The Availability of Substitutes for Soft PVC Containing Phthalates in Certain Toys and Childcare Articles

Final Report - July 2000

prepared for

European Commission, Directorate-General Enterprise

by

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EXECUTIVE SUMMARY

1. Background

This report details the findings of a study conducted for the Enterprise Directorate General of the European Commission. The remit of the study was to assess the 'availability of substitutes for soft PVC containing phthalates in certain toys and childcare articles'.

Several Member States have introduced national measures restricting the marketing and use of PVC toys and childcare articles which contain phthalates. In addition, in December 1999, the European Commission issued an emergency ban upon the use of phthalates in toys and childcare articles which are intended to be placed in the mouth by children under three years of age.

The aims of this study were to provide an overview of the situation on the EU market following restrictions on the use of phthalates in certain toys and childcare articles, to assess the risks to health of children of possible substitute plasticisers and plastics and to consider the technical problems and economic implications of switching to substitute plasticisers and plastics.

This report is based upon a review of the relevant literature, trade/market data and consultation with relevant industry stakeholders.

2. The EU Market for Toys and Childcare Articles

Around 5.5 million tonnes of PVC are used in the EU each year. The European market for PVC is worth around Euro 50 billion per annum in terms of finished products, of which plasticised PVC accounts for around 32%.

Around 1 million tonnes of plasticisers are used in the EU each year, the majority of which are phthalates. This market has an estimated value of Euro 1 billion per year. Of this quantity, however, the use in all toys and childcare articles is estimated to be only around 1 to 2 percent.

The overall market for toys in the EU is worth Euro 13.5 billion, the majority of which is accounted for by imports, mainly from the Far East. Of this, it is estimated that the market for toys containing flexible PVC is worth around Euro 2.7 billion. However, the value of those articles which have been affected by restrictions upon items *intended to be placed in the mouth* by children under three years of age is estimated to be only around Euro 140,000. Of all articles containing soft PVC for children under three years of age, the market is considerably larger (estimated at Euro 680 million).

3. Technical Issues in Substitution

Toy companies have, as required by the emergency EU ban, replaced phthalate plasticisers in their products which are intended to be placed in the mouth by children under three years of age. Depending upon the companies in question, both substitute plasticisers and substitute plastic materials have been employed.

In terms of the substitute plasticisers, the only one which has been confirmed as definitely being used is o-acetyltributyl citrate (ATBC). Products using PVC formulations containing ATBC can reportedly match all of the technical requirements which are met when phthalates are used.

Other plasticisers which have been reported as being suitable in technical terms include benzoates, alkylsulphonic phenyl esters and possibly adipates, polymerics, trimellitates, sebacates and azelates.

A number of companies have undertaken substitution to entirely different plastic products rather than simply different plasticisers. This applies significantly to those products which are intended to be placed in the mouth by children under three years of age but also to products which are not specifically intended to be placed in the mouth. For those products which are specifically intended to be placed in the mouth, the substitute plastics which appear to be most widely used are polyethylene (PE) and ethylene vinyl acetate (EVA). These materials can reportedly be used adequately in the products in question. However, the technical performance of the final product has been indicated to be often slightly inferior to that obtained with PVC. For example, products produced from these materials may sometimes have lower resistance to biting and tearing than plasticised PVC. The products may also have reduced longevity. In terms of the wider range of toys and childcare articles, plastics which are reported to be used as substitutes for plasticised PVC include various forms of polyethylene (LDPE, and LLDPE) styrenic block copolymers and again EVA.

One of the key issues in the use of substitute plasticisers is the ability of reformulated products to be processed in the same way as phthalate-plasticised PVC. This is particularly true in the case of certain rotationally moulded products: while a substitute may be suitable for use in some processing techniques, including some rotationally moulded products, it may not be suitable for use in other techniques (for example, different rotationally moulded products). Furthermore, such substitution may not be possible in other toys (which are not specifically intended to be placed in the mouth or which are for older children) given the huge diversity of products on the market which contain phthalate-plasticised PVC.

Table 1 provides a summary of the findings of this study in terms of the technical suitability of substitute plasticisers. Indications are given as to the technical suitability for use in toys and childcare applications and their actual use in these products *where they have been reported to be used as substitutes* is also indicated. Table 2 provides a summary of the findings of this study in terms of the technical suitability of substitute plastics.

Table 1: Technical Suitability of Substitute Plasticisers		
Plasticiser Type	**Technical Suitability**	**Actual Use as Substitute**
Citrates (ATBC)	I, II	I, II
Adipates (DEHA)	II (some)	Unknown
Benzoates	I (possibly), II (some)	II (probable)
Alkylsulphonic Phenyl Esters	I (possibly), II (some)	Possibly
Trimellitates	II (some)	Unkonwn
Polymerics	II (some)	Unknown
Key: I - products intended to be placed in the mouth II - other plasticised PVC toys and childcare articles		

Table 2: Technical Suitability of Substitute Plastics		
Plastic Type	**Technical Suitability**	**Actual Use as Substitute**
Polyethylene (various forms)	I, II (some)	I, II (some)
Ethylene Vinyl Acetate (EVA)	I, II (some)	I, II (some)
SBS Block Copolymers	I (possibly), II (some)	I (unknown), II (some)
Polyester Elastomers	II (some)	Unknown
Key: I - products intended to be placed in the mouth II - other toys and childcare articles		

In general, the use of substitute plastics would appear to be less technically feasible than the use of substitute plasticisers.

4. Risks to Health Associated with Substitutes

Two substitute plasticisers have been examined in terms of their potential risks, acetyltributyl citrate (ATBC) and diethylhexyl adipate (DEHA). Based on the available information, the margin of safety for DEHA would appear to be less than for ATBC. Furthermore, this analysis found that the margin of safety for DEHA is lower than that for DINP (the key phthalate used in soft PVC toys), while that for ATBC is higher. This suggests that ATBC may be preferable to DINP on health grounds but that DEHA may not.

However, it is recognised that the amount of information available regarding toxicity and migration for these substances is less than that which is available for the phthalates. Where any plasticiser - phthalates or their substitutes - is used, there exists a *potential* risk associated with use. This will be highly dependent upon the nature of individual products in question.

In terms of substitute plastics, very little information is available on the migration of organic additives from toys and childcare articles. One additive, butylated hydroxytoluene (BHT), has been taken as an illustrative substance since this is known to be used in some teething products made from substitute plastics.

However, there is insufficient information available to conduct a meaningful risk assessment for this substance. This is equally true for other organic constituents of alternative plastics used in products which are intended to be placed in the mouth. The consideration of BHT for the purposes of this study serves only to highlight that there exists a *potential* risk associated with other organic additives used in the products in question.

BHT would appear to be more toxic than any of the plasticisers which have been considered (phthalates, ATBC, DEHA), and should thus be considered more *hazardous* than those substances with respect to its tolerable daily intake. However, BHT is used in much lower quantities than the phthalates, decreasing the likely risk. It must also be remembered that it has passed food safety tests and that safe levels have been found for the migration of this substance (and indeed phthalates, DEHA and ATBC) from other plastic materials, such as those which are intended to come into contact with foodstuffs.

The fact that no quantitative data has been obtained regarding the migration of organic additives from substitute plastic materials which are intended to be placed in the mouth is likely to be a consequence of the fact that companies are not legally required to assess the extent of migration from these products. In other comparable situations, such tests are required and companies can generally demonstrate compliance with the relevant standards and legislation. Such comparable situations include:

- migration of additives from plastic materials and articles which are placed in contact with foodstuffs (through Directive 90/128/EEC); and

- migration of heavy metal additives (such as lead, arsenic and cadmium) from toys and childcare articles as set out in the European Standard EN 71 which provides elaboration on the 'Toy Safety Directive' (88/378/EEC).

In the absence of any widely accepted tests for assessing the migration of organic additives (plasticisers and other additives in both PVC and also other plastics) from toys and childcare articles, the uncertainty regarding the risks associated with the use of these products will exist, whether phthalate-plasticised PVC is used or any substitute plasticiser or plastic.

5. Economic Implications of Substitution

5.1 Substitute Plasticisers

Consideration has been given to the economic implications of using ATBC as a substitute for phthalates in toys and childcare articles. As stated above, other plasticisers could potentially also be used but this substance has been examined in more detail because it has been reported by the plasticiser and toy industries (and trade associations) to be the most widely used substitute.

Quantitative estimates have been made for the increases in raw material costs which would be associated with the use of this plasticiser as a substitute (ATBC is around 3.3 times more expensive than DINP). These estimates are as follows:

- for the quantities of products which are the subject of the EU ban (probably only around 2.9 tonnes of plasticiser for those intended to be placed in the mouth by children under three years of age), increased raw material costs would only represent an estimated Euro 6,000;

- for all soft PVC products for children under the age of three years of age, increased raw material costs would amount to around Euro 13 million; and

- for all soft PVC products for all uses and all ages, increased raw material costs are estimated to be around Euro 50 million[1].

In addition to the above ongoing costs, there would also be some one-off costs associated with reformulation and testing of products, although these would tend to be relatively minor due to the technical suitability of ATBC.

If these costs were all passed on to consumers, it is estimated that finished product prices would rise by almost 4% (although this does not take into account the one-off costs associated with the need for product development.

5.2 Substitute Plastics

As for substitute plasticisers, estimates have been made of the costs of using substitute plastics in terms of the raw materials costs. Raw material costs for replacement plastics tend to be around 60% to 100% higher than those of flexible PVC. However, in the case of replacement of the entire plastic, both the PVC and the phthalate must be replaced. Since the phthalate constitutes a small proportion of the product as compared to the PVC polymer (on average although not in all cases), the overall increased raw material costs would be greater for the use of substitute plastics:

- an estimated Euro 23.5 million increase for all toys and childcare articles for children under three years of age; and

- Euro 94.1 million for all plasticised PVC toys and childcare articles on the EU market.

1 Consideration has been given to these wider ranges of products since these products can be (and are) affected by legislation in countries which have more restrictive legislation than the Community measures and are also affected by the negative *perception* which has become associated with PVC.

In addition, as with the use of substitute plastics, there will be one-off costs associated with product development. These would tend to be significantly greater than for substitution with just a different plasticiser since an entirely different product is used. Information received from companies which have substituted flexible PVC with different plastics suggests that there has been little requirement for the purchase of new processing equipment. However, this will not be the case for all substitution possibilities and the associated costs for those products would be greater still.

6. Overall Conclusions

The EU ban has wider implications for the perceived acceptability of phthalates and PVC as a whole, as evident from the more stringent restrictions which have been brought in by some EU Member States. This, along with campaigns against PVC, has led some companies to use alternative plasticisers and plastics for products which are not specifically intended to be placed in the mouth. The technical implications of using alternative plastics for these applications raises far greater concerns since many of these alternatives cannot match the performance in production and use of plasticised PVC.

In addition, given the paucity of comparable data for both the substitute plasticisers and plastics, it remains unclear as to whether adoption of these substances would lead to lower health risks. It would appear that the use of ATBC should lead to lower risks, however, no comparable conclusions can be drawn concerning the use of substitute plastics.

The economic implications of using a substitute plasticiser or plastic are estimated to have been relatively minor for those products which are intended to be placed in the mouth by children under three years of age. However, other soft PVC toys and childcare articles constitute a far greater use and the economic implications for substitution in those products, in terms of increased raw material costs alone, would be much higher.

CONTENTS

1. BACKGROUND

1.1 Introduction

This report details the findings of a study conducted for the Enterprise Directorate General of the European Commission. The remit of the study was to assess the 'availability of substitutes for soft PVC containing phthalates in certain toys and childcare articles'.

The study comprises four key components, which are as follows:

1. To provide an overview of the situation on the EU market with regard to materials used for toys and child care articles, following the introduction of national measures restricting the use of phthalates. Also to examine the situation in the US and Canada.

2. To address the risk to health of children, including safety aspects, of possible substitutes (plasticisers and alternative polymers). To provide information on toxicological profile and potential for migration as well as an appreciation of the sufficiency of the data.

3. For each substitution possibility in a toy or child care article, to consider the technical problems of design and production and the ultimate utility and appeal of the toys and child care articles after substitution.

4. To examine the market situation and economic implications of switching to a substitute. To address major economic effects in terms of cost, investment, employment, competitiveness. Deliberations on potential benefits of switching to a substitute (reduced health risk, lower cost for the health care systems) are also part of the study.

The study has been undertaken by Risk & Policy Analysts Ltd (RPA), an independent UK-based consultancy, and the Research Institute for Toxicology (RITOX) at the University of Utrecht in the Netherlands.

1.2 Context of the Study

Phthalates are organic chemicals which are added to a wide variety of PVC (polyvinyl chloride) products in order to impart softness and flexibility to those products. These products are termed plasticisers.

Phthalates have historically been of concern regarding their toxicity where used in certain consumer products. For example, in the mid 1980s, concerns were raised regarding their use in food wrapping materials due to their potential to migrate into those products.

Phthalates are used in a range of toys and childcare articles to enable toy manufacturers to produce a wide range of PVC types which are suitable for use in numerous applications and which can be processed using a variety of techniques.

There exists a concern that phthalates can migrate from soft PVC toys and childcare articles where these are chewed and sucked by small children and thus have toxic effects in the long term.

In July 1998, the European Commission issued a Recommendation to the Member States that they should ensure that phthalates do not migrate in unacceptable quantities from toys and childcare articles which are intended to be placed in the mouth of children under three years of age. This followed an opinion expressed by the Scientific Committee for Toxicity, Ecotoxicity and the Environment (CSTEE) that there exists the potential for unacceptable levels of phthalates to migrate from these products. Note that this recommendation did not apply to toys and childcare articles which are not intended to be placed in the mouth or to toys for children over three years of age (since no risk had been identified for these products).

On the basis of this Recommendation, Member States were required to take the measures necessary to ensure a high level of protection of the health of children as regards these products. Eight Member States adopted national restrictions upon the use of phthalates in these products, following the Commission's Recommendation. However, a number of these national restrictions were more stringent than the Recommendation provided for, encompassing other toys which are intended for children under three years of age but that are not specifically intended to be placed in the mouth.

In December 1999, the European Commission issued an emergency ban upon the use of phthalate plasticisers in toys and childcare articles which are intended to be placed in the mouth by children under three years of age. This measure was taken because it was considered that the use of phthalates in these toys can pose a 'serious and immediate risk' to the health of children and because test methods which had been developed had not been validated and standardised at the Community level. It was also taken as a means to ensure the proper functioning of the common market, due to the disparate restrictions across the Member States.

In the context of the restrictions on the use of phthalates, this study has sought to examine whether there exist alternative plasticisers or indeed plastics which are suitable in technical terms for use in toys and childcare articles, specifically those for the under three's which are intended to be placed in the mouth. It has also sought to examine what the likely risks to the health of children would be if these were used instead of phthalates or indeed PVC itself. The economic implications of using substitute plastics and plasticisers has also been examined.

1.3 Approach to the Study

The approach to the study is outlined in the tender document for the Enterprise Directorate General (Tender Ref. No. III/99/064).

This report is based upon a review of the relevant scientific literature, trade/market data and consultation with relevant industry stakeholders. Questionnaires have been sent to 58 toy companies and 21 plasticiser manufacturers. Whilst the response rate from these companies has been poor, significant information has been made available by a small number of toy companies and their trade associations in the EU and elsewhere.

The European toy association, Toy Industries of Europe (TIE), has distributed a communication from RPA to all of its members in the hope of obtaining further information to support this study. Unfortunately, this has elicited no response whatsoever.

In terms of the risks to health of substitutes, two non-phthalate plasticisers have been examined in terms of their toxicological profile and potential for migration from PVC toys and childcare articles. For substitute plastics, one plastics additive which is used in some substitute plastic toys and childcare articles has been examined for illustrative purposes.

1.4 Structure of the Report

The remainder of this report is structured as follows:

- Section 2 provides an overview of the use of PVC and plasticisers as a whole;
- Section 3 provides details of the legislative context of the study;
- Section 4 provides an overview of the market situation as concerns PVC and phthalates in toys and childcare articles;
- an appraisal of the technical suitability of alternative plastics and plasticisers is given in Section 5;
- an assessment of the risks to health of alternative plasticisers is given in Section 6;
- Section 7 provides an appraisal of the economic implications of using substitute plasticisers and plastics; and
- the conclusions drawn from this study are outlined in Section 8.

2. SOFT PVC AND PHTHALATES

2.1 Introduction

This section provides an overview of the use of and market for PVC and phthalates. This relates mainly to general issues regarding their use (with more specific details on their use in toys and childcare articles provided in Sections 4 and 7). The information herein is based upon a review of relevant literature and consultation with relevant stakeholders.

An overview of the use of PVC is provided, detailing its manufacture and use. Specific attention is paid to the market for PVC products in terms of applications and values.

Following that, the use of plasticisers in PVC products is discussed, with specific reference to phthalates. A background is given to the technical requirements for and benefits of their use. The market for plasticisers is discussed and an analysis of their specific applications is provided.

2.2 Polyvinyl Chloride

2.2.1 PVC Manufacture

Figure 2.1 provides an overview of the production processes leading from raw materials to finished articles.

PVC is produced from two primary raw materials - ethylene and chlorine. These are reacted to form ethylene dichloride (EDC) which, upon cracking, yields vinyl chloride monomer (VCM). Free radical polymerisation of VCM is used to produce the PVC polymer itself.

There are a number of polymerisation techniques which are used in the production of distinct types of PVC polymer. The two most important polymerisation techniques are suspension polymerisation and emulsion polymerisation[1], leading to the production of S-PVC and E-PVC respectively. These two types of PVC polymer have different properties and are used for distinct applications:

- the S-PVC process yields granules of polymer of 100 to 200 microns in diameter (Summers, 1997) which is used in processes such as injection moulding, extrusion and PVC film manufacture; and

1 The other two polymerisation techniques (mass polymerisation and microsuspension polymerisation are not considered further in this report.

