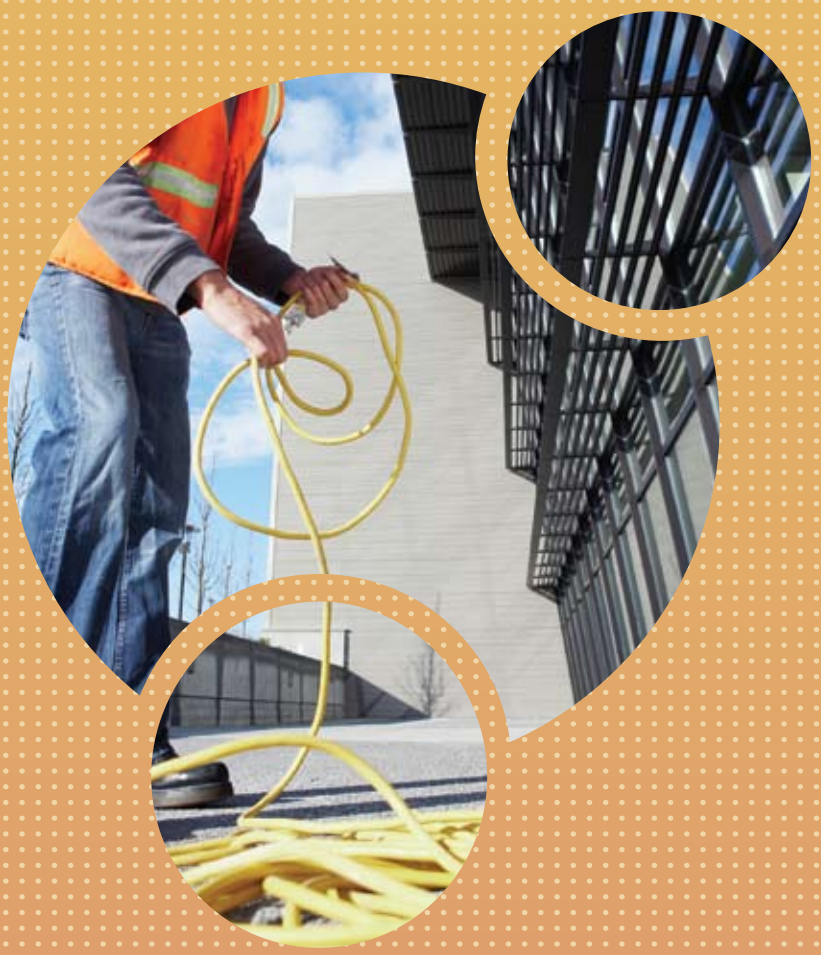
essential$_2$know

about Phthalates

Phthalate Esters Panel



www.phthalates.org

Table of Contents

About the Panel

The Phthalate Esters Panel (the Panel) of the American Chemistry Council is composed of all major manufacturers and some users of the primary phthalate esters in commerce in the United States.

Since the Panel's inception in 1973, members have demonstrated their commitment to the safe use of their products by sponsoring health, safety and environmental research on phthalate esters. Since its inception, the Panel has funded more than $15 million of research, excluding research conducted by individual companies.

Results of Panel-sponsored research are routinely shared with government agencies around the globe in order to support a comprehensive and thorough assessment of the products' safety. Panel research and conclusions are peer-reviewed and published in respected scientific journals. Phthalate esters produced by Panel members have been subjected to extensive health and environmental scrutiny by both independent scientists and national and international government bodies.

The Panel is committed to research and testing of phthalate esters and will continue to work closely with government agencies so that these materials can be used safely in a wide array of products consumers find valuable in everyday life.

Panel Member Companies

BASF Corporation
Eastman Chemical Company
ExxonMobil Chemical Company
Ferro Corporation
Teknor Apex (Associate Member)

Panel Manager

Marian Stanley

Q & A

Q. What are phthalates?

A. Phthalates are a large family of compounds used in a wide variety of everyday products. They are colorless, oily liquids with little or no odor and low volatility.

