

## The Safety of Convenience-Size Plastic Water Bottles

### OVERVIEW

- To help assure the safety of our food, the U.S. Food and Drug Administration carefully reviews food and beverage packaging materials, including plastics for water bottles, before allowing them on the market.
- Most convenience-size water bottles sold in the United States are made from polyethylene terephthalate (PET). PET has become the material of choice for bottled beverages because it is lightweight and shatter resistant, and PET has been extensively tested for safety.
- Consumers can continue to trust the convenience and reliability of plastic water bottles knowing that the safety of these products is demonstrated through extensive testing and protected by FDA regulations.

### QUESTIONS AND ANSWERS

#### When consumers choose to refill and reuse convenience-size plastic water bottles, should they be concerned about potentially harmful bacteria?

Not if they clean their plastic bottles between uses just as they would other drinking containers. Plastics are by nature extremely sanitary materials, and plastic bottles are no more likely to harbor bacteria than other kinds of packaging or drinking containers. Bacteria thrive in warm, moist environments. Once bacteria have been introduced, virtually any drinking container (coffee mugs, drinking glasses, serving pitchers, etc.) becomes a suitable environment for bacterial growth.

Consumers should clean any drinking container with hot soapy water and dry thoroughly between uses. Bottles specifically designed for extended reuse are often made with wide openings that allow consumers to use cleaning instruments and easily dry them.

#### What about the University of Calgary study?

A University of Calgary study found bacteria in water samples taken from bottles that were refilled by elementary school students without being cleaned. The author of the study concluded that the source of the bacteria was inadequate personal hygiene practices on the part of students reusing the bottles. The fact that the bottles in this particular study were plastic is irrelevant.

#### How do I know that the plastic in my bottle is safe?

Consumers can be confident that the U.S. Food and Drug Administration carefully reviews new substances intended for food contact before allowing them on the market. This includes materials, like plastics, intended for food and

#### FDA Regulations

Under the Federal Food, Drug and Cosmetic Act, FDA regulates materials and substances used to make plastic packaging as **indirect food additives**. According to FDA, indirect food additives are “substances that may come into contact with food as part of packaging or processing equipment, but are not intended to be added directly to food.”

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beverage packaging. Both plastics and plastic additives are subject to FDA review and regulations.

New packaging materials are permitted for food use only after FDA reviews the submitted test data and is satisfied that they are safe for their intended use. As part of its review, FDA assesses the migration potential of plastics and the substances with which they are made. Scientific tests are conducted to establish that there is a minimal amount of transfer between a plastic package and the food it contains and that any transfer does not pose a risk to human health.

### **Will a plastic water bottle leach harmful substances into water if I reuse it?**

Most convenience-size water bottles sold in the U.S. are made from polyethylene terephthalate (PET). The FDA has determined that PET meets standards for food-contact materials established by federal regulations and therefore permits the use of PET in food and beverage packaging for both single use and repeated use. FDA has evaluated test data that simulate long-term storage and that support repeated use.

The toxicological properties of PET and any compounds that might migrate under test conditions have also been well studied. The results of these tests demonstrate that PET is safe for its intended uses. (For details, see *The Safety of Polyethylene Terephthalate*.)

### **What about the student project that claimed to have found unhealthy compounds in water samples from reused bottles?**

The subject of a widely circulated e-mail hoax, these claims stem from a University of Idaho student's masters thesis that was promoted in the media but was not subject to peer review, FDA review or published in a scientific or technical journal.

While the student project may have been suitable work for a masters thesis, it did not reflect a level of scientific rigor that would provide accurate and reliable information about the safety of these products. Fortunately for consumers, FDA requires a much higher standard to make decisions about the safety of food-contact packaging.