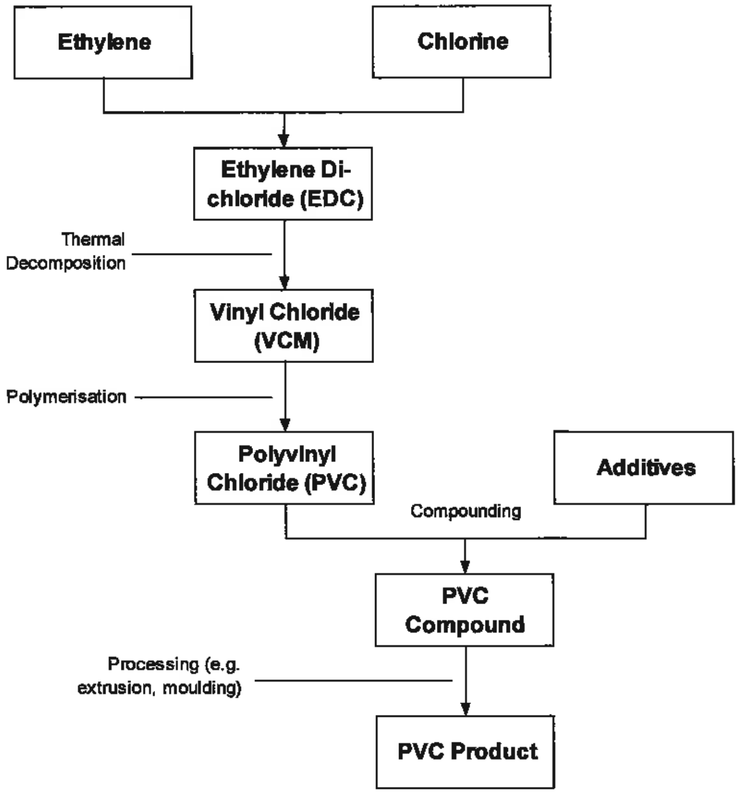

Figure 2.1: Overview of Production of PVC Articles

Pure PVC polymer is thermally unstable and cannot be used alone for the production of commercial products because of thermal degradation. Various additives are mixed with the PVC polymer in order to enhance certain properties and make it suitable for a vast range of applications. These additives include:

- heat stabilisers which help prevent degradation (reductive dehydrochlorination) of the PVC polymer during both processing and use. They are generally metals and metal derivatives such as calcium/zinc, lead, cadmium and tin;
- plasticisers which afford the PVC polymer flexibility, softness and increased impact resistance;
- fillers, such as clay, which are generally used to reduce costs but may also impart strength and fire retardancy to products;
- impact modifiers which improve the toughness of PVC. These are generally elastomeric polymers such as acrylonitrile-butadiene-styrene (ABS);
- lubricants which aid processing of the PVC polymer;
- antitstatic agents for use in applications such as computer housings;

- flame retardants; and
- dyes/pigments (Titow, 1990).

Of particular importance to this study is the use of plasticisers. Plasticisers are used because PVC is an inherently hard material at room temperature. Their incorporation into PVC formulations allows them to become soft (to the required extent) at room temperature and below. PVC which contains a plasticiser is referred to as 'flexible' or 'plasticised' PVC and that which contains no plasticiser is unplasticised PVC (U-PVC).

2.2.2 PVC Compounds

All commercial products based upon PVC include a variety of different additives, as is the case for many polymer products. The type and concentration of the additives used depends upon the specific application in question. Most additives are used in relatively small quantities but some may be used in quantities equivalent to that of the polymer itself. These include fillers and, of relevance to this study, plasticisers[2].

PVC, therefore, undergoes mixing ('compounding') with the various additives in order to produce a compound/formulation which will provide certain desired physical properties in the end product (such as hardness, flexibility or tear resistance). The compounding process involves mixing and sometimes heating and, depending upon the compounding process and the nature of the additives, can be used to produce both solid and liquid types of PVC compounds.

2.2.3 Processing Techniques

Once PVC (granules or powder) has been mixed with the required additives, some form of heating is usually required. This binds the PVC particles together and helps to incorporate the additives into the polymer matrix. During heating, some molecules of PVC become freed and become entangled. Upon cooling, these recrystallise to form a three dimensional structure, a process known as *gelation* or fusion (Summers, 1997).

A wide range of techniques is used in order to process the various PVC compounds into a huge range final products. Some of the key processing techniques are as follows:

- *extrusion* is used for both plasticised and non-plasticised PVC. The PVC is passed into an extruder where it is heated and compressed to form a melt using screws. This melt is forced through a die which shapes the PVC product. This technique is used for products such as window frames, cable sheathes and tubes;

2 The concentrations of additives are generally referred to in terms of the quantity used relative to that of PVC polymer. Thus, if the weight of plasticiser used is 30% that of the polymer, the concentration will be referred to as 30 phr (parts per hundred of PVC resin).

- *injection moulding* involves melting of PVC compounds and then forcing them using a screw machine into a mould. This technique is used for products such as electrical components and footwear;

- the process of *calendering* entails passing a PVC formulation through heated rollers. It is used to produce both rigid and flexible PVC sheeting of diameter between 75μm and 1.5mm;

- by expanding heat-softened U-PVC into a mould using pressurised gas, very thin PVC products can be produced for applications such as packaging. This is referred to as *blow moulding*;

- *rotational moulding* involves part-filling a mould with PVC (generally in a plastisol form). The mould is rotated bi-axially in an oven so that the polymer coats the inside of the mould and cures. The mould is then cooled and the hollow PVC product can be removed. A number of PVC toys are produced using this method;

- products such as disposable gloves can be produced using *dip moulding*. As the name suggests, this involves dipping a mould into a PVC plastisol and then heating until the product is set; and

- PVC plastisols can be applied to various substrates. This *coating* process is used in the manufacture of products such as PVC wallcoverings.

Both the wide range of PVC formulations and the range of processing techniques make it possible to produce a diverse range of products with markedly different properties and applications.

2.2.4 PVC Markets

PVC Polymers

The total market for PVC in Western Europe was just over 5.5 million tonnes in 1997. Over the five years previous to this, there was a general growth in the market for PVC. Figure 2.2 details the total market for PVC over the period 1992 to 1997. It also shows total PVC sales by Western European manufacturers over the same period.

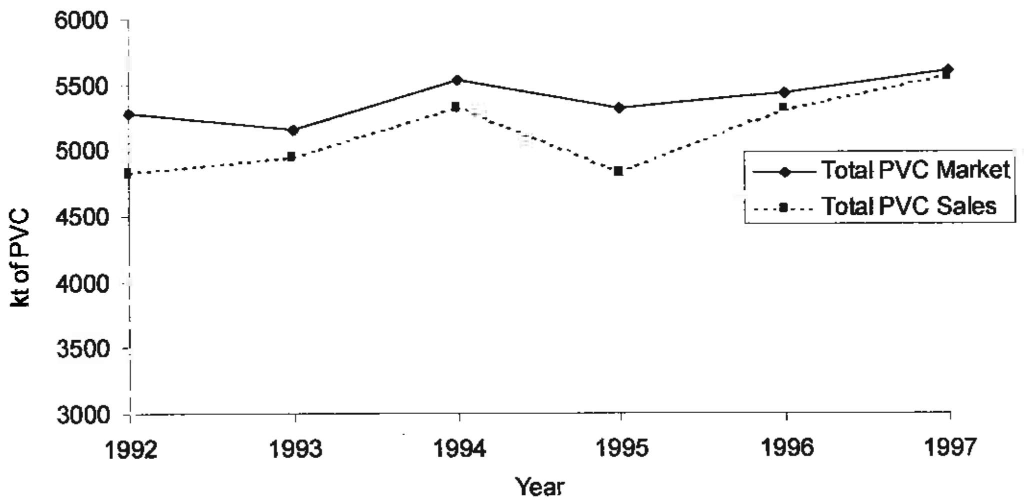

Figure 2.1: Market for and Sales of PVC in Western Europe (ECVM, 1999)

As can be seen from Figure 2.1, the total market for PVC within Western Europe is almost exactly the same as its production (around 5.5 million tpa). This compares to global PVC consumption of around 22 million tpa. Despite the fact that West European sold production is of a similar magnitude to the market for PVC, this is not to say that trade in this substance is not important. As illustrated in Table 2.1, imports and exports of unmixed PVC are significant throughout the EU.

Of the 5.5 million tpa market for PVC in Western Europe, around 5.0 million tpa is accounted for by S-PVC and the remainder (0.53 million tpa) by E-PVC. The European market in 1996 was dominated by eight major companies. Production capacity for Western Europe in 1996 is illustrated in Table 2.2.

Trade in PVC is significant in terms of the quantities imported and exported in almost all Member States. Imports and exports are generally greater within the EU than outside, though the latter can also be significant. These data help to reflect the diversity of PVC, even in its primary form.

Table 2.1: Imports and Exports of Primary Unmixed PVC in 1998 (all values in kt)					
	Imports		Exports		Domestic Market
	Intra-EU	Extra-EU	Intra-EU	Extra-EU	
Belgium	231	19	341	81	598
Denmark	43	12	10	0	43*
Germany	503	151	439	113	-
Greece	30	24	10	33	107*
Spain	134	42	89	14	440
France	343	28	537	108	866
Ireland	47	1	0	0	54*
Italy	317	175	83	72	479
Luxembourg	-	-	-	-	-
Netherlands	155	29	351	3	-170
Austria	47	40	-	-	-
Portugal	47	16	42	10	-
Finland	16	6	32	6	-
Sweden	37	32	-	-	-
United Kingdom	290	61	38	2	781*

* 1997 data

Source: EUROSTAT (1999)

Table 2.2: Major Producers of PVC in Western Europe in 1996		
Company	**Total PVC (k tpa)**	**E-PVC (k tpa)**
EVC	1200	120
Solvay	970	135
Atochem	730	110
Shell/Rovin	595	-
Vinnolit	570	115
Norsk Hydro	470	70
LVM	435	-
Vestolit	350	103
BASF	250	-

Source: Corden, 1998

In 1996, the total value for sold production of PVC was 2.45 billion Euro[3] (EUROSTAT, 1999). Table 2.3 illustrates an estimation of the value of PVC polymer over the period 1994 to 1998.

Table 2.3: Estimated Value of PVC Polymer

Year	Value (Euro per tonne)
1994	690
1995	810
1996	590
1997	620
1998	520

Calculated using ratio between value and quantity for Member States' domestic markets in unmixed PVC (from EUROSTAT, 1999)

The European PVC industry directly employs around 50,000 people and a further one million are employed in related industries (EVC, 1995).

PVC Products

Figure 2.2 details the relative share of the PVC market which is used in the various applications for PVC.

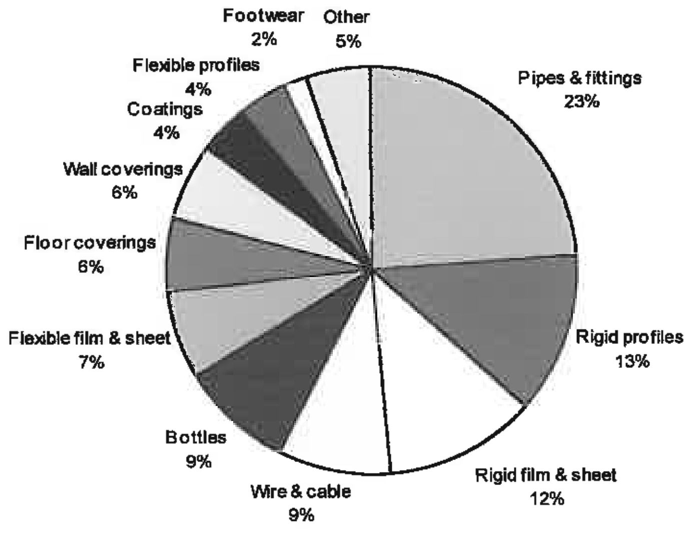

Figure 2.2: Applications for PVC (EVC, 1996)

3 It is assumed that 1 ECU (data are provided as ECU in EUROSTAT) is equivalent to 1 Euro.

The total market for finished PVC products is worth around Euro 50 billion per annum. This compares to the value estimated above of Euro 2.45 billion for PVC polymers. It is evident, therefore, that there is considerable added value when PVC is combined with the various additives and manufactured into finished products.

Of this, toys and childcare articles containing soft PVC are estimated to account for around Euro 2.7 billion per annum. This use falls mainly into the 'other' category in Figure 2.2, though some may be accounted for by different categories.

2.3 Use of Plasticisers in PVC

2.3.1 Requirement for Plasticisation

As mentioned above, plasticisers are added (along with a variety of other additives) to PVC in the production of a large proportion of PVC formulations. These formulations are then used in the manufacture of the wide variety of final PVC products which are available.

PVC is an inherently hard material and will turn from a hard, glassy material into a soft and rubbery one at a temperature of around 80°C. This is referred to as its glass transition temperature (T_g). Inclusion of plasticisers causes a lowering in T_g such that PVC can be a soft material at room temperature (and below).

Without the use of plasticisers, the development of many of the products which are currently on the market would not have been possible using this material.

2.3.2 Mechanism of Plasticisation

The European Council for Plasticisers and Intermediates (ECPI, nd) describes five distinct stages in the incorporation of a plasticiser into PVC products. These stages are as follows:

1. Plasticiser is mixed with the PVC resin.

2. Plasticiser penetrates and swells the resin particles.

3. Polar groups in the PVC resin are freed from each other.

4. Plasticiser polar groups interact with the polar groups on the resin.

5. The structure of the resin is re-established with full retention of the plasticiser.

Stages one and two are referred to as physical plasticisation. In Stage 2, the extent to which a plasticiser will penetrate the resin (PVC polymer) particles depends partially upon the size of those particles. It will tend to occur to occur to a greater extent with E-PVC than with S-PVC due to the smaller size of E-PVC particles and thus their higher surface area to volume ratio.

Stages three and four are referred to as chemical plasticisation since they are dependent upon the chemical properties of both the PVC polymer and the plasticiser.

The extent to which the structure of the PVC resin is re-established (Stage 5) is of great significance since its success will affect the degree to which the plasticiser is retained within the PVC product. If the plasticiser is not sufficiently retained within the polymer matrix, the physical properties of the material will be lost. In addition, this has implications for the migration of plasticisers into various media such as saliva (in the mouthing of toys and childcare articles) and food which is packaged in plasticised PVC.

2.3.3 Plasticiser Types

A variety of plasticisers are used in the production of flexible PVC products. In fact, there are around 800 different plasticisers manufactured, of which around 100 are of commercial importance (Cadogan and Howick, 1996). These are, almost exclusively, organic esters. A plasticiser can constitute between 10% and 60% by weight of a flexible PVC compound. It may, therefore, be present in a greater quantity than the PVC polymer itself (although this is not usually the case). The composition of a typical flexible PVC product is outlined in Table 2.4.

Table 2.4: Typical Flexible PVC Compositon

Ingredient	Content (phr[a])	Content (%)
PVC Polymer	100	50
Plasticiser	60	30
Filler	35	17.5
Stabiliser	4	2
Lubricant	1	0.5
Total	200	100

Source: Cadogan and Howick (1996)
a phr refers to 'parts per hundred resin' which is a term frequently used in relation to PVC additives. It is the amount of additive relative to 100 parts of PVC.

Plasticisers should be of low volatility and should be of similar polarity to the PVC polymer in order to minimise migration from the product (Wilson, 1995). Plasticisers of greater molecular weight tend to be less volatile and migrate less readily out of PVC products. However, higher molecular weight plasticisers may also be less effective in terms of their plasticising effects.

Phthalates

Phthalates are esters of o-phthalic acid (benzene-1,2-dicarboxylic acid). The most commonly used phthalate is di-2-ethylhexyl phthalate (DEHP) which accounts for around 50% of European plasticiser use. Other phthalates include di-isononyl phthalate (DINP), di-isodecyl phthalate (DIDP), di-butyl phthalate (DBP) and butylbenzyl phthalate (BBP).

DEHP (which is also referred to as dioctyl phthalate, DOP) is considered to be the industry standard plasticiser since it's properties are in the mid range for the various plasticiser types. In Western Europe, DEHP accounts for around 50% of all plasticiser usage since its properties are adequate for use in a wide range of applications and it is competitive in price terms in relation to other plasticisers (Cadogan and Howick, 1996).

Phthalates, like most plasticisers, are organic esters. They are produced through reaction of a carboxylic acid (in this case o-phthalic acid) and an alcohol. For example, DEHP is produced through reaction of o-phthalic acid with 2-ethylhexanol. This is illustrated in Figure 2.3.

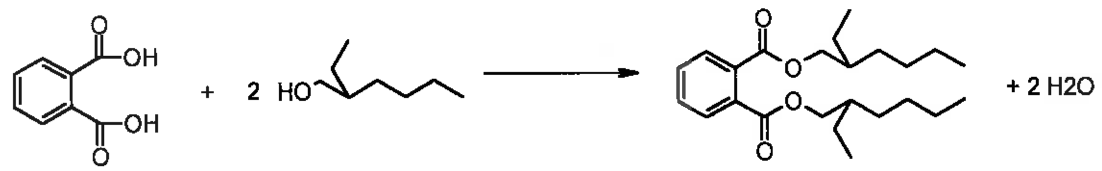

Figure 2.3: Production of Di (2-ethylhexyl) Phthalate

DINP has similar properties to DEHP and is generally competitive with DEHP as a general purpose plasticiser. DINP has, in recent years, been the most widely used phthalate plasticiser for childcare products such as teethers.

The other types of phthalate plasticisers referred to above tend to be used in more specialised applications where certain physical and chemical properties are required, such as different viscosity or increased rate of gelation.

Adipates

Adipates are esters of a linear C_6 di-carboxylic acid (as opposed to phthalates which are esters of an aromatic di-carboxylic acid). They have the general structure illustrated in Figure 2.4.

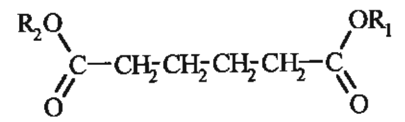

Figure 2.4: Chemical Structure of Adipate Plasticisers

The most commonly used is di (2-ethylhexyl) adipate which is used widely in food wrapping applications (such as 'cling films') as replacements for phthalate plasticisers.

Citrates

Citrate plasticisers are esters of citric acid produced through reaction with a variety of alcohol types. Western European usage for citric acid is around 230,000 tpa (ECPI, 1999b). The major uses for citric acid are in food and beverages (58%), household detergents and cleaners (24%), pharmaceuticals (9%) and for industrial uses (9%). Use as plasticisers falls into this latter category. The generic structure of citrate plasticisers is illustrated in Figure 2.5.

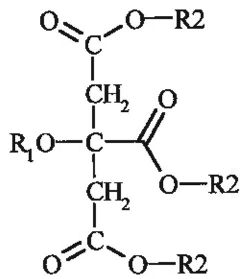

Figure 2.5: Chemical Structure of Citrate Plasticisers

Citrates which are commonly used in PVC applications include triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate and di (2-ethylhexyl) citrate. These products are, like citric acid, also used in other applications such as inks, hair sprays and flavourings.

Benzoates

In general terms, benzoates are similar to phthalates in their chemical structure: they are mono-carboxylic acids as compared to phthalates which are di-carboxylic acids. However, for use as plasticisers in PVC, the benzoates used are frequently more complex substances, such as diethylene glycol dibenzoate, illustrated in Figure 2.6.