Q. What are they used for?

A. The dozen or so phthalates in use today find thousands of applications. Their chief use is to make vinyl soft and flexible, without sacrificing its durability. They are used as softeners (or plasticizers) in toys, cars and products found in the home and in hospitals. For example, they are an important ingredient in vinyl medical devices used to help save lives. One member of the phthalate family is used in perfumes and other personal care products to make their fragrances last longer. Another type of phthalate is used in items such as tool handles and nail polish to help resist chipping.

Q. Are they safe?

A. Regulatory agencies and independent authorities have found phthalates to be safe as used in vinyl products and personal care products. There is no reliable evidence that any phthalate has ever caused any harm to any human in their fifty-year history of use. Phthalates are one of the most thoroughly tested families of compounds in use today. An immense amount of information on their safety profiles is available to users.

Q. Who says so?

A. The European Union has conducted extensive safety reviews of all the major phthalates, and has found they present no concern to the general public in their current uses. Its reviews specifically cover uses in nail polish and in toys.

The U.S. Consumer Product Safety Commission has found that the principal phthalate used in toys presents "no demonstrated health risk" to children.

The U.S. Centers for Disease Control and Prevention (CDC) has tested thousands of Americans for evidence of exposure to phthalates (as well as to more than one hundred other chemicals and elements). CDC data show that average human exposure is far below levels set by the U.S. Environmental Protection Agency as protective of human health.

Q. Why have phthalates been banned from personal care products in Europe?

A. Not because any human health effects have been found. The European Cosmetics Directive says that any substance known or strongly suspected to have certain health effects in laboratory animals—even if this occurs only at extremely high doses—is assumed to present similar risks to humans, and may not be used in cosmetics. The directive is not based on any evidence that there is any actual risk to humans. In fact, an EU safety review states that there is "no concern for consumers" who use nail polish containing the phthalate DBP.

Q. Why have some phthalates been banned from use in toys in the EU?

A. The European legislature voted to pass that ban, even though the draft conclusion of an exhaustive safety review of the principal phthalate used in toys stated it was "unlikely to pose a risk" even for newborns. In other words, it was a political decision, not a regulatory one based on science.

Q. The EU risk assessments studied the effects of each phthalate individually. But shouldn't their effects be added and studied as a whole, because various phthalates can act in the same ways on organisms?

A. Even if you add up the effects of the different phthalates that might be expected to act in the same way on organisms, data from the federal government's CDC tells us that exposure is still below federal safety levels.

Q. But we are exposed to them every day, in many ways. Doesn't that add up to trouble?

A. We are exposed to lots of things every day. But phthalates do not build up in the body the way certain other substances do. The process of breaking them down begins within minutes, and their half lives are measured in hours.

Q. Isn't it true that phthalates cause health problems in laboratory animals?

A. Some—not all—phthalates interfere with the development of the reproductive system of male rodents when administered in huge doses—doses far larger than CDC data tells us humans experience. Rodent effects are not necessarily relevant to humans.

Q. What do phthalates do to rodents?

A. Researchers believe that extremely large doses of certain phthalates suppress the production of testosterone, which is necessary for the normal development of the male reproductive system. The doses that result in these effects are orders of magnitude larger than the exposures humans receive. There is no evidence that this occurs in humans.

Q. Does the same thing happen to humans?

A. There is no reliable evidence that it does. There is some evidence that it does not. A small study of children who were highly exposed through life saving medical devices as infants found no ill effects as teenagers.

Q. Is there any evidence that phthalates don't affect humans?

A. Tests on male marmosets, which are primates, concluded that even huge doses administered from weaning until sexual maturity had no effect on their reproductive organs. Other studies indicate that humans do not absorb phthalates as readily as rodents do. Humans break them down and excrete them much more readily than rodents do. This evidence suggests that rodent effects may not apply to humans.

