ORGANIC: THE ORIGINAL CLEAN FOOD

In Packaged Foods, ‘Organic’ Not Only Bans Toxic Pesticides but Thousands of Added Chemicals

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ABOUT EWG
The Environmental Working Group is the nation’s most effective environmental health research and advocacy organization. Our mission is to conduct original, game-changing research that inspires people, businesses and governments to take action to protect human health and the environment. With your help—and with the help of hundreds of organizations with whom we partner—we are creating a healthier and cleaner environment for the next generation and beyond.

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Americans are increasingly seeking “clean” foods that are free from artificial colors, flavors and preservatives. But although consumers who want to avoid toxic pesticides and antibiotics know to look for foods that are certified organic, many don’t know that federal rules also dramatically limit the use of synthetic substances in packaged organic foods like cereals, snacks and dressings.

No artificial preservatives, colors or flavors are ever allowed in organic food. Fewer than 40 synthetic substances can be used in organic packaged foods, and only after they have been reviewed by independent and government experts. By contrast, thousands of chemicals can be added to conventional packaged foods, including preservatives, flavors and colors linked to health problems.

What’s more, many consumers are unaware that food companies don’t need government approval for most of the chemicals added to conventional packaged foods. The same companies that manufacture these chemicals are allowed simply to declare that they are “safe,” and there is no requirement that the chemicals added to conventional packaged foods be periodically reviewed in light of new scientific research.

In contrast, federal regulators and independent experts must screen synthetic substances before approving their use in organic packaged foods. These ingredients are permitted for use in organic packaged food only if there is no natural or organic alternative. Ingredients that “have an adverse effect on human health” are prohibited from use in organic packaged foods, as are synthetic ingredients that adversely affect the environment. What’s more, synthetic ingredients added to organic packaged foods must be reviewed by independent and government experts every five years to ensure they continue to meet these strict standards.

Organic packaged food currently constitutes 3 percent of the U.S. packaged-food market, demonstrating that packaged foods can be produced at commercial scale without using thousands of poorly regulated chemicals. Experts estimate that by 2020, sales of organic packaged food may reach $16 billion, or 4 percent of all packaged foods. As consumers are increasingly seeking “clean” foods, organic brands are the only commercial option backed by enforceable standards.

† There is no authoritative count of the number of synthetic chemicals that can be added to conventional food. Many approved food additives can be natural ingredients, synthetic chemicals, or both. Based on personal communication with an author of a study on the FDA’s food additive regulatory program and EWG’s review of direct food additives, color additives, and substances classified as generally recognized as safe, or GRAS, we estimate that at least 2,000 synthetic chemicals can be added to food. This does not include so-called secondary additives, which are needed during manufacture or processing but not expected to be present in the final product.

* In this report, “chemical” refers to a synthetic substance added to processed food, unless otherwise specified.
### Table 1. Synthetic Preservatives of Concern That Are Commonly Used in Conventional Packaged Food but Not Allowed in Organic

<table>
<thead>
<tr>
<th>SYNTHETIC PRESERVATIVES</th>
<th>CONCERNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butylated Hydroxyanisole (BHA)</td>
<td>Listed by the state of California as a carcinogen and classified as a potential endocrine disruptor by the European Union.</td>
</tr>
<tr>
<td>Sodium Nitrate</td>
<td>Determined by the World Health Organization to be probably carcinogenic to humans.</td>
</tr>
<tr>
<td>Sodium Benzoate</td>
<td>At high doses, causes developmental toxicity and DNA damage in laboratory studies.</td>
</tr>
<tr>
<td>t-Butylhydroquinone</td>
<td>World Health Organization reports hematologic effects in laboratory studies.</td>
</tr>
<tr>
<td>Diacetyl tartaric and Fatty Acid Esters of Glycerol</td>
<td>World Health Organization reports inflammation of the heart in laboratory studies.</td>
</tr>
<tr>
<td>Butylated Hydroxytoluene (BHT)</td>
<td>Causes lung and liver tumors in studies of laboratory animals.</td>
</tr>
<tr>
<td>Disodium Inosinate</td>
<td>World Health Organization and the U.S. Food and Drug Administration have determined can increase uric acid levels, increasing the risk for kidney stones or gout.</td>
</tr>
<tr>
<td>Disodium Guanylate</td>
<td>World Health Organization determined can increase uric acid levels, increasing the risk of kidney stones or gout.</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>Environmental Protection Agency reports potential to be an endocrine disruptor in studies of cells. Disrupts gut microbiota in laboratory studies.</td>
</tr>
<tr>
<td>Polyoxyethylene Sorbitan Monostearate</td>
<td>Affects reproduction and lactation in laboratory studies.</td>
</tr>
<tr>
<td>Natamycin</td>
<td>World Health Organization reports gastrointestinal effects.</td>
</tr>
</tbody>
</table>

*Source: EWG, from EWG’s Food Scores database*
INGREDIENTS YOU WON’T FIND IN ORGANIC

No Chemical Preservatives
Chemical preservatives added to conventional packaged foods can increase the risk of various diseases, from cancer to hormonal problems.