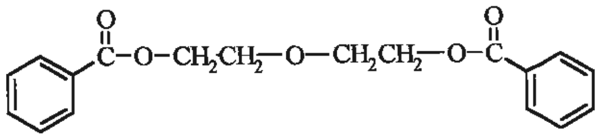

Figure 2.6: Diethylene Glycol Dibenzoate

In addition to being used in a variety of PVC products with a range of different processing techniques (application and processing techniques will dictate the most suitable plasticisers), benzoate plasticisers are also used in products such as adhesives and sealants. In commercial use, blends of different benzoates are frequently used (and also blends of benzoates with other plasticisers).

Sebacates and Azelates

These types of plasticisers generally command a higher price than many of the other products considered (though not more than some of the citrate products). They are suitable for certain specialist applications where greater low temperature performance is required than with, for example, phthalates.

In terms of chemical structure, these substances are similar to adipates: they are esters of linear di-carboxylic acids with nine or ten carbon atoms (for azelates and sebacates respectively) as compared to adipates which are based on acids having six carbon atoms. This is illustrated in Figure 2.7. As with all of the plasticisers considered, the most common esters are those which occur by reaction with alcohols such as 2-ethylhexanol. Typical examples of these plasticisers include di-2-ethylhexyl azelate (DOZ), di-2-ethylhexyl sebacate (DOS) and diisodecyl sebacate (DIDS),

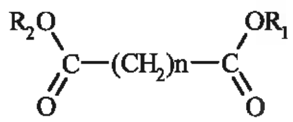

Figure 2.7: Structure of Azelates (n=7) and Sebacates (n=8)

Trimellitates

Trimellitate plasticisers have a similar chemical structure to phthalates[4]. Once again, common members of this group are produced through a reaction with the same types of alcohols, to produce plasticisers such as tri (2-ethylhexyl) trimellitate.

4 They are based on trimellitic acid which has three carboxyl groups as compared to phthalates which have just two.

Trimellitates tend to be less volatile and more resistant to migration as compared to the phthalates. They are thus used in applications such as automobile interiors (where there are requirements for low 'fogging') and in high specification electrical cable insulation and sheathing. Their chemical structure is illustrated in Figure 2.8.

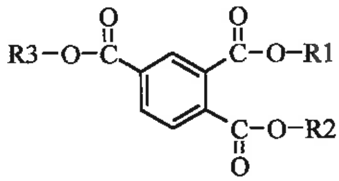

Figure 2.8: Chemical Structure of Trimellitates

Polymeric Plasticisers

These substances are similar to other types of plasticisers in that they are organic esters produced through reacting carboxylic acids and alcohols. In this case, however, both of the starting products have reactive groups and thus long molecules (up to 4000 units) of plasticiser can be formed.

Since they are such large molecules, they can become well contained within the polymer and will thus be very resistant to migration. They are used for applications such as hoses, films and sheeting. However, polymeric plasticisers are more expensive than many of the other types of plasticisers and are thus used mainly for quite specialist applications which require good performance at high temperature.

Alkylsulphonic Phenyl Esters

These plasticisers are esters produced through reaction of aromatic compounds (such as phenol) with alkylsulphonic acids. They are reported to be suitable for a wide range of processing techniques and are resistant to migration and weathering.

2.3.4 Market for Plasticisers and Plasticised PVC

Around 1 million tonnes of plasticisers are produced and used in Western Europe each year. Of this, 90% is used in the plasticisation of PVC products. The remainder is used in rubber products, paints, printing inks, adhesives, lubricants and some cosmetics[5].

DEHP accounts for around 50% of all plasticiser use in Europe, with DINP and DIDP being the other major phthalate products.

The market value of common phthalate plasticisers is around Euro 800 per tonne. Using information supplied by a major toy company on the comparative prices of different plasticisers, the values for purchase prices have been calculated and the figures given in Table 2.5.

5 A number of cosmetic products contain significant quantities of plasticisers such as diethyl phthalate.

Table 2.5: Comparative Prices of Plasticisers	
Plasticiser	**Price (Euro)**
DINP	800
Adipates	1040
Benzoates	1600
Trimellitates	2000
Sebacates	2400
Polymerics	2400
ATBC	2640

It must be remembered that this study is specifically concerned with flexible PVC. Of the PVC used in Europe, around 68% of the market is associated with rigid products (U-PVC) and the remaining 32% consists of flexible applications (those which employ a plasticiser). Thus, flexible PVC accounts for around 1.75 million tpa of PVC used in Europe. This is illustrated in Table 2.6.

Table 2.6: West European Market for Flexible PVC (kt)			
Application	**S-PVC**	**E-PVC**	**Total Flexible PVC**
Cables	540	-	540
Flexible Film/Sheet	300	-	300
Flooring	70	180	250
Synthetic Leather	-	120	120
Fabric Coat	-	55	55
Flexible Profile	160	-	160
Wallcoverings	5	75	80
Sealants	-	55	55
Others	140	45	185
Total	**1215**	**530**	**1745**
Source: Corden, 1998			

It is evident from Table 2.6 that, whilst E-PVC constitutes a relatively small (10%) proportion of the total PVC market, it represents a far greater amount of the flexible PVC market (30%). This is because all E-PVC is used in plastisol PVC compounds (plastisols, by their very nature, contain plasticisers).

Once again, flexible PVC toys and childcare articles will fall mainly into the category of 'others' in Table 2.6. Both S-PVC and E-PVC are of relevance to this study since they are both used in toy products. However, the proportion of soft PVC toys which are based upon E-PVC is unknown.

E-PVC is of particular relevance since plastisols based upon E-PVC are used in the rotational moulding of a range of different soft PVC toys. Plastisols are similar in appearance to paints (and are sometimes also referred to as paints) and are used in a number of processing techniques. One of these techniques, rotational moulding, is used for the manufacture of certain toy products. Other types of plastics cannot generally match the performance of PVC plastisols in certain rotational moulding processes, having implications for the possibility of using different plastics as substitutes for PVC in toys (discussed further in Section 5).

3. LEGISLATIVE CONTEXT

3.1 Introduction

This section provides a background to the legislation in place to reduce the risks associated with the use of phthalates and soft PVC. The bulk of the discussion relates to legislation concerning soft PVC and phthalates in toys and childcare articles although some attention is given to other, relevant legislation.

The remainder of this chapter is structured as follows:

- firstly, a background to the concerns leading to the regulation of phthalates and soft PVC is given, including reference to the control of the risks associated with their use in plastic materials intended to be placed in contact with food. This discussion is then focussed upon the restrictions which have been introduced in the EU;

- secondly, the various restrictions which have been invoked in a number of EU Member States are considered in the context of a Recommendation made by the Commission in July 1998;

- this is followed by a discussion of the emergency ban upon the use of certain toys and childcare articles which was introduced in December 1999; and

- finally, consideration is given to the legislative controls in place in countries outside the EU. Particular attention is paid to regulations in place in the United States and Canada (with a further discussion of the market situation in those countries given in Section 4).

3.2 Background to Restrictions

On 24th April 1998, the EU Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) expressed an opinion on phthalate migration from soft PVC toys and childcare articles. This examined the toxicity of various phthalates and made estimations of exposure to these substances through chewing/mouthing. The CSTEE adopted a margin of safety approach to its assessment which expresses the ratio of the No Observed Adverse Effect Level (NOAEL) to the estimated exposure. The margins of safety for DINP and DEHP were both found to be below the threshold value of 100 which was used to indicate a concern. The margin of safety values were 8.8 and 67 respectively.

Shortly after the CSTEE expressed this opinion, the European Commission issued a Recommendation to Member States to assess the migration of phthalates from the toys and childcare articles in question and to take the necessary measures to ensure the protection of the health of children. This Recommendation is discussed in Section 3.3.2 below.

On 28 September 1999, the CSTEE expressed its opinion on a number of test methods which had been developed in order to assess migration of phthalates from PVC toys and childcare articles. It concluded that these test methods were unsuitable for the purposes of enforcement. Soon after this opinion was expressed, an emergency ban on the use of phthalates in toys and childcare articles intended to be placed in the mouth by children under three years of age was introduced. This is discussed below in Section 3.4.

3.3 Restrictions in EU Member States

On 1 July 1998, the European Commission issued a Recommendation (98/485/EC) to the Member States[6] concerning childcare articles and toys intended to be placed in the mouth by children of less than three years of age, made of soft PVC containing certain phthalates. Member States were recommended to do the following:

1. Adopt measures required to ensure a high level of child health for toys and childcare articles intended to be placed in the mouth of children under 3 years of age. Specific attention was to be paid to DEHP and DINP since these are used in the greatest quantities in the soft PVC products in question. Attention was also to be paid to DBP, DIDP, DNOP and BBP.

2. Monitor the migration of phthalates from the products in question, taking into account the migration limits recommended by the CSTEE.

They were also recommended to inform the Commission of the test methods used, results obtained and conclusions drawn and to participate in the exchange of information amongst Member States and to work to ensue a consistent test method.

This Recommendation effectively allowed Member States to invoke restrictions upon the marketing and use of the toys in question if they had been found to exceed the migration limits. They were to take the measures required to ensure a high level of child health protection.

Whereas Recommendation 98/485/EC relates to phthalate-plasticised PVC toys and childcare articles which are *intended to be placed in the mouth* by children under three years of age, certain Member States have introduced national restrictions which go beyond those specified:

- in Greece, restrictions include the import and marketing of teething products and also certain soft PVC toys intended for children under three years of age;

- in Austria, the ban extends to toys containing phthalates for children under three years of age which *are frequently sucked, chewed or otherwise put in the mouth under normal and foreseeable conditions of use*;

[6] OJ L 217, 5.8.1998, p. 35.

- the Danish restrictions prohibit production, import and marketing of childcare articles intended *or likely to be* placed in the mouth and of toys and products which must be expected to be used as toys by children under three years of age;
- in Sweden, the ban includes toys *which can be put in the mouth* by children under three years of age;
- as with the Swedish restrictions, Finnish restrictions also include toys *which can be put in the mouth*;
- the Italian restrictions encompass also those toys *which are likely to be put in the mouth*; and
- in Germany, the restrictions extend to teething rings and certain plastic toys which are intended to be *or can be foreseen to be* placed in the mouth by children under three years of age.

Member States have varied in the measures taken to deal with the risks in question. A number of the Member States' restrictions go considerably beyond the scope of the Recommendation which was concerned with only those toys and childcare articles which are intended to be placed in the mouth. They have included those products which might feasibly be placed in the mouth. There are also differences amongst Member States in terms of their national restrictions.

3.4 The Emergency EU Ban

On 7 December 1999, the European Commission issued a Decision (1999/815/EC)[7] which banned the marketing of soft PVC toys and childcare articles[8] intended to be placed in the mouth of children under three years of age and which contain one or more of six phthalate plasticisers. Specifically, it referred to those which contain more than 0.1% w/w of DINP, DEHP, DNOP, DIDP, BBP or DBP. The 0.1% limit effectively prohibits their incorporation into these articles for use as plasticisers whilst accounting for their potential presence as impurities.

The Decision was adopted under Council Directive 92/59/EEC on general product safety. That Directive requires that only safe products be placed upon the market and that a high level of protection of the health and safety of children is ensured. It allows the Commission to temporarily prohibit the placing on the market of products which pose a "serious and immediate risk" to the health and safety of consumers and which has been restricted in one or more Member States. Such a measure can be applied when:

- Member States differ on the measures used to deal with the risks;

7 OJ L 315, 9.12.1999, p. 46.

8 For the purposes of the Decision, childcare articles are defined as "any product intended to facilitate sleep, relaxation, the feeding of children, or sucking on the part of children."

- the existing specific Community legislation does not provide the means to deal with the risks in a manner compatible with the risks; and
- only Community level measures can adequately address the risks and at the same time ensure the proper functioning of the internal market.

Such a Decision was deemed to be required because the CSTEE had concluded that none of the phthalate migration test methods were suitable for control purposes. Thus, the Commission concluded that the 1998 Recommendation was not sufficient to ensure a consistent high level of child health protection.

The Commission proposed an amendment to Directive 76/769/EEC to ban the use of the products in question and, in the interim, it was deemed that it was necessary to prohibit their placing on the market immediately.

3.5 Restrictions Outside the EU

3.5.1 Restrictions in the United States

In the US, there is no legal restriction on the use of phthalates in soft PVC toys or childcare products. As with the EU, there have been concerns raised about the use of phthalates in these products and several studies have been commissioned to address the risks to children from phthalates in toys and childcare articles. These have mainly focussed upon DINP, which is the most widely used phthalate in toys and childcare articles.

A review during 1999 of the health effects of DINP with specific reference to toys was conducted. Although the report did recognise that more information was required on the actual exposure to phthalates from mouthing of PVC toys, it was concluded that:

> "Although results of animal toxicity tests suggest the need for thorough evaluation, the Panel concludes that much of this evidence has little relevance for humans and that DINP in toys is not harmful for children in the normal use of these toys." (Koop and Juberg, 1999).

In addition, the US Consumer Product Safety Commission (CPSC) published a report in December 1998 which examined the risk of chronic toxicity associated with exposure to DINP in children's products (CPSC, 1998a). This report concluded that few, if any, children are at risk from liver or other organ toxicity from the release of DINP from children's products since the amount they might ingest does not reach a level that would be harmful. However, the CPSC also concluded that uncertainties remained regarding some aspects of the toxicity of DINP, including the risk of cancer.

Due to this uncertainty, the CPSC requested industry to remove phthalates from soft PVC rattles and teethers. However, this did not constitute a legally binding agreement (CPSC, 1998b).

However, Toy Manufacturers of America (TMA), the trade association representing the US toy industry, have indicated to RPA that manufacturers are unable to sell teethers, rattles and pacifiers made of PVC containing phthalates to retailers in the United States. Rather than being a legal requirement, producers and marketers of these products have been affected by a requirement of retailers not to use these plasticisers. This response on behalf of the retailers has occurred as a result of reports in the media although the TMA does not support the views of these media reports.

3.5.2 Restrictions in Canada

Health Canada have also undertaken an assessment of the risks posed by DINP in children's products. They have been concerned with the use of phthalates in PVC products since the mid 1980s. At that time, the concerns for toys related to DEHP, since that was then the predominant plasticiser. Concerns shifted to DINP when much use of DEHP was voluntarily phased out because "it was assessed that DEHP could give reason for concern regarding the health and safety of children" (Health Canada, 1998a).

An investigation conducted by Health Canada (1998a) concluded that:

- under the experimental conditions used in the *in vitro* study, no significant correlation was found between the total DINP content in a given PVC children's product and that of its DINP release rate;

- the quantity of DINP released from soft PVC products designed specifically to be mouthed by young children may pose a risk to the health and safety of children between the ages of 3 months and 1 year; and

- a reasonable extrapolation of the cancer risk found in the animal model to humans cannot be made given current available information.

Though there is not any specific legislation requiring that phthalates are not used in these products, Health Canada issued an advisory (Health Canada, 1998b) in November 1998 which requested that parents and caregivers dispose of any PVC teethers and rattles which contain phthalates (and, in particular, DINP). This was taken as a precautionary measure. The advisory did not apply to pacifiers and feeding bottle nipples since these had not been identified as containing phthalates.

Parents were advised to dispose of the above products for children weighing less than 8kg, to monitor their child's use of other small, soft PVC toys and to remove these toys if they observe that their child is sucking or chewing them for prolonged periods of time, on a daily basis.

It was also advised that retailers remove these products from their shelves, with Health Canada publishing a list of teethers and rattles which were known not to contain DINP.

3.5.3 Restrictions in Other Countries

The Australian Toy Association have recommended that members cease the use of phthalates in infant products following the EU ban while the Japanese Toy Association reports that there is no national legislation in Japan governing the use of phthalates in toys.

4. THE MARKET SITUATION

4.1 Introduction

This section provides an overview of the markets for the toys and childcare articles which have been the subject of restrictions in the EU. The discussion is placed in the context of the effects which the restrictions in individual Member States have had and also the effects of the emergency EU ban[9].

Estimations are made as to the volumes of products which have been affected by the restrictions and the value of those markets in terms of raw materials, processed materials and finished products.

The market situation in both the US and Canada is discussed in the context of their national restrictions mentioned in Section 3.5 and also the effects of market pressures upon the levels of use of these products.

A discussion of the markets for PVC and phthalates in general was provided in Section 2. In this section, the discussion relates specifically to the use of and market for these materials in toys and childcare articles.

As stated in Section 1, the information which has been used as the basis of this discussion was largely obtained from the literature. Such literature includes statistics and costs from the PVC, plasticiser and toy industries and their trade associations. In addition, information has been made available from consultation with industry as to the specific effects for certain companies. However, this information is limited.

4.2 European Market for Toys and Childcare Articles

4.2.1 Overall Market

The following discussion is based mainly upon a review produced for Toy Industries of Europe (TIE, 1999).

The EU toy industry has a market value of Euro 13.5 billion in terms of retail prices. Total production of toys and games in the EU has a value of Euro 4.75 billion.

Around 2,000 companies are involved in the EU toy industry. Of these companies, over 80% employ fewer than 50 people. Five percent of these companies have a turnover of more than Euro 40 million.

9 Note that the study specification, issued on 29/9/1999, required that an overview be provided following the introduction of national measures restricting the use of phthalates. However, the emergency ban has been introduced since that time and it is more appropriate to consider the effects of the combination of restrictions.

Over 100,000 people are employed directly in the European toy industry. 53,500 of these are employed in production and 45,000 are employed in research and development, marketing, sales and other services.

Table 4.1 details the share of the toy market occupied by the various categories of toy products. Data are provided which relate to total toys and games and those without inclusion of video games.

Table 4.1: Shares of Main Categories of Toys in 1998

	Incl. Video Games	Excl. Video Games
Video Games	21.5%	-
Activity Toys	13.0%	16.0%
Infant/Pre-school	11.0%	14.0%
Games/Puzzles	10.5%	13.5%
Dolls	9.0%	13.5%
Vehicles	4.0%	11.0%
Ride-ons	5.0%	5.0%
Action Figures	5.0%	6.0%
Plushes	5.0%	6.5%
Other Toys	10.5%	14.5%
Total	**100.0%**	**100.0%**

Source: TIE, 1999

According to the above categorisation, video games account for the single largest type of toy in terms of market share (21.5%), with the remaining toys ('traditional toys') accounting for 78.5%.

The data in Table 4.1 are divided into the categories which are generally used by the toy industry and are also the same as those which are used for the purposes of imports and exports. Unfortunately, these do not provide an indication of the relative quantities of toys which are made out of plastic or, more specifically, PVC. However, as indicated in Section 4.3, around 40% of toys on the EU market are reported to contain soft plastics.

Toys can be categorised according to the age group for which they are deemed to be suitable, as follows:

- babies aged from 0 to 12 months;
- toddlers aged from one to three years;
- pre-school intended for children aged three to five years; and
- children aged from five to seven years (BTHA, 1998).

Thus, toys which are intended for children under three years of age will come under the above categories of babies and toddlers.

