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Bill would let federal health researchers ban certain chemicals

By **William Hudson**, CNN

July 8, 2011 -- Updated 1813 GMT (0213 HKT)



Each generation of children is exposed to more chemicals in the womb.

Editor's note: In his ongoing *Toxic America* investigation, Chief Medical Correspondent Dr. Sanjay Gupta is uncovering the health effects of chemicals and other pollutants in our environment.

(CNN) -- A new bill could alter the landscape of chemical regulation in the United States by empowering researchers to take swift action against the most potentially harmful chemicals in use today. The bill, to be introduced later this month, would give the director of the National Institute of Environmental Health Sciences, and a panel of experts selected by the director, the power to ban up to 10 chemicals from commerce each year by categorizing them as being of high concern. Those chemicals would become unlawful to use 24 months after receiving that designation. Among the chemicals that could be subject to a ban is bisphenol A, or BPA, a hormone-disrupting substance widely used in plastics that has been the target of controversy in recent months.

[Dr. Gupta: We must know more about toxic chemicals](#)

The bill is to be introduced by Rep. Jim Moran, D-Virginia, and Sen. John Kerry, D-Massachusetts, later this month.

The fate of the legislation, though, is far from certain. It will have to make its way through committee in both the Republican-controlled House and the Senate, where Democrats have a small majority. CNN received an [advance copy of the bill](#)*, called the Endocrine-Disrupting Chemicals Exposure Elimination Act of 2011, which has a self-executing statute under which the listing of high concern by the NIEHS automatically would outlaw the chemical or class of chemicals, and would require each regulatory agency to take action to prohibit the chemical.

**Editor's note: This is an advanced draft of the bill. It could change before being introduced.*

If the bill were to become law, the NIEHS, a part of the National Institutes of Health, could have chemicals outlawed much sooner than otherwise possible.

It represents a dramatic change in approach to regulating chemicals and points both to the frustrations many have with the glacial pace of regulatory agencies and to the mounting scientific evidence available

to scientists at the National Institutes of Health indicting endocrine-disrupting chemicals in some of the developed world's gravest health problems.

The chemicals, which can be either naturally occurring or artificial, are found in everyday products like detergents, flame retardants, foods and cosmetics. Researchers have found they interfere with the function of hormones and could adversely affect human health.

[Apples top 2011 'Dirty Dozen' produce list](#)

NIEHS conducts original research into this class of chemicals, and funds additional research at laboratories across the country. Their scientists are widely considered to be most familiar with the latest research, but while they can inform the regulatory agencies, they have no regulatory power.

This bill would change that.



Rep. Jim Moran, D-Virginia, will be introducing the bill with John Kerry, D-Massachusetts, later this month.

Research into endocrine-disrupting chemicals began when biologists started noticing bizarre reproductive problems in many wildlife populations. One of the most famous examples from the 1970s, DDT, accumulated at higher and higher concentrations up the food chain, nearly driving the bald eagle, which preys on large fish and other birds, to extinction.

Adult bald eagles didn't immediately die from DDT, but the chemical affected their ability to produce healthy offspring. That's what many fear is happening to humans too, as we sit at the top of our food chain and expose ourselves to many types of endocrine disruptors, like BPA, through the products we use every day. In addition to plastics, BPA is also found in the lining of canned foods.

For regular poisons, a higher dose correlates directly with greater toxicity, but endocrine disrupting chemicals may be counter-intuitively more potent at lower levels, even infinitesimally low levels, according to the Endocrine Society, the world's largest organization of endocrinologists.

That poses a problem for the Environmental Protection Agency's screening tests, which are based on traditional toxicology and cannot detect the low-dose effects of chemicals on the endocrine system, said Frederick vom Saal, a member of the Endocrine Society.

And the effects can show up years later, too, like the higher rates of infertility and cancer in the children of women who were prescribed DES, also an endocrine disruptor, during pregnancy.

We are almost like a third world country when it comes to regulating chemicals.

--Frederick vom Saal

Congress charged the EPA in 1996 with setting up a program to screen for endocrine disrupting chemicals. The Endocrine Disruptor Screening Program has been created, but by 2009 the EPA had still not tested any chemicals for their endocrine-disrupting effects.

But 2009 was a watershed year.