### **But I read that the student's project found carcinogens?**

The student's thesis incorrectly identifies di(2-ethylhexyl) adipate (DEHA), a plastics additive, as a human carcinogen. DEHA is neither regulated nor classified as a human carcinogen by the U.S. Occupational Safety & Health Administration, the National Toxicology Program or the International Agency for Research on Cancer, the leading authorities on carcinogenic substances.

In 1991, on the basis of very limited data, the U.S. Environmental Protection Agency classified DEHA as a "possible human carcinogen." However, in 1995, EPA again evaluated the science and concluded that "...overall, the evidence is too limited to establish that DEHA is likely to cause cancer."

Further, DEHA is not inherent in PET as a raw material, byproduct or decomposition product. DEHA is a common plasticizer that is used in innumerable plastic items, many of which are found in the laboratory. For this reason, the student's detection of DEHA is likely to have been the result of inadvertent lab contamination. This is supported by the fact that DEHA was detected infrequently (approximately 6% of the samples) and randomly, meaning that the frequency of detection bore no relationship to the test conditions.

Moreover, DEHA has been cleared by FDA for food-contact applications and would not pose a health risk even if it were present.

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Finally, in June 2003, the Swiss Federal Laboratories for Materials Testing and Research conducted a scientific study of migration in new and reused plastic water bottles from three countries. The Swiss study did not find DEHA at concentrations significantly above the background levels detected in distilled water, indicating DEHA was unlikely to have migrated from the bottles. The study concluded that the levels of DEHA were distinctly below the World Health Organization guidelines for safe drinking water.

### **Is it true that the U.S. Food and Drug Administration (FDA) only allows plastic water bottles, such as those made with polyethylene terephthalate (PET), for one-time use?**

No, FDA allows PET to be used in food-contact applications, including food and beverage packaging, regardless of whether the packaging is intended for single or repeated use. PET water and beverage bottles sold in the United States are designed for single use for economic and cultural reasons, not because of any safety concerns with PET.

In fact, refillable bottles made with the same PET resin as single-use bottles are safely reused in a number of other countries. The only difference is that refillable bottles have thicker sidewalls to enable them to withstand the mechanical forces involved with industrial collection and commercial cleaning and refilling operations.

### **Can freezing water bottles cause dioxins to leach into water?**

This is the subject of another e-mail hoax. There simply is no scientific basis to support the claim that water bottles will release dioxin when frozen. Dioxins are a family of chemical compounds that are produced by combustion at extremely high temperatures. They can only be formed at temperatures well above 700 degrees Fahrenheit; they cannot be formed at room temperature or in freezing temperatures. Moreover, there is no reasonable scientific basis for expecting dioxins to be present in plastic food or beverage containers in the first place.

## **RESOURCES**

International Life Sciences Institute: *Packaging Materials: 1. Polyethylene Terephthalate (PET) for Food Packaging Applications*, July 2000.  
<http://www.ilsa.org/file/ILSIPET.pdf>

International Life Sciences Institute: *White Paper on Refillable Plastic Packaging Made from PET (Polyethylene Terephthalate)*, 1994.

U.S. FDA Information on Food-Contact Substances  
<http://www.cfsan.fda.gov/~dms/opa-notf.html>

U.S. FDA's List of "Indirect" Additives Used in Food-Contact Substances  
<http://www.cfsan.fda.gov/~dms/opa-indt.html>

Title 21 of the Code of Federal Regulations. For information on PET, see 21 CFR Section 177.1630 and 21 CFR Section 177.1315.  
[http://www.access.gpo.gov/nara/cfr/waisidx\\_01/21cfrv3\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfrv3_01.html)

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Swiss Federal Laboratories for Materials Testing and Research: *Migration of organic components from polyethylene terephthalate (PET) bottles to water*, June 2003.

[http://www.sodis.ch/files/Report\\_EMPA.pdf](http://www.sodis.ch/files/Report_EMPA.pdf)

National Center for Food Safety and Technology's Food Packaging Research

<http://www.iit.edu/~ncfs/RESEARCH/respack.html>

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