Figure 4.1 details the share of the EU markets for toys (including video games) in 1998. The largest markets are those in the UK, Germany, France, Italy and Spain in descending order.

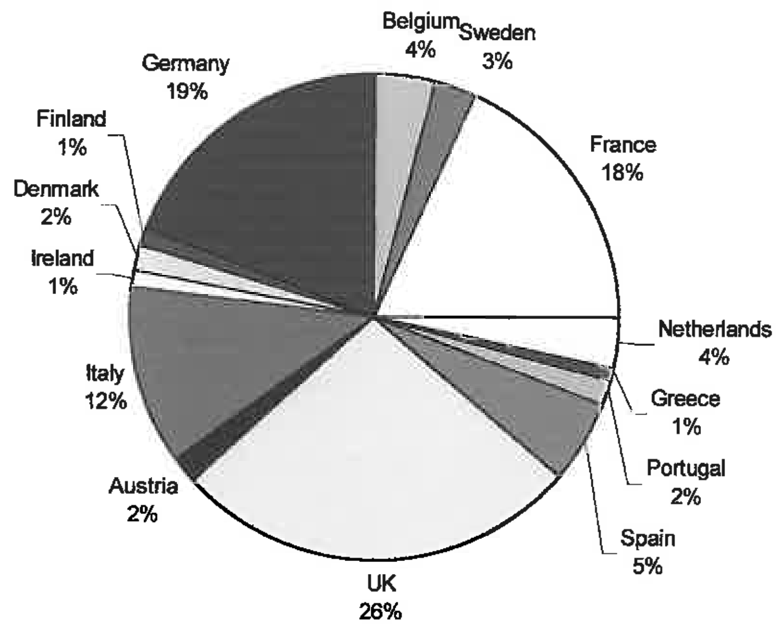

Figure 4.1: EU Market for Toys by Member State in 1998 excluding Luxembourg (Source: Euromonitor, 2000)

4.2.2 Extra-EU Imports and Exports

Imports of toys and childcare articles from outside the EU constitute the greatest proportion of value of all products sold in the EU. These imports originate primarily from Asia, of which imports from China constitute by far the greatest proportion.

The toy companies themselves are often multinational organisations which specify the requirements for certain products to manufacturers based primarily in the Far East. The products are then shipped to the EU. Plasticisers for PVC toys may be produced in the EU and then transported to toy production facilities outside the EU, before the finished product is returned for sale in the EU.

Table 4.2 provides details of the major countries which are involved in trade with the EU. Both imports into the EU and exports from the EU are given. Exports from the EU are dominated by dolls and accessories, construction toys, board games, soft toys and baby toys. Imports are dominated by dolls and accessories, soft toys, electronic toys and games, video games and action toys.

Table 4.2: Extra EU Imports and Exports in 1998

Country	**Imports to EU (%)**	**Exports from EU**
North America	3.9%	31.2%
(USA)	3.3%	(28.3%)
(Canada)	0.6%	(2.9%)
South America	-	3.4%
Asia	81.6%	8.0%
(China)	(52.8%)	
(Japan)	(21.5%)	
(Other)	(7.3%)	
Eastern Europe	3.0%	16.5%
Other Europe	3.1%	18.1%
(Switzerland)	(3.0%)	(12.6%)
(Norway)	(0.1%)	(5.5%)
Australia	-	1.8%
Other	8.4%	21.0%
Total Percent	**100.0%**	**100.0%**
Total Value	**Euro 6.04 bn**	**Euro 1.13 bn**
Source: TIE, 1999		

The largest customer for EU-produced toys is the US followed by other (Western and Eastern) European countries, with Switzerland being the largest of these.

Exports and imports from the EU Member States are detailed in Table 4.3. The UK and Germany are the biggest importers and these countries, along with Italy, are the largest exporters of toys in the EU.

The information presented in this Section makes it possible to provide some indications as to the effects of certain Member States having more stringent restrictions than those imposed by the emergency EU ban. This is discussed further in Section 4.3.2.

Table 4.3: Imports and Exports of Toys by Member State in 1998		
Country	**Imports**	**Exports**
The Netherlands	13.40%	3.59%
UK	25.60%	16.26%
Ireland	0.61%	0.95%
Belgium/Luxembourg	4.64%	1.73%
France	9.36%	7.19%
Portugal	0.46%	0.29%
Spain	4.50%	6.87%
Finland	0.59%	1.65%
Sweden	1.97%	4.17%
Denmark	2.20%	2.56%
Germany	25.59%	28.46%
Austria	0.99%	2.31%
Italy	8.93%	23.44%
Greece	1.16%	0.53%
Total Percent	**100.0%**	**100.0%**
Total Value	**Euro 6.04 bn**	**Euro 1.13 bn**
Source: TIE, 1999		

Figure 4.2 indicates the key distribution outlets for toys in the EU. The two largest outlet-types are toy specialists and supermarkets/hypermarkets.

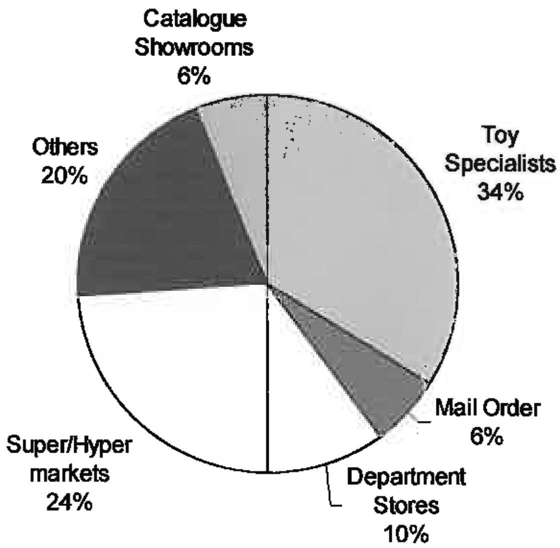

Figure 4.2: EU Distribution Channels for Toys (TIE, 1999)

4.3 Soft PVC Toys on the EU Market

4.3.1 Background

The range of toys on the European market which contain plasticised PVC is very diverse. Almost all of the categories of toys listed in Table 4.1 will include some plasticised PVC products.

It has been estimated that 40% of toys on the EU market contain soft plastics (TIE, 1998). It is assumed that half of this 'soft plastic' is accounted for by flexible PVC. Therefore, since the market value of toys for sale in the EU is Euro 13.5 billion, the total retail value of toys containing plasticised PVC will be around Euro 2.7 billion.

Data in Table 4.1 indicate that 11% of toys are for infant/pre-school. This category includes children in the age ranges 0 to 5 years and cannot, therefore, be used to estimate the relative value of toys containing soft PVC which are for children under three years of age. However, based upon extrapolation from the situation in the US, it is estimated that 25% of toys containing soft PVC are for children under three years of age and 75% for children over three years[10]. Thus, the value of toys containing soft PVC which are for children under three years in the EU is estimated to be around Euro 0.68 billion. The majority of these toys will contain phthalate plasticisers (since phthalates are by far the largest type of commodity plasticiser).

In terms of the quantities of PVC and phthalates used in toys in the EU, these are estimated to be as follows:

- 150,000 tonnes of PVC and 28,000 tonnes of phthalates for total toys containing flexible PVC; of which
- 37,000 tonnes of PVC and 7,100 tonnes of phthalates are used in toys for children under three years of age[11].

4.3.2 Effects of the EU Restrictions

In terms of those plasticised PVC products which are intended to be placed in the mouth by children under three years of age, these have been estimated to account for only around 18 tonnes of plasticised PVC use per annum (around 15 tonnes of PVC resin and 2.9 tonnes of plasticiser)[12].

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10 In the US, around 100 million toys containing soft PVC are for children under three years and around 300 million for children over three years.

11 It is estimated that of toys which contain flexible PVC, an average of 50% of the toy will be made up from PVC. The quantities used have been estimated from the above values using the average value of products which are made from PVC.

12 The estimate for the quantity of material affected is based upon an industry estimation that the emergency ban has affected only around one tonne of PVC resin use in the UK. This has been conservatively extrapolated to the rest of the EU. It has been assumed that an 'average' product contains 16% w/w of phthalate based upon an analysis of DINP content of plastic children's products by Health Canada (1998a).

The value of this in terms of finished products can be estimated to be Euro 140,000 based upon the average value for all finished PVC products relative to European consumption of PVC. However, this was the situation before the emergency ban was introduced. As these products are no longer allowed to be sold in the EU, this figure can be assumed to represent the loss in value to the affected producers.

Thus, in terms of the products under consideration, the quantities and values directly affected by the emergency ban were relatively minor, compared to the market for all toys at Euro 13.5 billion per annum and for all finished PVC products at Euro 50 billion per annum.

However, the effects of the national restrictions raise far greater concerns since the scope of many of these goes beyond only those toys and childcare articles which are *intended to be* placed in the mouth of children under three years of age. Many of them include those products which *might feasibly be* placed in the mouth. This compares to the US where the market situation has mainly affected teethers and rattles (as a result of the CPSC's recommendation). Similarly, in Canada, the advisory issued by Health Canada applies specifically to only rattles and teethers (although they also advised parents and caregivers to monitor children's mouthing of other products).

Of the eight Member States which have introduced their own national restrictions upon the use of phthalates in children's products, those in Germany, France and Greece do not appear to go significantly beyond the scope of the EU ban. However, those in the other Member States do:

- in Denmark, reference is made to those products which *are intended to be* or *likely to be* placed in the mouth;
- in Sweden, the prohibition extends to those articles which *can be* put in the mouth;
- the Finnish restrictions refer to those articles which *can be* put in the mouth; and
- the Italian ban refers to products which are *intended to be* or are *likely to be* placed in the mouth.

Furthermore, the Austrian restrictions refer to those products which are, under normal and foreseeable conditions of use, sucked, chewed or otherwise placed in the mouth.

The differences in national restrictions have led to a number of concerns for manufacturers and importers of toys and childcare articles and also for manufacturers of plastics and plasticisers.

For those Member States which have more stringent requirements a significant issue has arisen in terms of the imports of toys and childcare articles for children under the age of three years. Three of these countries (Sweden, Finland and Denmark) account for a relatively minor percentage of imports and also have relatively low values for production of these products. However, these countries do import a significant proportion of these products.

Since these three countries account for relatively minor proportions of toy manufacturers' custom, difficulties have arisen in obtaining toys and childcare articles which will comply with national requirements. Box 4.1 illustrates the situation in Sweden, based upon a response provided by the Association of Swedish Suppliers of Toys and Hobby Articles (pers. comm.).

Although the restrictions in Sweden, Finland and Denmark are unlikely to affect a significant amount of the production of companies which export to those countries, they will have very significant implications for the importers and retailers of toys within those countries.

Box 4.1: The Situation in Sweden
Swedish production of products which are intended to be placed in the mouth by children under three years of age is close to zero. Their production of toys which are intended for use by children under three and which contain phthalates is also very small. As of 1 May 2000, the Swedish Government has decided to ban all toys and childcare articles for children under three years of age if these products contain phthalates. Thus, the Swedish restrictions will cover products for children under three *which are not specifically intended to be* placed in the mouth. These will include items such as dolls, many of which contain PVC in significant proportions. Other products will include inflatable balls, swimming aids and clothing. Since the Swedish market accounts for only a small proportion of toy manufacturers' production (the majority of imports in Sweden and for the EU as a whole are from Asia), these companies have not been willing to produce toys which do not contain phthalates for what is only a small segment of their sales. The Swedish restrictions are expected to have very significant economic implications within that country: possibly around 5 to 10% of the market will be affected by the national restrictions. This will be significantly more than is affected by the EU-wide restrictions. The Association of Swedish Suppliers of Toys and Hobby Articles is of the opinion that the extension of a ban to include those articles for under three's *which are not specifically intended to be* placed in the mouth is unwarranted since there has been no identification of a risk arising from these products. Pers. Comm. 2000

As indicated above, the ban in Italy, also goes beyond what is required by the EU-wide restrictions. Italy is a major producer of toys and also a major exporter. Imports of toys into Italy are also significant (around 10% of all European toy imports). The effects of their national restrictions are, therefore, likely to be more wide-reaching than those in Sweden, Finland and Denmark.

The Italian ban extends to those products which *are likely to be* placed in the mouth of children under three years of age. There will, therefore, be increased pressure upon toy manufacturers to supply products which do not contain phthalates for this market. This will have further implications for other countries in that some products would be altered such that no phthalates are used, despite there being no national restrictions in those countries. Thus, companies may reformulate all of their toy products which have contained phthalates, despite there being no legal requirement for them to do so.

For example, one major toy manufacturer (with a turnover greater than Euro 5 million and employing over 250 people) has indicated that PVC has been replaced in all of their products. That company has a policy that none of their products shall contain PVC due to the associated health and environmental issues.

It is evident, therefore, that the EU ban has had implications for products beyond the scope of those which *are intended to be* placed in the mouth of children under three years of age. Where companies decide to replace products containing phthalates for other applications (such as those which are not specifically intended to be placed in the mouth or even those for children over the age of three years), there will be significant knock-on effects for companies involved in the production of PVC and plasticisers.

Using the information presented above, the value of the PVC polymer and phthalate used in toys for children under three are estimated as Euro 24 million and Euro 5.7 million respectively. For all toys containing PVC, the values are estimated to be Euro 95 million for PVC polymer and Euro 23 million for phthalates.

However, it is not likely that all toy manufacturers will cease using phthalate-plasticised PVC in all of their products for the under three's (i.e. those which are not specifically intended to be placed in the mouth), nor that all companies will extend the non-use of phthalate-plasticised PVC to products for the over three's.

In addition, although sales of alternative plasticisers/plastics would increase, their use would depend upon the ability of these substitutes to meet the technical requirements of the PVC products (see Section 5) and the ability of companies to bear the costs of reformulating their products (as discussed in Section 7).

4.4 Countries Outside the EU

4.4.1 United States

A background to the legislative situation in the US and Canada was provided in Section 3. In the US, there is no legal obligation for phthalates not to be used in soft PVC toys or childcare products. However, the US CPSC has requested industry to remove phthalates from soft PVC rattles and teethers though this did not constitute a legally binding agreement.

As stated in Section 3, manufacturers are unable to sell teethers, rattles and pacifiers made of PVC containing phthalates due to a requirement of retailers not to use phthalates (rather than any legislative requirement).

The situation on the market in the US can be summarised as follows:

- there are few, if any toys which are intended to be placed in the mouth which are made of soft PVC containing phthalates. The size of the market for these types of products (not containing phthalates) is around US$ 30 million (around Euro 30 million);

- there are around 100 million pre-school toys which are made from phthalate-plasticised PVC;

- there are around 300 million such toys for children over the age of three years.

Where phthalates are used in these toys and childcare articles, the primary substance used is DINP.

4.4.2 Canada

In Canada, there is not any specific legislation requiring that phthalates are not used in these products. However, Health Canada issued an advisory (Health Canada, 1998b) in November 1998 which requested that parents and caregivers dispose of any PVC teethers and rattles which contain phthalates (and, in particular, DINP). This was taken as a precautionary measure. The advisory did not apply to pacifiers and feeding bottle nipples since these had not been identified as containing phthalates.

Health Canada have published a list of these products which do not contain phthalates.

Further information will be gathered regarding the situation on the Canadian market for inclusion in the Final Report.

4.4.3 Japan

The Japan Toy Association (pers. comm.) estimate that around US$ 110 million worth of soft PVC toys are produced and sold within Japan. Of this, they estimate that around US$ 1 million would be exported to the EU.

Japanese toy manufacturers are generally of the opinion that the EU restrictions are not justified by the preventative principle and strongly support the use of the appropriate dissolution test method and judgement standard (i.e. the relevant migration tests).

Furthermore, the EU ban has had implications for Japanese manufacturers of toys: it has stimulated the anti-PVC movement by some consumer groups and caused a consequent increase in consumers' concerns. It has also caused buyers to refrain from buying PVC products.

They also report that, where companies are using substitute plasticisers, the most suitable is ATBC. In terms of alternative plastics, the most suitable at this time would be thermoplastic olefins (TPOs) or styrenic block copolymers (SBC).

5. TECHNICAL ISSUES IN SUBSTITUTION

5.1 Introduction

This section provides details of the technical problems associated with the substitution of phthalate-plasticised PVC in toys and childcare articles. The discussion is concerned with those products intended for children under three years of age *which are intended to be* placed in the mouth and also those *which could be mouthed* by those children.

Specific attention has been paid to those plastics and plasticisers which are indicated (through review of the literature and consultation) as being already in use in toys and childcare articles. Experience of materials substitution for children's products which are not specifically intended to be placed in the mouth will have implications regarding the suitability for those products which are. Furthermore, consideration of those articles which are not intended to be placed in the mouth is required due to the national restrictions which extend beyond the EU ban.

Attention is given to the technical problems associated with the design of products based upon substitutes and also to the utility and appeal of these products following substitution. The technical suitability of the substitutes is considered in terms of the processing techniques required to produce the wide range of toys and childcare articles which are currently available.

The section is divided into two main sub-sections as follows:

- firstly, a discussion of the technical suitability of using entirely different plastic materials in the toys and childcare articles is provided; and
- this is followed by a discussion of the technical suitability of using substitute plasticisers (whilst continuing to use PVC) in the toys and childcare articles.

Information within this section is based upon a review of relevant literature and also on information received through consultation with industry (particularly those companies which have experience with testing of alternative plastics and plasticisers).

5.2 Technical Requirements for Substitutes

In order for a plastic material or alternative plasticiser to be suited for a particular application, there is a number of requirements for physical properties which must be met. The various toys and childcare articles currently produced from plasticised PVC are very diverse in terms of the types and quantities of additives used. If one component (such as the plasticiser) is substituted, other changes in the formulation may be required, such as the use of a different quantity or different type of stabiliser. Furthermore, processing routes and conditions are also very varied and substitution of the plasticiser or PVC will often require changes in the processing conditions. In addition, where a substitute is found to be suitable for use in one application (such as an injection moulded PVC teether), that same material may not be found to be suitable for substitution in a different product (such as a rotationally moulded doll's head).

Thus, the suitability of substitutes varies significantly depending upon the application for which substitution is intended to take place.

