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The USA and the EU: Two perspectives on phthalates

(1) Introduction

In this presentation I will analyze some of the controversial issues related to the use of phthalates in the production of toys and other products made of PVC for children under three years of age. I will focus on the origins of the phthalates ban by the European Union (EU) and the consequent reactions from the European and American industries. Secondly, I will examine how the precautionary principle was applied in the decision to prohibit the use of phthalates.

This paper is part of an ongoing research project focusing on the emergence of the precautionary principle and legislative regulation of polyvinyl chloride (PVC).

Phthalates (phthalic esters or benzenedicarboxylic acid esters) are colorless, odorless liquids, used mainly as plasticizers/additives of PVC in making the material softer and more elastic. Plastic-coated PVC has a wide range of applications. It is used in medical tubing and blood bags, footwear, stationery items, flooring and wall coverings, electrical cable insulation, clothing, and toys. Phthalates are also used in non-PVC applications such as paints, rubber products, adhesives, and some cosmetics.¹ Despite their broad range of applications and importance, the phthalates used in the making of flexible PVC do face a fair amount of prohibitive regulations and bad publicity.²

Many of the concerns about the potential dangers posed to children's health by phthalates, and particularly by Diisononyl Phthalate (DINP), one of the principal components of PVC toys, began in early 1997, when several groups and agencies in Denmark found what were to be considered unacceptable levels of DINP leaching from teething rings made of PVC imported from China.³ Since then, public interest groups and regulating agencies in Europe, Canada, and the United States began to speak out about the potential adverse effects to children's health, due to the migration of DINP from the toys they put in their mouths.⁴ The concerns were centered on the potential chronic effects to the liver and kidneys since studies with rodents exposed to high doses of DINP revealed that they were developing carcinogenic tumors in these organs.

The particular concern about the risks of phthalates for children is due, on the one hand, to the relative immaturity of their somatic systems, and on the other, to the ease of their exposure to phthalates through toys and other items for children.⁵ Many toys and teething products on which infants and small children suck and chew, as well as bottles and sterilizers, are made from PVC. Such a reality lead to the idea that children under three years old might be suffering certain risks as a consequence of this migration of phthalates from toys and other articles put into their mouths.⁶

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¹ "Phthalates: a ban too far?", *J. Environ. Monit.*, Vol. 2, Issue 1, 2000, p. 4N.

² Alexander H. Tullo, "Cutting Out Phthalates", *Chemical & Engineering News*, Vol. 83, No. 46, November 14, 2005, pp. 29–31.

³ Chris F. Wilkinson and James C. Lamb, "The Potential Health Effects of Phthalate Esters in Children's Toys: A Review and Risk Assessment", *Regulatory Toxicology and Pharmacology*, Vol. 30, 1999, p. 141.

⁴ *Ibid.*, p. 140.

⁵ "Phthalates: a ban too far", *op.cit.*, p. 5N.

⁶ *Ibid.*

(2) Europe and the phthalates ban

The sensitive nature of the issue of children's health undoubtedly contributed to the beginning of a political discussion about phthalates.⁷ As such, in 1998 the EU began to discuss the possible risks phthalates might pose to children's health. In November 1999, evoking a "serious and immediate risk" the body (EU) proposed an emergency ban of six phthalates (DINP, DEHP, DBP, DIDP, DNOP and BBP) in all toys with the likelihood of being placed in the mouths of children under three years of age.⁸ It was the first time that the European Commission (EC) initiated an immediate prohibition, effective throughout the EU, under the General Product Safety Directive.⁹

Given their wide range of applications, the effects of phthalates on the environment and on health have been extensively studied. Phthalates, therefore, are one of the most investigated compounds, and consequently one of the best understood, in the world.¹⁰ Moreover, the risks of DINP have been the object of an extensive scientific evaluation with the approval of scientific experts from various EU Members States.¹¹ This assessment explicitly states that "there is no risk to human health or to the environment from the use of DINP in any application — including toys intended to be put in the mouth by children under three years old".¹² Nevertheless, the fears continue and the controversy concerning the risks posed to children by phthalates in toys continues. The principal point of contention is related, on one hand, to the quantity of phthalates that leaches from the toys, and on the other, to the amount ingested by the children.¹³ However, published reports indicate the quantity of DINP ingested by children to be substantially below the levels that might cause harm.¹⁴

Phthalates thus appear in the European regulatory agenda for the first time in the end of 1990's, after the announcement of the Nordic countries' findings. And as will be further examined below, the timing of this legislative process may also have been affected by the onset of a series of "inflammatory" campaigns waged by Greenpeace activists against the use of PVC toys.

