

## The FDA Takes on BPA

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The Food and Drug Administration (FDA) is poised to issue a final ruling on the use of bisphenol-A (BPA) in food packaging on March 31, 2012. Anthony Hopp and Leonard Kurfirst, partners with Edwards Wildman, spoke with *Food Manufacturing* about what the ruling could mean for food manufacturers.

### **Q: What are the details of the ruling the FDA is expected to issue regarding BPA use in food and beverage packaging on March 31?**

**A:** The FDA is considering a ban of BPA in all food packaging, including plastic containers and the epoxy lining of canned foods. This activity is in response to a citizen's petition to ban BPA that was filed by the Natural Resources Defense Council (NRDC) in October 2008. When the FDA missed its initial 180-day deadline to respond, the NRDC filed suit. The FDA's delay was due, in large part, to its ongoing evaluation of the continuing research being conducted on the potential human health effects of BPA.

In December 2011, the FDA agreed to address this issue by March 31, 2012. The settlement agreement, approved by U.S. District Judge Barbara S. Jones in New York, said the FDA must issue a final decision, not a "tentative response."

### **Q: What caused consumers to become concerned about BPA in food packaging?**

**A:** In 2008, a firestorm of media attention focused on potential BPA exposure from baby bottles and sippy cups erupted. Disputed exposure studies asserted that chemical migration increased at high temperatures (i.e. boiling water and

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microwaving) or with old, scratched bottles. Elevated levels of BPA were also reported to have been found in cans of baby formula.

Given these developments, the National Toxicology Program (NTP), part of the National Institute of Health (NIH), initiated a comprehensive review of BPA. In a draft brief issued April 14, 2008, the NTP acknowledged some concerns — based upon animal studies — for neural and behavioral effects in fetuses, infants and children at current human BPA exposure levels. However, in October of 2008, the FDA released its own draft safety assessment of the use of BPA in food contact applications. In it, the FDA concluded that, based on all available evidence, current levels of exposure to BPA through food packaging did not pose an immediate health risk to the general population, including infants and babies. Since then, the FDA's conclusions have been both challenged and supported by a number of different groups and studies. The NRDC is one of the organizations that has challenged the FDA's draft findings in 2008.

Due to market pressures, manufacturers stopped using BPA in baby-bottle and sippy-cup plastics years ago. The focus now has shifted to the use of BPA in other types of food packaging and containers.



**Q: What are the risks of packaging containing BPA?**

**A:** According to the North American Metal Packaging Alliance (NAMPA), metal packaging enables high temperature sterilization of food products when initially packaged, which is critical in maintaining the sterility and safety of the food product. BPA-based epoxy coatings are applied to the inside wall of cans to eliminate interactions between the metal package and the food contents, which prevents perforation defects in the can that would allow bacteria and microorganisms to enter. By maintaining the integrity of the can, the coatings protect against food poisoning caused by microbiological contamination.

The health risks, if any, of consuming food packaged in materials containing BPA

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are completely speculative. Although some studies have suggested that BPA might be related to obesity and cardiovascular disease, the quality of these studies has been questioned. To date, there have been no peer-reviewed studies demonstrating that BPA in food packaging poses a serious health risk to humans. Regulatory agencies around the world have determined that BPA is safe as it is currently being used. The evidence of endocrine disruption as a result of BPA exposure comes from animal studies. Significant scientific debate exists over whether these animal studies accurately predict the manner in which humans are affected.

Perhaps a better question is what are the health risks of alternatives to BPA, especially with regard to its use in the lining of metal cans? None of the alternatives being considered have been tested as extensively as BPA. Therefore, the move toward substitute products could represent a move toward greater uncertainty.

### **Q: In the event the FDA rules that BPA should be phased out, how will this affect the food industry?**

**A:** BPA has already been phased out by many in the food industry. Many food products are now in packaging advertized as BPA free. These moves have been motivated by perceived consumer demand for BPA free products. In effect, consumer pressure based on publicity over BPA's perceived dangers already has resulted in a partial phase-out of BPA in consumer products and food packaging. If the FDA rules that BPA should be phased out, it will be "closing the barn door after the horse is gone" for many products. The industry participants who still use BPA will be forced to move toward alternatives. It is unlikely, however, that any ban would be immediate.

### ***Interview by Lindsey Coblentz, Associate Editor***

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**Update: The FDA decided to not ban BPA from children's products or food packaging.**

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