Q. Haven't recent studies shown phthalates to have effects on human sexual development or function?

A. The National Institutes of Health, through its National Toxicology Program studies, has reviewed all studies claiming to show human effects, and in late 2006 called them "insufficient" to warrant drawing any conclusions. All such studies are statistical in nature—that is, they claim to show a correlation between phthalate exposure and certain health effects. But flaws are common, and in these cases, flaws make the results questionable. And none of them claims that phthalates caused any health effect—just that they are statistically correlated with the effects. Such correlations can turn out to be statistical flukes.

Q. Does that include the Swan study?

A. That's certainly what many experts think. The study claims to show certain changes—not actual damage—in the reproductive development of infants, correlated to exposure of their mothers to a combination of four phthalates. Dr. Rebecca Goldin, a Ph.D. mathematician at Statistical Assessment Services (STATS), asked about Swan's study, "how much data fiddling was required to find a result?" Others have criticized the study's methodology, its clinical data, and even its biological plausibility.

Q. Aren't phthalates endocrine disruptors?

A. In lab tests with rodents, phthalates do not block the action of male or female hormones, or mimic their behavior.

Q. Don't they cause cancer?

A. The International Agency for Research on Cancer, an arm of the World Health Organization, says DEHP is "not classifiable" as a human carcinogen. The basis for that decision is ample evidence that the biological process leading to cancer in rodents does not occur in humans.

Q. Haven't phthalates been linked to asthma?

A. Some claims to that effect have been made, but recent laboratory studies have shown that phthalates do not trigger immune responses in rodents, and do not intensify an existing asthma attack. Phthalate levels in house dust have been shown to be very low.

Q. Why do you claim that state or local bans on the use of phthalates in toys are illegal?

A. Many federal laws provide that when a federal regulatory agency has taken an affirmative action on a particular substance for a particular risk, states or localities cannot then regulate it. That is the case here—the CPSC, a federal regulatory agency, has reviewed the use of DINP, the principal phthalate used in toys, and found "no demonstrated health risk."

Phthalates & Your Health

There is no reliable evidence that any phthalate has ever caused any harm to anyone.

The cancer story:

In the 1980s, some phthalates were shown to cause liver cancer in rodents when administered at high doses over long periods of time.

Subsequent research showed that the cancer was caused by a biological process in rodents that does not occur in humans.

In 2000, the International Agency for Research on Cancer, an arm of the World Health Organization, declared DEHP to be “not classifiable” as a human carcinogen.

The reproductive effects story:

High doses of some phthalates have been shown to interfere with the development of the male reproductive system in rodents, an effect believed to be caused by suppression of testosterone production.

Some studies claim to show a link between phthalate exposure and reproductive effects in humans. Those most often cited were reviewed in 2006 by an independent government-sponsored panel and found to be “insufficient” for drawing any conclusions.

Some research suggests that reproductive effects seen in rodents are not relevant in humans, as is the case with cancer. Huge doses of a phthalate fed to male marmosets (a small monkey) as they matured resulted in no damage to their reproductive organs. Other studies show that marmosets (which are primates like humans) do not absorb phthalates as readily as rodents do, and break them down and excrete them more quickly. Research is continuing on this point.

Phthalates—The Basics

What are phthalates?

Phthalates are a family of compounds made from alcohols and phthalic anhydride. They are oily, colorless, odorless liquids that do not evaporate readily.

Used primarily in vinyl, they are an important part of our everyday lives.

Most phthalates are used to make vinyl soft and flexible. From their use in medical devices to toys to cars to homes, flexible vinyl products help make our lives better and safer. And in hospitals and emergency rooms, they help save lives. They make our homes more decorative, easier to clean, more energy efficient and durable. Flexible vinyl products are high-performing and cost effective; their performance is difficult or impossible to match with competitive substitutes. They save money for consumers.

Some phthalates deliver unique benefits to the personal care products industry.

For more than fifty years, they have been a key ingredient in fragrances and in nail polish. One kind of phthalate fixes the fragrance in perfumes and other products to make it last longer. Another type is used in nail polish (as well as in tool handles and outdoor signs) to help prevent chipping and breaking.

Many independent reviews have declared them to be safe as used in toys and cosmetics.