In essence, the ban in Europe of phthalates in toys and other articles intended to be put in the mouths of children under three years of age was based, on one hand, on fears of their potential migration levels in toys when chewed and sucked by children for long periods of time, and on the other hand, on the absence of tests to control for such levels of migration.¹⁵ The Committee on Toxicology, Ecotoxicology, and the Environment (CSTEE), a European scientific commission that had been called upon to examine the dangers of phthalates plasticizers, concluded that few or no children were at risk when exposed to toys containing DINP. But in spite of such results, the EU, surprisingly and against the opinion of its own scientific committee, went on to propose the ban as a precautionary measure, underscoring the lack of any thorough test that validated the true migration levels of phthalates in toys.¹⁶ Such a standing on the part of the EU was met with explicit disapproval by the CSTEE. The commission accused the EU of incorrectly interpreting its words, and consequently expressed their disagreement with the emergency ban, considering it unjustified.

⁷ *Ibid.*

⁸ DINP – di-isononyl phthalate; DEHP – di-2-ethyl hexyl phthalate; DBP – dibutyl phthalate; DIDP – diisodecyl Phthalate; DNOP – di-octyl phthalate; BBP – benzylbutyl phthalate. *Ibid.*

⁹ Kris Christen, "European Union bans phthalate softeners in baby toys", *Environmental Science & Technology*, January 1, 2000, Vol. 34, Issue 1, p. 11A.

¹⁰ "The Phthalate Esters Panel of the American Chemistry Council Statement on the Centers for Disease Control and Prevention (CDC) National Report", March 21, 2001;
<http://www.phthalates.org/mediacenter/panelstatement.asp?ID=28>.

¹¹ European Council for Plasticisers and Intermediates (ECPI), "Should toys containing phthalates be banned?", <http://www.pvc-toys.com>.

¹² *Ibid.*

¹³ "Forum" *Environmental Health Perspectives*, Vol. 107, No. 6, June 1999, p. 294.

¹⁴ *Ibid.*

¹⁵ US Product Safety authority agrees with use of DINP in toys, 22 February 2003;
<http://www.ecpi.org/pressrelease/details/index.asp?id=8>.

¹⁶ European Council for Plasticisers and Intermediates (ECPI), "Should toys containing phthalates be banned?", <http://www.pvc-toys.com>.

(3) The ban and European industry

Surprised by the ban, Europe's plasticizer industry reacted negatively, accusing the measure of being incomplete and labeling it "a measure that just does not relate to the size of the problem".¹⁷ David Cadogan, director of the European Council for Plasticizers and Intermediates (ECPI), the organization that represents the European plasticizers industry, went even further, accusing the decision of being unilateral, not reflecting, and basically not respecting the scientific committee's opinions. In its report, the commission did not mention any serious or immediate risks, previously a necessary condition for the issuance of an emergency ban.¹⁸ Cadogan went on to point out that the responsibility for any future health risks to which children might be exposed would lie with those who enacted the ban. Such risks might occur given that, as a result of the ban, toy manufacturers would be compelled to search for alternative products whose toxicological profiles were unknown or less researched than those of phthalates, which had been used for more than forty years without any known cases of harm to the health of children.¹⁹

The European chemical industries and toy producers hoped that a new test on the migration of phthalates would put an end to the legislative confusion about PVC toys. If such a test were developed, it would be possible to impose a Europe-wide standard limit for migration levels.²⁰ This measure would avoid great losses for commerce, as the ban would inevitably lead to a decline in sales, imports, exports and the manufacture of such articles as teething rings and pacifiers, as well as to the removal of all articles already in circulation.²¹ In fact, as a consequence of the ban, and in order to safeguard the interests of the consumers, the PVC toy industry throughout Europe presented a proposal to phase out soft PVC toys from the market on a voluntary basis.²² (Ninety percent of the manufacturers agreed to remove phthalates from rattles and teething rings beginning in early 1999.) (The EU did not accept this proposal because it doubted that all of the manufacturers would make the voluntary commitment.) The industrialists were nearly unanimous in reacting negatively against the ban. They argued that the biggest losers would be consumers, whose choices would be either considerably more limited by the lack of plasticizers or they would pay much more for products made of substitutes as yet unidentified and not as well studied as phthalates.²³

