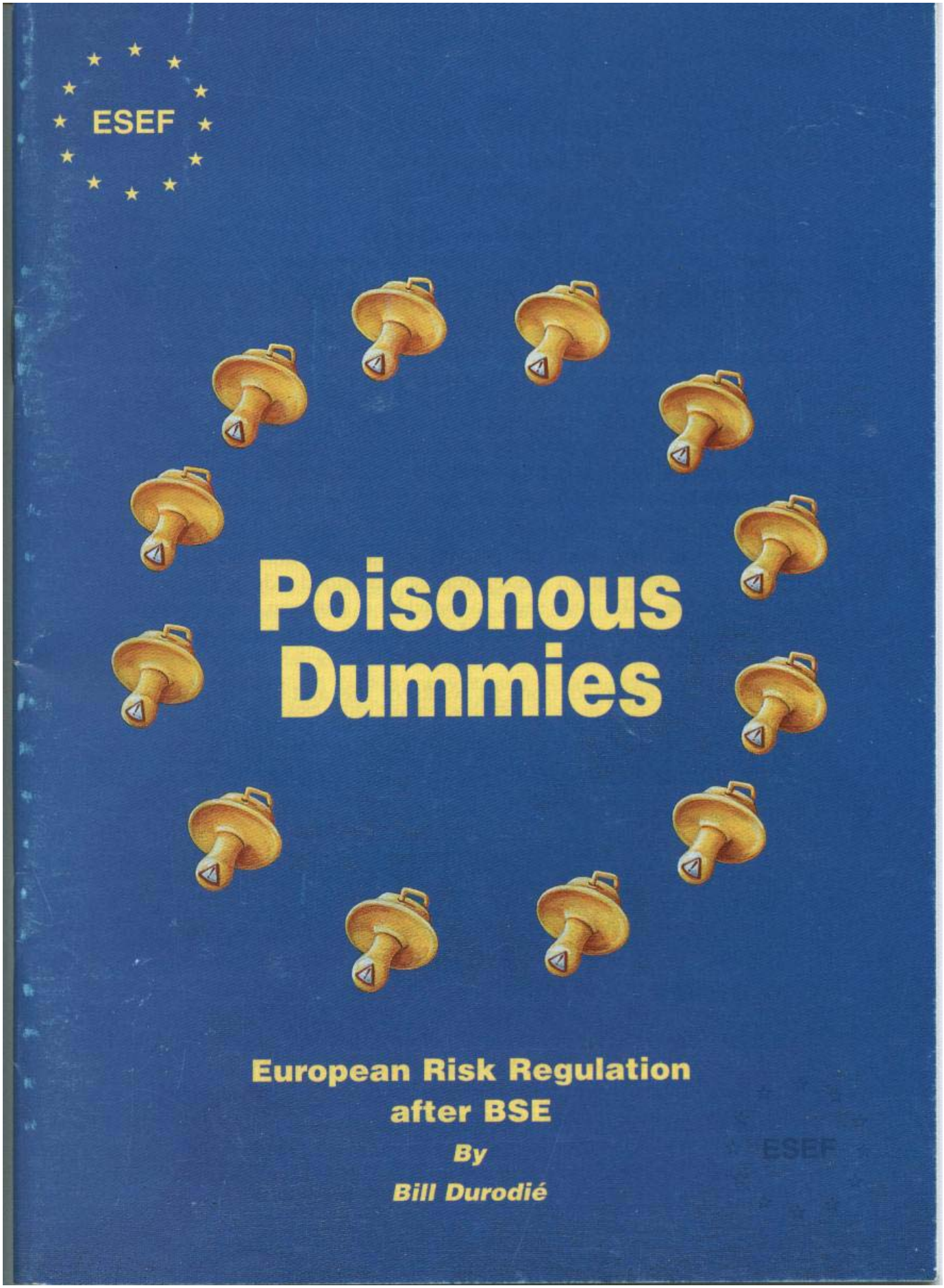
ESEF
Poisonous Dummies
European Risk Regulation after BSE
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Executive Summary

Environmental activists and consumer protection groups claim that phthalates, organic compounds added to hard PVC to make it more flexible, are responsible for numerous adverse health effects, including cancer and damage to the human reproductive system. Governments, the European Commission, the media and retailers have taken these claims seriously. In this latest European Science and Environment Forum working paper Bill Durodié, researching at the London School of Economics and Political Science, shows how using a carefully timed and crafted sequence of stunts, press releases, and often unsubstantiated scientific papers, campaigners have managed to play off these major interested parties against one another. As a consequence, reams of scientific and statistical documents have been commissioned and produced in evidence, raising concerns and unnecessarily exacerbating fears amongst consumers. Yet in more than 40 years of phthalate use, no researcher has ever demonstrated any harm.

More broadly he situates this campaign, along with another opposing the inclusion of toys in food products such as crisps, cereals and chocolate eggs, within the context of the far-reaching reactions to the European BSE (‘mad cow’) debacle. The paper examines the work of the European Commission Scientific Committee for Toxicity, Ecotoxicity and the Environment, and its Committee on Product Safety Emergencies, which met twice to discuss these issues in 1997. The rise of a more consumer-oriented social agenda is discussed, along with the growing use of the ‘precautionary principle’ in assessing environmental health risks. Both are held to be problematic, assuming in the former that consumers hold homogeneous interests, whilst the latter reverses the burden of scientific proof, thereby effectively paralysing social

development.

Suggesting a common dynamic to these matters stemming from claims that everyday activities, or products, are problematic, he explores how campaigners gain support for their views by generating waves of adverse publicity. Then through a process he labels as 'advocacy research', which often produces unspecified and uncorroborated evidence, the problem can be redefined or expanded. This 'evidence' is usually used to confirm that it was correct to identify the problem in the first place thereby encouraging self-regulatory behaviour amongst a target audience, and in turn using this to pressurise others into introducing more formal restrictions.

A number of tentative conclusions are drawn and recommendations made, ranging from a critique of the increasing trend to pre-publish research outcomes to the need for the media to acquire and promote higher levels of scientific and technical expertise. Further, it is shown that the cost to society of not heeding these warnings will be far greater than a narrow economic one. Already the campaign against phthalates in children's toys has turned into one opposing their presence in medical devices such as intravenous tubing and blood bags. Whilst many companies are now being pressed into using alternatives the inevitable logic of these irrational ideas is coming to the fore: the European Commission has instigated investigations into the toxicologically less-well documented replacement products, thereby showing that the fear of phthalates will simply be transferred onto their proposed solutions. The conclusion drawn is that it is a broader loss of trust within society which will need to be addressed, if a generation of young people are not to be brought up questioning the ability of science and reason to cast light upon their lives.

1. Introduction

On 29th March 1999 three Greenpeace campaigners were freed from a Japanese jail. They had been arrested 11 days earlier for abseiling down the side of a building at the Tokyo Toy Fair to unfurl a banner that read 'Play Safe, Buy PVC Free'[1]. This repeated a stunt played out the previous year on 13th February, at the opening of the

International Toy Fair in New York, and became just the latest high profile twist in a two year worldwide campaign by environmentalists and consumer protection groups against esters of o-phthalic acid, more commonly known as phthalate esters, or phthalates. Phthalates are liquid organic compounds which are added to hard polyvinyl chloride, or PVC, to act as softeners or 'plasticisers'. These make the compound more malleable and hence more versatile.

Despite substantial scientific evidence to the contrary, the activists' claims that phthalates are responsible for numerous adverse health effects, including cancer and damage to the human reproductive system, have been taken seriously by governments, the media, retailers and even by the increasingly defensive plastics industry. Co-ordinated and well-crafted stunts, press releases, often promoting unpublished scientific papers, have enabled the campaigners to play off all the major interested parties against one another. As a consequence reams of scientific and statistical documents have been commissioned and produced in evidence, raising concerns and unnecessarily exacerbating fears amongst consumers.

Yet phthalates have been in widespread use for almost 50 years, and have had particularly close scrutiny and attention paid to them over the last 25 of these.[2] Due to their low cost and excellent performance characteristics, including flexibility, which they impart to PVC, they are found in products as common and diverse as medical devices, particularly fluid containers, tubing and gloves; children's toys including teethers, rattles and bathtime rubber ducks; and household and industrial items such as wire and cable coating, flooring and clothing. The vast majority of phthalates (about 97%) are used in the production of flexible PVC. The remainder are used in conjunction with other polymers and to a small extent in the production of printing inks and perfumes. Now, regardless of the quality of the evidence in their favour, and as a direct result of the campaign against them, several formal and informal bans are coming into operation across the world.

This paper seeks to explore how this could have come about, focusing upon the specific role of the European Commission, and in particular its Committee on Product Safety Emergencies, which met twice in 1997. Among other issues, this Committee discussed the issue of softeners in plastic products intended for children, as well as the supposed problems related to an entirely separate matter, that of non-edible items in foodstuffs.[3] Both these investigations are examined here in some detail, in order to explore those mechanisms that have encouraged a tendency towards self-regulatory behaviour.

The examples suggests a common dynamic stemming in part from the new credence afforded to environmentalists and consumer protection groups in the aftermath of the European BSE ('mad cow') debacle. In the first instance such groups claim an everyday activity, or product, to be problematic. They then gain support for their views by generating a wave of adverse publicity. Evidence is produced, through a process probably best defined as 'advocacy research'. This 'research' is often unspecified and uncorroborated, allowing for the redefinition or expansion of the problem, if needed, at a later date. In each case however, findings are used as an affirmation that it was correct to identify a problem in the first place. Finally, self-regulation begins amongst a target audience, and this in turn is used to pressurise others into altering their behaviour.