The Endocrine Society released its first-ever "scientific statement," which systematically laid out the evidence against endocrine disrupting chemicals and called for more research into their role on human health, and the adoption of a so-called "precautionary principle," where human exposure to chemicals is reduced if their effects are not properly understood.

Scientists warn of chemical-autism link

Also in 2009, Linda Birnbaum, a senior adviser at the EPA, left the agency and became the director of the NIEHS, the very position that would hold the power to outlaw up to 10 chemicals a year for 10 years. If this bill passes, she will have swifter regulatory powers at the NIEHS than ever possible at the EPA. Birnbaum's office said the NIEHS does not comment on pending legislation.

In December 2009, a bill was introduced in Congress to establish better interagency research on endocrine disrupting chemicals -- the Endocrine Disruption Prevention Act of 2009, which the Endocrine Society fully supported.



Kerry also introduced the Endocrine Disruption Prevention Act of 2009 into the Senate.

That bill, also introduced by Moran and Kerry, sketched out a terrifying narrative, in which once-rare disorders like autism, ADHD, learning disabilities, and obesity have become commonplace in the developed world. Many researchers suggest these disorders are due to widespread use of synthetic chemicals that mimic and disrupt the delicate function of hormones like estrogen and testosterone in the human body.

"These disorders began to increase noticeably at the population level in the early 1970s when the first generation exposed in the womb to post-World War II synthetic chemicals reached maturity. Prior to 1950, these disorders were rare, which rules out the influence of inherited disorders," begins the 2009 bill.

"Today, among the fourth generation of children exposed in the womb, one in three children and one in two minority children will develop diabetes; one in six children is born with neurological damage; one in 100 children has an autism spectrum disorder and among boys the occurrence is one in 58; one in 125 boys is born with hypospadias, a condition where the urethra does not open at the end of the penis." Just this week a new study found that environmental factors play a much bigger role in causing autism spectrum disorders than previously thought.

Pediatricians want more chemical safety laws

"It's not so easy to make the connections in humans because we live so long and are exposed to so many things across our lifetime that trying to link a single compound to a disease state is hard," says Andrea Gore, who researches neural endocrine disruptors.

"On the other hand, I think that what we've learned from animal studies, and from cell lines and mathematical modeling is that many of these mechanisms are the way things work in humans, too."

The bill is expected to meet strong opposition from chemical manufacturers.

In 2009 and 2010, the American Chemistry Council, representing the largest chemical manufacturers, spent \$10.25 million lobbying on the Endocrine Disruption Prevention Act of 2009 and other chemical legislation, according to lobbying disclosure forms compiled by the Center for Responsive Politics at the request of CNN.

CropLife America, a trade association of companies making pesticides and other chemicals used in agriculture, spent \$2.88 million lobbying on the 2009 bill and similar legislation.

The bill never made it out of committee.

[EPA proposes new standards for PVC plants](#)

The American Chemistry Council says it has no comment on legislation it has not seen. But in a written statement, it said chemicals like BPA have been shown to be safe.

"BPA is one of the most thoroughly tested chemicals used today and has a safety track record of 50 years," it said. The council also pointed out that government regulatory agencies "have declared that BPA is safe for use in many applications."

Vom Saal says that's based on junk science, reminiscent of how the tobacco industry defended smoking cigarettes.

"BPA is a good example of a situation where there's this huge disconnect between literally hundreds and hundreds of studies done both by people in the government and in the academic side," vom Saal said, "and then a small number of studies done by corporations where 100% of the corporate studies say this chemical is safe."

If industry can mitigate a chemical's pathway into humans, for example by preventing it from leeching into food, the bill would allow its use in commerce, even if it had been determined to be of high concern.

"We are almost like a third world country when it comes to regulating chemicals," vom Saal said. "It's very difficult for people interested in the public's health to understand how does this become a political, partisan, issue when people on both sides have family that are showing diseases related to these chemicals. What is going on here?"

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A balanced diet plus low dose BPA exposure in womb and while nursing causes fatter, sicker rats.

Jul 05, 2011

Wei, J, Y Lin, Y Li, C Ying, J Chen, L Song, Z Zhou, Z Lv, W Xia, X Chen, and S Xu. 2011. **Perinatal exposure to Bisphenol A at reference dose predisposes offspring to metabolic syndrome in adult rats on a high-fat diet.** *Endocrinology* <http://dx.doi.org/doi:10.1210/en.2011-0045>.

