# Red dye No. 3 is now banned in the US. Here's what studies show about more common dyes

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CNN —

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Now that the US Food and Drug Administration has <u>banned red dye No. 3</u>, many people are criticizing or questioning the safety and the FDA's allowance of red dye No. 40 and five other color additives commonly used in the United States.

Made from petroleum and chemically known as erythrosine, red dye No. 3 is

a synthetic color additive used to give foods and beverages a cherry-red color. The dye has been permissible for use in food, beverages and ingested drugs even though the Delaney Clause of the Federal Food, Drug and Cosmetic Act "prohibits the FDA from approving a color additive that is ingested if it causes cancer in animals or humans when ingested."

The dye was found to cause cancer in rats more than 30 years ago. The FDA's decision this week to revoke the authorization for the use of the dye was acting on a 2022 petition by advocacy organizations and individuals citing this research.

Red dye No. 40, also derived from petroleum, has been considered a healthier alternative since it hasn't been extensively associated with cancer in animals. But experts say cancer isn't the only potential health threat to consider when it comes to artificial colorants, and that there are other reasons why the FDA should take another look at its regulation of red dye No. 40 — as well as yellow dyes Nos. 5 and 6, blue dyes Nos. 1 and 2, and green dye No. 3. All these additives are derivatives of petroleum.

"The FDA is actively working to develop transparent processes for prioritizing chemicals in food for a safety review as part of the agency's efforts to build a robust and systematic post-market review program," an FDA spokesperson said in a statement via email. "Food dyes, such as Red 40 and Yellow 5, are among the chemicals that are being strongly considered for prioritization and assessment. The number of chemicals that can be assessed and the speed at which we can complete those assessments is limited by the availability of resources."

In September, the FDA <u>held a public meeting</u> to share the agency's approach and receive stakeholder input, the spokesperson added. The docket for public comments related to that meeting closes on January 21. Following "a thorough review of stakeholder comments," the FDA will finalize its

approach.

Here's what the research shows and how you can avoid consuming these dyes.

### Health risks of dyes

Governments, researchers and nonprofit groups have raised concerns about other dyes for years.

"In 2021, the California Office of Environmental Health Hazard Assessment completed the most rigorous <u>and comprehensive assessment</u> to date of the evidence linking synthetic food dyes to neurobehavioral problems in some kids," said Dr. Thomas Galligan, principal scientist of food additives and supplements at the Center for Science in the Public Interest. That assessment included all the artificial food dyes — not just red dye No. 3.

In September, California <u>banned red No. 40</u> from foods and drinks sold in public schools, citing these concerns. Another study <u>found a potential link</u> between red dye No. 40 and accelerated immune system tumor growth in mice, and <u>other sources say</u> the dye contains benzene, a known carcinogen.

Blue dye No. I <u>has been linked with</u> developmental delays, behavioral difficulties, and inhibited nerve cell development in animals, while blue dye No. 2 has led to an increased incidence of tumors in rats, according to <u>a 2021 study</u>. Blue dye No. I and yellow dye No. 6 may also be toxic to some human cells, according to <u>a 2015 study</u>.

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Of the seven artificial dyes, green dye No. 3 is the least used, according to the Environmental Working Group. But consumption of this chemical has been

linked with a significant increase in bladder tumors in animals.

As little as I milligram of yellow dye No. 5 may negatively affect the mood or behavior of sensitive children by <u>potentially causing irritability</u>, restlessness and sleep disturbances. And both yellow dyes No. 5 and No. 6 have been found to <u>be contaminated with</u> the cancer-causing chemical benzidine or other carcinogens.

In animals, many of these dyes have also been associated with altered memory and capacity for learning, said Dr. Michael Hansen, senior scientist at Consumer Reports, a nonprofit helping consumers evaluate goods and services.

The potential mechanisms underlying the relationships between artificial dyes and neurobehavioral health outcomes are unknown, experts said.

# Quantifying the risk of dyes

Some animal studies have shown that dyes are metabolized quickly and excreted in the urine within hours or days after consumption. But it's still likely that food dyes could have a cumulative effect on the body, evidenced by studies on the short-term exposure of pregnant rats to dyes and the long-term effects on their offspring, Hansen said.

That's part of why in conversations about health harms of dyes, much of the focus is on children — who, in addition to being in critical periods for development, also have smaller bodies. Children may be more attracted to brightly colored foods, too.