That such a frenzy could have been stirred up around phthalates, which from a health and environmental viewpoint must qualify as among the most studied and understood family of compounds, should serve as a dire warning to scientists and industrialists, and even retailers and consumers. It would appear that the real poisonous dummies in the whole affair are not necessarily the plastic teethers which so many are still seeking to ban.

2. Mad cows

2.1 The stampede

The impact upon the contemporary European imagination of the scare surrounding the suggestion of possible links between bovine spongiform encephalopathy (BSE), commonly known as 'mad cow disease', and its transmission to humans in the form of new variant Creutzfeldt-Jakob disease (nvCJD), should not be underestimated. Subsequent to parliamentary statements giving credence to a possible link by the then health secretary, Stephen Dorrell, who quoted from an official report by the Spongiform Encephalopathy Advisory Committee (SEAC) in the UK House of Commons on 20th March 1996, (a view then echoed by agriculture minister, Douglas Hogg), attitudes to consumer protection and public health services across Europe have undergone a momentous and total transformation. It would be fair to say that the issue of British beef herds occupied much of the European Commission's time over the course of 1996 and 1997.

Grasping the impact the then British prime minister, John Major, speaking at the height of the mad cow panic in April 1996, described it as 'the worst crisis a British government has faced since the Falklands'.[4] For the European Community's agriculture and rural development commissioner Franz Fischler, speaking in September 1996, it was 'the biggest crisis the EU had ever had'.[5] According to Scott C Ratzan, introducing an authoritative collection of papers on the subject, the BSE/CJD problem was 'arguably one of the greatest human-made disasters in history',[6] whilst for food policy professor Tim Lang, it 'provided an object lesson in how not to manage risk'.[7]

Regardless as to the evidence of the proposed link to CJD,[8] (after all the jury in the form of the BSE Enquiry is still out on the matter, and there are also a small number of dissenting voices),[9] it is undeniable that the scale of reaction was quite unprecedented, revealing a new low in levels of public confidence. At the time a death rate as high as 500,000 per annum was predicted – to date the actual figure has been 39. Also, the cumulative total of confirmed BSE cases in Great Britain has now

reached 174,433, however, only 38,975 of those have been subsequent to the introduction of the ban on ruminant protein in cattle feed,[10] suggesting to some that the actions taken by ministers and officials prior to the panic had already been wholly sufficient.[11]

The debacle has acted as a catalyst for a more profound reorganisation of the industry and beyond. Subsequent developments, referred to by the European Commission variously as 'farm to fork', 'plough to plate', or 'stable to table', to indicate how all-encompassing they are expected to be, will allow for faster and tougher responses to perceived problems, food-related or otherwise. They look set to have far-reaching implications long after the destruction of the last suspect beef herd has been completed.

2.2 The Commission's reaction

The European Commission, the executive body of the European Community, is generally regarded as the guardian of European treaties and the interests of the Community. It was shocked into action by BSE. Over a two year period hardly a single speech by the president at the time, Jacques Santer, numerous commissioners and their officials, failed to refer to the crisis. These speeches all pointed towards the need for substantial organisational and legislatory reform. This reorganisation was then formally established on 12th February 1997,[12] and publicly launched by Jacques Santer who made 'a plea for the gradual establishment of a proper food policy which gives pride of place to consumer protection and consumer health'.[13]

The potential for the Commission to intervene more within the fields relating to human health protection, consumer protection and the environment, had been contained within Articles 129, 129a and 130r respectively of the 1992 Treaty on European Union (Maastricht Treaty). The BSE crisis triggered these into action. It has been argued for instance that 'nobody could have predicted how public health at EU level would be plucked from obscurity and thrust into the political spotlight as a result of the BSE affair'.[14] Now, a new, more substantial Article 153, within the 1997

Amsterdam Treaty, further expanded the remit, placing consumer policy and health protection more centrally as 'rights',[15] although this has been criticised 'as a sudden and political response to the BSE crisis'.[16]

The Consumer Policy Service at the Commission which had itself only became established as a new directorate-general (DG XXIV) in 1995 was, on 1st April 1997, expanded to take on health protection matters and has since witnessed a truly astonishing pace of transformation. The number of staff has risen from 96 to 322 officials, absorbing 94 staff from other areas, including the Food and Veterinary Office, which relocated to Dublin.

Under the stewardship of high-profile commissioner Emma Bonino, the directorate, which expects to further rise to a full staff complement of 350 before the end of the millennium, became responsible for providing scientific advice, risk analysis and control, whilst other directorates maintained their legislatory roles.

Over the course of 1997 a wave of landmark documents was produced, including, on 30th April, a communication on 'Consumer Health and Food Safety',[17] and a Green Paper on 'The General Principles of Food Law in the European Union'.[18] An 'Inter-Services Operations Manual establishing cooperation procedures between Directorate General III, V, VI, and XXIV' followed on 4th July. This represented the interests of the industrial policy; employment, industrial relations and social affairs; agriculture and rural development; and consumer policy and consumer health protection, directorate-generals respectively.

A Multidisciplinary Scientific Committee (MDSC) set up in 1996 to deal specifically with BSE,[19] was replaced by a Scientific Steering Committee with a far broader mandate.[20] Some 131 leading European scientists (selected from a pool of 1,126 who had applied),[21] were then co-opted to sit on its eight new scientific sub-committees,[22] thereby replacing the six former scientific committees.

Most notably the Commission established a Rapid Alert System and a Risk Assessment Unit within DG XXIV, and overtly adopted the 'precautionary principle' as the basis of its approach to all future investigations. The latter is popularly understood to imply that in all matters involving uncertainty, one is to err upon the side of caution. More recently a unit responsible for international affairs has been created,[23] indicating no doubt the desire to have an even more global reach.

2.3 The UK parallels

Similar adaptations and transformations have occurred within the UK, which has also had to handle a well-publicised fatal outbreak of the e-coli bacterium over the same period. The Ministry of Agriculture, Fisheries and Food, and the Department of Health Joint Food Safety and Standards Group (JFSSG) was formed on 1st September 1997. A Risk Communication Unit has been established within this, and decisions were already being based on a 'safety first' principle prior to the establishment of a national Food Standards Agency,[24] which whilst substantially delayed in its genesis, is still expected to further transform the British regulatory landscape.

3. Choking fears

3.1 Triggers

In February 1997 the Belgian authorities notified the European Commission of two (non-fatal) incidents involving children choking on parts of toys contained in food products. By Royal Decree from 27th May 1997, Belgium banned all such non-edible items from inclusion in food products.[25] The introduction of this new national technical standard required the Commission to be notified as it created a non-tariff barrier to the free movement of goods within the internal market.[26]

This reached the Commission's Committee on Product Safety Emergencies which had been set up in 1992 through the directive on General Product Safety,[27] and had during the course of 1996 relocated from DG III (industrial policy) to the new DG XXIV (consumer policy and consumer health protection). Now, subsequent to its 30th June 1997 meeting it decided to issue a 'serious and immediate risk to health'

warning. It requested all 15 member states to examine the risks associated with the inclusion of unwrapped non-food articles mixed with food products, (typically toys in chocolate eggs, crisps and cereal packets), review national policy on such matters, and report back to the Commission by September 1997 so that it could consider 'further steps' at its October meeting.[28]

Little over a year earlier the Belgian minister for public health, Marcel Colla, had already tried to ban similar items after the (on this occasion fatal) suffocation of 68 year old pensioner, Susanne de Rieck from Gentbrugge, on a 'flippo' (or 'pog') contained in a packet of crisps.[29] At the time this had led to a satirical response, which compared the regulatory haste to ban 'flippos' in crisps with the minister's more lethargic and bureaucratic approach to what were considered to be more pressing health issues.[30]

Over the intervening period however, BSE had exploded onto the scene followed by its concomitant expansion of activity to DG XXIV and relocation of the Committee on Product Safety Emergencies. The public mood was now more attuned to safety issues, and the relevant Commission staff more numerous, prepared and expected to react. But there is little evidence relating to incidence and incidents of choking which could justify the measures now being sought.

3.2 Incidence

Research presented to the Commission into the actual numbers of such choking events included a key paper by Dr. Elena Petridou of the University of Athens Medical School from April 1997, entitled 'Injuries from Food Products containing Inedibles', (FPCIs). Dr. Petridou indicates that 'accidents represent now the most important cause of childhood morbidity and mortality', a sentiment echoed by the Commission communication of 14th May 1997 establishing a Common Action Programme relating to the prevention of injury.[31]

But the figures, based upon the Emergency Department Injury Surveillance System developed by the Athens-based Centre for Research and Prevention of Injuries, which specifically recorded such incidents from September 1996, are unconvincing. They suggest a mortality rate from FPCIs lower than 2 per annum across the EU, which tallies with research commissioned in 1996 by the UK Department of Trade and Industry.[32] The latter built upon a previous four-country analysis conducted by the Child Accident Protection Trust, as well as data from the Home Accident Surveillance System. It encompasses all the European Community's member states with the exception of Luxembourg, and provides a rich source of counterpoints against overreaction.

Whilst choking fatalities are undoubtedly tragic, they are fortuitously rare. Of the over 550,000 deaths per annum in England and Wales for example, 6,000 involve children under the age of 10. Three quarters of these are under the age of one. Of the total deaths 16,000 can be attributed to external factors, and after excluding road accidents and suicides there remain approximately 6,000 accidental deaths among people of all ages, of which about 5% involve choking. Approximately 200 of the accidental deaths involve children under 10 and 15-20% of these (some 30 to 40 cases a year) are the result of choking.