Representatives of the industry state:

It is very concerning that legislators are ignoring the potentially much greater dangers of forcing manufacturers to turn to the use of alternative plasticisers about which far less is known with regard to possible human health and environmental effects.²⁴

The ECPI continues, stating:

Some of the potential alternatives, including many 'natural' sounding products, are known to contain toxicants which can have adverse health effects and which can be extracted by mouthing.²⁵

For the ECPI,

Preventing the use of plasticisers which have been vigorously researched and which have been positively found to be safe is undefendable, even on the basis of the precautionary principle.²⁶

¹⁷ Kris Christen, *op. cit.*

¹⁸ *Ibid.*

¹⁹ *Ibid.*

²⁰ *Environmental Science & Technology*, October 1, 1999, Vol. 33, Issue 19, pp. 398 A-399A.

²¹ "Momentum grows for phthalates", *J. Environ. Monit.*, Vol. 1, Issue 5, 1999, p. 89N.

²² Kris Christen, *op. cit.*

²³ "Greenpeace Targets Mattel; Toy Company Complies", November 26 1999;
<http://www.ecpi.org/index.asp?page=54>.

²⁴ European Council for Plasticisers and Intermediates (ECPI), "Should toys containing phthalates be banned?",
<http://www.pvc-toys.com>.

²⁵ *Ibid.*

In the opinion of Tim Burns, director of the Vinyl Institute, the EU's decision to ban phthalates in toys for children under the age of three, is not only a bad politics, but also dangerous.²⁷ Such a decision raises more questions than answers:

What will soft toys be made of? Do alternative plasticizers have as much scientific study supporting them as phthalates do? Most important, how is the public good served by policy making that declares an emergency without significant new evidence of a problem?²⁸

In fact, in the wake of the ban, many countries introduced unilateral restrictions, leading the industry to express its concern with this fragmentation that, in certain respects, would only serve to weaken confidence in all European policy dealing with chemical products.²⁹

(4) The US and the phthalates controversy

A – Scientific evidence

The debate on phthalates in the US was less heated than in Europe.³⁰ In 1998, following the measures taken by Danish and Austrian authorities, the US Consumer Product Safety Commission (CPSC), the body responsible for toy safety regulations, developed its own study on the effects of DINP in toys and other PVC products for children.³¹ The CPSC developed the study after having received a petition brought by representatives from eleven different consumer groups demanding an analysis of PVC toys. In its report, published in December of 1998, the CPSC concluded that

few if any children are at risk from the chemical because ... the amount that they ingest does not even come close to a harmful level.³²

The final decision of the CPSC on this issue was based, in part, on a new study of the mouthing habits of children.³³ Its analysis showed that even the children who chewed the toys most (the 95th percentile) would ingest DINP at levels very much below the acceptable daily intake level.³⁴

In June of 1999, another independent panel, convened by the American Council on Science and Health (ACSH) and lead by C. Everett Koop, announced its findings on phthalates. The members of the panel reviewed a vast body of scientific literature, published and unpublished in the US, Canada and Europe, in order to assess the potential risks of the two most widely used phthalates: DINP (used in the production of toys) and Di-(2-ethylhexyl) phthalate (DEHP) (used in many soft PVC medical devices).³⁵ They concluded that the phthalates used in these products posed no threat to children or patients.³⁶

Based on this evidence, the panel concluded that DINP and DEHP were not carcinogenic and nor did exposure to these compounds have any dangerous effects.³⁷ In addition to these conclusions, the researchers also reaffirmed that the toxicology and biochemical mechanisms of these substances were

²⁶ *Ibid.*

²⁷ "European Ban on Phthalates in Toys Flies in Face of Decades of Safe Use", November 11, 1999; http://www.vinyltoys.com/docs/news-info/vi-eur_phth11_11_99.html.