Key properties which are considered to be requirements for the use of substitute plastics and plasticisers in toy and childcare applications include the following:

- *hardness* is essentially a measure of a material's resistance to indentation. It is measured in degrees and based upon the penetration into the polymer of a defined indentor under a set load (Harboro, nd). In PVC products, it represents the degree of plasticisation by a plasticiser;

- *stress-strain properties* measure the flexibility and strength of a polymer. Common parameters include tensile strength, elongation and 100% modulus[13];

- *taste and odour* are important properties in terms of the appeal of the final product. This is a vital factor in the success of any product. For example, a teething ring which is not pleasing to taste will not be purchased by consumers;

- *bite and tear resistance* are important factors in the durability of a toy or childcare article. If a product is not durable in this respect, it will again not be successful. Moreover, if small parts can readily break off from a product, they can pose a health hazard in terms of choking. Regulations are in place to test the performance of toys under conditions of teething which specify that metal teeth are used. Some companies will go beyond such standards; using, for example, a repeated scraping test;

- a substitute plastic should have a *softening temperature* which is suitable for the application in question. In the case of PVC, the amount of plasticiser added will primarily determine the softening temperature (glass transition temperature) of the final product. By varying the quantity of plasticiser, the softening temperature can also be altered;

- *UV resistance* is an important property in any plastic product. It is important that the product does not break down when exposed to sunlight and, indeed, PVC polymer is not itself stable to UV light; hence, there is a requirement for stabilisers to be added to PVC products;

13 Tensile strength is a measure of the force per unit area required to induce breaking in a polymer specimen; elongation is a measure of the length at breaking point of a polymer sample relative to its original length; 100% modulus is the force per unit area required to extend a polymer to 100% of its original length.

- the *decoration* of a toy or childcare article is another vital factor in the ultimate utility of a product. Depending upon the application, the plastic product should be suitable either for incorporation of a dye or pigment directly into the product or for painting. In relation to the latter point, the material should display good paint adhesion properties; and

- the available *processing techniques* for a particular plastic material determine its suitability for use in any particular toy or childcare application. There is a wide range of processing techniques used in the manufacture of these products (as discussed in Section 2). PVC is, by virtue of the additives used, a very versatile material and can be used in a greater variety of these applications than most other plastics.

In relation to this latter point, a recurring problem in the replacement of phthalate-plasticised PVC has been the suitability of substitute materials for use in rotational moulding. This is discussed further in Box 5.1.

Box 5.1: Rotational Moulding

Rotational moulding (also called rotocasting) is a process which can be used with a range of plastic materials. However, some plastic materials are not suitable for use in rotational moulding for the manufacture of some products.

Rotational moulding involves part-filling a mould with a plastic (such as PVC in a plastisol form). The mould is rotated bi-axially in an oven so that the polymer coats the inside of the mould and cures. The mould is then cooled and the hollow PVC product can be removed.

This process can be used to make hollow products with wall thickness of between 0.5mm and 15mm, depending upon processing conditions and the type of plastic used. Finished products can be produced which do not have any outside seams (a problem of some other processing techniques). Although heating is required, there is no requirement for increased pressure, making rotational moulding considerably less expensive than processes such as injection moulding or blow moulding.

A key requirement for materials used in rotational moulding processes is that they should flow readily, thus enabling them to coat the inside of the mould as it is rotated. Therefore, plastic materials used for the manufacture of toys and childcare articles must either be in liquid form or must be a very fine powder. Whilst a range of plastics, such as polyolefins, EVA and PVC, can be rotationally moulded, not all polymers are suitable for producing certain rotationally moulded products. In this respect, PVC plastisols are most suited to certain products such as some dolls heads.

PVC plastisols can be produced with a range of properties, such as viscosity. Properties such as this allow the PVC to readily coat the inside of the mould when rotated. Plastisols are prepared by cold-mixing of the raw materials (PVC, plasticiser and other additives) and thus the PVC will not initially absorb a significant quantity of plasticiser (making the viscosity low). When heated during rotational moulding, however, the plasticiser does become absorbed, allowing for the formation of a solid product upon cooling.

Phthalate plasticisers are particularly suited to use in plastisols since they can be used in a wide range of concentrations, resulting in versatility in terms of properties such as viscosity. Furthermore, when phthalates such as DINP are used, the viscosity will not increase significantly over time (i.e. between preparation of the plastisol and moulding of the final product), unlike some other plasticisers.

5.3 Technical Suitability of Alternative Plastics

5.3.1 Background

The toy manufacturer Mattel has provided the European Commission with details of their testing of substitute plastics for PVC. This is reproduced as Table 5.1. The information contained in this section provides a background to the data in that table and also information obtained from other consultees and from the literature as to the technical suitability of substitute plastics for various applications and using various processing techniques.

In the following sections, an overview of the technical suitability of a variety of plastic materials is provided.

Table 5.1: Technical Suitability of Flexible Plastics as Substitutes for Plasticised PVC

Material	Hardness	Taste/ Odour	Bite/Tear Resistance	Softening Temperature	UV Resistance	Decoration	Surface Cleanliness	Rotocasting
Polypropylene[a]	N	Y	Y	Y	Y	N	Y	N
LDPE[a]	N	Y	N	Y	Y	N	Y	N
Chlorinated PE	Y	N	Y	Y	Y	Y	N	N
Metallocene PE[a]	Y	Y	N	N	Y	N	Y	N
Thermoplastic Olefin	N	Y	N	Y	Y	N	Y	N
PP/EPDM[a]	Y	N	N	Y	Y	N	N	N
S-B-S Block Copolymer[a]	Y	Y	Y	Y	N	Y	Y	N
S-EB-S Block Copolymer[a]	Y	Y	N	Y	Y	N	Y	N
S-SB-S Block Copolymer[a]	Y	Y	Y	N	Y	Y	Y	N
EVA[a]	Y	Y	N	N	Y	N	Y	N
EEA[a]	Y	Y	N	N	Y	N	Y	N
Ionomer	N	Y	Y	Y	Y	Y	Y	N
Polyester Elastomer	Y	Y	Y	Y	N	Y	Y	N
Plasticised PVC	Y	Y	Y	Y	Y	Y	Y	Y

[a] Includes Blends
Y = Acceptable, N = Unacceptable
Source: Mattel Inc. (pers. comm. 2000)

5.3.2 SBS Block Copolymers

A copolymer is a polymer which is produced from two distinct types of monomer unit (as compared to, for example, polyethylene which is generally produced from a single monomer unit - ethylene). There are two categories of block copolymer:

- random copolymers in which the arrangement of the two types of monomer unit is random; and

- block copolymers in which there are alternating 'blocks' of a number of each type of monomer unit.

SBS block copolymers are copolymers of the monomers butadiene and styrene. They are part of a group of plastics referred to as *thermoplastic elastomers*. Typical physical properties of SBS block copolymers are detailed in Table 5.2.

Table 5.2: Typical Properties of SBS Block Copolymer

Property	Value
Hardness, Shore A, (ASTM D2240)	33 to 47
Specific Gravity	0.92 to 0.98
Tensile Modulus at 300% elongation (psi)	282 to 551
Tensile Strength at Break (psi)	256 to 711
% Elongation at Break	347 to 742
Uses	Extrusion, injection moulding

Source: GLS Corporation Website

SBS block copolymers can be produced with a variety of physical properties. As indicated by Table 5.2, they can be used to meet almost all of the requirements for product properties and processing in toys and childcare articles. They can be used in injection moulding in the production of articles such as teething rings.

Although these substances can reportedly be used in rotational moulding techniques (Tickner, 1999), Mattell report that this is not the case for some of their products. Products which are made by rotational moulding include, for example, hollow doll's heads. In these applications, rotational moulding is preferable since it allows for production of a part which has no seams. When plasticised PVC plastisol (E-PVC) is used in rotational moulding, the moulded product has a good memory and will retain its shape to a greater extent than SBS block copolymers.

These polymers are also reported not to have the same degree of UV resistance as PVC formulations.

5.3.3 Ethylene Vinyl Acetate

Ethylene Vinyl Acetate (EVA) is being used by a number of companies in the production of products such as teething rings. EVA is produced through the reaction of vinyl acetate with ethylene. It can be produced to give a range of properties, depending upon the level of vinyl acetate used.

EVA is used widely in packaging applications such as 'cling film', where it has to some extent replaced PVC. A number of organisations contacted have indicated that they are using EVA as a replacement for plasticised PVC due to the introduction of the emergency EU-wide ban[14].

However, whilst EVA can be, and is, used by a significant number of companies in the production of teething products, companies have reported that the performance of products made with this substance is reduced as compared to plasticised PVC products. These include, for example, a reduction in the bite and tear resistance of the product. This has implications for the longevity of the products in question. In addition, it may also increase the hazard posed to children through a greater probability of pieces of the product breaking off and causing a risk of choking.

As with all of the products listed in Table 5.1 (except for plasticised PVC), EVA is reported not to be suitable for use in some rotational moulding processes.

5.3.4 Polyolefins

Polyolefins constitute the greatest proportion of all plastics used globally. By far the most common polyolefin is polyethylene (PE), which is produced through the polymerisation of ethylene. Forms of polyethylene have been identified as being used by some companies as a replacement for soft PVC in toys and childcare articles.

A common form of polyetheylene is low density polyethylene (LDPE) in which the polymer has some degree of chain branching. LDPE is widely used in packaging applications. It is a rubbery polymer and has good toughness.

High density polyethylene is, like its name suggests, of a higher density than LDPE. It is also a tougher material than LDPE. In between LDPE and HDPE, there is a form of polyethylene called linear low density polyethylene (LLDPE). This material is both a tough one and can also have rubber-like properties.

Metallocene polyethylene is produced using metallocene catalysts. This allows for the production of polymers in which the material properties can be better controlled than in standard polyethylene products.

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14 As indicated previously in this report, the level of response received from toy companies has been insufficient to provide quantified information on the extent to which EVA and other polymers have actually been substituted for flexible PVC.

As illustrated in Table 5.1, some forms of polyethylene cannot be decorated as readily as PVC and also do not display the same resistance to tearing and biting. Polyethylene can be used in some forms of rotationally moulded products. However, it is not suitable for use in a number of children's products, such as doll's heads.

It has been indicated that some companies have begun to use polyethylene as a replacement for soft PVC in toy products. This is true of companies producing both for the EU market and those elsewhere (such as in the US). It has been indicated that there has been little requirement for new processing equipment in the production of childcare articles using these polymers. However, the products have required significant efforts in terms of determining the correct processing characteristics.

Furthermore, products[15] produced using polyolefins instead of flexible PVC have reportedly suffered in terms of their performance in use: longevity of the products has been reduced and performance under some of the tests for physical properties, such as bite/tear resistance, has also suffered. Information received from these other sources serves to verify that the indications in Table 5.1 are borne out in practice when these alternatives to PVC are used commercially.

5.3.5 Polyester Elastomers

These polymers are also copolymers based upon various monomer units. For example, one commercial type is a block copolymer of hard, crystalline domains of polybutylene terephthalate and soft areas based upon long chain polyether glycols. The ratio of hard to soft segments determines the material properties of this range of polymers[16].

In terms of the use of these polymers in children's products, they can have a variety of properties which will make them suitable for a wide range of applications. The data in Table 5.1 indicate that these types of polymers are suitable for toy applications in terms of almost all of the criteria considered by the company in question.

However, as Table 5.1 indicates, these polymers are unable to match the resistance to ultraviolet light of plasticised PVC. Like PVC, therefore, these polymers often require additives to impart enhanced UV resistance.

As with all of the possible substitute polymers which are considered in Table 5.1, it is reported that these products are not suitable for rotational moulding applications. This is not to say that they cannot be used in rotational moulding (since they can and are used for this application), but that they cannot be used for certain rotational moulding applications used in the manufacture of some toys and childcare articles.

15 Those which are intended to be placed in the mouth by children under three years of age (since relatively little substitution has occurred for other applications).

16 This compares to the structure of PVC, where crystallites of polymer are tied together by molecules in areas of randomly packed PVC molecules (amorphous regions). A plasticiser will enter the amorphous regions and make the tie molecules elastomeric.

Although potentially suitable, no specific evidence has been found as to companies currently using these polymers as a replacement for plasticised PVC.

5.3.6 Conclusions on Alternative Plastics

There is a vast range of polymers which can and are used for applications in which plasticised PVC might otherwise be used. This has been reflected in the fact that some companies have indeed replaced plasticised PVC with entirely different plastics in their toy and childcare products.

This is particularly evident in those toys which are specifically intended to be placed in the mouth, such as teethers. A number of companies have replaced soft PVC with plastics such as EVA and polyolefins. Although products manufactured with such materials can suffer from slightly reduced performance in use and may require some changes in processing equipment, companies have often used an entirely different plastic in order to make a product which is PVC free and which can be marketed as such.

In terms of those products which *are not specifically intended to be* placed in the mouth, this represents a far wider range of products with varying requirements for material properties. In these products, there will not be one single type of polymer which could be used to replace plasticised PVC. Indeed, for certain products, there will be no suitable polymer which can meet the material specifications of PVC.

This has obvious implications for products other than teethers and rattles, where there is an intention not to use plasticised PVC (either through more stringent requirements in some Member States or through pressure from consumers or retailers). Substitution of plasticised PVC in those products which have been the subject of the emergency EU ban has not posed many significant technical problems as compared to those which could be expected to occur if manufacturers are required to use polymers other than PVC for a wider range of toys and childcare articles[17].

The US toy association, TMA, reports that some of their members have been using SBS block copolymers and polyethylene in certain children's products. However, these are limited to products manufactured by injection moulding and there are several technical shortcomings with their use:

- they are more difficult to decorate;
- they are less resistant to abrasion;
- they are more expensive than soft PVC; and
- they are less flexible than PVC.

Furthermore, the TMA support the assertion that there are no suitable alternative plastics for some rotationally moulded plastic children's products.

17 This is indeed the case in Sweden, where there is a more stringent requirement than the EU ban (applying to all toys for children under three years of age). Importers and retailers have experienced significant difficulties in obtaining toys without phthalates for the wider range of articles.

In conclusion, for products which are intended to be placed in the mouth (a relatively small market), substitute plastics are - by necessity - already in use. These are generally polyolefins or EVA and reformulated product can generally meet the technical requirements for use. However, the technical performance as compared to that of plasticised PVC is generally somewhat lower.

In terms of those products which are not specifically intended to be placed in the mouth, relatively less substitution of plasticised PVC has occurred. This is to be expected given that there is generally not a legal requirement to use substitutes. However, where such substitution has taken place this has tended to be dependent upon the specific applications in question and also specific companies' policy with respect to the entire issue.

5.4 Technical Suitability of Alternative Plasticisers

5.4.1 Background

As mentioned in Section 2, there is a wide range of plasticisers on the market which can be used in a variety of different PVC products. Almost all of the commonly available plasticisers are, like phthalates, organic esters produced through reaction of carboxylic acids with alcohols.

There are several reasons why phthalate plasticisers are used so widely in soft PVC products. These reasons include the versatility in terms of flexibility afforded through being able to use anything up to around 60% of plasticiser by weight in the plastic material.

Their migration from polymers during use is also lower than a number of other plasticisers. This migration is determined by factors such as the polarity of the plasticiser, its volatility and its molecular weight (Exxon Chemical, 1999). Migration from the polymer is a key factor in determining the associated risks to heath of phthalates and other plastic additives (see Section 6). In the context of the current discussion, plasticiser migration has implications for the performance (and also safety) of toys and childcare articles. For example, if a plasticiser migrates from a PVC product to a great extent, the PVC material will become brittle. This not only has implications for the appeal of the product but also may cause pieces of the plastic to break off and pose a hazard of choking for children.

Low levels of migration also mean that other physical requirements of a PVC material are retained during the product's lifetime. Accelerated aging tests can be used to artificially age a plastic product (through using heat or humidity). Material properties such as tensile strength and elongation can then be tested and compared to a non-aged product.

Furthermore, there is an advantage of low migratory potential in the processing of PVC products: lower volatility results in lower losses of plasticiser during the gelation process (discussed in Section 2). This results in improved manufacturing efficiency.

5.4.2 Adipates

Adipates are widely used in a number of applications instead of phthalates. A key example of this is their widespread use in 'cling films' following concerns over the possible toxicity of phthalates in the mid 1980s.

The most widely used adipate is di (2-ethylhexyl) adipate or DEHA. This is an analogue of the most common phthalate, DEHP. However, in technical terms, it would be likely that slightly higher molecular weight adipates, such as diisononly adipate (DINA) may be more suitable for toys and childcare applications. DINA would appear to be more suitable for use in plastisol-based products due to a greater viscosity stability than is possible with DEHA.

Adipates are one of the likely candidate plasticisers which could be used to replace phthalates in soft PVC products. However, losses via migration are likely to be greater than for the phthalates which would mean an increase in raw material costs and a more rapid reduction in product properties over its lifetime. This results from the lower inherent viscosity of adipates as compared to phthalates.

However, no specific evidence has been provided of companies actually using adipates to replace phthalates in toys and childcare articles. This may be due to their higher migration rates.

5.4.3 Trimellitates

Common members of this group include trioctyl trimellitate (TOTM) and triisononyl trimellitate (TINTM). The latter of these is the highest molecular weight monomeric plasticiser.

These products are of very similar molecular structure to the phthalates but have a greater molecular weight. This makes them more resistant to migration and extraction by liquids than the phthalates. They are generally suitable for high specification applications such as high temperature electrical wire and cable insulation.

As with a number of possible substitute plasticisers, these substances are reported not to be suitable for use in some rotational moulding applications, particularly for certain PVC toys. This is possibly due to their greater viscosity as compared to phthalates.

Actual use of these plasticisers has not been reported in toys or childcare articles and thus their technical suitability is not considered further in any detail.

5.4.4 Polymerics

As reported in Section 2, polymeric plasticisers are formed from the same types of raw materials as many other plasticisers (these raw materials are carboxylic acids and alcohols). The fundamental difference between polymerics and other plasticisers is their molecular size: polymerics can contain up to 4,000 units, as compared to the monomeric plasticisers which contain one molecule of carboxylic acid and between one and three alcohol units per molecule of plasticiser.

Polymeric plasticisers are of greater viscosity and lower volatility than the phthalates. This makes them suitable for applications where migration is a problem, including high temperature applications.

Once again, no evidence has been obtained as to actual use of these plasticisers in PVC toys and childcare articles. Furthermore, it is also reported that they are not suitable for use in manufacture of some rotationally moulded PVC articles (again likely to be due to their greater viscosity).

5.4.5 Alkylsulphonic Phenyl Esters

Information has been made available by one company producing these plasticisers for the EU market (in quantities of around 10,000 tpa). These plasticisers are reported to work well as general purpose plasticisers as they undergo gelation well and are resistant to saponification (and are thus suitable for use in materials which come into contact with alkalis and water). They are reported to be suitable for use in a number of other plastics as well as PVC.

They are suitable for use in a range of processing techniques such as calendering, extrusion, injection moulding and coating and are also approved for materials which come into contact with food. The company producing these products reports the technical properties of these plasticisers are comparable to those of the phthalates (although there will be requirements for reformulation of products where and if substitution occurs). The company promotes their use as a replacement for phthalates in toys and childcare articles. However, they report that the price of these plasticisers is generally deemed to be prohibitive. No hard information has been received to suggest that these plasticisers are actually being used as replacements for phthalates in toys and childcare articles.