Unsurprisingly perhaps, the vast majority (84%) of deaths by choking involves food items. Sweets, peas, sausages, bananas, apples and nuts are all cited as potentially hazardous. Of the non-food items leading to choking incidents, coins form by far the largest single category. 'The remaining accidents are caused by a wide variety of items not many of which involve toys'.[33] Cotton wool, conkers, stones, silver foil, tissue paper, even a child's dummy and half a penicillin tablet have proved fatal. Very few incidents ever involve toys, let alone toys associated with food products.

3.3 Incidents

In the UK for instance there have only been three recorded child fatalities relating to toys enclosed with food items over the last 15 years: Roddy Breslin from Northern

Ireland, aged 3 in May 1985, Jennifer Ashton, from Birmingham, also aged 3 in November 1989, and Caren Day from Beighton, near Sheffield, aged 4 in November 1991.

The association between the toy and the food item was not even central to each of these. For instance, the first was caused by the wheel and axle of a toy lorry which had already been assembled by the child's father, and mostly cleared up by his mother subsequent to having been broken during play. As was argued by the responsible Minister in response to Parliamentary questions on the matter at the time, all fatalities are regrettable, but the world is full of small objects which can cause death by choking.[34] While the death of the little boy was very regrettable, it would be of no consequence to prohibit the sale of such products.

During Court proceedings surrounding the second incident caused by the foot of a Pink Panther model, Ferrero, manufacturers of Kinder Surprise eggs, pointed to worldwide sales in excess of 4,600 million since 1974, 218 million of which had been in the UK, and 58 million of those in the preceding 12 month period.[35] It was suggested that Birmingham City Council, which had issued a suspension notice against the eggs, had reacted emotionally rather than rationally. Legislating on such matters would prove futile as well as being irrational.

It is just such reasoning which ought to have led the Committee on Product Safety Emergencies to conclude that there was little risk and no need to issue a warning to all member states in the first instance.

3.4 Precautions

Of course due caution is taken in preventing choking incidents where possible. Children under 3 years of age are particularly vulnerable as, after 1 year when they learn to use their thumb and first finger as a pincer, they experiment by placing objects into their mouths, yet do not have a coughing reflex or a fully developed cricoid (the narrowest part of the larynx and trachea), until they are over 2 years old.

In this regard reasonable actions have in the past been taken, such as the labelling of toys containing small parts as unsuitable for those under 36 months of age, or the creation of ventilation holes in the tops of pen caps. The 'small parts cylinder test' provides a reliable guide as to the potential hazard proffered by such items.

As the DTI report pointedly indicates, 'putting objects in the mouth is an important part of learning and should not be restricted',[36] and further that it is 'unrealistic to segregate toys at all times, and in all circumstances'.[37] With respect to those children who are outside the main danger zone, the report asks the question, 'is it realistic or practical to stop three and four year olds from playing with marbles, small building bricks or tiddlywinks?'.[38]

3.5 Confusions

Dr. Petridou's paper however suggests that 'a minute probability is never negligible', and, presumably concerned by the small numbers recorded due to 'reporting limitations', proposes that in future there should be 'epidemiological investigation of events, that are more frequent than those that represent major health risks but sharing the same risk profile (in the way near misses are studied to identify risk factors for the very rare air-crashes).'

She remarks that 'there is little information concerning the incidence of non-fatal injuries because most injury classification systems in existing large databases in the European Union have been developed before these objects became widely used'. For instance the European Health and Leisure Accidents Surveillance System (EHLASS) had, until 1997, recorded incidents involving FPCIs within the category for incidents involving non-identified objects.

However scientifically, it is vital to clearly differentiate choking incidents, caused by the ingestion of a food or non-food item from other similar yet substantively different problems. In particular these are, (a) choking on a regurgitated food item, (b) external

blockage of the nose and mouth, (c) external compression of the chest, and (d) blockage of the oesophagus leading to a restriction on the passage of air.

The first of these is usually not disaggregated from other causes of choking in morbidity statistics, whilst the others are commonly confused with choking in non-fatal accidents which do not necessitate a post-mortem. Choking itself involves the prevention of the passage of air to the lungs. When fatal the victim is usually unconscious within one minute, and by two minutes will have suffered irreparable brain damage. They would be dead shortly after.

Such differentiation is extremely important if Elena Petridou's suggestion of recording 'near misses' is to be considered, especially as in addition the swallowing of foreign bodies or their complete inhalation into the lungs, which is rarely fatal, are also commonly confused with choking amongst accident reports. These latter are, 'less serious, even trivial, and, though alarming to a parent, are probably not life threatening',[39] and further 'from the descriptions in HASS it appears that accidents are often classified as choking when a foreign body or piece of food in the mouth causes concern or discomfort even if it has no more than very temporarily obstructed the airway.'[40]

The recording of 'near misses' then, far from providing a wealth of new scientific evidence, would only serve to confuse the issue and raise anxieties. Choking is extremely rare and sometimes fatal; most other incidents involving ingestion of foreign bodies are neither choking nor potentially fatal. These sets of circumstances should never be allowed to become confused, yet it is easily done, even by medically trained professionals, when there is no need for a post-mortem.

3.6 Concessions

When the Committee on Product Safety Emergencies met to discuss the outcome of their investigations they concluded that sufficient protections were already in place. For a number of years already, non-edible items contained in food products within

most European states, had been separately wrapped, and those countries outstanding were soon to harmonise their procedures.

However despite the evidence, consumer groups vowed to continue their campaign to see all such products, including those under wraps, removed from the market place. More recently the parents of the three UK child fatalities have been encouraged to petition the European Parliament to introduce mandatory safeguards.[41]

Similar pressures have elsewhere already led to the introduction of self-restriction, as evidenced by the withdrawal from the American market almost two years ago of 'Nestlé Magic', a chocolate ball containing Disney characters, even before any ruling had been reached as to whether it satisfied the far more stringent food regulations already in place there.[42]

Despite the product, whose parts are substantially larger than those found in 'Kinder Surprise' eggs, subsequently being found to satisfy Food and Drug Administration requirements and the Consumer Products Safety Commission who undertook 'small parts' and 'use and abuse' tests on it, protests against it had come from the Consumers Federation of America and the US Public Interest Research Group, amongst others.

More recently it would appear that Nestlé has agreed to pay out $1.5 million in compensation after being approached by 13 attorneys representing the families of children supposedly distressed through choking incidents related to the product.[43] However there appears to be little evidence for such purported incidents, especially as 'Nestlé Magic' continues to be widely available outside the United States. Further, as has been well exposed elsewhere, the settlement of claims is often a defensive reaction by businesses unwilling to be exposed to adverse publicity, even when they feel confident in their product.[44]

Such developments should serve as a salutary warning to others such as Kellogg, Smiths, Ferrero and Westimex, who may also find themselves on the receiving end of

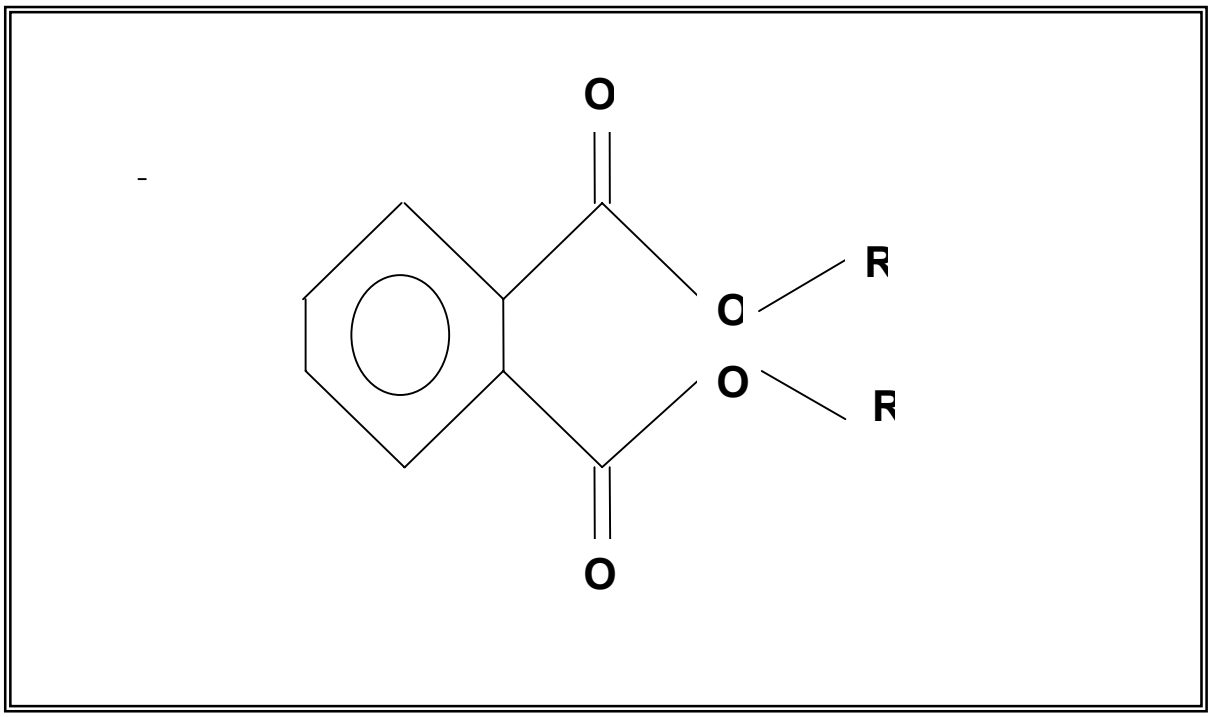
an irresistible wave of demands for self-restraint marshalled by the increasingly vociferous and self-appointed representatives of consumer interests.