"The FDA has not thoroughly reviewed these dyes since the 1960s, 1970s, and 1980s, long before toxicological studies could detect their effects on behavior and our kids' brains," said Scott Faber, senior vice president of government affairs at the Environmental Working Group, via email.

"Meetings held in 2011, of the FDA's Food Advisory (Committee), and in 2019 of the FDA's Science Board, were meetings of professionals, not thorough reviews that agencies conduct when deciding whether chemicals are safe," added Faber, also an adjunct professor of law at Georgetown University Law Center. "If there is a doubt about the safety of a food chemical, the FDA is legally required to ban or restrict its use."

Exposure levels determined to be safe decades ago should be reconsidered given new evidence, experts said. If the current acceptable daily intake levels were to be reduced, it's likely people's current diets would exceed those doses, according to the 2021 California assessment.

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"Because (the dyes) are listed by name, but not necessarily by amount, it's pretty much impossible for a consumer to know exactly how much they're being exposed to," the Center for Science in the Public Interest's Galligan said. "What CSPI recommends is that consumers entirely avoid products that contain any of these."

It's also true that of all the contributors to chronic disease, food dyes alone aren't the most significant compared with factors such as obesity, said Dr. Jerold Mande, adjunct professor of nutrition at the Harvard T.H. Chan School of Public Health.

Which dyes carry more risks than others is also unclear due to the lack of research and funding, which is hampered by industry lobbying, added Mande, CEO of Nourish Science, a nongovernmental organization focused on US nutrition crises. But some of these colorants have long been banned in the European Union, Canada and other countries without the pressure of a Delaney Clause.

"The American people are different about this. We wear sort of a badge of honor that we reject the precautionary principle," Mande said — which prioritizes doing something to reduce potential harms of an issue even if the exact level of risk isn't totally clear.

## Steering clear of artificial dyes

"The only thing consumers can do right now is look at the ingredient lists of the foods that they think about buying in their grocery store. I will say, though, that's a pretty big burden," Galligan said. "Grocery shopping is already time-consuming enough. ... This is why we have the FDA, so that consumers are able to shop confidently and without having to think about these things.

"So the fact that the FDA is placing this burden on consumers is entirely unacceptable," Galligan added. "That issue is only made worse when we're talking about dining in restaurants, where ingredient lists are not exactly widely available."

Artificial food colorings are mostly found in ultraprocessed foods and beverages, so avoiding those products is one shortcut to eliminating dyes from your diet, Dr. Jennifer Pomeranz, associate professor of public health policy and management at New York University, told CNN earlier this week.

#### QUIZ: How much ultraprocessed food are you eating?

However, dyes aren't only found in foods that look conspicuously colorful, which is why reading labels is important, Galligan said.

Chain restaurants may be more likely to have ingredient lists for their foods or beverages online, Galligan said, whereas an independent restaurant may not be able to provide a detailed list.

On ingredient lists, these artificial dyes are <u>sometimes referred to</u> using the following terms:

- Red dye No. 3: red 3, FD&C Red No. 3 or erythrosine
- Red dye No. 40: red 40, FD&C Red No. 40 or Allura Red AC
- Blue dye No. 1: blue 1, FD&C Blue No. 1 or Brilliant Blue FCF
- Blue dye No. 2: FD&C Blue No. 2 or indigotine
- Green dye No. 3: FD&C Green No. 3 or Fast Green FCF
- Yellow dye No. 5: yellow 5, FD&C Yellow No. 5 or tartrazine
- Yellow dye No. 6: yellow 6, FD&C Yellow No. 6 or sunset yellow

Dyes listed with the word "lake" in any ingredient list indicate the dye is a fat-soluble version, meaning it can dissolve in oily foods or drinks.

In the United States, red dye No. 3 is already banned from use in topical medications, and it's not disappearing from food or ingested medicines right away. Manufacturers using red No. 3 in food and ingested drugs have until January 15, 2027, and January 18, 2028, respectively, to reformulate their products, the FDA said.

Several other dyes are still permitted for use in both topical and ingested drugs, so you can find whether your medications contain dyes by reading the ingredient lists on the drug labeling or package insert, experts said.

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Alternatives to medications with dyes include purchasing drugs without them or going to a compounding pharmacy that could possibly manufacture them without additives. But pursuing these options can be challenging, Galligan said, especially if you or your child are sick.

Always consult your medical provider before switching medications or

adding one to your routine.

15 comments