5.4.6 Benzoates

No specific evidence has been received to indicate that toy manufacturers are actually using benzoates as direct replacements for phthalates in toys and childcare articles. However, certain members of this group of plasticisers can reportedly be used as replacements in terms of their technical performance. It is thought that any use of these plasticisers in toys and childcare articles is minimal.

Different types of commercial benzoate plasticisers can be used for the various PVC processing techniques, including injection moulding and rotational moulding. There is, however, generally a requirement for a significant degree of reformulation of the products. For example, in rotational moulding, this is due in part to the greater efficiency[18] of some benzoate plasticisers in PVC plastisols: if they are used as

18 Plasticiser efficiency is a measure of the concentration of plasticiser required to impart a specified softness to PVC (Cadogan and Howick, 1996).

replacements for phthalates in the same quantities, the finished products will be too soft. Therefore, a smaller quantity (generally 15-20% less) of benzoate plasticiser is required.

Furthermore, PVC compounded with benzoate plasticisers tends to undergo fusion at a lower temperature than with phthalates. A lower oven temperature is, therefore, required in order to obtain the necessary physical properties and appearance. In addition, various factors sometimes required adjustment in order to achieve the necessary plastisol viscosity for rotational moulding.

5.4.7 Citrates

Citrates are esters of citric acid, which is commonly found in foodstuffs such as lemons and oranges (citrus fruit). They are formed through reaction of citric acid with alcohols such as ethanol, butanol, and 2-ethylhexanol. Some types are also formed through additional reaction with acetic acid. These reactions lead to formation of the common citrates such as triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate (ATBC) and di (2-ethylhexyl) citrate. Citrates are most widely used in other applications such as food additives, and medical applications (such as dissolvable pill coatings). Also, like DEHA, ATBC is widely used in food packaging applications (such as cling film) as a replacement for DEHP.

As compared to the other plasticisers discussed above, ATBC is indeed being used in the manufacture of soft PVC toys and childcare articles. It has a proven suitability for use as a replacement for phthalates in these articles and, of particular relevance, it is suitable for use in rotationally moulded products. It is also suitable for other PVC processing techniques such as injection moulding.

In terms of the technical requirements for the use of ATBC instead of phthalates such as DINP, it is reported that there would be no requirement for additional processing equipment since PVC containing ATBC can be processed using the same techniques as PVC containing DINP. Equipment does, however, require thorough cleaning before products using ATBC are used. Thus, one company reports that it currently produces phthalate and citrate plasticisers using the same equipment, necessitating cleaning each time production is switched from one product to the other. Such cleaning (or use of alternative tanks for production) obviously has implications for the time and resources devoted to production of these plasticisers.

Consultation has indicated that ATBC is being used in PVC toys and that the finished products show no difference in their performance as compared to DINP. All physical and stability parameters are reported to be equivalent to those when phthalates are used.

For manufacturers of children's products, there is a requirement for the plasticiser product to be pure. Thus toy manufacturers tend to specify that, where ATBC is used, the grade should be of the same type used for medical applications. This requirement for purity means that some ATBC produced is not suitable because the product is manufactured in reaction vessels which are used for making other chemicals (and will thus contain traces of those chemicals which will contaminate the ATBC).

5.4.8 Conclusions on Technical Suitability of Alternative Plasticisers

There are a number of plasticisers other than phthalates which can be used in a variety of PVC end products. Many of these, however, are not suitable in technical terms for use in PVC toys and childcare articles. Furthermore, the plasticisers which are suitable for some toy products will not be suitable for others. Most notably, many of the substitute plasticisers are not suitable for use in rotationally moulded PVC products.

The only plasticiser which has been specifically identified as being used in toys and childcare articles is ATBC. It is reported that this substance can meet the product requirements for use in a majority of applications. ATBC is being used by toy manufacturers and is present in toys and childcare articles in the EU, the US and Japan. Furthermore, toy companies and citrate manufacturers are working with the manufacturing companies in Asia to develop new soft PVC products which incorporate this substance.

There are reported to be few technical difficulties in substitution of phthalates with ATBC in PVC toys and childcare articles.

Adipate plasticisers would also appear to be relatively well suited for use in toys and childcare articles in technical terms. However, there exist certain questions regarding a potentially higher level of migration and extraction than the phthalates (as discussed further in Section 6). No specific use of adipates in toys and childcare articles has been reported for the purposes of this study.

Benzoate plasticisers can reportedly be used for toys under a wide range of processing conditions. However, there is a greater requirement for reformulation of products with these plasticisers, which has reportedly led some companies to be discouraged from their use. No information has been made available to suggest that benzoates are actually being used as substitutes for phthalates in toys and childcare articles. The same is true for alkylsulphonic phenyl esters and polymerics which may also be suitable for some applications.

6. RISK ANALYSIS OF SUBSTITUTES

6.1 Introduction and Objective

6.1.1 Introduction

As has been indicated in Section 5, the substitute plasticisers and plastics which can be and are being used as replacements for phthalates and PVC are varied. The range of products which are not specifically intended to be placed in the mouth is very wide and encompasses too many products to be considered in depth. Therefore, the following discussion is essentially concerned with the potential risks and hazards arising from the use of substitutes in products which are specifically intended to be placed in the mouth.

In terms of substitute plasticisers, consideration has been given to two substances: o-acetyltributyl citrate (ATBC) and diethylhexyl adipate (DEHA). These substances were chosen on the basis that they have been considered in other sources (such as the CSTEE's Opinion of 28th September 1999) to be the most suitable substitute plasticisers in technical terms. This has also been confirmed in information obtained for the purposes of this study, especially in the case of ATBC.

The situation for substitute plastics is more problematic. There is no single class of additives which can be examined in a similar way to the phthalates in the case of PVC. Furthermore, and more importantly, there is very little available information on the migration of any organic additives (or monomers) from toys and childcare articles. This is not the case for heavy metals, for example, for which limits are set for use in these products.

In the absence of any adequate data on the migration of additives from substitute plastics, it has not been possible to undertake a quantitative comparison of the risks in relation to phthalates in PVC.

Therefore, for alternative plastics, one additive has been taken as an example: butylated hydroxy toluene (BHT). This substance has been indicated through consultation as being present in some teething products using substitute plastics. It is used as an antioxidant in plastics such as EVA and polyolefins. The information obtained regarding the migration of this substance from teething products cannot be compared to the migration rates of phthalates and other plasticisers from PVC products. However, no other information regarding migration of any other organic additives has been identified for the purposes of this study.

It should not be inferred though that this substance is that which is either the most hazardous substance used in substitute plastics or the substance which is likely to pose the greatest risk. It is used herein merely to provide an illustration of the *potential* risks which may arise.

6.1.2 Objective

The aim of the risk analysis is to address the risks to the health of children, including safety aspects, of possible substitutes (plasticisers and alternative polymers). In the remainder of this section, information on the toxicological profile and potential for migration is provided, as well as an appreciation of the sufficiency of the data.

Most of the information available on the replacement plasticisers has recently been summarised by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) of the European Commission in an opinion (CSTEE/99/11). From a review of this information, and that collected from other sources for this study (including information provided by industry on a confidential basis), we share the opinion expressed by the CSTEE that inadequate data are available to perform a reliable risk assessment of their use in PVC.

However, based on the limited information of exposure, migration potential and toxicological profile available, a preliminary risk analysis for the use of ATBC and DEHA in children's toys has been prepared. All assumptions are stated, together with areas where insufficient information exists. The point of reference in these cases is always the phthalates, in particular diethylhexyl phthalate (DEHP) and diisononyl phthalate (DINP).

In the case of substitute plastics, very little information is available regarding the migration of additives from these materials. BHT has been taken here, with the scope of the analysis limited to this one additive due to the lack of available information regarding migration of additives from these products, resulting from the lack of a requirement for testing of these products. The objective of this investigation has been to highlight the fact that constituents of other plastics may also pose a potential risk. The information presented in relation to BHT is based mainly upon the IUCLID database but also on information provided on a confidential basis by industry.

6.2 Risk Analysis of O-Acetyltributyl Citrate (ATBC)

6.2.1 Potential for Exposure

Migration Potential

The migration of ATBC from PVC containing 30% plasticiser to various media was compared to that of DEHA and DEHP. The migration of ATBC into oil was similar to that of DEHP, into water or soapy water it was 2-3 times greater than that of DEHP. Another study compared the migration of ATBC into synthetic saliva with that of DINP and found the migration of ATBC to be about three times less. However, DINP migrates about an order of magnitude faster than DEHP.

- hematological and biochemical changes in the liver at 300 mg/kg/d, indicating a NOAEL at 100 mg/kg/d.

Genotoxicity

Weak *in vitro* indications of genotoxicity (increased mutant frequencies in various cell lines) have been found but no *in vivo* evidence has been found in rats found (unscheduled DNA synthesis after oral gavage).

Chronic Toxicities/Carcinogenicity

Incomplete data on carcinogenicity exist as the only study on the carcinogenicity of ATBC did not follow modern guidelines. The study was negative.

Reproductive Toxicity

In terms of reproductive toxicity, decreased body weights in F1 male rats, exposed to 300 mg/kg/d and in F0 male rats at 1,000 mg/kg/d has been found. This indicates a NOAEL at 100 mg/kg/d.

Assumptions regarding toxicity

Again, relative to the phthalates, considerably less information is available on the toxicological profile of ATBC. The skin sensitisation by several citrates observed in rats has not been found in humans. However, the mechanism for this sensitisation is unclear and should be addressed as there is the theoretical possibility that exposure to a non-sensitising citrate may have the potential to cause cross-sensitisation to other (related) chemicals. There is also a clear lack of consistent genotoxicity data and a convincing carcinogenicity study. Teratogenicity is not considered relevant for exposures to young children. Overall, however, it appears that ATBC is virtually non-toxic.

For the purpose of the present risk analysis, it has been assumed that carcinogenicity is not relevant at concentrations at or below the NOAEL of 100 mg/kg/d. Using the assumptions stated above, margin of safety values have been calculated. These are presented in Table 6.1.

Table 6.1: Summary of Risk Analysis for ATBC	
Critical effect and NOAEL	100 mg/kg/d (hematological & biochemical changes)
Tolerable daily intake (TDI): NOAEL/100	1 mg/kg/d
Intake dose for children from toys	10 µg/10 cm^2/min (estimate of CSTEE/99/11)[a]
Maximum emission rate from PVC toys	3600 µg/10 cm^2/6 h
Intake dose	450 µg/10 cm^2/kg/6 h
Margin of safety (MOS) (NOAEL/Intake)	222
Guidance value for maximum tolerable extractable amount of ATBC in PVC toys for an 8 kg child:	0.8 mg/10cm^2/6 h/8 kg.
[a] This value lies between the estimate for DINP and that for DEHP. See also the sections on migration potential and exposure of children	

6.3 Risk Analysis of Diethylhexyl Adipate (DEHA)

6.3.1 Potential for Exposure

Migration Potential

In food related studies, migration has been found to be dependent on lipid content of food, with an estimated maximal intake of 16 mg/kg/d. Estimated exposures to DEHA based on urinary excretion of 2-ethylhexanoic acid range from 0 to 8.2 mg DEHA/d.

Migration from PVC film into foods has been found to range between 0.6 and 19 mg/dm^2. Migration into brie cheese from 17.2% DEHA-containing PVC film was 195 mg/dm^2.

The rate of extraction into oil of DEHA is three times more than for DEHP.

Exposure of Children

Information on exposures of children from PVC products is not available. Exposure from food is as above.

Assumptions Regarding Exposure

In comparison with phthalates, there is very little information on the concentrations of DEHA found in PVC toys and other products or amounts found in food. It is also not known how much exposure takes place via other routes (air, water etc.). Migration from PVC toys into saliva is not known. Thus, a reliable exposure assessment cannot be made. In lieu of DEHA-specific data, it has been assumed that exposures to DEHA are similar to those that occur to the phthalates for the purpose of this risk assessment.

6.3.2 Toxicological profile

Toxicokinetics

DEHA is rapidly absorbed and possible hydrolysis occurs to 2-ethylhexanol, mono(2-ethylhxyl)adipate and adipic acid. Extensive metabolism occurs to mainly 2-ethylhexanoic acid in humans (found in plasma). Urinary metabolites of DEHA are 2-ethylhexanoic acid, 2-ethyl-5-hydroxyhexanoic acid, 2-ethyl-1,6-hexanedioic acid, 2-ethyl-5-ketohexanoic acid and 2-ethylhexanol. Half-lives for excretion are about 1.5 h. No data is available on body distribution.

Short Term Toxicities and Irritation

Virtually no short term toxicity has been observed in rat, mouse and rabbit studies.

Sensitisation

There is no evidence for sensitisation in the Draize test.

Repeated Dose Toxicities

Peroxisome proliferation (PP) occurs in rat liver at 1,000 mg/kg/d. This is more pronounced in males than females. PP is most likely caused by metabolites of DEHA, particularly 2-ethylhexanoic acid. There are insufficient subchronic/long term studies on DEHA available to make reliable estimation of a NOAEL.

NOAEL set at 100 mg/kg/d for DEHA, DEHA is less potent than DEHP (NOAEL = 5 mg/kg/d)

Genotoxicity

There are weak *in vivo* indications of genotoxicity in dominant-lethal test in mice, but this is likely due to cytotoxicity and not mutagenicity. DEHA is considered to have no genotoxic potential.

Chronic Toxicities/Carcinogenicity

DEHA causes increased incidence of liver tumors in B6C3F1 mice (both sexes) at 1800 and 3750 mg/kg/d.

No cancer incidence has been observed in F344 rats up to 1250 mg/kg/d.

The mechanism of carcinogenesis for DEHA may be PP and/or production of reactive oxygen species.

Reproductive Toxicity

In Wistar rats a slight reduction in maternal body weight was observed at 720 mg/kg/d. Kinking of the ureter in fetuses was observed at 110 and 720 mg/kg/d.

The NOAEL is set at 30 mg/kg/d.

Assumptions Regarding Toxicity

Relative to the phthalates, less information is available on the toxicological profile of DEHA. It appears that DEHA has a toxicity profile similar to that of DEHP but with lower potency. DEHP causes testicular toxicity, but for DEHA this has not been investigated. For the purpose of this risk analysis, it is assumed that DEHA is considerably less potent than DEHP and a NOAEL of 30 mg/kg/d is assumed as the critical NOAEL. The associated margins of safety are calculated in Table 6.2.

Table 6.2: Summary of Risk Analysis for DEHA	
Critical effect and NOAEL	30 mg/kg/d (fetotoxicity)
Tolerable daily intake (TDI): NOAEL/100	0.3 mg/kg/d
Intake dose for children from toys	10 µg/10 cm^2/min
Maximum emission rate from PVC toys	3600 µg/10 cm^2/6 h
Intake dose	450 µg/10 cm^2/kg/6 h
Margin of safety (MOS) (NOAEL/Intake)	67
Guidance value for maximum tolerable extractable amount of ATBC in PVC toys for an 8 kg child:	2.4 mg/10cm^2/6 h/8 kg
[a] This value lies between the estimate for DINP and that for DEHP. See also the section on migration potential	

6.4 Butylated Hydroxytoluene (BHT)

6.4.1 Potential for Exposure

Butylated Hydroxytoluene (BHT) is used as an antioxidant in plastics. It is also used as a food additive. Concentrations of BHT found in plastics range from 0.2 to 0.5%. BHT has been reported to be used in certain childcare articles which are intended to be placed in the mouth. These materials include teethers made from EVA and polyethylene.

Information has been received from one company which conducted tests on a teething product containing purified water enclosed within a teething product. This water was extracted from the teether and tested using UV spectrophotometry. The water within the product was found to contain BHT. Thus, there exists the potential for BHT to migrate from the product to some extent into the water, which would tend to be equally true for saliva.

However, no quantification of the concentration of BHT in the water was made available. In any case, the test was not intended to simulate extraction by teething or mouthing. These results should not, therefore, be seen to provide any indication of the associated risk.

The view of those persons who conducted the test, a view which is shared by the authors of this report, is that while BHT (and indeed other constituents of plastic materials) can migrate from these products, this provides no indication of the risks associated with the use of these products. It does, however, serve to indicate that there exists a potential hazard associated with the product in question and indeed almost any other such product.

Therefore, there is indeed the potential for exposure of children to BHT used in plastic materials intended to be placed in the mouth by children. However, it is not possible to determine quantitatively the extent of the associated risk since there is no standard testing upon which to base any comparison between these risks and those associated with phthalate plasticisers used in PVC. This is because toy companies are not required to test for migration of organic plastics additives and, therefore, generally do not undertake such testing.

6.4.2 Toxicological Profile

General toxicities have been observed in rats, mice, hamsters and Macaca rhesus monkeys.

Observed effects on the liver include:

- histopathological liver changes;
- periportal and centrilobular necrosis;
- proliferation of the endoplastic reticulum (ER);
- cytochrome P450 induction; and
- altered lipid metabolism, fatty liver.

Observed effects on the blood include:

- decreased prothrombic index; and
- hemorrhageing in various organs.

Acute Oral Toxicity

LD50s in rats range from 890 to 10,000 mg/kg, with most being around 2,000 mg/kg. LD50s in mice range from 138 to 8,000 mg/kg.

Irritation/Sensitisation

Slight skin irritation has been observed in rabbits at 420 mg/kg (on a shaved back). Slight eye irritation has also been observed in rabbits with reversible conjuctivitis following 24 hour exposure (reversed after 72 hours).

BHT is not reported to be sensitising in guinea-pigs.

It is reported to be moderately sensitising in humans following 48 hour exposure to 100% BHT, (challenged 14 days later). No effect was observed in another test at 2% concentration of BHT.

Repeated Toxicity Tests

In Sprague-Dawley rats in a 40 day feeding study with 0.58% to 1.44% BHT in their diet (420 to 1250 mg/kg/d), deaths occurred above 526 mg/kg/d (0.69%). Also haemorrhaging and a decreased prothrombic index were observed.

In a rat, oral 1 week study at 0.0085 to 0.5% (7.54 to 529 mg/kg/d), a LOAEL for decreased prothrombic index was determined at 14.7 mg/kg/d (0.017%).

In a Fischer Rat feeding study over 12, 36, 48 and 76 weeks, rats were fed 100 to 6,000 ppm (7.5 to 450 mg/kg/d). A NOAEL of 75 mg/kg/d after 76 weeks was determined. No tumors were found but slight hyperplasia of the forestomach was observed at 225 mg/kg/d.

In a Wistar rat oral gavage study over 7 and 28 days at 25 to 1250 mg/kg/d, a NOAEL of 25 mg/kg/d for biochemical changes enzyme induction (CYPs and epoxide hydrolase), liver damage (periportal necrosis) was observed.

In a further study, rat liver toxicity was observed above 25 mg/kg/d.

Genetic Toxicities - In Vitro

Ames tests (various) and Bacillus subtilis recombination tests have proved to be negative.