²⁸ *Ibid.*

²⁹ "Phthalates: a ban too far", *op. cit.*

³⁰ *Ibid.*

³¹ *Ibid.*

³² *Ibid.*

³³ "CPSC Validates Use of DINP in Vinyl Toys", February 22, 2003; <http://www.phthalates.org/mediacenter/panelstatement.asp?ID=42>.

³⁴ *Ibid.*

³⁵ ECPI, "US Independent Expert Panel Confirms Safety Of Phthalates", 22 June 1999; <http://www.ecpi.org/pressrelease/details/index.asp?id=6&startday=1&startmonth=1&startyear=1998&endday=30&endmonth=6&endyear=2006&keyword=>

³⁶ *Ibid.*

³⁷ *Ibid.*

quite different in rodents and humans. Therefore, it would be wrong to directly extrapolate the studies effectuated in mice and rats to the health of humans.³⁸

A comparative analysis of the findings of the scientific commissions in both the US and in Europe leads us to conclude that, between the two, there are no differences in opinion on the effects of phthalates on children's health. Similarly, within the industries of both continents, opinions also coincide on this issue. As we will see in the following section, the differences are, instead, found primarily at the political level.

B – US government and industry

Citing a lack of scientific evidence, both the US government and industry vigorously opposed the EU's ban on soft PVC toys.³⁹ Despite its well publicized objective to safeguard children's health, the Clinton administration, always concerned with commercial interests, aggressively pressed the EU to obstruct the ban on PVC toys.⁴⁰

The industry, along with various North American agencies, supported by the conclusions of Koop, the CPSC, and the Chronic Hazard Advisory (a body of experts nominated by the National Academy of Sciences), immediately began to publicize the safety of their PVC products. In their opinion, the long debate over the safety of PVC toys containing DINP had come to an end.⁴¹

Marian Stanley, director of the Phthalate Esters Panel, an association of the American Chemistry Council composed of the principal manufacturers of phthalates in the United States, delighted in the results of the CPSC. She expressed the satisfaction of the panel, stating:

We are pleased that rational, science-based decision-making has prevailed in this regulatory process. For anyone willing to look at the evidence, the great vinyl toy scare is history. Five years of intense study by a panel of independent experts and the CPSC scientific staff, including some new, detailed research on the mouthing habits of young children, has finally put the unfounded vinyl toy scare story to rest. The petitioners have had their concerns heard fully and fairly. Now it's time to move on.⁴²

Another industry representative, David Miller, president of the Toy Industry Association (TIA), formerly Toy Manufacturers of America, Inc. (TMA), in light of such results, which in his opinion would resolve the arisen controversy, stated that justice had be done for the industry. According to the TIA, the vinyl plastics containing DINP have, for 50 years, proven their value as appropriate and efficient materials in the manufacture of toys.⁴³

We feel vindicated. We think DINP is a good material and we hope it can be used again in children's products because it's the best material out there.⁴⁴

The TIA, proclaiming toys' safety a principal priority of the industry, accused the "watchdogs" of provoking alarmism and promoting a campaign of counter-information, even in the face of scientific

³⁸ *Ibid.*

³⁹ "Commission Unlikely to Take Action On PVC in Toys Until Fall, Official Says", *International Environment Reporter(News)*, Vol. 21, No. 13, June 24, 1998.

⁴⁰ Charlie Cray, *Experimenting on Children* in "Rachel's Environment & Health News", No. 603, 17 June, 1998; <http://www.rachel.org>; see also "Phthalates: a ban too far", *op. cit.*, p. 6N.

⁴¹ Toy Industry Association, *Consumer Product Safety Commission Denies Petition to Ban PVC Use in Toys*, February 21, 2003.

⁴² "CPSC Validates Use of DINP in Vinyl Toys", *op. cit.*

⁴³ Toy Industry Association's, "Statement Concerning The Consumer Product Safety Commission's Chap Report On Diisononyl Phthalate (DINP)", June 19, 2001.