Safety reviews by European and American scientific panels have specifically cleared phthalates for use in toys and in nail polish. The different reviews use phrases such as “safe as used,” or “no concern,” or “no demonstrated health risk.” No governmental review has found any phthalate unsafe as used in products for the general public.

In more than fifty years of use, no reliable evidence has ever shown that any phthalate has ever caused harm to anyone.

Phthalate Risk Assessments United States and Europe	The six phthalates mentioned in state legislative proposals have been reviewed by various government and government-sanctioned scientific bodies. All the listed phthalates are subject to bans or restrictions in the European Union.				
	CPSC Consumer Product Safety Commission	**EU** European Union	**CERHR** U.S. Center for the Evaluation of Risks to Human Reproduction (All CERHR reports are expressed in levels of concern)	**CIR** Cosmetic Ingredient Review	**CDC** Centers for Disease Control and Prevention biomonitoring studies
DINP	"no demonstrated health risk"	"unlikely to pose a risk for consumers (adults, infants and newborns)"[1]	"minimal concern" for children, adults and fetuses		not detectable in most test subjects
DIDP		no likely risks for any groups as currently used	"minimal concern" for adults, fetuses and children		not monitored; based on physical properties and uses, probably similar to DINP
DnOP		not assessed	"negligible concern" for adult reproductive system; insufficient animal data for other effects on adults		not detectable in most subjects
DEHP		preliminary conclusion: safe for general public (excluding neonates)	"serious concern" for critically ill neonates; "concern" for infants under one; "some concern" for toddlers over one and male offspring of exposed pregnant women; minimal concern for general public		average exposure 10-33 times below EPA reference dose[2] (safety level)
DBP		"no concern for consumers using nail polish containing DBP"	"minimal concern" for fetal developmental effects for pregnant women with typical exposure; "some concern" for male fetal development in women with high exposure (conclusion based on exposure estimates that turned out to be higher than actual)	"safe as used" in current applications and concentrations	average exposure more than 100 times below EPA reference dose
BBP		"no concern" for children or adults (final draft)	"minimal concern" for developmental effects in children and fetuses; negligible concern for reproductive effects in adult males		average exposure 400 times below EPA reference dose

FOOTNOTES:

[1] European Union risk assessments were performed by member states under the management of the European Chemicals Bureau.

[2] For phthalates, the EPA reference doses are calculated from the no effect level in the most sensitive rodent studies, divided by a safety factor of 100 to 1000.

DINP—Vinyl Toys and Health

DINP is the principal ingredient used in vinyl toys to make them soft, flexible, and affordable, as well as to increase their safety profile.

- DINP is the overwhelming choice of U.S. toy manufacturers to make vinyl toys soft because of its performance characteristics and its affordability.
- DINP has been used to make vinyl toys soft and flexible for decades.
- The U.S. Consumer Product Safety Commission has advised that "If DINP is to be replaced in children's products… the potential risks of the substitutes must be considered. Weaker or more brittle plastics might break and result in a choking hazard. Other plasticizers might not be as well studied as DINP."

Independent safety reviews of DINP have found it to be safe as used in vinyl toys.

- The U.S. Consumer Product Safety Commission spent four years studying DINP and conducted original research on the amount of time children hold toys in their mouths, and concluded that there is "no demonstrated health risk" from its use in toys and "no justification" for banning its use.
- A European Commission safety review, conducted under the direction of the European Chemicals Bureau, found that DINP's use in consumer products, including toys, is "unlikely to pose a health risk to adults, infants, or newborns."
- The National Toxicology Program, an arm of the U.S. National Institutes of Health, found "minimal concern" for the use of DINP in toys.
- Data from the Centers for Disease Control and Prevention show that average human exposure to DINP is far below safety levels set by the EPA.

No human health effect has ever been reliably linked to exposure from any phthalate, or any combination of phthalates.

- Average exposures of U.S. citizens to phthalates are well below government safety levels—even when exposures are added together.
- No study claims to show a link between DINP and effects on humans.
- Health effects seen in rodents are caused by doses of some phthalates that are far beyond what CDC data show people experience in daily life.

