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Precaution In Applying The Precautionary Principle

Law360, New York (November 26, 2008) -- With the election of a new Democratic president and a larger Democratic-majority in Congress, it is expected that environmental and human health issues will receive increased attention. This is good news to consumer groups that have been pushing for stricter legislation to protect against potentially harmful substances.

Even under the direction of the current president and the current Congress, there has already been some movement towards policy-making based on the "precautionary principle," which has been popular in the European Union, but has been slow to find support in the United States.

The recently enacted Consumer Products Safety Reform Act may be a preview of future legislation in this area, and provides insight into how thinking on these issues has changed and may continue to change.

Overview Of The Consumer Products Safety Reform Act

On Aug. 14, 2008, President George Bush signed into law a bill that would impose stricter regulations on consumer products, including children's products, that contain certain chemicals.

The bill bans lead and phthalates from children's products, creates a searchable database of product complaints filed with the government for consumers to access, requires manufacturers to make it easier for consumers to learn about recalled products, increases fines and other penalties for safety violations, and increases the responsibilities and budget of the federal Consumer Product Safety Commission.[1]

Of particular significance is the section pertaining to phthalates. Phthalates are a group of chemicals often used to make plastic products more soft and pliable. They are found in a variety of children's products such as rubber ducks, soft books, and teething rings.

Supporters of the law claimed that toxins can be ingested when toys made with phthalates are placed in a child's mouth. Due to this concern, the new law permanently prohibits the sale of children's toys or child care articles manufactured for children of the age 12 and under that contain more than 0.1 percent of the following three phthalates: (1) di-(2 ethylhexyl) phthalate (DEHP), (2) dibutyl phthalate (DBP), and (3) benzyl butyl phthalate (BBP).[2]

The law also temporarily prohibits the sale of children's toys or child care articles manufactured for children of the age 12 and under that contain more than 0.1 percent of three additional phthalates: (1) diisononyl phthalate (DINP), (2) diisodecyl phthalate (DIDP), and (3) di-n-octyl phthalate (DnOP).[3]

Whether the temporary prohibition becomes permanent will be decided at a later date after a scientific review by a Chronic Hazard Advisory Panel. The ban would become permanent unless the Panel determines, and the Commission agrees, that there is a "reasonable certainty of no harm"[4] to children, pregnant women, or other susceptible individuals.

Potential Harm Versus Proof Of No Harm – A Change In Policy

The "no harm" standard found in this recent law marks a significant shift in the way chemicals are regulated in the United States. As an example of how things have been done until now, one need only look at the regulatory history of the other major chemicals addressed in the new law: lead, which has a long regulatory history stemming from its use in lead-based paints.

In 1978, the Consumer Products Safety Commission banned the sale of lead paint for use in residences.[5]

This regulation banned "paint and similar surface-coating materials for consumer use that contain lead compounds and in which the lead content is in excess of 0.06 percent of the weigh of the total nonvolatile content of the paint...."[6]

The regulation also banned toys, furniture, and other articles intended for use by children that contain "lead-containing paint."

At the time of the lead paint ban, the burden was on the government to prove that a certain chemical was dangerous prior to its regulation. In the case of lead paint, the government was prompted to investigate its dangerousness, in part, by the findings of a study conducted by Dr. Philip J. Landrigan, an American epidemiologist, pediatrician and advocate of children's health.[7]

In 1970, Dr. Landrigan tested the blood of children attending schools near a large smelting company in El Paso, Texas. Dr. Landrigan concluded that 60 percent of the children living within one mile of the smelting plant had elevated blood lead levels and that even exposure to lead at low levels could lower a child's IQ.[8]

This study, as well as additional scientific studies conducted in the 1970s, provided evidence to regulators that lead, even at low levels, had proven adverse health effects on humans, particularly on children during key developmental periods.

When it issued its ban on sale of lead paint for residential purposes, the Consumer Products Safety Commission listing in its findings the reason why such a ban was necessary.[9]

In addition to the work of Dr. Landrigan, scientific studies had already been conducted by the President's Council on Environmental Quality who had prepared an Environmental Impact Statement on Lead in Paint, complete with a detailed appendix of the health effects of lead in paint.

In § 1305.5, the Commission summarized the established adverse health affects of lead as detailed in Appendix A of the Environmental Impact Statement.[10] These findings stated that:

Lead is a cumulative toxic heavy metal which, in humans, exerts its effects on the renal, hematopoietic, and nervous systems. Newer concepts indicate that there are three stages to childhood lead poisoning. The adverse health effects in the first stage are not clinically present but metabolic changes can be observed.

During the second stage or symptomatic stage such symptoms are loss of appetite, vomiting, apathy, drowsiness, and inability to coordinate voluntary muscle movements occur. The after effects of this stage include seizure disorders as well as various behavioral and functional disorders which are often included under the heading of minimal brain dysfunction. Studies suggest that this syndrome may include hyperactivity, impulsive behavior, prolonged reaction time, perceptual disorders and slowed learning ability.

The adverse health effects of the third stage may be permanent and can include blindness, mental retardation, behavior disorders and death.[11]

At the time it issued its ban, the Commission specifically noted that "there is an unreasonable risk of lead poisoning in children associated with lead content of over .06 percent in paints and coatings" and that "no feasible consumer product safety standard under the CPSA would adequately protect the public from this risk." [12]

Through the lead paint regulation, the Commission enumerated the many scientifically-proven harmful of effects of lead exposure even at low levels. These were not effects that the government and policy makers thought might potentially occur, but had in fact, already been conclusively documented in populations that had been exposed to lead paint.