One can only be left wondering how it was possible for previous generations of young children to have survived being brought up by the apparently thoughtless parents who encouraged them to hunt for the three-penny coins once concealed in traditional British Christmas puddings, or the fève in the French Galette des Rois!

4. Poisonous dummies

4.1 Phthalates

Polyvinyl chloride or PVC is a rigid material which can be made soft by the addition of plasticisers. These compounds generally have a high boiling point and, when incorporated into polymers, cause a greater workability of the material, by increasing the flexibility of the individual polymer chains. The most commonly used compounds for this purpose are esters of o-phthalic acid, which are more generally known as phthalate esters or phthalates. Several of these are used as plasticisers in PVC and their general structure is shown below, where the group **R** is usually the same aliphatic (carbon chain) or aromatic (carbon ring) side chain, varying in length for different compounds.



Name	Acronym	R
Dibutyl phthalate	DBP	n-C_4H_9
Dipentyl phthalate	DPP	n-C_5H_{11}
Butylbenzyl phthalate	BBP	n-C_4H_9 and -C_6H_5
Di(2-ethylhexyl) phthalate	DEHP	-C_2H_4 (C_2H_5)C_4H_9
Di-iso-octyl phthalate	DIOP	-C_8H_{17}
Di-n-octyl phthalate	DNOP	n-C_8H_{17}
Di-iso-nonyl phthalate	DINP	-C_9H_{19}
Di-iso-decyl phthalate	DIDP	-$C_{10}H_{21}$

Phthalates, including DEHP, DINP, DIDP, DNOP, DBP and BBP, which became the objects of the European Commission's investigations, have been in widespread use for almost 50 years. Particularly close scrutiny and attention has been paid to them over the last 25 of these.[45] Due to their low cost, and the flexibility they impart to PVC, they are found in products as common and diverse as medical devices, particularly fluid containers, tubing and gloves; children's toys including teethers, rattles and bathtime rubber ducks; and household and industrial items such as wire and cable coating, flooring and clothing. They are also used to a more limited extent in printing inks and perfumes.

As a result of their diverse and widespread use and relative resistance to degradation, phthalates are ubiquitous in the environment.[46] Yet, compared to many other commonly used products, such as solvents, they can readily be removed by photochemical, oxidative and biological processes.[47] They also break down in low oxygen environments such as sediment, but at a lower rate,[48] and levels in natural waters are reported to be decreasing.[49]

The quantity of phthalate plasticiser added to a PVC product can be determined by measuring weight loss after diethyl ether extraction. For example, at the Laboratory of the UK Government Chemist over 100 plastic teethers and toys have been assessed for plasticiser content. In these, and other investigations including those by Greenpeace, losses of up to 50% are found to be fairly common, with DEHP, DINP and DIDP identified as major components, (DNOP is not produced on a commercial scale and is difficult to detect in the presence of the multi-component product DINP). DBP and BBP are usually found at levels below 1% and are taken to arise as impurities or by-products not intentionally added. However, whilst it is not difficult to extract phthalates from PVC using a suitable solvent, it is problematic to determine the level of migration of phthalates from PVC into saliva.

4.2 Concerns

Since August 1996 Greenpeace has been contacting major toy manufacturers around the world requesting meetings to discuss concerns about PVC toys.[50] This formed part of a wider Greenpeace agenda against PVC in particular and the chlorine industry in general. Then, on 23rd April 1997, the European Commission services were approached by the Danish authorities regarding three emergency notifications taken out five days earlier upon the recommendation of the Danish Environmental Protection Agency,[51] and concerning various teething rings manufactured in China for the Italian company 'Chicco – Artsana'.[52]

According to these notifications the analyses carried out showed that the articles released certain phthalates in quantities considered to be unacceptable for babies. The

Danish importer had thus withdrawn these products from the market. The manufacturers, who considered that the teethers were in conformity with Community legislation,[53] and did not present any danger, nevertheless on a preventative basis, and awaiting the results of their own analyses, also decided to voluntarily withdraw them from the market. The results of their analysis, which took into account the latest working draft proposing a test method to determine the migration of phthalates in articles destined for child-use and care, conflicted with those of the Danish authorities.

Reactions by other member states to these notifications indicated important differences regarding test methods used to measure phthalate migration, focusing specifically on such assumptions as period of exposure, contact area, and type of stimulus. An experiment in the Netherlands which led to reported doses marginally above the tolerable daily intake (TDI) has been criticised by others for its methodology of mimicking chewing through the use of an ultrasonic bath which produces a 55,000 Hz vibration.[54] Not what one would expect from a child's mouth!

Some took account of the TDIs fixed by the Scientific Committee for Food, in its Opinion on phthalates in infant formulae, expressed on 7th June 1996.[55] However Belgium and the UK in particular, required the Commission's services to ask for the opinion of experts and/or relevant scientific committees at the European level, prior to proceeding with the matter.

Hence unable to issue a 'serious and immediate risk to health' warning, as it had done over the issue of non-food articles mixed with food products, the Committee for Product Safety Emergencies would have to refer the matter on to the new Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE). Due to reorganisation, this did not meet for its first plenary session until 17th November 1997.

4.3 The Greenpeace campaign

Encouraged by the Danish notification to the Commission and its impact upon the Italian owned distributors, as well as the results of the Dutch 'in vitro' experiment and longer standing Swedish concerns regarding PVC use, Greenpeace began approaching the Commission on the matter.[56] Frustrated by the prevarication caused, unnecessarily in its view, by the need to substantiate and corroborate scientific data, Greenpeace continued independently to approach politicians and officials in member states at a local, regional and national level, as well as manufacturers and retailers and their professional associations. It sought to use the various notifications, voluntary withdrawals and early investigations as proof of a wider concern.

On 17th September 1997 – 100 days before Christmas – Greenpeace launched the 'Play Safe' campaign in New York and London.[57] This included a list for parents of PVC and non-PVC infant toys as well as a message outlining the supposed adverse health effects – purported to be liver and kidney damage leading to cancer, the mimicking of sex hormones and reproductive abnormalities.

The campaign was set to target major toy manufacturers such as Mattel, and retailers such as Toys 'R' Us, who were refusing to conform to the scare which had by now affected a number of retailers in Denmark, the Netherlands and Sweden, as well as clients of the Italian suppliers in Spain, Portugal, Greece and Italy itself.

Greenpeace claim that they 'first drew attention to the problem by releasing a scientific study'.[58] This actually amounted to no more than a Technical Note identifying the types and amounts of phthalates contained in PVC.[59] But the level of phthalate contained by a compound is not an indication of the amount which actually leaches from it, and even if this latter quantity can be determined, it remains to be proven whether this poses a risk to human health.

By October however, no doubt concerned by increasingly alarmist pronouncements and responses, a number of prominent politicians entered the fray. Austrian

Consumer Affairs minister, Barbara Prammer, stated that 'based on precautionary consumer protection, PVC toys are not desirable',[60] whilst Belgian minister for Public Health, Marcel Colla (who had previously tried to ban 'flippos' from crisp packets), urged retailers to 'voluntarily discontinue marketing these products'.[61]

This added further pressure upon retailers in those countries, such that subsequent Greenpeace direct action against Toys 'R' Us in Austria led to the company's top management agreeing to withdraw ten specific PVC toys from the shelves,[62] although these were subsequently reinstated at the behest of their US head office. In Belgium, FEDIS, the retail federation, agreed to immediately withdraw all soft PVC products designed to be chewed by young children.[63]

Each of these steps however, simply fuelled further activity and alarmist press releases by the campaigners. In Italy activists entered the Ministry of Health in Father Christmas costumes carrying boxes full of PVC toys.[64] Three weeks later Health minister, Rosi Bindi, was also encouraging manufacturers to look into alternative materials.

In Germany it was the Association of Toy Retailers, Vedes, which in December took the lead and called upon its members to withdraw such products, whilst the Federal Institute for the Protection of Consumer Health and Veterinary Medicine, BgVV, urged manufacturers and industry to act responsibly by doing likewise. This was then predictably followed, with statements from the Ministry of Health and the Ministry of Family Affairs suggesting that it would be highly desirable for industry to voluntarily refrain from selling such products.[65]

Nor was it simply to be trade and retail associations, in addition to Greenpeace, who would now put pressure upon national ministries. The municipality of Bilbao, in Spain, introduced its own ban,[66] a measure to be widely repeated amongst other local and regional assemblies, including many in Italy, no doubt keen to be seen to be taking a greater interest in their electorates' well-being, than that taken by central government.

Revealing its own uncertainties, the European Commission itself, in February 1998, removed all soft PVC teething toys from its childcare facilities,[67] prompting a new and understandable round of calls from campaigners that if the products were not good enough for the Commission, then they should not be inflicted upon the rest of the population.

Relentless pressure by Greenpeace, including the placing of adverts in newspapers seeking to 'name and shame' firms who would not comply led individual businesses such as Dutch retailer, Bart Smit, to order its shops to remove all listed soft PVC toys.[68]

Effectively governments and retailers across Europe had removed soft PVC products from their shelves and markets on a voluntary basis recognising, in one instance at least, that whilst the claims against such products had 'not been scientifically substantiated' nevertheless 'we choose to give our customers the benefit of this doubt'.[69]

4.4 The CSTEE investigation

It is within this evolving climate that the European Commission had invited its new Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), at its first plenary meeting in Brussels on 17th November 1997, to give its opinion as to;

- the impact on children's health of the use of soft PVC containing phthalates in child-care articles and toys, which children of a young age could put in their mouth;
- the limits which ought to be respected in relation to the migration of phthalates from these products;
- the test method to be followed and the standards or parameters that should be taken into consideration to measure the phthalate migration level.