⁴⁴ "Statement of the Phthalate Esters Panel of the American Chemistry Council on The U.S. Consumer Product Safety Commission Chronic Hazard Advisory Panel's (CPSC CHAP) Evaluation of Diisononyl Phthalate (DINP)", June 19, 2001 (<http://www.phthalates.org/mediacenter/panelstatement.asp?ID=26>).

evidence, against phthalates, which had been used for many years in the production of toys.⁴⁵ The association also points to its history of more than six decades of experience in toy safety, noting:

Toys produced and sold in the United States are not only more highly regulated and monitored than in any other country in the world, but also the safest.⁴⁶

(5) Greenpeace

In contrast with the aforementioned positions of the industry and scientific panels are those of Greenpeace, the environmental group accused of agitating consumers and governments with aggressive campaigns against the use of PVC toys. For some in the industry, the environmental groups' actual target has long been PVC industry as a whole.⁴⁷

In Greenpeace's opinion, the regulations and directives introduced in Europe to deal with the problems with dangerous chemical products have been terribly slow in coming and completely inadequate.⁴⁸ It argues that the praiseworthy objectives of protecting human health and the environment, consecrated in the EU Treaty are, in practice, reduced to long debates on acceptable exposure, economical disadvantages, and legal responsibilities.⁴⁹ For this reason, the organization assumes a radical position, favoring the elimination of dangerous substances, instead of dispensing further efforts on attempts to "manage" the risks and exposures at what are considered to be "acceptable" levels. As a solution, Greenpeace calls for the use of alternative materials to PVC plasticizers, and adherence to the precautionary principle to resolve the crisis of chemical products.⁵⁰

(6) Phthalates and the precautionary principle

The phthalates debate provides an important example of how the precautionary principle has been applied. Several countries have adopted this principle in order to limit exposure to phthalates due to a lack of scientific evidence. While such unequivocal scientific proof is yet awaited, we might ask: under which circumstances should we resort to precautionary action?⁵¹ In the opinion of EU policy-makers, given a lack of evidence, a precautionary principle may justify immediate action.⁵² For its critics, the principle is the latest manifestation of the "paralysing sensitivity to risk" of European environmental policy.⁵³ The precautionary principle has produced a seemingly endless controversy, in part because its critics have interpreted many of the "precautionary" decisions as veiled forms of trade protectionism.⁵⁴

But the principle's biggest problem as a political tool lies in its extreme variability in interpretation.⁵⁵ The term "precautionary principle" is a translation to English of the German word "Vorsorgeprinzip", used in German environmental policy. In 1998, a consensual definition described the precautionary principle as:

when an activity raises threats of harm to human health or the environment, precautionary measures should be taken, even if some cause and effect relationships are not fully established scientifically.⁵⁶

⁴⁵ Toy Industry Association's, "Statement Concerning The Consumer Product Safety Commission's Chap Report On Diisononyl Phthalate (DINP)", *op. cit.*

⁴⁶ *Ibid.*

⁴⁷ Bill Durodié, "Calculating the cost of caution", *Chemistry & Industry*, 6 March 2000, p. 170.

⁴⁸ <http://www.greenpeace.org.uk> ; (<http://www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/5585.pdf>).

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*

⁵¹ "Proof or precaution?", *J. Environ. Monit.*, Vol. 2, Issue 1, 2000, p. 7N.

⁵² *Ibid.*

⁵³ *Ibid.*

⁵⁴ Kenneth R. Foster; Paolo Vecchia; Michael H. Repacholi, "Science and the Precautionary Principle", *Science*, Vol. 288, No. 5468, May 12, 2000, p. 979.

⁵⁵ *Ibid.*

⁵⁶ Peter L. deFur and Michelle Kaszuba, "Implementing the precautionary principle", *The Science of the Total Environment*, Vol. 288, 2002, p. 155.

Despite the precautionary principle's many and varied interpretations, in its simplest form the principle consists of four basic elements. In their article entitled "Implementing the precautionary principle", deFur and Kaszuba identify these four elements as follows:⁵⁷

- 1 – there is a threat of harm, either credible or known;
- 2 – the situation presents a lack of scientific certainty or evidence;
- 3 – cause and effect relationships are not yet proven;
- 4 – there is a necessity or duty to act.