Phthalates in Cosmetics & Personal Care Products

Phthalates deliver unique benefits to the personal care products industry. For more than fifty years, they have been a key ingredient in fragrances and in nail polish.

- The three phthalates used in personal care products (DBP, DMP, DEP) are "safe for use in cosmetic products in the present practices of use and concentration," according to an FDA-sanctioned panel of university scientists, the Cosmetics Ingredient Review.
- Average human exposure to the phthalates used in personal care products is far below safety levels established by the Environmental Protection Agency, based on government biomonitoring data.
- DEP, DMP and DBP do not build up in the body. They break down rapidly and are cleared from the system within 24 hours. In the environment, they break down readily.

Major reviews have found DBP safe as used in nail polish.

- DBP has been used in nail polish for decades to help prevent chipping.
- An extensive safety review by a European Union scientific panel found "no concern for consumers using nail polish containing DBP." The Cosmetics Ingredient Review found DBP "safe for use" in nail polish.
- Average human exposure to DBP is 300 times below the safety level set by the EPA, according to its 2006 draft calculation. That is three times more of a safety cushion than the original calculation.
- Exposure to DBP for women of childbearing age is the same as or below that for other age groups, according to CDC biomonitoring data. (Pressure-group statements to the contrary are wrong, based on an early CDC estimate of a very small number of subjects, which the CDC later corrected.)

U.S. and European experts chose not to conduct safety reviews on DEP; the evidence shows that it causes no health effects in rodents.

- DEP has been used for 40 years as a solvent to make fragrances in perfumes and personal care products last longer.
- Consumer exposure to DEP is less than 1/100th of the safety level set by the EPA as shown by CDC data.
- The CIR review of DEP found it "safe as used."

Phthalates in Medical Devices

The use of phthalates in medical devices revolutionized the storage and delivery of whole blood to patients and the military.

- Vinyl bags softened with a phthalate (DEHP) replaced glass bottles in the 1950s.
- Clear, strong, easily sterilized, shatter-resistant and flexible, vinyl blood bags remain the blood-storage device of choice for those who collect and deliver whole blood.
- Vinyl blood bags double the shelf life of whole blood from 21 to 42 days, greatly easing the pressure on blood supplies.

Vinyl tubing and other phthalate-softened vinyl medical devices are critically important tools for the medical profession, especially in crisis situations.

- Vinyl tubing softened with DEHP is the overwhelming choice for use with patients needing dialysis or receiving intravenous fluids, because it is strong, clear, does not kink, and returns to its original shape when stretched or pinched. Kinking can restrict or stop the flow of lifesaving blood, fluids, or medications.
- Vinyl tubing and medical devices are used to oxygenate the blood of critically ill newborns.

Vinyl tubing and other phthalate-softened vinyl medical devices are already well and appropriately regulated.

- The FDA regulates the use of these products, noting that they have been used for years in such cases “without apparent ill effect.”
- Exposure levels of DEHP can approach FDA safety levels when a critically ill neonate’s exposure to the equipment is prolonged, and the FDA has recommended “considering” alternative materials, but it has advised that “the risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP.”
- These concerns are based on effects of high doses seen in rodents, not on any effects ever observed in humans.

Why Did the European Union Ban Phthalates?

An Exercise in "What If" versus "What Is"

Introduction

In September 2004, after more than five years of deliberation, and twenty applications of supposedly 'temporary' restrictions (first introduced in December 1999 on the grounds of dealing with an 'emergency'), the European Union banned the use of all phthalate softening agents in toys and products intended for children under the age of three.

This was ostensibly to protect infants from the possible adverse effects (held to include carcinogenicity and endocrine disruption) of ingesting phthalates through chewing on toys, pacifiers and other items. But research commissioned by the European Union's own executive branch, the European Commission, had already concluded that the chance of a child exceeding the recommended limits through exposure to such products was 'so rare that the statistical likelihood cannot be estimated.'