Synopsis by [Renee Gardner](#)

Prenatal exposure to low levels of BPA caused rats to become obese and unhealthy as adults, finds a new study. Pups exposed to a low dose through their mothers while in the womb and nursing – but fed a balanced diet as they grew – were fatter and had a suite of metabolic problems later in life when compared to unexposed rats.

Worse health effects occurred at a younger age in exposed animals fed a high fat diet. The effects were seen at a low dose currently considered safe by the U.S. Environmental Protection Agency but not at a medium or high dose.

Studies find almost everyone in the United States is exposed to BPA since it is used widely in polycarbonate plastics, dental sealants, resins that line food cans and some store receipt paper.

What did they do?

Researchers treated groups of pregnant rats from the beginning of their pregnancy to the time the pups were weaned with several different doses of BPA. The lowest was the 'reference dose' – a which the dose the EPA considers safe, – of 50 micrograms of BPA per kilogram of body weight per day ($\mu\text{g}/\text{kg}/\text{day}$). Other groups of rats were given a dose 5 or 250 times the reference dose.

The offspring were divided into two groups: one group was fed a a balanced diet and one group was fed a high fat diet to mimic the fat- and calorie-rich diets increasingly eaten throughout the world. None of the rats were given any BPA after they were weaned.

Researchers monitored the offspring as they grew to adults. They calculated weight gain and measured markers of metabolic syndrome, including levels of glucose (sugar), insulin and cholesterol in the blood.

What did they find?

There was no apparent size difference between the BPA-exposed and non-exposed rat pups at birth. However, as they grew, the rats treated with the reference dose of BPA but fed a normal diet were heavier, had a higher percentage of body fat and were more insulin resistant and glucose intolerant than rats who were not exposed to BPA.

These problems developed even earlier and were more severe in BPA-treated rats that were fed a high-fat diet. These rats also had higher LDL ("bad cholesterol") and lower HDL ("good cholesterol").

With both the regular diet and the high-fat diet, males were more sensitive than females to the effects of BPA. The effects of BPA exposure compounded with age.

Interestingly, rats exposed to doses 5 and 25 times higher than the lowest dose did not show any adverse effects in terms of weight gain, fat mass or metabolic function.

Context

Bisphenol A (BPA) is a component of polycarbonate plastics used for food and drink containers. It is also found in resins that line food and beverage cans, thermal paper used to print many retail receipts and dental sealants.

Humans are exposed to BPA through **eating**, drinking and absorbing through the skin. Eating canned foods and handling retail receipts may increase exposure. Because the chemical is so common, exposure is widespread. Researchers detect BPA in over 90 percent of urine samples tested in the United States. BPA can cross the placenta into the womb during pregnancy and can pass from mother to baby after birth through breast milk.

BPA is an endocrine disrupting chemical, or EDC. These chemicals can interfere with the natural signals of the endocrine system, which uses hormones to relay important biological messages throughout the body. Evidence is increasing that BPA exposure may increase risk of obesity and its complications. Previous studies in animals show that BPA exposure early in life increases body fat and weight gain later in life. Some studies in humans have shown that exposure to BPA and other endocrine disrupting chemicals is associated with increased risk of obesity, cardiovascular disease and metabolic syndrome.

Metabolic syndrome is a set of medical problems associated with obesity, including increased insulin resistance and blood insulin levels (hyperinsulinemia), increased glucose tolerance and blood sugar levels (hyperglycemia), high blood pressure (hypertension), and high levels of triglycerides and LDL (“bad cholesterol”) in the blood. Individuals with metabolic syndrome are more likely to develop Type II diabetes and cardiovascular disease.

Insulin is a hormone that regulates metabolism in the body. Normally, when blood sugar starts to rise after eating a meal, insulin rises as well so that muscle and fat cells will take up the sugar, keeping the balance of blood sugar level. As people become overweight and obese, their cells often stop responding to the normal levels of insulin, leading to insulin resistance and potentially dangerous elevated blood sugar levels.

The lowest dose of BPA used in this study was the reference dose – a dose estimated by the U.S. Environmental Protection Agency (EPA) to be the dose that humans can be exposed to on a daily basis for their entire lives without experiencing any negative health effects. This dose was estimated from animal studies in which rats were given high doses of BPA, and was last updated by the EPA in 1993. There is controversy as to whether the current reference dose is low enough to protect human health.

What does it mean?

