

Voluntary Report – Voluntary - Public Distribution

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Report Name: Titanium Dioxide Banned as a Food Additive in the EU

Country: European Union

Post: Brussels USEU

Report Category: SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural Exports

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Report Highlights:

The European Commission is banning titanium dioxide (E171) as a food additive in the EU, starting with a six-month phasing out period as of February 7, 2022, until August 7, 2022, after which a full ban applies. Following the publication of Commission Regulation (EU) 2022/63 in the EU's Official Journal (OJ) on January 18, 2022, Annex II and III to Regulation (EC) No 1333/2008 on food additives will be amended accordingly. The Regulation also includes a commitment to review the necessity to maintain or delete titanium dioxide (E171) from the EU list of food additives for exclusive use as a color in medicinal products. On November 30, 2021, the Commission had already published Commission Implementing Regulation (EU) 2021/2090 in the OJ, denying the authorization of titanium dioxide (E171) as a feed additive for all animal species.

General Information:

[Commission Regulation \(EU\) 2022/63](#), which was published in EU's the Official Journal (OJ) on January 18, 2022, is amending Annexes II and III to Regulation (EC) No 1333/2008 on food additives regarding the use of titanium dioxide (E 171). This Regulation will be banning the use of titanium Dioxide (E171) as a food additive in the EU, allowing a six-month phasing out period followed by a full ban. The six-month phasing out period starts on February 7, 2022, when the Regulation enters into force. Foods containing titanium dioxide (E171) that are produced according to the rules applicable up until that date may continue to be placed on the market until August 7, 2022. After that date, they may remain on the market until their date of minimum durability or 'use by' date and from then a full ban applies.

The Annexes to Regulation (EC) No 1333/2008 on food additives are laying down a Union list of food additives approved for use in foods (Annex II) and approved for use in food additives, food enzymes, food flavorings, nutrients (Annex III) and their conditions of use. Annex II and III will be amended according to the measures provided in the Annex to Regulation (EU) 2022/63.

Following consultation of the European Medicines Agency (EMA), and in order to avoid shortages of medicinal products that could have an impact on public health, the European Commission will review the necessity to maintain or delete titanium dioxide (E 171) from the Union list of food additives for the exclusive use as a color in medicinal products in Part B of Annex II to [Regulation \(EC\) No 1333/2008](#). This will happen within three years after the date of entering into force of this Regulation, or before February 7, 2025, and should be based on an updated assessment by the EMA (performed before April 1, 2024). More information is available on DG SANTE's [webpage](#). Meanwhile, the Commission urges the development of adequate alternatives by the pharmaceutical industry to replace it while ensuring the quality, safety, and efficacy of the medicinal products concerned.

This Regulation follows the publication of [Commission Implementing Regulation \(EU\) 2021/2090](#) on November 30, 2021, in the OJ, which denies the authorization of titanium dioxide (E171) as a feed additive in animal nutrition, in the category of "sensory additives" and in the functional group "colorants", that are adding or restoring color in feeding stuffs. The existing stocks of the feed additive must be withdrawn from the market by March 20, 2022. Feed materials, compound feed or premixtures containing titanium dioxide (E171), produced before that date must be withdrawn from the market by June 20, 2022.

Background:

Titanium dioxide (TiO₂) is a naturally occurring mineral that is mined from the earth, processed and refined, and added to a variety of foods, as well as other consumer products. White in color, it is used to enhance the color and sheen of certain foods. The food-grade form of titanium dioxide is used to color confectionery goods, bakery products, dairy products, cheeses, icings and decorations, frozen desserts, non-dairy creamers, dried soup, pet foods, pharmaceutical products, and cosmetics.

On October 8, 2021, the European Commission [announced](#) that the Standing Committee on Plants, Animals, Food and Feed approved the European Commission's proposal to ban the use of titanium dioxide

(E171) as a food additive. The EU notified the [regulation](#) to the World Trade Organization (WTO) on October 13, 2021 under G/SPS/N/EU/512. The USG submitted comments to object to the European Commission's use of the precautionary principle to restrict the use of titanium dioxide (E171) as a food additive the EU.

According to the European Food Safety Authority's (EFSA) Expert Panel on Food Additives and Flavorings 2021 [opinion](#) regarding titanium dioxide, it could not rule out a 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 current proposed action. This 2021 opinion diverges from the previous EFSA opinions on the safety of titanium dioxide, since the 2016 opinion did not raise any genotoxic concern regarding the use of titanium dioxide as a food additive. EFSA's subsequent opinions in 2018 and 2019 appeared to reaffirm this conclusion of lacking a genotoxic concern. However, the 2021 opinion did not consider the different particles sizes (macro, micro or nano) of titanium dioxide and their effect on toxicity and did not include some of the most relevant safety studies. Therefore, the 2021 opinion reflects a hazard assessment of titanium dioxide nanomaterials but does not reflect human exposure to titanium dioxide and is not relevant as such to demonstrate its use as a food additive.

The food industry has indicated to the U.S. that there are no good alternatives to titanium dioxide that can provide similar pigment/opacity properties. Titanium dioxide (E171) is used in many different food products and industry has indicated replacements require studies and regulatory filings which would take significant time, up to 10 years or more and reformulation cost estimates range from \$600,000 to \$1.8 million per product depending on the complexity of the product, which would be passed on to the consumer.¹ There is significant potential for trade disruption in food products when implementing Regulation 2022/63 as titanium dioxide is a widely used additive to color foods.

Attachments:

No Attachments.

¹ This is an industry estimate.