The final European Union decision was a rearguard action, implemented at a time when the effects of a non-binding recommendation—explicitly introduced as such in July 1998 for fear that an outright ban might be successfully challenged in court—followed by the impact of the 'temporary' restrictions noted above, had all but killed off the use of phthalates anyway. Certain member states were also by then introducing various formal and informal bans on the sale and use of such products. This was despite—as officials at an April 2000 meeting of the European Parliament Environment Committee meeting conceded—the fact that none of these could point to any scientific evidence to back up their cases.

How did this state of affairs come about? How did an entire family of chemicals that had been used widely and safely in a vast range of plastic products for over fifty years, due to their softening properties (akin to those of baby oil on skin), come to be banned across Europe?

According to standard safety procedures and toxicity margins few, if any, of these compounds registered any cause for concern and not many of them were even being used in children's' items.

I was first drawn to examining this debate in 1998 as part of my doctoral research into risk communication. What I discovered was a convergence of social, cultural and political forces that were forcing the agenda and which had little to do with any scientific evidence for a ban.

Indeed, when the first restrictions were introduced, Professor Jim Bridges, Chair of the European Commission's own Scientific Committee on Toxicity, Ecotoxicity and the Environment, sent a note to the Head of the European Commission Directorate for Public Health and Consumer Safety expressing 'very serious concern at the gross misuse' of his Committee's Opinions in seeking to justify a ban.

Context

The campaign to ban phthalates occurred at a time of unprecedented turmoil within Europe. Only a few years earlier the debacle over BSE (bovine spongiform encephalopathy—commonly known as 'mad cow disease') in cattle, and fears as to its possible transmission

to humans in the form of vCJD (variant Creutzfeldt Jakob disease) had rocked the Commission's services.

It is worth noting that to date, the worldwide human toll of this episode is put at less than two hundred individuals. As some analysts and commentators pointed out at the time, far more serious sources of risk abound. But, driven by a wider mood of social anxiety, combined with a growing mistrust of scientists, politicians and corporations, the European Commission was drawn into introducing a wide range of new instruments and measures with sweeping powers, to preclude, it hoped, similar health crises from occurring again in the future.

Such concerns and their responses, towards conditions where evidence is either lacking or unclear, are not untypical within the contemporary period. In the risk management literature, these are characterised as situations of uncertainty. But where in the past scientists and officials held a clear appreciation that few things in life were ever certain, today a growing social and cultural momentum has evolved towards being unable to accept or tolerate uncertainty—even in situations of relative clarity.

Other examples of this phenomenon, and the perverse consequences for society that can be unleashed when we act as if the worst case scenario were true, have included the politically driven determination to uncover weapons of mass destruction in Iraq, or new legislation to treat anyone who comes into contact with children as if they were potential paedophiles—which in the United Kingdom now necessitates the disclosure of criminal records. This approach, increasingly shaped by non-specialists erring toward acting on the basis of what might be, rather than systematically clarifying what is, is driven more by possibilistic imagination than probabilistic evidence and has variously been referred to as 'precautionary' or 'pre-emptive'.

But while, on occasion, officials have been criticised for their 'failure of imagination', it is clear that making policy on the basis of 'what if?', rather than 'what is', is almost guaranteed to cause disruption. This has been facilitated by the advent of a new breed of what some have coined 'fear entrepreneurs' whose business is to encourage individuals and institutions to speculate wildly as to the worst that may happen.

In the phthalates example, some of these latter came from well-organised lobby groups including Greenpeace, who had been campaigning against PVC (polyvinyl chloride) plastic for quite some time. But these were effective only inasmuch as scientists, officials, industry and consumers alike were also prone to a new and heightened degree of nervousness as to their own positions.

Space here precludes a detailed examination of the processes whereby a profound crisis of trust in all forms of authority—scientific, political and corporate—developed over the course of the latter part of the twentieth century. But by early 2000, the European Commission—keen to be seen to be acting in the supposed interests of the public—had officially instituted the use of the

'precautionary principle' at the heart of all of its policies relating to public health and consumer safety.