The CSTEE established a working group which first met on 8th December 1997 and formulated a preliminary position expressed at the Second CSTEE plenary meeting held in Brussels on 9th February 1998. This related to the six phthalates; DEHP, DNOP, DINP, DIDP, DBP and BBP found in infant teething rings, and was based on the documents and literature available to it at that time. This confirmed the existence of different methodologies and highly variable results for the estimation of emission of phthalates from toys. Nevertheless, true to the precautionary approach, it used the highest reported emission levels as a baseline and sought to homogenise all available research evidence to an equivalent exposure dose.

The exposure dose was initially based upon the maximal amounts extracted over 12 hours, from a phthalate containing PVC-toy surrogate of 10 square cm, by a saliva solution under dynamic conditions, and assuming an infant body weight of 5 kg for the risk assessment. This was changed at the time of the expression of its formal opinion on the matter by the CSTEE at its third plenary meeting in Brussels on 24th April 1998, to a more realistic extraction for 6 hours using an infant body weight of 8 kg.

A margin of safety was estimated for each phthalate by dividing the No-Observed-Adverse-Effect-Level (NOAEL) values obtained through animal experimentation, by the worst predicted exposure dose. A level of little concern was assumed for exposure situations with margins of safety in excess of 100. This figure is taken to derive (according to a recent US study)[70] from allowing an extra factor of 10 for variation between species, and a further factor of 10 for variation between individuals.

A further opinion expressed as answers to four new questions put to the committee on the occasion of the CSTEE fourth plenary meeting in Brussels on 16th June 1998, emphasised the need to wait for the outcome of an ‘in vivo’ Dutch study using adult human volunteers, expected later that year. This was expected to provide more realistic estimates for the quantities of phthalate leached, as well as the duration of exposure.

Predictably however, Greenpeace used the launch of investigations by the Commission and the publication of preliminary opinions as a further stick to beat recalcitrant governments, manufacturers and retailers. Under increasing pressure to be seen to be taking action,[71] the Commission agreed the need for a directive specifically to address soft PVC toys intended for young children and babies.

Consumer Policy and Consumer Health Protection commissioner, Emma Bonino, drew up proposals for an emergency ban, reducing its scope to objects designed to be put in the mouth.[72] However fearing that an outright ban might be successfully challenged in court, the Commission voted against it on 10th June 1998, adopting instead a non-binding recommendation on 1st July 1998.

The recommendation covered child-care articles and toys made of soft PVC containing phthalates and intended to be put into the mouth by children under the age of three.[73] It invited member states to take appropriate safety measures whilst Community legislation for permanent protection was under way. Indicating that such products 'are considered to be liable to provoke negative health effects at high level of exposure', it also requested member states to check levels of phthalate migration, comparing these to limits now proposed by the CSTEE. It also effectively conceded the importance of non-scientific factors by indicating that; 'Other Member States had announced that they would act on their own if the Commission does not find a Community solution'.[74]

4.5 The moving safety margin

One of the major problems throughout this process has been the adoption of continuously shifting baselines and data. The margin of safety, arbitrarily considered as needing to exceed 100, is determined by dividing the NOAEL value by the exposure dose. Yet each of these quantities has varied according to particular experiments or has been the subject of systematic revision or reinterpretation. Even samples from parallel batches of PVC and using identical techniques, yield low

correlative precision due to the uneven release of phthalate particles from within them.[75]

In all instances the worst data or the worst-case approach was adopted in order to err on the side of caution, even if this meant variations as great as four orders of magnitude (5 10,000) between experimental data! Such an approach was considered reasonable as no account was being made for exposure to more than one phthalate in a toy, and for additional exposures through food, air or dermal contact. Nor was there any allowance for the assumed enhanced sensitivity of young children to these products. The possibility that the phthalates could be hydrolysed or broken down by saliva into simpler compounds was also not considered,[76] nor the fact that young children do not swallow all their saliva.

The various opinions did recognise however, that where calculable, intake from toys was not the only, nor indeed the major, source of exposure. A European Committee for Standardisation draft report in 1997 estimated exposure from toys to be 10% of total exposure for a given phthalate.[77] For at least one such compound (BBP), 'Food is by far the major source contributing over 90% of intake'.[78] A UK Ministry of Agriculture, Fisheries and Food (MAFF) information sheet indicates that far from being caused by plastic containers or wrapping, the presence of phthalates in food is due to general environmental conditions, as core content levels of phthalates in food items often exceed surface content levels.[79] Indoor air provides most of our remaining exposure to phthalates.

In all, well over one hundred documents have now been presented to the CSTEE in evidence over the issue of phthalate toxicity. Whilst some are merely member state notifications of intended action, others are of a more scientific nature. One of the key, and shifting, areas for debate and experimentation has been over what is assumed to be the critical end point of phthalate toxicity. This means an indication as to the type of adverse effect to be expected from each compound.

NOAEL values are determined by administering phthalates in varying concentrations to the diet of test animals, usually rats. Typically concentrations go up in factors of ten, and after a specified period the animals anaesthetised, terminated, and analysed for abnormalities with respect to a control group. The NOAEL value is then taken to be the highest dose producing no statistically significant variation, whilst the critical end point is the type of variation first noticed. In certain instances Lowest-Observed-Adverse-Effect-Level (LOAEL) values were taken, where appropriate data did not exist. These were for the two phthalates DBP and BBP, which occur as contaminants at low levels, and in consequence a further factor of 5 was incorporated in determining their safety margins.

From early on in the proceedings the two phthalates to come under most scrutiny were to be DEHP and DINP. This is because they had been the most commonly found phthalates in toys and various child-care articles, but also because they each had a margin of safety determined right from the start as being below 100. These particular margins were based on the least reliable available data, provided by Greenpeace and the Danish authorities who had initiated the matter, and varied by a factor of 2,500 and 10,000 respectively from other experimental sources.

Initially DNOP also produced a margin of safety below 100 and in its preliminary position 9th February 1998 the CSTEE declared all three phthalates as giving cause for concern. Later revisions to NOAEL values and exposure doses removed DNOP from the list. By the time of the formal opinion expressed on 24th April 1998 the CSTEE had concluded that only the very low margin of safety for DINP (8.8) caused concern, 'since humans appear to be less sensitive towards the critical effect of DEHP (hepatic peroxisome proliferation)[80] identified in rats'.[81]

4.6 Are phthalates carcinogenic?

DEHP has been found to be hepatocarcinogenic (liver cancer inducing) in rats and mice,[82] and it is accepted that after long-term exposure, peroxisome proliferation (an increase in those parts of cells which generate or break down hydrogen peroxide),

which is the most sensitive change found,[83] acts as an early indicator of this. However there is a marked species variation in response to peroxisome proliferation. Rats and mice are very sensitive, whereas guinea pigs and monkeys appear to be relatively insensitive or non-responsive at dose levels that produce a marked response in rats. There is no indication of human sensitivity.[84]

Yet now, based upon figures 2,500 times greater than from other sources, scaled up by a further safety margin of 100, using the most sensitive critical end point of dubious relevance, and despite the fact that a 1996 risk assessment of DEHP, which reviewed more than 500 studies, concluded that the threat of human liver cancer is extremely unlikely under any anticipated exposure dose,[85] DEHP was considered as giving cause for concern.

Campaigners against phthalates have attached great importance to the fact that the US Environmental Protection Agency (EPA) classified DEHP as a 'probable human carcinogen'.[86] But this decision was taken over 10 years ago and has not formally been re-evaluated since. Not only has the relevance to humans of liver tumours in rodents induced by peroxisome proliferation become more questionable, but our understanding of carcinogenic processes themselves have evolved. Nevertheless in the mid 1980s the US toy industry had removed DEHP from children's products to maintain consumer confidence until further scientific research could be conducted.[87]

Regulation of carcinogens in the United States is still based on the 'no-threshold' assumptions adopted over thirty years ago.[88] Since then however, not only have we become more conscious of the various non-zero doses which the body can tolerate, but our understanding of the biological processes involved, particularly in relation to mitogenic and mutagenic carcinogens,[89] have allowed for a far more sophisticated view than the 'one hit, one cancer' approach which used to determine EPA policy.[90] In addition according to the biochemist who developed the primary test for carcinogenic substances, Dr Bruce Ames, about one-half of all chemicals tested, both natural and man-made, are toxic when tested at high doses in either rats or mice.[91]

Recently the head of the EPA's Science and Policy Staff stated in a section of an article published in the Journal of Regulatory Toxicology and Pharmacology that, 'No evidence exists to suggest that these agents (peroxisome proliferators) are carcinogenic in the human liver'.[92] Health Canada has classified DEHP as 'Unlikely to be Carcinogenic to Humans',[93] the European Commission's own official decision states that DEHP, 'shall not be classified or labelled as a carcinogenic or an irritant substance',[94] whilst the World Health Organisation (WHO) Environmental Health Criteria document for DEHP concludes: 'Currently there is not sufficient evidence to suggest that DEHP is a potential human carcinogen'.[95]

For DINP there is a recognition that 'different commercial products may vary in composition',[96] which might explain the factor of variation in excess of 10,000 between experiments to measure the exposure dose. It has also been found to cause hepatic peroxisome proliferation in rats, but an even more sensitive critical end point has been established. This is an increase in liver and kidney weight after feeding significant dietary levels of DINP for up to 2 years.[97] Scaled up to human levels this is equivalent to a child consuming a sizeable chunk (50 grams) of plastic each day.[98] As Michael Fumento, senior fellow at the Hudson Institute, has said, 'If your child EATS toys, phthalates are the least of your worries'![99]

