2021 opinion are based on an entirely novel, untested approach to risk assessment rather than any new safety concerns. To state that E171 can no longer be considered safe when used as a food additive is not supported by the data reviewed by EFSA over the last six years, and to remove a food additive from the market that has demonstrated no safety concerns is a mistake and unwarranted.

Trade Impact

Titanium dioxide has a long history of safe use as a color additive. The Joint FAO/WHO Expert Committee on Food Additives (JECFA)[9] has evaluated $TiO_2$ and established an acceptable daily intake (ADI) of "not limited." In response to the 2021 EFSA opinion, the JECFA Secretariat signaled its intent to issue a call for data for purposes of conducting its own re-evaluation. While new specifications for $TiO_2$ were established by JECFA in 2012[10], the last toxicological assessment was conducted in 1969.

During the recent 52nd Codex Committee on Food Additives (CCFA) meeting, held virtually September 1-10, the CCFA agreed with JECFA's proposal to add the re-evaluation of $TiO_2$ to its priority list. This action was taken to minimize any further disruption to international trade that is expected to be caused by the proposed actions of the European Commission. [11]

Additionally, there are currently no substances that can match the whitening color or opacity of $TiO_2$ when used as a food coloring agent while not imparting unwanted flavors, requiring significantly higher

[8] EFSA Scientific Committee, 2018a. Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: part 1, human and animal health. EFSA Journal 2018;16(7):5327, 95 pp. https://doi.org/10.2903/j.efsa.2018.5327

[9] Joint FAO/WHO Expert Committee on Food Additives (JECFA), 1969. Titanium dioxide. FAO Nutrition Meetings Report Series 46a. https://inchem.org/documents/jecfa/jecmono/v46aje19.htm.

[10] http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph13/additive-466-m13.pdf

[11] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-52%252FCRDs%252Ffa52_CRD06.pdf

usage rates, or affecting the texture in food products. $TiO_2$ is exceptionally stable across a wide variety of applications, including in coatings, where it provides a smooth surface covering.

While there may be some applications where alternatives can be used to provide a similar white shade, removing E171 as an approved food additive in Europe will have an impact on the ability of global food and beverage companies to provide consumers with the following food products that most frequently contain titanium dioxide: extruded snacks, tortilla chips, potato chips, granola bars, macaroni and cheese, confectionery goods including chewing gum and those that contain compound coatings, bakery products, dairy products, cheeses, icing and decorations, frozen desserts, nondairy creamers, soups (including dried soups), beverages, plant-based meat alternatives (meat analogues), non-alcoholic drink mixers, popcorn, nuts and seeds.

Therefore, IACM urges the European Commission to reconsider its proposed action to remove E171 authorization as a food additive due to the lack of safety concern for E171 when used as a pigment to provide color in food. IACM also encourages the European Commission to consider the outcome of the JECFA re-evaluation of $TiO_2$ prior to finalizing any risk management actions, to minimize any disruption to international trade.

While not scientifically warranted, if the EU ultimately maintains its decision to restrict the use of E 171 as a food additive, the regulation must provide more time to remove the material from the supply chain. Even given normal global supply chain practices, 6 months would be challenging to meet, but with the COVID-19 pandemic and time needed to identify alternatives to enable products to remain on the marketplace, which includes substitution, reformulation, consumer acceptability testing, and packaging graphics updates, a transition of 2-3 years would be needed to ensure compliance across the supply chain.

Additionally, we note that the EU recently published Commission Implementing Regulation (EU) 2021/2090 of 25 November 2021 concerning the denial of authorization of titanium dioxide as a feed additive for all animal species effective December 20. While not subject to this WTO notification, the removal of titanium dioxide as a color additive for feed is also not warranted from the perspective of safety and will have substantial impact on global pet food companies to provide certain pet food products to consumers in the European Union.

IACM appreciates the opportunity to provide this information.

Sincerely,

Sarah A. Codrea

Sarah Codrea
Executive Director