In cytogenic assays (chromosome abberation tests), Chinese Hamster fibroblast proved negative; Chinese Hamster ovarian cells also proved negative (although positive at the cytotoxic concentration of BHT); and in human WI-38 cells (2.5 to 250 ug/ml) tests proved to be positive.

In DNA damage and repair assays, tests on E. Coli were negative, tests on rat primary hepatocytes were also negative and other tests were also negative (although one was positive at the cytotoxic concentration of BHT).

Genetic Toxicities - In Vivo

Most tests have proved to be negative in rat and mouse. Increased sperm abnormalities in mouse were observed at 50 mg/kg and above.

Carcinogenicity Studies

In Wistar rat, exposure to BHT in utero, during lactation and until 141 to 144 weeks of age with a dose range of 25 to 500 mg/kg/d led to:

- increased bile duct proliferation and occurrence of cysts in males;
- focal cellular enlargement in females;
- increased serum phospholipids and cholesterol in females; and
- increase in hepatocellular adenomas and carcinomas in both sexes at 250 mg/kg/d.

Tumors were only detected at 2 years of age. Other tumors were also found but not significantly more often than in controls. BHT-treated rats lived longer than the control, confounding the observed increase in tumor incidence.

Initiation/Promotion Studies

In a study employing initiation with 2-acetylaminofluorene and promotion with BHT (0.5%), gamma-glutamyltransferase positive foci in the liver increased time-dependently at 3, 6 and 14 weeks.

In a bladder carcinogenesis study, increased promotion of preneoplastic lesions (papillary and nodular hyperplasia) was observed at 0.25% (significant at 1%). A NOAEL of <0.25% or 125 mg/kg/d was determined.

Other studies have found the following effects:

- increased bladder preneoplastic lesions at 0.8 % (400 mg/kg/d);
- increased nodular hyperplasia of bladder at 150 mg/kg/d;
- promotion of esophageal carcinoma increased at 500 mg/kg/d BHT;
- promotion of metastases of lung, and hepatocellular carcinomas at 0.7% BHT (350 mg/kg/d);
- hepatic fibrosis and bile duct hyperplasia at 250 mg/kg/d BHT;
- urinary bladder tumors in rats Fisher 344 at 1% BHT (500 mg/k/d); and
- increased thyroid tumor incidence at 1% BHT, and also at 0.8 % (350 mg/kg/d).

BHT also has the ability to reduce the incidence of certain tumors in initiation/promotion protocol.

Other Carcinogenicity Studies

Doses of 0.05 and 0.5% BHT (39 and 390 mg/kg/d) both increased the incidence of liver tumors in mice.

Reproductive Toxicities

Slight decreases in weight gain were observed in the offspring of Wistar dams fed 500 mg/kg/d BHT for 5-7 weeks. A NOAEL of 250 mg/kg/d was determined.

No effects on reproduction or neurobehaviour were observed in mice and a NOAEL of > 600 mg/kg/d was determined.

Developmental Toxicities/Teratogenicity

For mice exposed to BHT on the 7 to 13th day of gestation (at 70-800 mg/kg/d), a NOAEL maternal (increased spleen weight) = 240 mg/kg/d and NOAEL teratogenicity (none seen) > 800 mg/kg/d.

Biochemical Interactions

BHT often demonstrated (some) protection against exposures to acutely toxic chemicals. BHT is metabolised extensively by certain members of the cytochrome P450 enzyme system, and the formation of reactive intermediates may be responsible for the toxicities of BHT. BHT toxicities are lowered by glutathione and other sulfhydryl-containing agents and enhanced by inducers of the cytochrome P450 2B and 3A family such as phenobarbital.

BHT causes cytotoxicity in vitro in various cell systems. These studies indicate that the bioactivation of BHT to (a) reactive intermediate(s) is responsible for the toxicity. This reactive intermediate (putatively the quinone methide) may also compete with vitamin K function in activating blood clotting factors II, VII, IX and X.

Effects of BHT on Gap junction intercellalar commmunication may be important in the tumor promoting effects of BHT.

Toxicokinetics

Long-term feeding of BHT led to accumulation in rats, in adipose tissue and liver. Half lives ranged from 7-10 days.

Human Exposure

Average concentrations of BHT in the adipose tissue of humans are detailed in Table 6.3.

Table 6.3: Concentrations of BHT in Humans

Country	N (male)	N (female)	Fat (mg/kg)	Daily Intake per person
Japan	11	7	0.02-0.18	0-5.2
Great Britain	6	5	0.01-0.49	1
USA	7	5	0.34-3.19	2
Canada	4	2	0.07-0.19	7.4

Critical Effect and NOAEL

Table 6.4 provides details of the critical effect, NOAEL and tolerable daily intake (TDI) for BHT.

Table 6.4: Critical Effect and NOAEL	
Critical effect	decreased blood clotting/prothrombic index
LOAEL	14.7 mg/kg/d.
NOAEL	7.5 mg/kg/d.
Tolerable daily intake (TDI): NOAEL/100	0.075 mg/kg/d.

6.4.3 Summary Statement

BHT is a compound with various sublethal toxic effects and is tumorigenic at greater concentrations via the mechanisms of both promotion and initiation. The proposed mechanism of action where bioactivation of BHT to a reactive intermediate is held responsible for the adverse effects (in order of increased sensitivity: decreased prothrombic index and impaired blood clotting, hemorrage, cytotoxicity, hepatocellular injury and carcinogenesis) suggests that BHT may pose a threat when exposures are beyond a certain 'threshold' concentration.

Strict efforts should be made to have protective guidelines for this substance based on conservative NOAELs. The most sensitive effects linked to the bioactivation of BHT appears to be decreased prothrombic index (due to decreased effectiveness of vitamin K) which results in impaired blood clotting and hemorrhageing. One study in mice shows a remarkably low liver carcinogenic potential of BHT. We do not have the original study to our disposal.

On the exposure side very little is available to us about the concentrations of BHT in toys and childcare articles (although they are likely to be from 0.2% to 0.5 %), migration rates into children and levels found in children. A thorough risk assessment of the use of BHT as a anti-oxidant in childrens toys is clearly needed.

6.5 Conclusions on Risks of Substitute Plasticisers and Plastics

6.5.1 Substitute Plasticisers

As expressed by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) of the European Commission, inadequate data are available to perform a reliable risk assessment of the use of phthalate-replacement plasticizers such as the citrates and adipates in plastics. An assessment has been carried out here based on the assumptions presented above.

Based on the available information, the margin of safety for DEHA would be less than for ATBC. Furthermore, this analysis found that the margin of safety for DEHA is lower than that for DINP (the key phthalate used in soft PVC toys), while that for ATBC is higher. This suggests that ATBC may be preferable to DINP on health grounds but that DEHA may not.

Information from a manufacturer of ATBC indicates that the migration rates of this plasticiser may be as little as one third those of DINP. If these data could be substantiated, the risks associated with ATBC may proportionately lower than those estimated in this report.

6.5.2 Substitute Plastics

Consideration has been given only to one substance used as an additive in substitute plastics, BHT. There is insufficient information available to conduct a meaningful risk assessment for this substance. This is equally true for other organic constituents of alternative plastics used in products which are intended to be placed in the mouth.

Therefore, and as indicated previously in this section, the consideration of BHT for the purposes of this study serves only to highlight that there exists a *potential* risk associated with other organic additives used in the products in question.

BHT would appear to be more toxic than any of the plasticisers which have been considered (phthalates, ATBC, DEHA), and should thus be considered more *hazardous* than those substances with respect to its tolerable daily intake. However, BHT is used in much lower quantities than the phthalates, decreasing the likely risk. It must also be remembered that it has passed food safety tests and that safe levels have been found for the migration of this substance (and indeed phthalates, DEHA and ATBC) from other plastic materials, such as those which are intended to come into contact with foodstuffs.

The fact that no quantitative data has been obtained regarding the migration of organic additives from substitute plastic materials which are intended to be placed in the mouth is likely to be a consequence of the fact that companies are not legally required to assess the extent of migration from these products. In other comparable situations, such tests are required and companies can generally demonstrate compliance with the relevant standards and legislation. Such comparable situations include:

- migration of additives from plastic materials and articles which are placed in contact with foodstuffs (through Directive 90/128/EEC); and
- migration of heavy metal additives (such as lead, arsenic and cadmium) from toys and childcare articles as set out in the European Standard EN 71 which provides elaboration on the 'Toy Safety Directive' (88/378/EEC)[19].

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19 This Directive specifies maximum daily levels for bioavailability of certain heavy metals resulting from the use of toys for the protection of child health.

In these cases, companies producing the relevant plastic products are required to demonstrate compliance with the defined migration/extraction limits. These companies, therefore, undertake testing of their products on a routine basis. Corresponding tests for migration of *organic* additives (including plasticisers in PVC and also organic additives in other plastic toys and childcare articles) from these products are not routinely carried out by these companies since there is no requirement to do so. This finding has been borne out through consultation with toy manufacturers.

7. ECONOMIC IMPLICATIONS OF SUBSTITUTION

7.1 Introduction

This section provides details on the economic implications for various stakeholders of switching to use of substitute plasticisers and plastics in toys and childcare articles. Once again, information is provided which relates both to those toys and childcare articles for children under three years of age *which are intended to be* placed in the mouth and also other products which are or could be affected directly by more stringent restrictions in other Member States or which might be affected indirectly through, for example, retailers requiring that other products be affected.

Therefore, not only are the effects of the national restrictions and the emergency EU ban considered, but also the possible knock-on effects for other products which may be incurred through a diminished perception of phthalates and PVC for applications in which no unacceptable risks to health have been found.

The economic effects are considered in terms of cost, investment, employment and competitiveness. These issues are related to relevant stakeholders such as raw materials manufacturers, toy manufacturers, importers and retailers.

Where data are available, special reference to the potential impacts on small and medium sized enterprises is made.

7.2 Business Sectors Affected by the Restrictions

The key business sectors which are affected by the national restrictions and the emergency EU ban are as follows:

- manufacturers of PVC both in Europe and internationally;
- manufacturers of phthalates and other plasticisers;
- manufacturers and importers of toys and childcare articles; and
- retailers of toys and childcare articles.

Table 7.1 provides some key details on the sizes of these sectors in terms of the market value, size classes of companies and employment (see also Section 2 for more general information on these industries).

Table 7.1: Business Sectors Affected by Restrictions				
Sector	**Number of Companies**	**Size Classes**	**Value**	**Employment**
PVC Manufacture	8 companies dominate European production	All large companies	Euro 2.45 billion for sold production of PVC polymer (Euro 50 billion in finished products)	50,000 directly and 1 million indirectly
Plasticiser Manufacture			Estimated Euro 1 billion[a]	
Toy Manufacture (all toys)	2,000	80% have under 50 employees. 5% have more than 40 mEUR turnover	Euro 4.75 billion for production of all toys. Imports of Euro 6.4 billion and exports of Euro 1.13 billion	100,000 directly
Toy Retail			Euro 13.5 billion retail value	
a Around 1 million tonnes of plasticiser are produced in the EU each year, most of which will be phthalates. Cost of phthalates is assumed to be Euro 800 per tonne and thus average cost for plasticisers estimated to be Euro 1000 per tonne				

In Section 4, estimates were made as to the sizes of the markets which have been affected by the EU ban (those which are intended to be placed in the mouth by children under three years of age). Estimates were also made as to the markets for soft PVC toy products as a whole and those which are intended for children under three years (but which are not specifically intended to be placed in the mouth). These data are summarised in Table 7.2.

In terms of the effects of the emergency EU-wide ban, the economic implications of these restrictions are generally thought to have been borne already due to the fact that there is now a legal obligation not to use phthalate in those toys *intended to be* placed in the mouth by children under three years of age.

For example, one Swedish company reports that, before the introduction of national restrictions, they produced 70 tonnes of plasticised PVC toys per year. All of these products contained phthalate plasticisers and have since been phased out. Due to the specific requirements in Sweden, the company will no longer produce any PVC products and instead uses various forms of polyethylene. The company has experienced a reduction in the value of its products due to small reductions in product performance and also a loss in custom.

It has been reported by another company that, in using substitute plastics for their products (which include articles such as teething rings), an increase of 60% in raw material costs as compared with PVC has been experienced.

Table 7.2: Estimates of Markets Affected		
	Quantity (Tonnes)	Value (mEUR)
Products Intended to Be Placed in the Mouth by Children Under Three Years[a]		
PVC Polymer	15	0.0096
Phthalate Plasticiser	2.9	0.0023
Finished Toy Products	-	0.14
Soft PVC Toys for Children Under Three Years		
PVC Polymer	37,100	2.4
Phthalate Plasticiser	7,100	5.7
Finished Toy Products	-	680
All Soft PVC Toys		
PVC Polymer	150,000	95
Phthalate Plasticiser	28,000	23
Finished Toy Products	-	2,700

a Note that these estimates refer to the situation before the EU ban was introduced. In reality, there will be no use made of these materials at the current time.
Note that this information takes into account only the PVC polymer and plasticiser. In reality, other additives are used in PVC formulations (though these are likely to constitute only a few percent of the total weight). Furthermore, toy products themselves will also contain other materials (though this should not affect the assumption used regarding the cost of finished PVC products relative to volumes of PVC polymer used (which have been interpolated from the PVC industry as a whole).

The majority of companies (80%) in the European toy industry have fewer than 50 employees. Thus, while the majority of small companies are not involved in the production of the relatively small quantity of products which are affected by the emergency EU ban, there will be a significant proportion which do produce plasticised PVC products for children under three years of age (but which are *not specifically intended to be placed in the mouth*). It is likely that a far greater number of these companies will be affected by restrictions which are more stringent than the EU legislation. Furthermore, if these companies are required to use alternative plastics or plasticisers for articles which *are not intended to be placed in the mouth* (for example due to market forces), it is likely that a number of these companies will be unable to absorb the costs of substitution. Passing the costs on to consumers would impact on the price competitiveness of their products.

7.3 The Costs of Substitution

7.3.1 Introduction

Table 7.3 summarises the alternative plastics and plasticisers which companies and the literature have indicated are being used as alternatives to soft PVC or to phthalate plasticisers. Table 7.3 is based upon information provided by individual companies involved in the manufacture of plasticisers and toys and also by trade associations in the EU, US and Japan.

Table 7.3: Substitutes Currently Used in Toys and Childcare Articles	
Substitute Plasticisers	Acetyltributyl Citrate (ATBC)
	Benzoates (possibly)
Substitute Plastics	Styrenic Block Copolymers
	Thermoplastic Olefins
	Low Density Polyethylene (LDPE)
	Linear Low Density Polyethylene (LLDPE)
	Ethylene Vinyl Acetate (EVA)

Further information was given as to the use of these plasticisers and plastics in Section 5 which discussed the technical suitability of substitutes. However, the choice of substitutes has not only been influenced by technical suitability since some companies report that they have chosen substitutes based also upon their own assessment of potential risks and also - from a commercial perspective - the *perceived* risks associated with PVC itself.

7.3.2 Costs of Using Substitute Plasticisers

In terms of the plasticisers which are currently being used as alternatives to phthalates, the only type which is reported to be used widely is acetyltributyl citrate (ATBC). As reported in Section 5.4, this can be used as a replacement for phthalates such as DINP with very few technical difficulties.

Where toy manufacturers have begun to use ATBC as an alternative, it is reported that there will be very little in the way of increased costs through the need to reformulate products or to purchase new processing equipment since that which was used for phthalates can equally be used with ATBC (provided that the equipment is cleaned). The majority of costs associated with using ATBC will, therefore, occur as a result of increased raw material costs (ATBC is more expensive than phthalates such as DINP or DEHP).

Table 7.4 provides an indication of the likely changes in costs which would be experienced by a toy manufacturer through using ATBC instead of a phthalate in plasticised PVC toys containing a total of one tonne of PVC polymer plus phthalate.

Table 7.4: Costs of Using ATBC Compared to a Phthalate in 1 tonne of Plasticised PVC Product		
	Using Phthalate	**Using ATBC**
Mass of PVC (Tonnes)	0.84	0.84
Value of PVC (Euro)	540	540
Mass of Plasticiser (Tonnes)	0.16	0.16
Value of Plasticiser (Euro)	130	420
Increase in Raw Material Costs (PVC and Plasticiser Only)	-	43%
Cost of Finished Product at Retail (Euro)	7,600	7,900
Increase in Cost of Finished Product	-	3.9%

It is evident from Table 7.4 that, whilst there would be a significant increase in raw materials costs if ATBC were to be used as an alternative, raw materials account for a relatively minor proportion of the cost of the finished product. Thus, finished product costs would not be significantly increased.

The increase in cost of production of toy products associated with the higher raw material costs could be borne by the toy manufacturer (in which case, the retail price would not change). Alternatively, it could be passed on to the consumer through an increase in the retail price of products, as is illustrated in Table 7.4.

The increased costs associated with using this substitute plasticiser, whilst not insignificant, would not appear to be prohibitive at the market level (as opposed to the individual company level). This is borne out by the fact that a major manufacturer of this plasticiser has reported that sales of ATBC to toy manufacturers has increased by several hundred percent in recent years[20].

Using the estimates of increased costs in Table 7.4, it is possible to estimate what the increases in costs would be for the markets examined in Table 7.2, assuming that all phthalates used in the toys and childcare articles in question are replaced with ATBC. This is detailed in Table 7.5.

Based upon the data in Table 7.5, the implications of using ATBC as an alternative plasticiser for those quantities of products covered by the EU ban would be relatively minor (around Euro 6,000). In reality, significant substitution has been reported to have occurred using alternative plastics *for those materials which are the subject of the EU ban.*

20 In many cases, the plasticiser itself will be shipped to countries such as China, where the soft PVC are made and then shipped back to the EU.

Table 7.5: Estimated Effects for Markets of Using ATBC Instead of Phthalate		
	Using Phthalate	**Using ATBC**
Products Intended to Be Placed in the Mouth by Children Under Three Years[a]		
Quantity of Plasticiser Used (Tonnes)	2.9	2.9
Cost of Plasticiser Purchase (mEUR)	0.0023	0.0075
Increase in Raw Material Costs	-	0.0052
Cost of Finished Products (mEUR)	0.136	0.142
Soft PVC Toys for Children Under Three Years		
Quantity of Plasticiser Used (Tonnes)	7,100	7,100
Cost of Plasticiser Purchase (mEUR)	5.7	19
Increase in Raw Material Costs	-	13
Cost of Finished Products (mEUR)	675	688
All Soft PVC Toys		
Quantity of Plasticiser Used (Tonnes)	28,000	28,000
Cost of Plasticiser Purchase (mEUR)	23	75
Increase in Raw Material Costs	-	52
Cost of Finished Products (mEUR)	2,700	2,750

a Again, these estimates refer to the situation before the EU ban was introduced. In reality, there will be no use made of these materials at the current time.