In effect, officials now had to apply the 'act first, find the evidence later' logic of precautionary thinking to all situations, with a view to restoring a degree of public trust, almost irrespective of the actual facts or evidence at hand. Indeed, some Commission officials went so far as to suggest that this should apply 'even where there is no known scientific uncertainty' as, in relation to the actual evidence, 'too great an emphasis on this may be undesirable from the consumers' point of view'.

This is not to suggest a wilful desire to engender panics or impose restrictions, but rather that society as a whole had become increasingly risk-conscious, and even risk-averse. Politicians, officials and even scientists and corporations have simply been responding to, rather than seeking to challenge, this pre-existing public mood. Far from stabilising matters, such an uncritical over-responsiveness to public opinion can become quite problematic.

Process and Evidence

What is so remarkable in the European case has been the extent to which decisions came largely to be dictated to by the process, rather than the evidence. Assuming worst-case scenarios for childhood phthalate ingestion required the assumption of speculative and highly dubious factors, many of which have since been shown to be entirely fallacious. But this has not led to the decision being revoked.

Upon being asked to investigate the possibility of a problem at the behest of certain member states and regional governments who had come under pressure from a well-co-ordinated campaign by Greenpeace and other environmental interest groups, the new Commission services put in place in the aftermath of the BSE episode swung into action requesting voluntary restrictions pending a final decision.

By layering worst-case estimates for possible phthalate ingestion on top of equally worst-case views as to the possible outcomes they effectively constructed a highly implausible model for what was happening.

From the outset this assumed that a child could chew a plastic item for up to twelve hours a day, despite more recent studies, based on actual observation, having reduced this to as little as two minutes. They also presumed that all the phthalate contained in the item would leach out and be ingested, again despite considerable evidence to the contrary.

In addition, it should be noted that while some laboratory experiments on rodents—whereby the animals are either fed or sub-cutaneously injected significant doses of phthalates over considerable periods of time—had raised concerns as to the possibility of carcinogenic or endocrine disrupting properties, neither of these outcomes has ever been observed in higher-order mammals, such as guinea pigs and rabbits, let-alone humans, on a reliable and repeatable basis.

Indeed, over the same period, a specially convened panel concluded that at least one of

these products (DINP – di-iso-nonyl phthalate) posed no risk of cancer or reproductive and developmental harm, and that it should officially be reclassified accordingly.

Irrespective of this, and opting for a 'quiet life', it was already the case that due to the adverse publicity surrounding these issues, a number of manufacturers, retailers and local authorities were already withdrawing such items from sale while admitting, in one significant case at least, that this was largely 'a marketing decision'.

According to the European Commission's own rules, application of the precautionary principle should be 'proportional', 'consistent' and 'subject to review'. Yet despite the considerable information and evidence that has emerged since the introduction of the ban, suggesting that most of the initial assumptions were flawed, the restrictions remain in place. This is, in part, because the drive to err towards the side of caution encourages officials to continuously defer to previously obtained worst-case estimates and scenarios, irrespective of any evidence gathered since.

Precaution also encourages a tendency among officials to keep waiting for yet another study, rather than risk the presumed wrath of those who have staked so much of their careers behind this campaign.

It should be noted, in conclusion, that my initial study into these processes—which contains far greater detail—was conducted in pursuit of my own research and not funded by any industry lobby or association. Indeed, I am highly critical of the industry in my findings. Their own reluctance and nervousness to take on the agenda of defending scientific integrity and evidence contributed in no small way to shaping the growing culture of fear and precaution that we now find ourselves with, and which, in the long run, will prove extremely debilitating for them and society alike.

By becoming unwilling, as a society, to take on such debates we will increasingly find that events are forced upon us that shape the world through the prism of our growing anxieties. Worst case thinking has encouraged society to adopt fear as a new organising principle. Far from protecting citizens it institutionalises insecurity and fosters a mood of confusion and vulnerability that further undermines the possibility of rational debate.

Bill Durodié
Senior Lecturer in Risk and Corporate Security
DCMT
Cranfield University
Shrivenham SN6 8LA
United Kingdom