In applying the principle to the phthalate's case, the EU's decision to ban PVC toys appears to have been based more on political rather than scientific criteria. Such an assessment is based on the weak and uncertain nature of the evidence evaluating the potential risks to human health; for example, the lack of epidemiological studies for understanding and characterizing the exposures of potential high-risk groups, such as babies, patients and pregnant women.⁵⁸ Even in studies of laboratory animals, there are important gaps in the data, especially with respect to the exposure to phthalates for prolonged periods and over multiple generations.⁵⁹ There also exists a lack of reliable analytical methods for assessing the migration of phthalates from PVC toys and other products for children and medical devices.⁶⁰ In the absence of such data, an acceptable solution might include the substitution of new materials for the phthalates in question. However, according to Bill Durodié, preeminent scholar and critic of the precautionary principle at the London School of Economics, the fears thus far held with respect to phthalates would then be transferred to the substitutes within the framework of the precautionary principle.⁶¹

(7) Conclusions

Since the introduction of the emergency ban in early 2000, the EU had reached an impasse on the phthalates issue as a result of concerns about the possibility of phthalates migration in certain PVC products. In contrast, the debate in the US never reached such a degree of controversy. The federal government readily accepted its scientific committee's findings proclaiming the safety of phthalates, and even lobbied against the ban in Europe. At the centre of the debate lies the question: how and to what degree must we be prepared to eliminate the risk?⁶² For some researchers, the evidence on human exposure provides conclusive proof that phthalates do not constitute a health risk, even for vulnerable groups, such as children and patients.⁶³ For others, exposure alone does not constitute sufficient proof, given the importance of a deeper understanding of the nature and relevance of the underlying biological mechanisms in determining the effects of phthalates migration.

Due to the overwhelming evidence against the allegations of carcinogenicity and the conclusions that there is no risk for the use of DINP in toys and baby care items put in children's mouths, the necessity of any permanent legislation may be called into question; particularly given the uncertainty as to whether or not the substitution of phthalates or soft PVC may actually benefit children's health.⁶⁴

In the words of Durodié, the ban is no more than a cowardly attempt on the part of the European Commission to legitimize its authority, while appealing to consumers in the name of health protection.⁶⁵

⁵⁷ *Ibid.* p. 157.

⁵⁸ David Kriebel et al, "The Precautionary Principle in Environmental Science", *Environmental Health Perspectives*, Vol. 109, No. 9, September 2001, p. 872; See also "Phthalates: a ban too far?", *op. cit.*, p. 6N.

⁵⁹ David Kriebel et al, *Ibid.*

⁶⁰ "Phthalates: a ban too far?", *op. cit.*, p. 6N.

⁶¹ Bill Durodié, *op. cit.*, p. 170.

⁶² "Proof or precaution?", *op. cit.*, p. 7N.

⁶³ *Ibid.*

⁶⁴ European Council for Plasticisers and Intermediates (ECPI), "Should toys containing phthalates be banned?", <http://www.pvc-toys.com>; Bill Durodié, "Calculating the cost of caution", *Chemistry & Industry*, 6 March 2000, p. 170.

⁶⁵ Bill Durodié, *op. cit.*, p. 170.

Durodié also accuses Greenpeace of having orchestrated intimidation tactics and having made inflammatory comments about “corpses” and “Russian roulette,” and therefore having played a central part in this decision.⁶⁶

In a similarly critical vein, the industry expressed its conviction that this decision will surely place into doubt the EU’s procedures for evaluating the risks of chemical substances, and even more so, the future process of Registration, Evaluation and Authorization of Chemicals (REACH), the Union’s chemical regulation agency.⁶⁷ Echoing this sentiment, a representative from the Toy Industries of Europe declared that the ban would have

... a serious and negative impact on the toy industry and will set a dangerous precedent for REACH and sound science ...⁶⁸

During this presentation, some of the points I have attempted to highlight have included: the divorce between politics and science, the scientific and technological ignorance of alternative substances, and the difficulty in agreeing upon a standard conception of what does and does not constitute sufficient scientific evidence. These issues, coupled with the fact that we must always and instinctively take precaution to avoid the many and various risks with which we are daily faced, and in addition to other questions not yet raised, we might then ask the question: When and under which circumstances is such a ban appropriate?

⁶⁶ *Ibid.*

⁶⁷ “Phthalate ban final”, *J. Environ. Monit.*, Vol. 6, Issue 11, 2004, p. 135N.

⁶⁸ *Ibid.*