4.7 Are phthalates endocrine disrupters?

If the potential carcinogenicity of phthalates, in high doses and over long periods of time on rodents, were not relevant to obtain desired restrictions upon their use, campaigners had already prepared themselves to move onto a more emotive critical end point. This shifting of the argument had begun through focusing media attention onto the most extreme possible outcome, presenting phthalates as so-called 'endocrine disrupting chemicals' (EDCs), calling them 'gender benders',[100] and claiming that they mimic oestrogen. This approach successfully generated shock headlines such as 'Human sperm count could be zero in 70 years',[101] and 'Sex change chemicals in baby milk'.[102]

The endocrine system is held to be that complex of processes whereby a number of fundamental bodily functions are kept in check through the action of an appropriate balance of hormones. An endocrine disrupter is then held to be any chemical which interferes with the synthesis, secretion, transport, binding, action or elimination of the natural hormones which are responsible for homeostasis, reproduction, development and/or behaviour.[103]

The popularity of this hypothesis, and the belief that artificial hormones released into the environment through human activity are responsible for the identification of unexplained phenomena upon the endocrine systems of various organisms, in particular aquatic-related life forms, stems from the publication in March 1996 of 'Our Stolen Future' by Theo Colborn, Dianne Dumanoski, and John Peterson Myers.[104]

This book, built upon previous work by Colborn with some of her earlier collaborators,[105] has a foreword by US Vice President Al Gore, and has now been cited as the first reference to the recently released CSTEE Opinion on EDCs.[106] Yet its so-called scientific content has been extensively refuted by those who, amongst others hold that 'none of the authors is a real scientist who conducts scientific research or publishes peer-reviewed studies'.[107]

A review of 'Our Stolen Future' by Professor of Environmental Toxicology, Michael Kanvin, at Michigan State University, appeared under the title 'The Mismeasure of Risk', in the September 1996 issue of *Scientific American*.[108] This described the book as 'not scientific in the most fundamental sense', arguing that 'the authors present a very selective segment of the data that has been gathered about chemicals that might affect hormonal functions', and further that 'it obscures the line between science and policy to the detriment of both', echoing a view expressed some months earlier in *Business Week Magazine* where it had been suggested that 'with its selective use of data, dubious logic and relentless hype, 'Our Stolen Future' ends up doing a serious disservice to its own cause'.[109]

Nevertheless based upon the Colborn book, Greenpeace released their own version a month later under the title 'Taking Back Our Stolen Future: Hormone disruption and PVC plastic'.[110] This also repeated a widely criticised study published in the *British Medical Journal* earlier that year which claimed to provide evidence of a serious decline in the quality of human semen in the UK.[111] Yet even if this widely disputed claim were to be proven true,[112] it would remain to be demonstrated whether this had any causal connection with the release of artificially produced endocrine disrupting chemicals.[113]

The authors of the 1992 study considered to provide the most conclusive evidence of declining sperm counts, Niels Skakkabaek and Richard Sharpe, have since indicated that the implications of their work have been overstated. In the July 7, 1995 of *The Independent* newspaper, the two accused Greenpeace of 'taking something which is a clearly stated hypothetical link and calling it fact'.[114]

Others meanwhile have indicated that 'the major human intake of endocrine disrupters are naturally occurring oestrogens found in foods (Safe, 1995). This exposure is several orders of magnitude higher than the exposure to pesticide EDCs'.[115] Such naturally occurring phyto-oestrogens, commonly found in plants and vegetables such as soya, hops, peas, beans, sprouts and celery, appear to be overlooked by environmental campaigners. Yet Safe calculated daily human intakes of such oestrogens, based on potencies relative to 17 β-oestradiol. Oral contraceptives are found to represent 16,675 μg equivalent per day, and postmenopausal oestrogen therapy would provide 3,350 μg per day. By contrast oestrogen flavonoids in food represent 102 μg per day, whilst daily ingestion of environmental organochlorine oestrogens a mere 0.0000025 μg![116]

Rather obviously then, substances designed to be endocrine disrupters, such as the contraceptive pill, are, whilst those which are not, such as phthalates, are not. However, presumably recognising the sensitivities of potentially alienating over half the constituency they seek to influence, Greenpeace and other environmentalists

chose tactically, not to highlight the extent to which the presence of such substances in the environment, in addition to naturally occurring substances, actually stems from the widespread use of oral contraceptives.

The supposed oestrogenic properties of phthalates have recently been thoroughly examined, both 'in vitro' and 'in vivo'.[117] This research indicates that whilst some of the shorter chain esters (e.g. DBP, BBP) display a weak effect in some 'in vitro' assays at high concentrations,[118] none of the eight phthalates elicited 'in vivo' oestrogenic effects based upon both uterotrophic and vaginal cornification assays, which determine the response of the uterus to hormones as well as their ability to induce the oestrous cycle. This suggests that metabolic events may inactivate the oestrogenic activity of certain phthalates, thereby indicating that whilst 'in vitro' assays may allow prioritisation for further testing, they should be used as a complement to 'in vivo' testing which can more accurately model sensitive processes and interactions.[119]

In addition, numerous multi-generation fertility studies have been carried out on several different phthalates. Again phthalates with short carbon chains include known reproductive toxicants and have produced teratogenic (causing birth defects) and embryotoxic effects at doses well in excess of the NOAEL in continuous breeding studies upon mice, which are known to be more sensitive than rats.[120] Very few teratogenicity studies have been performed in other species. However the most recent two-generation studies demonstrate that exposure of rats to DINP and DIDP in utero, during lactation, puberty and adulthood does not affect testicular size, sperm count, morphology or motility, or produce any reproductive fertility effects.[121]

4.8 The CSTEE Opinion on EDCs

The European Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) within DG XXIV has set up a Working Group which published in March 1999 its own 'Opinion on Human and Wildlife Health Effects of

Endocrine Disrupting Chemicals, with Emphasis on Wildlife and on Ecotoxicology Test Methods'.

Unfortunately the tone of this document is set from its opening line; 'There is growing concern on possible harmful consequences of exposure to xenobiotic compounds that are capable of modulating or disrupting the endocrine system'.[122] Thus 'growing concern' of 'possible' effects now suffices to obtain Commission level action, a trend more recently repeated elsewhere.[123] Indeed the document somewhat self-consciously justifies itself in part on the basis that 'the media and consequently the public at large have (therefore) developed an interest on the subject'.[124]

Apart from citing the widely discredited work of Theo Colborn, the document also lends further credence to the disputed claims over falling sperm counts and the rising incidence of prostate cancer. No doubt Greenpeace and their allies, who have been responsible for a substantial element of the 'growing concern', will draw upon the document itself as further evidence as to the objectivity of their claims.

Whilst the original intention of the work, as revealed through the various CSTEE plenary meeting minutes, was 'to finally produce a report that covers human health and environmental effects of EDCs',[125] the final product placed a far greater emphasis upon wildlife, 'due to the fact that it is where the greatest impact is felt. The human health effects part was therefore correspondingly reduced'.[126] In other words unable to come up with sufficient evidence for effects upon humans, the committee simply decided to play this down rather than highlight the fact.

The document accepts that for humans 'a causative role … has not been verified', and that 'for most reported effects in wildlife (however) the evidence for a causal link with endocrine disruption is weak or non-existing',[127] adding further that 'the mechanisms of pollutant-induced reproductive toxicity observed in wild mammalian species generally remain unclear but could also involve endocrine disruption'.[128]

Needless to say, many of the purported effects upon wildlife are themselves speculative. Two recent studies in the journal *Science* for example, have concluded that defects found in frogs throughout the Western United States, cited in the CSTEE document,[129] may be caused by a trematode, a simple parasitic flatworm, which infects tadpoles and leads to multiple or malformed hind legs.[130] No doubt some will now argue that chemical pollution was responsible for the increase in water snails which act as a key host of the parasite. But this is to reveal such views as based upon simple association, rather than the scientific analysis necessary to provide insights into causal mechanisms and metabolic pathways.

4.9 Reactions to the Dutch 'Consensus Group' study

The only logical outcome of adopting the precautionary principle is to accommodate the lowest common denominator. This effect was perfectly exposed by reactions to the outcome of the Dutch 'Consensus Group' study into the oral leaching of phthalates by adult human volunteers.[131] This coincided with a review of other data made available to the CSTEE subsequent to April 1998, such as an Austrian investigation which appeared to corroborate the results of the Dutch study, and a US Consumer Product Safety Commission report on DINP which showed that the high levels of release that had previously been used could not be reproduced.[132]

The final report by the Dutch 'Consensus Group' study, indicated that the possibility of a baby exceeding the recommended limits was 'so rare that the statistical likelihood cannot be estimated'.[133] It also revealed that previous estimates as to the amounts of time spent chewing on soft PVC products by children had been grossly exaggerated reducing this from 6 hours to a maximum of 3 hours exposure. A joint press release issued by Toy Industries of Europe, the European Council of Plasticizers and Intermediates, and the European Council of Vinyl Manufacturers, assumed that their position had now been vindicated.[134]

The Greenpeace view on the Dutch study at this stage was predictably antagonistic, arguing not only that it had failed in its task to develop a standardised procedure for

measuring the quantities of phthalates leached from PVC, but also, and more pointedly, questioning the integrity of the study group for having representatives from both the toy industry; Mattel, and the chemical industry; Exxon, upon its technical committee.[135] Exxon production facilities in particular had been systematically targeted by activists during their campaign, due to the company being the world's single largest producer of phthalates.[136]

A little over 2 months later however, the CSTEE announced its own views on the new research,[137] and now Greenpeace announced itself to be in full agreement.[138] A new and less extreme determination of the NOAEL value for DINP had been made available,[139] but as this yielded a value four times greater than that derived from the earlier research,[140] the CSTEE decided 'from a precautionary standpoint',[141] to maintain its use of the pre-existing value in its revised assessment. In other words the new evidence was quite simply ignored.