Further, the Commission affirmatively stated that there was no way to eliminate the risks of adverse health effects from exposure to lead paint aside from a complete ban of the product.

The Precautionary Principle In Action

The recent legislation does not rely on similar evidence of harmful effects from exposure to phthalates used to manufacture consumer products. Instead, the reasoning for why a ban is necessary is no longer because the government has proven that the chemical is harmful to children, but shifts the burden to manufacturers to demonstrate that the product in fact causes no harm.

The underlying premise for this “no harm” standard is what scientists, policymakers, and environmentalist have termed the “precautionary principle.”

At its most basic level, the precautionary principle is a moral and political idea that places the burden of proof on proponents of an activity rather than on potential victims of the activity. The 1988 Wingspread Statement on the Precautionary Principle defines it this way:

When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically.[13]

While the precautionary principle has been widely supported and adopted in the European countries for some time now, it has been slow to find similar support in the United States. In fact, former Secretary of State Colin Powell once said that the European legislation “would be significantly more burdensome to industry” than the more scientific approach used in the United States.[14]

But the most recent legislation banning phthalates suggests a strong shift in American legislative philosophy. Supporters of the transition believe that the burden of scientific proof is too high, and by the time action is taken, it is too late.

Representative Hilda Solis, vice chairman of the House Environment and Hazardous Materials Subcommittee, said, “The environment seems to have changed in our favor ... Consumers are expecting the federal government to do something. They don’t want to hear about it at the last minute, after their children have been exposed.”[15]

Precautionary policymaking has found similar support from multiple advocacy groups, including the American Nurses Association, the National Autism Association, the Service Employees International Union, and the National Council of Churches, among others.[16]

Chloe Schwabe, Assistant Director of Environmental Health at the National Council of Churches, thinks that the precautionary approach is important because it “can protect

people first, before they or their children are exposed to toxic chemicals ... We are educating and engaging congregations to take action to improve our system to regulate chemicals and protect God's creation.”[17]

On the other side, industry is concerned about the precautionary principle because it may lead policymakers to sacrifice chemicals that have been thoroughly tested, including to meet FDA approval, have not been proven to be dangerous, and are far more effective and economical than alternative products.

To require more raises the philosophic problem that one cannot actually prove a negative – i.e., it cannot be proven that a chemical does not cause harm; one can only establish that there is not evidence of harm.

Thus, if precaution is taken too far, it will likely impede development and cause manufacturers to forego marketing certain products because of an inability to satisfy consumer groups.

There is also concern of misapplication of the principle when it is results from political pressure, rather than scientific justification. It is difficult for any politician to stand up for a product when there is a consumer group accusing it of potentially causing harm.

On the other hand, there may be political gains for supporting that cause. That political disparity can lead to products being banned when there is no scientific need to do so.

Between consumer advocacy groups and the plaintiffs' bar – which always benefits from more opportunities for litigation over banned products – there will be a loud voice pushing for more precautionary action. Any industry opposition will face accusations of bias and a desire for profit. In that climate, the science can easily be lost among the clamor for action.

Where We Are Heading

It is currently unclear how the introduction of the precautionary principle into consumer laws will affect future legislation. It could be just the beginning of a broad legislative overhaul for chemical reform that we may see in the coming years, especially as consumer group exert more pressure on the government to regulate potentially harmful substances.

While it may no longer be acceptable to legislators or society to implement a "wait and see" approach to chemicals in consumer products, banning a substance with little evidence of its harmful effects will pose its own challenges, especially during the current economic crisis.

Precaution has a price – it results in more expensive products, and at some point, lost jobs and businesses. Often lost in this debate is also the impact on misleading consumers into believing that a banned product is harmful, even though there may be

ample evidence to the contrary, but simply not enough to rule out the potential of some harm.

Although the future of the precautionary principle approach to regulating chemicals is unknown, it is probably safe to say that this is not the last time the issue will be up for debate.

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[1] 15 U.S.C. § 2051 et seq.

[2] Id.

[3] Id.

[4] Id.

[5] 16 C.F.R. § 1303.

[6] Id.

[7] Angela Pirisi, Philip Landrigan: Children's Health Crusader, 365 *The Lancet*, Issue 9467, p. 1301 (2005), available at www.thelancet.com/journals/lancet/article/PIIS014067360561015X/fulltext#

[8] Linda Marsa, How Much Do Chemicals Affect Our Health? *Discover Magazine* (published online Apr. 25, 2008), available at discovermagazine.com/2008/may/25-how-much-do-chemicals-affect-our-health

[9] 16 C.F.R. §1303.5.

[10] Id.

[11] Id.

[12] 16 C.F.R. §1303.1

[13] *The Precautionary Principle, A Common Sense Way to Protect Public Health and the Environment*, Science and Environmental Health Network, January 2000, available at www.mindfully.org/Precaution/Precautionary-Principle-Common-Sense.htm (last visited Nov. 10, 2008).

[14] DiGangi, Joseph, REACH and the Long Arm of the Chemical Industry, The Multinational Monitor, September 2004, Vol. 25, No. 9, available at multinationalmonitor.org/mm2004/09012004/september04corp3.html (last visited Nov. 10, 2008).

[15] Loewenberg, Samuel, Chemical Industry to Fight New Proposal, Politico, Sept. 18, 2008, available at www.breastcancerfund.org/site/apps/nlnet/content3.aspx?c=kwKXLdPaE&b=697605&content_id=%7B1EFDE704-4FAA-44AF-9975-9309694ACC1F%7D-oc=1 (last visited November 10, 2008).

[16] Id.

[17] Id.