

Why Did the European Union Ban Phthalates?

An Exercise in “What If,” versus “What Is”

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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 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.

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