For example, butylated hydroxyanisole, or BHA, a preservative commonly added to frozen foods like pizza, or sausages and pepperoni, may increase the risk of cancer. BHA has also been listed by the state of California as a carcinogen and is classified as a potential endocrine disruptor by the European Union. Butylated hydroxytoluene, or BHT, a common preservative synthesized from coal tar or petroleum, which has been found in hundreds of cereals, causes lung and liver tumors in studies of laboratory animals.

No Chemical Flavors
Synthetic chemical flavors are not allowed in organic packaged food.

Some “flavors” in conventional foods can actually be made up of more than 100 chemicals that do not have to be labeled on the package. The flavor may be made up of any of 2,700 other chemicals not regulated directly by the Food and Drug Administration but rather approved for use by an industry group, the Flavor and Extract Manufacturers Association.

By contrast, only flavors derived from natural, non-synthetic substances can be used in organic packaged food and, beginning in December 2019, natural flavors cannot be used if organic flavors are commercially available. In addition to being derived from natural sources, the flavors in organic food must be produced without synthetic chemicals and cannot include any artificial preservatives.

No Synthetic Colors
Synthetic colors are also prohibited in organic packaged foods.

Unlike preservatives and flavors, all food colors must be reviewed for safety by the FDA. Nevertheless, some colors have raised health concerns. For example, caramel colors III and IV may be contaminated with 4-methylimidazole, which has been associated with cancer. Although you may find organic caramel color in organic foods, the organic rules set by the federal Department of Agriculture, or USDA, require that it be made in a way that does not produce 4-methylimidazole contamination.

Experts are also concerned about the impacts of synthetic colors on children.

A 2010 report for the FDA’s Food Advisory Committee, which is based on 35 years of scientific studies, found that “certain food additives may exacerbate hyperactive behaviors (inattention, impulsivity and overactivity) in some groups of children.” The experts found that children with ADHD were particularly sensitive to artificial food dyes.

Minimal Environmental Impacts
Organic standards also prohibit the use of ingredients in organic food when the manufacture, use or disposal of such ingredients causes adverse effects on the environment. For example, calcium acid pyrophosphate, a leavening agent for baked goods, was prohibited for use in organic food products partly due to concerns about “heavy metal contamination from mining operations” and the “environmental effect of the phosphoric acid component of the manufacture.”
<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>CONCERNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diethylaminoethanol</td>
<td>On the EPA list of hazardous substances and causes severe skin and eye irritation. It is considered a hazardous air pollutant under the Clean Air Act.</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Manufacture of substance produces two known carcinogens, including formaldehyde, a volatile organic compound subject to emission restrictions set forth by the Clean Air Act.</td>
</tr>
<tr>
<td>Propane</td>
<td>Substance is a byproduct of the petrochemical industry; the effects of exploration and drilling are destructive to the environment. In addition, substance is a volatile organic compound and a precursor to ozone, a pollutant.</td>
</tr>
<tr>
<td>Nitrous Oxide</td>
<td>Substance is a potent greenhouse gas with a half-life of 120 years.</td>
</tr>
<tr>
<td>Synthetic Beta Carotene</td>
<td>Solvents used in the manufacturing process are not easily biodegraded and the potential exists for improper disposal or spillage if not properly recycled.</td>
</tr>
<tr>
<td>Calcium acid pyrophosphate</td>
<td>Phosphoric acid used during manufacture of substance can cause toxicity to aquatic organisms if released into the environment.</td>
</tr>
<tr>
<td>Sugar Beet Fibers</td>
<td>Processing this substance generates wastewater with high biologic oxygen demand that can cause nitrification and degrade water quality if released directly into a water source. May also be treated with formaldehyde, a volatile organic compound subject to emission restrictions set forth by the Clean Air Act.</td>
</tr>
<tr>
<td>Ammonium hydroxide</td>
<td>Toxic to aquatic organisms if spilled; if volatized to the atmosphere, contributes to greenhouse gases.</td>
</tr>
<tr>
<td>Morpholine</td>
<td>Substance is a volatile organic compound subject to emission restrictions set forth by the Clean Air Act.</td>
</tr>
<tr>
<td>Sulfuric Acid</td>
<td>Manufacture of this substance generates acid rain and other adverse environmental impacts if substance is improperly disposed.</td>
</tr>
</tbody>
</table>

*Source: EWG, from USDA’s National Organic Standards Board*
KEY DIFFERENCES BETWEEN CONVENTIONAL AND ORGANIC REGULATORY REVIEWS

The Conventional Process

Thousands of chemicals can be added to conventional packaged foods. These chemicals serve many purposes, such as preserving food or improving taste, texture or appearance. Some of the chemicals added to conventional food have been reviewed by the FDA. In these cases, food and chemical companies must submit a formal petition supporting the safety of the food additive that is under review and being considered for approval by the FDA. But many of these reviews were conducted decades ago. If new evidence suggests a food additive may be unsafe, the FDA can choose to re-evaluate the additive, but it is not required to review additives periodically to reflect new science or changes in eating patterns.