In addition, a study which had examined the effects of exposing female rats to DEHP in drinking water from day 1 of pregnancy to day 21 after the delivery, indicated damage to the testes of the offspring.[142] Despite water intake not having been accurately measured, the NOAEL derived was taken to substantiate an earlier low NOAEL value which had, at the time of the 24 April 1998 opinion, been ignored in favour of that derived from 'a well-performed study'.[143] Now however, the critical effect was taken to be the testicular effects which, although known at the time of the earlier opinion, had not been used.[144]

The recalculated margin of safety for DINP, whilst providing improvement due to the reduction in exposure time, remained below 100, thereby suggesting continued cause for concern. That for DEHP was now both lower than the previous value and also had a critical end-point assumed to be of greater relevance than hepatic peroxisome proliferation, thus actually raising the level of concern. These views were submitted to the DG XXIV Risk Evaluation Unit who in January 1999 suggested 'that the Commission should be looking for a phase out of phthalates as soon as possible'.[145]

4.10 Ever decreasing circles

The official view from the Commission was, by now, hardly contentious as a number of member states had, since the issuing of the last formal opinion on the matter in November 1998, finally been convinced by the various voluntary restrictions in operation, as well as pressed through the actions of environmentalists and consumer groups, to take matters into their own hands. They had started notifying the Commission of their intentions to introduce formal restrictions on such products, particularly those aimed at children under 3 and intended to be placed in the mouth. These included Austria, Denmark, Finland, Greece, Italy, Norway and Sweden, who were all expected to have formal bans in place by the middle of 1999.[146]

Whilst not the subject of this essay, it is interesting to note how the gradual collapse by member states across the European Community increased the pressure on America to follow suit. Despite one commentator's view that, 'Multinational companies are under attack everywhere – but nowhere more than in Europe',[147] it may yet prove to be the case that Europe is just a stepping stone to actions further afield. In the US the Greenpeace campaign took a longer time to become effective, in part due to the fact that DEHP had already formally been withdrawn as a precautionary measure in 1986. Also most pacifiers on the American market are made of latex rather than PVC.

Nevertheless concerned by the direction of events in Europe, the US Ambassador to the European Community, Vernon Weaver had sent a blunt letter to the EU Directorate General for External Affairs in February 1998, stating that 'a sudden ban on products which have been sold for years and which is based on incomplete and perhaps erroneous information could cause trade misunderstandings between the US and the EU'.[148]

With widespread restrictions in place across most of Europe by the autumn however, Greenpeace accelerated its American campaign, releasing a new report on phthalates in November 1998. This amounted to little more than a press release with

footnotes,[149] but led to a flurry of toy manufacturers, including Toys 'R' Us, issuing assurances, as to their intentions to phase out the products.[150]

Three days later, Health Canada, a Government consumer protection body, issued an advisory calling for soft PVC teethers and rattles to be removed from shelves and calling on parents and childcare facilities to immediately dispose of these toys.[151] Then, on 2nd December 1998, when the US Consumer Product Safety Commission (CPSC) released its latest results of a study on DINP which showed that 'the amount ingested does not even come close to a harmful level', it also requested industry, 'as a precaution while more scientific work is done', to remove phthalates from soft rattles and teethers.[152]

In those countries where there had been regulatory successes against toys, the campaign now moved onto medical devices. PVC softened with phthalates provides amongst other products flexible tubing, intravenous bags, catheters and protective gloves. It allows hospitals access to quality disposable items which are durable, flexible, inexpensive and safe.[153]

Yet building upon their earlier gains Greenpeace and others, such as Health Care Without Harm in the US, are seeking to limit or prohibit the use of PVC in healthcare facilities despite there being no evidence as to adverse effects, even amongst patients receiving dialysis for kidney disease, the group most exposed, and hence supposedly at risk, from such products.[154]

PVC plasticised with DEHP is the only flexible material approved by the European Pharmacopoeia for life-saving medical devices such as blood and plasma transfusion equipment.[155] The safety of these materials has been confirmed by more than 40 years of use, with five to seven billion patient days of acute exposure and one to two billion patient days of chronic exposure without any indication of adverse effects.[156] But again companies with a vital interest at stake, both private and public, have proven to be remarkably defensive in their stance.

Baxter Healthcare's own environmental manager in Sweden, Birgitta Lindblom admits for example that 'It's unfortunate that [the Stockholm County Council] have taken a decision that may have tragic consequences for many people. We probably have to shoulder part of the blame ourselves as we have not succeeded in informing the politicians in the County Council about the necessity for PVC in medical products'.[157] Yet Baxter, a world leader in healthcare products, has come under increasing pressure to develop alternative materials to PVC by its own shareholders,[158] despite seeking to indicate that 'in many applications, PVC remains the material of choice'.[159] Unfortunately one of those new materials is currently recognised as having odour problems and causing skin irritation.[160]

Unsurprisingly therefore the European Commission's CSTEE has already initiated investigations into the potential problems associated with their possible replacements. [161] Both adipates and citrates which have started to be used as substitutes in countries where phthalates are no longer available, have been criticised, not least for appearing to offer little toxicological documentation in the literature.[162] In this, the inevitable logic of the precautionary principle has come to the fore. The fear of phthalates has simply been transferred onto the supposed solution.

Finally, it should be noted that the campaign against phthalates forms part of a wider Greenpeace agenda against PVC specifically and the chlorine industry in general. Greenpeace has made it clear that it has no intention of calling a halt to its campaign subsequent to the demise of phthalates, having argued explicitly that 'PVC is a poisonous plastic – replacing phthalates won't solve the problem'.[163]

These views are based upon the fact that through the technical synthesis of certain chlorinated organic compounds, dioxins can be produced as a by-product. These have often been referred to as the most toxic man-made chemicals known, although this accolade is considered by many to be a gross exaggeration.[164] Only exposure to quite substantial doses has ever posed a threat to human health.

Substantial scientific evidence supports the view that dioxin contamination in the environment has dramatically decreased over the last twenty years to their lowest levels this century,[165] despite a three-fold increase in PVC production.[166] This has been helped by the more advanced technology now used for cleaning the products of combustion prior to release into the atmosphere.[167] Nevertheless part of the campaign against PVC medical products consists of highlighting the contribution which hospital waste purportedly adds to atmospheric dioxin levels. In fact PVC forms but a minor contribution, as the vast majority of dioxins are released through natural burning processes, such as forest fires or other wood combusting processes.[168]

5. Retreat from reason

5.1 The consumer agenda

In her speech to the Joint European Parliament and Commission Conference on Food Law and Food Policy in Brussels on 4th November 1997, Consumer Policy and Consumer Health Protection Commissioner, Emma Bonino, placed great emphasis on the increasingly important agenda-setting role of consumers. Suggesting that 'pressure from public opinion and interested bodies has often appeared to be the strongest driving force to guarantee that all necessary measures to protect public health are effectively taken',[169] she endorsed the enormous boost which such organisations had received over the course of the BSE debacle.

Earlier that year Agriculture and Rural Development Commissioner, Franz Fischler, had actively encouraged this approach in direct relation to BSE, indicating that, 'It is time we heard from the consumers. These are the most important people of all in this equation'.[170] Environment Commissioner, Ritt Bjerregaard, too has echoed this line, commenting in addition that, 'Retailers can play a crucial role. They are ecological gatekeepers'.[171] Clearly then, the consumer voice, in all its guises, is actively being sought and promoted across the board.

But whilst the advent of a better informed and more questioning attitude by consumers could be welcomed as long overdue, there appears to be a lack of serious

debate as to who 'the consumers' actually are. Such views appear to express an inherent assumption that there is a singular, or at least majoritarian, consumer voice or interest, which finds expression through existing consumer groups. It is worth noting that support for this approach as being either potentially effective or truly representative is not without criticism.[172]

Also, the broader climate within which the new structures, roles and procedures are arising should be recognised as one which prioritises caution over production, and risk over opportunity.[173] This is not to suggest a wilful desire to engender panics or impose restrictions, but rather that society as a whole has become increasingly risk-conscious, and even risk-averse.[174]

It has been argued that, 'We no longer choose to take risks, we have them thrust upon us',[175] and further that, 'Society becomes a laboratory, but there is no one responsible for its outcomes'.[176] As a consequence the drive to regulate, or re-regulate, to restore a form of moral responsibility, has become a strong one in the 1990s. But there is also a growing aversion to official regulation, which suggests that to be effective regulation may need to occur more informally, at the level of the firm or the individual, through self-imposed restrictions, which may be externally-monitored.[177]

Echoing this mood, Emma Bonino herself has suggested that, 'there are times when legislation does not happen, and we need to ask ourselves whether it is better to have nothing at all or self-regulation in some form or other'.[178] Again, in a similar vein, the *Financial Times* columnist Lionel Barber has astutely observed in relation to the Commission, that 'the flood of EU legislation accompanying the single market has slowed to a trickle. Today, Brussels is using peer pressure and voluntary codes of conduct to encourage minimum standards of compliance'.[179]

As a consequence a climate has been created whereby social control is increasingly exercised, or moderated through self-restraint, and marshalled by the explosion of highly vociferous, and inevitably self-appointed representatives of consumer interests. If left unchecked this can only lead to instances of overreaction and

unnecessary interference, justified through an appeal to a supposed consumer mandate.

