

PQRI Workshop:

*TiO<sub>2</sub> Use in Pharmaceuticals*

*Global Regulatory and Technical Challenges*

June 13-14, 2023

# NGO Efforts in the US to Ban TiO<sub>2</sub> in Various States and Through a Color Additive Petition

---

Jay West

Product Quality Research Institute Workshop

June 13, 2023



Titanium Dioxide  
Stewardship Council

# Titanium Dioxide Stewardship Council

The **Titanium Dioxide Stewardship Council (TDSC)** represents manufacturers of titanium dioxide ( $\text{TiO}_2$ ) and was formed to promote the safe use of  $\text{TiO}_2$  through research, product stewardship, advocacy and outreach.

- TDSC is a sector group of the American Chemistry Council (ACC).

The TDSC's European counterpart is the **Titanium Dioxide Manufacturers Association (TDMA)**.

- TDMA is a sector group of the European Chemical Industry Council (CEFIC).
- CEFIC is a separate entity, not part of or an affiliate to ACC.



# California AB 418

- Introduced February 2, 2023
- Passed Assembly (54-12) and sent to Senate May 15, 2023
- Was amended to exempt animal feed when sent to Senate
- Currently in Senate Health Committee
- Follow the bill at [Bill Text - AB-418 Food product safety](#)

# CA AB 418

*“Commencing January 1, 2025, a person or entity shall not manufacture, sell, deliver, distribute, hold, or offer for sale, in commerce a food product for human consumption that contains any of the following substances:*

- (1) Brominated vegetable oil (CAS no. 8016-94-2)*
- (2) Potassium bromate (CAS no. 7758-01-2)*
- (3) Propylparaben (CAS no. 94-13-3)*
- (4) Red dye 3 (CAS no. 16423-68-0)*
- (5) Titanium dioxide (CAS no. 13463-67-7)”*



# New York A6424

- Introduced April 6, 2023
- Referred to the Committee on Agriculture
- Bill information at [NY State Assembly Bill A6424](#)
- Legislature adjourned June 8

# New York A6424

*“Notwithstanding any other provision of law to the contrary, . . . it shall be unlawful . . . to manufacture, compound, brew, distill, produce, process, sell, deliver, distribute, hold, offer or expose for sale any of the following substances as food additives or food color additives or any food or food product containing any of the following substances:*

- (i) brominated vegetable oil;*
- (ii) potassium bromate;*
- (iii) propylparaben;*
- (iv) red dye 3; and*
- (v) titanium dioxide.”*



# New York A6424

*“Within thirty days of the effective date of this subdivision, . . . the substances prohibited in this subdivision shall not be deemed to be safe for human consumption on or after January first, two thousand twenty-five.”*

*“In an action instituted . . . to enforce compliance . . . recognition by the federal food and drug administration of any of these substances as safe may not be alleged as a defense (emphasis added).”*



# New Jersey A5436

- Introduced May 11, 2023
- Referred to the Committee on Agriculture and Food Security
- Bill information at [NJ Legislature \(state.nj.us\)](https://legislature.state.nj.us)
- Legislature does not adjourn until December 31

# New Jersey A5436

Would amend New Jersey law concerning what constitutes “adulterated food” by adding:

*“If it contains any of these substances:*

- (1) brominated vegetable oil (CAS no. 8016-94-2);*
- (2) potassium bromate (CAS no. 7758-01-2);*
- (3) propylparaben (CAS no. 94-13-3);*
- (4) red dye 3 (CAS no. 16423-68-0); or*
- (5) titanium dioxide (CAS no. 13463-67-7).”*

What does New Jersey law say about adulterated food (and other products)?

*“No person shall distribute or sell, or manufacture for distribution or sale, or have in his possession with intent to distribute or sell, any food, drug, cosmetic or device which under any of the provisions of this subtitle is adulterated or misbranded.”*

2022 New Jersey Revised Statutes Title 24 - Food and Drugs Section 24:5-1. Sale, distribution or manufacture of adulterated or misbranded article

# U.S. Food & Drug Administration

# U.S. Food & Drug Administration

“The FDA reviewed the findings of EFSA’s 2021 Opinion on titanium dioxide. The FDA notes that EFSA’s 2021 Opinion continued to confirm no general and organ toxicity, as well as no effects on reproductive and developmental toxicity. In its 2021 Opinion, EFSA noted that it could not rule out genotoxicity and included genotoxicity tests on titanium dioxide nanomaterials. Some of the genotoxicity tests included test materials not representative of the color additive, and some tests included administration routes not relevant to human dietary exposure. The available safety studies do not demonstrate safety concerns connected to the use of titanium dioxide as a color additive. The FDA continues to allow for the safe use of titanium dioxide as a color additive in foods generally according to the specifications and conditions, including that the quantity of titanium dioxide does not exceed 1% by weight of the food, found in FDA regulations at 21 CFR 73.575.47.”

Titanium Dioxide Manufacturers Association (TDMA), US FDA confirms the safety of titanium dioxide as a food additive, January 25, 2023, at <https://www.tdma.info/news/us-fda-confirms-the-safety-of-titanium-dioxide-as-a-food-additive/>.

# U.S. Food & Drug Administration

- Color additive petition filed with FDA April 14, 2023 (though the date on the petition itself is March 12, 2023)
- FDA noticed receipt of the petition in the Federal Register May 3, 2023 (88 Fed. Reg. 27818; Docket FDA-2023-C-1487)
- “[A]sking FDA to remove approval of synthetically-prepared titanium dioxide (CASRN 13463-67-7) for use as color additive in food pursuant to 21 USC § 379e.”
- Petitioners: Environmental Defense Fund, Center for Food Safety, Center for Science in the Public Interest, and Environmental Working Group



# U.S. Food & Drug Administration

## Petitioners' claims:

- *“Recent scientific studies raise serious questions . . . such that there is no longer the legally required ‘convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive’ . . .”*
- *“FDA has not reviewed the safety of synthetic TiO<sub>2</sub> since 1973 . . .”*
- *“Nanoparticles - unlike their larger counterparts - are more likely to bypass the body’s natural defenses in the gastrointestinal tract and be absorbed into the bloodstream where the nanoparticles can reach other organs and may cause harm.”*

# U.S. Food & Drug Administration

- Petitioners rely almost exclusively on 2021 EFSA opinion.
- With respect to FDA's statement affirming the safety of TiO<sub>2</sub>
  - *“We respectfully disagree with this analysis of the EFSA Expert Panel Report.”*
  - Petitioners → FDA statement fails to address bioaccumulation, immunotoxicity, inflammation, and aberrant crypt foci
  - *“Without evidence to suggest that a more detailed and rigorous analysis and description is forthcoming, we submit this petition to prompt FDA to undertake such assessment and request such a revocation.”*
  - *“FDA is obligated to revoke its approval for the chemicals use as a color additive in food.”*

# Conclusions

- Campaign to sidestep federal processes and create a patchwork of state regulations.
- Complicate sale of foods containing  $\text{TiO}_2$  by adding complexity to the regulation by different states.
- Food colorant petition appears to be the mechanism for bringing EFSA opinion and subsequent regulations to U.S.
- Which uses are next?

# Thank you! Any Questions?