Two groups of food additives are exempt from FDA review: additives the FDA deemed safe before Congress passed a food additives law, in 1958; and additives that are deemed “Generally Recognized as Safe,” or GRAS, by the FDA, a food or chemical company, or a food industry trade association.

Experts estimate that roughly a third of the chemicals and other ingredients added to conventional packaged food have been approved for use by private parties, not the FDA. The GRAS exemption was initially created to cover ingredients widely known to be safe, like vinegar. But the FDA expanded the loophole to allow manufacturers to conclude that a chemical was “safe” for use in food without notifying the agency.

Rather than close the loophole, the FDA has instead allowed companies to voluntarily notify the agency about food chemicals and to allow companies to summarize the industry science supporting their conclusions. Many of the scientists conducting these reviews have been paid by industry, and the FDA does not review the underlying biological and chemical data.

The Organic Process

In contrast, fewer than 40 synthetic additives can be used in organic packaged foods. Any synthetic ingredients that can be added to organic packaged food must be formally added to an official registry, known as the National List, of substances that have all been reviewed by independent and government experts. The list is reviewed and approved by the National Organic Standards Board every five years. Since 2008, 72 synthetic additives have been removed, denied or further restricted from use in organic food, whereas only six synthetic substances have been allowed.

To add or remove an additive to the National List, a petition must be submitted for review by the National Organic Standards Board and the USDA. Once a petition has been filed, a subcommittee of the National Organic Standards Board will determine whether additional information is needed, and the subcommittee may request a technical report by a third-party expert. When reviewing the petition, the standards board must consider criteria such as the toxicity of the substance and potential health and environmental impacts.
Synthetic substances proposed for use in organic packaged foods must not have an adverse impact on the environment or reduce the nutritional quality of the food. Petitioners must also demonstrate that the substance cannot be produced from a natural source and demonstrate that the substance is not being used as a preservative or to enhance flavor, color or textures.28

Synthetic ingredients allowed in organic food include ingredients that act as leavening agents, such as ammonium carbonate or potassium carbonate; help thicken food, like sodium phosphate or xanthan gum; or are used to clean food equipment. Many of these synthetic substances are further limited by specific manufacturing criteria or use in certain foods.

Once the National Organic Standards Board has submitted recommendations, the USDA makes a final determination about whether to add the substance to the list of synthetic substances allowed as ingredients in organic packaged food.29

The standards board must review every substance on the National List every five years to confirm that it continues to meet all required criteria. During this review, the board considers any new information, including potential impacts on human health and the environment, and any new natural alternatives.

In contrast, none of the substances added to conventional packaged foods—grandfathered chemicals, chemicals subject to formal FDA review, or substances deemed “safe” by the food and chemical companies—are subject to periodic reviews to reflect changes in science. And there is no requirement that the industry scientists conducting reviews of chemicals added to conventional foods be free from conflicts of interest.

### Table 3. Key Differences Between Conventional and Organic Review

<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL</th>
<th>ORGANIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory pre-market reviews?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Mandatory post-market reviews?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Are reviews by independent experts?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Chemical preservatives prohibited?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Chemical flavors prohibited?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Chemical colors prohibited?</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Source: EWG*
RESOURCES


2. 7CFR205. The National List of Allowed and Prohibited Substances. Title 7 Code of Federal Regulations (CFR) Part 205, Sec. 206.600 through 206.606. Available at https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=9874504b6f025eb0e6b6cad9f3b40&rgn=all&view=text&node=7:3.11.9.32.7&idno=7#s7g3.5.205.sq0


7. Ibid.


12. European Food Safety Authority. Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of Butylated Hydroxytoluene BHT (E 321) as a food additive. EFSA Journal, 2012. 10(3):2598


25. 7CFR205. The National List of Allowed and Prohibited Substances. Title 7 Code of Federal Regulations (CFR) Part 205, Sec. 206.605(b). Available at https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=9874504b6f025eb0e6b6cad9f3b40&rgn=all&view=text&node=7:3.11.9.32.7&idno=7#s7g3.5.205.1605


29. 7CFR205. The National Organic Program, Evaluation criteria for allowed and prohibited substances, methods, and ingredients. Title 7 Code of Federal Regulations (CFR) Part 205, Sec. 206.601. Available at https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=9874504b6f025eb0e6b6cad9f3b40&rgn=all&view=text&node=7:3.11.9.32.7&idno=7#s7g3.5.205.1605

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