5.2 The decline of rationality

Of even greater concern however, is the suggestion that 'consumers are not easily convinced by scientific evidence and advice'.[180] Indeed the Commission's own Consumer Committee,[181] responded to the 'Green Paper on The General Principles of Food Law' by proposing the application of the precautionary principle 'even where there is no known scientific uncertainty'.[182] Furthermore it argued that when the scientific evidence, which it recognised to be necessary, was available, that 'too great an emphasis on this may be undesirable from the consumer's point of view'.[183] These views again raise questions as to who 'the consumers' are, and how their interests are to be represented.

More damagingly they present science as just one of many 'readings' of the world. This suggests that no amount of experimentation or evidence would ever suffice to determine the outcome of an issue, and effectively recognises that the assessment of risk is a social, rather than a scientific, exercise. Such an approach merely extends that proposed by the official Commission documentation itself, which had called for the precautionary principle to be highlighted, and had even gone so far as to suggest that, 'there may be demands … to go further in the area of the health protection measures than the scientific evidence suggests is necessary'.[184]

The 'First biannual BSE follow-up report', communicated to the European Parliament in May 1998, took this approach to its logical conclusion, suggesting the need for 'the possibility of taking into account minority scientific views',[185] in other words of accepting worst-case scenarios regardless of what the majority of scientists say. But when hard facts and analysis are replaced by individual views, emotion can take over from reasoned debate, and in a climate of heightened sensitivity to risk, the only possible outcome is to adapt to the lowest common denominator.

Reflecting the growing confusion and what has elsewhere been dubbed a 'retreat from reason',[186] Jim McQuaid, Director of Science & Technology for the UK's Health and Safety Executive, has suggested, in a general guest editorial about risk for a new journal, that 'there are then great difficulties in seeking a rational debate – rational in the sense of being based on a consensus on the evidence that matters and on the implications for a course of action that will engender support'.[187]

But a notion of reason as depending on 'consensus' and 'support', is not one which would have been recognised by Galileo or Darwin. It effectively allows for the eventual rejection of science altogether. The hard-done-by consumer has become the alternative voice which now has to be taken into account within all decision making. Such views, supported by the supposed authority of the precautionary principle, and endorsed by environmentalist and feminist critiques of science, have increasingly become accepted by all social actors. They look set to have a profound impact upon the scientific community, as well as the business and social worlds dependent upon it.

If scientific reason based upon quantifiable and repeatable evidence, is just one amongst a number of competing views, then it need no longer be the arbiter for decision-making, particularly when the concerns of consumer-groups or environmentalists have been raised. As Environment Commissioner, Ritt Bjerregaard rhetorically asked in a speech given at a brainstorming workshop on chemicals in the EU, 'Should a lack of sound scientific evidence stand in the way of action?'[188] This echoed a similar call for action expressed by Dr. Ann Soto, an early collaborator of Theo Colborn, during a 1996 BBC Horizon programme on EDCs, when she exclaimed, 'The stakes are so high here that I don't believe we can wait'.[189]

5.3 The precautionary principle

The precautionary principle departs from the usual scientific rationale in that it reverses the burden of proof. Science proceeds on the basis of evidence, which is a positive finding that is reproducible. The precautionary principle on the other hand, postulates that all assumptions can be considered valid unless the contrary has been

demonstrated. This negative proof is impossible to ascertain. The precautionary principle thus contributes to the deconstruction of the process leading to scientific opinion, since it distances conclusions from evidence-based rationale. It further considers that valid decisions can be made on beliefs without requiring solid evidence.

An international agreement on the precautionary principle was reached during the United Nations Conference on the Environment and Development (UNCED) in Rio de Janeiro in 1992, becoming part of Agenda 21. This is laid down for environmental matters within the European Community, in the Maastricht Treaty under Article 130r. Recently the Commission's Consumer Committee has argued for the principle to be extended into the realm of food law.[190]

A Commission communication of December 1996,[191] announcing the review of directive 90/220/EEC concerning the deliberate release of genetically modified organisms into the environment now seems set to bring a much needed process of clarification about these issues to a head. A detailed communication on the precautionary principle is also expected shortly.

The principle is subject to much debate, particularly in relation to the tension between demonstrated actual risk and anticipated plausible risk, as well as the problems associated with enforcing what are inevitably variable standards.[192] A further problem of using the precautionary principle is that all results inevitably become provisional.[193] Targets are relative, and no conclusive outcomes can ever be reached, as situations continuously await clarification through further analysis. In this respect the investigations into phthalate toxicity have been perfect exemplars.

Such an approach has also inevitably encouraged the release and use of results prior to peer reviewed publication. In addition, frank and open discussions held by interested parties are increasingly entering into the public domain through a desire for greater 'transparency'. But the views expressed through both of these means are not the same as reasoned reflection or verified evidence, and should therefore not be used

in the establishment of policy, as was for instance the case in the then UK Agriculture Minister's decision to ban beef on the bone.[194]

Of more direct concern to the main subject of this paper has been the fact that some supposed research into the endocrine disrupting properties of phthalates was released through the media, rather than the academic literature. Indeed in one such high-profile instance, a full peer-reviewed version of the work had still failed to appear over two years after raising significant concerns through articles in the popular press,[195] despite assurances that the work 'is still in the phase of being written up'.[196]

Dr. André Prost, Director of Non-Communicable Diseases for the World Health Organisation Headquarters in Geneva, has also expressed reservations as to the use of the precautionary principle arguing that, 'precaution becomes a political instrument used on a selective basis by certain sectors of society in support of their own beliefs'.[197] He goes on to suggest that situations can only be made worse through the advent of a 'victimisation culture', concluding that, 'If the dilemma facing the policy-makers results in a systematic application of the precautionary principle, it will lead to abstention and paralysis in innovation and technology development'.

Implicit within the Commission's approach however, is the assumption that the precautionary principle is a zero-cost, or something-for-nothing option. In reality, apart from the narrow economic costs to those businesses directly concerned, there is a far greater social cost which has yet to be taken into account. At an immediate level replacing plastic medical devices or toys, opens the door to the dangers of injury and infection from replacement materials, which are either less flexible or have been subject to less scrutiny. Phthalates are amongst the most understood of organic compounds. There is simply not a single shred of evidence that they have ever harmed any human being. Similarly, banning toys from chocolate eggs or crisp and cereal packets would quite simply make bad law. The statistical evidence and logic show that it is the food items themselves which should be banned, or alternatively all small objects.

More important has been the amount of time and effort, let alone cost, expended by all sides of this dispute. Whilst the attention of large numbers in the scientific community and others has been turned onto these products countless numbers of people, right across the globe, continue to die of diseases for which cures might be found if only the resources expended elsewhere were to be made available.

Finally, the panic and hysteria which has been created around these issues reflects a far wider loss of trust within society rather than any inherent problem with the products themselves. The real cost will be that of a generation of young people brought up to live in fear from the dangers posed by harmless products, and questioning the ability of science to cast light on such issues. A broader climate of fear is being created which in turn will lead many to an even more misguided assessment of risk and greater inflexibility towards innovation and change.

6. Conclusions and Recommendations

1. A widespread and paralysing sensitivity to 'risk' has entered the consciousness of politicians, public officials, the media, manufacturers and retailers. The continuous elevation of risk over opportunity, and caution over production, can only damage business, reasoned debate and ultimately, consumers. Further research into, and public debate about, this phenomenon, to which there can be no easy solutions, is needed with a view to countering it.

2. The BSE debacle has catalysed a sea-change in the way that the European Commission handles consumer policy and consumer health protection matters. In particular the 'precautionary principle' has explicitly been adopted as a guide to analysing such issues, but this is not a zero-cost option either financially or socially. An urgent, multi-national and public critique is needed to explore the usage, limitations and costs of this approach.

3. Growing aversion to official regulatory interference is creating a climate whereby social control is increasingly exercised, or moderated, through self-restraint. This 'hidden' self-regulatory framework is beginning to have an affect as real as its

formal legal counterpart. Efforts need to be made to measure and assess the impact of this, both in quantitative and qualitative terms.

4. The attack upon scientific rationality stemming largely from environmentalist and feminist critiques needs to be rigorously examined. In particular, more investigations need to establish the limitations of consensus, the plausibility of holding simultaneously competing views on an issue, and the relationship between individuals, society and the natural world.

5. There is a growing tendency, amongst a range of social agents, to pre-publish outcomes of scientific inquiries (some of which never achieve peer review), or to release the frank and open deliberations of scientific committees in the pursuit of 'transparency'. If we are not to curtail such discourse, the views thereby expressed need to be more clearly promoted as opinions rather than as facts.

6. In the absence of a wider and more polarised political debate, the media has found itself promoted to a role of increasing social significance as a source of comment and opinion. As a consequence, far higher standards of journalistic competence are to be expected than previously, particularly within areas requiring technical and/or scientific expertise, if the media is to be perceived as establishing a degree of objectivity.

7. Existing consumer groups are far from representative and therefore the agenda they express needs to be weighted accordingly. Research is needed to present alternative and counter-balancing arguments from those who perceive the benefits of development. This would prevent consumers from being used as an ideologically driven stage army and, in many instances, allay unnecessary anxieties.

8. The interests of private firms have increasingly come under the scrutiny of public bodies, and their behaviour affected in accordance. This process is 'one way', as attempts by the private sector to influence public debate are perceived as self-

serving and hence unbalanced. Attention needs to be given as to how counter-balancing views from private actors and agencies can effectively enter into public discourse.

9. The existing civil liability system should be reviewed with a view as to its appropriateness for dealing with those instances when firms are found to be acting negligently with respect to consumers. This system should handle matters efficiently and at a scale commensurate to the problems created. Any proposed new regulatory mechanisms should first be examined for their hidden social, as well as economic, costs.

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