Note that the values for all soft PVC toys relate to all EU sales, which includes a significant quantity of imports (from Asia and N America). These data assume that 40% of toys contain soft plastic and that 50% of this is accounted for by PVC. (and also that, on average, these toys contain 50% flexible PVC).

If the scope of any future restrictions were to be wider than those products containing phthalates which are specifically intended to be placed in the mouth, the economic implications would be far more substantial. For example, for all soft PVC products for children under three years, there would be increased costs of around Euro 13 million. Furthermore, for all soft PVC toys (including those for children over three years), increased costs could amount to around Euro 50 million.

In cases where other plasticisers are used, the costs will also increase, although not always to the same extent. For example, if benzoate plasticisers were used as a replacement for phthalates instead of ATBC, the increase in raw material costs would amount to around Euro 5.7 million for all soft PVC toys which are for children under three years of age and Euro 23 million for all soft PVC toys[21]. However, as indicated in Section 5, it is thought that - up to the present time - toy companies have tended to favour ATBC as a substitute for phthalates.

21 As indicated in Table 2.5, benzoate plasticisers are approximately twice as expensive as common phthalates, as compared to ATBC which is around 3.3 times as expensive.

The above data assume that there is no requirement for reformulation of plasticised PVC products which, in reality, is not the case. The technical requirements for using this plasticiser as an alternative to phthalates will, however, be less demanding than those for the use of entirely different plastics.

The use of ATBC is relatively minor in comparison to the overall use of plasticisers[22] and, in particular, the phthalates. It could be argued that the cost of ATBC would fall over time through economies of scale if toy manufacturers were required by legislation not to use phthalate plasticisers in their products. Indeed, the major EU manufacturer of ATBC for toys reports that the price of ATBC fell by 20 to 25% over the past two years. However, there are two primary reasons why the price of ATBC will not be reduced to a level comparable to phthalates:

- the raw material prices for manufacture of ATBC are, and will continue to be, greater than those for the manufacture of phthalates such as DINP; and
- the quantities of phthalates which are used in toys in the EU are relatively small in comparison to the overall market for phthalates (around 1 to 2%) and so, even if all soft PVC toys were to employ ATBC, the quantities used would still be relatively minor in comparison to the phthalates.

Although the quantities of PVC and phthalates which have been directly affected by the EU ban are relatively small, there has been a more widespread shift away from the use of phthalates (to include other products for the under three's and also product for older children). Thus, as a result of the EU ban, there will have been some decrease in sales of plasticisers to the toy industry but this will not have been very significant in the context of total plasticiser use. There will be greater economic implications for plasticiser manufacturers if toy companies stop using phthalates for a wider range of applications. This is likely to be the case for toy companies complying with the more stringent restrictions in some Member States and also for toy companies responding to pressure from retailers and consumers. For all toys, (those not specifically intended to be placed in the mouth and those for children over three years), plasticiser use is much greater; possibly as much as 5% of all plasticiser use.

The companies which manufacture phthalates are generally separate companies from those which manufacture ATBC (the only plasticiser which has been definitely identified as being used commercially as an alternative to phthalates in the products in question). Therefore, there is the potential for creation of jobs in the manufacture of ATBC. There is also the potential for loss of jobs in the manufacture of phthalates, with this being a more serious concern if the use of phthalates is reduced in more applications than toys intended to be placed in the mouth by children under three years of age (such as the full range of toys and childcare articles).

22 A few hundred tonnes, as compared to the EU market for phthalates which is close to 1 million tonnes.

7.3.3 Costs of Using Substitute Plastics

As indicated above, some companies have decided to use alternative plasticisers (particularly ATBC) as a substitute for phthalates in their products which are intended to be placed in the mouth of children under three years of age (mainly teethers). Some companies, however, have used substitute plastics which are reported to be generally either polyethylene, ethylene vinyl acetate (EVA) or, in some cases, styrenic block copolymers.

Due to the relatively small amount of information which has been made available from industry, it has not been possible to quantify the extent to which each of these materials is actually being used.

In terms of the articles which have been directly affected by the EU ban (essentially just teethers and rattles[23]), it would appear that companies have generally been able to bear the costs of the restrictions. However, these companies have also experienced significant increases in material costs. The cost of materials such as EVA is around 60% more than PVC and that for materials such as styrenic block copolymers can be much higher (e.g. 100% more). These costs will be recurring costs since the introduction of these materials into toys will not lead to a significantly greater level of their use and thus no reductions would be expected through economies of scale.

Consultation with industry has indicated that the relative cost of raw materials for teething products tends to be higher than the average estimated for toys containing soft PVC as a whole. In some cases, raw material costs may account for up to 20% of the cost of finished products. Therefore, the above increases in material costs are significant in terms of their effect upon the final product and companies have reportedly passed on their own cost increases through increased prices of their products.

The costs of actually processing teething products has reportedly not been very high in comparison to other costs incurred since they can be processed using essentially the same equipment as with flexible PVC (although this will not be the case for many other products - many of those which are not intended to be placed in the mouth).

However, the (one-off) costs of product development for the use of substitute plastics in articles which are intended to be placed in the mouth by children under three years of age have reportedly been significant. This is because, producing a product (such as a teether) using an entirely different plastic requires significantly more resources devoted to product development than to produce it from PVC using an alternative plasticiser, such as ATBC. It has not been possible, however, to estimate the one-off costs associated with product development.

As indicated previously in this report, the number and quantities of products and their variability in properties and materials is relatively limited in terms of those products which are intended to be placed in the mouth by children under three years of age. Those

23 Since items such as babies bottle nipples are usually made of materials such as latex.

products which do not fall under this category constitute by far the greatest use of flexible PVC in toys and childcare articles.

Table 7.6 provides an indication of the likely increases in raw material costs if toy manufacturers all chose to use substitute plastics in their products for:

- all flexible PVC toys for children under three years; and
- all flexible PVC toys.

The estimates in Table 7.6 assume an increase in raw material costs of 80% as compared to the use of PVC with phthalate plasticisers.

Table 7.6: Estimates of Increases in Raw Material Costs (mEUR) in the Event of Wider Restrictions

	Children Under 3 years	All Soft PVC Toys
Cost of PVC	23.8	95.0
Cost of Phthalate	5.7	22.6
Cost of Raw Materials (PVC & Phthalate)	29.4	118
Cost of Raw materials (Substitute Plastic)	53.0	212
Increase in Raw Material Costs	23.5	94.1

The figures given in Table 7.6 indicate that moving to substitute plastics results in almost twice the increase in raw material costs as moving to substitute plasticisers (i.e. Euro 13 million for substitution with ATBC and Euro 23.5 million for an alternative plastic in the case of all soft PVC toys for children under three years of age). However, the total costs of using an alternative plastic will be even greater due to the significantly higher costs associated with product development for the use of substitute plastics.

The potential impact upon small companies of using alternative plastics is great. As indicated above, over 80% of toy companies in Europe have fewer than 50 employees and, if these companies are required to use entirely different plastics for a wider range of children's products (e.g. through market pressures), there is a definite risk that some of these companies will go out of business.

8. CONCLUSIONS

8.1 The EU Market for Toys and Childcare Articles

Around 5.5 million tonnes of PVC are used in the EU each year. The European market for PVC is worth around Euro 50 billion per annum in terms of finished products, of which plasticised PVC accounts for around 32%.

Around 1 million tonnes of plasticisers are used in the EU each year, the majority of which are phthalates. This market has an estimated value of Euro 1 billion per year. Of this quantity, however, the use in all toys and childcare articles is estimated to be only around 1 to 2 percent.

The overall market for toys in the EU is worth Euro 13.5 billion, the majority of which is accounted for by imports, mainly from the Far East. Of this, it is estimated that the market for toys containing flexible PVC is worth around Euro 2.7 billion. However, the value of those articles which have been affected by restrictions upon items *intended to be placed in the mouth* by children under three years of age is estimated to be only around Euro 140,000. Of all articles containing soft PVC for children under three years of age, the market is considerably larger (estimated at Euro 680 million).

8.2 Technical Issues in Substitution

8.2.1 Substitute Plasticisers

Toy companies have, as required by the emergency EU ban, replaced phthalate plasticisers in their products which are intended to be placed in the mouth by children under three years of age. Depending upon the companies in question, both substitute plasticisers and substitute plastic materials have been employed.

In terms of the substitute plasticisers, the only one which has been confirmed as definitely being used is o-acetyltributyl citrate (ATBC). Products using PVC formulations containing ATBC can reportedly match all of the technical requirements which are met when phthalates are used.

Other plasticisers which have been reported as being suitable in technical terms for certain toys and childcare articles include benzoates (such as diethylene glycol dibenzoate) and alkylsulphonic phenyl esters. No companies have specifically reported that they are using these substitutes, although a producer of the former type reports that their product has been used in toy products. Use of these two types of plasticisers reportedly requires that more effort be devoted to reformulation of the products, as compared to use of ATBC. However, in technical terms, substitution does appear to be possible.

There is a great variety of other plasticisers on the market, such as adipates, polymerics, trimellitates, sebacates and azelates. Some of these may also be suitable in technical terms for use in toys and childcare articles, although no evidence has been obtained to suggest they are actually being used.

One of the key issues in the use of substitute plasticisers is the ability of reformulated products to be processed in the same way as phthalate-plasticised PVC. This is particularly true in the case of certain rotationally moulded products: while a substitute may be suitable for use in some processing techniques, including some rotationally moulded products, it may not be suitable for use in other techniques (for example, different rotationally moulded products).

Furthermore, such substitution may not be possible in other toys (which are not specifically intended to be placed in the mouth or which are for older children) given the huge diversity of products on the market which contain phthalate-plasticised PVC.

Table 8.1 provides a summary of the findings of this study in terms of the technical suitability of substitute plasticisers. Indications are given as to the technical suitability for use in toys and childcare applications and their actual use in these products *where they have been reported to be used as substitutes* is also indicated.

Table 8.1: Technical Suitability of Substitute Plasticisers

Plasticiser Type	Technical Suitability	Actual Use as Substitute
Citrates (ATBC)	I, II	I, II
Adipates (DEHA)	II (some)	Unknown
Benzoates	I (possibly), II (some)	II (probable)
Alkylsulphonic Phenyl Esters	I (possibly), II (some)	Possibly
Trimellitates	II (some)	Unknown
Polymerics	II (some)	Unknown
Key: I - products intended to be placed in the mouth II - other plasticised PVC toys and childcare articles		

8.2.2 Substitute Plastics

As indicated above, a number of companies have undertaken substitution to entirely different plastic products rather than simply different plasticisers. This applies significantly to those products which are intended to be placed in the mouth by children under three years of age but also to products which are not specifically intended to be placed in the mouth.

For those products which are specifically intended to be placed in the mouth, the substitute plastics which appear to be most widely used are polyethylene (PE) and ethylene vinyl acetate (EVA). These materials can reportedly be used adequately in the products in question. However, the technical performance of the final product has been indicated to be often slightly inferior to that obtained with PVC. For example, products produced from these materials may sometimes have lower resistance to biting and tearing than plasticised PVC. The products may also have reduced longevity.

In terms of the wider range of toys and childcare articles, plastics which are reported to be used as substitutes for plasticised PVC include various forms of polyethylene (LDPE, and LLDPE) styrenic block copolymers and again EVA.

The suitability of these substitutes depends very much upon the particular applications in question. Again, it has been reported widely that technical problems occur in the use of rotational moulding of certain products. Indeed for certain rotationally moulded products, none of the substitute plastics have been found to be technically suitable (although for other products made using this and other processes, these materials may well be suitable).

Overall, in technical terms, there would appear to be suitable substitutes for those products which are intended to be placed in the mouth by children under three years of age. For some toy products not intended to be placed in the mouth and for older children, there appear to be no suitable substitute plastics at present. It has not been possible to provide quantification of the relative amounts of products for which substitution could possibly occur. Table 8.2 provides a summary of the findings of this study in terms of the technical suitability of substitute plastics.

Table 8.2: Technical Suitability of Substitute Plastics

Plastic Type	Technical Suitability	Actual Use as Substitute
Polyethylene (various forms)	I, II (some)	I, II (some)
Ethylene Vinyl Acetate (EVA)	I, II (some)	I, II (some)
SBS Block Copolymers	I (possibly), II (some)	I (unknown), II (some)
Polyester Elastomers	II (some)	Unknown

Key: I - products intended to be placed in the mouth
II - other toys and childcare articles

In general, the use of substitute plastics would appear to be less technically feasible than the use of substitute plasticisers.

8.3 Risks to Health Associated with Substitutes

Two substitute plasticisers have been examined in terms of their potential risks, acetyltributyl citrate (ATBC) and diethylhexyl adipate (DEHA). Based on the available information, the margin of safety for DEHA would appear to be less than for ATBC. Furthermore, this analysis found that the margin of safety for DEHA is lower than that for DINP (the key phthalate used in soft PVC toys), while that for ATBC is higher. This suggests that ATBC may be preferable to DINP on health grounds but that DEHA may not.

However, it is recognised that the amount of information available regarding toxicity and migration for these substances is less than that which is available for the phthalates. Where any plasticiser - phthalates or their substitutes - is used, there exists a *potential* risk associated with use. This will be highly dependent upon the nature of individual products in question.

In terms of substitute plastics, very little information is available on the migration of organic additives from toys and childcare articles. One additive, butylated hydroxytoluene (BHT), has been taken as an illustrative substance since this is known to be used in some teething products made from substitute plastics.

However, there is insufficient information available to conduct a meaningful risk assessment for this substance. This is equally true for other organic constituents of alternative plastics used in products which are intended to be placed in the mouth. The consideration of BHT for the purposes of this study serves only to highlight that there exists a *potential* risk associated with other organic additives used in the products in question.

BHT would appear to be more toxic than any of the plasticisers which have been considered (phthalates, ATBC, DEHA), and should thus be considered more *hazardous* than those substances with respect to its tolerable daily intake. However, BHT is used in much lower quantities than the phthalates, decreasing the likely risk. It must also be remembered that it has passed food safety tests and that safe levels have been found for the migration of this substance (and indeed phthalates, DEHA and ATBC) from other plastic materials, such as those which are intended to come into contact with foodstuffs.

The fact that no quantitative data has been obtained regarding the migration of organic additives from substitute plastic materials which are intended to be placed in the mouth is likely to be a consequence of the fact that companies are not legally required to assess the extent of migration from these products. In other comparable situations, such tests are required and companies can generally demonstrate compliance with the relevant standards and legislation. Such comparable situations include:

- migration of additives from plastic materials and articles which are placed in contact with foodstuffs (through Directive 90/128/EEC); and

- migration of heavy metal additives (such as lead, arsenic and cadmium) from toys and childcare articles as set out in the European Standard EN 71 which provides elaboration on the 'Toy Safety Directive' (88/378/EEC).

In the absence of any widely accepted tests for assessing the migration of organic additives (plasticisers and other additives in both PVC and also other plastics) from toys and childcare articles, the uncertainty regarding the risks associated with the use of these products will exist, whether phthalate-plasticised PVC is used or any substitute plasticiser or plastic.

8.4 Economic Implications of Substitution

8.4.1 Substitute Plasticisers

Consideration has been given to the economic implications of using ATBC as a substitute for phthalates in toys and childcare articles. As stated above, other plasticisers could potentially also be used but this substance has been examined in more detail because it has been reported by the plasticiser and toy industries (and trade associations) to be the most widely used substitute.

Quantitative estimates have been made for the increases in raw material costs which would be associated with the use of this plasticiser as a substitute (ATBC is around 3.3 times more expensive than DINP). These estimates are as follows:

- for the quantities of products which are the subject of the EU ban (probably only around 2.9 tonnes of plasticiser for those intended to be placed in the mouth by children under three years of age), increased raw material costs would only represent an estimated Euro 6,000;
- for all soft PVC products for children under the age of three years of age, increased raw material costs would amount to around Euro 13 million; and
- for all soft PVC products for all uses and all ages, increased raw material costs are estimated to be around Euro 50 million[25].

In addition to the above ongoing costs, there would also be some one-off costs associated with reformulation and testing of products, although these would tend to be relatively minor due to the technical suitability of ATBC.

If these costs were all passed on to consumers, it is estimated that finished product prices would rise by almost 4% (although this does not take into account the one-off costs associated with the need for product development.

8.4.2 Substitute Plastics

As for substitute plasticisers, estimates have been made of the costs of using substitute plastics in terms of the raw materials costs. Raw material costs for replacement plastics tend to be around 60% to 100% higher than those of flexible PVC. However, in the case of replacement of the entire plastic, both the PVC and the phthalate must be replaced. Since the phthalate constitutes a small proportion of the product as compared to the PVC polymer (on average although not in all cases), the overall increased raw material costs would be greater for the use of substitute plastics:

25 Consideration has been given to these wider ranges of products since these products can be (and are) affected by legislation in countries which have more restrictive legislation than the Community measures and are also affected by the negative *perception* which has become associated with PVC.

- an estimated Euro 23.5 million increase for all toys and childcare articles for children under three years of age; and
- Euro 94.1 million for all plasticised PVC toys and childcare articles on the EU market.

In addition, as with the use of substitute plastics, there will be one-off costs associated with product development. These would tend to be significantly greater than for substitution with just a different plasticiser since an entirely different product is used. Information received from companies which have substituted flexible PVC with different plastics suggests that there has been little requirement for the purchase of new processing equipment. However, this will not be the case for all substitution possibilities and the associated costs for those products would be greater still.

8.4.3 Other Considerations

Disparities in legislation amongst the Member States raises concerns for those countries with more stringent requirements than those set out in the EU-wide ban. This is especially evident in the case of smaller countries such as Sweden where importers and retailers have experienced difficulties in obtaining toy products which do not contain phthalates (for those toys which are *not specifically intended to be placed in the mouth*).

8.5 Overall Conclusions

The EU ban has wider implications for the perceived acceptability of phthalates and PVC as a whole, as evident from the more stringent restrictions which have been brought in by some EU Member States. This, along with campaigns against PVC, has led some companies to use alternative plasticisers and plastics for products which are not specifically intended to be placed in the mouth. The technical implications of using alternative plastics for these applications raises far greater concerns since many of these alternatives cannot match the performance in production and use of plasticised PVC.

In addition, given the paucity of comparable data for both the substitute plasticisers and plastics, it remains unclear as to whether adoption of these substances would lead to lower health risks. It would appear that the use of ATBC should lead to lower risks, however, no comparable conclusions can be drawn concerning the use of substitute plastics.

The economic implications of using a substitute plasticiser or plastic are estimated to have been relatively minor for those products which are intended to be placed in the mouth by children under three years of age. However, other soft PVC toys and childcare articles constitute a far greater use and the economic implications for substitution in those products, in terms of increased raw material costs alone, would be much higher.

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