Exposure to a low dose of bisphenol A (BPA) while in the womb and while nursing may increase the risk of obesity and a suite of metabolic problems even if eating a balanced diet into adulthood, finds a study with rats. Similar effects were seen earlier in animals exposed to the same low dose but fed a high-fat diet. These health effects were not seen in the growing rats exposed to medium and high doses.

This study is one of a number of recent studies that suggest that BPA may have adverse health effects at or even below the current reference dose. It also adds more detail to studies that point to BPA affecting weight and metabolism.

Even though this was an animal study and the results can't be directly applied to people, it's a first step in understanding how environmental chemicals like BPA may influence development in ways that last a lifetime. More research is needed to determine if the results apply to people.

The research shows one example of a chemical for which the health effects observed after a small dose are not just a milder version of the health effects that observed after a big dose. Rather, the health effects seem to be completely different at the different dose levels.

This study finds that exposure to BPA while in the womb and from the mother's milk increases weight gain and a host of health problems associated with obesity later in life. The effects of BPA were magnified in rats that were fed a high fat diet after weaning. BPA exposure at the early stages of development may lead to a “metabolic reprogramming” that sets the exposed offspring on an early path toward an increased risk of obesity and its associated health complications.

Additionally, this research suggests that we may need to rethink the method for testing the toxicity of certain chemicals by evaluating the potentially toxic effects of chemicals at doses that reflect realistic human exposures. Health effects were only observed at the lowest dose in this study – a dose that is supposed to reflect a “safe” exposure to BPA.

The rates of obesity and overweight in adults and especially in children are on the rise, though some recent studies indicate that the rates may be at least leveling off among adults. According to the Centers for Disease Control, 34 percent of adults are obese and a further 34 percent are overweight. Twenty percent of children 6-11 years old are also obese, as are 10 percent of children 2-5 years old.

The risk of obesity is clearly influenced by the increasingly high-fat and calorie-dense diets of most of the world's population. In addressing the obesity epidemic, less attention has been paid to the potential role of other environmental exposures.

Because the time before and after birth is an especially crucial period for development, changes in the early life environment can have potentially profound impacts later in life. This study showed that the time period surrounding birth may be particularly crucial for the effects of BPA exposure on later metabolism. Researchers are now working to understand whether these sorts of early life exposures in humans may be contributing to the obesity epidemic, especially among children.

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Microtest Laboratories Announces New Fast-Track Toxicity Testing for Medical Devices Using Zebrafish Embryos

AGAWAM, Mass. July 6, 2011 /PRNewswire/ -- Microtest Laboratories has announced a new fast-track test to screen plastics and polymers in medical devices for toxicity using Zebrafish embryos (*Danio rerio*), a technique already widely utilized in drug development studies.

"Testing has revealed that Zebrafish embryos are highly susceptible to toxins. In fact, Zebrafish labs are ubiquitous in most universities and research hospitals," said Steven Richter, Ph.D., president and scientific director of Microtest Laboratories, and former U.S. Food & Drug Administration (FDA) official.

"We've confirmed the application of Zebrafish embryos in the toxicity testing of materials used in medical devices," Dr. Richter said. "With our in-vitro test, manufacturers and bio materials researchers can screen thousands of polymers in less than a week – yielding significant economic savings in both the time and expense of medical device testing."

In its research, Microtest Laboratories found that the current "gold standard" USP Cytotoxicity Assay, which utilizes live mouse fibroblasts (L929) cells in culture, failed to detect the toxicity of a BPA extract during testing – while Microtest's new Zebrafish embryo screen succeeded.

BPA (bis-phenol A) is a suspected toxic polymer assumed as having both carcinogenic and teratogenic effects on humans. The U.S. Environmental Protection Agency (EPA) has indicated that BPA will be slated for screening soon.

"Microtest's new Zebrafish embryo assay has better sensitivity and generates more scientific data than the small animal tests currently recommended by the FDA," Dr. Richter said.

"The use of Zebrafish embryos will reduce or eliminate the current animal testing required for all medical devices testing. This important vertebrate model has demonstrated similarities to mammalian models and humans in toxicity testing," he noted.

Microtest Laboratories' new Zebrafish embryo assay for the toxicity testing of medical devices is immediately available. For more information, visit <http://www.microtestlabs.com/zebrafish-embryos-testing> or call 1-413-786-1680 or toll-free 1-800-631-1680

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